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TRANSLATIONAL TOOLBOX

# How to Start a Biomedical Device Company

## Physicians Can Lead the Team Effort

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**SUMMARY**

Taking a solution for a clinical unmet need from a mere idea to a profitable medical device company is a long and complex process. After developing a prototype solution, the physician-inventor must quickly file a patent to protect his or her intellectual property. After the patent is secured, the first major business decision arrives: should the inventor sell the patent or maintain ownership? If the inventor decides to maintain ownership, he or she will face a series of hurdles from obtaining additional funding to device development, and ultimately, commercialization and marketing of the product. Although this process is daunting at first glance, and physicians certainly face unique challenges in this endeavor, clinicians are uniquely and strategically positioned to identify clinical unmet needs and, therefore, have the ability to fundamentally transform the way we treat our patients. (J Am Coll Cardiol Basic Trans Science 2017;2:328–34)


Although medical school and residency typically do not provide formal training regarding biodesign or business principles, physicians should be leaders at the cutting-edge of innovation in health care. After all, physicians are uniquely positioned to identify clinical unmet needs and to develop practical solutions with the potential to widely affect patient care. These unmet needs manifest in a variety of ways, but the best method is for the physician to simply pinpoint a problem that routinely bothers him or her during everyday clinical activities. This step of the biomedical design process is the easiest and, unfortunately, is the one at which the vast majority of physicians cease their efforts. After all, successfully addressing a clinical unmet need by developing a novel drug, device, or process is neither straightforward nor guaranteed. Any physician with an insatiable passion to improve some element of patient care, big or small, can nevertheless find success, which may then afford him or her the opportunity to commercialize the solution. Herein, we will provide an overview of the fundamental principles for starting a company in the medical device industry based on our own experience in taking a potential solution for a clinical unmet need from the bench-top to in-human clinical trials.

## THE "3 Is" PROCESS (IDENTIFICATION, INVENTION, IMPLEMENTATION)

The initial steps in starting a successful medical device company center on the "3 Is" process (identification, invention, implementation). A detailed description of this process, as implemented in the

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Stanford Biodesign Program, was provided in a recent issue of *JACC: Basic to Translational Science* (1). Briefly, a commercial venture begins with the identification of an unmet clinical need. Physicians, more than potentially any other group of professionals, can provide important expertise at this stage due to their first-hand experience with the need as well as their understanding of the pathophysiology underlying and current treatment methodologies available for the need. Once identified, the unmet clinical need informs the invention of a solution that will ultimately be commercialized. However, this solution cannot be invented by the physician alone; instead, a team approach is often imperative for success. If the physician identifies an unmet need that may be solved by a medical device, for example, he or she might enlist an engineer with the skills to design such a device, from prototyping through final aspects of development. Finally, after a solution has been invented, the team may incorporate a business expert to assist with implementation of the device into the market, including considerations regarding intellectual property, credible reimbursement options, and investment strategies for further research and development (R&D) and commercialization efforts. Fundamentally, the "3 Is" process characterizes the dynamic relationship among professionals in at least 3 different arenas (medicine, engineering, and business) that is required to identify, invent, and implement a commercially viable medical device.

## PATENTING AN INVENTION

After the physician and his or her team have identified a clinical problem and invented a solution, patenting this solution is critical for protecting the team's ability to commercialize their medical device. There are 3 important milestones in the process of patenting an invention: the date of conception, the date of actual reduction to practice, and the date of constructive reduction to practice. The date of conception describes when the invention was first conceived in its completed form. The date of actual reduction to practice refers to the date when a working model or prototype was completed. The date of constructive reduction is the date on which the patent application was filed.

Prior to 2013, the United States followed a "first-to-invent" patent system. Under this system, when 2 inventors filed patents for the same invention, an interference hearing before the Board of Appeals and Interferences at the U.S. Patent Office was scheduled to determine the legal date of priority based on the date of conception for each inventor. Although this system was designed to protect inventors' intellectual property, several major flaws, including the lengthy and costly legal process and difficulties in determining accurate dates of conception, limited its effectiveness. Therefore, in 2011, the U.S. Congress passed the America Invents Act, which introduced a "first-to-file" patent system that gives priority to the inventor who first files a patent application. Beginning on March 16, 2013, the first-to-file system took legal precedent in the United States, the final country to adopt this system worldwide. Therefore, the date of constructive reduction to practice is now used to determine which inventor has priority over a patented technology.

Inventors must navigate the patent system under the first-to-file system in a dramatically different fashion than under the first-to-invent. Previously, inventors who were confident that their date of conception would hold legal precedent had little incentive to keep their inventions secret or to rush toward a patent application. Instead, they could take their time to diligently reduce their invention to practice and to prepare a patent application, knowing that their date of conception would give them priority to the patent. Under the first-to-file system, however, inventors are now most likely to secure a patent by keeping their technology secret from others and by filing for a patent (demonstrating constructive reduction to practice) as quickly as possible. Otherwise, the inventor risks losing the patent to someone who files first, even if the first-to-file party had conceived of the patented technology second.

Another key consideration when filing for a patent is the patent policy at the inventor's institution. If a physician conceives or creates a patentable medical device or technology through research conducted at his or her institution, it is very likely that the university, practice group, and/or employer has rights to both the patent and any royalties that stem from commercialization of the device that is patented. In fact, many universities generate a significant income from technology and patent licensing of their faculty's inventions (2).

Finally, although it may be possible for physicians to patent an invention on their own, hiring a patent lawyer is strongly recommended given the complexities of the patenting system and the speed with which a patent application needs to be filed under the governing first-to-file patent system. A strong relationship with a patent lawyer is also essential to ensure that the inventor is ready to protect his or her invention against potential patent challenges and

### ABBREVIATIONS AND ACRONYMS

**FDA** = Food and Drug Administration

**NIH** = National Institutes of Health

**R&D** = research and development

**SBIR** = Small Business Innovation Research

**STTR** = Small Business Technology Transfer