A Roadmap to Success for Surgeon Inventors, Part 5: The Top Ten Things to Avoid

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This is the second half of a two-part installment on the top ten things for surgeon inventors to avoid. In the previous installment, we touched on numbers one through five. (See the sidebar to review, or the full article in *ORTHOPRENEUR* May/June 2010.)

Today we highlight numbers six through ten. Just like last time, keep in mind that these pitfalls are in no particular order and all of them can happen if you're not careful.

#6: Unrealistic Expectations

Surgeons who have not previously traveled down the bumpy road of product development are more often than not surprised by the time, cost and effort required to translate a napkin sketch into a finished product. I have also seen this phenomenon with surgeons who have developed products in the past, but only with large orthopaedic companies. Developing products directly with industry can be misleading in terms of making assumptions about the process. For example, it is very difficult to grasp the total cost of product development in dollars since that cost is absorbed by the company in exchange for ownership of the idea. Furthermore, management of the process, selection of key suppliers, development of associated quality-related documentation and many more steps are, for the most part, completed "behind the scenes." The surgeon inventor is often unaware of the overall effort involved. While this is not necessarily a bad thing, caution must be exercised when attempting to translate your experience in developing products with industry partners to developing products on your own.

It should come as no surprise, then, that projects will tend to take longer and cost more than you might at first believe. The main reason for this is tied to underlying assumptions about how far along you are in the process and about how much effort it will take to reach your goals. Assumptions drive expectations, and unrealistic expectations are the cause of many development headaches.

One way to mitigate the risk of unrealistic expectations is to hire a team that has successfully developed products with surgeon inventors in the past—and not just one or two products, but many and with various inventors. The right team will help foresee potential problems and should be able to align expectation with reality.

#7: Inadequate Intellectual Property Protection

Much has been written about the value of patents and other forms of intellectual property (IP). For all of the collective knowledge in the public domain, though, I still see many cases of inadequate protection of an inventor's IP. Do yourself a favor and don't wait too long before engaging the services of a patent attorney. At minimum, a provisional patent should be pursued for ideas that you believe merit protection. Provisional patents are easy to obtain, are cost-effective and benefit you by drawing a line in the sand to establish your invention date. In the subsequent year that you have to submit a more formal utility patent application, the idea can be refined, expanded and improved.

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This design evolution process of refinement, expansion and improvement highlights the equal but opposite risk of obtaining IP protection too early. While obtaining protection too late in the game (or not at all) is to be avoided, going after protection too early may also limit the value of your invention. Often patents that are written too prematurely will result in narrow coverage because all of the different permutations of your idea will take time to develop. In the first half of this two-part article, I advised the reader not to shortcut the design process by assuming that your first idea is your best idea. The best designs come out after multiple brainstorm sessions, feasibility work and team collaboration.

Taking these two points into consideration, there is an optimal window of time during development in which to pursue IP protection. This window starts after initial ideas have been discussed with your team (confidentially, of course), fleshed out through quick design and prototyping (and potentially early testing) and followed by thorough review of the surrounding IP landscape. The window closes as you begin to sell your idea through public disclosure. More on what constitutes public disclosure should be discussed with an experienced patent attorney, who can help craft a strategy that protects your investment while maximizing the value by broadening your claims.

#8: Scope Creep

Scope creep – otherwise known as not sticking to the plan – can happen in any project. It is our natural tendency as humans to want more than we originally ask for, especially if things are going well, and to change our minds along the way. Why not sneak in that extra feature, new size or new and improved instrument into your plan? The answer lies in whether or not the changes will result in budget or timeline overruns. A critical assessment of the impact of changing project scope is necessary for proper decision-making. Keep in mind that the cost of changing the project will rise exponentially as the project progresses.

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Skilled project managers are taught to execute according to plan. This puts a lot of emphasis on thorough planning at the beginning of a project, a topic that we have covered in past articles. One critical piece of the planning function is to determine the scope of the project. Whether your project scope is narrow, as in the case of a single surgical instrument, or broad, as in the case of a complete implant and instrument system, proper definition and documentation are essential.

While everyone wants to remain flexible up to the point of freezing a design, it is in the best interest of the team to execute crisply on an agreed-upon plan in order to be first to market, come in under budget, on time, etc. Changes to the plan do not automatically result in scope creep. To the contrary, they are natural and to be expected, since we all learn as we go. The key to preventing scope creep is to control the changes and assess the impact before changes are made. Controlled changes are manageable; uncontrolled changes are a killer.

#9: What Competition?

All men make mistakes, but only wise men learn from them. By the same token, successful inventors learn from the mistakes – and the successes – of those around them. While intimate knowledge of competitive products is not an absolute requirement for successfully developing your own idea, a targeted review of the competitive landscape will most certainly yield benefits. Some of the biggest benefits include:

- Identifying features and performance criteria that are deemed critical to your target market
- Assessing what has worked, and not worked, among various designs
- Understanding the marketing and selling dynamics at work in your target market (i.e., average selling prices or reimbursement structure) that may affect the valuation of your idea

Looking Back at the Roadmap to Success: First Five Things to Avoid

#1: Shortcutting the Process. Going straight to prototype may provide instant gratification, but may cause you to miss a viable solution to the problem you're trying to solve by focusing too early on a single design.

#2: The Cost of Change. It is more expensive to make changes later in the process of device development vs. earlier.

#3: Poor Documentation (or none at all). The work needs to be done if you expect a patent to protect you.

#4: Inadequate Funding. Knowing the major cost drivers and being realistic about total cost potential are two keys to success.

#5: No One Has Ever Thought of This Before. Keep in touch with industry contacts and comb through booths at medical conferences to keep your finger on the pulse of what others are doing.

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- Identifying the appropriate regulatory pathway for your idea
- Gauging the merger and acquisition activity in your target market
- Knowing where potential patentability or patent infringement issues may arise

Just like a solid product development plan will help guide you and your team toward success in designing your product, a good marketing plan that takes into account your potential competition and market opportunity will help point you toward a realistic valuation for your idea and hone in on the list of potential acquirers of your product.

#10: Underestimating the Impact of Your Words

A good supporting team should act as a guide along your journey from initial invention to successful commercialization. While they are the experts at product development, regulatory affairs or patent protection, you are the inventor, clinical expert and chief proponent of the idea. Therefore, don't be casual with your comments; people really do listen (especially when you are paying the bill!). Carefully consider how your comments, feedback and decisions weigh on the rest of the project.

What you say will become the "bible" for the engineering staff that carries your project forward. They will pick apart the clinical requirements that you establish and translate them into actionable design inputs upon which the development process will be based. These requirements will also find their way into design reviews, analysis of risk and many other fundamental building blocks of the project.

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Take, for instance, your clinical goals for the device. You aim to treat a specific type of patient with certain pathology in a unique way. Perhaps your first thoughts are too narrow, and there is a much broader set of indications out there waiting to be explored. Conversely, maybe you are too ambitious at the outset and need to consider selecting only one or two indications so that you have a better chance of proving feasibility. In either case, your initial direction to the team has a huge impact down the road. What you say about patient selection and potential indications will morph into a firm set of Indications for Use by your design team. This set of Indications for Use will touch the spectrum of development activities, including the design, testing methods, material choices, regulatory pathway and marketing plan, just to name a few.

Conclusion

The last two articles in this series have attempted to lay out for the reader ten of the most common potential pitfalls that routinely occur in the process of developing an invention, based on my personal experience. Some of them are obvious, others are more subtle and only learned (or at least appreciated) after working through the process multiple times. It is my hope that awareness of these dangers, while not guaranteeing success, will at least minimize some of the inherent risk and increase the value of your invention.

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