GUEST EDITORIAL

Doctor With Ideas, or Doctor Who’s Intoxicated?

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DWI, the acronym that commonly stands for “Driving While Intoxicated,” took on a new meaning for me back in medical school. That’s when I overheard an orthopaedic implant sales representative use DWI to describe one of his surgeon clients. The rep was on the phone arranging a meeting for the surgeon to pitch an idea to one of the rep’s regional managers.

“Dr. Smith is a DWI,” said the rep, hanging up the phone.

In this context, the rep explained, DWI stood for “Doctor With Ideas.” That was this rep’s term to describe surgeons who believed that their ideas would revolutionize orthopaedic surgery—while at the same time making them rich! Dr. Smith’s financial reward for genius would presumably come from a large, established implant company whose CEO would produce a fat check and a pat on the back in exchange for the DWI’s brilliant ideas that he’d scribbled on a bar napkin. All of this was to occur, in Dr. Smith’s mind, at this upcoming meeting.

I remember thinking, “Is Dr. Smith’s vision of success remotely realistic, or instead of Doctor With Ideas, should DWI stand for Doctor Who’s Intoxicated?”

Intoxication can mean inebriation or drunkenness, but it can also mean overpowering exhilaration or excitement of the mind or emotions. If you’re an inventor, you know that ideas can be intoxicating. (See Exhibit 1.) As an inventor, it is easy to become emotionally affected—intoxicated, if you will—by your ideas. Just as for the driver of an automobile, though, intoxication for the surgeon inventor can lead to unrealistic expectations and bad decisionmaking. Once intoxicated, objectivity goes out the window, and like Dr. Smith, you see the world through rose-tinted glasses.

If you’re a surgeon who reads ORTHOPRENEUR, you’re probably a doctor with ideas. You’re most likely intoxicated by the thought of transforming your ideas into reality. You’re in all likelihood intoxicated by the prospect of contributing to your field. You’re most definitely intoxicated by the possibility of improving people’s lives with your inventions. However, while the intoxication that comes with a new idea may be pleasant, the process of transforming that idea into a real-world device requires a sober, methodical approach. If you hope to move your project past the pipe-dream phase, there comes a time when it’s best to remove those rose-tinted glasses and take a critical look at your ideas, as well as your plan to turn them into reality.

Exhibit 1: Orthopaedic Hardware Martini, shaken, not stirred. Intoxicating!
As you slide behind the wheel of entrepreneurship, it is therefore important to keep a clear head, maintain control of your vehicle and steer it purposefully toward your destination. With that, I offer a few tips that I hope will help keep your vehicle on the road.

What’s My Idea Worth?
I have been asked by other orthopaedic surgeons what they might expect, were they to present their original idea to the executives at Big Implant Company (BIC). The answer is, “It depends.” The harsh truth is that an idea scribbled on a bar napkin by a world-renowned, podium-presenting, paper-publishing orthopaedic surgeon may be quite valuable to BIC, but a napkin with the same idea coming from a surgeon who doesn’t have the ear of the orthopaedic community is probably worth next to nothing. Much to our chagrin, most of us are holding napkin #2.

Don’t be discouraged. Just because the big boys aren’t interested doesn’t mean that the idea is worthless. It does mean that you will have to consider alternatives to turn your idea into something that has value. One of the best ways to do this, in my opinion, is to pursue development on your own. Put yourself in the shoes of the executive at BIC, and visualize two different people presenting the same idea. The first surgeon is enthusiastic, but his ideas are sketched on a napkin and his presentation disjointed. The second surgeon provides a succinct, well-organized summary of her idea, and hands you a working prototype of the device and a glossy product brochure that she had professionally made. Surgeon #2, of course, stands a better chance.

You Can Do It! …but Should You?
Ideally, you may want to sell your idea to an established company. However, even if your presentation is rejected by the big boys, it may still be worthwhile for you to bring your device to market yourself if the idea is truly a good one. Increasing availability of resources for inventors and decreasing costs associated with market entry have changed the question for the orthopaedic inventor from could you to should you pursue development. There is no doubt that barriers for entering the orthopaedic device market are lower now than they were 20, ten, five or even two years ago.
Pursuing development by yourself may seem overwhelming, but the good news is that today, more and more resources are available for turning your ideas into reality—and it is now less expensive to do so than ever. Search on Google using the terms “OEM,” “orthopaedic” and “implants,” and you will find multiple companies that offer services ranging from product design assistance to prototype production to full-blown implant manufacturing. With resources like these, it is entirely possible for the little guy to independently launch an orthopaedic implant company. For those who are still intimidated due to a lack of business acumen, there are companies such as Redyns Medical, LLC (www.redynsmedical.com) and Kapstone Medical, LLC (www.kapstonemedical.com) whose mission is to advise and guide the orthopaedic surgeon inventor every step of the way—from an idea on a bar napkin to, well, however far you want to take it.

Of course, while the cost of product development may have decreased, driving your project down the road independently will likely still require a substantial financial contribution on your part. Consequently, you will need to decide your tolerance for risk. Assessing the risk is difficult at this stage, because the information that is needed to make an intelligent decision has not yet been acquired. Therefore, before you invest time, money and effort on product development, I suggest that you expend significant energy on two things: understanding the patent process, and performing a feasibility study.

**Patenting 101**

As an inventor with a new idea, the first step that you should complete is to make a sketch of your idea and describe it on paper. It is important to sign and date your work, and have a witness sign and date it. This documentation might turn out to be very important if someone were to challenge the legitimacy of your patent. This is the *scribble-an-idea-on-a-bar-napkin* phase. It is fun, easy and inexpensive.

The next step, however, is where dreaming turns into real labor. You’ll need to perform a patent search. A patent attorney recently told me that the risk for the entrepreneurial surgeon was not so much that his original idea would be stolen, but rather that someone somewhere else would come up with the same idea and patent it first. After all, we surgeons are all trying to solve similar problems. Since there are a lot of us, it should not be surprising that several of us might independently come up with the same solution to the same problem.

So, before you get too carried away with developing your idea any further, you’ll need to make sure that you were the first person to document your great idea. Notice that I said *document* and not *think of*; it is the *documentation* of the idea that counts.

I learned this lesson the hard way. One day, while looking at a pair of tennis shoes, I had the idea to make an eyelet device to prevent sutures from cutting through osteopenic bone during rotator cuff repair. I performed a rudimentary search to make sure that my bone eyelet idea had not already been developed or patented by someone else. I couldn’t find evidence to indicate that any such product existed. Excited by the prospect of making a huge contribution to the field of shoulder surgery, I performed rudimentary biomechanical testing in my office with synthetic foam blocks. The test results seemed to validate the concept! On to the next step! Call in the engineers! I began to talk with them about product development.

Then a sales rep told me about a product by Mitek called the Cuff Link. The rep did not know about my bone eyelet idea, but was aware of my dissatisfaction with the use of suture anchors as a way to anchor rotator cuff tendon to bone in patients with osteopenia.

As you can probably guess, the Cuff Link device was almost exactly the same as the bone eyelet that I had independently conceptualized. The rep was disappointed when I explained that the reason my jaw had hit the floor wasn’t because I was blown away by his product, but rather due to the time, money and effort I’d wasted as a result of my insufficient patent search efforts.

There was really no excuse for me not discovering the prior art for the Cuff Link device—other than the fact that intoxication with the idea had impaired my judgment. These days, you can perform a thorough patent search on your own, online, for free. Visit the website of the U.S. Patent and Trademark Office (www.uspto.gov) or try an alternative site such as Patent Storm (www.patentstorm.us) that utilizes the same information but in a more user-friendly format.

In my opinion, it is probably most effective to perform the initial search yourself as opposed to hiring a lawyer to do this. Why? Because as an orthopaedic subspecialist, you speak a subspecialized language, and anyone who is not facile with this subspecialized language might have a harder time finding the relevant prior art. The title of the patent for the Mitek Cuff Link device is *Methods and apparatus for...*
Guest Editorial

preventing migration of sutures through transosseous tunnel. It would have been more difficult to discover this patent without using the search term “transosseous,” and most of the lawyers that I know aren’t throwing that term around much at cocktail parties.

Once you’ve completed your initial search and are fairly sure that your idea hasn’t already been claimed, it is prudent to give your search results to a patent lawyer and ask him to perform his own search. Patent lawyers speak their own subspecialized language, and a search performed by a good one will surely augment your results. It might also be wise to speak with the patent lawyer about the merits of submitting a provisional patent application at this time.

The Feasibility Study

If after searching you still believe that your idea hasn’t already been claimed, the next step is to figure out if the device even makes sense. In other words, will your idea translate into a practical, real-world device?

I don’t claim to know the best way to perform a feasibility study, but I think a good start would be to ask the following questions: Does your device solve a known problem? Why would a surgeon use your device vs. an alternative? Will your device lead to superior surgical outcomes compared to competing devices? Might use of your device create new problems? How easy will it be to convince orthopaedic surgeons that your device will lead to superior outcomes?

Further, will your device be sleeker and sexier than competing devices? Will it decrease operative time? How big is the market for your device? Will it work in the hands of the average orthopaedic surgeon (large market), or only in those of the super-subspecialist (small market)? Are there any world-renowned, podium-presenting, paper-publishing orthopaedic surgeons who share your way of thinking enough to use your device and extol its merits to the masses? Can your device be manufactured at a realistic cost, and sold for a price that will be reimbursed by Medicare and private payers? Is there a good chance that your device will be FDA-cleared through the relatively inexpensive 510(k) process, or is it so radically different that the more daunting and expensive Premarket Approval process will be required?

You’ll need to solicit feedback from others as you seek answers, and this means showing your idea to other surgeons, engineers, manufacturers, marketers, etc. Consider writing a mock brochure for your product prior to approaching others. This will help you to answer at least some of the above questions, and will give others a good visualization of your idea. It will also help organize your thoughts. Being able to describe your device to others in a well-organized, succinct manner will be important. It is also prudent to have others sign a nondisclosure agreement before showing them your work.

Be prepared for harsh criticism. In fact, you should ask for it.

To Drive or Not To Drive—That is the Question…

It is now time to remove the rose-tinted glasses, pour a cup of black coffee and take a sober look at the information in front of you. You’ve documented your idea on paper. You and a witness have both signed and dated your work. You’ve performed a patent search and completed at least a rudimentary feasibility study. You’ve protected yourself along the way via nondisclosure agreements and possibly a provisional patent application. You’ve asked and answered a lot of hard questions, and you’ve obtained opinions regarding your idea from multiple unbiased experts.

Finally, if you’ve made it this far, you’re most definitely an orthopaedic inventor who has been intoxicated by the possibility of improving people’s lives with your invention. Now the question is, are you really a Doctor With Ideas, or in hindsight were you a doctor who was intoxicated? Intoxication with your idea may have served as the inspiration that was needed to complete the above work. But, just as it is for the driver who unknowingly steers his automobile toward a police roadblock, intoxication now becomes a liability. Everything that you do to develop your idea beyond this point is most likely going to cost lots more money, so a clear-headed assessment of the potential risk at this stage is mandatory. However, completing these steps will help you decide if it makes sense to continue to sit behind the wheel of entrepreneurship, or if it would be better to pull over, abandon the vehicle and walk home.

I wish you safe and successful driving!

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