

The Pursuit of Innovation

Pearls from a Physician-Inventor.

By Malik Y. Kahook, MD

My first experience with inventing a device started during my last year of residency at the University of Colorado. For all residents, that is the point in training when you spend the most blocked time in the OR, whereas during the first 2 years you are trying to hone your basic clinical and examination skills. Once you get into the OR, you start to learn the fundamentals of being a surgeon and a whole new world opens up for discovery and innovation.

It turns out that the time spent learning the basics of surgical practice is actually an excellent opportunity to start thinking about new ways to do things. As a resident, you do not have any biases, and you do not have the years of experience to have developed entrenched habits. Instead, you have a fresh mind and a fresh outlook. Therefore, it was during residency that I started dabbling with new devices for cataract surgery and glaucoma surgery. At that time, I was fortunate to have the support of my department, which was very forward thinking about translational research. I was given resources to spend time in the laboratory and some financial backing to start building prototypes to test in the preclinical setting.

THE LIFE OF AN INVENTION

There are different periods of time within the life of any invention. First, there is the birth of the invention, when you have to show to yourself and to your team that there is merit behind the idea, that it is unique, and that it will serve a purpose. Next, there is the period when you are building a prototype and testing it to show that it can be done, that the mechanism of action is what it should be, and that it produces the intended results.

After those 2 phases, you reach a period in which you have to spend a great deal of resources not only financially but also from an infrastructure and time standpoint. At this stage, it starts to make a lot more sense to partner with a larger strategic—and “larger” is a relative term. It could be a small-sized company that specializes in the area in which you are working, or it could be one of the larger companies such as Allergan, Alcon, or Abbott Medical Optics that provides years of expertise and the potential for the needed financial backing. These partnerships will allow you to take the device to the next phase of clinical testing, which is usually beyond the capabilities of a single researcher at an academic institution or in private practice because it becomes

a major expenditure at that point. From the beginning, I considered partnership with industry necessary for some of the devices that we were working on to succeed.

LESSONS LEARNED

The major point that I like to stress to younger doctors and to residents and fellows is that the easy part of the invention process is thinking of the idea. The hard part is really pushing that ball down the road to completing a patent search, where you see if the idea is unique, and to start thinking about what team members you need to include; certainly, physicians cannot do these things alone and need to collaborate with engineers, individuals with regulatory backgrounds, and business-savvy partners. Once you have the idea and start marching down the road, you have to think about these collaborators who can help you because it really does take a team of invested individuals to achieve success. It is only in rare circumstances where a single individual has the complete package to take something from idea all the way to the market.

Early in my experience, I learned that I was pretty good at coming up with ideas, and the proof of concept phase was something that I felt I did well. However, the business aspect, the regulatory aspect, and certainly the engineering aspect were all things that I realized I had to partner with others to undertake. Some of those partners came from my medical campus, and some were contract manufacturers who were in town; these are outfits that will team up with any inventor to help with the engineering and manufacturing processes and exist all over the country. As I completed several projects and became more familiar with the business, regulatory, and engineering aspects of projects, I gained a level of comfort that allowed me to engage more in these areas of the development process. However, I still rely on members of our team with specific skillsets in these areas to provide advice and share their wisdom. I am always looking to learn and expand my own skillset.

I also learned that simply talking to partners in industry—whether someone from the R&D side or the marketing side—can provide a great deal of input early on in the process of determining if an idea has merit. You do not necessarily have to team up and have a company license your product, but you can reach out to industry partners and talk to them in basic and high level terms about the R&D process and the marketing process that

they go through and what they look for in a successful product. I have found the industry partners in ophthalmology to be extremely approachable and very willing to share their thoughts, both because they want to be helpful and value relationships and because they are always looking for an idea that will make their products better or potentially a new product to grow their business. I also found that discussions with strategics can sometimes be helpful in the decision to license products directly from our lab to collaborators versus forming our own startup company that can develop specific devices further prior to any collaborations taking place. Each device requires a unique approach, and collecting as much information before deciding how to move forward is always of value.

FORMING COLLABORATIONS

I always make it a point to have discussions with industry partners about the devices we are working on so that I can get a sense as to whether there is a real niche or appetite for what we are doing. However, in the early stages, these conversations are usually in very general terms and do not go into the specifics of how the device works or any of the novelties behind it.

I do not approach companies to discuss collaboration until I have figured out a few extremely important points. The first point is going all the way to proof of concept with a device before approaching anyone. Proof of concept could be as simple as building a device and showing that it works in the intended fashion or doing preclinical work in which you take the device to the laboratory and perform treatments on different preclinical models to demonstrate its efficacy. Some strategic companies prefer not to have discussion regarding any device without actual clinical data that they can analyze. In addition to showing that the device can be built and works as intended, it is crucial to complete some of the tasks that physicians are not necessarily comfortable with—things like performing market research, describing what the device's regulatory pathway may be (whether it a Class I, II, or III device), and determining where it fits into the market, how big that market is,

Dr. Kahook has filed for 21 patents, several of which have been licensed by companies for development and commercialization, earning him the title New Inventor of the Year for the University of Colorado in 2009 and Inventor of the Year for 2010.

Dr. Kahook has ownership in OcuTherix, ClarVista Medical, ShapeTech, Shape Ophthalmics, Mile High Ophthalmics, and Aerie Pharmaceuticals and patent interest in OcuTherix, ClarVista Medical, ShapeTech, Shape Ophthalmics, Mile High Ophthalmics, Abbott Medical Optics, Glaukos, Oasis, and New World Medical.

what niche the device will fit into within that market, and whether it will displace other devices or piggyback onto existing devices.

Another extremely important effort for inventors to spend time on is to look at the current portfolio and pipeline of the company you are talking to. You need to see if your product merges well and can piggyback on top of some of the company's existing devices or upcoming devices, or if it produces a completely different product line for that company. The discussion is very different between those 2 factors. There is a lot of value in understanding all of these aspects before sitting down with the companies because these are all things that will be on their mind and they appreciate answers to them in the early phase.

POINTS OF ADVICE

Finding mentorship is vital for the young physician-inventor. If you are starting out in an academic setting or private practice and know that you want to make translational research and innovation part of your practice, it is extremely important to find someone who has been there and done that and can talk to you about mistakes he or she has made, lead you toward other high-quality collaborators who he or she has worked with in the past, and steer you toward an understanding of what the financial undertaking might be, including how to approach getting funds and then, once they are in place, how to manage them.

Beyond mentorship, it is a wise idea to be introspective. Even though we physician-inventors view our inventions as our babies and want to make sure that they succeed, the majority of ideas and projects will not actually make it to market. It is important to be comfortable with the go/no-go decision. You must come up with a process in your own mind and with your collaborators on board so that you have a constant discussion of go/no-go throughout the process of invention. If something appears to not be working, the inventor and collaborators all need the courage to acknowledge the project is a no-go before too much time and money is spent and then to move on to the next idea.

I believe translational research is a worthy endeavor for any clinician-scientist and can enrich the lives of those who choose to pursue innovation as part of their career path. While the road can be bumpy at times, there will be moments of great joy after achieving success in developing novel devices that can enhance clinical outcomes and benefit the patients we care for on a daily basis. ■

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