Podcast Transcript

How to Protect and Clear Your Medical Device During Development

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Rubenking: When developing a medical device there are countless questions and challenges that keep you up at night. Whether it's concept, design, manufacturing or sale, no doubt at some point you will ask, what patent strategy do I employ to fully protect my idea? I'm Randall Rubenking, and you're listening to BakerHosts. On today's episode we explore specific patent protection and clearance strategies for each stage of medical device development with Hussein Akhavannik. Hussein is a partner in the Intellectual Property Group at BakerHostetler and is co-leader of the firm's Life Sciences Industry team. He has a technical background in biomedical and computer engineering and focuses his practice on medical device and software prosecution. Welcome Hussein.

Akhavannik: Thank you for having me Randall.

Rubenking: Hussein, I'm looking to enter a market and I have an idea for a new medical device. What's the very first thing I should do to protect my idea and to assess the risk of coming to market?

Akhavannik: Well, that's a great question Randall. So, during the medical device development process there's four stages: the concept stage, the design stage, the manufacturing stage and finally, the sale stage. So, we're going to focus here on the concept stage, when you've identified a product that you want to bring to market. The first thing that you want to see is, what are the risks associated with that design or with that product? So that's what's typically called a landscape search. In this search you want to look for a few different things. The first is, who are the big players in this space? What are the other companies that are

manufacturing similar products? The second is, what patents have been asserted for similar products? So, are there litigious competitors out there who we should really assess before entering the market. And finally, which companies are the most active filers? And we can determine that by looking at the recent PTO filings for that technology, and also looking up on the internet to see what new products have come out that you will be competing with. This search would typically uncovers about 50 to 100 patents that are the most relevant and including some competitors that we take a look at. What you're gonna look for among all of those patents is what we call blocking patent. It's a patent whose claims are so broad that it makes it very difficult for you to bring a similar product to market. Assuming there's no patents like that, the risk assessment at a high level is low.

The second thing you wanna do is file a provisional application. If you've gotten to the sort of a concept stage where you have a drawing, whether it's a CAD drawing, a drawing on a piece of paper, or even something you can sketch out and have a draftsman formalize, it's a good idea to get your idea within the patent office as soon as possible. Since 2013, the USPTO has been working on a first-to-file basis. And so the earlier you file with the patent office, the earlier, you know, your priority date is. And so, we recommend a generally high-level provisional patent application at this stage as well.

Rubenking: Okay. So, I've done my initial research and now I've settled on a design. What are my next steps?

Akhavannik: Much like the previous steps, it's gonna be in two-part, clearance and patent application. On the clearance search, the focus is going to be a lot different. You've kind of formalized the design. What we recommend doing with your patent attorney is looking at the features of that design that are commercially significant and new. Those are the two main features you should focus on. So, if we're going through a design, what is it that differentiates your product relative to others on the market, and which of those features are absolutely crucial for you to have in order to go on your market share and sales? What we do is once we identify those features, typically a good number is, you know, two to five, roughly, is something that's normal. We'd send that off to a third-party searcher to identify claims of patents that may pose a risk for those features 'cause again, those are the most important, those are ones you can't really live without. When those come back to the patent attorney they'll be identified and be analyzed, and if there are any that are risks you can do a validity or a true noninfringement assessment of those high-risk patents. And then if you don't find any risks, that gives you very good clarity that your risk level is low. That's what you would do on the clearance side, a much more focused search than the landscape search.

On the patent application side, you know, as long as you're within 12 months which we recommend you to be, you wanna convert that provisional application to a nonprovisional application. So again, you have a design, we can file a very robust application describing that design. In addition, you should start thinking about future-proofing your invention as well. So, what are some additional features the second-generation product may include? How would a competitor get around your patent, or get around your product? We wanna include all that

detail in this one robust nonprovisional application. Typically this first patent application, this first nonprovisional, we recommend to be very thorough, and really cover all your bases. Because it's gonna be the bedrock to protect your product down the road.

In addition to the nonprovisional application, you can also think about a design patent if there is an ornamental aspect of your design perhaps the signature of your company that you want to include, like a certain logo that's gonna be part of the design as a whole, not just a logo itself but the logo incorporated in the design. Or maybe there's, part of the ornamental design really makes it distinctive and, so it will stand out in the marketplace. That will be good to protect in addition to the utility of the invention itself. In addition, design patents are fairly low cost, so there's not a large investment there.

Finally, you wanna think about trademarks. Are you gonna have a name for this product, where are gonna be your major markets, where do you wanna file that trademark application? And again, that's fairly low cost as well relative to the nonprovisional.

So for the nonprovisional patent application, you also wanna think about what other countries outside the United States to file your patent in. So, every patent gives you protection within the geographic boundary of the country in which you patent. And so, a U.S. patent will cover the United States. It's also typical for our clients to file in Europe, Canada, Japan, China, Australia, Mexico. Those are some of the major jurisdictions. One of the interesting things about Europe is that you can file a single European application and upon its grant, then decide which countries within Europe you want to seek protection. Now, the major jurisdictions there, they tend to be France, Germany, Spain, the United Kingdom, you know, really the big economies, and more recently some of clients have been filing in Ireland, as there's been a lot of R&D on the medical device side and manufacturing that's being done in Ireland now relative to one or two decades ago.

One component of cost that you should keep in mind is translations. When you're filing in a jurisdiction that is a non-English jurisdiction like Japan or China, there's gonna be a translation cost associated with that. Another cost you want to keep in mind is annuities. So in the United States, maintenance fees or annuities are not due until the patent grants. Whereas in a lot of these foreign jurisdictions, a majority I should say, of those foreign jurisdictions, annuities are due every year. So, there can be sort of a multiplier effect in terms of cost when you wanna file overseas and that's why you wanna be strategic about that. We recommend looking for markets where you think you can get considerable sales, where you have competition in terms of sales, and where you have competition for manufacturing as well.

Rubenking: Okay. That's all good. So let's say I've done all my research, I've filed all my patents, and now I'm ready to start manufacturing. How can I avoid the expensive costs that might be involved with retooling?

Akhavannik: Yeah, those can be considerable, six figures or more based on what my clients tell me. Here we recommend to update the freedom to operate search. So some time may have passed since you finalized the design to when you want to start tooling. During that time period, there may have been patents that were previously unpublished, or hadn't granted, which may pose risks. We recommend doing the relatively low-cost update to the freedom to operate search you did in the previous stage, in the design stage, here right before you order the tooling for your design. In addition, assuming enough time has passed and there's been any updates that have come up for the design, or that you have thought about for a next generation product, a continuation-in-part application what's built on top of your previous nonprovisional application is also a good idea.

One thing a lot of our clients ask us is about the method of manufacturing the product. They wanna know whether we should file a patent application on that. The short answer is no. But there are some caveats. If the way that you're manufacturing your product can be determined based on a visual inspection of the product and there's value added based on that method of manufacturing, perhaps it hasn't been done in the past, it might be more efficient, lower cost, higher throughput, it may make sense to cover your method of manufacturing because it is a commercial advantage and it can be determined by a competitor. However, in most cases we find that the method of manufacturing cannot be known just by inspecting the final product itself. So instead of having a 20-year monopoly on that design, we recommend you keep that method of manufacturing a secret and really that way you have almost a lifetime of trade secret protection for that method.

Rubenking: Okay. The product is being manufactured and I've started sales. Does this mean I don't need to do anything else to protect my property, my patents? Is that right?

Akhavannik: A lot of folks typically stop both the clearance analysis and the patent application filings at this stage. I tend to counsel my clients to do a little bit more. And so, patents generally do not publish for 18 months until after they're filed. So, again there could be a risk that at some point following your initial sale, there may be another risk that comes up that we weren't aware of in the past. So, what I tend to counsel my clients is to wait 18 months following that first sale to do a final update freedom to operate search. So again much like the manufacturing stage, well we're not starting from scratch. It's kind of a temporal limit on what patents we're looking for, which tends to lead to a fewer number of search results and lower costs. We want to do an 18-month search following your first sale. So that's the first stage. The second stage, again you want to be in the patent office as soon as possible. So at that 18 month is a good check-in time to see whether there's been updates to the design. At that point you've presumably received some customer feedback and perhaps there's changes that you wanna make that are, that can be patent protected. And so, starting to create that second generation of patent applications, it's a good time to do that.

Rubenking: Excellent. Thanks very much, Hussein. If you have any questions for Hussein, his contact information is in the show notes. As always, thanks for listening to BakerHosts.

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