BCLT-Oregon Start-Up Series: Session 2 Transcript

Allison Schmitt 00:30
Hi everyone and welcome to today's Startup Series program. We're going to be focusing today on intellectual property issues for medical device startups. We are really lucky to have two expert attorneys from Fish & Richardson who are going to be walking us through the ins and outs for those of you who are thinking about bringing medical device startups online and heading towards market, and I think that there's going to be some good nuggets in here, even for those of you who may not be operating in the medical device space, just more generally, in terms of how to be thinking about IP. So with that, I'm going to turn things over to our speakers.

Tyler Train 01:04
Thanks, Allison. Well, as you all just heard, today, we're going to be discussing IP for medical device startups. This is part of a collaboration between Fish & Richardson and UC Berkeley School of Law. So first, I'll start by introducing ourselves. My name is Tyler Train. I'm a principal and patent litigator in the San Diego Office of Fish & Richardson. With me is my colleague, Giordana Mahn. She's a patent prosecutor in our Chicago office. So just to get us started, we'll give a quick overview of a few key topics. First, let's look at what is a medical device. The FDA defines a medical device as an instrument, apparatus, implement, machine, contravance, implant, in vitro reagent or other similar or related article that is intended to either diagnose disease or diagnose disease or other conditions, cure, mitigate, treat, or prevent disease or affect the structure or function of the body. Now the FDA breaks these up into three classes of device based on risk of the device to the patient, and we'll discuss that a little bit later. So now let's take a look at what is intellectual property. Intellectual property is a category of intangible rights protecting commercially valuable products of the human intellect in a concrete or abstract form. So IP includes patents, copyrights, trademarks, and trade secrets. We'll walk through each of these today, focusing mostly on patents, but just as a brief overview, patents protect inventions and provide a temporary monopoly in exchange for public disclosure. Copyrights protect written or recorded expressive content. Trademarks protect words, symbols, logos, designs, and slogans that identify and distinguish products or services. And trade secrets protect confidential business information. There are a few legal considerations we're going to be discussing today that medical device startups should be thinking about. First, we'll discuss patents generally and cover patent prosecution and patent litigation, and then we'll get into the non-patent IP. So that's the trademarks, trade secrets and copyrights we just discussed. And then we'll briefly touch on IP agreements and a few regulatory issues. So with that, I'll pass it to Giorie to start talking about patent background and prosecution.

Giordana Mahn 03:37
Thanks, Tyler. So what is a patent? A patent is a limited monopoly over the rights to exclude others from making, using, selling, offering for sale, and importing your patented invention in the US. The most

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important parts of a medical device patent are the claims description and the figures. So in exchange of your disclosure to the public after the patent term exclusivity with over that patent term. So what can you patent? Any useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof that meets the statutory requirements of subject matter, eligibility, novelty, and non-obviousness. So how long is it patent valid for? Well, I just mentioned over the patent term. And so as long as you pay the maintenance fees after your patent issues, and your patent isn't later challenged and invalidated, then 20 years from filing the application for utility, and for design patent, that's only 15 years. Now, it's important to note that a US patent will only allowed you to exclude others in the US for exclusionary rights in other countries, you must get patent protection in those countries. The first requirement is statutory subject matter, eligibility, and this is a requirement that you cannot patent a product of nature, a product of nature, law of nature, a natural phenomenon, or an abstract idea. These are considered the basic tools for innovation. And monopolizing one of these tools would stifle innovation. I focus my practice in women's health. So many of my examples I'll be discussing today is on this theme. So an example of a natural phenomenon is when decreased estrogen levels causes a female body to become more sensitive to slight changes in body temperature that cause a hot flash. This in itself, cannot be patented, as this is a natural phenomenon. Giving one entity exclusive rights to this would prevent many possible discoveries and solutions to learning more about treating hot flashes. However, creating a wearable that can detect when estrogen levels are spiking, or that can send a cooling signal to your pulse when you are experiencing a hot flash, may be patent eligible. The most important things scientists and engineers should know about IP is that there is a limited time in which you can file a patent. In the US, you have one year grace period from a public disclosure. While this can be as little, which is can be as little as discussing your work with friends at a party, or offering your product for sale, even a secret sale, to file a patent application with the USPTO. Also patents are awarded to the first to file a patent application on an invention, the first one in the door may receive the patent, but not necessarily the first one who invents the technology. In most cases, filing a patent application should always be sooner rather than later. The nonobvious requirement is essential. Even if your idea is novel, an invention is not patentable if it differs from the prior art only by way of an obvious modification. For example, you might not want you might not find a wearable breast pump that exists in the market in a certain color, but you shouldn't be awarded in a patent for an obvious modification. "Obvious" means obvious to a person of ordinary skill in the art at the time the invention was made. Be careful not to use obvious in writing, as this word carries a lot of weight that can come back to haunt you in litigation. The obviousness requirement keeps inventors from claiming something that is not inventive over something belonging to the public or someone else, and this is a very is a highly subjective requirement, and is probably one of the most difficult parts of my job. A patent application filed with the USPTO ensures a priority claim to your invention and serves as an objective measure of your contributions to a technology at a given point in time, being the first to file at the patent office makes it much more difficult for someone to steal your technology. The Patent Office is diligent about comparing patent applications to existing patents, and often will reject patents requests ideas that don't meet rigorous standards for originality or novelty, obviousness, and eligible subject matter. If you're not quite ready to file a nonprovisional patent application, which is examined by the PTO, a provisional application, which is a placeholder application and is not examined by the USPTO, may buy you at least a year of time to get your house in order. A provisional application, as I said, is a placeholder application and is not examined. But of the types of applications that are examined, which are nonprovisional applications, you have a utility application, design, or plant and from either utility or

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design applications, you can file subsequent related applications with different claims, called continuations or divisional applications. All applications stemming from the first nonprovisional application are considered a patent family. I'll briefly speak about a PCT application, or this is an application related to the Patent Cooperation Treaty, and it's like an international patent application that never becomes an international patent. You basically gives you an extra 18 months in some countries, 19 months to file national stage applications in each country, in each member country of the PCT, and each of those can issue as a patent in that country. The claims of the utility patent define the outer bounds of the patented subject matter. On this slide, I provided an issued independent claim that I did not write of an example patent that entitled menstrual cups and methods of use. The first menstrual cup patent, issued in 1937, and improvements to the menstrual cup are still being patented, especially in very recent history. The bolded text here, as you see in the claim, this is an independent claim, and figure one is right next to it, part of the application, and the bolded text recites a textured pattern. And in the specification, this textured pattern is described "as apparently aiding, and resisting ripping, tearing, and or breaking of the receptacle of the menstrual cup." On the left, you'll see the same menstrual cup with a hexagonal pattern, but this figure is from an issued design patent, which is totally separate from the utility patent. The other two figures in this on this slide are also issued claims of menstrual cups, but of different design patents. A design patent protects the way an article looks. The ornamental appearance for an article includes its shape, configuration or surface ornamentation applied to the article or both. Unlike a utility patent, a design patent does not cover the utility or functionality of the product. In other words, the design patent cannot exclude menstrual cups that have an hexagonal, hexagonal pattern that may resist tearing. Each design pattern has a single claim that covers the ornamental design for a menstrual cup. And the claim is defined by solid lines in the figure. Here, the claim includes the ornamentality of the hexagonal pattern as well as the other features of the cup, but not its utility. On average, it takes two to three years to obtain an issued US patent from the date the utility application is filed, and this varies wildly, depending on the art unit and the examiner and the backlog at the USPTO. But here is a simplified back and forth with the patent office on the slide. So you file the applicant, files a non provisional utility application with the USPTO. It will publish in about around 18 months after the earliest filing date. Then in six to 24 months after filing, you'll receive a first nonfinal office action, and this is when the USPTO picks up your application, reviews it then performs a prior art search. And then, when forming the nonfinal office action, provides reasons for rejections, objections or other required action. Next, you have three to six months after receiving the office action to reply. In this the applicant addresses each ground of rejection with arguments, evidence and or amendments to the claims figures and specification as appropriate. So, as we talked about the three requirements for patentability, the examiners will find issues or will try to find issues with each of these requirements, and those are the types of rejections you'll receive. So 101 rejection question, our question would be, are the claims directed to eligible subject matter? Do they fall under an exception? So technologies using software or digital health technologies or machine learning and artificial intelligence can run into patent ability, patent eligibility rejections at the patent office. These are known as Alice or 101 rejections, and some key rebuttals include pointing out that the claim subject matter, is not directed to an abstract idea, law of nature, physical phenomenon, or that the claims provide a technical, technological solution that is something significantly more than an alleged abstract idea. For the novelty rejection The examiner will look: Are all elements of the claims found in one prior art reference? Now, if just one element is missing in that cited reference, then the 102 rejection is improper.

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Giordana Mahn 13:21
For 103 rejections, questions will be asked, are the claims obvious in view of one or more prior art references? Would it be obvious to one having ordinary skill in the art to combine the cited references, and would they reach the claims of the patent? Or Would you have to remove a key component from that primary reference that the examiner cited to result in the combination for it to even work? So these are the questions that I also ask when I draft arguments to in response to a 103 rejection, other rejections also include 112 rejections, and this is based on clarity and support for the claims. Well, our job as patent prosecutors is to claim your invention as broadly as possible without being invalid. The claims must have support in the specification, so we'll draft your claims to try to cover future iterations of your medical device that you haven't contemplated yet. But that patent office will reject any claims that don't reasonably support the broadest interpretation of those claims. Then the examiner will respond with the final rejection, for example, and this is where they hopefully will respond to the applicants arguments and provide reasons for any remaining issues. Let's say all goes well and and the applicant files after final response submitted to either amend the claims finally or provides persuasive arguments for, again, you know, to overcome the rejections, then you'll get a Notice of Allowance. So, once the patent is allowed, you pay your issue fee, and now you can exclude others from practicing the claims of your patent. However, you have to monitor the market to see if anyone is practicing those claims, and if they are, you call Tyler.

Tyler Train 15:13
Thanks, Giorie. So you're exactly right. So once you get a patent allowed, there might come a time where you need to enforce the patent, and one of the main ways to enforce your patent is through patent litigation. So we'll go through that a little bit now. Just to start, we'll look at a normal US Patent Litigation timeline. As you can see, the average time to trial and US district courts is a little bit over two years. That can vary a lot based on what district and state that you're you're litigating in, but we'll look at this average here. So first, the first stage is the pleading stage. Now this normally begins with a complaint from the patent owner alleging infringement of a product or service, followed by a response from the accused infringer. After the pleading stage, you move on to discovery. So in this case, you start with fact discovery, which involves written and oral discovery, and also something unique to patent law, called contention discovery. Usually in the middle of the discovery stage, you have a clean construction proceeding, which is also unique to patent law, where the judge clarifies the meaning of a few key disputed terms. Then you move on to expert discovery, where competing experts on both sides provide technical and economic opinions to be used later at trial and before trial, the parties file dispositive motions trying to get the judge to rule in their favor on certain issues before they reach the jury. These are called summary judgment motions, and the parties can also file motions to exclude evidence or expert opinions that they don't think should be presented to the jury. We'll talk about those two. Those are called Daubert motions and motions in limine. Once all of these motions have been settled and determined, the parties present their cases to a jury at trial for determination. We'll start with the complaint. This is the first document that initiates the lawsuit. The patent owner must put the accused infringer on notice of the alleged infringement. Normally in these cases, the patent owner will be the plaintiff. So I'll probably use that interchangeably, the patent owner and the plaintiff, and the accused infringer and the defendant. So when the patent owner puts the accused infringer on notice of infringement, they usually do it through what's called a claim chart, which is shown here on the on the

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right hand side. Now, claim charts usually show claim language in the left column broken up by individual claim elements or limitations. And then on the right hand side, the right hand column, they show evidence of infringement of the accused product that tracks each element of the claim. Now, once the defendant has has received this complaint, they have a few options to respond. Defendant can simply answer the complaint, and they would usually, in that case, deny the plaintiffs infringement allegations. Or if the defendant thinks the complaint doesn't have any merit, they can move to dismiss the complaint. This is a high bar for the defendant to get a lawsuit dismissed at such an early stage, so the defendant's argument needs to be pretty strong at this point. Otherwise, it might be best just to answer the complaint and move on to the discovery stage. In patent litigation, there are two main forms of discovery. There's fact discovery and expert discovery. Back discovery includes written discovery, oral depositions, and contention discovery. Written discovery includes document production, interrogatories, and requests for admission. So document production is where you will ask the other party for them to produce documents within their possession or control, and you will review those documents in hopes for later use in the case. Interrogatories are where you ask questions, written questions to the other side, and they have a certain time to provide written answers to those questions. Requests for admission are generally, generally something used to streamline the litigation, trying to get admissions for generally simple and nondisputed issues, trying to get the other party to admit those so that you don't have to spend a lot of time proving them up. Now witness depositions are where the attorneys sit down with witnesses and ask questions orally about the case. Examples of witnesses and patent cases can include inventors, engineers, executives, and accountants. Now a part of the discovery stage, that is you. Need to patent law is called contention discovery. The plaintiff must submit infringement contentions which are similar to those that they submitted with the complaint, but much more detailed charts. So instead of just having to put the defendant on notice, now, the plaintiff must lay out all of the evidence they intend to use later to show infringement through their experts into trial. T he defendant then responds with invalidity contentions showing that the asserted patent should never have been granted based on available prior art references. These invalidity contentions are laid out in similar charts, but instead of showing infringement evidence in the right hand column, they show disclosures from the prior art that track each claim element. Moving on to expert discovery, this focuses on expert reports submitted by both parties. The plaintiff will hire an expert to explain why the accused product infringes their patent. The defendant will hire an expert to explain why the asserted patent is invalid. And both parties can also submit damages reports from their economics experts. Then the parties have an opportunity to submit rebuttal reports, so they'll hire the same or different technical and economic experts to poke holes in the initial expert reports. After all, the expert reports are submitted, the parties have the opportunity to take depositions of the experts again, trying to poke holes in the reports that they can use later trial. Now, something that normally happens during fact discovery is called Clean Construction, or the Markman process. And this is a process unique to patent law, where parties dispute the meaning of certain claim terms, and the court will determine the correct interpretation. So we see an example here from a medical device patent lawsuit. The claim term in dispute is vascular system, and we see the in the next column, the plaintiff has proposed a construction of circulatory system, of blood vessels. And we'll see in the right hand column, the defendant has proposed a different construction circulatory system, including the heart and blood vessels. So in this case, the defendant's construction is narrower than the plaintiff's construction, because the defendant's construction requires the claim to include both the heart and the blood vessels; whereas the plaintiff's construction, while it could also use heart only, requires blood vessels. So this is a broader

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construction, and this is normal for the patent owner to want their claims to be as broad as possible to show infringement, and for the defendant to want the claims to be as narrow as possible to try to escape infringement. Now, before parties get to trial, they can file certain pre-trial motions attempting to streamline the issues for trial. Parties can file motions for summary judgment, where they ask the judge to decide certain issues in their favor without having to present them to a jury. The parties can also file motions to exclude evidence and opinions from being presented to the jury. Daubert motions are used to preclude experts from offering certain testimony and opinions to the jury based on those opinions being unreliable. Motions in limine are used to exclude evidence from being presented to the jury, for example, because the evidence is not relevant to the case, or what unfairly prejudice the jury begins to party. After the pre trial motions are decided, you move on to a trial where the parties present their cases to a jury. The jury is selected from a group of strangers off the street, so normally, they don't have much, if any, technical background. And this is one of the most challenging aspects of patent litigation, where you have to not only persuade but also educate a jury as to why your technical argument is correct. At the end of trial, the jury will decide if the asserted patent is valid and infringed, and if the jury does find the patent both valid and infringed, then the jury may also provide a recommendation as to the amount of money the infringer owes the patent owner.

Tyler Train 24:09
So we'll take a look at that. Now, after a trial, if there's a determination and plaintiff's favor that the patent is valid and infringe, you have to move on to remedies, and there are two types of remedies, first monetary damages, and second, injunctions. Now for monetary and damages, the plaintiff can either receive a reasonable royalty or lost profits. To receive lost profits, the plaintiff must show that it had a competing product on the market and that it would have sold but for the defendings, the defendants infringement. If the plaintiff can't show entitlement to lost profits, then they must take a reasonable royalty. And this is determined by looking at a hypothetical negotiation from the time of first infringement, and decided based on what the parties would have agreed was a reasonable royalty for the use of the patent through the end of trial. But a plaintiff can also ask for an injunction, which is a court order to the defendant to stop the infringing activities. In medical device cases, this can be especially difficult to obtain as a matter of public policy, because many times you're asking a judge to take a potentially life saving device off the market. So we'll move on to a brief discussion on each of the other non-patent types of intellectual property, trade secrets, trademarks, and copyrights. We'll start with trade secrets, which are most similar to patents, and we'll get trade secrets through a comparison to patents. So trade secrets protect confidential business information. So this is inherently information that is private. Patents, on the other hand, protect inventions, so this is information that is public by virtue of filing for a patent application that eventually gets published. Trade secrets are the subject of reasonable efforts to maintain its secrecy with actual or potential economic value from being, from not being, generally known to or readily ascertainable by proper means. On the other hand, the patent comes from a document that provides to the patent owner the right to prevent others from making, using, offering, to sell, selling, or importing the inventions that are claimed in the patent. So a trade secret, again, is something that is secret, something that you can't—the general public cannot see. And on the other hand, a patent is a document that is telling the public exactly what your rights are and putting them on notice of your rights to that invention. For trade secrets, they have no set expiration, but if ever they are made public, they are destroyed, even if they're made public by improper means, the loss of the secrecy destroys the trade secret. On the other hand, patents expire 20 years after filing.

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This is the quid pro quo of patent law, where, in exchange for a limited 20 year monopoly, you are giving to the public and disclosing to the public your invention that they can then use after expiration of the patent. We'll quickly look at the general elements of a trade secret. First, as we've discussed, they must be secret. The information at issue must not be generally known or readily ascertainable. Next, they must have some value. The information has to have actual potential value that arises from the fact that it is not generally known. And finally, you must show that there were reasonable measures to preserve the secrecy. The owner has to have taken reasonable steps to ensure that the information remains secret. So reasonable measures can be things like legal documents like NDAs and employee agreements and policies. It could also be just limiting the information to high level employees on a need to know basis. It could also include physical protection, like keeping the information, such as a recipe, under actual lock and key. Next, we'll look at trademarks. What is a trademark? Well, a trademark is something that identifies to the public that the goods bearing that mark come from or are quality controlled by a single source. And a service mark is a subset of trademarks, but it protects services instead of goods, and a service mark identifies a single source of services. So we'll look at a few types of marks. First, there are word marks, as you see here, such as Uber or Xbox. You can also trademark symbols, such as these symbols for Nike, Red Cross, and Microsoft. Other things you can trademark include slogans such as KFC's "Finger licking good," NBC's three note chime, the red bottoms of Louboutin's shoes. You can trademark the smell, such as scented yarn. And you can also trademark nonfunctional shapes of packaging or a product itself, and that's called trade dress. So examples include Coca Cola bottle shape and Hershey's Kisses. Last we'll move on to copyrights. Now, a copyright is defined as an original work of authorship, fixed in a tangible medium of expression. So break that down into an authorship component and a fixation component. Copyright protects original works of authorship, including graphic, literary, dramatic, musical, and other types of works. So you can see a few examples here on the slide, photographs, illustrations, books, songs, musical compositions, sound recordings, and computer programs. What something that is not copyrightable are facts. So facts include things like phone book listings and sports statistics, something that is not an original work that was created, but yet, are inherent facts that are not protectable. You also must show fixation to be entitled to a copyright. Now, something important and different about copyright protection, as opposed to trademark and patent, is that copyright protection arises automatically from the moment a work is first fixed in a tangible medium of expression. Copyrights can be registered, and there are certain incentives to registering a copyright, just like patents and trademarks, but they don't have to be the the protection arises automatically upon fixation. So in other words, it's no longer just in the author's head. So there are many ways to show fixation of a copyright. Some examples include written down on paper, recorded on a video, captured in a photo, a song that's that's been recorded, many ways to show to show fixation. Now, the owner of a copyright has certain exclusive rights to that copyright, and these are called the exclusive bundle of rights. So these rights include the right to reproduce the work, to prepare derivative works based on the copyrighted work, to distribute and sell copies of the work to the public, to perform the work publicly, to display the work publicly, and to perform the work by means of a digital audio transmission, in the case of sound recordings. Now I'm going to hand it back over to Giorie to discuss IP agreements.

Giordana Mahn 31:56
Thank you, Tyler. Before I talk about the most common patent contracts the med device startup may face. I want to mention an agreement between the applicant and the USPTO. As an applicant, you

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have a duty to disclose all art relevant to the subject matter of your patentable invention, to the PTO that you know of while your non provisional application is pending, if you hide novelty, destroying art, and it comes out later in litigation, you could lose your patent entirely. Now back to the slide. First. IP ownership is important to understand at the start of any project you work on, assignments is crucial, unless otherwise identified at filing, the inventors are assumed the owners of the patent, and an assignment is an ownership agreement that assigns all rights to the invention from the inventor to another person or entity or between entities. If you invent a patentable med device during the course of your work as a student or while you're employed with a company, you may have an obligation to assign the rights in that invention to the university or employer. This may be detailed in your university IP policy agreement or employment agreement. Confidentiality is key. Do you have an idea? Well, don't disclose it. Yeah, a disclosure starts the clock for filing a patent application if you want to pitch the idea or work with a product design firm, consider putting a non disclosure agreement in place. Similarly, a CDA allows you to discuss your work with a third party comfortably without holding back details that might compromise your ownership as with other contracts, don't use an office supply store contract. You want in an agreement that is specific to your situation. For example, a CDA might say that each party retains ownership of its pre existing technology and shares ownership of jointly developed technology. If data is shared, you might have a provision saying it must be returned upon request and remains the property of the original owner. As I just mentioned, joint collaboration agreement is is can be part of a CDA or separate. So this happens when you've identified a problem and you're working on a solution with a third party outside of your organization. You may consider a joint collaboration agreement, which could should clearly identify who owns what intellectual property created during the joint collaboration. Now, after you have an issued patent and you need some help manufacturing and marketing your protected medical device, you may want to consider licensing your patented technology. A license is an agreement that permits a person or entity to practice the claims of your patent without being sued for infringement. You can do carve outs based on subject matter or territory time limits. Again, it can be curtailed to the specifics of your situation. If your research and work contributed to a patentable idea while you are a student or employed at a university. See your the university may or employer may own the patent. You may be able to spin out and start your own company to further develop, manufacture and market the patented device. The tech transfer office at universities help negotiate licenses to further develop the product or otherwise practice the patent owned by the university without being sued for infringement. This is very common at research institutions that do not have the capacity or interest in bringing a patented product to market, but would still wants to retain their ownership in the IP to recover their investment. Back to you, Tyler.

Tyler Train 35:36
Thanks, Giorie. So we'll finish this up by briefly discussing regulatory issues, specifically FDA regulatory issues for medical devices. Quick note on this, regulatory is something separate from intellectual property. There are separate regulatory attorneys that can help you with your regulatory issues, but it's so important, especially in the medical device space, to have an understanding about regulatory issues. So we wanted to include just a brief note about that here at the end. So the FDA is the governing body that that oversees medical device regulation now authorization for a medical device to be put on the market is based on risk. So we look here, the FDA has broken up medical devices into three classes. Class I is lowest risk. Class I devices are generally going to be exempt from needing FDA authorization, such as the 510(k) authorization we'll discuss with Class II device, but there are still general controls

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that apply. So for example, manufacturers must still register with the FDA unless their device. There are still certain labeling and compliance requirements for Class I devices, and you still must report adverse events to the FDA. Now for Class II devices, this generally represents medium risk devices, and for a medium risk Class II device, you must demonstrate a substantial equivalence to a predicate device under the FDA 510(k) program, this requires the same this requires a showing of the same intended use as a predicate device, and either a showing of the same technological characteristics, or if there are different technological characteristics, that is showing that the differences do not raise new questions of safety and effectiveness, and that the new device is as safe and effective as the predicate device. Finally, we have Class III devices. Now these are the highest risk and novel devices, and these require pre market approval applications which are more thorough than the 510(k) authorization for Class II devices. This applies, again, to certain high risk devices and devices that do not have a predicate device. Generally, only about 1% of all medical device, of all medical marketed devices, fall under Class III. The vast majority fall under Class I or Class II. So we're at the end, and we just want to say thank you for your time. We really appreciate you joining and hope that you you learned something from this presentation. We wish you the best of luck with your medical device startup, and if you ever have any questions or need any assistance with your IP issues, we've included our contact information here our emails. So please feel free to reach out, and we'd be happy to talk with you and interested to hear about what you're doing. So I'll send it back to Allison to wrap us up.

Allison Schmitt 38:53
I think everybody in the audience is going to take away some really useful information from today's presentation, and so I'm so grateful to both of you for your time and your effort in putting together this really terrific piece, I really do encourage the audience to continue the conversation with our speakers. Don't hesitate to reach out, and I look forward to seeing everyone for our next program.

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UNIVERSITY OF CALIFORNIA

IP for Medical Device Startups

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Meet the Speakers

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FISH.

What is a Medical Device?

- Instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article that is intended to:

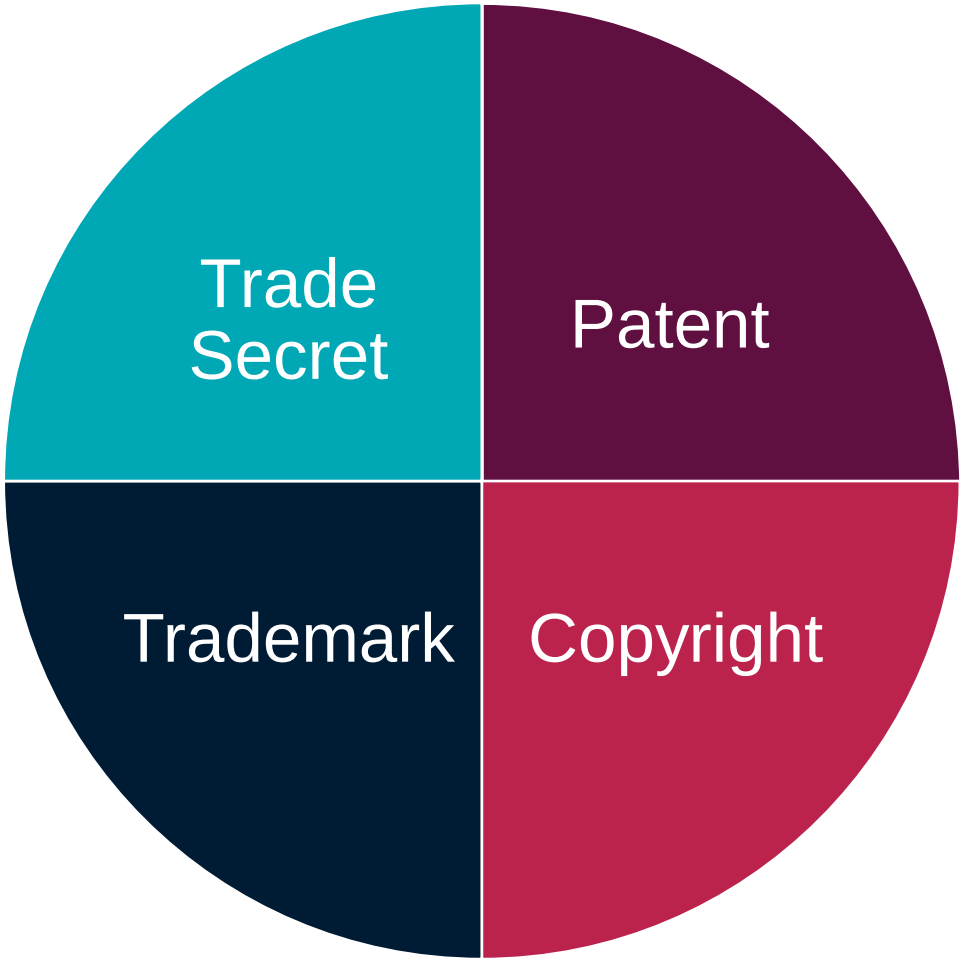
1) Diagnose disease or other conditions,
2) Cure, mitigate, treat, or prevent disease, or
3) Affect the structure or function of the body

- Class I, II, and III devices

What is Intellectual Property?

A category of intangible rights protecting commercially valuable products of the human intellect, in a concrete or abstract form.

Black's Law Dictionary (11th ed. 2019)



Legal Considerations for Medical Device Startups

- Intellectual Property – Patents
  - Patent prosecution
  - Patent litigation
- Non-patent IP
- IP agreements
- Regulatory

Patent Background and Prosecution

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What is a Patent?

- **A limited monopoly** granted by the government over the rights to **prevent others** from: making, using, offering to sell, selling, or importing the invention(s) claimed in the patent.
- Any “useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof” that meets statutory requirements of
  - ***subject matter eligibility***,
  - ***novelty***, and
  - ***nonobviousness***
- **Limited Term** – 20 years for utility and plant patents; 15 years for design patents, in exchange for a description on how to make and use the claimed invention
- **Territorial** – must obtain patent in every country where protection is desired.

§101: The Statutory Subject Matter Requirement

- Invention must fall into a category that Congress deemed patent eligible.

Patent eligible	NOT eligible:
✓ Process (or method)	✗ Product of Nature
✓ Machine	✗ Laws of Nature
✓ Manufacture	✗ Natural Phenomena
✓ Composition of matter	✗ Abstract Ideas

§102: The Novelty Requirement

Public Disclosure and Grace Period

- **An inventor's public disclosures will not preclude a patent in the U.S., *unless* the patent application is filed within one year of the disclosure.**
  - AKA the "grace period"
  - An inventor's public article and speeches are not prior art if made within one year of patent application.
- **File a patent application sooner rather than later**
- **Typical bar date triggers:**
  - Journal articles
  - Product release brochures
  - Conference presentations, abstracts
  - Disclosures not protected by non-disclosure agreement (NDA)
  - Website postings
  - Selling/Offering for sale (even under a secrecy agreement)

§103: The Non-obviousness Requirement

- Even if novel, an invention is not patentable if it differs from the prior art only by way of an “obvious” modification.
- “Obvious” means obvious to a person of ordinary skill in the art at the time the invention was made.
  - Careful not to use “obvious” in writing as this word carries a lot of weight and can come back to haunt you in litigation
- Keeps inventor from claiming something that is not inventive over something belonging to the public or someone else.
- Highly subjective.

Types of Patent Applications

- Provisional (Utility only)
- Non-provisional Application
  - Utility & Design
    - Continuation
    - Divisional
    - Continuation-in-Part
  - Plant
- Patent Cooperation Treaty (PCT) application

Utility Patents

Improved Device

1. A menstrual cup, comprising:

a rim having an upper portion, a lower portion, a first end, a second end, and an exterior surface, the rim defining a first lip adjacent the upper portion, the first lip extending along the exterior surface of the rim, the rim comprising silicone; and

a receptacle disposed adjacent and attached to the lower portion of the rim, the receptacle defining an interior surface, the interior surface comprising **a textured pattern**, the receptacle comprising silicone, wherein a slope of a first end of the receptacle adjacent to the first end of the rim is less than a slope of a second end of the receptacle adjacent to the second end of the rim;

wherein the first end of the rim extends away from the receptacle.

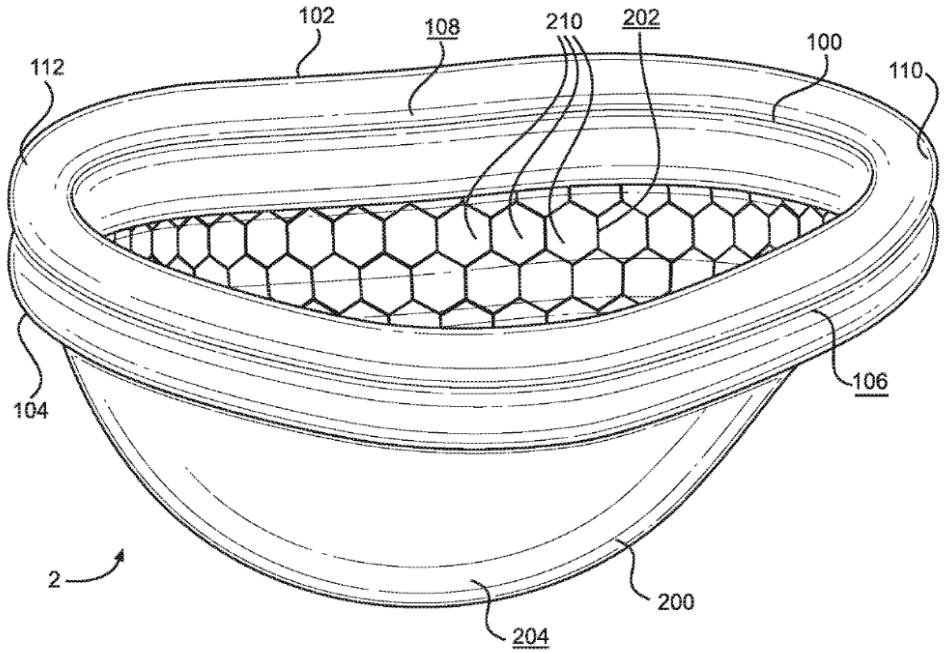

FIG. 1

US 10,888,450
Menstrual cups and methods of use

Design Patents

Ornamental appearance of the design

"I claim the ornamental design for
a menstrual cup, as shown and described."

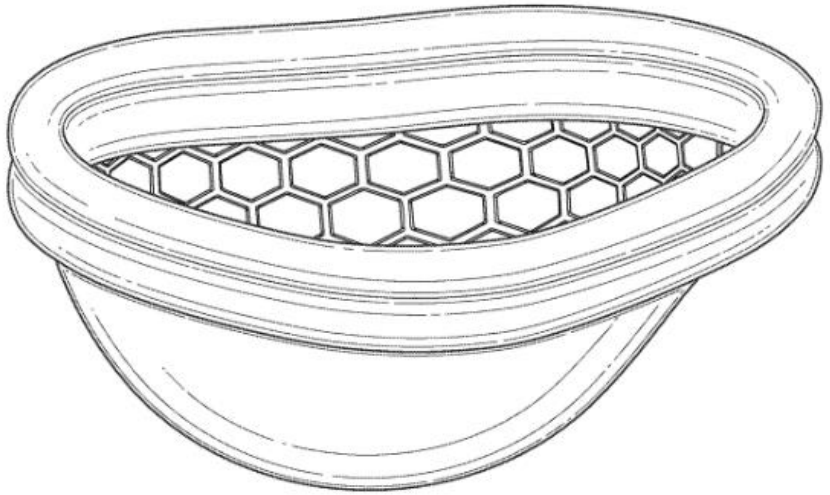

FIG. 1

D837980

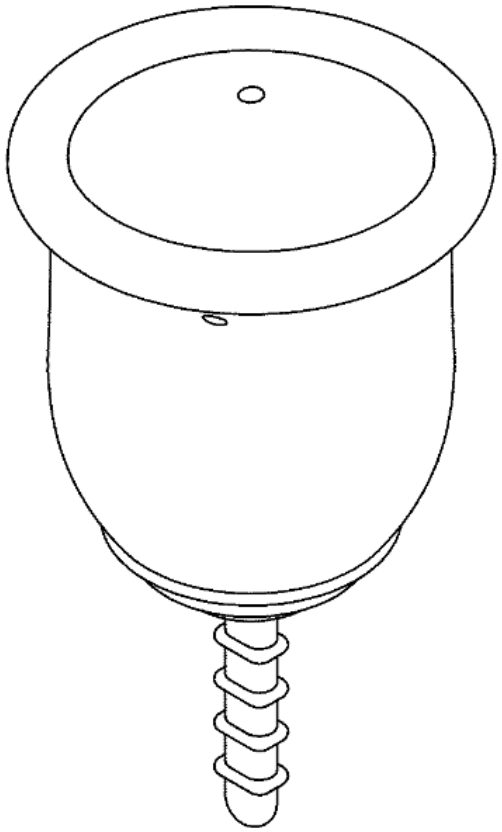

FIG. 1

D746452

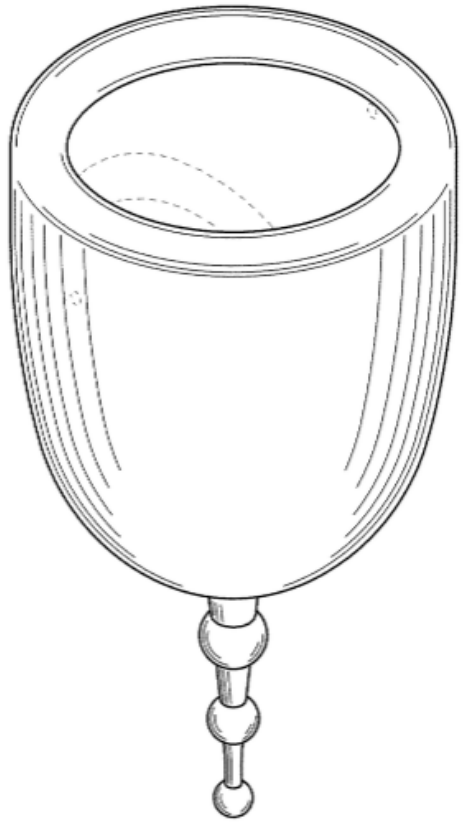

FIG. 2

D832438

Patent Prosecution - Example

- Applicant Files Nonprovisional Utility Application with the U.S. Patent & Trademark Office (USPTO)
- Application Publishes ~ 18 months after earliest filing date
- First Non-final Office Action Issues ~ 6-24 months after filing
  - USPTO performs a prior art search
  - Provides reasons for rejections, objections, or other required action
- Reply to First Office Action Submitted ~ 3 to 6 months after receiving office action
  - Applicant addresses each ground of rejection with arguments, factual evidence, and/or amendments to the claims, figures, and/or specification, as appropriate
    - §§ 101, 102, 103 Rejections – Are the claims directed to eligible subject matter? Do they fall under an exception? Are all elements of the claims found in one prior art reference? Are the claims obvious in view of one or more prior art references?
    - §112 Rejections – Are the claims clear? Are they supported by the written description?
- Final Rejection Issues ~ 2 to 6 months
  - Provides response to Applicant's arguments, provides reasons for remaining issues
- After Final Response Submitted
- Notice of Allowance Issued

Patent Litigation

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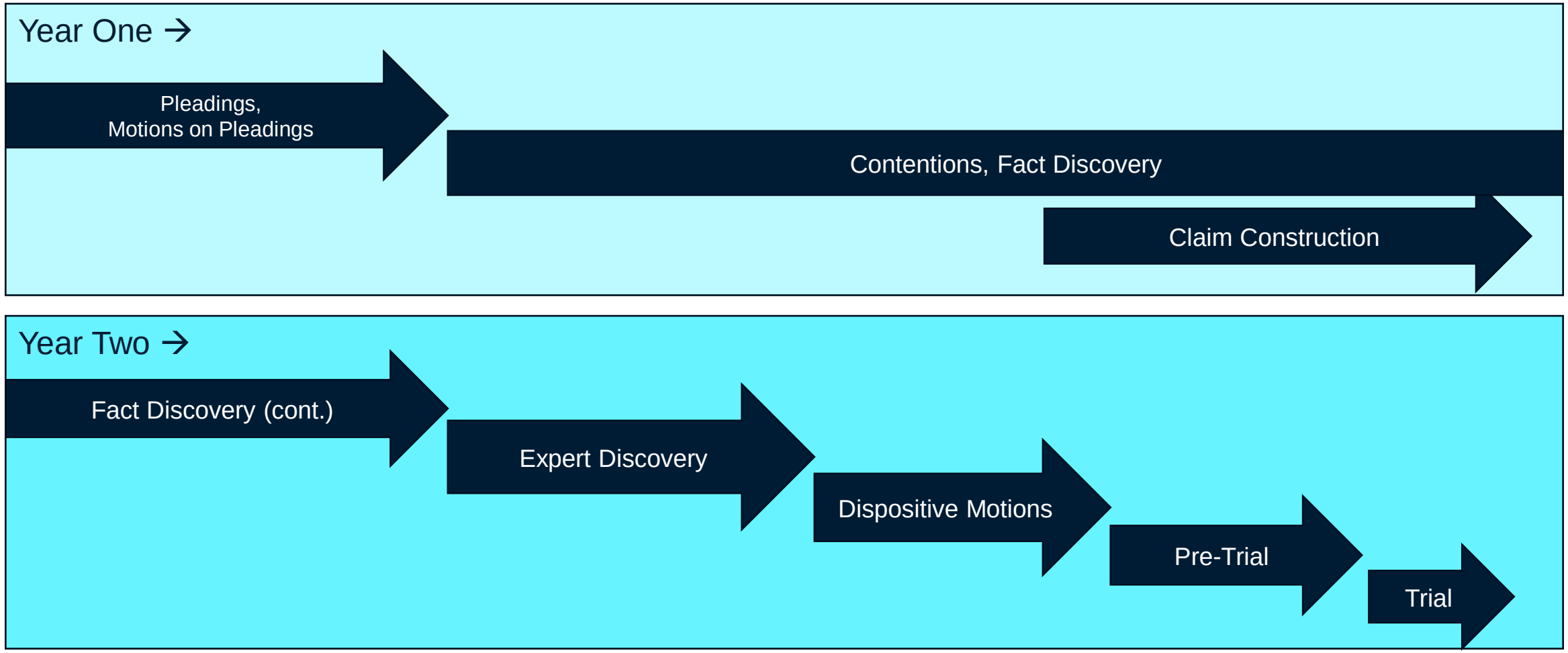
U.S. Patent Litigation Timeline

- Average time to trial in U.S. District Court: 25.9 months



Complaint

- Initiates lawsuit
- Must put accused infringer on notice of the alleged infringement
  - Often done through a claim chart
- Defendant responds:
  - Answer
  - Motion to dismiss

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SPEYSIDE MEDICAL, LLC,
Plaintiff,

v.

MEDTRONIC COREVALVE, LLC; MEDTRONIC, INC. and MEDTRONIC PLC,
Defendants.

Civil Action No. _____

DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff Speyside Medical, LLC ("Speyside Medical"), for its Complaint against Defendants Medtronic Corevalve, LLC; Medtronic, Inc.; and Medtronic PLC (collectively, "Medtronic"), hereby alleges as follows:

PARTIES

1. Plaintiff Speyside Medical is a limited liability company organized under the laws of Delaware with a place of business at 592 Rosso Court, Pleasanton, California 94566.

2. Upon information and belief, Defendant Medtronic Corevalve, LLC is a limited liability company organized under the laws of Delaware with a place of business at 3576 Unocal Place, Fountaingrove, Santa Rosa, CA 954031. Upon information and belief, Medtronic Corevalve, LLC has designated Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808 as its registered agent for service of process.

3. Upon information and belief, Defendant Medtronic, Inc. is a corporation organized under the laws of Minnesota with a place of business at 710 Medtronic Parkway,

The '118 Patent	Medtronic Marketing Materials
1. A method for replacing a patient's native aortic heart valve in a heart, the method comprising:	Without conceding whether the preamble is a limitation of this claim, the quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes a method for replacing a patient's native aortic heart valve in a heart. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision." (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).
delivering an implantable expandable carrier element and an implantable replacement valve having leaflets endovascularly to a vicinity of the native aortic heart valve while the heart is beating.	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes delivering an implantable expandable carrier element and an implantable replacement valve having leaflets endovascularly to a vicinity of the native aortic heart valve while the heart is beating. "The bioprosthesis is manufactured by suturing 3 valve leaflets and an inner skirt, made from a single layer of porcine pericardium, onto a self-expanding, multi-level, radiopaque frame made of Nitinol. The bioprosthesis has a porcine pericardial tissue outer skirt (wrap), which is 1.5 cells in height and is sutured to the inflow section of the bioprosthesis. It is designed to replace the native or surgical bioprosthetic aortic heart valve without open heart surgery and without concomitant surgical removal of the failed valve."

Discovery

- Fact Discovery
  - Written discovery:
    - Document production, interrogatories, requests for admission
  - Witness depositions
    - Inventors, engineers, executives, accountants, etc.
  - Infringement and invalidity contentions
    - Unique to patent law

- Expert Discovery
  - Infringement, invalidity, and damages reports
  - Rebuttal reports
  - Expert depositions

Claim Construction (*Markman*)

- Unique to patent law
- Parties dispute meaning of patent terms
- Court interprets meaning

U.S. Patent No. 9,445,897

Claim Term	Speyside Proposed Construction	Medtronic Proposed Construction
"vascular system" (claim 1)	"circulatory system of blood vessels" **Supporting Intrinsic Evidence:** Ex. G., '897 patent at, *e.g.*, Figs. 1, 2A; 1:22-25; 1:56-61; 3:48-54; 3:58-60; 5:8-24; 5:45-58; 24:26-33; 26:14-21; 29:59-67; 32:38-50. Ex. H, '897 FH: 6/25/15 Response to Non-Final Office Action (SPEYSIDE0003479-83).	"circulatory system including the heart and blood vessels" **Supporting Intrinsic Evidence:** Ex. G, '897 patent at, *e.g.*, 1:22-26; 2:23-28; 3:48-54; 5:49-52; 5:61-6:4; 6:12-14; 24:29-33; 26:19-21. FIGS. 1 and 2.

Pre-trial and Trial

- Pre-trial motions
  - Motions for Summary Judgment:
    - Judgment of issues before trial
    - No genuine dispute of material fact
  - *Daubert* motions:
    - Exclude expert witnesses' testimony
  - Motions *in limine*:
    - Exclude evidence
- Trial
  - Jury decides infringement, invalidity, and if necessary, damages

Remedies

- Monetary damages
  - Reasonable royalty
  - Lost profits
- Injunctions
  - Order to stop infringing activities
  - Can be difficult for medical devices (public policy)

Non-Patent Intellectual Property

Trade Secret

Trademark

Copyright

Trade Secrets

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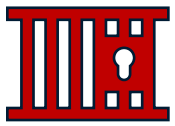
Trade Secrets v. Patents

- Trade Secrets:
  - Protect confidential business information (private)
  - The subject of reasonable efforts to maintain its secrecy with actual or potential economic value from not being generally known to or readily ascertainable by proper means
  - No expiration, but destroyed if made public
- Patents:
  - Protect inventions (public)
  - A document that provides to the patent owner the right to prevent others from making, using, offering to sell, selling or importing the invention(s) claimed in the patent
  - Expires 20 years after filing

General Elements of a Trade Secret

Secret: The information at issue is not generally known or readily ascertainable

Value: The information has actual or potential value arising from the fact that it is not generally known



Reasonable Measures to Preserve Secrecy: The owner has taken *reasonable* steps to ensure the information remains secret

Trademarks

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What is a Trademark?

- Trademark
  - Something that identifies to the public that the goods bearing that mark come from or are quality controlled by a single source
- Service mark
  - Subset of trademarks, but for services instead of goods
  - Identifies a single source of services

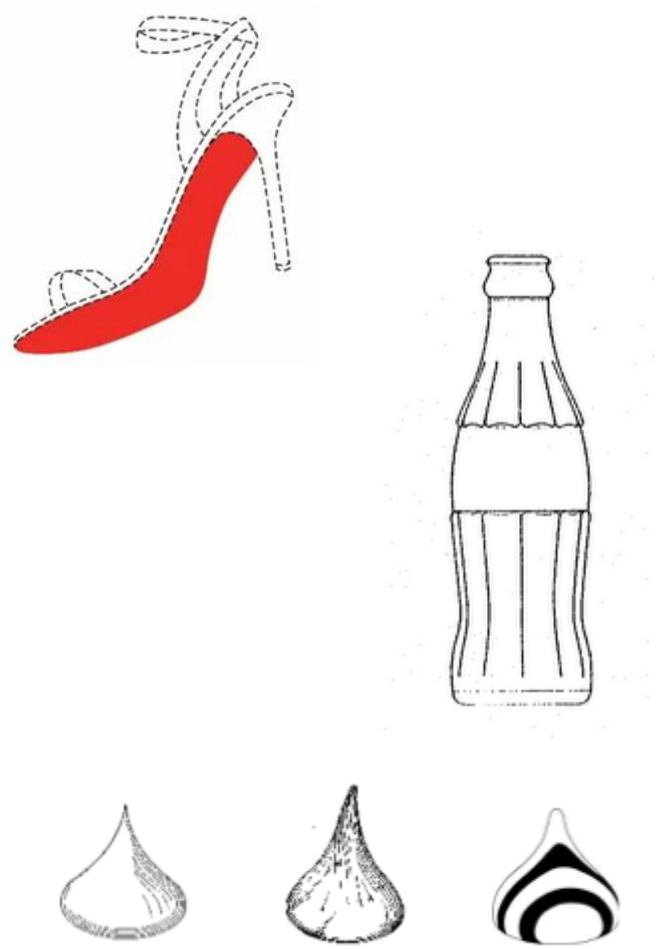
Types of Marks: Word Marks

Uber

Types of Marks: Symbols

Types of Marks

- Slogans: “Finger Lickin’ Good”
- Sound: The 3-note chime for NBC
- Color: Red bottoms of Louboutin shoes
- Smell: Scented yarn
- Non-functional shape of packaging or product itself (“trade dress”):
  - Coca-Cola bottle shape
  - Hershey’s Kisses



Copyrights

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What is a Copyright?

- **Authorship**: Copyright protects “original works of authorship” including graphic, literary, dramatic, musical, and other types of works
  - Examples: Photographs, illustrations, books, songs, musical compositions, sound recordings, and computer programs
  - Facts are not protectable (e.g., phonebook listings, sports statistics)

- **Fixation**: Copyright protection arises automatically from the moment a work is first “fixed in a tangible medium of expression” (i.e. no longer just in the author’s head), e.g.:
  - Written down on paper
  - Recorded on video
  - Captured in a photo

Copyright Owner's Exclusive Rights

- The copyright owner has the exclusive "bundle of rights" to:
  - Reproduce the work
  - Prepare derivative works based on the copyrighted work
  - Distribute/sell copies of the work to the public
  - Perform the work publicly
  - Display the work publicly
  - Perform the work by means of a digital audio transmission (sound recordings)

IP Agreements

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IP Agreements

- Assignments
  - Employment Agreement
- Non-Disclosure or Confidentiality Agreements (NDA/CDA)
- Joint Collaboration Agreements
- Licenses
  - Technology Transfer

FDA Regulations

FISH.

FDA Classification

Authorization process based on risk

- Class I – lowest risk
  - Generally, no FDA authorization required
- Class II – medium risk
  - Demonstrate substantial equivalence to a predicate device under 510(k) program
- Class III – highest risk/novel devices
  - Demonstrate safety and effectiveness via “premarket approval”

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Thank you

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Offices

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