

MEDICAL DEVICES

February 28, 2017 Webinar

“How to Check Your Patents for Loopholes”

[Doug Limbach](#) | [Shay Glenn LLP](#)

[Joe Hage](#): Hi, this is Joe Hage. And I have the privilege of leading your Medical Devices Group, which as of this recording has 345,000 members worldwide. And one of the reasons we've grown as large as we have is we educated members like Doug Limbach. He is an Attorney with Shay Glenn, and he is going to teach us today about "How to Check Your Patents for Loopholes".

Doug, take it away, and have a good show. I will be on mute.

Doug Limbach: Okay. Thanks Joe, and welcome everybody joining the webinar today. As Joe said I'm going to walk through a number of things you can check your existing patents for potential problems. You don't have to be that knowledgeable about patent law. These are some tips you can quickly go through your existing patents and look for problems and I'll tell you what you may be able to do about them.

And certainly you want to keep these things in mind when creating new patents. And you can also check through your competitors' patents, and if you find some of these problems you may be able to use them to your advantage.

And so, let me see. I'm trying to get the screen to advance. It doesn't appear to be advancing on screen here. Here we go.

Okay, so here's an overview of the 8 different types of problems. They can be commonly found and fairly easy to spot. So I'll walk through these as an overview here.

The first is "Patent profanity". And this is a term that legally was coined by Tom Finnigan, I mean sorry, Tom Irvin of Finnigan Henderson and he's a patent attorney and has identified these types of terms as patent profanity. The types of words that are just so bad you don't want to see them uttered in a patent.

And I'll walk through how those can cause you problems and what you can do about those. Not only in your patents but in, when you're corresponding with a patent office you want to avoid using these type of terms as patent profanity.

The second type of loophole I'll talk about is something called "Objects of the invention". And you don't want to use those in general in your patents. The third thing is misuse of the word "invention". You don't even to use the word invention anymore when you're writing your patent applications.

The fourth loophole is something called "Means-plus-function" language. Something you should avoid using or if you're going to use you want to use very carefully.

The fifth type of loophole is claims that are overly detailed or not focused on the right features. I'll also talk about keeping your patent families alive.

And the seventh thing you should keep in mind is co-coordinating the efforts between your patent and regulatory folks.

And the last item I'll be talking about is marking your products with patent information.

First, just some quick background on myself. I've been doing patent law, intellectual property law for 23 years now. My experience includes working in a multinational general practice law firm. I've worked in IP boutique law firms, like the one I'm in now. I've also been in-house counsel. I've had a good fortune to work in-house at one medical device startup that was acquired for \$1.2 billion just seven years after its inception.

I also was a founder of a mobile device startup company, so that exposed to a number of issues that a lot of early-stage companies are facing. I think that's helped me represent early-stage companies better. Before going into patent law, I spent six years as an electromechanical engineer mainly in the fields of robotics and industrial automation, but also did some work in medical device and in medical clipping 00:04:43 as an engineer. And my technical degree is in mechanical engineering.

The firm I'm with, I've been here, just celebrated my 10th Anniversary here at Shay Glenn. We're a 12-attorney in Silicon Valley. I do nothing but intellectual property law. I said we were formed over 10 years ago.

We specialize in counseling early-stage companies and the VCs and other investors who invest in those early-stage companies. About 80-90% of our work is in the medical device life science area. Many of us here have previous litigation experience, but we're not doing litigation, which is part of why our rates tend to be about 25% lower than the large law firms.

Each of the patent attorneys has at least a technical degree, and often an advanced degree. And here are the degrees that our patent attorneys hold. We've got degrees in aerospace, biomedical, chemical, electrical, material science, mechanical, neuroscience, and optical engineering.

And there's still one last bit of housekeeping. And I have to remind everyone that the information provided in this webinar it's for educational purposes only. It's not a substitute for obtaining legal advice regarding your specific situation.

And just listening to the information in this webinar and contacting me, which I encourage you to do, does not in itself create an attorney-client relationship. That only happens when both of us agree that's what we want to do and do that in writing.

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And any views that I state here in the webinar are mine only and may not necessarily be shared by my law firm or its clients.

Joe Hage: Why am I not surprised that a lawyer had this in his presentation?

Doug Limbach: Hey, I didn't start with it, I just...

Joe Hage: Sorry, please continue.

Doug Limbach: So getting into the actual subject matter here, the first type of loophole that I mentioned is "Patent Profanity". And I think the best way to illustrate the dangers of using patent profanity in your patents is with a story about two implantable battery companies.

About 10 years ago, an attorney I have worked with, was representing an implantable battery company. They'd come up with, developed a new battery that looked very promising. They'd just got funding and were about to ramp up production of this battery. And at that time they discovered a patent held by another implantable battery company that read right on their new device.

So their initial thought was, "We're dead in the water. This patent covers us, we're going to have to stop ramping up production, figure out what to do. Either redesign the battery or figure out a way around this patent." It looked like the patent was going to keep them from developing and selling this battery. But this patent attorney, a good a great patent attorney actually, he delved into the detailed description of the patent and normally it's the claims at the end of the patent that determine whether the patent covers the patent or not.

But he delved into the detailed description section of the patent and found a sentence or two in there that used one of these patent profanity words, the word was "necessary". And the patent talked how this one particular was necessary to have in order to get the results that the patent had talked about.

And so normally that one feature it's not in the claims would not be required to infringe the claims, but because the way they used this patent profanity, this lawyer was able to determine that based on the case law a court would read that limitation, that element that the patentee had said was necessary, they would read that into the claims and the claims would require that element for infringement.

And fortunately for this attorney's client they didn't have that element in their battery. So they were able to side-step this patent. This other battery company had spent a lot of time and money on this patent and had the opportunity to knock this competitor out before they got started, but because of this patent profanity in their detailed description, their patent really became ineffective against this other company.

Let me dig down a little deeper into the details of how this works. As I said normally it's the claim language that determines the scope of a patent. Claims are, for those that are not familiar with patents, claims are the number of paragraphs at the end of the patent. And it's the claims, not the written description or the drawings of the patent that precisely define what is and what is not covered by the patent. And to get a claim through the patent you want to put just enough elements into the claim to get it allowed, but no more than that.

And so I've got two examples of claims up here. A broader claim on the left, and a narrower claim on the right; Claim 2 is narrower. And the only difference between the two is Claim 2 has element D as well. Claim 1 just has elements A, B, and C, and Claim 2 has A, B, C, and D. And it may be a little counterintuitive to think the more elements in a claim, the broader, the more things to cover.

It's actually the opposite. You want a claim like Claim 1 that's got just the three elements: A, B, and C. And if you have to add element D as in Claim 2 to get through the patent office, that's going to be a narrower claim.

And so in the case of these two battery companies, the attorney colleague that represented this one company, they fortunately did not have element D. I don't recall what it was, it was an extra layer or an electrode or a contact or some feature on their device that was required, that ultimately was required by the patent that they did not have.

And so as I said normally it's just the claims that stand on their own that determine the scope of the invention. They are interpreted in light of the description section of the patent. So sometimes there'll be some ambiguity of what a claim term means, and courts will need to go to the detailed description and shed light on what exactly do those claim elements mean.

And in this case they actually imported a claim element from the detailed description section of the patent into the claims that caused the problem. And so here I've graphically illustrated that on the left the detailed description section of the patent discusses elements A through Z, talking about all these different elements of the batteries. I mean they show them in the drawings. But in the claims section, the patent attorneys had only claimed elements A through C, trying to keep the claims quite broad.

But in this case because they had used the word "necessary" when referring to element D, that element was read into the claims and the claims became narrower, and no longer covered this battery company.

So there are a number of other words besides "necessary" that are considered Patent Profanity that can trip you up, and they're shown here. You can see that there if you use the word: always, solely, fundamental, preferable, key, important, must, peculiar, critical, necessarily, preferred-embodiment, superior, essential, or special.

Words like this that really highlight an element when you're talking about it in the description, can be too strong and cause you problems if you use this type of patent profanity. These elements when described that way can end up in your claims when you don't want them out there.

So my recommendation would be for you to scan your patents for these words and note how they words are used. If you find them in the first section of the patent in the background maybe they're not such a problem, but any other section of the patent, some section of the detailed description or the abstract. If these words are used it's a red flag that you may have some problems and your claims may not be as broad as you think they are.

So what do you do when you find one or more of these words in your patent or your patent applications and it appears that the word is being used in a limiting fashion? Well if you're involved in writing or reviewing your patent applications, it's far better to remove these words before the patent application is ever filed. That's the easy thing to do.

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Once the application is filed at the patent office it can be difficult to change the language of the application other than to fix typographical or grammatical errors. And once the application issues into a patent, it becomes even more difficult to remove these offending words.

So I'd recommend you talk to your patent attorney about your specific situation to see if anything should and can be done to improve the situation. Even if nothing can be done to correct the problem in the existing application or the issued patent, you can at least make ensure the problem's not propagated in future patent applications.

As I alluded to at the beginning of the webinar, if you find patent profanity in your competitors' patents, there's a good chance you will be able to exploit it to your benefit and get around some of their claims. So I think that's it for patent profanity.

I'm going to talk about the second type of loophole, and that's Objects of the Invention. Objects of the Invention used to be very commonplace in patents. Almost all patents used to have in the summary section a listing of what the Objects of the Invention are. You might have one or two dozen things that paragraphs each one saying, "An Objects of Invention is this or that." Trying to show the world what the highlights are of the invention. And they would be used to list the very features of the invention.

They fell out of favor several decades ago actually because defense counsel can go through the Objects of the Invention and show how some or none of them apply to their client's device.

So an example given here, the one shown under "Problematic" is "It is an object of the present invention to provide an improved vertebral distraction device for use in discectomy procedures."

So distraction device is something that spreads to vertebrae apart 00:17:55 in a discectomy procedure where you're removing the disc between the two vertebrae.

And how this can be a problem is a potential infringer may have a distraction device that is otherwise covered by the claims of your patent, but you said, "Well it's an object of the present invention to use in a discectomy procedure." They may not use it in a discectomy procedure, they may use it in a motion-preserving procedure that just is aligning the spine, or is doing something else.

And so you've got one or more of these Objects of the Invention in your summary section of your patent. Their defense counsel can, your competitor can say, "Hey, we don't do this and this," and they can quickly sway a jury to believe that, "Hey your patent is completely different. It's covering things that we don't do."

The simple solution here is just don't use Objects of the Invention. Instead you would say something like, as shown here, "According to some aspects of the present disclosure, an improved vertebral distraction device for use in discectomy procedures is provided."

Or you can say something like, "In some embodiments, an improved vertebral distraction device may be used in discectomy procedures."

So you're still getting the information across, you're just not using this wording "Objects of the Invention" that can come back to bite you.

So what do you do if you find these Objects of the Invention listed in your patent applications? Like Patent Profanity, Objects of the Invention can be difficult to remove after the patent application has been filed or if it's issued into a patent. Although in some situations it may be possible to change the language, as I just described in a previous slide, after that application has been filed.

But it's good to know at least you've got these potential problems in there, you should look through your patents and see if you've got. You'll see in the summary section it may say, "An Object of the Invention is," and lists some feature. Ideally you don't want that in there.

So the third type of loophole is misuse of the word "Invention". And in general you really don't even need to use the word invention. It used to be used all the time. Typically you'd find the word "invention" all throughout a patent, but in recent years people, patent attorneys have figured out that that can really come back to bite you and be used against you in court and when you're trying to assert your patent. So best to keep that word out.

As I had said before, your invention should be defined by the claims section of your patent and not by other sections of the patent. And when you've got the word "invention" listed in your detailed description, it can cause problems and allow the other opposing counsel to define for themselves what is or is not your invention.

So anytime you use the word "invention" in the summary section of your patent, you're inviting defense counsel to redefine, to their advantage, what is and what is not your invention.

The example given up here is under "Problematic" "The present invention provides a lever arm for adjusting the spine." If a competitor has a spinal adjustment device that doesn't have a lever arm, they can use this statement against you, saying, "Well you say not only do you have a lever arm, but your present invention has a lever arm for adjusting the spine."

And much like Patent Profanity, that can change the meaning of the claims, by this statement that's not in the claims. It's in another section of the patent. So just avoiding the word invention altogether gets around that.

So you can say something instead like, "In some implementations of the present disclosure, a lever arm is provided." Or you can say, "A lever arm may be provided for adjusting the spine." And that won't be used against you. You'll still get the information across but not limiting yourself.

Joe Hage: Doug, Collin asks, "I guess with the word "invention" most things are recognized as being already invented. And then most new ideas are merely using an original invention." He asks, "Is that an accurate reflection of why not to use the word invention?"

Doug Limbach: I say that's partly right, that in some cases it may have already been invented, but in a lot of situations the person drafting the patent applications believes this is the invention. At the time they're thinking, "Hey, you have to have a lever arm; this is part of the invention," but they're unnecessarily limiting themselves in that way. It's the claims that ... You want to define your application or your invention with the claims, and the claims will change over the years.

But these statements can't be changed. When you say, "The present invention is this or it is not that," that wording in the detailed description cannot be changed and it kind of locks you down. If you don't

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have those words in there, you can change the claims at a later date and not be bound by what you've originally thought was your invention.

Joe Hage: It looks as though a find-and-replace of the word "invention" for the word "disclosure" will do just fine.

Doug Limbach: Exactly, yeah. That's a good way to fix a problem, just take out "invention" and replace it with "disclosure". And even in the headings, there used to be headings in the older patents and sometimes patents are being written today will say "Summary of the Invention". That section just should be changed, the heading should be changed to "Summary of the Disclosure" or just "Summary". Same thing with the detailed description section and the background section. Just leave out the word "Invention".

Okay. So you should scan your patents and applications for the word "invention". This word rarely is needed in a patent application, and when it's used it's a red flag that there may be potential problems. Like Patent Profanity and Objects of the Invention, the earlier you detect these potential loopholes, the easier they are to change.

So the fourth type of loophole I want to talk about is "Means-plus-function" language. "Means-plus-function" language, the easiest way to explain what it is is to provide an example. So in a claim you can either recite, as shown here under "Problematic", "a means for fastening part A to part B," or you can directly recite the element "a fastener," and say it's used to fasten part A to part B."

So this "Means-plus-function" language comes from, it's provided by statute. The statute provides that a claim element may be expressed as a means for performing a particular function without the recital of actual structure. And the claim will be construed to cover the corresponding structure that's been described in the specification, and the equivalence of that structure.

So often times patent attorneys will put a means for fastening part A to part B in there, thinking, "Okay, I want it to cover a nail, a screw, a bolt, a rivet, a clamp, a weld, glue or poxy 00:26:58, any possible way of fastening part A to part B."

But the reality is that "Means-plus-function" language is going to be most often interpreted more narrowly. Unless you've done an outstanding job of thinking of all the ways you can fasten part A to part B, and describe it in great detail in your detailed description section of the patent, you're limiting yourself by using "Means-plus-function" language.

It's going to only cover those things you specifically laid out, whereas if you had a claim that said, "a fastener" or another claim that said, "a weld," you're going to get much broader coverage, and make it harder for your competitors to design around your patent by coming up with another way of fastening part A to part B.

And if there's no corresponding structure given in the specification for your "Means-plus-function" language, then that means-plus-function term will be considered indefinite and it renders the claim invalid.

The problem a lot of times when "Means-plus-function" language is used in a claim, the claim can be invalidated because the patent attorney hadn't put enough corresponding structure in the description or none at all.

When I started practicing patent law in the early 1990s, probably a quarter to a third of all patents had "Means-plus-function" language in them, in at least one of the claims. That percentage of patents has steadily declined over the years, and now it's down to about 5%.

And I think that's because attorneys have realized through different cases and watching patents getting invalidated or not cut 00:28:56 to do what they're supposed to, just to see how "Means-plus-function" language is usually not very effective.

On occasion "Means-plus-function" language can serve a valuable purpose, but more often than not when you see it in a patent or an application these days, especially if it's used in every single claim, it's being used incorrectly and it's narrower in the scope of the claims.

So scan your patents and applications for the word "Means" or "Means for". And the good news here is that in general you can change "Means-plus-function" language in a claim at any time while a patent application is still pending.

And for patents that have already issued, you can file new claims without the offending "Means-plus-function" language. You can do that in a continuing application as long as you've kept the patent family alive. And I'll explain what it means to keep a patent family alive when I discuss that loophole a bit later. So the fifth type of loophole is having overly detailed claims or claims that are not focused on the right features.

And compared to the previous loopholes we've been talking about, these potential loopholes do not lend themselves to quickly scanning through your patents. But I wanted to give you a sense of these two issues, both claim length and claim focus.

You can get a sense by studying your patents whether you may have an issue with the claims being too detailed or focused on the wrong things.

So regarding claim length patent attorneys have joked for years that the way the patent office determines whether a claim is patentable is that the patent examiners use the one-hand rule, which says that if they can put their hand over your claim and cover it up with their hand, then it's too short and therefore it's not patentable.

On the other hand if they can't cover your claim with one hand it sticks out on either side, then the claim's long enough and they can grant you that claim.

Obviously it's not nearly as simple as that, but in general I mean there is some truth to the one-hand rule that the longer the claim is, the more likely it is to be patentable. And if it's shorter it may run into problems getting it through the patent office.

So it's a balance. Ideally you'd like to have your claims as short as possible, that means they're broad. But that means it's difficult to get through the patent office and it may be easy for your competitors to invalidate them after you do have an issued patent.

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But if you got short claims, it makes it much easier to ensure they cover what your competitor is doing. Conversely if you've got long claims, they typically are going to be easier to get through the patent office, and are going to be harder to invalidate, but they will be easier for your competitors to find a feature or two that they don't have or that they can remove or change on their device to around that claim, and so it doesn't, your patent won't cover it up.

So how long a claim? It should be all depends on the invention and it depends on the prior that came before your invention. But you can at least get a general sense of how detailed your claims are by looking at their length.

If they fit under one hand, probably in good shape. If they fill an entire column or two when the patents are printed out there's two columns per page. If they fill an entire column and spill on to the next column or even sometimes you'll see a column that spills onto a second page filling two columns, odds are when they're getting that long and detailed, they're probably not worth much.

So if you've got some longer claims it would be worth inquiring with your patent attorney as to why that's necessary. Maybe you want to sit down with your patent attorney and go through and see if there are some elements in there that can be removed to shorten up the claim and make it broader.

And so the second aspect of this is Claim Focus. What should the claim be focusing on to make it most valuable?

In general the claims should be focused on the most complicated technology you've got, or the hardest thing it was for you to come up with, or the most impressive or sexy technology you've got. It should be the commercial features of your product that give you an advantage in the marketplace.

Often times those are very plain simple humanly obvious features, and it may be difficult to get patent protection on those, but that's really what you want to focus your claims on, because that's what you want to protect. You want your claims, those types of claims to keep your competitors from having that same feature.

You want to be in the situation where patients and physicians are saying, "Yeah, I want the device that's got that; that one little feature on it." And that's what you provide and that's what your patents cover and keep other people from providing.

And I've got an example picture here. When I was in-house at Therasense, it was a blood glucose monitoring company. We made the freestyle meter that's down in the lower left side of that that picture showing all those blood glucose meters. And the test drip 00:35:33 is shown there on the left that fits into the meter. And the left side of the strip is the end of the test drip that goes into the meter, and the right side is with the two semicircles on it is where you apply a drop of blood to check the glucose level in the blood.

And in that working end, the right side of the test drip there's just amazing technology that's going on with how it's manufactured and the tolerances of the micro-channels in there and the electrochemistry and chelometry 00:36:12 and various things that are going on. It's really impressive technology, and it's what the engineers and the often the business people and even the patent attorneys want to focus the patents on often times.

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But sometimes it's the much simpler features that can be just as important or more important. In this case on the left side of the strip you see a vertical bar that's just an ink strip that is used when you insert test drip into the meter, the ink strip connects to electrical contacts and turns the meter on.

But just a way to, when you put the test drip in the meter it turns on the meter without you having to press a button to turn it on. Pretty simply technology and something that can be invented by a junior high-schooler, but it ended up in our case being very important technology in the early 2000s. I mean you just couldn't sell a meter without having that feature. You couldn't sell a meter that required putting the test drip in and pushing a button. It was just thought that's too inconvenient for the patient.

Being able to have a patent that covers that technology can be very powerful, even if you're not suing others on that, just having that and other companies that are using that technology and they have patents that cover you, having a patent that covers something like that, in our case turned out to be a very powerful weapon.

The moral of the story here is make sure you're focusing the claims on the right things. And in general that's features that are really going to help you make, help you be successful in the marketplace. And the sixth type of loophole is, as I alluded to before, is Keeping you Patent Families Alive. And I'll tell you why this is important and how you can tell whether you've done this or not.

And this is different than paying a maintenance fee on an issued patent. When you've got an issued patent, every four years basically you have, four, eight, and 12 years after issuance you have to pay a maintenance fee to keep that patent enforced.

What I'm talking about here is something different, and it involves filing a continuation or continuing applications. And in this first bullet point I show the three different types of continuing applications. So Continuation, or a Continuation-in-part, or a Divisional, and I won't go into the details here of what those three, what the differences are between those three different types of continuing applications.

But those are, if you're spending any time obtaining patents you'll hear these three types quite a bit. And so get familiar with those names, and just know that you'll want to be filing these types of applications to keep your patent families alive.

In order to keep a patent family alive, you must file one of these type of continuing applications while the patent application is still pending. So for example, you file a first application say in the year 2000. Maybe it takes a couple of years to get it issued. Right before it issues, you want to file say a Continuation application. Either right before you abandon your original application or before it issues or is still pending, you want to file a Continuing application.

Then that application may take say till 2004 to issue, and right before it issues you want to file another either a Continuation-in-part, or a Divisional, or another Continuation, to keep a string of patent applications or patents that are connected together, alive. And yet they're all claiming priority back to that original filing in 2000.

The advantages there is you can use that original filing date and as you draft new claims in the continuing applications that are different than the claims from the first patent application that issued.

And so I've listed some of the main reasons here why you want to keep a patent family alive. And the first one is to correct problems in a parent application, as I'd previously talked about.

You've got a Means-plus-function that's problematic or some other problems with the claims. If you've allowed your first application to issue into a patent without filing a Continuing application, you're kind of stuck with what you've got.

But as long as you've got something still pending in the string of applications, you've left your options open to pretty much right whatever claims you want that are supported by the original application. You can fix a lot of problems and write different claims.

So the second bullet point is draft new claims to cover a new product line not covered by the original claims. Often times a company's technology will change over the years and drift away from the claims that were originally drafted to cover it. And if you kept your patent family alive, you can keep pace with the changing technology, and draft new claims and still go back to that original 2000 filing date, and get the benefit of that.

Another reason you want to keep patent families alive is to overcome newly discovered prior art. Your patent issues and you later find out that someone else came up with a very similar or the same invention before you and somehow the patent office in you missed that, and your patent issued. Your claims, the original claims may become invalid, and if you don't have a Continuation on-file, you're kind of stuck; you've lost everything.

But you can often overcome that problem if you've got a Continuation where you can change the claims a bit.

A fourth reason to keep your patent families alive it allows you draft new claims that are tailored to a recent competitor's product. You see them come on the market and you can draft claims. Based on your original description you can go back and draft very narrow claims that cover your competitor's product and keep them out of the market. And you can make it difficult for all competitors to design around your patents because you always have that option of changing your claims if you've kept your patent family alive.

And the fifth reason I've given here is it safeguards against changes in the patent law. For example, there have been a number of Supreme Court cases recently that have cut back on what is considered a patentable subject matter. You may have heard the Supreme Court Alice 00:44:04, that narrows a bit more closely defining what's an abstract idea. And it's made some software patents invalid, some diagnostic testing patents invalid.

And if you've got, kept your patent family alive, you're able to often times go back and reword the claims a bit to get around the change in the patent law.

So the seventh type of loophole is coordinating the efforts between your patent people and your regulatory people.

As you're probably aware you often have to prove substantial equivalence to a predicate device when you're making an FDA filing like a 510(k). And you're also, when working with a patent office, you have a duty to disclose any relevant prior art that you're aware of to the patent office.

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And so if you're working in silos and your regulatory people are doing their thing and your patent people are doing their own thing and not talking to each other, you can get into problems.

The first could be if you're obviously of the predicate device and you don't disclose that to the patent office, somehow your patent office doesn't know about this. You can end up with an unenforceable patent because you didn't comply with your duty to disclose it to the patent office, and that's considered fraud on the patent office. It renders your patent unenforceable.

Another situation that can occur is you're arguing two different positions. You can imagine if you're saying one thing to one Federal agency, and saying exactly the opposite to another Federal agency that you're going to, you could easily be accused of a fraud on the patent office.

And this comes up with the regulatory efforts. You've got a predicate device and your goal is to say, "Hey, we're just exactly like that device. FDA you've approved that device, and we're so similar to that, you should approve our device as well." And you're making all these arguments about how similar your device is to the predicate device.

But at the patent office you're doing just the opposite. You're saying, "Oh that predicate device that came before ours that's nothing like what your device is. Our device is novel and unobviously over that predicate device, because we're completely different than that device."

And often times your patent attorney is making different arguments to the arguments that are being made by your regulatory folks at the FDA. And you just need to make sure your patent attorney is talking to your FDA people, your regulatory people, and you're coordinating your arguments.

Sometimes you can't have it both ways. You can make arguments saying you're similar in this way but you're different in another way, but you at least need to be aware of what arguments are being made and making sure you're coordinating.

And so the last type of loophole I wanted to cover is Marking Products with Patent Information. And the purpose of doing this is to provide what's called constructive notice to the public that the article is patented. And if you fail to do this you can preclude recovering damages for infringement, and so effective notice is given. And effective notice is basically writing a cease and desist letter to a competitor saying to stop infringing your product.

And you really don't want to limit yourself to damages going back at just the date of that letter; you want to collect damages going back to actually the date when your patent had issued.

So the recently enacted America Invents Acts provides patentees with the option of using "virtual marking". For the America Invents Acts you needed to put the patent numbers on the device itself, or at least if they wouldn't fit on the device, put it on the packaging.

But now you can just put "Patent" or "PAT." and provide a website, and then on the website you can put all the solid 00:49:04 patent numbers, or how that the device is covered by patents.

And the last bullet point here is you've got to be sure not to just be marking your own products, but if you're licensing your technology to another company, you need to make sure they are marking all their products too, or you lose the ability to take advantage of this patent marking statute.

And so to draft a license to license your technology to another company you've got to make sure there's a clause in there that requires the company to mark all of its products covered by your patents.

So those are the eight different loopholes. I think if you're not don't have the desire to get immersed in patent law, you can at least quickly look through your patents and applications to see if there may be some issues there.

And as Joe said, copies of these slides will be available after the webinar in addition to the video of the webinar and a later date a translation of the audio.

So I think we've got about 10 minutes left, I'd be happy to take some questions.

Joe Hage: And there are a few. The first one is what is, on your screen there it says "Additional information posted on www.medtechbriefs.com." What is that?

Doug Limbach: That's a website I put together a few years ago that just has information that's useful to people in the medical device community. It's mainly focused on patent law, but occasionally I'll have other news in there in the, regarding regulatory or other areas.

Joe Hage: Okay.

Doug Limbach: And you can sign up on there for periodic updates. I used to do it quarterly, it's been a while since I wrote an article, but quarterly or sometimes monthly I'll write some articles. So there's resources on that, on medtechbriefs, and also you can sign up for these emails that will update...

Joe Hage: Okay, more good stuff from Doug. Collin asks a clarifying question, "Would it be best if everything that's in the description section is also in the claims section?"

Doug Limbach: No, generally there's, the description section has a ton of information on it...

Joe Hage: "Specifically the number of elements," he asks. "If one specifies the number of elements, should all those be in the claims section?"

Doug Limbach: Typically not. Typically it's just the most important elements, and you leave yourself open. Often times you're just using 5% or 10% of what you've described in the claims section. But over the years if you keep your patent families alive, eventually you may in Continuing applications claim further elements.

But it's rare that you ever claim all of the elements you've described. You wait till they're needed till you see what's important because there's a ... The first 20 claims you put into patent application are free at the patent office, but beyond that you start paying a charge for an excess claim fee. And so it takes attorney time to write all those claims.

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So there are patents with hundreds of claims in them, but it becomes very expensive, and typically you don't know until years down the road which elements are going to be important. Your technology may change, and what you thought was important when you filed the application is no longer important.

So it's best to put way more information and elements into your description than you think you'll ever need, and then over the years you can pick and choose from that menu, and put those into your claims.

Joe Hage: Annan 00:53:38 asks, "Even independent claims?"

Doug Limbach: So a dependent claim is a claim that is narrower than an independent claim. You start off with like an independent Claim 1 and then Claim 2 will depend from Claim 1 and add additional elements.

So yeah it's good to have a broad range of claims, some of them are very broad, some of them are medium scope, and some are very narrow. And you do that by adding lots of dependent claims.

So it's good to have lots of dependent claims, but again there's a limit to it. To be cost-effective you rarely get to the point where you're putting everything in your description into your claims.

Joe Hage: Brian wants to know how much is a patent application fee?

Doug Limbach: So the patent office if you're a small entity meaning you're a company under 500 people, will charge I think all the filing fees added up cost about \$800, or for a micro-entity that may get down to \$400.

Joe Hage: What is a micro-entity?

Doug Limbach: What's that?

Joe Hage: How many people constitute a micro-entity?

Doug Limbach: If you have less than five patents already that you've applied for, if your annual income is below a certain number, a few other requirements, you can ... Which don't apply to companies, they're usually individual inventors or early-stage companies just starting up. That cuts your fees in half again.

But the expense you're probably most concerned about is the total expense of filing a patent application. The patent office fees are typically a small portion of that.

If you're going to pay a patent attorney to file a patent application, it all depends on the situation invention, but it's going to be a few thousand dollars, typically between \$5,000 and \$10,000 to prepare and file a provisional application.

And then a non-provisional application typically the cost gets up to \$10,000 to \$15,000. So it's not cheap. It is possible for you to do it yourself. There's a good resource I recommend called, a book called "Patent It yourself" by David Pressman. You will get this information from the medtechbrief.com website. But "Patent It Yourself" put out by Nolo Press walks you through the

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process, and you can prepare a patent application yourself or at least get it started. And it's a good resource even if you're working with a patent attorney to learn more about patent law.

Joe Hage: While it sounds expensive for some to spend \$10,000 on a patent attorney, from what you've taught today it sounds scary to maybe try to do this on your own. I mean one mistake and it could cost you many times more.

Doug Limbach: Yeah...

Joe Hage: I'm sure you have an opinion...

Doug Limbach: ... 00:56:59 a lot of inventors who have started out and trying to do it themselves, and almost 100% of the time you realize that you get what you pay for, and you're going to make a bigger mess than if you spend a lot of time of your own doing it yourself. And in the end most realize you really need a patent attorney to do it.

But when you're starting out sometimes, better than nothing.

Joe Hage: Yeah okay.

Doug Limbach: If you don't have the money early on getting something on file yourself will be better than nothing.

Joe Hage: I've had a few requests for the slides, I've just sent out a link to everyone for that. Steve asks, "Can software or artificial intelligence be used to review patents for patent profanity or other loopholes?"

Doug Limbach: I bet it could. I've heard of software over the years being written to do various things like write claims, which I don't think will ... I think we're decades away from being able to do that. I don't know of anybody who's written software to look for that, but I think that's a great idea. I think it'd be very helpful to at least flag these words...

Joe Hage: Is that a patentable idea for Steve?

Doug Limbach: It could be.

Joe Hage: All right, there we go.

Doug Limbach: There might be some aspect of that that's patentable.

Joe Hage: Stuart 00:58:28 asks, "How does one decide if it's worth patenting to fill a loophole of a competitor's portfolio?"

Doug Limbach: The loophole that I'm talking about here you wouldn't be able to patent. But I think maybe what he's talking about is a gap or something that a competitor hasn't covered in their patent application and maybe you could patent.

And there really is it's tough to make any generalization there, it's on a case-by-case basis. I think you'd have to look at it and see what the competitor hasn't covered in their patent and what you may be able to yourself patent, fill that gap. What you patent would have to be novel and unobvious over what they've patented. So it can be tricky, but it really depends on the particulars of the situation.

Joe Hage: What about protecting your own IP even if your own company doesn't have freedom to practice? Is that worth it?

Doug Limbach: It still would make sense. If you don't have freedom to practice, if you can protect your own IP and that ends up covering the patents that are preventing you to having your freedom to practice. You may be able to horse-trade with that other company and cross-license your technologies, and you would have value in that case.

Again it all depends on the situation, but just because you don't have freedom to operate it doesn't mean that there might not be something that you can patent yourself.

Joe Hage: We are at the top of the hour, but let me squeeze in one or two more questions. Marick 01:00:35 asks, "If there's an existing drug indicated for the treatment of Disease A and his group finds that it can also cure Disease B but it's not in the current claims, what is the inference?" What is patentable there? Can he patent the cure for Disease B?

Doug Limbach: Freedom-to-operate-wise you still may be covered by that patent, but depending on the situation if you've found a new use for an existing drug, you may not be able to get claim, you won't be able to claim the composition of the drug but you might be able to get a method claim that covers the use, that new use, of that existing drug.

Joe Hage: Okay. Brian asks, "Is there a length of time, is there a term to a patent or does it need to be continually updated to avoid obsolescence?"

Doug Limbach: The term of a patent generally is 20 years from the earliest filing date. So that it does not start when you file a provisional application, but when you file a non-provisional application 20 years from that date is the term of the patent.

And if you keep the patent family alive as I talked about by filing these continuing applications, all of those continuing applications key off the original filing date. So you may be filing 10 years into the life of the patent family, you may be filing a Continuation. The term of that patent is only going to be another 10 years.

So you never get beyond the 20-year date. But it is good to keep filing fresh patents on improvements to your technology. So when your original patents expire at the end of 20 years you still got some coverage of your products.

Joe Hage: I suspect you'll need to follow up with Jim on his question, which will be our last. Is doug@shayglenn.com the best way to get in touch with you? Would you like to give out your phone number?

Doug Limbach: I do screen my calls so yes email's the best way to...

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Joe Hage: Okay.

Doug Limbach: ...get a hold of me.

Joe Hage: Jim asks, "Are there any suggestions on overcoming obviousness when patenting IP for miniaturizing and making an existing technology or device portable for remote uses?"

Doug Limbach: There are limitations on ... It is difficult to just miniaturize something and get a patent on it if it's already known in a larger scale and all you're doing is making it smaller. The patent office's initial reaction is going to be, "Well, that's obvious."

But it's not impossible; I've done it before. If there's serious challenges to making it smaller and you put enough limitations in your claims, you can patent something that's already known but you've made it smaller.

I'm sorry, what was the second part of that question?

Joe Hage: And making it available for remote or portable uses.

Doug Limbach: Yeah, the test comes down to get a patent something has to be useful, it has to be novel, and it has to be unobvious. And yeah, that could be a topic of many webinars, of what constitutes unobviousness. So just making something portable often times is obvious but there may be aspects of how you've made it portable that can be patented.

Joe Hage: It does sound like 01:04:33 a good subject for your next blog post. So we'll look for that at medtechbriefs.

And I'm confident I'm speaking on behalf of those who attended today and for those who will listen to this presentation in the future. Thank you Doug, this was very informative.

Doug Limbach: All right, quite welcome.

Joe Hage: Thank you very much. A lot of "Thank You's" being typed into the comments here. Thank you Doug, we'll speak again soon.

Goodbye everyone.

Doug Limbach: Oh great. Thank you.
