UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Vascular Solutions LLC, Teleflex Innovations S.a.r.l., Arrow International, Inc., and Teleflex LLC,	)	File No. 19-CV-1760 (PJS/TNL)
Plaintiffs,	)	Minneapolis, Minnesota December 27, 2019 8:30 a.m.
v.	)	
Medtronic, Inc., and Medtronic Vascular, Inc.,	)	
Defendants.	)	

BEFORE THE HONORABLE PATRICK J. SCHILTZ
UNITED STATES DISTRICT COURT JUDGE
(MOTIONS HEARING)

APPEARANCES

For the Plaintiffs:	**CARLSON CASPERS VANDENBURGH & LINDQUIST, P.A.** **TARA NORGARD, ESQ.** **MEGAN HINGTGEN, ESQ.** **JOSEPH WINKELS, ESQ.** **DEREK VANDENBURGH, ESQ.** 225 S. 6th St., #4200 Minneapolis, Minnesota 55402
	DORSEY & WHITNEY, LLP **KENNETH LEVITT, ESQ.** 50 S. 6th St., #1500 Minneapolis, Minnesota 55402
For the Defendants:	**FREDRIKSON & BYRON, P.A.** **KURT NIEDERLUECKE, ESQ.** **LORA FRIEDEMANN, ESQ.** 200 S. 6th St., #4000 Minneapolis, Minnesota 55402
Court Reporter:	DEBRA BEAUVAIS, RPR-CRR 300 S. 4th St., #1005 Minneapolis, Minnesota 55415

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P R O C E E D I N G S

IN OPEN COURT

THE LAW CLERK: All rise. United States District Court for the District of Minnesota is now in session, the Honorable Patrick J. Schiltz presiding.

THE COURT: Good morning. Please be seated.

We are here this morning on the case of Vascular Solutions, LLC, et al. v. Medtronic, Inc., et al. The case is Civil No. 19-1760.

If I could have the attorneys make their appearances beginning over here (indicating).

MR. VANDENBURGH: Good morning, Your Honor. Derek Vandenburgh from the Carlson Caspers firm. I also have with me from my firm Tara Norgard, Joe Winkels, Megan Hingtgen; also Ken Levitt from the Dorsey firm. We also have some attorneys in the audience. We have two in-house lawyers from Teleflex and Vascular Solutions, Howard Cyr and Greg Smock. We also have some business people from the Vascular Inventions group who came to join us today. We also have Howard Root here, who's one of the inventors and founder of Vascular Solutions.

THE COURT: Okay. Welcome to all of you.

MR. NIEDERLUECKE: Your Honor, Kurt Niederluecke at Fredrikson & Byron on behalf of the Medtronic defendants. With me today is my partner, Lora Friedemann.

MS. FRIEDEMANN: Good morning.

MR. NIEDERLUECKE: Chad Hanson, who's in-house counsel for Medtronic.

MR. HANSON: Good morning.

MR. NIEDERLUECKE: And George Mayleben, who is our graphics person.

THE COURT: And good morning to all of you.

So before we get started, I think Beth came out and told you how I want to do this today. As I know some of the lawyers in this room know well, I struggle with patent law. It's the area of law I know the least about and I have kind of the least instincts in. So when I have arguments in patent cases, whether it be *Markman* hearings or summary-judgment hearings or preliminary-injunction hearings, I like to break it up into bite-sized pieces, so we'll be doing lots of bite-sized pieces today.

I brought Beth an index card where I jotted notes as to how I wanted to do this, and I asked her to come out and talk to you about it, and she thought it would be helpful just to give you a copy of my notes. So I'm sorry that you literally have photocopies of an index card on which I jotted notes, especially given all the Power Point presentations. If I knew how to use Power Point, I would've done a Power Point presentation for you, but I only know how to look at Power Point slides.

So that's how we're going to do it today. I think there's nine, basically. We're going to break this up into nine pieces, some which should just take a couple minutes. Some will take a lot longer than that. But that's the way I want to do it today.

Then before we start working our way through the arguments, there's a pending request to supplement the record with things. Those are all granted. You can supplement the records. I think -- is it Medtronic that still -- I think you asked for permission to supplement, but you didn't actually supplement. You can send along whatever you wanted to supplement.

All right. So why don't we start. I'd like to start with infringement, working our way through each of the asserted patents. Let's see. For this one -- it's going to take me a minute to remember who is who. Mr. Niederluecke, you've got Medtronic, right?

MR. NIEDERLUECKE: Yes.

THE COURT: So are you going to address this or Ms. Friedemann?

MR. NIEDERLUECKE: I'll be addressing the technical things.

THE COURT: Okay. Let me just have you at the podium maybe just for a moment on the '776 patent.

MR. NIEDERLUECKE: Certainly, Your Honor.

THE COURT: So unless I missed it, I don't recall you arguing for purposes of today that you don't infringe the '776 patent. Did I misunderstand or miss that?

MR. NIEDERLUECKE: That's correct. Can I hand you the presentations before I begin?

THE COURT: Sure.

MR. NIEDERLUECKE: If I could just go to slide 24 of our presentation.

Your Honor, this slide kind of summarizes our substantial questions that Medtronic has raised. And I can go through this later, but this kind of demonstrates where we are and what questions we've asserted for purposes of this motion. We're certainly not conceding anything.

There's two blanks you see there on the chart, but basically we've raised the invalidity as you've got in your outline.

THE COURT: Okay.

MR. NIEDERLUECKE: And for the '776 we have not, for the purposes of today and the arguments of today, tried to raise a substantial question as to infringement of that.

THE COURT: Okay. I just wanted to verify that. I said that would be a really quick argument and it was.

All right. Let's turn, then, to the '379 patent, which is a method patent. And let me horrify all the patent lawyers in the room by asking what I'm sure to you is a very

simple question and it's always been a struggle for me. I don't understand the difference between method patents and system patents. I tried to Google it last night, and I still don't understand the difference between system patents and method patents.

I understand what an apparatus patent is. I mean, here's the device. We hold it in our hands. We hold this guide-extension catheter in our hands and it's an apparatus. You can't make that apparatus. You can't sell it. You can't use it, whatever.

The method patent, '379, seems to be a method for making the apparatus.

MR. NIEDERLUECKE: Correct.

THE COURT: So my first question is since patent law already makes it illegal for you to make a patented apparatus, why do you need method claims that make it illegal for you to make a patent apparatus? What's that about?

MR. NIEDERLUECKE: Well, I think with regard to method of manufacturing -- method of forming is what this one is called -- I think sometimes there can be manufactured means that go into how you form it, how you make a product that can be different than the product itself. So the way in which you make it can be unique. And I think that's where at times people will try in their claim strategy --

THE COURT: Yeah, I have had cases with "real" -- I use "real" in quotations -- method claims. These method claims just seem to basically take apparatus claims and turn them into claims for making the thing that we already have a patent on in the apparatus claim. Am I missing something?

MR. NIEDERLUECKE: You're not. In the context of these, you're exactly right, Your Honor. It's the way to try to put a method of forming claim in, which is actually just an apparatus claim. When you start using words like "provided," all you're saying is here's our apparatus, but it's in the form of a method claim.

Method claims, as they differentiate between system claims -- I mean, methods are the actions. So you see a lot of i-n-gs in terms of the start of them, and here the i-n-g is providing for a number of these.

THE COURT: Okay. The system claims seem to be a system for making the apparatus. What does the system claim add to the method claims? I know we're talking at a very high level of generality here.

MR. NIEDERLUECKE: In this case, Your Honor, I don't think the system claims are systems of making the apparatus. They are the system of a multiple-component apparatus. So it's like an apparatus claim.

THE COURT: When I read the system claims, they seem to be describing the use of the patented apparatus made

through the patented method.

MR. NIEDERLUECKE: Yeah. It is still an apparatus-type claim. So it still is a structural claim. But it's a structural claim often with multiple components that aren't necessarily connected together; like in this case a guide-extension catheter and a guide catheter, those together create a system.

So if you manufacture those two together, they create a system. If you sell those two in a package, those could be a system that you sell together.

THE COURT: Okay. Let's get back to the infringement of the '379 patent. Your main argument here is a *Cross Medical* argument. I think it was a *Cross Medical* argument because it's the case I cited in my *QX Medical* case.

So when I faced this in *QX Medical*, I don't think I confronted this exact language here. Your view is that the language at issue here in claim 25 and claim 38 of the '379 patent basically recites structure, not capability, and that your client doesn't infringe because as it rolls off the assembly line the structure isn't there. That's a fair summary?

MR. NIEDERLUECKE: That is a fair summary, Your Honor.

THE COURT: Okay. Of course, Teleflex's response

is that this is basically reciting pure capability, not structure. They point to this prospective-sounding language here. What is it that you think most points me to your argument, rather than Teleflex's argument?

MR. NIEDERLUECKE: Certainly, Your Honor.

If we can go to slide 91.

Your Honor, each of the claims in the '379 -- and, as we discussed, you know, the '379 patent is a method of forming. So what we're talking about is does Medtronic take the steps to form a device that meets the limitations of the claim.

As you noted, the limitations of the claim are essentially structural limitations. While they're couched in a providing action, they're essentially structural limitations, Your Honor.

So what you have and I think what you --

THE COURT: But what I struggle with on this claim -- I think your *Cross Medical* argument on the system claim is really good because -- I don't even know if Teleflex opposes it -- in the sense that the system claim reads as a system comprising a guide catheter. If you don't have a guide catheter, you don't have that system. So that's easy.

Where is the equivalent of a method comprising/providing a guide catheter? They don't really have that in the '379 patent.

MR. NIEDERLUECKE: But what they do have and they have -- as you can see here and I think what Teleflex has done is they've tried to focus Your Honor on the intended use, the adapted for use in the preamble, which I think --

THE COURT: Well, this is definitely -- oops. I'm sorry.

MR. NIEDERLUECKE: That portion I don't think we have a disagreement about, that that's intended use. That's not structural limitation.

Then when you read the claim of how to form it and you walk through the steps and you see whether or not -- when you think about the Medtronic guide-extension catheter coming off of the manufacturing plant in Ireland, you have a device and you say could this infringe this claim?

You just formed it. Now let's look at the product that's been formed by the method and let's look at what you have done. Have you taken the steps that meet these claim limitations?

So when you step away from the intended use in the preamble and you get down -- and I've just highlighted, obviously, on the next two slides for the '379, claim 25 -- it requires that that forming form a device length that is longer than the predefined length of the continuous lumen of the guide catheter.

So now you've taken a claim that was for a device

that was adapted for use with it and now you've actually put on a structural limitation very similar to your one French structural limitation, Your Honor, that you addressed in the *QX Medical* case. You've got now a structural limitation that requires you to evaluate the method of forming the guide catheter along -- I'm sorry, the guide-extension catheter along with the guide catheter.

So similar to it's a one French difference or it's not --

THE COURT: Well, so your argument is that essentially you can't know if it's longer than the predefined length of the guide catheter without the guide catheter, but the preamble says it's for use with a standard guide catheter. And your opponent argues that everybody knows how long the standard guide catheter is. It's whatever it is, X centimeters long.

So that what we have here is -- the language is you form a device -- forming a device length, and we're talking about the length of the guide-extension catheter that is longer than the predefined length of the continuous lumen of the guide catheter.

If instead of the predefined length of the continuous lumen of the guide catheter we had 100 centimeters, if that was -- what was the language -- forming a device length that is longer than 100 centimeters wouldn't

suggest the presence of anything. It would just be the measurement of the guide-extension catheter.

Essentially, your opponents say this should read the same way. It's referring to a standard guide catheter. There's a standard measurement of a standard guide catheter. So it's the equivalent of putting in here whatever that number is.

MR. NIEDERLUECKE: Well, Your Honor, I'd say, number one, what a standard guide catheter is today, tomorrow, and the next day can certainly change. So the question is when I take my product and I have it here in a package that I formed, am I going to end up a week from now, a year from now, five years from now to find out that the exact same thing I did in my exact same product may or may not infringe depending on what a standard guide catheter length is at that time. So it doesn't give a specific. Certainly they should have done it that way. They should have said 100 centimeters.

If we could turn to the next slide.

Your Honor, I think this even points it out more to their claim 38. Claim 38 we have the same situation, the intended for use. And now you see the language there says when the flexible tip is extended distally in the guide catheter, the proximal end of the substantially rigid section extends proximally of a proximal end -- sorry for

all the patent language.

THE COURT: Me, too.

MR. NIEDERLUECKE: Your critique of patent lawyers is fair here.

Proximal end of the guide catheter and the side opening is positioned within the continuous lumen of the guide catheter. So now you have a number of structural limitations that you're tying to --

THE COURT: I'm sorry, you won't be the first one I have to ask just to be quiet for a second. If you'd just give me a second to focus on the language. It's like reading mud, this stuff, and it just takes a minute.

Such that when the flexible tip segment is extended distally of the guide catheter, the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter and the side opening is positioned within the continuous lumen of the guide catheter.

So what your opponent says about that, and I thought there was something to this argument, it seems to be talking about something that's going to happen in the future. In other words, it's a method for forming a device and the device is going to work this way in the future, which almost sounds more like capability language than structural language.

MR. NIEDERLUECKE: I don't think that can be read as capability. When it's there, it's still talking about the structural requirement between that guide-extension catheter and the guide catheter itself. It's defining -- importantly, Your Honor, defining the structure that is required within this method of forming.

Again, if you say prospective language, into the future, the Court has to be able to, obviously, determine when this thing comes off of the manufacturing line whether or not it infringes. And the question of whether or not when it comes off the manufacturing --

THE COURT: Yeah, that's true, but the argument is that that doesn't require a guide catheter to come off the assembly line with it. That if it comes off the assembly line and you can pick it up and the question you're asking is when this thing is later used with a guide catheter, is it arranged in such a way that the flexible tip segment will be extended distally of the guide catheter blah, blah, blah in the future when it's used? I mean, you can pull something off the assembly line. You can say when this is used in such and such a way, will it behave in such and such a way.

MR. NIEDERLUECKE: And that would be a method of use, Your Honor, with due respect. When you're talking about something like that, that's a method of use. We're

not talking about a method of use here. We're talking about a unique method of forming.

All this activity has to happen when it's formed. This isn't about a method of use or the use of a product. This isn't about indirect infringement because, as they admit, Medtronic is the only one that claims to take these steps. So it's not like a method of use step where you say, oh, is it infringing when it's used? Did you contribute to someone else's infringement?

This is about a method of forming the device and, therefore, all the method steps have to be complete once that device is formed. And by putting in these structural limitations that incorporate the physical characteristics of the guide-extension catheter along with the guide catheter, you create a structural limitation that has to be present at the time that you completed your forming of this device.

THE COURT: Okay. So this would normally be something I would -- or I guess this is something I eventually will have to confront at a *Markman* hearing, right?

MR. NIEDERLUECKE: Yes, Your Honor.

THE COURT: Okay. I mean, there's like three or four things here that look to me like normally -- this is the problem with PI motions, is you have to try to compress an entire patent case, which is normally two or three years

of litigation, into a morning. It's a struggle.

Is there anything more you wanted to say about infringement of the '379 patent?

MR. NIEDERLUECKE: No, Your Honor.

THE COURT: Okay. Let me have you be seated, then. And then who is going to address it on Teleflex's side? Mr. Vandenburgh?

MR. VANDENBURGH: Yes.

THE COURT: Before you say anything, this equipment in here is new and right now this (indicating) is too thick.

MR. VANDENBURGH: Your Honor, if I could also approach with slide binders?

THE COURT: All right.

(A brief discussion was held off the record.)

THE COURT: So, Mr. Vandenburgh, you've heard my concerns. Let me just have you --

MR. VANDENBURGH: If I could take 30 seconds just to start with one point, and that's to look at these particular two claims I put up on the screen. I am glad Your Honor started with '776 and '379, because throughout the discussion today we're going to be talking a fair amount about these two dependent claims of the patents.

These are two dependent claims that are directed to what we call the complex side openings -- not simply an

angled side opening where you just have a simple angled cut, but you have a complex shape of some sort. And, you know, it's important, one, because at the end of the day we only have to show likelihood of success of one claim.

THE COURT: Yeah, well, you have three on infringement.

MR. VANDENBURGH: I have three on '776. And that, of course, makes this a pretty unusual case where you don't even have somebody contesting infringement of one of the patents.

These dependent claims are important. First of all, if I can just jump back to slide 4. Medtronic has this feature, and it's one of those that they took directly from V3 of GuideLiner.

We emphasize in our materials our half-pipe technology and how valuable that is in facilitating entry of interventional cardiology devices like a stent.

THE COURT: What precisely do you mean by the "half-pipe technology"? I tried to Google that too and I got a bunch of ramps for skateboards.

MR. VANDENBURGH: Right. Right. I mean, it's a marketing term by Vascular Solutions. But they use it to refer to -- they have an extended side opening that has an angled portion at the beginning of the side opening, an angled portion at the end, and then a half pipe, a half

cylindrical portion in the middle. So they have adopted that as part of their V3. It's a very important part of the commercial success.

THE COURT: So you literally -- I assume that's what you meant, literally you mean cutting the pipe in half?

MR. VANDENBURGH: Cutting it in half, but then also the slants at either end.

Of course, Medtronic has what they call their on-ramp. Their marketing term for the same concept is their on-ramp. So they talk about the same benefit that we get from our half pipe they advertise in their on-ramp.

I'll skip by that one.

It's interesting that in their brief they actually claim that as a unique feature to Your Honor. They say the Telescope has several unique features, including the polymer coated on-ramp with two distinct tapers. So they recognize there is benefit in that feature as well.

So when we get to these dependent claims of '776, claim 36, no dispute as infringement. Dependent claim 44 of '379 they don't dispute infringement of the dependent claim. Their only argument is the one that Your Honor has already had some discussion on relating to the independent claim, which is 38.

So with that, if I could then jump ahead to slide 10. So this is claim 38 of the '379 patent. And there's

basically two limitations relating to the guide catheter. One is this language of adapted for use with a standard guide catheter.

I think what I heard from Your Honor -- it's certainly consistent with what you said in the *QX Medical* case -- is that "for use with" is a statement simply of --

THE COURT: Yeah, to me at least, it sounds clearly to recite capability.

MR. VANDENBURGH: Right. Right. So it's really the second set of language at the bottom.

Now, let me start with the first claim that Mr. Niederluecke started with is claim 25 that has the "formed for" language "for use with a standard guide catheter." That's not in this claim.

The only language in this claim is this "such that when" limitation. I guess I read it the same way it sounds like your initial inclination is, which is that this is talking about you know when it comes off the assembly line, that when you put it into a guide catheter, certain things -- let me rephrase that -- in a standard guide catheter, certain things will happen.

THE COURT: What would you say if -- suppose the word "standard" there didn't appear. So you had a method of forming a device adapted for use with a guide catheter having blah, blah, blah arranging such that when the

flexible tip -- you wouldn't be able to know when you manufactured whether you were infringing or not, would you, without the word "standard"?

MR. VANDENBURGH: The fact is this product is longer than any guide catheter out there in the real world. There's no limitation specific to a type of guide catheter.

Let's also keep in mind, practically speaking, what is the language that we're talking about there? It's basically a patent lawyer's complex way of saying that when you stick this guide-extension catheter down a guide catheter, one end will stick out the far end while the other end remains out the proximal end. The device doesn't work if you don't have that feature.

At the end of the day the purpose of this product is to facilitate delivery of devices by allowing the doctor, while they're sitting outside the patient's body, to push this guide-extension catheter past the distal end of the guide catheter.

So they've made a lot out of this limitation, but it's simply a limitation that goes to the fundamental nature of what these products do. A product would not work if it didn't satisfy this limitation.

THE COURT: But you agree that when it comes -- well, I know we're talking about a method thing, but you have to be able to know at the time you're -- whatever

you're doing, practicing the method -- whether you're infringing it. So you have to know at the time -- this is a method for essentially manufacturing the device. So you have to know while you're manufacturing the device if you are in fact manufacturing a device via a method that comprises arranging blah, blah, blah such that when the flexible -- you have to be able to know that at the time you're manufacturing, right?

MR. VANDENBURGH: Correct.

THE COURT: And the way I know that is because "standard guide catheter" means a specific distance or just because this thing is so much longer than any guide catheter that a person of ordinary skill would not have any trouble knowing?

MR. VANDENBURGH: I lean more towards the latter, Your Honor. If you look at this slide, this is just confirming that the Telescope devices are 150 centimeters long. They haven't put in any evidence of a guide catheter longer than even 100 centimeters.

They make guide catheters. If there was a practical argument to be made that there were guide catheters out there that were longer than 150 centimeters for which this device might be used with, they would be talking about it.

Of course, if you look at their instructions for

use, they know how this device is used. They know that it's going to be used with devices that are always less than 150 centimeters. So that's how it's adapted for use, is simply by arranging it in a way that's it's called out for in the claims at a length that's longer than a standard guide catheter.

THE COURT: Okay. Can you go to the claim 25.

MR. VANDENBURGH: I actually don't have a slide with claim 25.

If we could go to slide 91 in your presentation?

MR. NIEDERLUECKE: Yeah, I can get it for you. It's 91.

MR. VANDENBURGH: Okay. So here we have the additional language of forming a device length that is longer than a predefined length of the continuous lumen of the guide catheter. But, again, you know -- at the time you make it, you know how long a guide catheter is. You know the product has to work. And you're forming a device that is longer than the continuous lumen of the standard guide catheter.

THE COURT: You do not ascribe any significance to the fact that this uses the definite article "the" rather than the indefinite article "a"?

MR. VANDENBURGH: I don't, Your Honor. It's really one of those patent practice things. The standard

practice examiners want this. Once you've introduced a term, you change to the definite article, and the use of the definite article actually tells you that you're referring back to the thing that you talked about earlier. And in this case, it's the standard guide catheter that's talked about in the preamble.

THE COURT: Okay. I mean, I have to say my lean is in your direction on these. It seems to me that they're saying that you have to be able to look at the thing and know that when it's put into operation in the future it will perform -- it will stick out both ends essentially -- rather than that there has to be a guide catheter packaged with it or as part of it. It's seems to me different than, say, the system language, which I think --

MR. VANDENBURGH: It would make no sense with just the first five words of the claim. It's not a method of forming if it's got to be in a package. So it just doesn't make any sense.

Just on your comment on claim construction, of course, one of the reasons that this case was filed in this court, one of the reasons we think preliminary-injunction relief is appropriate here is because the claim has been subject -- or the claims of this patent family have been subject to extensive litigation in a *Markman* proceeding.

I think we have perhaps, as you mentioned, three

or four claim construction issues that get raised in the course of this motion, but that's a lot less than you would usually see in patent litigation over five patents.

THE COURT: Well, this being one of them.

MR. VANDENBURGH: Yes. Thank you.

THE COURT: Thank you.

Mr. Niederluecke, anything more that you wanted to say about that issue about that patent?

MR. NIEDERLUECKE: Your Honor, I think just again briefly, number one, this is a product that's made in Ireland, not in the U.S., and so this is about a method that occurs outside the U.S. It has to be complete. If you sell it in the U.S., it has to be the complete product.

The question -- as you say you're leaning towards that, I think to the extent you're leaning towards this not being a structural limitation, then I think what we're going to find is we have just as serious an indefiniteness question here because when that comes off in Ireland, off in that manufacturing plant, the question of a standard guide catheter -- I can tell you my brother unfortunately just had to go through this procedure yesterday. They went in through the arm. It's now a different length guide catheter when they go through the arm and so it does change. It can change all the time.

THE COURT: Do you disagree with what

Mr. Vandenburgh said, which is this device when it comes off the assembly line is much longer than any guide catheter in existence?

MR. NIEDERLUECKE: I won't concede that, Your Honor. There are different size guide catheters. When I've Googled that question, it comes up with different guide catheters, so I can't concede that as a matter of fact. But certainly there are many guide catheters that are less than 150.

THE COURT: Okay. Well, patent litigation, it's like whack-a-mole. You whack one and the other one pops up. So your indefiniteness can be the next mole that I whack.

Is there anything more you wanted to say about that patent before we turn to the '760 patent?

MR. NIEDERLUECKE: No, Your Honor.

THE COURT: Okay. You know, for the '760 patent I think it might be best if I start with Mr. Vandenburgh.

Mr. Vandenburgh. So, Mr. Vandenburgh, this is one of these system patents. I couldn't tell whether you disagreed with Medtronic's initial argument, which is the *Cross Medical* argument, which is essentially this discloses a system that includes a guide catheter, which seems clear to me, and that for direct infringement you would need a guide catheter and they don't have a guide catheter, so there's no direct infringement of this claim.

MR. VANDENBURGH: Your Honor, certainly for the purpose of today, we are not disagreeing that you require a guide catheter, and we are not addressing asserting direct infringement.

THE COURT: Okay. So really, only for purposes of today, we're only talking about indirect infringement?

MR. VANDENBURGH: Correct, Your Honor.

THE COURT: Okay. So the first argument Medtronic makes is they don't induce or contribute to any third party's direct infringement because you haven't shown that there is any third party that's directly infringing.

I'm inclined to agree with you that the evidence in the record would be overwhelming that there are doctors who've used the Telescope and you kind of have to use it with the guide catheter. It seems just common sense that there are third parties that infringe.

I mean, I know the record doesn't contain the name of the doctor and the date that the doctor used it, but the record does contain evidence that Telescope has been purchased and has been used, and Medtronic has surveyed those who have used it and so on. And I know there is a footnote there that has a couple of those responses, so that argument doesn't trouble me.

The argument that does trouble me is the not more than one French size limitation. And, honestly, I just

can't follow your argument.

MR. VANDENBURGH: Okay.

THE COURT: Your -- not you the attorney, but your client stood before me in *QX Medical* and told me one French meant 0.0131 inches. There was no it means something in some patents and it means something in other patents. Your argument is essentially an inch doesn't mean an inch. I'm not trying to be argumentative here. I honestly can't follow the argument.

MR. VANDENBURGH: Well, then shame on us because we should have done a better job, but let me try to explain.

Let me start with this was an issue that simply was not contested, for whatever reason, in the *QX Medical* case. It was just assumed that one French size meant the same thing as one French, that those were treated as synonymous. The point that is really raised by our brief is that there is a difference.

We don't dispute that the word "one French" in this industry means 0.0131 inches. But that some of the claims have a different phrase, which is "one French size." Then you change to a different thing in this industry.

People know, you know, there's this thing out there called an eight French catheter. There's something called a seven French. People know what it is. They call it that and they don't necessarily -- what they know that by

is its outer diameter. They're sized by their outer diameter.

The inner diameter of an eight French and the inner diameter of a seven French is not necessarily 0.0131 inches different because the wall thicknesses are different. And that's what creates the confusion here, and that's why you need to look to the spec.

The point that we are making with respect to the one French size limitation, in particular claim 25 of the '760 patent, is this is one of those instances where the patentee acted as their own lexicographer.

You go to the -- so we have the one French size smaller. That's the claim language. You go to the specification and it goes through in detail and it's explaining really what people skilled in the art know, which is that a six French guide catheter has a six French outer diameter, but that then it has a certain inner diameter that also takes into account the wall thickness.

And then it goes on to say what a five French, what a six French, seven, and eight and ultimately says, the last sentence, for a five French in a six French coaxial guide catheter the internal diameter should be greater or equal to 0.056, even though up above it says a six French guide catheter has an internal diameter greater than or equal to 0.070. Obviously, do the math. You've got a 0.014

difference in the inner diameter. The specification is telling you that's a one French difference -- I'm sorry, one French size difference, even though it's not exactly 0.0131 or less inches.

THE COURT: So you're saying that this language is meant to define "one French" as 0.014?

MR. VANDENBURGH: In the real world of this invention where you're putting one catheter inside another, where inner diameters matter -- not outer diameters, but inner diameters matter -- this is the language that's defining a "one French size" difference for a guide-extension catheter fitting inside a guide catheter.

THE COURT: You know, I have had patents where the patentee acted as its own lexicographer. When that happens, it almost always sounds like that. It sounds like for purposes of this patent "substantially" means at least two-thirds covered or something like that.

This doesn't sound like -- I mean, you have to work really hard. You have to work really hard to come at the conclusion you've just come at. Given that one French is, from what I can tell from the *QX Medical* case, a term of art -- I mean, it is in the manufacturing world like saying one inch, one foot, one meter.

If you were going to literally say one French, think one inch, doesn't mean one inch in our patent, it

means something different than one inch, wouldn't you call that out more clearly than this?

MR. VANDENBURGH: I think the practical thing, Your Honor, is that the inventors were designing this for doctors. You know, the math you're talking about, that's an engineer. An engineer thinks in terms of -- doctors don't sit there and say, okay, I want a guide catheter that's 0.084 inches. Get me that, please, nurse.

THE COURT: Well, doctors don't read patents.

MR. VANDENBURGH: Yeah, but they say, Give me an eight French catheter, Give me a seven French catheter.

An important part of this invention, it goes back to the fact that real estate is critical to this invention. You want to give up as little real estate as possible with this guide-extension catheter so that you can get as big a device down it. What this paragraph from the specification is telling you is that we're giving up minimum real estate. We're only giving up one French size in terms of the device we can then ultimately put down the catheter.

Your Honor, there are cases that made clear that you don't need a definitional-type statement to be a lexicographer.

THE COURT: I know it's not necessary. I would expect that especially if I was not defining a word like "substantially," which sort of begs for a definition, but

rather defining a word like "inch," which the whole world believes means something, and you're going to use it in a different way in your patent, I would just expect that to be called out more clearly.

Now, this is our second *Markman* term or whatever. It will be for a future *Markman*, but --

MR. VANDENBURGH: It is.

THE COURT: I just have to say that I give you kudos for your creativity, but I think that's a hard argument. You're going to be walking uphill for me on that argument.

MR. VANDENBURGH: All right, Your Honor. Well, since we've got a lot of issues ahead of us and, as I said, we only need to succeed on one patent, one claim today --

THE COURT: So if I disagree -- I'm trying to think of what the one French thing matters with. So they would be arguing -- so this would defeat your indirect -- I know this is very simple to you, but for me I have to think this through. If I didn't agree with your argument about one French size, it would defeat your indirect infringement argument with respect to the '760 patent, right?

MR. VANDENBURGH: That's correct. I would just -- we could take a quick look at this slide. So this is what Medtronic says their device is. Their Telescope in their six French size has exactly actually what's described in the

specification as a 0.056 inner diameter and needs a required guide catheter of at least 0.070. You do the math and that's 0.14. But this is --

THE COURT: Which is not less than 0.131. It might be that come *Markman* time you'll convince me of this, but this is a first look thing and it seems to me a hard argument.

MR. VANDENBURGH: Thank you, Your Honor.

THE COURT: Thank you, Mr. Vandenburgh.

Mr. Niederluecke, I'll give you a chance to snatch defeat out of the jaws of victory on this if you want.

MR. NIEDERLUECKE: The only comment I'll have here, Your Honor, is it was absolutely contested. Not just "one French," but "one French size" was in the last case. They were all together. They were all treated together.

THE COURT: Well, this argument just never came up in the last case. We all agreed "one French" meant 0.131 inches.

MR. NIEDERLUECKE: Right. And the issue in the earlier case was the difference between something that was 0.14 and something that was 0.13, and the question was indirect infringement.

They had one example where it was used in this case. It's never used -- by their own evidence that they put in here, it's never used in a circumstance where it

would be one French size or less.

THE COURT: I would just think if you were going to tell manufacturers and engineers and others that one inch doesn't mean one inch in our patent, it actually means something different than one inch, that would be something you would call out very clearly, not in a description of one embodiment and having people have to do the --

MR. NIEDERLUECKE: Absolutely, Your Honor.

Cognizant of not snatching defeat out of the jaws of victory, all that's doing is saying if you put this size in this size, this is the inner diameter you end up with to use. That's all that says. It just walks through and says, Here's three different sizes, and that's all it's telling you. It's not trying to define it.

THE COURT: I think it's being descriptive rather than --

MR. NIEDERLUECKE: And, Your Honor, just back to your question --

If we can go to slide 24.

-- in terms of the impact of this one. Again, as we mentioned -- and I do want to keep cognizant here, we're certainly arguing this like it's a summary judgment or like it's a trial, but certainly the real question here is have we raised a substantial question. I don't want to lose sight of that, Your Honor. We don't have to prove anything

today. We have to raise substantial questions that they can't say lacks substantial merit.

So when we look at the '760 patent, there's four different reasons why we believe we've raised substantial questions. That no infringement one on the right, Judge, if you are inclined to agree with us, what that means is the '760 patent for purposes of this PI motion is gone. They can't show infringement on that. So that whole line -- they've got to knock all of these out. Every one of these -- for them to win, they've got to knock out every one of these checks. For us to win on any given patent, we just need to sustain one of those checks.

THE COURT: Right. I think at least at this point I don't find their case for infringement of the '379 patent to be very compelling.

MR. NIEDERLUECKE: Thank you, Your Honor.

THE COURT: Okay. Let's see. Mr. Niederluecke, maybe while you're there -- it doesn't matter who goes first. I want to turn to the '380 patent, then.

And this, again, is a system patent. And I assume Mr. Vandenburgh will make the same concession he'd made with respect to the prior patent, that you don't have direct infringement because you don't package this or manufacture guide catheters and the system requires a guide catheter.

So we're only talking about -- well, there's also

a separate argument here about direct infringement regarding the connection, right?

MR. NIEDERLUECKE: Yes, Your Honor.

THE COURT: Why do I need to reach that issue? I guess it would be necessary because of the indirect infringement arguments. Right?

MR. NIEDERLUECKE: Correct. Correct. It's a question of indirect infringement and can they argue that somehow we're indirectly infringing by providing this to doctors for use.

THE COURT: So your argument is -- this is our third *Markman* hearing, future issue for a *Markman* hearing. So your argument is that "connected" can mean any kind of connection, whether direct or indirect, right?

MR. NIEDERLUECKE: No.

THE COURT: Yours is the opposite.

MR. NIEDERLUECKE: Yes, Your Honor. Ours is that the specification, reading it in light of the specification, requires a direct connection both in terms of the way it's used in the claims.

THE COURT: So you've read their argument back to me that says that they've cited some cases in which both direct and indirect connections were considered to have met connection language, and what is your --

MR. NIEDERLUECKE: And I think they've cited a

case. And if you read that case, the specification -- I mean, it's very important, Your Honor, as you know, and when you do claim construction, you have to look to the specification. You have to look to the claims themselves. You have to look to the specification to try and interpret what "connected to" means. It can certainly mean different -- have different meanings in the context of different patents.

They've cited you to a case that talked about a patent where in the specification itself it contemplated these indirect connections. In this case, when you read the specification of the -- what are we on here -- the '380 patent, what you see is whenever they talk about any kind of direction connection, they talk about a physical direct connection, Your Honor. And what's important too --

THE COURT: I would be with you as a matter of first impression. You know, the leg bone is connected to the knee bone. The knee bone is connected to the thigh bone. The leg bone isn't connected to the thigh bone. Normally when we talk about connected, we mean direct connection.

The one argument that they made that gave me pause is they say if we construe this this way, then claim 12 wouldn't cover any of the embodiments of the patents. And, of course, we try not to construe claims that don't cover

any of the embodiments. What is your response to that?

MR. NIEDERLUECKE: Your Honor, two things. First of all, in terms of where you look at the claim language within the claim itself, which you'll notice is the reinforced portion that they talk about, all they say is proximal to the flexible tip. So when you read through the elements as you go down, it says a flexible tip, a reinforced portion proximal to, and then they say a substantially rigid portion proximal of -- and then they comma -- connected to and more rigid along an axis than the flexible tip.

So they literally stuck language in there to not only say proximal, of which they could've left, but they literally -- as opposed to the reinforced portion -- put in the term "connected to" the flexible tip. So they chose to do that --

THE COURT: I don't remember you making that argument in the brief, but that's actually a good argument, which is they're requiring not just that it be close to, which proximal gets -- or the side of, but connected to. So they must mean something by "connected to."

MR. NIEDERLUECKE: Right. And they use different language for the two different elements. One they added in the "connected to" where the other element they didn't. I apologize if we didn't come clear. We tried to make that

point.

THE COURT: That's a good point. Otherwise, everything in the guide-extension catheter is, in their theory, connected to everything else.

MR. NIEDERLUECKE: Right, they would have to be.

THE COURT: What do I do about their argument if we construe it the way I would be inclined to construe this, which, as you would put it, requires a direct connection, then the claim wouldn't cover any of the embodiments because all the embodiments have this reinforced portion in between the substantially rigid portion and the flexible tip?

MR. NIEDERLUECKE: Yes, Your Honor. And I would say that while certainly the idea of covering the embodiments is one of the canons that can be followed, when you have explicit language, clear language that is written in the claims, you can't just rewrite that language so that you follow one of those canons.

They choose what they want to do. And as we've seen in the last case and in this case, for instance, the side opening. As Your Honor addressed in the last case, the side opening was claimed while it's not disclosed anywhere in the patent. The side opening is claimed in the lumen, in a separate segment. That's what we have here as well. We'll be addressing that argument. What the Court made clear was that's what they claimed. And even though that

didn't cover any of those embodiments, that wasn't shown in any of those embodiments, that requirement, this is what they claimed.

So you can't vitiate their language just because it doesn't fit within there when it's very clear that they added "connected to" for a purpose in these claims.

Remember, these claims weren't original claims. All of these claims we're dealing with are claims that are a decade later. So they're creating claims to cover their product. They're not creating claims to cover what is in the patent, what was invented.

So they can do that if they want to try, but just because they try to create claims that cover their product and not what's disclosed in the patent doesn't mean you rewrite those claims and redefine those claims. We have to define them based on what's in the patent and what their language is. And if it doesn't cover those embodiments but it's clear -- and "connected to" is certainly clear -- then the Court should define it as it is, and then we deal with things like written description or other aspects.

Just like with the side opening, Your Honor, this is the same circumstance. They've written claims to put a certain limitation on there that they like for a purpose perhaps other than what is actually within their specification back from 2006.

THE COURT: Okay. You don't dispute the premise of their argument, which is that construing the way you would like, claim 12 would not cover any of the embodiments? You agree that that's factually correct?

MR. NIEDERLUECKE: Certainly as they're applying them to our product I would agree with that because in each one they have that. I don't know if they would ever have a different application where they would construe "flexible tip" to be different portions, but certainly as they're applying it to our product.

THE COURT: Okay. Thank you, Mr. Niederluecke.

Mr. Vandenburgh.

MR. VANDENBURGH: Go to slide 46.

THE COURT: So my struggle here is between two principles here. One is, as I read this language, I read "connected to" to mean directly connected to. That's the way "connected to" is normally used in the song, you know, the leg bone is connected to the knee bone. The leg bone is not connected to the jaw bone. It's all part of the same body, but we don't talk about them being connected. The United States is connected to Mexico and it's connected to Canada. We wouldn't really say it's connected to Bolivia, even though it's all part of the same land mass.

So normally I would say "connected" means directly. And that would be bolstered by this claim

language, which first requires that the substantially rigid portion be proximal of, meaning on a particular side of the flexible tip portion. That in itself means they have to be part of the same unit. So as you read "connected to," it really doesn't have any purpose. It just emphasizes again they have to be part of the same unit.

So I read the language as Medtronic does. At the same time, I'm cognizant of the principle you should try to avoid reading claims to not cover any of the disclosed embodiments, which Medtronic concedes this would do, and that's what I'm struggling with.

MR. VANDENBURGH: Okay. I appreciate that. So let me start with the case law, of course. And it goes back to your feeling that "connected to" ordinarily means directly connected. The case law does say otherwise. They say that, well, we only have one case. Your Honor, I believe our first draft of our reply brief had four or five cases. Your Honor may understand we were sorely in need of words trying to stay within your word count. So if Your Honor wants another four or five cases, we can easily give them to you. It comes up a lot in patent cases.

THE COURT: I don't contest that "connected to" can mean indirectly connected to. I realize it is used that way. But, as I said, this language suggests it's not to me.

MR. VANDENBURGH: But that's really where I think

particularly Mr. Niederluecke's argument breaks down, because that principle that we don't construe claims to exclude all the embodiments of the patent, that's an extremely strong principle. You know, we have all these rules that we apply. That one is right on the edge of -- you know, you can count on one hand the cases where they say, yeah, I know if we construe it this way, it doesn't cover anything that's in the patent, but, you know, the language is clear. Those few handful of cases it has to be painfully clear that that's what the claim means.

When you have a half a dozen cases that say "connected," ordinary meaning, can mean indirectly connected, the argument immediately breaks down that this claim language is unequivocally clear that it needs to be that way.

THE COURT: Putting that principle aside, which does give me pause, if we didn't have the embodiment problem, what's the answer to the point that Mr. Niederluecke made and I think is a good one, which is when the claim already tells us the substantially rigid portion is proximal of the flexible tip portion, it's already telling us they're part of the same unit, they're indirectly connected? To read "connected to" to just mean part of the same unit, they're indirectly connected, that renders "connected to" to be superfluous, and that's another

principle of patent law, you're not supposed to read terms to be superfluous.

MR. VANDENBURGH: True. But, again, the reality of that principle of claim construction is there are a lot of claims where if you look at them hard, we didn't really need that word, we didn't need that word.

The other thing to keep in mind, this is a system claim. So it is talking about components that aren't necessarily attached to one another. It starts out with a guide catheter. We know it's not attached to the device.

Now, I know that we're talking about elements of the device, but again given the fact that this is a system claim, it's not unreasonable that somebody would want to, perhaps in hindsight, be a little redundant but to make clear that there is a connection between that substantially rigid portion and the flexible tip portion.

The other point that I really want to make with respect to this, because it's one that did not get into our brief, is that the claim language -- there's other claim language that also shows that "connected to" in this instance means indirectly connected to. And it happens when you dig into the remainder of that paragraph that we're talking about right there, because basically what it shows -- and I color-coded it to try to explain what we're indicating there -- okay, it's proximally connected to the

flexible tip portion such that when the distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, in other words, it's at one end, the blue then says, the reinforced portion is inside the lumen of the guide catheter. Okay, it's in the middle. And then the green says, the proximal portion of the substantially rigid portion extends proximally out the hemostatic valve, which is the proximal end of the guide catheter. So that claim language is telling you the order of the components.

To go to our specific embodiment of our patent, it's what we know it is in all our embodiments, it's red tip portion, blue in the middle stays inside the guide catheter, rigid portion extends out the other end.

So yet another one of those principles of claim construction in talking about what sort of connection we have, it says that such that these three things happen and it orders the components for us.

THE COURT: This is in claim 12.

MR. VANDENBURGH: This is the claim we've been talking about.

THE COURT: I'm sorry, the same claim.

MR. VANDENBURGH: Correct.

THE COURT: There are so many numbers floating around.

MR. VANDENBURGH: Yeah, I know. I know.

THE COURT: Okay. I mean, I think that's a good argument, which is the same claim that has this language also tells us that the reinforced portion is in between these two. So it would self-destruct to read "connected to" to mean a direct connection. Yeah, I understand.

MR. VANDENBURGH: Now, they do also make some of these indirect infringement -- ultimately our case on claim 12 is an indirect infringement case.

THE COURT: I meant to make you -- not make you. I meant to ask you -- I assume we're -- for the same reason we're not talking about direct infringement?

MR. VANDENBURGH: Correct. If there is any question in Your Honor's mind about the indirect infringement issues here, as you said, there is evidence in the record that doctors actually use this with a guide catheter. And the law doesn't actually require that direct evidence. And I think that's important to keep in mind ultimately. We have it, but we don't need it. The average case is not proved that way.

Let me go -- I've got a case law slide here. Just to be clear, Medtronic says a guide catheter is required. It's not optional. It's required. They specifically instruct doctors how to use the guide-extension catheter with a guide catheter. So this isn't one of those use it

one way -- this way if you want to use it another way.

THE COURT: I don't understand Medtronic to be seriously arguing that this has never been used in the system with a guide catheter by a surgeon in America.

MR. VANDENBURGH: Okay. And even if we didn't have the direct evidence, the case law actually says in the ordinary case you could infer the direct infringement from the instructions.

THE COURT: And we're just here on a PI motion. We're just talking about probabilities as it is.

MR. VANDENBURGH: I'll sit down, Your Honor. Thank you.

THE COURT: I don't have any problem with that. Okay.

Mr. Niederluecke, anything more you wanted to say about infringement before we turn to validity?

MR. NIEDERLUECKE: No, Your Honor.

THE COURT: And, Mr. Vandenburgh, is there anything more you want to say about any of the infringement issues before we turn to validity?

MR. VANDENBURGH: No, Your Honor.

THE COURT: Okay. You know, we've gone over an hour now. This is a hard day for my court reporter because we read things and she has to type really fast, so let's take a short maybe 10-minute break. We'll come back at

quarter 'til and turn to the validity issues.

THE LAW CLERK: All rise.

(A brief recess was taken.)

THE LAW CLERK: This court is now in session.

THE COURT: Please be seated. I'm sorry the break went extra long. My court reporter is under the weather today, and we may have to take more breaks and longer breaks than I normally would. Normally she's the iron maiden, but she was with her grandchildren over Christmas. That's what you get for being with small children.

So with respect to infringement, just to summarize -- we'll, obviously, write this up in an order, but as things stand, I do think that Teleflex has shown a likelihood of success in showing infringement of the '776 patent, which isn't really contested; in showing infringement of the '379 patent; and in showing infringement of the '380 patent.

I don't think they've shown a likelihood of success on showing infringement of the '760 patent. I think I've made my views as to why I'm leaning that way pretty clear. I reserve the right to change my mind when we actually write up the order, but that's at least where I'm leaning right now.

Okay. Let's turn, then, to the question of validity. The first question that I want to address is

whether the Itou reference is or is not prior art, if that's the way you say this. It makes no difference to me who goes first. Mr. Vandenburgh?

MR. VANDENBURGH: I leaned forward, so I guess that means --

THE COURT: You leaned forward, so I'll have you go first.

MR. VANDENBURGH: All right. Thank you, Your Honor.

THE COURT: So, as I'm demonstrating, I have trouble with all of patent law, but I've never faced this issue before as to swearing behind the filing date of a reference, and so this is a particularly awkward topic for me.

Largely this seems to be a fight about when this invention was reduced to practice. Right? Isn't that kind of the focus of the disagreement?

MR. VANDENBURGH: I believe that's the true dispute, if there is one. They did dispute conception in their brief, but --

THE COURT: Well, I mean, they sort of mention the conference, but their brief really focuses on reduction of practice. Also on diligence, but I believe diligence doesn't -- the little bit I was able to read of the law, I think you're right that diligence doesn't matter if there

was reduction to practice prior to our September 23rd, 2005.

MR. VANDENBURGH: Just one point, though, I would clarify is they have to show both. I wanted to make sure I say that the right way. They have to show it wasn't reduced to practice prior to September 23rd, 2005. And they have to show there was no diligence. In other words, Mr. Niederluecke did the, well, we've got to win on all these things. They have to win on both of those things. And we actually did put quite a bit of evidence in on diligence.

So we think it's clear that this invention was reduced to practice is in fact undisputed in the evidence at this point. But if we want to get to conception, we certainly have the evidence -- I'm sorry, we want to get to diligence, we also have evidence on that as well.

THE COURT: Okay. Let me just start to ask you just something really basic, but something that keeps slipping from my grasp, which is explain to me exactly what the invention was. What's the invented element here?

The briefs in this case, and this was true in *QX Medical* as well, talk about mother and child catheters. They talk about over-the-wire catheters. They talk about rapid-exchange catheters. I'm not exactly sure what each of those mean. They get used kind of sloppily sometimes. I'm still not entirely clear exactly what is the -- what is it

that set the world on fire? What's the invention?

MR. VANDENBURGH: Right. The invention here, I think it's fair to say, was a rapid-exchange guide-extension catheter that, you know, in that rapid-exchange format so you didn't have all sorts of problems with the doctor having to handle a really long wire, they could use it via rapid exchange, could be extended through a guide catheter into sort of, you know, difficult shapes inside a coronary artery.

THE COURT: And what exactly do you mean by "rapid exchange"?

MR. VANDENBURGH: "Rapid exchange" is essentially the idea where you have a push wire and just a smaller tubular portion towards the end, and it allows a doctor to exchange more simply.

THE COURT: So when we talk about a mother and child catheter, we're generally talking about sort of one long tube inside of another long tube, but both tubes are sticking out the proximal end and, therefore, you need two hemostatic valves to control it?

MR. VANDENBURGH: Correct. Correct. And I would say, as I understand it, "over the wire" is essentially synonymous with -- or mother and child would be a type of an over-the-wire design, that being that the entire catheter is running along a very long wire.

THE COURT: Okay. So those are synonymous as far as you're concerned?

MR. VANDENBURGH: I think for the purpose of our case. People in the art might draw distinctions or one is broader than the other, encompasses the other. But for the purpose of the evidence we're talking about, for example, when we were talking about an over-the-wire version that was in 2005 being developed by Vascular Solutions at the same time, that was -- you could call that like the mother and child.

THE COURT: So the rapid exchange is you take the child catheter, you make it really short, and you stick it on the end of a push rod so that the doctor can just quickly get it in and out of the guide catheter? There's not a second catheter to worry about?

MR. VANDENBURGH: Right.

THE COURT: Okay. Now, there were rapid-exchange catheters in the prior art, though, right?

MR. VANDENBURGH: There were, Your Honor.

THE COURT: So what's our invention?

MR. VANDENBURGH: But nobody had done it as a guide-extension catheter and there are reasons why that -- you know, that sounds like, well, isn't that just taking two ideas. First of all, that's right before the Patent Office in numerous examples, and it's not that simple.

THE COURT: This isn't a loaded question. I don't know enough to make it loaded.

MR. VANDENBURGH: Right. So in a guide-extension catheter something that was intended to be inserted -- as a rapid exchange inserted into ultimately the tip end going into the cardiac arteries and then being able to deliver interventional cardiology devices -- balloon catheters, stent-delivery catheters -- into that tube that's way down inside the guide catheter.

THE COURT: What were the small tubes on the end of big push rods used for in the prior art?

MR. VANDENBURGH: My understanding is that, for example, some of the balloon catheters were rapid exchange. So but what that would be, you would have a balloon preloaded in this tube at the end of a long wire. You would then put that on, send it down the guide catheter and again into a cardiac artery.

THE COURT: Okay. So the device would be kind of preloaded into the short tube?

MR. VANDENBURGH: That's my understanding, Your Honor.

THE COURT: But the short tube didn't extend beyond the end of the --

MR. VANDENBURGH: It would. It would. It would still then extend out the far end of the guide catheter.

You'd end up pushing out the balloon catheter and expanding it to -- that's what balloon catheters are designed -- you put a balloon down that then is inflated. It opens up and --

THE COURT: But that sounds very similar to the invention here. What did this invention do to improve over that?

MR. VANDENBURGH: See, this invention isn't about the actual balloon catheter itself. This is about a device that its purpose is to simply get you where you need to be, get you past that difficult lesion so that you then can put the next element down there.

THE COURT: Isn't that what the tube around the balloon catheter did in the prior art, get you closer to where you need to be with the balloon?

MR. VANDENBURGH: It did. But, again, this guide-extension method was not used in the art. A lot of inventions you look at them after the fact and say, boy, how did I miss that.

One of the interesting things here is Mr. Itou, the person we're talking about, is both, of course, an inventor on the suction catheter we're going to talk about, but also is an author of the paper cited in the patent specification. Our specification talks about the mother and child, describes it, acknowledges it as prior art. Mr. Itou

is an author of that article.

Mr. Itou, you know, there is no evidence he ever considered doing mother and child in a rapid-exchange version. He had a rapid-exchange version of a suction catheter. He certainly knew of the mother and child. There's no evidence he ever put it together.

So we shouldn't be -- so let's not be quick to say, oh, this is just the obvious combination of taking rapid exchange and taking mother and child and putting them together.

THE COURT: What I'm struggling with is so when this invention is being used, you have the guide catheter, you push the child catheter essentially -- I know it's not -- the short catheter you push through, and it gives you the extension into where you need to place the balloon or the stent, and then you push the balloon or the stent through. That seems very close to putting the balloon inside the tube and pushing them both together through there and then pushing the balloon out the tube. It seems almost the same thing.

MR. VANDENBURGH: Certainly a distinction is there that you don't need to deep inside the body push something inside a tube at the proximal end of the tube.

THE COURT: So the difference is instead of the balloon catheter riding down the guide catheter inside the

tube, first the little tube goes through and then the balloon follows later?

MR. VANDENBURGH: Correct.

THE COURT: That's the invention?

MR. VANDENBURGH: That is the -- one of the advantages of the invention is, in essence, coming up with a design that allows you to do that.

THE COURT: So this invention then -- so I have to know when it was -- and I don't -- I will ask Mr. Niederluecke about this. I didn't understand them to be contesting that your inventors conceived of this before whatever the 2005 date is, September 23rd, 2005.

The thrust of their argument mostly seems to be they didn't reduce it to practice. I mean, I've read all the stuff in the brief about -- I mean, my question is how do I figure this out on a motion for preliminary injunction? It seems that I have to basically put myself in the inventor's workshop and follow what they were doing and at some time declare that that has now been reduced to practice. And you say it doesn't have to be in a human being; it's okay if it's in a model as long as the model closely resembles the human body. This all seems really, really deep waters for a judge to swim in on a PI motion.

MR. VANDENBURGH: Let me try to give you some guideposts --

THE COURT: Okay.

MR. VANDENBURGH: -- to go by. First, of course, as I've got up on the stand, ultimately at trial Medtronic is going to bear the burden on these issues. And I know we're in a different situation here, but we need to keep that in mind as we're viewing the evidence.

The other thing is let's talk about this issue of corroboration. I believe, Your Honor, it was a different circumstance, but back in the *Spectralytics* case we had one of those issues, so Your Honor may have some familiarity with the ideas of corroboration. It's been a long time.

THE COURT: Let's just pretend that His Honor doesn't remember anything about that and barely remembers -- the Spectralytics was cutting the stents, right?

MR. VANDENBURGH: Correct. Correct. We're actually going to see some invoices from them in a minute.

THE COURT: I've just exhausted my memory with respect to *Spectralytics*.

MR. VANDENBURGH: So one of the things to keep in mind on the case law -- we tend to think we need corroboration of what the inventor says. You don't need to actually corroborate the conclusions. The inventor's testimony is what it is. It's evidence that can be given weight to say, okay, is there evidence of reduction of practice? The inventor says, I did this, I reduced it to

practice. The corroboration is simply is there documentary or third-party evidence corroborating the inventor's testimony.

And so when you look at it in that regard, what we really have is undisputed evidence of both conception and reduction to practice. We have Mr. Root's lengthy declaration. And, again, keep in mind we were very squeezed on pages in the brief. Mr. Root's declaration lays out in many pages, many exhibits to corroborate his reduction, his conception -- and I should say VSI's reduction to practice -- in the first half of [redacted]. And so that's really the evidence to focus on.

Now, you might say but I'm at a preliminary injunction. Of course it's undisputed. Keep in mind Medtronic was given an opportunity to do extensive discovery: documents, interrogatories, depositions. They took a couple of depositions. They had a 30(b)(6) category on conception and reduction to practice. They voluntarily withdrew it.

So if Your Honor is concerned about, well, maybe we just haven't gotten all the evidence in yet, the reason the evidence is one-sided, it's undisputed is because they chose not to try to get in any evidence going the other way.

THE COURT: So I did not have time -- I mean, there's so much in this case that I didn't have time.

MR. VANDENBURGH: Yeah, I've got summaries on some of my slides. Perhaps I can highlight -- direct Your Honor to the highlights.

THE COURT: So at some point I want you to address -- I just have notes of what Medtronic said in the briefs. They said that you didn't attempt to reduce to practice the invention until well after, they say, May of 2006. And they say that you previously admitted that you only constructively reduced to practice -- are they talking about in body and out of body?

MR. VANDENBURGH: No. Constructive reduction to practice is what happens when you file a patent application. So I will admit again, as the law defines constructive -- that was a little bit of a trick -- as the law defines constructive reduction to practice, of course we didn't do it until we filed the patent application. That doesn't mean anything.

THE COURT: Oh, okay.

MR. VANDENBURGH: There wasn't a need to address when did an actual reduction to practice occur.

THE COURT: Okay. So you're going to tell me how I can find at this point a likelihood that you'll succeed in showing actual reduction.

MR. VANDENBURGH: Right. So let's go through some of the slides. First of all, as I said, we have Mr. Root

who says -- and, of course, it's all backed up by a lot of detail, but we kind of put the most important paragraph here -- prototypes of the rapid-exchange GuideLiner were made and tested soon after the [redacted] laboratory notebook drawings, talking about how the testing was performed. It was in a model. He says it allowed him to determine that the device would work for its intended purpose; namely, the ability of a rapid-exchange catheter to deliver interventional cardiology devices into challenging coronary anatomy. So that's the evidence right there, again, backed up by a lot of other details surrounding it.

Now let's talk about the fact that it's in a model. First of all, we have Mr. Keith, and that's the quote on the right. He's the third-party expert who says in the catheter world that's how you do it. You don't reduce things to practice inside a human being. And they don't actually say otherwise.

They have an expert who purports to give an opinion on reduction to practice. He's not working off any evidence, just kind of saying things, and he hints around -- you know, has some words that when I first read it said, oh, isn't he saying you have to have it in a body? But then I re-read it. I was told to re-read it. And he doesn't actually say it. It's not surprising because that's not how people do it in this industry.

We also have on that point the *Mahurkar* case -- and I'll just jump ahead a couple of slides here -- which was a catheter case where the invention was found reduced to practice based on testing that the doctor did in his kitchen, obviously not inside a human being.

So that issue, I think, is really a non-issue of was the testing done inside or outside the body. Let's go forward to then what's some of the corroborating evidence for Mr. Root's testimony.

First, I said I'd show you some Spectralytics documents. Here you go. It turns out that the initial prototypes, including this what we believe is the first one, and this is -- I think you heard from QXM the cut-down hypo tube. This is a cut-down hypo tube that was laser cut by Spectralytics. It was done in [redacted] We have a picture. There is -- one of these still exists. This was a recently-taken picture of that first prototype. And so that was done in May.

Now, the case law again recognizes that building -- you know, evidence of purchase of components specific to building and testing a prototype are corroborating evidence of reduction to practice. I was going to make another point on this, but I'm losing my train of thought on that one.

We have then further prototypes coming along. There's actually -- there is a little bit of testimony, and

it's in what Medtronic submitted with their supplemental submissions. There's an old deposition from Mr. Root, not from this case, where he talks about the initial prototype actually had leakage problems. It was leaking blood out the back-end. And, first of all, I'm not sure that that would avoid a reduction to practice. The device doesn't need to work perfectly. And he said it wasn't a big deal. But he also said, We immediately fixed it. And you can see again the corroborating evidence here.

Here's the next prototype. This time we can tie Spectralytics' invoice of 20 prototype components to a specific drawing, and it's this one that is from the patent. You probably recognize the drawings from the patent. And it's the one that has a much flatter guide wire. Again, the purpose of which is -- the problem was when you had a half tube at the end, the hemostatic valve couldn't clamp down on it very well and you were getting leakage, so you create a flatter one. So this one was created and tested.

I remember the point I wanted to make on both of these, which is that one of their arguments is that all the work that was done prior to the critical date, that was all on the mother and child. That's what their expert says. He doesn't know. He wasn't there, but he says that. He says all the work prior to the critical date, that was being done on the mother and child full-length one. Well, you don't

make these parts for anything other than the rapid-exchange version. This shows you that --

THE COURT: That hypo tube was the port into the --

MR. VANDENBURGH: Right. Right. You don't have a cut-down hypo tube with a mother-and-child version. So, again, we know that we are working on the invention of these patents. Again, this is dated from July.

On [redacted] we have yet another drawing, one you recognize from the patents. It's of a complete device. What Mr. Root says is, Look, we get to the point of this sort of a detailed engineering drawing only once we've done sufficient testing to know it will work. So this corroborates the reduction to practice by [redacted].

And then I think this is probably the last document I'll hit on. This is a product requirements document dated [redacted] Now, "product requirements" is a little bit of a misnomer. Let's not think too much or draw conclusions from the title. It makes it sound like we're just getting started. In fact, the opposite is true.

What Mr. Root says in his declaration is that this is the document that starts the quality process. I'm not sure if Your Honor is familiar with medical products

companies and the whole idea of a quality process, but obviously tracking and maintaining the quality of their development in the ultimate product they're going to make is critical. So when they start the quality process, what that means is they have to track every little thing they do.

What Mr. Root says, and it makes sense, is that we don't start the quality process through one of these products requirements documents until we've done enough testing that we're confident it's going to work for its intended purpose.

Now, I think what Medtronic is going to come up here and say is, well, but a lot of work continued after that. First of all, the law doesn't require for reduction to practice that you show it will work beyond a possibility of failure. You merely -- and I think if I am getting it right, the phrasing in the case law would be probability of failure, that it's likely going to work. So the fact that you may have problems down the road doesn't undo your reduction to practice.

The other thing the case law says is, of course, the work that you do to commercialize a product, to make it commercially viable does not undo an earlier reduction to practice. That's not relevant. And so the fact that there were several years of fine-tuning this product, of getting the right materials so they could be made safely,

consistently, effectively -- it's one thing to make one of these. It's another thing to make 1,000 of these. So the fact that it took another three years before the product was commercially released doesn't disprove the evidence here on reduction to practice.

If I could, I do want to just briefly run through these slides. I have four slides listing all the documents on diligence. So, again, they have to show two things. They have to show that there was in fact a reduction to practice prior to September 23rd. They also have to show that there wasn't diligence between that date and, for example, that constructive reduction to practice that occurred in May of 2006 when the patent application was filed.

This isn't the evidence -- this isn't all the evidence. This is just a listing of the documents that corroborate the evidence of diligence. And it goes on for pages. I've highlighted the entries that, again, are specific to the rapid-exchange version of the prototype. But the work that was being done on both, I think, would count towards diligence. We certainly have lots of documents that were specific.

And then ultimately what are we doing with this diligence analysis? This is a very recent case from the Federal Circuit that emphasizes that all really diligence is

looking for is that you didn't abandon it, that you were working reasonably continuously on it. This is not a terrifically high standard.

So, again, Medtronic bears the burden. They've got to show both there was no actual reduction to practice and that there was not diligence even if there was no reduction to practice. We submit they haven't presented a substantial case on either.

THE COURT: All right. Thank you, Mr. Vandenburgh.

Mr. Niederluecke. Let me start by asking you -- I can't tell if you're disputing conception or not disputing conception.

MR. NIEDERLUECKE: For the purposes of today, Your Honor, we're not going to dispute conception in and of itself.

The thing we do raise in our papers and raise in terms of both that and reduction to practice is each one of those, as you have correctly started your question out, what is the invention? Well, the invention is what is exactly claimed in that patent. I agree with Your Honor, Medtronic agrees with Your Honor, rapid-exchange devices have been out there forever -- not forever, but --

THE COURT: Just so the record is clear, when I was asking what the invention is, I know what's described in

the apparatus patents. I mean, I know what that is. I meant what's the invented concept? What was the advance here? I think Mr. Vandenburgh understood me to be asking it that way.

MR. NIEDERLUECKE: But in terms of this question that we have here, when you look to when something was reduced to practice, what you're looking at to start with in the overarching is you look at a claim and you say here are the limitations and can you demonstrate that the inventor at a certain date reduced the invention that includes all of those limitations in that claim to practice, meaning constructed an embodiment of the device and tested that device to ensure that it would work for its intended purpose, both of those things.

So one of our points is they didn't even try to say here's the limitations, here's how this prototype met those limitations, and here's the testing that proves it met those limitations. The reason is, Your Honor, which I'll explain to you --

THE COURT: So that's what -- these are sincere questions. If I did deal with this issue before, I don't remember it. So you basically have to have patent litigation about a prototype in order to establish -- I mean, you've got to, like, have the prototype, have it sufficiently described that you can take the eventual patent

and match the claims up term by term to the prototype for each of the 50 or 60 or 70 claim terms?

MR. NIEDERLUECKE: Well, let's step back to start with, which gets to --

If we can go to slide 26.

When you file your patent -- and I'll get to the issue of constructive reduction to practice. You file a patent and you get that date as your patent filing. Okay? That's your date. That's presumed to be your date of invention, unless you have evidence otherwise.

Now, if you want to say, yes, I filed my patent application on that day, but I really invented it earlier, a patentee has the right to try to do that, but that's when it's got to show evidence that it in fact invented it earlier.

So it's only in the circumstance where a patentee is trying to what we call antedate, get behind another reference, that this issue comes up. And in terms of the burdens that are provided, we have the burden -- Medtronic has the burden to show that the particular piece of prior art antedates the patent. There's no dispute here that it does. It's September 2005. The patent was filed in May of 2006. We've now met our burden.

Then it turns to Teleflex. Teleflex has a burden of production. And I'll say, Your Honor, you should read

your opinion in *Spectralytics*. It was excellent because you told the Federal Circuit to clean this up. I don't know if they have or not.

THE COURT: This is all becoming vaguely familiar because I couldn't believe how intricate and ridiculously complicated they made it.

MR. NIEDERLUECKE: Yeah. So what happens is then Teleflex at that point has the burden of production, coming up with sufficient evidence to show that it actually conceived and reduced to practice. And as part of that burden of production -- that burden of production not only of providing testimony from inventors or from people who have a stake in the outcome, but also to provide the corroboration to show, with documentation, that this in fact happened. So that's where we get to --

THE COURT: Do you have the burden of persuasion then if they meet their burden of production?

MR. NIEDERLUECKE: If they meet their burden of production, which includes their burden to show corroboration -- and that's where I think the Court originally in your opinion the question of where that line was was difficult to say what exactly is sufficient corroboration -- then for the purposes of today, we just have to say -- we just have to create substantial questions for the Court to say --

THE COURT: But just for trial purposes, then you would have the burden of persuasion at trial?

MR. NIEDERLUECKE: Correct. And we would have the burden of persuasion to demonstrate that they, in fact, did not. So as the Court has laid it out, it's kind of a three prong.

THE COURT: There is a reason I repressed all of this from my memory. All right. So I understand that. We're on a PI context. Okay?

MR. NIEDERLUECKE: Right. So the standards are a little different. Certainly, we don't have nearly the burden that we will have at trial. We don't have to prove invalidity of the case. We just have to show a substantial question. And this is one of those things that all we have to show is a substantial question as to whether or not they can predate it.

I think the big picture here, before I get into the evidence --

THE COURT: This predating, this only comes up -- I mean, it comes up with the patentee is trying to swear behind prior art that would otherwise potentially invalidate the patent? Is that the context in which it comes up?

MR. NIEDERLUECKE: Yes, because there's two types of --

THE COURT: It doesn't mean that somebody could be

held liable for infringing a patent because, obviously, you wouldn't have notice of the patent because the patent itself didn't exist at this earlier date, right?

MR. NIEDERLUECKE: Right. Right.

THE COURT: This is only a concept that comes up when you're trying to swear behind prior art references?

MR. NIEDERLUECKE: Yes. Yes.

So, you know, the main point here, and I want to explain -- Mr. Vandenburgh pointed out that we had an opportunity for discovery, et cetera, and we'll get into that, but I do want to point out that almost 40 of the 60 exhibits that they put in with Mr. Root's declaration they literally served -- they produced those documents to us that same day in November -- or, actually, was it even in December. So we didn't even have any of that evidence.

What we had, as you'll see, is a document that didn't even identify a reduction to practice date. We didn't think they were really mounting one. And so that's important to keep in mind.

I'm going to walk through some of that, Your Honor, because the main point that you'll see is it was a very well-worded, very well-worded declaration. And what you'll see is the declaration speaks oftentimes about the GuideLiner and all the work on the GuideLiner. Everywhere it says, This proves we were working on the GuideLiner.

Every time they say that, unless they even try to allege that it was a rapid-exchange GuideLiner, it was the over-the-wire, full lumen guide wire because that is what they were developing in [redacted]. Yes, on the horizon they had this idea that they wanted to build a rapid-exchange version and they played around with it a little bit.

THE COURT: Well, those things that Spectralytics made for them, those clearly are components to a rapid-exchange catheter, right?

MR. NIEDERLUECKE: And I will get to that, Your Honor. Some of those are components. What they show you and what they connect together, again, doesn't really hold water when you look at it fully.

THE COURT: I'd just note again what I did at the beginning. I don't know how a judge can possibly figure this out on a PI motion. I mean, you literally have to be in the workshop with these guys. I assume there's all kinds of stuff they're working on and there's pieces of metal all over. I mean, they're working on a whole bunch of different things. How a judge can sit there and trace this all through on a PI motion and -- you know, you had very limited discovery on this. I assume at some point you're going to take the inventors through very carefully. I just see a big black hole right now. It's very hard for me to figure out who's going to -- unlike the infringement cases where I sort

of feel like I have a lean and my lean will probably be my final decision, here I just don't have any idea how I'm supposed to figure this out. To put myself in the workshop with these people and they're working on various concepts and --

MR. NIEDERLUECKE: And, Your Honor, I think that's the point. We certainly have met our initial burden of providing the art with a specific date that predates by nine months. So we've done that.

And I think the fact of Your Honor pointing this out demonstrates that there is a substantial question here. And I want to walk through --

THE COURT: But they produced evidence that -- they produced what they say is evidence of reduction to practice. For me to weigh that evidence I have to carefully pick through exactly what terms they're using when I don't even know exactly what terms -- I mean, I don't -- I mean, you're going to show me some of this, I realize. This is a really hard thing to ask a judge to do on a PI motion.

MR. NIEDERLUECKE: I would agree, Your Honor. It is very difficult. I apologize for the tediousness of it.

THE COURT: That's inherent in patent law.

MR. NIEDERLUECKE: Yes.

THE COURT: Okay. I'm sorry, I took you off here. You were going to take me through some of this.

MR. NIEDERLUECKE: So the question is -- so we're right now -- I'm going to address, now that we've met our burden, their burden of production and go through some of that evidence.

I don't think that they disagree -- I will tell you, Your Honor, the issue of it needing to be in a human body, tested in a human body, we're not contending it needs to be tested in a human body, but it does need to be tested in an environment that simulates that.

So what we need to look for is the invention, not an over-the-wire design, but the invention that is both built into a full prototype and then tested to see if it works. What we're going to see, Your Honor, is they have a lot of records. And I'll show you they have a lot of records. But all their records go to the over the wire.

All the lab notebooks -- you haven't seen a lab notebook showing this. They keep lab notebooks. Of course they do, because they're a sophisticated medical company in a highly-regulated industry. They have the lab notebooks that describe it all, how they built it, all of that.

I shouldn't probably preview too much of this, but you're going to see that they have all the evidence for over the wire and they have nothing for the rapid exchange.

So if we walk through it, first of all, the question was apparently what they felt was a game. Back in

the *Boston* case they were asked to identify the date on which you reduced the claimed invention to practice. Now, that wasn't asking for a constructive reduction to practice. That was asking the date on which they reduced the claimed invention to practice.

THE COURT: Yeah, it did, but they did say constructively, which they left themselves the ability to later answer that.

MR. NIEDERLUECKE: We'll go -- and now they're saying actual reduction to practice. This was as of November.

Prior to that, they had two earlier interrogatory answers -- this is Exhibit Y -- where they didn't even lay that out yet. So they just slowly built this up after they filed their motion.

But if you look at the question and you look at Interrogatory No. 1, it's identify the date on which you contend that the claimed invention was conceived and the date on which you allege that the claimed invention was reduced to practice. So there's no game here. Their answer was the claimed inventions were conceived at least as early as [redacted] and constructively reduced to practice with the filing of the first application May 3rd, 2006. That was their answer back then. Now they say it's a year earlier.

I've already kind of covered this in my preface,

Your Honor, but this is explaining the law here, what they have to show about the embodiment and evidence that it worked for its intended purpose.

So we start off by saying they didn't even try to do that comparison. I know it's hard, Your Honor, because it can come down to even a claim-by-claim comparison, but they didn't even attempt to do that with the prototype, and the reason is they don't have a prototype. You never saw a picture of a guide-extension catheter -- a rapid-exchange guide-extension catheter actually made. They don't have one, much less tested.

So let's walk through some of this evidence that they presented. As we walk through this, what you're going to see is this: You're going to see an over-the-wire version, a rapid-exchange version. And we're going to go through the types of records that you'd normally see. What you're going to see is that for lab notebooks, they have lab notebooks corroborating their work on the reducing to practice an over-the-wire device.

THE COURT: Just so I'm clear, "over the wire" you mean a traditional mother and child catheter?

MR. NIEDERLUECKE: Right, mother and child, full lumen all the way back --

THE COURT: For both the mother and the child?

MR. NIEDERLUECKE: -- to the end requiring two

hemostatic valves, as you noted earlier.

Same thing, prototype build records. We have build records for the over the wire. We have no build records for the rapid exchange.

Sterilization records. We have those for over the wire. We have nothing for rapid exchange.

Prototype photographs of the whole prototype. We have it for over the wire. We have nothing for rapid exchange.

Test results. We have test results for the over the wire. We have no test results for rapid exchange.

Company reports documenting that exact prototype. We have that for the over the wire. We have nothing for rapid exchange.

What was going on here, Your Honor, was they were working on the over the wire. They were working on making a device that was just like the device they talk about in their patent that Itou published in a mother-child system. They were trying to copy that. We know that because their testing actually was comparing it to the Terumo over-the-wire device.

With regard to the corroboration, invoices for component parts don't corroborate a reduction to practice. That's what Mr. Root primarily relies upon. So, first of all, they don't corroborate it.

Second of all, they're not tied to rapid-exchange versions claimed in the patents in suit.

THE COURT: Well, like, why aren't those Spectralytics parts --

MR. NIEDERLUECKE: Well, first of all, I'm going to pull that one back up and --

THE COURT: I don't know here by "corroborate" whether that means adequately corroborate or corroborate in any way. I mean, it seems to me those Spectralytics parts that he showed me are certainly evidence that they were at least messing around with the concept of a rapid-exchange catheter. Those are entry ports, is what I was looking at.

MR. NIEDERLUECKE: That was a portion of what looks to be -- the picture you saw was a portion of what looks to be a rigid push wire with an opening.

THE COURT: Yeah. Right. But you don't have an opening unless it's a rapid-exchange catheter. If it's an over-the-wire catheter, then the openings are both down outside the --

MR. NIEDERLUECKE: I'm not arguing that that picture doesn't show a portion of a component of that. The issue is that picture, as Mr. Vandenburgh noted, the only date we have for that picture is 2019. They didn't come out with a product until 2009.

THE COURT: Well, he showed me the bill that he

said was associated with the picture, that that was -- the picture was 2019, but he said the bill was from [redacted] for it.

MR. NIEDERLUECKE: He showed you a bill. We can pull those up and look at them in as much detail as you want to go through, because they don't all tie together. He has a lot of invoices, but those invoices don't necessarily correlate to what they correlated them to.

THE COURT: I thought he represented to me that the invoice he was showing me was for the device he was showing me, the --

MR. NIEDERLUECKE: That may be what they're trying to purport, Your Honor.

So the drawings themselves, again, aren't sufficient to show that the embodiment was built. The photo, which was dated November '19, only shows a part of a component of an alleged prototype.

THE COURT: Sorry, I think slower than you talk. So he showed me drawings that looked like a rapid-exchange catheter -- it looked like an entry port to a rapid exchange and said those were dated from [redacted]. You just don't believe that?

MR. NIEDERLUECKE: No, I don't -- I'm not saying that they weren't creating drawings.

THE COURT: I mean, there clearly was some kind of work going on on a rapid-exchange catheter in [redacted], right?

You don't dispute that?

MR. NIEDERLUECKE: We don't dispute that there was some work --

THE COURT: What you dispute is that it got to the point where it was actually reduced to practice?

MR. NIEDERLUECKE: Exactly, Your Honor. Exactly. Because what was happening was the over the wire is what they were working on and admittedly -- it's in their documents -- they had a plan to later on come out with a rapid exchange. So while they are working on the over the wire, they had in the background doing a little work here and there, but it was more on the conception, the conceptual designs, not actually reducing that to practice.

THE COURT: Okay.

MR. NIEDERLUECKE: Now, for example, they showed you that design drawing in [redacted] They say it's a full design drawing. What you see on that drawing, though -- and this is [redacted] -- is these are preliminary design assumptions. So these aren't actual designs. These are assumptions. Here's what we assume we could do. It's future looking. So it's not a design that, hey, here's what we built. It's a design of here are some concepts we can think about.

In fact, the drawing itself, if you look at it, you have the bottom drawing which shows -- and these are

both from the patent. You have the bottom drawing which shows that step down. The top drawing on the proximal end actually shows a full-circumference lumen, and it's because what I think this was was probably an over the wire that they were playing around with saying, hey, what could we do? That's a concept.

Similarly, as we talked about, Your Honor, they have Exhibit 10. They show this picture. I think they admit that this picture was taken in 2019. We have no corroboration as to when that was made, when this exact -- when this design was made.

We don't have any design drawings that were sent to or from the manufacturers. Obviously, if they were manufacturing this, we would have evidence of exactly the design, not just of the -- not just that it says step down or something in the description of it. We would have drawings, and we don't have any.

What's really interesting, Your Honor, is if we look at the design history file -- as we said, these are highly-regulated products; we have design history files that companies keep to lay it all out -- and if we look at what the evidence is, what the undisputed design history file shows, we see September 23, 2005 is when the Itou patent was filed in the U.S., that date that we get.

We have May 3rd, 2006, which is when we saw

Teleflex first filed its patent application, at least earlier said that was the first reduction to practice. [redacted] the design history file for this product is the first date that's listed, the market feasibility plan.

We go through this: [redacted] concept drawings. [redacted] product specifications/user requirements. [redacted] design verification testing. November 9th, 510(k) clearance. These are all after 2008. This product that they created that you've seen so many pictures of was created well after they filed the patent application.

Now, Your Honor, I'm just going to -- I don't know how much tolerance you have to walk through some of the evidence in particular, but I've certainly got a lot of it that I'd like to quickly walk you through --

THE COURT: Okay.

MR. NIEDERLUECKE: -- if you have the tolerance for it.

THE COURT: We'll find out, I guess.

MR. NIEDERLUECKE: Tell me to speed up if --

THE COURT: If I walk out of the room, you've reached the tolerance.

MR. NIEDERLUECKE: Okay. Well, we'll start, as we noted, with -- this is just the Takahashi and Itou

publication that's in the patent. This is what discloses -- you can see there this is the over-the-wire five and six system that Itou disclosed and was published and is itself prior art. It shows the five French guide catheter going into a six French guiding catheter. And they did both human and lab testing of that device. And that was the one that -- that was then around the same time as the conference that the inventor suggests was the genesis of their development.

The Itou patent itself was filed in September of 2004 in Japan. The reason we don't use that date is you don't get credit for that date. Actually, Itou filed his patent application in Japan in September of 2004. That (indicating) just shows that date.

As we'll get to, Itou discloses the guide catheter, guide extension suction catheter, and a protective catheter, just like the patent application shows.

Then we get into the development. So they talked about the beginning of [redacted] being the conception. And the question really as we go through all this, we have to think is it really a rapid exchange that they're working on or is it an over the wire.

If we look at [redacted] we see that they lay out in April that the general design will be a straight catheter. It'll be a composite assembly consisting of multiple durometers of Pebax, a TFE inner liner, solid

stainless steel coil and braid for stiffness, pushability and to prevent kinking.

So a couple important points there as you look at what they claim to be their corroboration. They point to a lot of evidence of purchasing Pebax. Well, Pebax is used in the over the wire all the time. That's a portion of it. And as you see here, so is the stainless steel. So when they talk about, well, that's used only for rapid exchange, that's not true, Your Honor. In fact, Nitinol and stainless steel can be used for over the wire as well.

Then we move to [redacted] And in [redacted] they're talking about the GuideLiner being a new product idea, of a liner to be delivered inside a standard guide catheter. And what they say -- what they point out in here when they're describing the liner -- and we just talked about this -- is also the GuideLiner should include a hemostatic valve to connect the guide catheter and lock the GuideLiner in place.

So what we know as we read this, as we try to jump into the lab, is that they're talking about an over the wire there. They're not talking about a rapid-exchange GuideLiner because it needs that second hemostatic valve. So it's what the patent talks about getting rid of with the rapid exchange.

Then in [redacted] they present to their sales

force the GuideLiner device, and they show it both in the deployment and in actually bench testing. You can see a picture down on the right. They've got a device they're running it through to see how it works. So they're presenting the GuideLiner, but it's the GuideLiner over-the-wire system. And you can see in the top left that picture with the green. That's a full lumen all the way back to the adapter.

So you see in July they're working on over the wire, they're presenting over the wire as their product. You don't see this type of stuff for the rapid exchange.

Also in July in the R&D update, they explain that the initial design is an over-the-wire configuration with a rapid-exchange version to follow. Now, Mr. Root took this document and told the Court this proves the prototypes of the rapid exchange were made. But when you read the documents, you can see that what they're talking about is the initial design, which is an over-the-wire configuration, that prototypes have been made and evaluated.

That's our concern, Your Honor, is this is the type of document that Mr. Root would characterize as proving that rapid exchange was built. When you look at the document, it's clear that it's the over-the-wire version that they're talking about.

THE COURT: It just doesn't tell us how far

developed this rapid-exchange version is?

MR. NIEDERLUECKE: Correct. It's to follow. That's the question, is when we follow.

Now, what we see in [redacted] are the product requirements for a GuideLiner. And, granted, it talks about either version. And what you see is it pulls out user requirements, performance requirements. What will this thing have to do? These are actually instructive, Your Honor, in terms of saying what does it take to demonstrate that it worked for its intended purpose.

So these are some of the product requirements that you'd say, okay, show me evidence that in fact your rapid-exchange GuideLiner prototype that you allege to have built would work for its intended purpose.

The other interesting thing about this document, Your Honor, that they propound is that while there are user requirements, the next column over is product specifications. I'm sorry I don't have it -- I have it just with this up here, but the next column is product specifications. There are none. There's none listed in this document. They don't have any product specifications listed.

Now, September 23rd -- again, we'll go through that quickly -- is the Itou. They say they already have evidence, Your Honor, that they have built the prototype and

they've tested a prototype. There's nothing in the record at all that will show you that they built a prototype, including all the parts, meaning the substantially rigid portion, the reinforced tubular portion, the tip portion. What they show you is substantially rigid invoices.

What we go to in [redacted] we start looking at testing. What we see is when they go to testing -- these are lab notebooks, Your Honor, their own lab notebooks; we're talking [redacted] -- and what we see they're testing -- you can see it in the picture and it's evidenced by the use of a 300-centimeter guide wire. 300-centimeter guide wires are used with over the wire because you have to have a really long guide wire.

So what this shows you is they were doing this -- this isn't disputed -- they were doing testing in August and September of an over-the-wire design in a model. The problem is there's no evidence to show that they did any testing for the rapid exchange. They have results of their testing.

And here's the interesting thing. As you see here, they're doing their own five and six over-the-wire GuideLiner and they're comparing it to the heart rail. That's the Itou reference. So they're basically building something like Itou and saying let's compare it to how Itou did and let's compare those in an over the wire.

Similarly, Your Honor, more lab notebooks. What are they showing? They're showing drawings and they're showing photographs of over-the-wire designs; nothing of rapid-exchange designs in those lab notebooks.

In fact, by [redacted] what Teleflex says is the over-the-wire version is expected to be launched in April. The rapid-exchange version requires additional engineering and is not included in our [redacted] forecasts. They don't even have a plan to go for that one yet. They're going to get that over the wire out and they need to do more engineering. That certainly doesn't sound like something that has been reduced to practice.

In fact, even with their over-the-wire design, Your Honor, in [redacted] they started their design verification testing and as of February they cancelled that, too. They stopped the build.

The other interesting point about this document, Your Honor, which is Exhibit RR of Friedemann, is this is a build log. There's not one entry on that build log through 2006 for a rapid-exchange catheter. These build logs, I don't think it's disputed, are all for the over the wire.

Now, here's what's interesting, Your Honor, and I'll finish up with this, [redacted] so we're down the road now a couple years after filing that patent application, and you say, Well, why is this taking so long? Because they

didn't come out with this product until 2009.

What Mr. Welch, who was one of the inventors on the patent, explained in [redacted] was that the GuideLiner, now they are working on that. They're certainly working on that, as we saw from the design file history. He says, "Throughout this project, timelines have been pushed out due to drastic design changes and resource constraints." If something worked for its intended purpose, you would not expect drastic design changes. And to date, as they note right there, we have prototyped and tested a new design.

So, Your Honor -- in fact, let me do one other thing. So that's kind of some of the evidence to demonstrate. And they don't have any evidence that perfectly correlates.

I want to pull up, if I can -- if we can switch over. Joe, would you mind pulling up A63.

So A63, I think, was one that you were looking at.

THE COURT: Yes. This is showing the entry port here (indicating).

MR. NIEDERLUECKE: Right. Right. And this drawing exists, and we don't argue about the fact that that drawing exists. But correlating it to this document on the right of [redacted] has some problems. For instance, while they don't have it on this drawing, this drawing is revision X2. It's not on this drawing unfortunately, Your Honor,

because they cropped it in, but this is revision X2.

If you look here (indicating) -- I didn't do a very good job there.

THE COURT: I see it says X1.

MR. NIEDERLUECKE: It's revision X1. If you read what they were doing, Your Honor, they were laser cutting customer supply tubes. "Spectralytics will machine the step." Well, this isn't a step. They'll machine the step in the outer diameter tubes. So that would be -- sounds more like cutting down the outer diameter a little bit. That's not correlating to what you see in that figure. You go further and you say it's going to be at least 42 inches long. Well, that device is 39 inches long, Your Honor.

So when you start to look at the evidence, you realize that perhaps what they're attributing and trying to combine together with invoices and such doesn't hold true upon further investigation. Of course, as you noted, Your Honor, this is for trial. This is for discovery. This is for trial. At this stage, they certainly can't show that they can prove without question that they built a prototype and reduced it to practice. And so they both built it and tested it.

What you didn't see here, Your Honor, was a prototype. You didn't see a full prototype. They have no evidence of a full prototype. They have not one speck of

evidence of testing of that prototype, whatever it would have been. That's why they can't show you a claim to prototype limitation by limitation, because they don't have a prototype. Yes, did they do some testing? Did they make some drawings with concepts on them? Absolutely, Your Honor, they did. But they didn't reduce this to practice.

And then May came along. Everything was going wrong. They had stopped their over-the-wire build. They said -- well, I shouldn't -- this is speculation, but perhaps they said let's just get something on file. Let's file a rough draft of whatever we have, and we'll throw in everything we've got at this point. But they certainly have not shown anything that would suggest that they were diligently reducing to practice an over-the-wire version or that they ever did before they filed their patent application.

THE COURT: All right. Thank you, Mr. Niederluecke.

MR. NIEDERLUECKE: You're welcome.

THE COURT: Mr. Vandenburgh.

MR. VANDENBURGH: So what we heard an awful lot of was that during the same time this invention was being developed, Vascular Solutions was also working on an over-the-wire version; stipulated and irrelevant.

We saw a lot of evidence showing that testing and

work was continuing on both versions after September 23rd of 2005; again, stipulated; again, irrelevant.

THE COURT: Well, the point I think that -- and I have no -- as I keep saying, it's just really hard for me to understand this stuff now. But the main argument Mr. Niederluecke was making was sort of a dog-that-didn't-bark argument. He concedes that you were messing around with a rapid-exchange catheter at the same time, but he's saying look at this pile of evidence of the work being done on the over the wire and look at this tiny, little pile of evidence with the work being done on the rapid exchange. At least as he presents it, and I have absolutely no way of knowing if this is representative or not, it seems like there's disproportional evidence of the over-the-wire work versus the rapid-exchange work.

MR. VANDENBURGH: But that maybe gets to the point. There's this much (indicating) evidence on the over-the-wire version, and there's this much (indicating) evidence on the rapid-exchange version. It doesn't matter how big this is. The fact that this may have been the focus doesn't matter. The question is whether this work, whatever it is, was enough to be reduction to practice.

THE COURT: Well, it matters in the sense that -- I think the point is that if you actually had developed -- successfully developed the rapid-exchange version and

reduced it to practice, one would expect to see this much evidence, because that's what you see when products are successfully launched. And you wouldn't expect a four-year gap between the reduction to practice and the actual marketing. You wouldn't expect to see some of the references in some of the documents, which I admit they're ambiguous. Some of them are capable of being read --

MR. VANDENBURGH: I think part of this is just overstating what is necessary to be reduced to practice. It comes up again and again in the case law that people argue that, well, work continued afterwards. Again and again the case law says, yeah, but that's commercialization. It's really just that threshold level of will it work probably for its intended purpose. That's the standard that's necessary.

Again, what we look for is whether there was corroborating evidence of the inventor's testimony that, yes, I did it, I tested it, I determined it would work for its intended purpose.

I'm going to start by putting up, if I could, a blurb from case law, a case that we did not -- I will apologize in advance, Your Honor. We have a number of documents or cases that were not in the briefs. This is one of them. This is *Loral Fairchild* from the Federal Circuit in 2001 where they reversed a judge's conclusion that there

was no reduction to practice and basically found that they'd set the standard too high on the corroborating evidence.

I'd start at the bottom of the second paragraph here: Dr. Amelio's alleged reduction to practice, to be sure, is not corroborated by documentary evidence of test results confirming process performance. It is, however, corroborated by the testimony of somebody else the delivery date of masks necessary to practice the invention and the Air Force proposal. Analogizing those second to ours, we have unquestionably evidence of prototypes of parts being made for rapid-exchange prototypes prior to the critical date.

Now, again, let's recall, ultimately, we review corroboration for rule of reason. You don't go to Spectralytics and say cut me eight of these prototypes to just get them and look at them and see if they're pretty looking. You get them so that you can test them. And it's a simple matter of -- again, we also saw that there's evidence of the tubing, and the tubing isn't specific perhaps to the rapid-exchange version, but we know that the Spectralytics cut-down hypo tube is.

It is completely reasonable under a rule of reason to conclude, to corroborate an inventor's statement that when we got these cut-down hypo tubes from Spectralytics, we didn't just look at them. We did something with them. We

built them. We tested them.

Going back to the point that we're overstating the level of testing necessary for reduction to practice, we cited in our brief the case law pointing out that many inventions you don't even need to do testing; use the word non-complex inventions can be reduced to practice simply by building it.

Here we do have evidence beyond that. We have Mr. Root's declaration corroborated by the creation of parts for the prototype indicating that they had indeed done testing, certainly not to the point of proving that you put this thing inside a human being and it would work perfectly, but enough to show the inventive concept here of the ability to deliver a rapid-exchange guide-extension catheter through a guide catheter into tortuous anatomy and then deliver an interventional cardiology device through it.

Again, Your Honor, what I ask that you do is focus not on all of the evidence that they point to of other things that were happening. We'd know a lot more about that if they had taken a deposition and put those documents in front of witnesses and they could explain what we're looking at. Instead, they want to throw lots of documents from other time frames on other products and say, well, that shows that Mr. Root is not being truthful when he said we were testing the rapid-exchange version as well.

THE COURT: But remember what Mr. Niederluecke started with was that chart which had all the green check marks and all the red Xs. You're right that the green check marks don't really prove much. It's the red Xs that are my concern. I mean, maybe it's -- one of the things that's hampering me here is I don't -- there's some gap here in the law, and I don't know what that gap is, which is I have no doubt that your folks were working on a rapid-exchange catheter in 2005, and I have no doubt that as part of their work they ordered parts. And so if it's simply enough for an inventor to say I swear I reduced this to practice and if it's sufficient to corroborate that to say here's some parts that I ordered and here's the invoice for those parts, if that's enough, you have that, I agree. But if you need more than that -- if you need the prototype, the photo of the prototype, the lab notes of the prototype, something like that -- I haven't seen that. I haven't seen that.

MR. VANDENBURGH: And that's what the *Loral Fairchild* case really says you don't need to have.

THE COURT: If literally all you need is the inventor says I made this thing and it has 5,000 parts in it and here's an invoice for one of the parts, I'm done. I realize that's not our case. I understand. I'm not suggesting that. But I just don't know -- the word you had -- it's gone now, but there was a sentence at the bottom

of your -- right, "sufficiently corroborated," so that's the keyword. I don't know what the sufficiency is.

MR. VANDENBURGH: Right. Right. So let's go back to -- let me start with -- there was -- I want to distinguish because I believe Mr. Niederluecke put up a case that purported to be contrary to this, that just ordering parts that would be for the product isn't enough. He talked about how they were put together. My guess is that might have been a more complex invention where just because I ordered a part doesn't mean you know what you're going to do with it.

Here we don't have that. Here this is more what it looks like the *Loral Fairchild* case is, which is once you're ordering that cut-down hypo tube from Spectralytics, you know what you're going to do with it. It's shown in our design drawings. You're going to attach a tubular portion to the end of it and you're going to test it.

The other thing that we do have, and it goes back to the over the wire, is we know testing was being done on -- we have a picture of the over-the-wire version being tested in I think the slides from June, so we know it's from before that.

Mr. Root explained why it was that they're showing sales people at that time the over-the-wire version. Again, no question, that product was at that point intended for the

market first. But it goes back to the rule of reason. We know we were ordering prototypes, easy to assemble -- or parts easy to assemble into a product. You don't just look at it, especially if you have a test set up there.

We know that at the same time we have corroborating evidence of doing tests on the over-the-wire version for the purpose of the rule of reason; it is a completely reasonable jump to say they didn't just look at that over-the-wire prototype that they got with the parts from Spectralytics. They actually put it in that same model that we have a picture of and did the same sort of analysis to make sure that it would work as well.

THE COURT: Okay. Anything more?

MR. VANDENBURGH: Thank you, Your Honor.

THE COURT: Mr. Niederluecke, you look like you wanted to say something more.

MR. NIEDERLUECKE: Yeah, I would just, if I may --

THE COURT: Just briefly. Then I want to give my court reporter a break.

MR. NIEDERLUECKE: -- a very recent case, Your Honor, with regard to that question of invoices for component parts. We've got it on page 34. That's a case really recent, from September of 2019, from the Federal Circuit that found exactly that, that an invoice for a component part doesn't demonstrate and corroborate a

reduction to practice.

THE COURT: This sounds very Federal Circuity, this law. As I've heard you out, it seems to me the issue is what is sufficient corroboration. I'm just going to have to read the cases on that. It sounds like the cases need some close attention to try to figure out where that line is.

I feel like I have a sense of what this is like from 30,000 feet, the evidence on this, which is, on the one hand, they were definitely working on a rapid-exchange version and they went so far as to order component parts to a rapid-exchange version. But, on the other hand, there does seem to be some lack of evidence that they actually got that into a working prototype. I realize this evidence could change a lot between now and summary judgment or now and trial. That's where we seem to be right now. I just have to figure out where the case law puts that sufficient line.

MR. NIEDERLUECKE: It's very important too, Your Honor, as you noted, where we are right now. They put in Mr. Root's declaration with a reply brief. We never had a chance to depose Mr. Root. There's certainly a lot of evidence out there we still have to get given what we have recently learned is their position. So we have to understand where we are in the context.

This is a preliminary injunction. They've got to show clearly that they will succeed on this. They have to be likely to succeed. If there's a question, if the record isn't sufficiently built, then they're not meeting their burden.

We certainly have met our burden. We certainly attacked and showed the Court the gaps, the Xs. This isn't a case where somebody comes in and says, gosh, we didn't keep our records very well; you know, we don't have a lot of records. This is exactly the opposite. It is we keep records very well and we have them for the over-the-wire device, and we just don't have them for this. Instead, we put in a declaration. It is a rule of reason, but it has to be independently corroborated.

THE COURT: Okay.

MR. NIEDERLUECKE: Thank you, Your Honor.

THE COURT: All right. We'll take a break now. When we come back, we'll turn to the issue of whether Itou actually does anticipate or at least in combination with the other references make obvious I guess this would be the '379 and the '760 patent, and then we'll turn to the Kontos and Ressemann references.

Let me just tell you, I don't have a lot of questions about this because I really couldn't follow it from the brief. There just wasn't enough. And I know you

were working under severe page limitations. I think it would probably make sense for you, Mr. Niederluecke, to go first, or Ms. Friedemann, whoever is going to take this. I'm just going to need a nice, clear explanation of what the Itou invention was and what the Kontos and Ressemann inventions were when we get to them and then claim by claim how it meets that.

It was just very hard for me to -- you put drawings in the briefs and things, and I just couldn't understand what these inventions were. And I didn't have time to go and try to read the patents myself. That might not have done any good anyway. So that's where I'd like to start when we get back out. We'll be back out in about 10 or 15 minutes.

THE LAW CLERK: All rise.

(A brief recess was taken.)

THE COURT: All rise. This court is now in session.

Before we begin, when I started work on the *QX Medical* case a long time ago, the parties referred me to a video I think that was on YouTube that showed how it works, how the invention works. I have a new law clerk working. It's actually my career law clerk. She's now the third law clerk to work on the *VSI* litigation. She'll be the last because she's my career law clerk. But I'd like to be able

to have her watch that video, and if somebody could just email me that video. I'm also certain it was in the *QX Medical* case that I saw the video. But it shows the surgeon actually doing it.

MR. VANDENBURGH: Your Honor, Mr. Root gave me a little nod like this (indicating), so --

THE COURT: So he knows. Obviously, copy Mr. Niederluecke on it, but send me an email or send our chambers an email with the link so we can look at it, because I was trying to explain to her the way this works.

Now, the one thing I can't remember is does the guide wire go in first or does the -- guide wire goes in the body first or the guide catheter goes in the body first? You can ask Mr. Root if you want.

MR. VANDENBURGH: Guide wire goes first.

THE COURT: Guide wire first. Guide catheter second. Then the guide-extension catheter is thread over the guide wire and pushed through, and then put -- the balloon is put on the guide wire and pushed down the guide catheter through the side opening and out the guide-extension catheter, right?

MR. VANDENBURGH: I believe so, Your Honor.

THE COURT: So there's three wires sticking out of the patient, one catheter and three wires: the guide wire, the push wire for the guide-extension catheter, and the push

wire for the balloon or the stent, right?

MR. VANDENBURGH: Generally, yes.

THE COURT: Close enough. Okay. That's what I want.

All right. Mr. Niederluecke, on we go with anticipation.

MR. NIEDERLUECKE: Let's go to page 24. So just to center ourselves again, Your Honor, what we're talking about here is this first column, which is whether or not Itou makes all of the claims in each of these patents invalid, at least all of the asserted claims for the purposes of this preliminary injunction.

So in the context if, in fact, the Court finds that there is a substantial question as to Itou being prior art and then finds that there is a substantial question that it invalidates -- that it either anticipates or makes obvious the other pieces, this would essentially take out this entire column and, therefore, the preliminary injunction wouldn't be granted because all of these patents would be potentially invalid.

THE COURT: Okay.

MR. NIEDERLUECKE: So that's what we're talking about.

THE COURT: To be more specific, you have "invalid" on the chart here, but you say Itou anticipates

all the claims except two; is that right?

MR. NIEDERLUECKE: Yes, Your Honor.

THE COURT: And that it makes obvious all of the claims, period, right?

MR. NIEDERLUECKE: Correct, Your Honor.

THE COURT: When combined with Ressemann and Katashai.

MR. NIEDERLUECKE: Yes. Yes. So that's what we're looking at here, Your Honor.

And I guess if we can go to 74. And I'm happy -- don't know how far you want me to step back, Your Honor, but I think the question you raised earlier was about -- I pronounce it Itou. I'm not sure how it's pronounced.

THE COURT: Like Judge Itou. Either way. I'm not trying to rush you, but at some point I would like to have somebody show me Itou and explain to me how Itou works.

MR. NIEDERLUECKE: Let me do that. We probably dived too quickly and too deeply. I will switch over to the document camera.

So Itou is for a guide-extension suction catheter, meaning that it is typically used to extend through a guide catheter and out a guide catheter and can be used to suck in material that is deep into the coronary arteries.

THE COURT: Is it like some kind of mini vacuum source of suction?

MR. NIEDERLUECKE: Yes. And rather than just do it with the guide catheter, this device allows you to extend deeper into the coronary arteries to be able to get further in to do the suction further in.

THE COURT: Okay. But there isn't another device that goes through Itou?

MR. NIEDERLUECKE: Well, in the disclosure they don't disclose putting another device through, but it is absolutely sized so that that can occur, so that you could have it in there, you could suck this out, and then you could put in the stent or a balloon.

THE COURT: What does the guide-extension catheter look like on Itou? Is it a little hole?

MR. NIEDERLUECKE: Your Honor, it's literally identical to the patent and what we're looking at here. So what you have in this picture, the top is a guide catheter. The second figure, figure 1b, is the guide-extension catheter. As you can see there, it has a long push wire. Then it has a side opening for that push wire. It has a tubular section. And then it has a tip section.

THE COURT: But why -- this is what I'm not getting, is if this is basically like a little vacuum cleaner at the end here, why is this open? Because nothing is going through that, so why is that open?

MR. NIEDERLUECKE: Material goes back and forth

through that, Your Honor. So this is just like this device. It's a tube, a full diameter tube.

THE COURT: So is there another device that's the vacuum that's going to go through that tube?

MR. NIEDERLUECKE: Well, it absolutely can, Your Honor. A surgeon could put anything through that that he wanted to. You can use a stent. You can go and put the vacuum in and vacuum out stuff, and then you could stick a stent, for instance, through that suction catheter and deliver a stent with that extended --

THE COURT: I'm sorry, I'm just missing something here. If Itou works by itself as a suction catheter, then this thing has to be sucking material in, right?

MR. NIEDERLUECKE: Correct.

THE COURT: How is it sucking material in if there's a hole here?

MR. NIEDERLUECKE: Because when you think about it in the context of where it goes into the top catheter -- so you have a top catheter, which is a full lumen, and then you have your rapid-exchange guide-extension catheter that goes inside of it and sticks out.

THE COURT: Okay. So now I have -- okay. So I have like my -- I have the Teleflex guide-extension catheter sticking out, but it's not suctioning anything. It's just a tube. It's just waiting for balloons and stents.

Now, how is this suctioning something if it's just a tube at the end of this?

MR. NIEDERLUECKE: And, in fact, Your Honor, interestingly enough, the VSI device can be used and has been used as a suction device.

THE COURT: What creates the suction?

MR. NIEDERLUECKE: It's on the right end of the guide. So on the outside of the body -- you know, you've seen those Y adapters in some of the pictures?

THE COURT: Yep.

MR. NIEDERLUECKE: On the outside of the body you can connect up a suction device that will suck, will create a pressure to pull.

THE COURT: Oh, is it sucking on the guide catheter?

MR. NIEDERLUECKE: Yes.

THE COURT: Oh, I see.

MR. NIEDERLUECKE: So, basically, you've got this whole device. You've got the guide catheter, and you've got the guide-extension catheter extending into the coronary artery. And you can then hook up to this device, to the VSI device, to any of these devices. You could then hook up a suction.

THE COURT: Then this would have to have a very tight fit, then, between the outside of the extension

catheter and the inside of the guide catheter, right?

MR. NIEDERLUECKE: It would have to have not a tight fit because it has literally got to be pushed in and through.

THE COURT: If you apply suction to the guide catheter outside the body, it's essentially -- so if this thing is -- sorry, I've got to clear this. Here's (indicating) the guide catheter. Okay? And this thing is sticking out the end of the guide catheter. For you to apply suction to the guide catheter outside the body and it to create suction here (indicating), there would have to be a fairly tight seal there (indicating). It can't be too loose there.

MR. NIEDERLUECKE: The only issue is you could still have suction, small amounts. And the patent talks about this coming between those two. But you don't want it too large because you want to try to bring it through this tube. It doesn't hurt bringing it through if there's a very small gap there.

But Itou does talk about, just like theirs -- the VSI one talks about keeping that -- you know, you have to be able to deliver it, but you want to keep it -- keep it wide, which actually goes to demonstrate that this absolutely is -- the structure of it is set up so you could deliver either a balloon catheter, a guide wire certainly or a stent

through this device.

THE COURT: So this is like some vacuum cleaners, canister vacuum cleaners, they have sort of a collapsing telescope wand, and this is a little bit like that, sort of like a littler wand sticking out of a bigger wand with the suction being applied to the bigger wand down here (indicating). I just couldn't picture what was going on. I was thinking that only this (indicating) was suctioning, and I couldn't figure out how that would be.

MR. NIEDERLUECKE: Does that make sense?

THE COURT: It does make sense.

MR. NIEDERLUECKE: Beyond extending beyond the main guide catheter.

THE COURT: Even though this isn't built to take balloons through, it's -- essentially they could. The guide wire is running through here and all they would have to do is stick a balloon on the guide wire and they could run it right up?

MR. NIEDERLUECKE: Absolutely, Your Honor. Absolutely.

THE COURT: This probably isn't a great entry port because it's not really built to be an entry port.

MR. NIEDERLUECKE: Actually, it is a great entry port. In fact, structurally, Your Honor, that's what a lot of the claims they go to is. The point of developing these

entry and exit points in this are developed to increase the surface area of those entry points.

THE COURT: But nothing is entering. This wasn't designed to be an entry point because nothing is entering there, right?

MR. NIEDERLUECKE: In its use as disclosed in the patent, it is designed to have the materials come from -- be suctioned from the front through to the back.

THE COURT: Right. Like this (indicating), right?

MR. NIEDERLUECKE: But as a part of that, these entry and exit points that are here are designed with inclines to increase the ability to suction and allow larger items to get through. So it increases the efficiency of it.

So, in fact, similar to this, those angles that are presented there are in fact angled in that manner to allow a better entry and exit of materials to come through it.

THE COURT: Okay. To be clear, this is the better entry and this is the better exit (indicating)?

MR. NIEDERLUECKE: In terms of what it's being used for in a suction environment, yes.

THE COURT: The Itou patent doesn't discuss or envision somebody sending a stent, a balloon or something else this way (indicating) through that extension thing, right?

MR. NIEDERLUECKE: It doesn't discuss it, no.

THE COURT: Okay. What it's discussing is material being suctioned this way (indicating) through it, right?

MR. NIEDERLUECKE: That's correct. But what's important as we get into this, Your Honor, is the intended use of this device isn't part of the analysis.

THE COURT: Yeah, I'm not saying it is.

MR. NIEDERLUECKE: I want to make sure, because the idea that this was used as a suction catheter, if it has the same structural components, anticipates the Teleflex patents no matter what it's used for. A new use for the same structural device is not patentable.

THE COURT: Okay. I didn't mean to even -- that's a different argument. I simply want to know how this thing works and that's how the thing works. Okay.

MR. NIEDERLUECKE: And so, Your Honor, what you see there -- you see in figure 1b -- you see that that's the guide-extension catheter.

I'm going to put up a picture here where you can then see from figure 5 -- what you see here are all the elements together. You have a guide catheter. You have the guide-extension suction catheter. You have a guide wire going through it. That's number 6. And so you have the little wires -- as you were pointing out, the little wires

with this single hemostatic -- actually, this has two hemostatic valves, but the single -- the rapid-exchange push wire coming out of it on the right. So that's very similar to the figure in the Teleflex patents.

THE COURT: Okay. Is 5 the extension or is 2 the extension?

MR. NIEDERLUECKE: 2, I believe, Your Honor.

THE COURT: What's 5? It looks like something sticking out of 2.

MR. NIEDERLUECKE: Let me make sure. The suction catheter is 2.

THE COURT: Is this the guide catheter here (indicating), I assume?

MR. NIEDERLUECKE: Yes.

THE COURT: So I just was curious as to what's the difference between 2 and 5?

MR. NIEDERLUECKE: I'm sorry, Your Honor. 5 is the protective catheter, and I'll explain that. If you remember, this is also in the patent figures. You can use this. Figure 1e is a protective catheter, is what it's called. And you can put that into the guide-extension catheter as you deliver it to ensure you don't damage the vessels as you're delivering it. So it provides a protective device.

That's similar -- if you look at some of the

figures in the Teleflex patent, they have a similar -- what they call a "navigation" catheter that just goes inside of it. That's what you're seeing if I put it back up.

THE COURT: Well, is this (indicating) withdrawn then? Does it have its own push wire? Is it withdrawn then before the suction is applied?

MR. NIEDERLUECKE: Yes.

THE COURT: All right.

MR. NIEDERLUECKE: Yeah, so that wouldn't be there as it's functioning. That would be then pulled out.

THE COURT: Okay. So it is almost like a balloon or a stent only it's a different device. And it sounds like it's not later sent down the line, but it's sent down with the guide-extension catheter to kind of pave the way for the guide-extension catheter.

MR. NIEDERLUECKE: Right. It's sent down along with it, yes. That's retracted, and then you have plenty of space to deliver any other stents or devices through that suction catheter if you so chose.

THE COURT: Okay.

MR. NIEDERLUECKE: So then if we look at -- just to now get into kind of the detail of the guide-extension catheter. And what you can see here, Your Honor, is 25, which is the rigid push wire. You have 23 there, which includes the side opening. You have 21, which is a

reinforced tubular section. And you have 22, which is a flexible tip. All those are fully described increasing the rigidity, as many of the claims discuss, as you move towards the proximal end, Your Honor.

So literally as you look at this device, other than -- we can argue about, well, what some people call the double skive or the specific pattern that's on that proximal incline, Itou discloses every limitation to every claim they've asserted in this preliminary injunction motion. It literally anticipates every claim.

THE COURT: So my question was -- it wasn't really addressed in the briefs, but you addressed this a minute ago. Teleflex mentions that this is not -- you know, it's not a catheter that has stuff go through it, balloons and stents and so on. The Federal Circuit case law says that doesn't matter. It's entirely different. If all the elements are there, then all the elements are there.

MR. NIEDERLUECKE: Yes.

And if we can go to 75.

Yeah. On page 75 we've got a couple cases, Federal Circuit cases, one which was one of the seminal cases explaining that. The Federal Circuit said, It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. And we just have another case there that's a

more recent case.

THE COURT: Okay.

MR. NIEDERLUECKE: So the purpose of it doesn't matter. It's what is structurally shown there. There's really not a dispute, in fact.

If we can go back -- I have it here. I can do it.

If we look at page 74 then, as you saw from their reply brief, Teleflex doesn't even try to support patentability --

THE COURT: Right, this is the only three they call specifically as not being anticipated.

MR. NIEDERLUECKE: Right. Right. They didn't even address the '380. Just like in our infringement issue for the invalidity, they don't even try to address the '380.

The only claims they call out with regard to trying to survive Itou are these three dependent claims all dealing with a specific design of that side opening portion or section, which is interesting to note, that in terms of what we were looking at earlier, in terms of the reduction to practice.

So for these claims they would have to show that in fact these claims -- 36, 32, and 44 of these different patents -- they'd have to show that whatever prototype they had made, which we never saw, met those limitations, had those specific designs in them, so not just any.

So with regard to Itou -- and we can walk through -- just I will do it fairly quickly, Your Honor, but happy to expound --

THE COURT: Well, I think the focus -- when you don't brief something on a PI motion, you waive it for purposes of the PI motion, not for the rest of the litigation. But those are the only three claims they called out as not -- their first argument is that -- obviously, that they swear behind Itou. But if they lose that argument, the only three they called out were those three claims.

MR. NIEDERLUECKE: Right. So I'll walk through those.

THE COURT: It was because of the double ramp basically, the double angles with the half pipe in between.

Can you put back up the prior slide that had the three. I can't remember the numbers. In terms of infringement, I think they're likely to succeed on three of the patents, but not on the fourth. Which one did I say they are not likely to succeed on?

MR. NIEDERLUECKE: '760, I believe, Your Honor.

THE COURT: '760. So then if I stick with that, you wouldn't have to worry about that.

So it would really be these two that would be in play.

MR. NIEDERLUECKE: Right, the '776 and the '379, Your Honor.

THE COURT: Okay. The problem with the '776 is the at least one incline region, the half pipe design. And the problem with the '379 is it has two inclines, whereas Itou only shows one, right?

MR. NIEDERLUECKE: Right. That's the issue they've raised.

THE COURT: I was just trying to center myself. You can go ahead and argue away.

MR. NIEDERLUECKE: Okay. So with regard to the '776 patent, claim 36, we know that we have to step back because it's a dependent claim. So we know that claim 25 discloses a rapid-exchange catheter with a substantially rigid section, a tubular structure defining a lumen, and a section defining the partially cylindrical opening. And you can see those sections here right in Itou. You have the substantially rigid section, the partially cylindrical opening, and the tubular structure. And they're not disputing this portion of it. Just trying to set our bearings for the dependent claim.

So what we have is it talks about that segment defining a partially cylindrical opening. And so claim 25, the one we were just looking at, has a guide-extension catheter comprising a segment defining a partially

cylindrical opening having an angled proximal end.

Claim 36 then adds to it that that segment has to include at least one inclined region that tapers into a non-inclined region.

Now, one of the important little details here is that what we're talking about defining is the segment that has the angled proximal end in it. It's that segment. They didn't define it as the angled proximal end has this. It's the segment that has it. So what we're looking at is the segment that defines a partially cylindrical opening that, if you recall, is between the rigid push wire and the lumen.

So when we look at that and we pull this out (indicating) -- and these are from the Itou patent -- what you have in the figures that I showed earlier is an inclined region, and then there's a flat, non-inclined region before the push wire starts.

And I didn't put it up previously, but there's a more blown-up picture of that section on the right here in figure 4 of the drawing in Itou that shows how the non-inclined region -- a little more detail how they have the inclined region and non-inclined region and then go on to the rigid push wire. So Itou itself has that structural disclosure.

THE COURT: And I think you mentioned this already, but to be clear, this isn't just the way that the

drawing was drawn? The specification actually calls out the angle and describes the purpose of the angle?

MR. NIEDERLUECKE: It talks about -- yes, it talks about that angle and talks about having that inclined angle.

THE COURT: Okay. Sometimes in patent litigation the parties will grab a tiny part of a drawing and they will blow it up and show it to me, but it's nowhere even mentioned in the specification. Itou is intending there to be an angle here because it increases the ability of things to go in and out of that tube?

MR. NIEDERLUECKE: Right. It's specifically increasing the opening area of both ends of the tube.

THE COURT: Okay.

MR. NIEDERLUECKE: So unless you have questions, I mean, it's that simple. It's that simple with regard to that one.

With regard to the other claims that require two inclines, now we're not arguing in this -- certainly in this defense we're not arguing that Itou itself has that. It shows that single incline to a flat. And so with regard to that, we have -- we're looking at again the independent claims of the -- the '760, I think if you agree, is gone. We're looking at the '379 requiring a substantially rigid segment, side opening portion, and flexible tip. I don't think there's any -- Mr. Vandenburgh can stand up, but I

don't think there's any dispute that those are present.

If we focus on the '379, claim 38, that independent claim, it's a method claim. It defines -- part of the method is defining the side opening. And then claim 44 is the dependent claim on that. It claims defining the side opening portion includes forming a first inclined sidewall, forming a second inclined sidewall, and separating the first inclined sidewall and the second inclined sidewall by a non-inclined region.

THE COURT: Okay.

MR. NIEDERLUECKE: Okay? So what we look at are two other types of devices. We have Kataishi and Ressemann. These are all interventional cardiology devices that are made to convey or suck. In fact, Kataishi is another suction catheter, guide-extension catheter. So it actually goes in and, again, has a type of opening that increases the surface area. This is on the distal end.

THE COURT: Which one is Kataishi?

MR. NIEDERLUECKE: Kataishi is on the left. I'm sorry.

THE COURT: Okay.

MR. NIEDERLUECKE: Kataishi is on the left.

What you see there, the two pictures on the left --

THE COURT: Is this the distal end here

(indicating)?

MR. NIEDERLUECKE: Yes, that's the distal end. In both of these, these are the distal ends. The purpose of the opening to increase the surface area will allow more easily objects to enter or exit the device.

So here you see Kataishi having what is almost identical to what you see in the Teleflex patent.

THE COURT: What you characterize as the double angle, is that called out in the specification or does it just appear in the drawing?

MR. NIEDERLUECKE: I believe it -- no, in Kataishi it calls out and discusses that again with the ability to utilize that to be able to go forward and then suck out materials.

THE COURT: But does Kataishi either in a claim or somewhere in the specification say the opening is comprised of two angles, similar to the way that the Teleflex patents do?

MR. NIEDERLUECKE: Well, first of all, Your Honor, I don't believe the Teleflex patents ever describe anywhere the double skive. The Teleflex patents --

THE COURT: You just showed me language that talked about two inclines.

MR. NIEDERLUECKE: The claim has it. In the Teleflex patent the only idea that you have more than one

angle is just in pictures. They never discuss that at all in terms of the description -- in terms of what the device is. So Teleflex has a picture that they attribute.

THE COURT: You just showed me claim language that said two inclines. So they do have it other than the pictures.

MR. NIEDERLUECKE: They have it in the claims. It wasn't in the original specification and claims.

THE COURT: Right. But what I asked about is in either the claims of Kataishi or in the specification of Kataishi do they describe two angles or does it only appear in the drawing?

MR. NIEDERLUECKE: I would have to confirm that, Your Honor. I'm happy to do that when I sit down.

THE COURT: Okay. Take a look at that, if you would, and just let me know.

MR. NIEDERLUECKE: I will.

And, similarly, you have on the right is the Ressemann reference, and that is a reference that is actually on the proximal end of the tubular portion that shows an entry port design that has --

THE COURT: What does Ressemann do? Is it also a suction catheter?

MR. NIEDERLUECKE: No. Ressemann can actually have devices go through it. So Ressemann allows other

devices to go through and extend out and then have another device go through it.

THE COURT: Okay. So this is a guide-extension catheter, and balloons and stents are coming into it through here (indicating)?

MR. NIEDERLUECKE: Yes. I think they are balloons. I don't know if it's used for stents, but I believe balloons come in through there.

THE COURT: Okay. And you see -- again, you say there's two angles here. I don't know if Ressemann -- I mean, this seems -- if I just looked at this, I wouldn't say this is two angles. Does Ressemann itself call out two angles in either the specification or the claims?

MR. NIEDERLUECKE: Again, for this particular part, I don't know if they specifically call that out, but I can confirm that, Your Honor.

THE COURT: Okay.

MR. NIEDERLUECKE: So those are the two devices. And, of course, you know, understanding your question, there's no requirement that it call it out in writing, as opposed to --

THE COURT: No, it's just that patent lawyers sometimes look really, really hard at drawings and find things that I sometimes suspect the inventor never realized he had even done. It's just the way the particular drawer

drew something. I don't know whether, say, Ressemann would know that he had invented something with two inclines or not. As I said, this looks to me more like a concave lip here than it looks like two angles to me, but it's just hard to tell from the drawing.

MR. NIEDERLUECKE: I would suggest it looks like the Medtronic where you bring it down and --

THE COURT: This looks kind of like an angle and a curve on a sleigh almost, but that's why I'm wondering if there is anything other than the drawings that talk about what I'm looking at there.

MR. NIEDERLUECKE: Again, when we look at these in terms of determining whether or not there is the combination of Itou in view of either of these references, and they can each independently be there, you don't need the combination, but we're showing two examples. It's about one of ordinary skill in the art, if they looked at these patents, would recognize. So the idea is would one of ordinary skill in the art look at this and see that angle design and say, hey, that would be a good design to combine with Itou, to add those -- the multiple incline.

THE COURT: So how do I know that? Having no mechanical ability -- so this (indicating) is the inflow to a suction catheter. I don't understand why what you call a two-incline device would work better than, say, just -- I

understand why by cutting it at a slant you're increasing the volume. But the two-incline device seems to, in the Teleflex patents, be aimed towards specifically making it easier for an object, a balloon or stent, to nestle in here.

I don't know, why would -- who -- is there an affidavit? What is the evidence -- it just doesn't seem to me to be apparent that somebody would look at this and say, well, boy, it would be great for us -- it's an obvious idea then to when we flip around a rapid-exchange catheter to have two angles there to make it easier to get the balloon or the stent through. It doesn't seem obvious to me. Who says that's obvious?

MR. NIEDERLUECKE: Well, first of all, our experts say it's obvious, Your Honor. And we've submitted, unfortunately, extensive evidence, more evidence than the Court probably wanted, but go through and walk through both the motivation to combine and explaining why someone of ordinary skill in the art would understand it.

I think we have to step back because I think there is an idea that somehow these claims -- again, it gets back to the claim language, Your Honor. Most of these claims don't ever talk about bringing a stent through or bringing a catheter through. They describe structure. So we've got to look at what the claim is and what's in the prior art.

So, again, the intended use, the idea of whether

or not --

THE COURT: Yeah, but the motivation to combine the two you'd have to ask what the thing would be used for. I mean, that's what creates the motivation to do something better than it's been done before.

MR. NIEDERLUECKE: Yes. Yes. And we discuss and our experts discuss that, Your Honor, in terms of why you would combine and add to that. And it is about the surface area.

And this (indicating), of course, shows the combination of these. If you put them together, it shows what you would come up with if you took those multi-inclined devices and modified slightly the Itou reference to get those.

THE COURT: Okay. Anything more you want to say about Itou? I want to talk to Mr. Vandenburgh about it.

MR. NIEDERLUECKE: Here's the point you were just raising on the next slide about why you would look to combine them. I don't have on this slide, other than a larger surface area, the exact structure of the --

THE COURT: Yeah, I mean, I get the larger area. I get cutting at an incline creates a larger area. But the double step, I'm having a hard time understanding why a POSITA would look at Kataishi or Ressemann and think that you should combine it with the rest of Itou. I haven't read

the affidavits. I mean, I --

MR. NIEDERLUECKE: Well, and -- we can't -- yes, and I think that's important, Your Honor. Certainly, again, with the limitations we had in the briefing, we have a more fulsome explanation of that, but --

THE COURT: Okay.

MR. NIEDERLUECKE: -- as you said, potentially in terms of trying to create a device that would allow that, the idea that you see this design and that someone of ordinary skill in the art would understand that -- create a design that's longer, that has those multiple inclines would more readily accept that device.

I would also say in the patent itself I don't believe there's any description of that multiple incline and its function. Indeed, I think the function of that multiple incline in the patent is to hold that navigation catheter that goes through, not for an entry of a stent or device.

So I think it's interesting that if you read the patent itself, you won't understand that that was created for the purpose of facilitating -- further facilitating a stent or a balloon catheter.

THE COURT: All right. Thank you, Mr. Niederluecke.

MR. NIEDERLUECKE: You're welcome. Thank you.

THE COURT: Mr. Vandenburgh.

MR. VANDENBURGH: Thank you, Your Honor.

With your permission, I would like to go back to quickly two issues from before our last break. First is simply I was putting up the *Loral Fairchild* case. I mentioned it wasn't in our briefs. Can I hand up a couple of copies? I happen to have copies.

THE COURT: Yeah. My law clerk was unable to take down the cite, which she was grumbling about on our way out. I know she would welcome a copy. I meant to ask you to give me the cite to the case and you've done even better. Thank you.

MR. VANDENBURGH: The other thing I want to do is just to make sure my words don't come back to be used against us in some later proceeding here or elsewhere.

THE COURT: Unimaginable.

MR. VANDENBURGH: I think what I said was strictly correct, but I want to make sure I put it in context relative to reduction to practice saying that we didn't need to show that it could be put in a human and work perfectly. That is certainly true from a couple of perspectives. One is that it doesn't need to work perfectly. The other is just reinforcing this point that the testing doesn't need to be in a human. It doesn't need to be in its intended environment. And it doesn't need to actually use the materials that ultimately are workable. That's the *Mahurkar*

case we talked about, that the inventor admitted he used in his testing in his kitchen a different material than you would actually use in the real world. That didn't avoid reduction to practice. So I just want to make sure, again, my words don't get used against me.

The other thing before I jump into the specific issue is to talk a little bit about this substantial question of validity standard that keeps coming up.

And, Joe, if we could jump to slide 90.

Your Honor, I don't know if you recall this, but you had a preliminary injunction case seven or eight years ago where you questioned whether the Federal Circuit was maybe messed up with this substantial question standard because it doesn't really comport with the Supreme Court's preliminary injunction standard, which is simply likelihood of success on the merits. It just sounds like a much lower, easier standard to meet that the Federal Circuit is giving us.

THE COURT: I don't remember the case, but I do remember having the thought.

MR. VANDENBURGH: Yeah. So this case, at least in parts, explains why there hasn't been the Supreme Court or an en banc Federal Circuit decision straightening that out because what they explain is that really, okay, we're using this term "substantial question," but it's really intended

to deal with the fact that we are at the preliminary injunction phase on an issue like validity where the defendant ultimately bears the burden of proof. And it becomes difficult to put words around what actually that means. And they've chosen the "substantial question" language, but as you see from the bottom part, what they're really saying that means is at the end of the day it's whether -- it is at this stage more likely than not the challenger will be able to prove at trial by clear and convincing evidence that the patent is invalid.

THE COURT: Yep.

MR. VANDENBURGH: Now, again, one more thing before I jump into what Itou shows. We heard a little bit, well, we just need to show a substantial question on Itou being prior art, and then we need to show a substantial question on Itou invalidating claims. I submit you shouldn't take it step by step. Ultimately, they want -- what they need to show is a substantial question of validity, that it's more likely than not that the claims are invalid, and that requires you to do a little bit of math.

And maybe this is -- I don't want to put too much of that into this, but we talked a lot about reduction to practice. Let's just say Your Honor concludes that's a 50/50 call. Okay. As I mentioned, they also have the burden of showing that there wasn't diligence, there wasn't

abandonment of the rapid-exchange idea between September of 2005 and --

THE COURT: We didn't really address that. So then you seem to disagree on the law. I thought they told me that if they reduced to practice before Itou's date -- September whatever it was, 23rd of 2005 -- that they don't have to show diligence. You say they do have to show diligence?

MR. VANDENBURGH: What I'm saying is they have to show both. And, again, talking about burdens, if it's reduced to practice before September 23rd of 2005, diligence is irrelevant. So if you agree with us, that's the first one. If it's reduced to practice prior to that date, don't worry about diligence. Itou isn't prior art.

But even if you were to conclude, well, you know, that's 50/50, that's a close call, maybe it wasn't reduced to practice, they then also have the burden of showing that there wasn't diligence between September 23rd of 2005 and --

THE COURT: Because it's undoubtedly reduced to practice constructively when you apply for your patent.

MR. VANDENBURGH: Exactly, Your Honor.

THE COURT: So they have to show a lack of -- okay. So they have to show a lack of diligence between Itou's date and your date, right?

MR. VANDENBURGH: Correct, Your Honor. And,

again, I showed you those long slides with all those actions. Again, what we heard was, well, you were working a lot on the mother-and-child version, the over-the-wire version, but that doesn't mean that there wasn't also work going on; that, in fact, our evidence showing work on that specific embodiment, the rapid exchange, I think is undisputed. The standard we're working with is essentially showing continuous work, not abandonment.

So, again, I think it's actually higher than 50/50 for us on that. But if we give that one 50/50, you do a little math and say they've got to win on both of those. That's only a 25 percent chance. So even before we get to the question of does Itou actually, if it is prior art, invalidate the claims, we're already down to a 25 percent chance that it's even prior art.

Now we go from that to what I'm going to talk about and is the point of this part of our discussion, which is even if it is prior art, does it invalidate.

Could I start with slide 16.

So it is true that for the purpose of today and today only, we are only going to focus on the two complex side opening claims that I talked about at the outset -- claim 36 of the '776 patent, claim 44 of the '379 patent -- the ones that have that complex side opening, because we think that's where they're particularly weak and, again, we

only have to show a likelihood of success on one claim.

We heard it confirmed today they're not contending, at least for today, that Itou meets the claim 44 limitation that has two angles and a non-inclined middle. What they do say is that this little area right here (indicating) meets the language of claim 36 of the '776 patent. What they're missing is the claim requires an inclined region and a non-inclined region that are part of a partially cylindrical opening. That is really simply an area where the end of the push wire is flattened as it attaches to the side opening. There's nothing cylindrical about it, and it's not part of the opening.

THE COURT: Other than looking at the drawing, do I have any way to know whether it's part of the opening or not? I mean, they say it is. It's, basically, like a lip off of the opening. You say it's actually the end of the wire. I agree that this draw drawing here (indicating) seems more consistent with your version than theirs, but do I have anything other than the drawing?

MR. VANDENBURGH: This is perhaps where the silence of the specification becomes relevant. Again, the specification talks about an angled opening. It does say, yeah, you've got an angled opening. But it just describes it as a simple angle. It's clear that they're talking about that angled surface. They're ascribing no importance to

that little, whatever, connection point, if you want to call it that.

THE COURT: Other than the drawing, there isn't any hint in either the claims or the specification that there's supposed to be two angles?

MR. VANDENBURGH: Correct. One hundred percent, Your Honor.

So, again, we start from the viewpoint that for both of these claims they've got to show obviousness for Itou. They don't have an anticipation case for it.

So then let's go on to the other prior art. I want to start with Ressemann. Ressemann, you asked what it is. It is a form of a suction device. It's actually an embolic protection device.

THE COURT: A what?

MR. VANDENBURGH: Embolic protection. It's trying to prevent embolisms from flowing into the heart and causing problems.

THE COURT: Okay.

MR. VANDENBURGH: And in order to do that, what it has is -- this structure that we're talking about has two inflatable balloons at the end that you put it down past -- well, put the end part past the end of the catheter and then you blow fluid or draw fluid into the balloons to blow them up to create a seal, one inside the catheter, one outside

the guide catheter. And what that means is that we have -- the push rod actually has lumens built into it. They're delivering the fluid from the portion outside the body to those distal balloons. And because of that -- and I'll get to explaining exactly why that is -- the opening in the device itself is a simple angled opening. There's nothing complex. It doesn't have those two angled surfaces, and it doesn't have two angles with a flat in between. The reason is because the part they're pointing to -- that's 16-J on the left -- that's showing the collar by itself. It's not showing the collar as it's ultimately built into the surrounding device.

And just to be clear, the other picture of this part that Medtronic keeps showing -- they showed it today; they show it in their brief -- that's their own computer rendering. That's not from the patent. This is the drawing of the collar from the patent.

But the important part -- and I'm going to show it in two ways; first in 16-D here on the right -- what you see is that collar [2141], is built into the device such that, I guess, the main angle -- this part here (indicating) -- is part of the full round. It's back here (indicating). But then this piece (indicating) is ultimately right on the bottom. You can see the arrows -- 2141, that's that part -- pointing to those darker lines. It's at the very bottom of

the device, and you've got structure on top of it. What's that structure on top of it? Well, first, there's a wire that runs through there and, secondly, there's those tubes with the lumens in them running through there.

So when you look at the device itself as manufactured --

THE COURT: Is that what this is here (indicating)?

MR. VANDENBURGH: That, I believe, is the wire, if I'm correct. Kind of back further -- and it's cut away in different parts. I've got to say this is a bad drawing where it just didn't photocopy well. I think what they meant to -- if it was a better drawing, you would see the angle drawing. My hand is going to shake as I do this. Kind of that's the angled drawing right there (indicating) and it disappeared a little bit in the photocopy.

So the important point, you know, we don't think we need to get to the question of does that collar before it's built into the device, does it have two inclines, does it meet the claim language. It doesn't matter because in the ultimate finished device the device only has a single angled opening. The structure they're pointing to to get to the second one is buried deep underneath other structure.

I said I'd show it in two ways. You can also get it from this figure 16e and some language from the

specification. It talks about the location of that support collar. Take the top and the bottom together. Essentially what they say is it's located between encapsulation material [2133] and the exterior walls of multi-lumen tube 2138.

THE COURT: Okay. So this bottom line is there's clearly material over the top of this (indicating)?

MR. VANDENBURGH: Right. There's material -- exactly.

THE COURT: This thing which Medtronic says is the first of the two angles is actually buried somewhere into the -- nobody ever sees it?

MR. VANDENBURGH: Exactly. Exactly. So that's our point. You get it from this figure as well. Ultimately, you take those two things together and what you know is that that collar is located between those two elements [2138], [2133]. It also means that you are below -- and you see it here in this drawing. Those are the two lumens [2142],[2143], the little ones. Those are the little holes. One is for a wire that goes through. The other is for the fluid that's going to blow up those balloons that are located at the distal end.

So our point on Ressemann is simply the device doesn't have that complex side opening, so it doesn't help you one way or the other of modifying Itou to get where Medtronic needs to get.

THE COURT: Okay.

MR. VANDENBURGH: So then let's talk about -- well, I included Kontos. It doesn't have the side opening at all. We'll get to that later. I don't think they're relying on that at this point at all.

Let's talk about Kataishi. Again, no question. As we all know, we're talking about an opening shape that's at the distal end of the suction tube, not at the proximal end where Medtronic needs it to invalidate our patent.

And you asked about what does the specification specifically say about that opening. Well, here's (indicating) where we have that. I have the highlighted language. It talks about the concave portion [161]. And if you look at the top of figure 1, that seems to be part of the opening. It says it's a means for improving flexibility of the catheter at the distal end and enabling that cut surface to absorb an expanded atheroma. The atheroma is the thing you're trying to suck out of there. You see it at the bottom on figure 10.

So what they're doing is trying to get something that's going to kind of -- I view it as sort of collapse or over that atheroma to really create suction right there so you can grab that thing and pull it out of there. That really then begs the question -- they want flexibility in order to grab onto an atheroma. Why are they saying let's

take that and modify the proximal end of Itou?

This is that classic hindsight. You know what the invention is. You're trying to find prior art that's going to get you there, but you just can't come up with a reasonable motivation to do it. Federal Circuit cases as recently as two weeks ago reversing the Patent Office Board because they're ignoring the need for that motivation to combine. They just don't have a reason why you would do Kataishi's opening on the other end of Itou.

The only other thing -- I don't know if at some point Your Honor wants to talk about the IPRs and if this is a good time to do that or a later time?

THE COURT: I'm sorry, I'm not ignoring you. I was just trying to -- the thing I'm hung up on is this language here (indicating). So the concave portion, which is 161 -- so this is 161 here (indicating), right?

MR. VANDENBURGH: I guess as I look at figure 1, 161 is here (indicating). It's just that curved part at the end.

THE COURT: This part.

MR. VANDENBURGH: It's consistent with them calling it concave.

THE COURT: A means for improving flexibility of the distal end, and that seems to be what they're trying to illustrate here (indicating), is it makes it more flexible,

easier to shove in there.

This (indicating), I assume, is the blockage in the artery?

MR. VANDENBURGH: Correct. Correct.

THE COURT: And enabling the cut surface, which sounds like it's this (indicating) here because -- no, 16 --

MR. VANDENBURGH: That's the whole thing at that point.

THE COURT: So it doesn't seem to be saying that the increase in absorbency is because of the angle of the cut. It seems to be saying by making this more flexible, more stuff will get in here.

MR. VANDENBURGH: I guess as I -- certainly one aspect is flexibility. I view it as more so that it can actually sort of flex down towards -- as the suction comes in, it will sort of flex down towards that atheroma, the thing you're trying to suction out of there. But the bottom line, again, it has nothing to do --

THE COURT: Well, the more it's about this (indicating), the less it has to do with -- I mean the less obvious it would be to combine it with Itou and your invention.

MR. VANDENBURGH: Right. Right. Certainly -- we haven't talked about this too much. Itou does disclose at its proximal end it has a metal collar. Why exactly that

is, it's not clear. But one thing that a metal collar is going to do is decrease flexibility. It looks like Itou is not interested in creating flexibility.

THE COURT: He doesn't explain? Why would he have a -- since nothing goes in there, why would he have a metal collar there?

MR. VANDENBURGH: It, of course, does have material that's going back out the other way. Plus you have the issue of you have to attach it to the push wire. It creates an attachment point. But it also does keep it open so that when material is flowing out through it --

THE COURT: I suppose, yeah. There's suction there, so you're trying to brace it against the suction. Yeah. I see.

MR. VANDENBURGH: But the bottom line is, again, there's no reason to combine these two references other than an infringer who's trying to come up with a reason why they don't infringe valid claims of a patent.

THE COURT: This is something that might be disclosed in the patents, and I missed it if it was: How does the two-angle design make it easier -- I assume the purpose -- well, I guess I shouldn't assume that because Mr. Niederluecke, like he said, he doesn't think it's a -- what's the purpose of two angles on the entry point?

MR. VANDENBURGH: Right. It is correct that I

think at the time perhaps the inventors didn't fully appreciate or make it into the patent application all the advantages of having that design.

In the real world part of what that does is it helps the device orient inside the heart and basically creates a curve that allows the stent or the balloon catheter to essentially slowly enter the full tubular portion and smoothly guide it into it, sort of grabs on the side of it and helps to push it in.

THE COURT: Can you put a picture of the two angles up?

MR. VANDENBURGH: In the patent?

I believe that's about slide 4 [sic], Joe -- 7.

THE COURT: In the patent, yeah.

This is the two angles here (indicating)?

MR. VANDENBURGH: Over on this end (indicating).

THE COURT: So I get why this first angle helps. The balloon is coming down. And I get why this angle helps to channel into this half pipe.

MR. VANDENBURGH: Right.

THE COURT: How does this second angle --

MR. VANDENBURGH: I guess the bottom line is the half pipe grabs on, stabilizes the thing that you're pushing and keeps it from moving as it's pushing into that full surround. You've got to have a transition from the half

that's holding it and guiding it to the full. And, again, having that happen gradually --

THE COURT: I see.

MR. VANDENBURGH: -- is important.

THE COURT: If the transition was a right angle here (indicating), that just might --

MR. VANDENBURGH: It might be more likely to catch, hang up on that wall.

THE COURT: Yeah, I see.

MR. VANDENBURGH: I don't want to digress too far. I think I've made my points enough here. I'm not going to go back on the other ones.

THE COURT: All right.

MR. VANDENBURGH: Thank you, Your Honor.

THE COURT: Thank you, Mr. Vandenburgh.

Mr. Niederluecke, did you want to say anything?

MR. NIEDERLUECKE: Your Honor, I think in --

Can I have you guys pull that slide you just had up? I think it's slide A23.

So Mr. Vandenburgh answered one of the questions in terms of the description, and the description actually starts up ahead.

I'd like to discuss this idea of the concave portion and the flexibility to be able to be flexible around. I think we need to keep this in context of what

does the patent say about it? The patent says nothing. The patent doesn't describe that. The inventors might not have appreciated all of the benefits. The inventors didn't appreciate anything. When you look at the patents, the specification, Your Honor, it doesn't describe this configuration or this double incline at all. These are patent attorneys a decade later that are saying, hey, look at that figure; let's create a claim that it has a double incline because we can point to the figure. To be clear, there's nothing in the patent about the purpose of that.

You can get that, to see it's part of the navigation catheter, by reading the whole patent and understanding what they're really trying to invent with this navigation catheter going through and being held by the suction catheter. You can imply that. But there is certainly not a discussion that this was here in any way for the purpose of better allowing the stent or catheter to enter the tubular section.

Now, when you look at this language, though, it's important to know when he talks about the real world, one of the real world important features of these devices is that they can go around various anatomical features and they have to be able to be flexible around those. So when you have the side opening, you want your side opening to be flexible so that when you do bend around things, you're able to do so

and increase that area at the same time.

So the improved flexibility, I would disagree that that says it teaches away. It actually would suggest to one of ordinary skill in the art that what you're doing is you're making sure that as you go around those curved surfaces you keep the opening, the cut surface, large enough so you could absorb an expanded atheroma AT by suction. So, in fact, what it's really saying is you want to be flexible so that when you go around these areas, the hole stays open and wide. That's what that's telling us.

THE COURT: I see what you're saying, but what it's talking about is improving the flexibility of the catheter's distal end. This (indicating) is the distal end. It's not talking about flexibility in curvation. It's talking about flexibility in the tip, the thing that's going to be poking in the area of the occlusion.

MR. NIEDERLUECKE: Right, but someone of ordinary skill in the art, Your Honor, can look at an opening, the design of that that increases the flexibility and keeps the opening larger, and can say I know that, you know -- as I'm trying to develop a device, I can look at this and say, you know, that creates a larger opening and that multi-angled design could be used on the proximal end to ensure that it's flexible and it keeps the opening larger. Certainly our experts have addressed that in the papers, Your Honor.

That's my best explanation aside from reciting just their statements.

THE COURT: Okay.

MR. NIEDERLUECKE: The other thing I did want to point out --

If we can go back to ours and if we can go -- excuse me -- if we can go to 76 [sic].

One thing I didn't -- in both of these for the 76 [sic] -- for the '776, excuse me, certainly the Ressemann and Kataishi could be applied to claim 36. We didn't do it in our presentation. I didn't walk through that. But, obviously, those could be as equally applied to have the angle and the flat section as claim 36 claims.

So if I show this (indicating), those other ones could be -- we didn't do it here because we're just showing the anticipation, but certainly those other ones, if it's not Itou alone, could be applied to that. I just want to make sure the Court doesn't think that if we don't get anticipation here we don't have any other arguments. We certainly do in terms of that.

The other thing I'd like to say about 36, there's a big difference here between how we're interpreting it. We talked about the cylindrical opening having to have certain features. What they're ignoring is that if you look at the sentence structure of claim 36, it's talking about the

segment defining that proximal end of the proximal cylindrical opening. So we're talking about the *segment* that includes this has to include one inclined region that tapers into a non-inclined region.

So it's not talking about the partial cylindrical opening includes that. It's the segment defining the angled proximal end of the partial cylindrical opening that includes it. So it's the segment. It's that opening segment. So it could be larger than just strictly the opening as the claim is held out.

They're pointing you -- they're highlighting other portions, but when you read grammatically the claim, it's the segment that has to include that.

I think, unless you have any other questions on those, I'll stop there.

THE COURT: Okay. I don't. Let me just take a break here for a second.

(A brief discussion was held off the record.)

THE COURT: Okay. I think I'd like to take a lunch break now and come back. If we could get this done in another 20 minutes or so, I would keep going, but I think it's going to be longer than that. So let's take a lunch break. We'll resume at 1:30 here. So please be back in the courtroom at 1:30, and we'll turn to Kontos and Ressemann at that point.

THE LAW CLERK: All rise.

(A lunch recess was taken.)

THE LAW CLERK: All rise. This court is now in session.

THE COURT: Welcome back. Please be seated.

All right. We are now going to turn to the Medtronic argument that the '380 and '776 patents are invalid in light of Kontos, in view of Adams or Ressemann.

Let's see. Mr. Niederluecke. As I said this morning, I'm sort of a clean slate on this. I just couldn't tell much from the briefs, and so I just need you to walk me through the argument.

MR. NIEDERLUECKE: Sure, Your Honor. And, Your Honor, I'm going to kind of focus on -- kind of get down to the meat of things and focus on the '776, claim 36 that we were talking about with the double skive, but I'll walk through a little of both.

Kontos --

If we can pull up Niederluecke Exhibit 5 at page 4. Flip that.

So Kontos is a guide-extension catheter that can be used to both extend out of a main guide catheter and allow an intercardiology device to be extended through it to fix the various stenosis.

So here (indicating) you have the device itself

that extends out of the main guide catheter. You have the lumen. The only thing that you're missing from here is the guide extension -- or the side opening itself.

THE COURT: This has an end opening?

MR. NIEDERLUECKE: Yes. As I understand, the Court defined it before as a straight opening there on the end. So if we --

THE COURT: So, in your view -- this is Kontos that we're talking about here?

MR. NIEDERLUECKE: Yes.

THE COURT: Kontos would anticipate were it not for the lack of an angled -- or a side opening? It's an end opening, instead of a side opening?

MR. NIEDERLUECKE: In terms of the '379 for the side opening, yes. Yes. It has all those others.

If we can turn to Exhibit 26.

In terms of Kontos, Your Honor, just for the record in case the Court wants to go back, I'd refer Your Honor to Exhibits 26 and 27, which are the IPR and our expert declaration explaining it in various detail.

But we'll pull up, if I can, page 23. And what you're going to see on page 23 is -- there we go.

Actually, go to page -- this will work. This will work.

So what you can see there -- this is just blown up

from the patent -- and you see the substantially rigid portion and the proximal. You see the blue, tubular reinforced portion. You have a pink, flexible tip on there. So in terms of any of the claims that don't need that side opening, it would anticipate or make obvious those claims. But as we're focusing on the '379 and the side opening, we have to look to a combination of art and so that's where Ressemann comes in.

If we look at page 28 of Exhibit 26 and if you see the Ressemann -- and this is the -- the collar on the right is the one we were speaking of earlier. Ressemann is a suction catheter, Your Honor. One of the embodiments of Ressemann you can see on the left. And that shows you, again, a suction catheter with a tubular portion, a side opening on the proximal end similar to Itou and some of the other ones we've looked at.

THE COURT: Okay. Just to remind myself, Ressemann is a suction catheter, but the -- this (indicating) is the distal end here, right? This (indicating) is the proximal end?

MR. NIEDERLUECKE: Correct. So on the left -- if you're looking at the figure in 1408, Exhibit 1408, Exhibit 1A on the left of this picture, you see you have an angled end on the proximal end. Okay? And exhibit -- so that's one. So any of the claims that go to just a side opening,

the first embodiment shows a side opening clearly.

THE COURT: Right.

MR. NIEDERLUECKE: When you go to then another embodiment, the 2100 embodiment that we've been discussing, it shows the multi-contoured end that would go onto the proximal end. It's a support collar. And it's described as providing -- just for the record, in column 24 through column 25 there's a description of figure 16j and the embodiment shown there. It's described as a support column to prevent against deforming forces, torsional forces that are created as you are rotating and maneuvering this through the body. So that is an optional collar that you can put on there.

I think earlier we were talking about -- Teleflex made the point about, well, this optional collar in its -- in one of the embodiments has other lumens and other materials that may be sitting on its surface.

But the important thing here is we're not trying to take all of Ressemann. What we're looking at is would someone of ordinary skill in the art look at Ressemann, look at this support collar and say, wow, that's a support collar that's described as providing torsional support to keep that opening open, and could I use that with another piece of art, such as Kontos or earlier, as we discussed, such as Itou to provide that. And our experts say certainly you

would. They're right in the same art. They're providing the benefit of keeping that open so that devices can be put through there.

THE COURT: I'm sorry, this is a basic question. So these are both Ressemann here?

MR. NIEDERLUECKE: Yes. These are -- this Ressemann has a lot of embodiments that it shows, a lot of variations that you could use. And so the left is the first one it shows, which is a suction catheter having an inclined surface on the proximal end. And the right is a collar that it describes that could be used on that proximal end as an alternative design for the collar.

THE COURT: Okay. And so this thing would actually be here (indicating)?

MR. NIEDERLUECKE: Correct. You would put that -- in this design, that goes right there (indicating).

THE COURT: Okay. It's just a little confusing because this doesn't look like this (indicating) and this does look like this (indicating).

MR. NIEDERLUECKE: Yeah. But you're right, the 2100 embodiment goes on the proximal end to provide that various incline shape to it.

So this is Ressemann, and Ressemann is describing the use of this collar or in claims that don't require anything more than a side opening certainly shows here.

THE COURT: Let me just try to follow you here. So in your view, Kontos -- we're talking about which patent now?

MR. NIEDERLUECKE: We're talking about the '776.

THE COURT: The '776 patent.

So Kontos gives you everything except the side opening?

MR. NIEDERLUECKE: Yes.

THE COURT: And then Ressemann gives you the side opening?

MR. NIEDERLUECKE: Correct. So using either, depending on what claim you're looking at, either the straight embodiment -- 100 as it's described here -- or the multi-contoured embodiment in 2100 you could put on there.

If we pull up page 29 of Exhibit 26.

Then we've created what would be shown if you took that collar, applied it to Kontos here where you have a guide-extension catheter, and rather than have an end opening, you would then simply have the contoured opening that Ressemann suggests.

Again, you're taking the collar and you're bringing the collar over. So the idea that somehow it was covered up in Ressemann with any other parts doesn't matter because what you're doing is looking at that collar and what that structure can provide.

THE COURT: Well, the covering up mattered in the last argument because we were talking about the two inclines. If one of the inclines is covered, it's not an incline. It's a different issue in this one.

MR. NIEDERLUECKE: Well, I don't think it is because the question was would somebody look at that support collar that has two inclines in Ressemann and say I could put that support collar on Itou that in fact doesn't have any multiple lumens going through it, but has -- but I could apply it to Itou; and if I apply it to Itou, there is nothing else over that collar. That collar connects up with the rigid section on the right here (indicating).

THE COURT: I don't want to re-argue that, but -- so I just want to -- so for the '776 claims your view is Kontos gives you everything except the side opening, Ressemann gives you the side opening, and a person of ordinary skill would have the motivation to combine the two?

MR. NIEDERLUECKE: Correct, Your Honor. And that certainly is laid out in detail in the exhibits I mentioned.

I will keep it brief for now, unless you want to hear more, but that's the basics of --

THE COURT: With respect to the '380 claims, you're just not pursuing those?

MR. NIEDERLUECKE: No, I think, Your Honor, we'll -- we have them in there. I guess from our conversation

Kontos, again, provides -- basically they're obvious. The reason I'm not going into them is we're kind of focusing on the Itou. At least for the presentation we focused on the Itou. I could try to run through that.

They've identified three infringement claims, Your Honor, and the '380 wasn't included in those in terms of what they responded to and, as you mentioned, what they focused on in terms of saying there's infringement.

THE COURT: Now I'm confused. We talked about the '380 claims and, in fact, I thought I found that they were likely to succeed in finding infringement under the '380 claims.

MR. NIEDERLUECKE: Okay. I'm talking about the invalidity side, that they're not -- if Itou --

THE COURT: You're the one that makes invalidity arguments, not them.

MR. NIEDERLUECKE: Right.

THE COURT: And if you're making an invalidity challenge to the '380 patent, then you have to explain it to me because I didn't pick it up from the briefs.

MR. NIEDERLUECKE: Okay. Okay.

THE COURT: I know you're doing Kontos in view of Adams. I've seen Kontos. What does Kontos not -- what does it not give you on the '380 patent so it doesn't anticipate, and what does Adams add?

MR. NIEDERLUECKE: Give me one second here to just --

THE COURT: Sure.

MR. NIEDERLUECKE: As we just described -- and if we go back to page 24, that figure, we show Kontos. And so Adams --

THE COURT: So what does Kontos not have that the '380 patent does have and that Adams supplies the missing ingredient?

MR. NIEDERLUECKE: Your Honor, I apologize. I wasn't prepared to argue this particular one, other than the papers. I'm happy to come back up.

THE COURT: Well, the papers don't get it done because I didn't understand the argument from the papers. That's fine.

Let me hear from Mr. Vandenburgh then on Kontos and the '776 patent, and then I'll have you back up on Ressemann and the other two patents.

MR. NIEDERLUECKE: Okay.

MR. VANDENBURGH: All right. I was getting a little confused. We'll stick with '776 and Kontos.

THE COURT: Yeah, '776. So the '776, Kontos, in your opponent's view, gives them everything they need for anticipation except the side opening, so they don't have anticipation. Ressemann gives them the side opening, and

Ressemann plus Kontos gives you obviousness.

MR. VANDENBURGH: 21, Joe.

So I'm going to go ahead and start with Ressemann because it's really -- the point we already made relative to the obviousness combination is clearly when we're talking about '776 claim 36, we have that what we call the complex side opening. Ressemann doesn't have it because what they keep showing us in 16j is not the device. It's a collar that gets embedded in the device. And once it's embedded --

THE COURT: Does the '776 patent have any claims that don't have the complex side opening, that just have a --

MR. VANDENBURGH: Independent claim 25, I believe, simply recites an angled side opening. And we would not dispute that that limitation is met in the ultimate Ressemann device, that it has an angled side opening. But it does not have the complex side opening of claim 36.

I believe there are some other limitations that I could go to in claim 25, but, again, I think for the purpose of today we're really fine focusing on that dependent claim, because that's really where their case --

THE COURT: On claim 36.

MR. VANDENBURGH: -- falls apart for that patent and no contesting infringement.

THE COURT: Part of this is just me. There's so

much going on here it's hard for me to follow.

So with respect to the '776 patent, the claim that matters is claim 36, which we, for today's purposes, have a concession of infringement.

MR. VANDENBURGH: Right.

THE COURT: I heard the Itou argument on invalidity. And this is basically -- since you need the complex opening, it's basically the same argument as far as Ressemann is concerned?

MR. VANDENBURGH: I believe so. Correct.

THE COURT: Okay. I see. I just didn't put that together. So you don't have anything you have to tell me in addition?

MR. VANDENBURGH: I don't have anything additional. I think it's clear. In fact, when we were talking before lunch, I don't think Mr. Niederluecke came up and tried to defend that in the final finished device Ressemann has the complex side opening. I think he recognizes that the structure is buried and it's not there in the final device.

THE COURT: Okay.

MR. VANDENBURGH: So then flipping to Kontos. Of course, Kontos doesn't have a side opening at all, so it really comes down to, well, why would we add not just any old side opening, but in fact one of these complex side

openings? The first thing that we get is to --

THE COURT: Were there side openings in the prior art?

MR. VANDENBURGH: Well, there's a limited number of them; for example, Ressemann. We're not disputing Ressemann. There was one that was of record in, I believe, all of the patents and it's come up in the prior *QXM* litigation, which is the Adams '280 patent. I don't know if Your Honor recalls that.

THE COURT: I remember one of the Adams patents had an end opening. Right?

MR. VANDENBURGH: There was an Adams '292 and then Adams '280. Adams '292 has an end opening. Adams '280 has an end opening. They really exist. It really just becomes that classic question of obviousness.

This is so much -- I wrote down -- where did I write it down? We're not taking all of Ressemann. We're just taking part of it. We're taking the part that we like that gets to your invention. And here what they say is, well, we want to take this collar of Ressemann that's buried inside the device. It's got holes in it so that the polymer will flow through it. And they want to say, well, just take that, even though it's designed to be sort of encapsulated inside something else, let's just take it and I'm just going to take my computer animated -- I've got a computer person

here who is going to just put it right in there. Well, why are we doing that? Why are we keeping that little nose portion when we bring it over? Why do we want a side opening at all in Kontos?

Can we go to slide 85.

You know, this is one of the -- this is similar to what we addressed when we were talking -- well, "we", when VSI's counsel was talking about Adams '292 in the *QXM* litigation of why would you add a side opening to Adams '292? The same thing applies here to Kontos.

The tube itself is smaller than the walls, and that's intentional. That's not accidental. So as soon as you're cutting a side opening into the thing, you end up with a device that's smaller than the guide catheter it's going into. That's a bad design. There's no reason to do it. But there's a reason not to do it, which is a guide wire is going to get jammed in there between the tube and the wall.

THE COURT: I'm just not following your explanation.

MR. VANDENBURGH: Yeah, and I'm -- so the yellow in that drawing is a guide wire.

THE COURT: Why is the guide wire not going through the --

MR. VANDENBURGH: The thing is in the Kontos

device as it exists, before they modify it, it has a funnel, and one of the things that funnel does is it helps make sure that a guide wire goes into -- the smaller tube, the red tube, doesn't go around it. As soon as you cut a side opening into it, you lose the funnel. You lose part of the funnel.

THE COURT: Oh, you've illustrated here that you lost your guide wire. I see.

MR. VANDENBURGH: Correct. Exactly. That's what we're trying to show. So the white portion would be the part we removed to create our angled side opening, and suddenly there's nothing to stop that yellow guide wire from not going where it needs to go, where it should go, and instead it sneaks around the outside of the red catheter.

So, again --

THE COURT: But the guide wire is -- it's in place before the red catheter is pushed into the guide catheter, right?

MR. VANDENBURGH: Your Honor, it can be, but it's also important that you be able to pull a guide wire out and reinsert it. Of course, you know, our claims are ultimately about putting something into a catheter that's down inside a larger guide catheter.

So the idea that you would -- all right. Excuse me, Your Honor. I'm getting a note from my colleague. So

this is the --

THE COURT: Just take a moment and go over and talk to him and come back. It's no problem at all.

(A brief discussion was held off the record.)

MR. VANDENBURGH: I think I understand the point now. So one of the things that Kontos is for is for putting ultimately down a balloon catheter down through this device. And one way that you do that is with a fixed wire catheter where you put the wire down first, so you have to get a wire down before you put the balloon catheter in there. So you're definitely going to have the circumstance where once it's in there, you're trying to feed a guide wire down into it.

But, again, I almost hesitate to get -- it's always great if you can say there's a reason you wouldn't make the modification, but really the stronger point here is why are you making the modification to start with? And why are you, particularly for claim 36, you know, creating this complex side opening by just taking out this part from Ressemann and just taking it, complete with the little holes sitting in the outside of that collar, and just gluing it onto the end of it? It just doesn't make any sense, Your Honor.

THE COURT: Okay.

MR. NIEDERLUECKE: Okay. I'm happy to talk about

'380 relative to Ressemann and Kontos because that is, again, one Your Honor found likely to be infringed.

THE COURT: Well, I don't know what to do about '380. Mr. Niederluecke didn't argue it today. I don't understand the argument from the briefs. So I'm obviously not going to -- I think by you addressing it, the only thing you're likely to do is make their argument for them.

MR. VANDENBURGH: Thank you very much, Your Honor. I'll sit down. Thank you.

THE COURT: Mr. Niederluecke, let's talk about Ressemann and why it makes the -- this would be the '379 and '760 patents obvious. So Ressemann, I know what that is.

MR. NIEDERLUECKE: Right. And Ressemann, in fact, for the '379 has all of the elements except for, again, as we're talking about --

THE COURT: I guess we only have to address the '379 because I don't think there's a likelihood of success on infringement on the '760.

So the question would just be with respect to the '379 patent, how does Ressemann, in view of Takahashi, make that obvious or anticipate?

MR. NIEDERLUECKE: Well, Ressemann anticipates directly a number of the claims of the '379 method of forming. Let me grab my Ressemann notes here.

THE COURT: Okay.

MR. NIEDERLUECKE: So as we described with Ressemann, what we have --

And let's pull up again Exhibit 26, page 28 showing those collars again.

You can just look to Ressemann for the method of forming claims for the anticipation of a number of those once he pulls it up. Oh, I have to switch over. That's the problem, Your Honor. I apologize.

So we see that Ressemann in and of itself describes both the simple angled and the multi-inclined end of the support collar. So Ressemann has all of the elements of 25, 38, and 44, Your Honor.

THE COURT: You know, so I understand why I'm putting you in a difficult -- they've already conceded that Itou wipes out everything except the three patents, so there would be no reason you'd have to argue. This would just be piling on.

MR. NIEDERLUECKE: I apologize, Your Honor.

THE COURT: You shouldn't apologize. It's my slowness. Yeah, so you have no reason to argue these because they've already conceded for today's purposes that Itou wipes out everything except '379, claim 44; '760, claim 32; and '776, claim 36. So whether the '379 patent is also obvious in light of Ressemann, that just doesn't matter. So I'm sorry, I'm asking you to argue things that you for good

reason --

MR. NIEDERLUECKE: And I apologize. Again, I understand --

THE COURT: Completely my fault. Why don't we pivot here.

MR. NIEDERLUECKE: Can I just for the record add one more thing?

THE COURT: Sure. Of course.

MR. NIEDERLUECKE: In terms of your earlier question of Adams, Adams adds two things to Kontos that it didn't already have. They're very simple things.

One is the hemostatic valve. It just doesn't technically disclose the hemostatic valve in the end, which somebody of ordinary skill in the art knows. And it does have a side incline. Those are the two things that got added. They're simple things.

THE COURT: I'm sorry for putting you in a difficult position like that. That was entirely my lack --

Why don't we pivot to the written description argument, if you can grab those.

MR. NIEDERLUECKE: Absolutely. You want us to go first?

THE COURT: I guess it's your burden. Ultimately at trial it would be your burden?

MR. NIEDERLUECKE: Yes.