

1 THE COURT: I've just found out in meeting with
2 the QXM attorneys that written description is a jury issue,
3 which came as a surprise to me. It doesn't seem like the
4 kind of thing a jury should decide, but everybody agreed
5 it's a jury issue.

6 You would bear the ultimate burden of proof on
7 written description, right?

8 MR. NIEDERLUECKE: Yes. Yes, for the invalidity
9 of written description. At this point it's whether we raise
10 a substantial question that they can't show lacks
11 substantial merit.

12 So why don't we go to page 84 if we can.

13 So, Your Honor, our written description argument
14 focuses on the side opening. And in -- actually, I'm sorry,
15 while I'm showing you this page I'm going to jump back, just
16 to orient ourselves quickly, to page 24.

17 So one of the things -- this is the third column
18 here that we're talking about now, which is invalid, lacks
19 written description. This applies to the '776, '760, and
20 '379. So what's important to know there is if this argument
21 raises a substantial question, all those questions about the
22 multi-incline planes, those were all within these same
23 claims that lack written description. So that would then
24 obviate the ability for them to get around the prior art as
25 they argue. This would make it such that the

1 preliminary-injunction motion --

2 THE COURT: So if I was not persuaded by your Itou
3 in light of Kontos and Ressemann, if I wasn't impressed by
4 this, this gives you a second shot at invalidity?

5 MR. NIEDERLUECKE: Right. This is another one of
6 our questions we're raising as to the validity.

7 THE COURT: So as I read this written description,
8 I don't -- again, if I faced it in the past, I don't
9 remember researching and trying to figure out what this all
10 means. But the dispute between you seems mainly to be a
11 legal dispute. I mean, what's in the original specification
12 is in there. I can see it for myself.

13 You both seem to be describing law differently.
14 They are obviously -- you know, basically -- I'm going to
15 slightly exaggerate, but their argument is there's no
16 problem adding new things to claims unless there's highly
17 unpredictable technology or the specification made clear
18 that the unclaimed element was somehow crucial. Your
19 argument is more about, you know, you can't be adding stuff
20 to claims.

21 It really seems like the two of you have a dispute
22 over what the law is more than the facts are -- they're
23 undisputed, right, the facts are?

24 MR. NIEDERLUECKE: No, they're not. They're not,
25 Your Honor. Certainly the patent specification is

1 undisputed. The original claims and where they place the
2 opening, that's undisputed.

3 But the other part that comes into it is the
4 question of what would one of ordinary skill in the art --
5 reading that patent, would someone of ordinary skill in the
6 art reading that patent understand that the inventors had
7 invented a side opening that was not within the rigid
8 structure? Okay. That's the question we're faced with. So
9 it's not just a legal question. It's a question of what
10 would one of ordinary skill in the art understand that as.

11 THE COURT: Help me with -- these are just sincere
12 questions. I don't understand how this -- so when you go
13 and get a re-issued patent -- so you have your original
14 patent, right, and then you go and get a re-issued patent.
15 The whole point of the re-issued patent is to expand the
16 claims, to add claims, right?

17 MR. NIEDERLUECKE: It depends on when you do it.
18 Yes, it can be expanding the scope of your claims or
19 limiting them, one or the other.

20 THE COURT: If you're concerned about a validity
21 issue?

22 MR. NIEDERLUECKE: Yeah.

23 THE COURT: But one of the purposes can be to
24 expand the scope of your claims. So I take it what the
25 written description requirement is is that you can expand

1 the scope of your claims, but they still have to be
2 sufficiently tethered to your original specification?

3 MR. NIEDERLUECKE: Correct, and that's the key,
4 Your Honor. What we have to look at is what was filed in
5 2006 and what was described in claims. So the claims count
6 in 2006, the original ones, and the specification. So
7 that's what you look to to say in the original one -- I
8 mean, I can go -- and in their re-issue they can claim a
9 spaceship if they want, and if they can get it through
10 because nobody else had the spaceship, they can get it
11 through. The question is did they disclose a spaceship or
12 did they invent a spaceship? That's what we're looking at
13 here. You look at the original specification.

14 And, Your Honor, in the *QX Medical* case this came
15 up because the side opening they put it in all kinds of
16 places in their claims later on, a decade later they put
17 claims in with the side opening being anywhere. But nowhere
18 in the patent --

19 THE COURT: It didn't come up for me to decide,
20 though?

21 MR. NIEDERLUECKE: No. Correct. What you decided
22 is the claims read that and I'm not going to say -- from a
23 pure standpoint of it says it's in the lumen, I'm not going
24 to say it's not in the lumen because it says it. But there
25 may be a written description question I think is what you

1 raised. That's the issue that we're dealing with.

2 THE COURT: So the issue is how sufficiently does
3 the expanded subject matter in the re-issued patent have to
4 -- the expanded claims have to be tethered to that original
5 specification?

6 MR. NIEDERLUECKE: Right. And the test is whether
7 one of ordinary skill in the art reading the specification
8 and the original claims, would they understand that the
9 inventor was in possession of an invention, for instance,
10 that had the side opening in a separate section, not in the
11 substantially rigid section.

12 THE COURT: So the law they cite me about with
13 this two-part test of technology highly unpredictable and
14 the cruciality of the element, you didn't even cite that
15 case law in your brief, so what's --

16 MR. NIEDERLUECKE: There's a lot of different
17 cases out there describing it differently. Highly
18 unpredictable, no. If it's something that would be in the
19 ordinary skill of someone of ordinary skill in the art, that
20 they would know, yeah, it didn't say this, but, you know, I
21 used a -- if it describes securing something with a nail and
22 you say, well, but then you claim securing it with a screw
23 and you say, well, someone of ordinary skill in the art
24 would know you could do either, okay, you don't have to
25 describe everything in a patent. That's the point. If it's

1 already within the ordinary skill of the art, you don't need
2 to put everything in your specification because they
3 understand that.

4 The question is when you start going into things
5 that are different and new. Remember, their whole claim
6 here is that putting this side opening in the substantially
7 rigid section, as they described in their specification, was
8 the voilà. So this is, you know, what they're essentially
9 claiming. And in every instance they claimed it within the
10 substantially rigid portion.

11 THE COURT: So what we're basically looking at is
12 does a person of ordinary skill when he reads the re-issued
13 claims, the new broader claims, does his eyebrows shoot up
14 thinking, well, where does that come from? I didn't see
15 that in the original specification.

16 MR. NIEDERLUECKE: Right.

17 THE COURT: But his eyebrows aren't going to shoot
18 up if it's a screw rather than a nail, but they're going to
19 shoot up if it's a side opening in a separate section rather
20 than in the substantially rigid section?

21 MR. NIEDERLUECKE: Yeah. Some examples of what
22 we're looking at here --

23 Let's go back to 84.

24 So, of course, we have the cases that we cite that
25 we discussed that may have a different flavor than the cases

1 that they cite to, but what's important here is let's look
2 at the facts. If we go to the facts, because in the end
3 written description comes down to the facts of each case,
4 what we know, as we discussed, it's undisputed, it doesn't
5 disclose a side opening or partially cylindrical in any
6 section but the substantially rigid. They point to figure
7 1, which shows an end opening, not a side opening. I don't
8 even understand their rigidity argument because we're not
9 even talking about relative rigidity.

10 What's important, though, is this: The POSITA.
11 We both have experts in this case. They've opined quite a
12 bit. Dr. Zalesky explained that a POSITA would not have
13 understood that an inventor would be in possession of a
14 guide-extension catheter with a side opening or partially
15 cylindrical opening in any location -- any other location
16 than substantially rigid one and, therefore, the asserted
17 claims lack written description.

18 Mr. Keith said nothing. They have no evidence in
19 the record as to what a POSITA would have reviewed this as.
20 Mr. Keith put in a reply declaration. He didn't address
21 this at all.

22 In fact, Your Honor, the Patent Office -- I'm
23 going to skip over this. One of their cases deals a lot
24 with genus and species.

25 THE COURT: I don't know what that means.

1 MR. NIEDERLUECKE: It means it's more chemical
2 related. If you describe enough examples of something, then
3 you can cover like a whole category. They try to rely on
4 that type of case. It's not applicable at all here because
5 they have one example. So that's just what we're pointing
6 out in your slide.

7 But here's the important thing. Let's look to the
8 objective third party, Your Honor. And this is what the
9 examiner told them with regard to the '379: She rejected
10 the '379 for lack of written description and she said the
11 original specification is very clear that the side opening
12 is part of the rigid portion and not its own segment apart
13 from the rigid portion.

14 Then what Teleflex did is they amended and they
15 put in some generic language that was unclear as to
16 position. It was allowed. But now what they're doing is
17 they're applying that to get right back out of the
18 substantially rigid section.

19 THE COURT: So if the examiner is essentially
20 saying you can't have any new claims that put the side
21 opening anywhere other than the substantially rigid portion,
22 how did they eventually get new claims that put the side
23 opening somewhere other than the substantially rigid
24 portion?

25 MR. NIEDERLUECKE: Well, in this specific case of

1 the '379 --

2 THE COURT: A different examiner?

3 MR. NIEDERLUECKE: Yes. You know, I wouldn't say
4 anything derogatory towards examiners, but this examiner --
5 this is the most recent patent, by the way. So this is the
6 latest one that came out.

7 One of my colleagues has mentioned to me that it
8 might be because this is a female examiner and the rest were
9 male, but I don't know if that's true or not. That was
10 pointed out to me.

11 MS. FRIEDEMANN: Smarter sometimes.

12 THE COURT: I see.

13 MR. NIEDERLUECKE: Yes. So this is the most
14 recent one that issued and this was -- made a point. It's
15 very possible. Written description examiners aren't trying
16 to go through the record all the time and figure that out,
17 especially when you start having serial applications.

18 So that's why we get an opportunity to address
19 invalidity, and that's why the -- while they get a
20 presumption, it's not a dictation of validity. It's a
21 presumption, because they spend a very minute portion of
22 their time versus the amount of attorneys, as you can see
23 here today, that can go into prosecuting patent
24 applications. So that's often why. It's a practical thing.
25 They don't necessarily catch it.

1 THE COURT: So their argument or one of their
2 arguments, as I understand it, is that this sort of only
3 matters if it's about an important thing. You know, they
4 essentially argue the location of the side opening just
5 wasn't important. You remember their argument in their
6 brief about it's not in the summary, it's not in the first
7 seven paragraphs. It's only in the eighth paragraph, and in
8 the eighth paragraph it is the first time the location is
9 even mentioned. Your view is, what, that they're just
10 misstating the law?

11 MR. NIEDERLUECKE: No. I think when you read the
12 patent, you'll see very clearly when it's fully described in
13 there, it's described in the detailed description of the
14 invention. The background or the summary isn't going to
15 describe everything, and it does describe it.

16 Every one of the figures they show it in the
17 substantially rigid section. The substantially rigid
18 section defines itself actually as including a side opening.

19 We know as we sit here today, because we're
20 talking about all the design of the side opening, we know
21 that the side opening in these claims appears to be their
22 critical feature.

23 We also have to remember that the side opening
24 being in a rigid section is going to be easier to keep open,
25 because it's in a rigid section, than a side opening that

1 isn't that could possibly collapse. That's why we're
2 looking at some of these pieces of prior art and saying,
3 well, if you took Kontos and said there's a stronger, more
4 supportive collar that you could apply to Itou to ensure
5 that you had an open and easily-accessible wider area,
6 that's why we see that, Your Honor.

7 THE COURT: Okay. I just have in my notes that
8 they did argue that figure 1 showed an embodiment where the
9 side opening wasn't in the substantially rigid portion but
10 instead was in the reinforced portion, which is something
11 different than the substantially rigid. Did you want to
12 respond to that argument?

13 MR. NIEDERLUECKE: Without spending too much
14 time -- I don't have a copy of the patent right in front of
15 me.

16 THE COURT: I don't have it either. It's in those
17 books somewhere.

18 MR. NIEDERLUECKE: Figure 1 and 2 shows an end
19 opening, Your Honor. It's the picture that has basically an
20 end opening.

21 THE COURT: Let's see if I can find it.

22 MR. NIEDERLUECKE: I can find one here, Your
23 Honor. I apologize.

24 THE COURT: 032 is the number of the original one?

25 MR. NIEDERLUECKE: I've got one here, Your Honor.

1 THE COURT: Can you just put it on the Elmo there.

2 MR. NIEDERLUECKE: Yeah. That's what they're
3 pointing to, Your Honor, figure 1, the lower portion there.
4 They're pointing to that opening, which is an end opening.
5 So they're just -- that's what they're pointing to.

6 THE COURT: How can you even tell this is in the
7 reinforced portion here?

8 MR. NIEDERLUECKE: 20, I believe, is the portion.
9 So this doesn't show a side opening at all.

10 THE COURT: You think 20 is the reinforced
11 portion?

12 MR. NIEDERLUECKE: No, 20 is the rigid portion, I
13 believe.

14 THE COURT: What's 12 then?

15 MR. NIEDERLUECKE: Two seconds, Your Honor.

16 THE COURT: Sure. Just take your time.

17 MR. NIEDERLUECKE: 12 is the entirety of the
18 coaxial guide catheter. So that's the catheter itself.

19 THE COURT: And 20 is the substantially rigid
20 portion?

21 MR. NIEDERLUECKE: 20 is the substantially rigid
22 portion.

23 THE COURT: What's 18 then?

24 MR. NIEDERLUECKE: 18 is the reinforced portion.

25 THE COURT: Oh. Okay. So, well, I mean, the end

1 of the reinforced portion is where the opening is.

2 MR. NIEDERLUECKE: Right. But it's not a side
3 opening, Your Honor. It's just a straight end opening. So
4 that's what they're trying to point to there. That's why I
5 said it doesn't find support.

6 THE COURT: One of the struggles of this case is
7 that the drawings in the original patent don't look anything
8 like the actual invention.

9 MR. NIEDERLUECKE: And that's really important
10 here, Your Honor. That's the point. You read this patent
11 and it doesn't look anything like the product they made.

12 THE COURT: I mean, usually when I get a new
13 patent case, before the first hearing I read the patent and
14 then I start reading the briefs. The device and the briefs
15 seem to have nothing to do with what I was seeing in the
16 drawings in the patent. It was quite a gap.

17 MR. NIEDERLUECKE: Right. And that's certainly a
18 gap right here when you're talking about where the side
19 opening is.

20 That's why for the '380 patent that doesn't
21 include a side opening requirement. That's why we didn't
22 seek this defense against that, because it didn't have that
23 side opening. That's the difference.

24 Thank you, Your Honor.

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

1 Mr. Vandenburg.

2 MR. VANDENBURGH: So, Your Honor, I want to start
3 with the law because I agree with where you started, that
4 what we really seem to be disagreeing on is the law that is
5 applicable to this case.

6 THE COURT: I assume you agree there has to be
7 some kind of tether between newly-claimed material and the
8 re-issued patent and the original specification.

9 MR. VANDENBURGH: So where I want to start with is
10 this *Ethicon* case. And I urge Your Honor to read the long
11 footnote 7. And what it does is it draws the important
12 distinction between claims that affirmatively recite a
13 feature that's not disclosed in the patent. That's the case
14 law they rely on. That can be a problem. But they're
15 distinguishing that from simply having broad claims that are
16 generic to both what's disclosed and things that aren't
17 disclosed.

18 And I think an analogy might help here, Your
19 Honor. Suppose I invent a new steering wheel column for a
20 vehicle and in my patent specification all my embodiments
21 show an American-style vehicle, steering column on the left
22 side of the passenger compartment. Okay. If that's my
23 disclosure, I can't -- absent satisfying their law of maybe
24 one skilled in the art could read it into it -- I can't add
25 a claim that says wherein the steering column is on the

1 right side because I haven't disclosed it. It's not
2 anywhere in my patent. I only disclosed the left side. But
3 what I can do is claim a steering column in the passenger
4 compartment. It's a perfectly valid claim, and it would
5 cover both the thing I expressly disclosed, that thing that
6 I sell in the United States, but would also cover the
7 vehicles that I sell out in Britain, in the United Kingdom
8 that have the steering column on the other side. I haven't
9 disclosed it, but I'm entitled to present claims that are
10 broad enough to cover it.

11 That's the situation we're dealing with here.
12 They're not talking about claims that say, you know, wherein
13 the side opening is in the flexible portion or something
14 like this. They're talking about claims that claim perhaps
15 a tubular portion and a substantially rigid section and then
16 say there is a side opening between them, that's where it
17 needs to be, but it doesn't specify whether it's rigid or
18 not or how rigid it is. That's the generic type of claim
19 where our case law applies, where you're not asking does one
20 skilled in the art understand that you invented each one of
21 the alternatives. Instead, the relevant question is does my
22 specification indicate to one of skill in the art that that
23 location is critical, necessary to my invention?

24 THE COURT: So to use your analogy, you can claim
25 the passenger compartment because you did disclose a

1 steering column in a passenger compartment?

2 MR. VANDENBURGH: Correct.

3 THE COURT: But you can't claim specifically a
4 steering column on the left?

5 MR. VANDENBURGH: I guess I was assuming it was on
6 the left. I'm thinking U.S., on the left. I can't claim on
7 the right. Correct.

8 THE COURT: So you can claim it, but you have to
9 claim it through generic language, rather than specific?

10 MR. VANDENBURGH: You can cover it. This is kind
11 of that difference in terminology that patent lawyers think
12 about. I can present a claim that is broad enough to cover
13 both alternatives. But I can't -- again, if one skilled in
14 the art wouldn't recognize that I had specifically disclosed
15 an embodiment where the steering wheel is on the right, I
16 can't claim that.

17 THE COURT: You take this thing you disclosed,
18 this steering column on the left, and you in your
19 application for re-issued patents try to blow this balloon
20 up to cover more and more. When does the balloon pop? I
21 mean, at what point have you gone too far?

22 MR. VANDENBURGH: I mean, I think certainly if you
23 cross that line and your -- I guess I can't make it fit my
24 analogy here. If I tried to -- I can't even come up with a
25 good example that fits in my analogy.

1 But, again, for a claim like this, what the case
2 law really looks to is did you say that the exact location
3 was critical or necessary? If I say, look, it's really
4 important that my steering wheel be on the left side, then
5 maybe I can't even claim as broad as the passenger
6 compartment.

7 But, again, that's why -- and, again, we didn't
8 have Mr. Keith --

9 THE COURT: The role a person of ordinary skill
10 plays in this area of the law, written description?

11 MR. VANDENBURGH: I'm sorry.

12 THE COURT: What role does the person of ordinary
13 skill play? In Mr. Niederluecke's description of the law,
14 what you are essentially asking is when the person of
15 ordinary skill reads the re-issued claim -- by that I mean
16 the broader claim -- is he surprised by what he reads there
17 thinking, well, I didn't see this anywhere in the original
18 patent? That's kind of Mr. Niederluecke's test. You say
19 that's not the correct test?

20 MR. VANDENBURGH: I guess I'm not sure that's
21 actually Mr. Niederluecke's test. The surprise is closer to
22 it from the standpoint of when I look at the specification,
23 is there anything that tells me that this opening that I
24 know has to be at the joint between the push wire and the
25 tubular portion, is there anything that tells me it's got to

1 be rigid, it's got to be in this part that I am calling the
2 rigid portion or else is this device -- you know, it's just
3 not what this inventor invented? It's the criticality
4 question, Your Honor.

5 THE COURT: I did not have time to go through it,
6 but what does the original patent, the 32 patent, what
7 exactly does it say about the location of the side opening?
8 Does it address it in words or is it just all the
9 embodiments shown in the substantially rigid portion?

10 MR. VANDENBURGH: All of the embodiments disclose
11 it in what the patent is calling the rigid portion. But
12 let's keep in mind that that concept of rigidity is also a
13 relative concept and varies in parts of each of what the --
14 you know, the tubular portion and the push wire. And this
15 was one of the key points in our brief.

16 Let me just jump ahead. Your Honor already
17 mentioned this one, that it's not until you get to paragraph
18 8 of the summary that you talk about the side opening. And
19 even here it says, well, the rigid portion may have that
20 cut-out portion, which is essentially the side opening. So
21 it's not saying it's critical that it be in this thing we're
22 calling the rigid portion versus the other half of the
23 device.

24 But then we have this embodiment from figures 10
25 and 11, which is an embodiment where, yes, we are talking

1 about the metal push wire, but it's also talking about
2 taking steps to increase the flexibility of the distal end.
3 And, in fact, there's an increasing. You've got a part with
4 no slits in it. And you have part 74 where you add some
5 slits to create some flexibility. Then at the tip portion,
6 which, again, is where the side opening is going to be in
7 this embodiment -- I think I said tip portion. I'm talking
8 about the end of what we're seeing here down by 72. It's
9 saying add a lot of slits to create a lot of flexibility.

10 THE COURT: Yeah, but this is still the
11 substantially rigid portion.

12 MR. VANDENBURGH: It's still -- yes.

13 THE COURT: The claim, I haven't read it for a
14 while, but the original claim keeps talking about this is a
15 device made up of a substantially rigid portion, a flexible
16 tip portion, and --

17 MR. VANDENBURGH: The claims are claimed in
18 different ways. So, for example, let me get specific. Now,
19 this isn't one of the original claims, but this is one of
20 the claims we're talking about now. This is the independent
21 claim from which -- claim 36 of '776 that we've talked about
22 a lot today with the complex side opening, it depends from
23 this claim. This claim has something called a substantially
24 rigid segment and a tubular structure and then this segment
25 defining a partially cylindrical opening, but then talks

1 about it needing to have elevated rigidity relative to the
2 tubular structure.

3 THE COURT: Yeah, but --

4 MR. VANDENBURGH: So it's not like there's no
5 limitation relating to the rigidity of the side opening. It
6 just doesn't say that it's part of this thing that this
7 claim calls a substantially rigid segment.

8 THE COURT: What is the language in the original
9 patent that places the side opening in the substantially
10 rigid segment?

11 MR. VANDENBURGH: Your Honor, I'm not sure at this
12 point that even the original claims as issued contained that
13 limitation. I'm not sure. And, again, I'm not going to
14 have access to that. I do know if you go to the original
15 claims as filed in 2006, not issued claims, that there was a
16 limitation about the substantially rigid portion having a
17 side opening.

18 But Your Honor picked up on this, I think, that
19 the whole point of re-issue can be -- the statute says you
20 can re-issue a patent when it turns out one of the reasons
21 is a patentee claimed less than they were entitled to; in
22 other words, their claims were too narrow. So this idea
23 that you can't go broader than what your original claims
24 looked like is not supported by the law. It's exactly the
25 opposite.

1 THE COURT: Well, Medtronic is not arguing that
2 you can't go broader at all. It's just this issue of how
3 tethered does it have to be to what's in the original
4 patent, and that's --

5 MR. VANDENBURGH: Their argument is even more
6 fine-tuned. They don't dispute that we don't have to claim
7 a side opening at all. We have claims that are asserted
8 here. It's why they haven't contested -- asserted their 112
9 defense against claim 12 of '380, because claim 12 doesn't
10 require a side opening. It reads on an end opening. As
11 we've discussed, we clearly have embodiments where the end
12 opening is in something other than the substantially rigid
13 portion.

14 So their argument boils down to you don't have to
15 claim a side opening, but if you do, you also have to have
16 something called a substantially rigid portion and you have
17 to put it there. You have to expressly say it's there.
18 That's a lot of steps that just don't make sense.

19 The fact that we can have an end opening not in
20 the substantially rigid portion is again one of those
21 indications that it's not critical where the opening -- be
22 it end opening or side opening -- is relative to this thing
23 we're calling substantially rigid and this thing we're
24 calling the tubular portion. It's got to be in that seam
25 between it.

1 The last thing, I do want to talk about what
2 happened during prosecution because we'll also happily
3 embrace our very smart examiner Catherine Williams. Yes,
4 she made a rejection of '379, and it's in a -- specifically
5 in a claim that's directed to a method of forming. We've
6 talked about these claims before. And she rejected the
7 claim on the left. But there was no change of examiner
8 here. There was an implication that she's the smart
9 examiner and other examiners never allowed this.

10 There was an amendment to the claim. What we're
11 looking at on the right is the '379 claim as issued. It's
12 the claim we're talking about today. Examiner Catherine
13 Williams allowed that claim, recognizing essentially -- you
14 know, it's pretty self-explanatory. You have to provide
15 three different things: a flexible tip segment, a
16 reinforced segment, and a substantially rigid segment. And
17 then you have to define a side opening portion and it
18 doesn't say where it is. It's like the claim to the --
19 where it says passenger compartment without saying which
20 side of the car it's on. It's agnostic to where the side
21 opening portion is. And Examiner Catherine Williams allowed
22 that claim, found no 112 problem with it.

23 Now, I want to take this even one step further.
24 Let me start by -- I'll give even more credit to
25 Ms. Williams. She is a member of the Central Re-Examination

1 Unit. I meant to have a slide on this, but I don't. But
2 this is the special group of experienced examiners that
3 handle re-examinations and re-issues. They're not the
4 average examiner. And I'm going to read from a Patent
5 Office document. It's staffed with senior primary examiners
6 and supervisory patent examiners having a wide range of
7 technical expertise and advanced patent legal knowledge.

8 So this examiner knows that it's okay to have
9 claims that are broader, that are generic, that don't
10 require a specific location of the side opening.

11 THE COURT: Can you go back to the previous slide.

12 MR. VANDENBURGH: Yes.

13 THE COURT: So she rejected this claim. Give me a
14 second to read this.

15 MR. VANDENBURGH: Yes.

16 THE COURT: So the difference here is that here
17 you provided for the side opening appearing in its own
18 segment, and that would be like you saying that the steering
19 column should be on the right. So she balked at that.

20 Here you just provided for a side opening
21 somewhere without being specific about where, and that was
22 like the passenger compartment?

23 MR. VANDENBURGH: Yes, relative to my analogy.

24 But I think it's a little more complicated here because
25 we're talking about a method of forming. I think it may

1 have had more to do with the fact that we're talking about
2 forming by providing separate segments.

3 THE COURT: What I have in mind is her
4 explanation, which Mr. Niederluecke read to me, which was
5 saying in the original patent you only disclosed this as
6 part of the substantially rigid portion.

7 What I'm wondering is why this (indicating) --
8 what I can't figure -- this sometimes happens in patent
9 cases. Somebody will read to me where the examiner says
10 no-go on this claim because of reason X, and then the
11 examiner eventually approves something that seems to be
12 contrary to what they said earlier.

13 So I'm trying to figure out how does this solve
14 the problem that is in the language that Mr. Niederluecke
15 read to me?

16 MR. VANDENBURGH: Right. For one thing,
17 Mr. Niederluecke was excerpting the language. He doesn't
18 have the whole paragraph of the rejection.

19 Joe, I believe I have a back-up slide that has a
20 paragraph of the rejection.

21 THE COURT: It seems pretty clear.

22 MR. VANDENBURGH: See if I can find a number to
23 it. 125. So here's (indicating) the entire paragraph of
24 the rejection.

25 THE COURT: Okay.

1 MR. VANDENBURGH: So if you look at the last
2 sentence, I think that's really where she's saying -- this
3 is like affirmatively claiming that the steering wheel is on
4 the right. She says, Claim 30 identifies a segment defining
5 the side opening as a completely different structure from
6 the rigid portion. So she's saying this isn't a generic
7 claim as phrased; it's specific.

8 THE COURT: Right. Okay. So, yeah, the patent is
9 very clear the side opening blah, blah, blah is not its own
10 segment. And this makes it its own segment, right?

11 MR. VANDENBURGH: I think she was interpreting
12 these claims as a way -- as affirmatively claiming that it's
13 not -- can't be in the rigid segment.

14 THE COURT: Okay. So then flip back to the
15 language.

16 MR. VANDENBURGH: What slide were we at? We were
17 at slide 39.

18 THE COURT: And this says nothing about where the
19 side opening is.

20 MR. VANDENBURGH: Correct. Correct. So then the
21 rejection gets withdrawn.

22 Now, I do have one more piece of evidence on this
23 point to talk about, Your Honor, when you're ready.

24 THE COURT: Okay.

25 MR. VANDENBURGH: Okay. So, again, the purpose of

1 this slide is really to point out that this same examiner
2 did in fact examine one of the other claims in this family.
3 This doesn't happen to be one that we're currently
4 asserting. This is the '116 patent, another one of the
5 re-issue patents.

6 This one is directed to a method of using, not a
7 method of forming, a method of using. But what you see if
8 you look at the highlighted and the bolded language is that
9 it very clearly recites a segment defining a side opening in
10 a substantially rigid segment as two different portions of
11 this guide-extension catheter.

12 So, again, it goes back to -- it's not entirely
13 clear why Examiner Williams made the rejection in '379, but
14 it appears that it was specific to the fact that it was a
15 method of forming. Here we have a method of use and the
16 same examiner saw no problem in calling out two separate
17 components.

18 THE COURT: I would flip that and say I thought
19 she made very clear why she was rejecting the earlier claim.
20 What's not clear is why she would have permitted this claim.

21 MR. VANDENBURGH: Well, what it goes down to,
22 though, is can you -- it was talking about forming something
23 apart from the substantially rigid segment. One of the
24 things we talked --

25 THE COURT: Why does that matter? Her language is

1 it was very clear in the original patent that it doesn't
2 support the side opening being anywhere other than the
3 substantially rigid portion. That was her description of
4 what was in the original patent, using the expression "very
5 clear." So this is the one that I find inexplicable as to
6 why she would have approved this.

7 MR. VANDENBURGH: Well, to the extent we need to
8 try to reconcile them, this certainly is evidence that we
9 need to deal with. I believe I --

10 THE COURT: It's a jury issue, as I've learned
11 recently.

12 MR. VANDENBURGH: Well, and, of course, there's
13 always the case law from the *Phillips* en banc case dealing
14 with claim construction that makes the point that I think
15 Your Honor recognizes, that often the prosecution history
16 lacks the clarity of the other tools of claim
17 interpretation, that it is this -- they talk about it being
18 an ongoing negotiation. And sometimes it's tough to draw a
19 firm conclusion as to what's going on.

20 But, again, for them -- really this is their --
21 they're the ones trying to embrace that prosecution history
22 as the thing that wins the day for them. At the end of the
23 day, we think it favors us or at the very least is a push.
24 But really the point that I think is the heart of it is
25 resolving the legal issue.

1 If we're right that this is a situation where it's
2 the passenger compartment broadly and do they have to -- is
3 it okay to present claims that are agnostic as to the
4 location of the side opening, if we're right on that, then
5 the evidence is clear here that we win.

6 THE COURT: Okay. We'll have to look at the
7 Federal Circuit law. I'm betting we're going to find cases
8 pointing both directions. Anytime you research, there is
9 cases on both sides of everything. Thank you.

10 Mr. Niederluecke. So just before you say what you
11 want to say, just two questions. One is how do you explain
12 this, the approval of this claim?

13 MR. NIEDERLUECKE: Well, first, I don't think this
14 was in their papers, so I haven't seen it at all. You and I
15 are both seeing this for the first time.

16 Am I wrong there?

17 MR. VANDENBURGH: I believe that's correct.

18 MR. NIEDERLUECKE: So this is new. This isn't in
19 the papers of the argument.

20 THE COURT: It's hard for me to reconcile her
21 approving this claim with what she said.

22 MR. NIEDERLUECKE: We can go back to the other one
23 as well. It comes down to a question of can you read this
24 to read that the side opening is actually in the rigid
25 segment? I was trying to read this just going on here and

1 I'm not sure if you can or can't.

2 THE COURT: Yeah.

3 MR. NIEDERLUECKE: It's unclear by the time you
4 get through all this whether or not the segment defining the
5 side opening, which is described as being in a more rigid
6 portion -- so it's describing the side opening as being in a
7 more rigid distal portion. So I'm not sure how she's
8 interpreting that. So I can't really respond to why she did
9 this or what her reasoning is.

10 But if we go back to --

11 Can you go to A39, Joe? Would you mind. Go back
12 to the change here.

13 So we know that she rejected claim 38 as clearly
14 trying to put a segment outside of the substantially rigid
15 section and she said there is no disclosure for it.

16 Then what they did is they rewrote it. So instead
17 of saying a segment defining the side opening portion or a
18 side opening and then down below have that segment in order
19 with the rigid, then the side opening, then the tubular,
20 then the tip, they change it and they just said -- they go
21 through the three sections -- the three segments: flexible
22 tip, reinforced segment, substantially rigid segment. And
23 then they change this to say defining a side opening
24 portion, which one would believe that's a portion of one of
25 those segments. So you have three segments and there's a

1 portion here.

2 THE COURT: Right.

3 MR. NIEDERLUECKE: It goes through and it's
4 interesting. This is a little bit important in terms of why
5 it got done. Including forming a proximal to distal
6 direction, cross-sectional shape, hemispherical
7 cross-sectional shape, and going on there. And I'll tie
8 that back in in a second.

9 And then they changed the last paragraph. So it
10 says arranging in a proximal to distal direction, the
11 substantially rigid section, the side opening portion, which
12 very easily could be within that substantially rigid
13 section. So there's enough here -- and then it goes on to
14 say --

15 THE COURT: I see what you mean. In the last
16 section they seem to -- it seems to line up substantially
17 rigid segment, side opening portion, reinforced segment, and
18 flexible tip segment. So that seems to suggest that the
19 side opening portion is either in the substantially rigid
20 segment or the reinforced segment.

21 MR. NIEDERLUECKE: And so she may have very well
22 interpreted this as describing that side opening in the
23 reinforced segment -- or, I'm sorry, in the rigid --
24 substantially rigid segment. That may have been why she
25 allowed that claim. I don't know. We don't know the head

1 of the examiner. But that would be my best guess.

2 The key is here, Your Honor -- and this comes up
3 sometimes in the context of claim construction where one --
4 the plaintiff will argue for a very broad claim construction
5 and the courts will say be careful what you ask for because
6 if you get a broad claim construction and you can't support
7 the full scope of that claim construction, you're going to
8 lose on written description. And that's what we have here.

9 They're seeking, like for this one, a broad
10 construction where they can have the side opening anywhere.
11 But if they do that, they're going to lose on written
12 description because they didn't disclose it.

13 I would like, if I can, Your Honor, to just go
14 back. I know Mr. Vandenburg showed you figure 10 and
15 talked about how that may not be how to look at this. This
16 could be an example. Well, figure 10 says that it's a flat
17 pattern for making relief cuts in a curved rigid portion.
18 The similar figure 12 is a plan view of the rigid portion in
19 accordance with the present invention. So even with those
20 figures, it's describing those as part of the rigid portion.

21 And then to your other question, Your Honor, here
22 (indicating) is what's described in the patent, describes
23 that the rigid portion includes first full circumference
24 portion 34, hemicylindrical portion 36, arcuate portion 38,
25 and second full circumference portion 40.

1 THE COURT: This is the '776 patent. What I was
2 asking about is what's in the original?

3 MR. NIEDERLUECKE: It's the exact same. The words
4 within the specification part are the same. I just pulled
5 this up as an example. This is what's in the original
6 specification.

7 The original claims also require that side portion
8 to be in the rigid section. And so this is the section --

9 THE COURT: It's the words of the specification
10 itself?

11 MR. NIEDERLUECKE: Yes. Yes.

12 So, Your Honor, it is very clear, as the examiner
13 noted, that this specification, which is just like the
14 original specification, does not describe a side opening or
15 partially cylindrical opening anywhere except in that rigid
16 portion. All of the drawings are very clear that it's part
17 -- when you look at the numberings on all the drawings, it's
18 in the rigid section. The specification describes it only
19 in the rigid section.

20 It is, despite what they want to say, a very
21 important part of this invention and how it would function
22 as to whether or not that side opening would be in the rigid
23 section. In fact, as we've seen, we know that
24 rapid-exchange catheters were in the prior art. We know
25 that over-the-wire mother-and-child catheters were in the

1 prior art. So it's really that side opening that they seem
2 to be claiming is their invention.

3 THE COURT: Okay. So just help me think this
4 through because I'm getting really tired. So the two claims
5 that we sort of still have in play today are the '379 --
6 claim 44 of the '379 patent and claim 36 of the '776 patent
7 because all the others are wiped out by Itou, and I've found
8 -- I'm going to find that they don't have a likelihood of
9 succeeding in showing infringement of the '760 patent, claim
10 32. Okay? So the '379, claim 44 and '776, claim 36, they
11 both disclose a side opening; is that right?

12 MR. NIEDERLUECKE: Correct, Your Honor.

13 THE COURT: So if I agree with you on the written
14 description issue, that would leave them with nothing to
15 have a likelihood of success against you?

16 MR. NIEDERLUECKE: Correct, Your Honor.

17 THE COURT: Anything more you want to say on the
18 written description issue?

19 MR. NIEDERLUECKE: No, Your Honor. I think this
20 may end. My ending note is, of course, that we can't forget
21 the context we're in and just, for example, for this issue
22 certainly, regardless of what happens at trial with a jury,
23 if we get that far, you know, here what we're talking about
24 is does our position -- does our argument here lack
25 substantial merit? It's hard to imagine that it lacks

1 substantial merit. It seems to be very meritorious. In
2 fact, we believe we'll be successful at trial.

3 But at this stage, that's the burden we have, is
4 to show that we've raised a substantial question as with all
5 of these. Their burden is to demonstrate that our
6 substantial questions lack substantial merit, that you could
7 look at them and say, no, Mr. Niederluecke, good try, but
8 you're not getting that one. That's really the test, is
9 whether we have to think hard about this or whether or not
10 you're going to look at me and say, Mr. Niederluecke, you're
11 just wrong.

12 THE COURT: I don't really have an instinct on the
13 written description point. You're both describing such
14 different law to me that I fear I have to research this. I
15 say "fear" because it's always quicksand when I research
16 Federal Circuit law. It's just so tough.

17 MR. NIEDERLUECKE: Yeah. But you can't lose
18 sight, as I mentioned, there is undisputed evidence in the
19 record, Your Honor. We have our expert explaining as one of
20 ordinary skill in the art. He concluded that one of
21 ordinary skill in the art would not deem the inventors to be
22 in possession of a side opening anywhere but the rigid
23 portion. There is no evidence to contradict that, Your
24 Honor.

25 So it's a fact issue, as you noted, for the jury.

1 You have to look at that, and right now it's unrebutted
2 testimony from our expert. And they had a chance to rebut
3 it in their reply and didn't. So I think it's really
4 important, not just the law, but in the facts, that we have
5 unrebutted testimony from our expert that concluded that
6 after an analysis of pretty much what we're going through
7 right here.

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

10 MR. VANDENBURGH: Your Honor, could I have just
11 two more minutes on this topic?

12 THE COURT: Yes, but no more than that because my
13 court reporter needs a break.

14 MR. VANDENBURGH: Put slide 39 back up.

15 First of all, trying to decide whether their
16 position is is Examiner Williams smart or dumb because, you
17 know, she is the one that allowed claim 38 on the right.
18 That's the claim that we are asserting in this case that has
19 dependent claim 44 that we've concluded there is a
20 likelihood of success on infringement, and their validity
21 arguments, they just don't have a reference that shows it.

22 So this claim it is agnostic as to the location of
23 the side opening, the examiner allowed this claim.

24 THE COURT: Well, not entirely. I mean, I think,
25 as Mr. Niederluecke pointed out, this is fairly clear

1 evidence that it's not in the flexible tip portion.

2 MR. VANDENBURGH: Yes. And, of course, we know
3 that from the device that's disclosed. It's between -- in
4 the grand scheme of things it's between the push wire and
5 the reinforced tube.

6 THE COURT: But we know that she gets her hackles
7 up when it's defined as its own segment. Right? Here it
8 uses the word "segment." Obviously, she is distinguishing
9 between segment and portion and segment and segment. So we
10 have segment, segment, segment, and then we have this
11 portion of something. It's a portion of a segment, I
12 assume. And it's either going to be a portion of the side
13 opening or a portion of the reinforced segment, it sounds
14 like --

15 MR. VANDENBURGH: Exactly.

16 THE COURT: -- but not its own segment. So
17 there's kind of clues here as to what --

18 MR. VANDENBURGH: First of all, we're talking
19 about method of forming and arranging. But, yes, that's
20 exactly the point, is the claim is generic as to which of
21 those segments it is a part of.

22 And remember these senior examiners are also
23 knowledgeable on the law. I guess what this does come down
24 to, Your Honor, is the law on this. Again, I would suggest
25 starting with footnote 7 of the *Ethicon* case which draws

1 this distinction between affirmatively claiming something
2 and generically claiming something.

3 Your Honor, have we ever been in a patent case
4 where the claims are limited to the preferred embodiment,
5 that that's all they cover? We actually know that's a tenet
6 against -- you know, when we're dealing with claim
7 construction, we don't construe claims to limit them to the
8 preferred embodiment.

9 Mr. Niederluecke pulls up the descriptions of the
10 preferred embodiments and says, look, look what it discloses
11 here. That's because he wants you to say if the claims
12 aren't limited to the preferred embodiment, they're invalid
13 under 112. We know from basic claim construction usage that
14 that's not true.

15 THE COURT: His position is not that limited, but
16 it's -- you know, I just don't know what to tell you. I'm
17 sort of at a loss not knowing this law better.

18 MR. VANDENBURGH: Okay. All right. I will be
19 done. I will close on, again, I also didn't hear
20 Mr. Niederluecke address the *Titan Tire*, what it means to
21 raise a substantial question. What it means on validity is
22 that we have to show that they are not likely to succeed in
23 proving at least one claim is invalid by clear and
24 convincing evidence.

25 One of the things *Titan Tire* says is we look at

1 all the evidence. It's not like summary judgment where we
2 look at one side and not the other. We look at all the
3 evidence. We keep in mind the legal standard of proof, and
4 we decide whether or not the evidence shows whether they are
5 likely to succeed on validity. That's all it means. They
6 haven't done it here, especially with these two claims that
7 we've talked about today.

8 THE COURT: Okay. Thank you, Mr. Vandenburg.

9 Let's give my court reporter a break. We'll come
10 back and talk about the irreparable harm issue. This is the
11 one part of the brief I did understand. I've read the
12 arguments and understood the arguments, but I'll just invite
13 both sides to tell me anything more they want to tell me. I
14 don't really have any or hardly any questions about it, but
15 I'll just let you highlight whatever points you'd like to
16 make. So let's come back in about 10 minutes and we'll do
17 that.

18 THE LAW CLERK: All rise.

19 (A brief recess was taken.)

20 THE LAW CLERK: All rise. This court is now in
21 session.

22 THE COURT: Please be seated.

23 Mr. Vandenburg, can I see you at the podium
24 again. So as I have been going back on breaks, I have been
25 talking with my law clerk about what my initial impressions

1 are and what research I want her to do and so on. Honestly,
2 I drew a blank on this. You will have to help remind me of
3 this.

4 We have two claims that are really at play in this
5 part of the day, claim 44 of the '379 patent and the claim
6 36 of the '776 patent. All the others are wiped out by Itou
7 except for claim 32 of the '760 patent. I don't think you
8 have a likelihood of success on infringement on that claim.
9 Okay? So that leaves us those two that are at play, right?
10 Not right, but --

11 MR. VANDENBURGH: For the purpose of today, I
12 understand your position. Itou -- again doing the math, we
13 think it's not likely to be prior art especially on that
14 claim if Itou is prior art.

15 THE COURT: If Itou is prior art, right. Right.
16 Right. Yeah, I meant to put all the if's, then we'd have
17 these two claims.

18 So they have an obviousness -- in the chart in the
19 brief it's an anticipation attack on claim 44 of the '379
20 patent based on Ressemann alone and in view of Takahashi.
21 And I can't remember whether I invited you to address that
22 and, if I did, I literally can't remember what you said
23 about that, if anything.

24 MR. VANDENBURGH: I'm not sure if I did, but the
25 answer is simple because they're relying on Ressemann for

1 the complex side opening of claim 44. It's the one that has
2 a first angled portion, second angled portion, and a flat
3 portion in between. And the whole point on Ressemann is in
4 the final device that collar they keep pointing to that's
5 hanging out in space is buried in the final product. So in
6 the final product there is no -- there's just a simple
7 angled opening. There's no --

8 THE COURT: So your answer to why Ressemann --
9 okay. So Takahashi is what got us the one French point,
10 right?

11 MR. VANDENBURGH: I think they have been relying
12 on Takahashi for that or -- no, we didn't have a one French
13 limitation. I think it was for a single hemostatic valve.
14 At this point, I'm not sure why they're relying on a
15 secondary claim. They're certainly not relying on Takahashi
16 for a complex side opening.

17 THE COURT: No, but Takahashi -- I thought they
18 were -- I'll have Mr. Niederluecke -- we're sitting here
19 talking about him like he's dead, but he -- so Takahashi was
20 where I believe they found the one French limitation.
21 They're relying on Ressemann for everything else, which
22 would include the complex opening.

23 So your response would be the same, essentially,
24 as your response to the attack on the claim 36 of '776 using
25 Kontos, that Kontos is missing the side opening. The

1 complex side opening, your view is Ressemann doesn't give
2 you the complex side opening.

3 MR. VANDENBURGH: Correct.

4 THE COURT: It's basically the same argument on
5 both?

6 MR. VANDENBURGH: Correct, and on the Itou in view
7 of Ressemann as well. Ressemann just doesn't have that
8 feature.

9 THE COURT: Okay. Okay. Now I've got that right.
10 I think we -- probably if we said anything, it probably was
11 just 30 seconds and that's why it slipped my mind.

12 Okay. Is there anything you wanted to add to the
13 conversation I just had? That was --

14 MR. NIEDERLUECKE: No, Your Honor.

15 THE COURT: Your attack on the '379 patent is
16 Ressemann plus -- you get everything out of Ressemann except
17 one French and one French you get out of Takahashi.

18 MR. NIEDERLUECKE: Correct, Your Honor.

19 THE COURT: Now I'm ready to turn to irreparable
20 harm. Ms. Friedemann, you could've just walked over at 3:00
21 and you would have been on time for your argument.

22 MS. FRIEDEMANN: And that would have been lovely.

23 There is one preliminary issue that we wanted to
24 address. Since this next portion of the argument is going
25 to delve into sensitive financial information for both

1 parties, it has been designated as for attorneys' eyes only
2 under the protective order.

3 We have a number of folks here present in the
4 courtroom who are not privy to that information under the
5 protective order that's been entered by the Court. We would
6 request that the Court seal this record and require those
7 who are not permitted access to that information to exit the
8 courtroom for this next argument since it's certain to delve
9 into all of that information.

10 THE COURT: So it is a really, really, really high
11 standard to close a public courtroom and do things in
12 secret. I'm just going to ask you folks not to disclose
13 anything you think is confidential because I've never closed
14 my courtroom, except for child victims of sexual abuse, and
15 I'm not going to do it now.

16 I've read the unredacted briefs and so I know
17 those financial arguments and, obviously, I won't disclose
18 them in my order, but I just have to ask the attorneys to
19 try to talk around them.

20 MS. FRIEDEMANN: Okay. It's going to be very
21 difficult to do, but I assume that both of us will make our
22 best effort to not reveal each other's financial information
23 in light of that.

24 MS. NORGARD: Your Honor, if I may? So I think
25 actually that this is going to impact our argument more

1 severely than Medtronic's, is my guess anyway. In fact, VSI
2 is comfortable with having its information in the public
3 courtroom.

4 We would ask for the right to redact the
5 transcript and the record after the transcript is made
6 available. But in terms of having the courtroom open, VSI
7 is okay with its information being in the public.

8 THE COURT: So all I can tell you is I'm not going
9 to shut the courtroom.

10 MS. NORGDARD: Right.

11 THE COURT: So you both know that. And you can
12 just take that into account. You know, you can -- if you
13 want, you can say I rest on my brief because the bulk of
14 both of your briefs was devoted to the irreparable harm so,
15 obviously, I've read a lot about it.

16 In terms of the transcript, you know, for good
17 cause we can redact the transcript. I think what goes out
18 on the internet is different than what gets said in this
19 courtroom, but I can't make any promise about any particular
20 thing. You'll have to persuade me that you have good cause
21 to redact the transcript.

22 MS. NORGDARD: Understood.

23 THE COURT: So if you're at all worried, don't say
24 it is what I'm saying.

25 MS. NORGDARD: My point is I want to make my

1 record. I want to make my argument. Even for the
2 irreparable harm part of the argument, we're very condensed
3 in our words, obviously, given the extraordinary focus on
4 the merits necessarily.

5 I want to preserve the right to make my argument
6 in my record, which necessarily involves -- in fact, some of
7 my best evidence is Medtronic information and it's part of
8 the slides I'd like to show the Court.

9 Perhaps as an alternative, and I would ask --
10 Ms. Friedemann may respond to this -- maybe we turn the
11 screens off that face in the back and so the Court can see
12 the screens.

13 THE COURT: I'll turn the screens off if you would
14 like. That's fine. I'm not going to close my courtroom.
15 Never done it in a civil case and don't want this to be the
16 first.

17 MS. NORGARD: I understood, and we're not asking
18 for that to happen for our information.

19 THE COURT: This is on you. The words you utter
20 will go down in the transcript. You'll have a chance -- it
21 will be uttered in a public courtroom. It will go on the
22 transcript. You can later request redactions, and if you
23 show good cause I'll approve redactions. I can't promise
24 any particular ruling, obviously. I will have to rule on
25 them at the time.

1 We can turn the monitor off. I think I can turn
2 all the monitors off except mine, if that's what you're
3 asking for.

4 MS. NORGARD: Would that be satisfactory?

5 MS. FRIEDEMANN: Yes.

6 MS. NORGARD: I would like mine on --

7 THE COURT: You're asking a lot of the Court.

8 MS. NORGARD: I'm asking for more than I can make
9 happen for sure.

10 THE COURT: Okay. I think all the monitors except
11 -- are the ones on the attorney table still --

12 MR. VANDENBURGH: They are.

13 THE COURT: Is the big one? Is that TV off?

14 Okay. So why don't you attorneys power off your terminals.
15 Everybody's will be off except my staff and up here. They
16 will be faced toward me.

17 I guess if the attorneys want to look at the -- if
18 you go to the side so they are out of the view of the people
19 in the gallery, you could follow it that way as well. I
20 have mine here. Okay.

21 MS. NORGARD: Did you have a preference for which
22 party goes first, Your Honor?

23 THE COURT: Nope.

24 MS. NORGARD: I'm happy to go first.

25 THE COURT: Okay. I thought you were going to do

1 it without notes. I was going to be very impressed, now
2 less so that you're getting them.

3 MS. NORGARD: Sorry. I hope it doesn't just go
4 down from here.

5 THE COURT: All right. Ms. Norgard.

6 MS. NORGARD: Thank you, Your Honor. And thanks
7 for your patience and your attention today.

8 Is everybody okay with how the screens are
9 showing? Okay. And I will do my best to respect the
10 information that Medtronic has designated confidential.
11 But, again, I do want the right and I do want to make my
12 record about the irreparable harm here because although it
13 was briefed, and hopefully well, again, it was condensed and
14 we do have some points that we need to make.

15 The first part of our argument I don't think is
16 confidential in the least, and it's a well-known concept
17 that a preliminary injunction is an equitable remedy and it
18 exists to preserve the status quo so that irreparable harm
19 does not occur. A PI gets ahead of the irreparable harm so
20 you're not in the situation where you cannot remedy what has
21 already occurred. And the PI, and the Federal Circuit case
22 law is replete with this, it protects the statutory right to
23 exclude, which, as we all know, is derived from the
24 Constitution.

25 Courts time and time and time again recognize the

1 importance of the patent system in encouraging innovation.
2 It incentivizes innovation in exchange for this exclusionary
3 period that we're all aware of.

4 I think it's also really important to recognize
5 that patent rights do not only protect commercial interests.
6 We heard Mr. Niederluecke at the beginning of the day speak
7 about his brother, I believe, who just had a procedure
8 yesterday most likely from a device that was patented. I
9 don't think there are many people in this room, if any, who
10 have not benefited from a patented medical device. The
11 bargain that's set up and rooted in the Constitution is
12 there for a reason, and it serves our population. It serves
13 our society well.

14 As the Federal Circuit has said, injunctions are
15 vital to preserving this system. As the Court knows, there
16 are four factors that we have to go through to obtain an
17 injunction. Mr. Vandenburg argued very well this morning
18 on the merits, and I'm now going to address the equitable
19 factors of the harm and the balance of harms and the public
20 interest.

21 So going to irreparable harm first. As the Court
22 knows, this case is about the GuideLiner, and the GuideLiner
23 is a product that was conceived in Minnesota. It was grown
24 in Minnesota. Mr. Root was here earlier today. He built
25 the company in Maple Grove, and the product is still made in

1 Maple Grove today.

2 It was a game-changer product for VSI, and it is a
3 game-changer product for Teleflex as well. And as we see on
4 this slide, which is addressed in the briefs, GuideLiner
5 came out in 2009, and it really created this guide extension
6 market that we've been talking about today.

7 It was, again, a product that put VSI, Vascular
8 Solutions when it existed in its prior form, on the map.
9 And it's also the primary reason that Teleflex purchased the
10 company. And it continues to this day to be a flagship
11 product and a business driver for what is now the
12 Interventional Business Unit of Teleflex. What used to be
13 VSI now operates as the Interventional Business Unit of
14 Teleflex.

15 [REDACTED]
16 [REDACTED]
17 [REDACTED] It is continuing to be a very
18 important product. It is the reason for hundreds of jobs
19 here in Minnesota and around the country, and I think that's
20 very important to recognize.

21 Before I move on, I just want to cut off an
22 argument that Medtronic has made kind of in a macro sense,
23 and that is this idea that GuideLiner is but a drop in the
24 bucket for its new owner, Teleflex.

25 We need look no further than the Federal Circuit

1 in the *Robert Bosch* case which flatly, flatly as a matter of
2 law says that does not matter. The fact that an infringer's
3 harm affects only a portion of the patentee's business says
4 nothing at all about whether that harm can be rectified.
5 And, in fact, in that case the Federal Circuit reversed the
6 district court for attributing too much weight to, in that
7 case, the non-core nature of --

8 THE COURT: But it's still relevant. I mean,
9 speaking generally, when you have a case involving two
10 billion dollar companies and the particular product accounts
11 for only a tiny, tiny fraction of either company's revenues,
12 you don't have the -- what your goal is in a patent case
13 when you're trying to get a PI -- and since everybody in the
14 courtroom is about money and it's about making money -- is
15 to try to show the judge there's something here other than
16 money, because money is rectifiable. You could get someone
17 to write a check. If it's some small company that might
18 literally be destroyed if they don't get a PI so that the
19 company no longer exists and people are no longer working,
20 that's different than if you have thousands and thousands of
21 employees in a company.

22 So it's still relevant, even though it's not
23 determinative. If it weren't relevant, you wouldn't have
24 made such a big deal -- when you were briefing in the voice
25 of VSI instead of in the voice of Teleflex, you wouldn't

1 have made such a big deal about the fact that it was the
2 core and it was basically the whole company built around it
3 and so on. Your own briefing recognizes the relevance.

4 MS. NORGDARD: Your Honor, I think that the *Bosch*
5 case says otherwise.

6 THE COURT: Well, your first brief -- then you
7 should have cut several pages out of your first brief. You
8 briefed the importance of this being a small company, and
9 this being when it was VSI, and this being critical to the
10 company, and it's the identity of the company, and it's
11 known as the GuideLiner company. All that mattered when it
12 was VSI, but then when it became Teleflex you're telling me
13 it's all irrelevant.

14 MS. NORGDARD: No, Your Honor, I'm sorry, that's
15 not the point I was trying to make. I'm not saying it's
16 irrelevant at all. I'm saying that, in fact, the GuideLiner
17 is still very important to the Interventional Business Unit.
18 It's absolutely important to that business unit. It's very
19 important to the jobs that that business unit creates.

20 What I'm responding to sort of peremptorily is
21 Medtronic's argument that the GuideLiner is but a drop in
22 the bucket for Teleflex. And I think what the *Bosch* case
23 does is just simply cut that argument off as a matter of
24 law. But I am by no means suggesting that the GuideLiner
25 doesn't continue to be a very important business driver for

1 the company today, and I'd like to actually speak to that
2 issue next if I may.

3 THE COURT: Oh, okay. I think we're talking past
4 each other. Go to the next point.

5 MS. NORGARD: I'd be happy -- I don't want to talk
6 past the Court on something that's --

7 THE COURT: The point I'm making is that the fact
8 that something is a drop in the bucket to a gigantic,
9 multi-billion dollar company makes it less likely that
10 there's anything at stake, other than money. If a product
11 is the entirety of some small business's business, there's a
12 greater likelihood that there will be something at stake
13 other than money.

14 It's not determinative. It's not a pure ratio.
15 It's just I don't think it's irrelevant, and I would bet my
16 life I could go find Federal Circuit cases on the other side
17 that as one of many factors to consider in deciding whether
18 harm is irreparable -- and, again, if it's just money, it's
19 reparable; money harms are reparable -- that the fact that
20 something has a tiny impact on a gigantic company versus has
21 a devastating impact on the small company is something that
22 the judge can factor into his calculus.

23 So I don't take this to mean that it's literally
24 irrelevant that what you're talking about is a teensy, tiny
25 impact on a gigantic company, as opposed to a devastating

1 impact on a small company.

2 MS. NORGDARD: Well, and certainly the Court sits
3 in equity and that --

4 THE COURT: In equity almost everything is
5 relevant.

6 MS. NORGDARD: Yes, I acknowledge that. But what I
7 do take issue with is this is not a drop in the bucket
8 either for the Interventional -- certainly not for the
9 Interventional Business Unit, nor is it a drop in the bucket
10 for Teleflex.

11 I also take issue with these are not two
12 equally-placed companies.

13 THE COURT: Well, Teleflex is, what, a couple
14 billion dollars a year in revenue and Medtronic is 30, 25
15 billion?

16 MS. NORGDARD: Many, many times that.

17 THE COURT: Right. But the small one is still a
18 \$2 billion a year company.

19 MS. NORGDARD: Right. And the business unit that
20 this product impacts is but a part of Teleflex.

21 THE COURT: But the business unit -- the plaintiff
22 here is Teleflex, not the business unit of Teleflex.

23 MS. NORGDARD: Understood. And, of course, I
24 understand the Court's position in view of the equities.

25 But I do want to explain and continue to make my record

1 about the GuideLiner being a very important product that is
2 not merely equatable to dollars and cents in lost GuideLiner
3 sales. It goes far beyond that.

4 What I've got before the Court here is a
5 presentation that was made to Teleflex when Vascular
6 Solutions was in its prior form showing GuideLiner's revenue
7 being significantly beyond anything in the top 10 products
8 of the company at that time and 25 percent of the company's
9 sales at that point in time. It was a major reason that
10 Teleflex purchased the company.

11 THE COURT: This is showing that GuideLiner made
12 up 25 percent of VSI's sales at the time VSI still existed?

13 MS. NORGARD: Correct. Yes. This was, again,
14 part of the presentation that Mr. Root made to Teleflex when
15 the two were negotiating and engaging in the negotiations
16 that led to the acquisition.

17 But on the right here -- and this is a major,
18 major point of our briefing, but I want to emphasize it
19 here -- pointing out GuideLiner as an in-the-door product.
20 That phrase becomes important not only for us, but we're
21 going to see it in Medtronic's own documents as well when it
22 talks about the Telescope, and right below that, as a "big
23 ticket" item.

24 Actually, I want to stop here for a moment because
25 one thing we haven't talked about, although the Court may be

1 aware, the GuideLiner is used in coronary catheter
2 procedures, but in a specific segment of those, in complex
3 coronary procedures. It's known as complex PCI. And that's
4 important because even the Interventional Business Unit of
5 Teleflex with GuideLiner and these niche products that it
6 has, GuideLiner is a niche product that serves the complex
7 PCI market, very differently situated than a Medtronic or a
8 Boston Scientific or an Abbott, which has a whole suite of
9 products that serves the entire coronary procedure from
10 normal stents to normal catheters and all the things that
11 the physicians or the doctors are using in these
12 catheterization labs. Medtronic has a whole suite of
13 products. VSI has a very small part of that. This complex
14 PCI market is what the GuideLiner serves.

15 THE COURT: What about Teleflex?

16 MS. NORGARD: Well, when I talk about VSI, as we
17 did in our briefs, we really have done that just to be
18 consistent with the way that the Court is dealing with the
19 company and --

20 THE COURT: Does Teleflex offer the entire suite
21 of products across the coronary --

22 MS. NORGARD: It does not, no. No. VSI, now
23 Interventional Business Unit of Teleflex -- and I'm happy to
24 use whatever nomenclature is most easiest for the Court.
25 Again, we chose "VSI" because that's the nomenclature that's

1 used in the *QXM* case, same party.

2 It does not have the full suite of -- any suite of
3 stents or normal catheters or anything else. The
4 Interventional Business Unit continues to serve a very niche
5 market, and the GuideLiner continues to serve this complex
6 PCI market. The Interventional Business Unit of Teleflex
7 does not offer -- we do not play on the same playing field.

8 THE COURT: What I'm trying to get at is whether
9 you're purposely saying the "Interventional Business Unit"
10 and cutting out a part of Teleflex that does play on the
11 same --

12 MS. NORGDARD: No. No. I don't believe so. No.
13 They have other divisions with other products for sure, and
14 I can't stand here before you and tell you what those are.
15 But I can tell you that they are not in this standard PCI
16 space. They are not -- as far as I know as I stand here
17 today, there is no other business unit of Teleflex that is
18 competing against Medtronic for stents or catheters.

19 THE COURT: That was my question.

20 MS. NORGDARD: Yeah. No, they are very different
21 kinds of products. And if I tried to describe them too far
22 beyond that, I might stray a bit too far.

23 THE COURT: That's okay.

24 MS. NORGDARD: So going back to this complex PCI
25 market, what it does -- what I'm trying to explain is that

1 this Interventional Business Unit of Teleflex even today
2 still continues to serve this niche market, which is really
3 important because it really explains why having GuideLiner
4 as this door-opener is so critical.

5 So VSI, or the Interventional Business Unit, can't
6 walk into a cath lab -- is the Court conversant with a
7 catheter lab, the place where these procedures are taking
8 place?

9 THE COURT: Uh-huh.

10 MS. NORGARD: -- can't walk into a cath lab and
11 say, oh, I can serve all of your needs for all of your
12 procedures here. VSI is coming in for these niche
13 procedures. So that makes them different and sort of
14 marginalized.

15 But when they came up with the GuideLiner -- first
16 as Vascular Solutions, now as the Interventional Business
17 Unit of Teleflex -- that opened the door for this little
18 niche player to these cath labs and all the other niche
19 products that the Interventional Business Unit sells.

20 So this concept of being a door-opener, GuideLiner
21 being a door-opener, is very critical not only for the
22 revenue of GuideLiner itself, but for making all of these
23 other sales of products possible.

24 What we see time and time again in the record --
25 both on our side and on Medtronic's -- is this concept of a

1 door-opener and its importance.

2 This is the declaration -- the first declaration
 3 of Amy Welch where she explains that the 353 hospitals that
 4 she is referencing in this paragraph purchased GuideLiner as
 5 their first VSI product; in other words, GuideLiner is their
 6 in-the-door product. These customers then went on to
 7 purchase and introduce into their labs on average five
 8 additional VSI products; in other words, non-GuideLiner
 9 products. The GuideLiner opened up the door for these other
 10 VSI products to be sold, in this example 353 hospitals.

11 Mr. Kouchoukos, another declarant on behalf of the
 12 plaintiffs, explained that

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

19 This is just an additional paragraph from
 20 Mr. Kouchoukos' declaration.

[REDACTED]

[REDACTED]

[REDACTED]

24 Here again we have Amy Welch explaining that
 25 because of how important GuideLiner is to its sales

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strategy, it's a [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Another declarant that we've submitted in the record, Josh Brenizer, he is a senior engineer in the R&D Department. He talks about GuideLiner being in the door for access, for the Interventional Business Unit's access to doctors. That's important because we always want to be talking to doctors about what we can be doing next, what's important, what are their needs, and how can we serve those needs. Because of the reputation of GuideLiner, doctors will talk to us about the technology. And, again, that's beyond just sales. That's R&D. That's going deeper into the company.

And just wanted to put this slide up before the Court as well because this is now a Teleflex document, and so now we're in the Interventional Business Unit of Teleflex. Here we have a slide from a sales and marketing presentation of -- I believe this is from 2018 or early '19.

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[REDACTED]

The case law endorses wholeheartedly the importance of door-opening and pull-through of a top-leading product like GuideLiner. We see it in *Metalcraft of Mayville*. This case happened to involve lawnmowers, but the Federal Circuit here says the sales lost by Scag, the patentee in that case, are difficult to quantify due to this ecosystem effect where one company's customers will continue to buy that company's products and recommend them to other others.

Apple v. Samsung, which is a Federal Circuit case from 2012, recognizes in that case Apple could lose sales of tag-along products, including apps, other devices, and future models of its products. Recognizing loss of customers and this downstream future purchases are difficult to quantify. These considerations support a finding that monetary damages would be insufficient.

Decade Industries, this is a case that Judge Doty decided a number of years ago, but it reflects the same concept. Here, again, the patentee had this business plan

1 based on a leading patented product, and the infringement in
2 that case frustrated the patentee's general business plan,
3 which was the success of that top product providing an
4 opportunity for Sanus, the patentee, to leverage its entire
5 product line into retail stores.

6 And just one final slide on this concept, Your
7 Honor. This is an older case, pre *eBay*, but the concept is
8 the same, endorsing specifically, in quotes, this
9 "pull-through" theory; that Ethicon, the patentee there, had
10 argued that its patented product was the top of the line and
11 it made all of its other sales -- many of its other sales
12 possible. And the court in *Ethicon* says, It would be
13 difficult to calculate money damages under these
14 circumstances.

15 So, again, the concept being when you have this
16 top-leading product that pulls through or opens the door for
17 other products, as is the case with the GuideLiner, the loss
18 of those sales, the loss of those relationships, the loss of
19 those future engagements, those are all difficult to
20 quantify and weigh heavily in favor of irreparable harm.

21 Here's, Your Honor, what I alluded to earlier. We
22 have evidence of the harm we've already suffered, but I'd
23 like to start with the harm that is amply shown in
24 Medtronic's own documents.

25 As I mentioned earlier, the GuideLiner and

1 Telescope, in fact, are sold for use in this complex PCI
2 space. I put this slide up here because I think it's
3 important to understand why Medtronic cares. Medtronic has
4 never been in this space before. We've never had to compete
5 against Medtronic with the GuideLiner or, as far as I know,
6 with any other products. Again, we play in this niche
7 market, this small part of the cath lab. Medtronic largely
8 owns these cath labs in other senses in the more commodity
9 space, but here's the reason: Medtronic is interested, and
10 I'm sure many are, because of the increased focus on complex
11 PCI patients. It's going to drive continued growth and
12 procedures. More procedures means more devices. More
13 devices means more revenue. That's the first part of the
14 story. Everybody knows that this complex PCI market is a
15 growing part of the market.

16 This article, and the entire link is in the record
17 for the Court should you be interested, but it talks about
18 why this is so. There was sort of a flattening of the kind
19 of standard cath lab procedure market. But it's this
20 complex space that's growing for lots of reasons, because of
21 the population, because of advancements in technology we're
22 able now to get to lesions in the heart and to treat people
23 that 10 years ago weren't really possible and in large part
24 made possible because of the GuideLiner for reasons that
25 we've been talking about.

1 So Medtronic sees this -- and this is a Medtronic
2 slide now, a Medtronic slide talking about why -- a
3 marketing and sales strategy slide -- why they're getting
4 into this market. How can Medtronic enter and become a
5 reference in this complex PCI market? They recognize that
6 this market is growing at a faster rate than non-complex
7 PCI, and they recognize that complex PCI is top of mind for
8 interventional cardiologists. Those are the physicians that
9 are using these.

10 So here's where their foot through the door or
11 their pull-through comes into play. They see Telescope --
12 "GEC," that's the shorthand for guide-extension catheter --
13 their first entry into this complex coronary toolkit, they
14 see that as their foot through the door.

15 Medtronic can hardly quibble with GuideLiner being
16 our foot through the door, our door-opener when this is top
17 of line and one of the main reasons that they're entering
18 this space themselves.

19 It's explained in the next bullet point, which I
20 think is very important. Their USA plan is to have
21 increased DES business -- and "DES," Your Honor, stands for
22 drug-eluting stent; that's in the non-complex space -- they
23 want to enhance and support and get their foot in the door
24 so that they can grow and support their DES business as a
25 result of improved complex PCI case access.

1 Of course, they want to gain access to a
2 previously untapped revenue stream. And how are they going
3 to do it? Well, the largest medical-device company in the
4 world is going to leverage their strong guide catheter
5 market position, they're going to leverage their brand, and
6 they're going to leverage their enormous sales force to
7 drive market share.

8 There's one more point on this slide that speaks
9 to what I mentioned earlier and it's actually above. The
10 preface is how do our competitors' portfolios stand out in
11 the complex PCI market? You'll see that neither VSI nor
12 Teleflex is among them. Medtronic's competitors in the cath
13 labs, as they see them, are Boston Scientific and Abbott.
14 These are the gorillas that are competing in the cath lab.
15 VSI, and even the Interventional Business Unit of Teleflex,
16 is simply in the way. We are not a major player. The big
17 three are Medtronic, Boston, and Abbott.

18 So another slide from one of Medtronic's sales
19 presentations. What are their commercialization objectives
20 for this product? Well, again, they want to grow revenue
21 and market share via [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED], VSI being the primary

1 market share owner in this case.

2 This is an important point, too. How are they
3 going to do it? They're going to rocket launch. This is a
4 theme that we see in their papers and their sales
5 presentations time and time again. It's not a slow entry.
6 They're not dipping their toes. They're going to rocket
7 launch into it, and they're going to get [REDACTED] percent market
8 share in three years. That, Your Honor, is indeed a market
9 launch in a situation where Teleflex and the Interventional
10 Business Unit holds 70 percent as we sit here today.

11 Here's another way they're going to do it; again,
12 another Medtronic presentation. I just want to take a
13 moment to say fiscal year for Medtronic goes from April to
14 April. So fiscal year '20 actually is April 2019 to April
15 2020, just to orient the Court to the years that we're
16 talking about here.

17 So what this slide is showing is that they're

18 [REDACTED]
19 [REDACTED]. The light blue that the Court sees on the
20 screen is how they're going to do it. Then the actual
21 numbers are on the bottom of the screen. [REDACTED]

22 [REDACTED]
23 [REDACTED].

24 And here again what is their goal? To convert --
25 again, not to create new accounts and not to say that that

1 would be somehow in their favor if they were -- but here
2 again they want to convert 45 percent of evaluated accounts.

3 This, also, is another slide from a Medtronic
4 presentation -- actually, it's a Medtronic -- it's called an
5 NPV. I believe it's net present value. What that is, Your
6 Honor, NPV, it's a tool. It's an analytical tool that
7 companies use to decide if an investment, like the Telescope
8 in this case, is a wise one for the company, if it's going
9 to create the business and generate the business that they
10 want it to.

11 So what I have before the Court right now is a
12 part of this very large Excel spreadsheet that they call the
13 NPV, their deep analysis into this product.

14 What we see here, Your Honor, is that the rocket
15 launch, they're going to sell [REDACTED] of Telescope in
16 the first three years alone and get [REDACTED] market share,
17 again, all of these consistent with this rocket launch
18 concept. They're going to come in and take our knees out
19 effectively.

20 So the other thing that we see a lot in the case
21 law, and I just want to emphasize it here, in Ms. Welch's
22 declaration she talks about how one of her sales people
23 named Kevin Daigle was signed up or -- these sales people
24 have opportunities to go into the labs. Those are called
25 lab days. Those are really important sales opportunities

1 for sales people to go into the cath labs, meet with the
2 doctors, the people who are using these devices.

3 Mr. Daigle went to his lab day, his prescheduled
4 lab day, and he was told to leave because Medtronic was
5 there presenting the Telescope. This head-to-head
6 competition -- Medtronic coming after the GuideLiner -- is
7 an important factor when considering irreparable harm; the
8 two cases I've noted here at the bottom just being examples
9 of that.

10 But what I've highlighted here in yellow is
11 important because it's otherwise pretty hard to see. It
12 goes to this head-to-head concept. Medtronic is not -- the
13 Medtronic device is the one with the green tab. The
14 GuideLiner is in the black. They're taking on GuideLiner
15 head to head.

16 This next slide is, again, from Medtronic's NPV
17 analysis, their deep dive into the economics behind this,
18 and it shows Medtronic's own evidence is illustrative of how
19 they are going to gut GuideLiner's market share. So they're
20 going to take us from [REDACTED] percent.

21 I've tried to align, Your Honor, the numbers with
22 the columns that are above so each number corresponds to a
23 year. But very clearly this is Medtronic's plan to take our
24 market share from [REDACTED] percent.

25 Here, again, is another slide from Medtronic's

1 sales presentation. They're going to gut prices to achieve
2 their rocket launch. Specifically, they're going to
3 minimize price barriers.

4 [REDACTED]
5 [REDACTED]
6 [REDACTED]. I assume we're
7 going to hear a little bit about this when Ms. Friedemann
8 takes the argument. Medtronic's not dumb, Your Honor.
9 They're not going to leave money on the table. They're
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED].

14 Here, again, another presentation showing -- this
15 is in the worldwide -- "WW ASP" is worldwide average selling
16 price. [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]

20 So here's what's going to happen to GuideLiner
21 prices in Medtronic's own documents and analysis. Again,
22 Medtronic's deep dive into why this makes sense for them to
23 be in the business. Medtronic sees VSI's average selling
24 price falling from \$454 down to \$332 annually over the
25 coming years.

1 Medtronic is doing this because before they
2 effectuated this strategy, they did a lot of research and
3 they studied what is going to motivate the market, what is
4 going to motivate these cardiologists to buy Telescope,
5 instead of the GuideLiner, and this is what they learned.
6 Your Honor, this is the results of a survey that Medtronic
7 did. The date is a little hard to see. It's April of 2018.

8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]

14 They also learned that part of -- the light blue,
15 I believe, is the European Union. The dark blue is the
16 United States. So the EU has some different reflections,
17 but the United States respondents mentioned that bundling
18 was important.

19 The Court may recall that bundling is something
20 that we talk about in our briefs. This concept of bundling
21 and rebates is a pricing strategy that Medtronic employs to
22 be able to maintain a high sticker price; in other words, to
23 maintain a high price on the package, but then be able to
24 really bring down the price. They do that by bundling the
25 Telescope with other of these ubiquitous Medtronic products.

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Here's what's important about this slide, Your

Honor:

[REDACTED]

. It's part of their strategy for this rocket launch and part of the reason they'll get the market share that they are going to get.

And the last slide from this particular survey is also very important because we have a declaration from a Medtronic employee named Mark Cardoso who says, Well, there's room on the shelf for everybody, that hospitals will stock other guide catheters or three. Medtronic's very own research disputes this. What Medtronic's own research says is

[REDACTED]

Your Honor, we also submitted evidence that

1 Medtronic is already winning this price war. This is from
2 Amy Welch's declaration where she's explaining the situation
3 that recently happened at the [REDACTED]. This
4 is an example of how these Medtronic pricing strategies come
5 into play. [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED].

10 Here's, again, another way that really the
11 difference in these companies' size and their market
12 position in the general sense comes into play. [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED].

16 We can't compete against Medtronic's ability to
17 offer these rebates based on -- rebates for Telescope based
18 on the entire suite of products that Medtronic is offering,
19 and that these hospitals are buying, and that they rely on
20 in their day-to-day procedures. We just can't compete
21 against it.

22 This slide, Your Honor, is simply to show the
23 instances in the record and their citations of where we have
24 lost accounts, where we have declining sales, and where
25 we've had to lower prices. I would submit, Your Honor, this

1 is just exemplary.

2 This is happening all over the country. It's a
3 fluid and rapidly-evolving situation. Our information at
4 this point was as good as the day that Ms. Welch was deposed
5 and then her later declaration. Again, the evidence is
6 certainly mounting every day, but this is what's in the
7 record, and I wanted to make it clear for the Court.

8 This next slide is just an example that Ms. Welch
9 includes in her declaration. It's an email from one of the
10 people that report up to her. In this case, Mr. Steitzer
11 (ph) reports in less than a week -- this is back in
12 September of 2019 -- three of the people in his region,
13 three sales people in his region, confirmed a threat,
14 including a lost account.

15 At this account [REDACTED] the doctors there had
16 this evaluation, presumably one of these eval free trials,
17 and they apparently feel they can use the Telescope. Quite
18 apart from whether they're going to convert or not, they've
19 already asked VSI, or Interventional Business Unit, to lower
20 its price. So the impact of even Telescope being in the
21 market and the pricing that they're able to offer has
22 already had this price erosion effect on VSI.

23 This next example is from a hospital [REDACTED]
24 [REDACTED], another example of Medtronic bundling Telescope with
25 balloons and stents, as I was explaining earlier, starting

1 immediately. That's a powerful way to reduce prices, and to
2 take away GuideLiner business, and to slam the door shut to
3 VSI and its other products.

4 Here, again, the *Metalcraft* case affirming the
5 district court preliminary injunction: It's impossible to
6 quantify the damages caused by the loss of a potentially
7 lifelong customer. It's impossible to quantify, Your Honor,
8 the losses that are mounting with Telescope sweeping over
9 the nation and reducing prices and converting accounts.

10 I mentioned lost lab days earlier, and I won't
11 belabor the point, but this is the point in Amy Welch's
12 declaration where Mr. Daigle was asked to leave because
13 Medtronic came in and was presenting the Telescope.

14 In her deposition Ms. Welch explained, again, this
15 concept of why it matters, why lost lab days matters,
16 because the sales people on a lab day are able to be in
17 there for cases. They're able to be training physicians,
18 not only on GuideLiner but other products as well, and to be
19 there to remind physicians, oh, you're doing this procedure,
20 well, I have even something else in my bag that might be
21 helpful to you, but again, GuideLiner making that possible.

22 So when Kevin Daigle loses his lab day, he lost
23 not only sales opportunities for GuideLiner, but everything
24 else in his sales bag.

25 And, again, this opportunity to engage with

1 doctors is also diminished when the GuideLiner sales and
2 access is diminished.

3 And, finally, Your Honor, on this point, lost
4 sales also -- we talk about how we believe it's going to
5 erode our sales force. We've already had a casualty in this
6 regard from our Marketing Director, Mr. Tom Kouchoukos, who
7 explained in his declaration [REDACTED]

8 [REDACTED]
9 [REDACTED].

10 Mr. Kouchoukos now works for a different company
11 in large part because, absent a preliminary injunction, [REDACTED]

12 [REDACTED]
13 [REDACTED].

14 He goes on to explain that he thinks -- and he was
15 with the company for a number of years -- as explained in
16 his declaration, he thinks [REDACTED]

17 [REDACTED]
18 [REDACTED]
19 [REDACTED]. So we

20 anticipate, Your Honor, that additional attrition is just
21 around the corner if a preliminary injunction is not entered
22 to preserve the status quo.

23 I want to address briefly another argument that
24 Medtronic makes, and that is about the Boston Scientific
25 license. We know, and the Court knows, and it's a plain

1 fact that VSI licensed Boston Scientific back in 2013. I
2 believe the license came to be in 2014. That was when -- it
3 occurred in the settlement of the litigation between VSI and
4 Boston Scientific.

5 The first critical point about that is that it was
6 a license of duress. It was not a license that VSI wanted
7 to enter. It was a license that VSI had to enter because
8 that was the time that the DOJ was bringing criminal charges
9 against the company and Mr. Root. We couldn't fight two
10 battles of those magnitudes at the same time, and the
11 GuideLiner would have to take second place in that when
12 Mr. Root's freedom was at play.

13 As we had put in the record, it was a \$25 million
14 case where we ultimately were exonerated, and Mr. Root in
15 full, but the company's full attention had to go to that
16 matter and so, therefore, we had to settle that case. We
17 didn't want to do it, but we did, and it's part of the
18 record.

19 So what does it show? I would submit, Your Honor,
20 that the VSC license and our experience with it actually
21 shows why a preliminary injunction in this case is
22 important.

23 First of all -- and I think that the Court
24 recognizes the case law that there is no -- the Supreme
25 Court has rejected any blanket rule that the fact that a

1 patentee has licensed the patent-in-suit, that there's any
2 sort of blanket rule that the patentee cannot get a
3 preliminary injunction in the case. That's the eBay case.
4 But it's also played out in the Federal Circuit time and
5 time again.

6 *Accumed* is an example where there were two prior
7 licenses in that case, and the Federal Circuit said the fact
8 that *Accumed* had had those licenses out there does not mean
9 that the district court abused its discretion in not holding
10 that *Accumed* must now grant a further license to Stryker.
11 In other words, in that case the district court entered the
12 preliminary injunction against Stryker in that case.

13 *Apple v. Samsung* is another example where the
14 Federal Circuit in that case found that the district court
15 abused its discretion when it gave improper weight to
16 *Apple's* previous licensing activities.

17 So while the license is a factor, it has to be
18 understood in context, and it certainly does not in any way
19 preclude a preliminary injunction, and here's why, Your
20 Honor: First of all, as a matter of law it doesn't, but
21 also as a matter of fact.

22 *Medtronic* has come forward with a declaration of
23 an expert named Mr. Lettiere, and he makes some macro
24 observations and some general calculations over time, but
25 what he doesn't recognize and what this Court, I think,

1 would want to know and I think is very important is to get
2 one layer deeper.

3 So the license to VSC was in July of 2014. At
4 that time, Guidezilla I -- that's VSC's product, Guidezilla
5 I -- was on the market. Guidezilla I -- and we talk about
6 this in our briefs and, in fact, we substantiate it with a
7 number of -- an exhibit with all the -- what's called the
8 MAUDE database; that's where they have to report failures of
9 the device. Guidezilla I was pretty much an inferior
10 device. It wasn't -- granted it did make inroads into the
11 market for sure, but it was largely seen as an inferior
12 device. Boston Scientific really didn't focus on blanketing
13 the country and selling that product the way that Medtronic
14 is with Telescope.

15 Things changed in March of 2017 when Guidezilla II
16 came along, a markedly better product. It solved a lot of
17 the issues that were experienced with Guidezilla I, and
18 Boston Scientific did a better job and has been doing a
19 better job selling it.

20 This is a slide where I'll pass, with the Court's
21 permission. I'm sensitive to the fact that Boston
22 Scientific information is at issue here, and so I've
23 genericized this slide. But with the Court's permission, I
24 would hand up a slide with the details, if that's
25 acceptable?

1 THE COURT: Okay. Sure.

2 MS. NORGARD: And so this slide contains VSC
3 outside AEO information, which is strictly confidential to
4 the outside lawyers and, obviously, the Court, but what it
5 shows is a comparator really of what Boston Scientific sold
6 of that Guidezilla I product in the first three years and
7 the total, and the numbers are there, compared to what
8 Medtronic projects that it's going to sell in its first
9 three years. I think the comparison speaks for itself and
10 really illustrates the difference in these products and
11 really the inferiority of the Guidezilla I product.

12 So, again, going back to Mr. Lettiere, his report
13 is attached to the Friedemann declaration at Exhibit HHH.
14 It's important to look at where Guidezilla II comes into
15 play, and here's why for each of these; and I'll start with
16 revenue. [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED].

20 So Medtronic would like to make the argument that
21 GuideLiner -- VSI didn't really suffer so much when Boston
22 Scientific came on the market, so there's really no reason
23 to think that we're going to suffer when Medtronic comes to
24 the market. And, Your Honor, this exhibit shows that when a
25 good product is on the market, things change.

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[REDACTED]

So this is another chart from Mr. Lettiere's report where he would like to mark in time the beginning with Guidezilla I. Guidezilla II shows in graphical format that a good product on the market really does have an impact. Now we see the revenue declining with the entrance of Guidezilla II.

[REDACTED]

So I think, Your Honor, that these numbers -- and, again, Medtronic's own numbers and analysis -- show that with a good product on the market, which we certainly expect and experience Telescope to be, especially in its very near similarity to GuideLiner, there is a material impact on GuideLiner, the products that follow GuideLiner, and the company, the Interventional Business Unit.

Again to address a point that Medtronic makes in its brief, they say and Mr. Lettiere's report attempts to substantiate that, well, the company continued to be profitable. This is the *Douglas Dynamics* case, which is a Federal Circuit case from 2013, that dismisses the idea that

1 just because a company battles through and competes
2 successfully or doesn't totally disintegrate in the face of
3 competition, that that somehow negates the irreparable harm.

4 And, again, this concept of market transformation
5 is an important one to recognize. Right now there are two
6 major players in the market. There's VSI and Boston
7 Scientific. A third market player, it's a game changer.
8 It's a dynamic shift in the market in large part, too,
9 because again we saw who the big gorillas are in the cath
10 labs. It's Boston and Abbott, along with Medtronic. But a
11 three-player market is very different than a two-player
12 market.

13 The *Accumed* case recognizes that adding a new
14 competitor to the market may create irreparable harm that
15 prior licensees did not. Again, *Accumed*, a case where there
16 had been prior licenses, and the Federal Circuit recognizing
17 that dynamic, that shift in the market.

18 This is Mr. Kouchoukos who explains that, again,
19 going from two to three players in this market is going to
20 drive the guide-extension market from what was a premium
21 market to a commodity market, and that guide extension
22 catheters will just become a price game. And that's
23 certainly what we see in Medtronic's own documents showing
24 the price gouging that they're willing to engage in to win
25 this business to open the door and really bring through

1 their other products and support their entire business line.

2 I'll just briefly touch on this concept of
3 forecasts. Medtronic has argued that while VSI didn't
4 change its forecasts so dramatically with Telescope on the
5 horizon, but when you look -- there were two forecasts that
6 they rely on. The first is Friedemann Exhibit U. That is a
7 2017 forecast, so long before Telescope was on the market.
8 What it's showing and what Medtronic had focused on was
9 GuideLiner being a limiter. This is what we see focused on
10 in Medtronic's brief.


11 Mr. Jagodzinski, who participated and was part of
12 preparing these forecasts, explains that GuideLiner was a
13 limiter because of Guidezilla II. We learned from the
14 previous slides why that was.

15 THE COURT: Remind me again what "limiter" means.

16 MS. NORGARD: Well, Medtronic came and they said
17 -- in Medtronic's brief they say, well, VSI kind of thought
18 that GuideLiner was going to be a limiter anyway. VSI
19 didn't have great hopes for GuideLiner in the future, even
20 in 2017.

21 THE COURT: What does "limiter" mean, though?

22 MS. NORGARD: Well, I think a sales limiter, a
23 revenue limiter. Some may be a limiter on the business.

24 But put in context, what Mr. Jagodzinski explains,
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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

The other forecast that we see Medtronic rely on from -- a VSI forecast is from May 9th, 2019 where we acknowledge the expected new competition in the market with Medtronic and forecast [REDACTED]. May 9th is before Telescope hit the market. It didn't hit the market until, I believe it was, May 16th when the worldwide launch press release came out and then it rolled out after that.

We didn't know at this time what Telescope really was going to be, what it was going to look like, how Medtronic was going to roll it out. So without knowing the dramatic impact it would necessarily have, we adjusted our forecasts. [REDACTED]
[REDACTED]
[REDACTED].

But, Your Honor, those are our forecasts. And, again, Medtronic's documents tell the better story and it's the next slide right here. Again, this is from that NPV document, that deep analysis that Medtronic did with the Telescope. They, Medtronic, anticipate that VSI is going to see a [REDACTED] market decline in the first year and a [REDACTED]

1 percent decline in the first three years.

2 So whereas our forecasts are now starting to bring
3 into sharp relief the impact that Telescope is going to
4 have, Medtronic, who knows what its game plan is, who knows
5 what its own force is, they see us declining [REDACTED] in
6 three years.

7 Your Honor, that's all I have on irreparable harm.
8 I'm happy to finish off the equitable factors and then turn
9 it to Ms. Friedemann if you'd like.

10 THE COURT: Yes, please do so.

11 MS. NORGARD: Okay. So the balance of harms is an
12 important factor here and one of the three equitable
13 factors.

14 And what we see on the VSI side and the GuideLiner
15 side, again, VSI built this market with the GuideLiner. We
16 saw that early, and it's been established in the briefs and
17 in the evidence. And VSI is still a niche player today in
18 this market, in this complex market. In catheter labs it is
19 still a small player next to Medtronic.

20 Teleflex paid a billion dollars for VSI in 2017,
21 and [REDACTED] of that, roughly, was for the GuideLiner and
22 patents that protect the GuideLiner and that protect that
23 right to exclude. Those patents don't expire until 2026.
24 So unless the status quo was preserved, Teleflex doesn't get
25 the benefit of its bargain, doesn't get what it paid for

1 when it purchased the GuideLiner and those patents.

2 As we saw before, GuideLiner is still the
3 Interventional Business Unit's biggest product by far. And
4 GuideLiner makes hundreds of jobs possible. The economics
5 of it are just that simple.

6 In the end without an injunction, essentially VSI
7 is going to have to compete against something that is so
8 similar to its own product, the Telescope, which is packaged
9 and bundled with all of the other products that Medtronic
10 sells and offered at a much lower price, and the equities of
11 that situation I think are readily apparent.

12 I'll go back to the *Metalcraft* case where the
13 court said, It is recognized that in the absence of an
14 injunction Scag, the patentee in that case, would face
15 substantial hardship and be forced to compete against its
16 own patented invention. It's the same thing here.

17 So what do we have on the Medtronic side? We have
18 the biggest medical-device company entering into a new
19 market that they've never been in for and that they've done
20 just fine without for a number of years. This product is a
21 rounding error for Medtronic. They don't even contest
22 infringement to several claims, and they went into this
23 situation with eyes wide open.

24 In our briefs we explain that Medtronic approached
25 us before they launched Telescope and asked for a license

1 and we said, No. The exclusivity that these patents provide
2 and the importance that these patents have to the GuideLiner
3 business and to the entire VSI business was far more
4 important to the company than a revenue stream that a
5 license might provide. We said no to that license and
6 Medtronic went ahead anyway.

7 The reality is that Medtronic could bring to
8 market a non-infringing device. But even if the status quo
9 was preserved with the preliminary injunction that we seek
10 here today, what we know is that the complex PCI market is
11 still going to be around in a couple of years if at the end
12 of the case somehow they were to prevail. They can enter
13 later if they can prove that they don't infringe, and I find
14 that a difficult road for them to hoe given what we've seen
15 here today.

16 The *Abbott v. Sandoz* case is, I think, a really
17 good one on the balance of harms that's similar to this one.
18 It's a Federal Circuit case in 2008, again, on this concept
19 of preserving the status quo. Again, in that case *Abbott*
20 had licensed other generic producers. That was a
21 pharmaceutical case. So there were licenses in place there.
22 In that case the Federal Circuit on the balance of harms
23 affirmed the district court, that the district court
24 received *Abbott's* arguments that it could not be made whole
25 if it prevails in this litigation, for the added erosion of

1 market, customers, and prices, is rarely reversible.

2 And then last, but not least, I'd like to address
3 public interest. Here I want to end where I began. This
4 idea of preserving the status quo and maintaining the
5 protections afforded by patents is essential in the
6 medical-device industry. And, in fact, I submit that the
7 medical-device nature of this case strongly favors a
8 preliminary injunction. Courts time and time again
9 recognize the patent system incentivizes medical advances.
10 Injunctions are vital to this system.

11 Here we have a case where the market has been
12 well-served since 2009 when GuideLiner came to the market
13 and created this market. This is not a situation where
14 there's a patient population that is not served by
15 GuideLiner. There is no evidence in the record that any
16 patient cannot be treated by a GuideLiner or a Boston
17 Scientific device.

18 THE COURT: I thought there was evidence in the
19 record of that. I thought they submitted affidavits from
20 doctors saying there are some procedures that they can use
21 the Telescope for and they could not use the GuideLiner.

22 MS. NORGARD: There's not one affidavit, Your
23 Honor, in this record from any physician.

24 THE COURT: What are they citing when they say
25 those things?

1 MS. NORGDARD: They're citing a survey, a survey
2 that -- a summary of a survey, in fact. It's a summary of a
3 survey, presumably by a market person, talking about doctors
4 who worked with Medtronic who expressed a preference in one
5 case that -- in a statement -- some statements about
6 Telescope is a great product.

7 I want to be clear, these are not affidavits.
8 They're not declarations. They're surveys of --

9 THE COURT: I thought there was more than
10 Telescope is a great product. I thought that they quoted a
11 doctor or doctors saying I was able to do something with
12 Telescope that I wouldn't have been able to do with
13 GuideLiner.

14 MS. NORGDARD: That's true, and I think we're going
15 to see that in Ms. Friedemann's presentation. There are
16 several quotes that come out of that survey. Here's I think
17 --

18 THE COURT: I can understand why that would bother
19 a judge if he thought he was taking a medical device off the
20 market that could save people's lives or at least spare them
21 from open-heart surgery.

22 MS. NORGDARD: There is not one shred of evidence
23 in this record, Your Honor, that any life will be saved by
24 Telescope.

25 A doctor's preference or the fact that in a survey

1 of an evaluation that these comments were made -- again, not
2 declarations, comments in a survey -- it is not evidence
3 that a life will be saved.

4 Medtronic, to be clear, could have come to this
5 Court, as happens in other cases, with physician
6 declarations saying I cannot save my patients without this
7 product. Medtronic works with thousands of doctors. There
8 is not one doctor declaration in this record.

9 What there is is a marketing survey with offhanded
10 comments, phrases in some cases, about how the perception
11 that in that case -- in that doctor about Telescope being a
12 good product or better than GuideLiner. But it was not in a
13 clinical head-to-head study. There is no clinical
14 peer-reviewed study at all to suggest one is better than the
15 other.

16 Medtronic has not come to this Court and said,
17 geez, GuideLiner is failing. I referenced earlier the MAUDE
18 database, and entries from the MAUDE database are in the
19 record. What MAUDE is is the acronym for where the FDA
20 records problems with devices. Medtronic has not come to
21 this Court and said Telescope has so many MAUDE failures, we
22 have to remedy this problem. That's not an argument they're
23 making; they can't.

24 They have no physician surveys. They have no
25 clinical studies. They have no reports of failures that

1 would somehow suggest that GuideLiner is inferior. And they
2 have no evidence whatsoever that there's a patient
3 population that is unserved by the GuideLiner.

4 And, Your Honor, I want to emphasize here, and
5 we've added it to the record yesterday with courtesy copies
6 to the Court, the *Edwards Lifesciences v. Corevalve* case.
7 Corevalve is actually Medtronic. Corevalve, I believe
8 purchased -- and the case really was *Edwards v. Medtronic*.

9 In the TAVI space -- and TAVI is where heart
10 valves are replaced through catheterization. So instead of
11 cracking a heart open to replace a heart valve -- it really
12 was a revolutionary -- is still a revolutionary medical
13 device where instead of cracking your heart open, you can
14 get a new heart valve put in through a catheter.

15 Edwards was the first to market in that case, and
16 Medtronic came later. And I won't -- the Court, I know, is
17 very capable of reading this case, but I want to emphasize
18 it because Medtronic made a lot of the same arguments in
19 that case that they're making here. And in that case there
20 were legions of doctor declarations, doctor testimony,
21 head-to-head clinical studies about whether these
22 products -- the Edwards product and Medtronic product --
23 were comparable, whether one was safer or better than the
24 other.

25 What the Court will see when reading that opinion

1 is in that case there was a patient population that the
2 patented device, the Edwards device, didn't serve. It was
3 people with 27-millimeter size part of their anatomy, that
4 the Edwards device wasn't sized that way. Medtronic did --
5 the infringing device did have a device that served that
6 27-millimeter population.

7 That was a case where there was a patient
8 population that wasn't served, and there was a bit of a
9 debate in the clinical setting with head-to-head
10 declarations and data and all the rest. And in that case --
11 this is in the District of Delaware -- Chief Judge
12 Sleet still entered an injunction. He recognized the
13 irreparable harm of lost sales, lost market share, lost
14 revenue, many of the same types of arguments; again, much of
15 the same evidence indeed at a high level.

16 What Judge Sleet said is there might be a
17 population here, based on the record of the scientific data,
18 because that one group wasn't served. So the injunction was
19 tailored to -- Judge Sleet, basically, told the parties go
20 figure out how you're going to make sure that the Medtronic
21 device can be available for that select group of patients
22 that needs it. Go figure that out. But he still entered
23 the injunction because the irreparable harm in that case, as
24 it is here, was clear about what was going to happen to
25 Edwards if an injunction weren't entered.

1 The rest of this slide, Your Honor, simply puts up
2 the cases that we've cited in our briefs about the strong
3 public interest; and the protecting patent rights; and the
4 fact, on the right-hand side, that medical devices are no
5 exception. I would submit, Your Honor, it's all the more
6 important in the medical-device context to make sure that
7 innovation continues to be protected.

8 Your Honor, that's all I have.

9 THE COURT: All right. Thank you, Ms. Norgard.

10 MS. NORGARD: Thank you.

11 (A brief discussion was held off the record.)

12 THE COURT: All right. Ms. Friedemann.

13 MS. FRIEDEMANN: Thank you, Your Honor.

14 The plaintiffs are here asking the Court for
15 extraordinary relief, and they bear a high burden to get it.
16 They have to show the likelihood of harms that are both
17 immediate and substantial and that cannot be quantified by
18 money damages. As I said, it's a very high burden. And
19 successful motions, as the Court knows, are rare in patent
20 cases. Despite that, they take kind of a kitchen-sink
21 approach.

22 THE COURT: I actually don't know that. I don't
23 have any idea what other judges do in patent cases. I mean,
24 if I take all their citations to the Federal Circuit at face
25 value, I can't imagine a patent case there wouldn't be an

1 injunction entered. Their cases seem to say that the
2 Federal Circuit wants them all the time in every
3 circumstance.

4 MS. FRIEDEMANN: Well, I can tell you that, based
5 on my review of the case law -- and I don't want to get
6 bogged down on this point, but it's somewhat unusual for a
7 preliminary injunction to issue in a patent case.

8 Nonetheless, here we've got --

9 THE COURT: How do I know that? Is that apparent
10 from the cases cited in the brief?

11 MS. FRIEDEMANN: I think it's apparent from the
12 extremely high burden here, not only on likelihood of
13 success on the merits, but in the subject matter I'm
14 focusing on here, the irreparable harm, the burden is
15 extremely high.

16 There are a number of categories of harm that have
17 been alleged here, six of them. In any given circumstance,
18 sometimes the Court has found that those categories can be
19 irreparable, but usually not. They're requiring something
20 more than simply lost sales, for example; something more
21 than simply a need to drop your price, because those things
22 can be quantified.

23 So in light of that, it's a tall order to qualify
24 for that type of injunctive relief and, more importantly,
25 they haven't met it here. These plaintiffs have not met it

1 here.

2 I do want to focus on the categories of harm that
3 have been alleged, at least a little bit, but I want to
4 start with the big picture because there are some
5 observations I want to make that may have been clear to Your
6 Honor from the briefs, but maybe were not.

7 First, as you know, there was a preliminary
8 injunction issued in the *Boston Scientific* case and then was
9 overturned in the Federal Circuit. So the plaintiffs need
10 to do something more here than they did in that case. But
11 yet the arguments are the same, including even
12 characterizing the plaintiff as this small company with
13 GuideLiner being the lifeblood product.

14 THE COURT: I remember the Federal Circuit had
15 like one sentence of explanation for why they were
16 overturning it. I remember they cited issues regarding
17 likelihood of success. Did they also mention irreparable
18 harm?

19 MS. FRIEDEMANN: In that one sentence, no, Your
20 Honor. But, as you observed, this case is pitting two huge,
21 multi-national companies against one another, and the market
22 is no longer exclusive. The plaintiffs having licensed its
23 patents to one of their largest competitors, a "gorilla" in
24 the space, as Ms. Norgard mentioned. So the arguments that
25 were not enough in the *Boston Scientific* case are even less

1 persuasive here.

2 And, as Your Honor pointed out, it is absolutely
3 relevant that these are two large companies fighting against
4 one another. They seem to be asking the Court to focus only
5 on a portion of the business unit to the exclusion of the
6 patent owner and the entity that makes the sales in the
7 United States, and we submit that would be improper. The
8 Court needs to look at the entire picture.

9 In fact, they're so focused on this business unit
10 that they have neglected to even name an important party
11 here. The patent owner is not a plaintiff in this action.
12 That's a huge standing problem. But beyond that, they also
13 haven't focused their argument on that party at all.

14 As the Court may know from the *QX Medical* case,
15 there was a transaction that occurred. The patents have
16 changed hands. This happened in August of 2019. And that
17 new patent owner is not a plaintiff, nor have they attempted
18 to address any harm to that party.

19 THE COURT: Who is the new patent owner?

20 MS. FRIEDEMANN: The party, as I understand it, is
21 Teleflex Medical Devices S.a.r.l.

22 THE COURT: That's not the Teleflexes that are
23 involved in my case?

24 MS. FRIEDEMANN: No. It's a problem.

25 The entity that sells the product in the United

1 States, Teleflex, LLC, is a plaintiff in this action, but no
2 focus has been paid on any harm to that entity.

3 THE COURT: Well, but if I don't have standing, I
4 don't have jurisdiction, so everything we talked about today
5 becomes -- so we wasted a day if I don't have standing.

6 MS. FRIEDEMANN: Well, that would be my view of
7 the case, Your Honor. This is not a surprise to the
8 plaintiffs. We have raised this issue with them.

9 THE COURT: Why didn't you raise this -- I mean, I
10 have an obligation as a judge to -- you're both going to
11 have to brief this now because I have an obligation as the
12 judge, an independent obligation, to assure myself I have
13 jurisdiction.

14 MS. FRIEDEMANN: I understand, Your Honor.

15 THE COURT: You can't just toss it out and not do
16 anything with it.

17 Well, why wasn't this brought to my attention
18 before I spent a week preparing for this hearing and spent
19 an entire day in here hearing this?

20 MS. FRIEDEMANN: The reason, Your Honor, is that I
21 believe this is something -- well, Your Honor could
22 disagree, but it's possible that this problem could be
23 resolved by adding the proper party to the action before the
24 Court would rule on the motion. I think that's how the
25 plaintiffs are looking at the situation.

1 Standing here today, though, making the arguments
2 to the Court, we are lacking a party that is essential for
3 standing.

4 THE COURT: Let me have you sit down for a minute
5 and just ask Ms. Norgard or Mr. Vandenburg to address this.

6 So do I not have the patent owner as a party
7 before me?

8 MS. NORGARD: Your Honor, the patent owner has --
9 the original patent owner has merged into a different patent
10 owner. But you do have standing, and the basis for your
11 standing -- basis for the proper party here today --
12 everybody being proper here today is found in Rule 25(c),
13 Federal Rule of Civil Procedure 25(c), transfer of interest.

14 So the S.a.r.l. entity that owned the patent when
15 this case was filed has now merged into a different S.a.r.l.
16 entity. We advised Medtronic --

17 THE COURT: So at the time the lawsuit was filed I
18 had the patent owner here?

19 MS. NORGARD: Correct.

20 THE COURT: And then there was a merger?

21 MS. NORGARD: Correct.

22 THE COURT: So it's a different entity now that
23 has it?

24 MS. NORGARD: Correct.

25 THE COURT: Under 25(c) the successor corporation

1 is automatically replaced?

2 MS. NORGDARD: That's correct, Your Honor. And
3 Medtronic is well aware of this.

4 We asked them to stipulate to -- I believe that
5 had already happened in the *QXM* case. The ball is in their
6 court to respond to us that they stipulate. They are very
7 well aware of this. And, regardless, 25(c) takes care of
8 it.

9 THE COURT: Okay.

10 Ms. Friedemann, that's my understanding of Rule
11 25(c), is the successor corporation is just automatically
12 substituted.

13 MS. FRIEDEMANN: My understanding is different,
14 Your Honor. I don't know that the substitution is
15 automatic. It, nonetheless, has to actually happen.

16 The patent owner does need to be a plaintiff in
17 the case, and we're in a situation here arguing today where
18 the patent owner is not actually a party in the case.

19 THE COURT: Okay. Well, you folks need to fix
20 this. I mean, this is just silliness. This should be
21 easily fixed. You have a lot of real things to be fighting
22 about without fighting about something that's not real. So
23 you folks get this fixed. Let's get a stipulation filed
24 next week that substitutes the proper party.

25 Okay. You can continue on the irreparable harm

1 argument.

2 MS. FRIEDEMANN: It is relevant to the irreparable
3 harm argument in that the big picture -- again, you can't
4 focus on a portion of the business unit to the exclusion of
5 the patent owner, and we've clearly done that here -- or the
6 plaintiffs have. The party is not even named in the case at
7 this point.

8 Another big picture observation is the stark
9 contrast in the evidence that we've presented on this issue
10 and that presented by the plaintiffs. So we presented an
11 expert on this subject, Richard Lettiere. His report is
12 attached to my declaration as Exhibit HHH. He's an
13 experienced damages expert. There are many opinions
14 throughout his report. The big picture ones are that the
15 claims being made of irreparable harm here are factually
16 unsupported and that they are quantifiable.

17 On the plaintiff's side we have a witness, Ms. Amy
18 Welch, who in light of her position at the company does not
19 receive access to Teleflex financial information, did not
20 get that information before she offered her declaration in
21 this case. It's above her pay grade, as she said. And she
22 acknowledges she's not in a position to offer any opinions,
23 legal opinions. And, in fact, her deposition shows that she
24 does not understand what irreparable harm means under the
25 law. Quite a contrast there.

1 I'd like to mention, too, in light of the argument
2 today we -- in discussing likelihood of the merits, success
3 on the merits, the Court sort of winnowed the claims down to
4 these two: the claim 44 of the '379 patent and claim 36 of
5 the '776.

6 In those two claims they're focused on, I guess,
7 I'll call it the sort of multi-incline configuration, if you
8 will. The plaintiffs have the burden of showing a nexus
9 between that patented feature and the irreparable harm that
10 they're alleging. That's very clear in the case law. We
11 haven't heard a single thing about nexus. There's not a
12 single thing in the briefs. There's not a single thing in
13 the record.

14 So there's nothing the Court could look at to say,
15 okay, it's that unique configuration that is helping drive
16 sales to consumers, and that is what is required to show
17 nexus. So that is absent as well.

18 THE COURT: I'm sorry, I just don't follow that.
19 I don't understand that. So if you're infringing, let's
20 say, claim 44 of the '379 patent and the reason it's not
21 invalid is because of the multiple inclines, you have to
22 show that it's the multiple inclines that it's the reason
23 it's not invalid that is driving the sales?

24 MS. FRIEDEMANN: No. I would frame the question a
25 bit differently, Your Honor. The nexus requirement requires

1 that there be a connection between the patented feature or
2 that which -- you know, the ah-ha, which for those two
3 claims is focused on that configuration.

4 THE COURT: Well, this is not a patent feature
5 here. It's a patent for the device.

6 MS. FRIEDEMANN: But --

7 THE COURT: This isn't where the patented item is
8 a component part of a larger device. This is the device
9 that's patented.

10 MS. FRIEDEMANN: The inventive feature that
11 they're arguing with respect to those two claims is that
12 multi-incline configuration. The case law then requires
13 that that, the inventive part, is what's driving sales or at
14 least it's a factor in driving sales.

15 THE COURT: So if you have an apparatus patent,
16 the judge has to identify what the inventive feature of it
17 is and connect the inventive feature to the irreparable
18 harm?

19 MS. FRIEDEMANN: Yes, Your Honor.

20 THE COURT: I've just never heard that before. I
21 don't even know how you'd do that. That's almost
22 metaphysical.

23 MS. FRIEDEMANN: It's very clear that this is part
24 of the burden. The *Apple v. Samsung* cases are instructive
25 on this point.

1 THE COURT: Well, I don't recall you even
2 mentioning this in your brief, and it would make everything
3 a lot easier because I assume nobody can show there is a
4 single sale because of two inclines, instead of one, or some
5 other side opening configuration.

6 MS. FRIEDEMANN: It's an argument that is
7 particularly appropriate for the claims that the Court has
8 winnowed this down to, because there are some other claims
9 that describe the guide extension catheters sort of more of
10 the whole being the invention, and these claims are focused
11 on that unique incline configuration.

12 So now that we are at that point where the Court
13 is focused on those, I think this nexus argument becomes
14 much more important or much more relevant.

15 THE COURT: Are those cases cited in your brief?

16 MS. FRIEDEMANN: The *Apple v. Samsung* case is,
17 Your Honor.

18 THE COURT: Okay. So this is not at all your
19 fault, Ms. Friedemann. Ms. Norgard went a lot longer than I
20 thought she would, but we have to wrap up in 10 or 15
21 minutes.

22 MS. FRIEDEMANN: Okay. I can do it.

23 THE COURT: I mean, there's been a lot of
24 repetition of what's in the briefs. I really truly swear to
25 God, I read the briefs. I read them all twice, once fast

1 and once slow. Focus on stuff. This is not your fault.
2 I'm not at all trying to sound harsh to you, but we have to
3 wrap it up.

4 MS. FRIEDEMANN: All right. What's most important
5 for the Court to look at is the past seven months, because
6 this is a unique case in that we don't have a preliminary
7 injunction motion filed right out of the blocks. We have
8 seven months to look at. And in that seven months -- here's
9 the seven-month reality: We've got a handful of alleged
10 lost sales. The slide that Ms. Norgard showed had 12. We
11 dispute that all of those are actually lost and what they're
12 due to, but, [REDACTED]
13 [REDACTED]. So they're minimal. They're quantifiable.
14 Ms. Welch testified as to the quantifiable nature of those
15 sales.

16 There's been no showing of lost market share. The
17 revenue in the business unit is up in the last nine months
18 when Medtronic has been on the market.

19 There's been no showing --

20 THE COURT: What do you do you with the fact that
21 your own client is projecting making major inroads into
22 Teleflex's market share?

23 MS. FRIEDEMANN: Let me address that. And that's
24 really -- all of that evidence was submitted on the reply.
25 A number of forecasts were submitted.

1 Could you give me slide 5, please, George.

2 And they vary quite a bit. So the plaintiffs are
3 focusing on the ones they like. They also submitted this
4 one. It's markedly different, predicting -- if it is, in
5 fact, a prediction. I will say that there's no context for
6 any of these documents, Medtronic documents submitted with
7 the reply brief. We don't know who drafted them for what
8 purpose or when.

9 THE COURT: These are the people who are doing the
10 projecting down here?

11 MS. FRIEDEMANN: This is a document that comes out
12 of Medtronic's files. Beyond that, we don't know anything
13 about it.

14 THE COURT: I see. This is not who's doing the
15 projecting.

16 So these are the separate projections, these
17 things here (indicating)?

18 MS. FRIEDEMANN: Yes, the lines by year with the
19 top line in gray showing VSI. The line below that in green,
20 Boston Scientific. Yellow is actually --

21 THE COURT: Who's doing this projecting here?

22 MS. FRIEDEMANN: This is from Medtronic's files.
23 But, again, because all of this evidence was submitted with
24 the reply brief, there is no context to any of it, no reason
25 for the Court to give any more weight to the projections

1 than --

2 THE COURT: Well, I don't think -- it's no great
3 stretch to think that when a \$30 billion dollar a year
4 company has a new product and goes out and tries to sell it,
5 they're going to take some sales. It would be a pretty sad
6 thing for your client not to, which has told me that they've
7 designed their product to be better than the GuideLiner
8 based upon talking to people who use the GuideLiner and
9 making improvements they sought.

10 So I don't think I have to go a long stretch to
11 say there's going to be sales lost. The question is, is
12 that irreparable harm. It doesn't seem to me it should be,
13 because if it is, then in every single patent case there's
14 irreparable harm.

15 MS. FRIEDEMANN: Yes, Your Honor.

16 THE COURT: But it's hard to find -- the Federal
17 Circuit may disagree with me about that.

18 MS. FRIEDEMANN: Well, the Federal Circuit does
19 require, of course, that it be not quantifiable.

20 So, yes, of course, we're going to try to make
21 sales. But it's the burden on the plaintiffs to show that
22 that they'll actually lose market share and then to put some
23 kind of -- to present some evidence as to how much, because
24 their burden is to show likely harms that are both immediate
25 and substantial.

1 There's no evidence in this record that would
2 allow the Court to put a number out there or even a range.
3 As you would note, the plaintiffs' own projections that
4 Ms. Norgard showed are quite different.

5 There is a case. I'll draw the Court's attention
6 to the *Abbott Cardiovascular* case -- it is cited in our
7 papers -- where the court said forecasts of the future,
8 somebody's best guess, that is not clear evidence of a lost
9 market share.

10 I want to deal a little bit with a couple of
11 causation issues. I'll do it as quickly as I can.

12 The plaintiffs acknowledge that they're losing
13 market share to Boston Scientific, but they don't deal with
14 that at all. So if they're --

15 THE COURT: Not only that, but they've said that
16 the Guidezilla II is a better product than theirs. So I
17 would anticipate they will lose more market share if that's
18 true.

19 MS. FRIEDEMANN: Yes. The plaintiffs themselves
20 are also shifting sales to their TrapLiner products, so
21 they're cannibalizing their own sales.

22 We can look at slide 13 really quickly. This is
23 in response to Guidezilla II. This is one of the
24 plaintiffs' own documents. It's one of the pieces of
25 evidence in the record on this. And the highlighted bullet

1 point, they're going to be trying to target complex users
2 with the new TrapLiner products. So if we're seeing
3 projections for losses, it can very well be their own
4 strategy.

5 And then, finally, in Ms. Welch's deposition she
6 acknowledges that some of the sales that they are allegedly
7 losing are because there are some hospitals who want to
8 purchase all Medtronic products or they really like their
9 Medtronic sales rep. That has nothing to do with the patent
10 and, again, presents a causation issue.

11 I want to make sure -- I'm going to go fast. I
12 want to talk about price erosion a bit and correct what we
13 think are some misstatements in the plaintiffs' reply brief.

14 Go to slide 8, please, George.

15 So the plaintiffs have argued, we think
16 incorrectly, that Medtronic has a stated goal of driving
17 further price erosion, and then they cite to the Vandenberg
18 declaration Exhibit 43 at page 14 and page 17. Those
19 citations provide no support for this assertion. We can
20 look at them.

21 Here's page 14 (indicating). The top has this
22 heading, "Pricing Strategy." Those are the first two bullet
23 points. Medtronic's pricing strategy is a [REDACTED]

24 [REDACTED]
25 [REDACTED].

1 Here's page 17 (indicating). Ms. Norgard showed
2 part of this quote but did not show that they were talking
3 about competitors may drive a pricing war.

4 They also make this allegation, that Medtronic set
5 out to price Telescope more than 10 percent below and have a
6 comparison of Vandenburg Exhibit 51 with another reference
7 in the record. So that second one there is from our
8 expert's report. [REDACTED]

9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED].

13 If you look at Vandenburg Exhibit 51, the other
14 reference cited, it's a big, long spreadsheet. They didn't
15 submit the whole thing. So there's a missing tab. But if
16 you calculate Medtronic's average selling price from that
17 missing tab from January to September -- well, actually, it
18 would be May through September of this year -- it's [REDACTED]
19 [REDACTED].

20 Then I know I have much more I could say, but I
21 want to go and make sure I cover the public interest,
22 because I think Your Honor was asking where some of that was
23 in the record. I want to make sure that I get to that.

24 There is a survey that was done. So before
25 actually launching, Medtronic had 90 cases tested with

1 Telescope and then sent out a survey. And the results --

2 If you could give me slide 19, please.

3 -- they show a strong preference for Telescope:
4 25 percent of respondents indicated Telescope is
5 significantly better. 52 percent indicated Telescope is
6 somewhat better. 7 percent said Telescope is equal to
7 existing guide-extension catheters. And 2 percent said
8 Telescope is significantly worse. The rest of the group
9 didn't respond. So of those who responded, 77 percent said
10 that Telescope is significantly or somewhat better.

11 We also presented evidence of several years and
12 \$13 million of investment to build a better product, and
13 that our own bench testing shows better deliverability and
14 pushability.

15 In addition, Teleflex concedes that physicians
16 like Telescope. In her deposition Ms. Welch acknowledged
17 that. Physicians like it. They like Telescope.

18 Then she was asked: "They like it better than
19 GuideLiner?"

20 She said, "Uh-Huh."

21 The court reporter said, "Is that a yes?"

22 And she said, "Yes."

23 Here's another quote. Your Honor mentioned some
24 quotes. I don't know that this one is cited in the brief.

25 That one is from Vandenburg Exhibit 36.

1 Then there are a number of quotations that were
2 from that survey, and here are some of those. And this is
3 what I think Your Honor was referencing, that there are
4 physicians who use Telescope in connection with that survey
5 and said this is better. Telescope would have succeeded
6 where GuideLiner would have failed.

7 You know, if it's your family member or friend who
8 has one of these issues, you certainly want the doctor to
9 have the tool that they want to use and that they're most
10 comfortable with, and we have evidence here that there are
11 some physicians who do think it does help save lives. We
12 have put that in the record. It is in the public interest
13 to keep the product on the market.

14 Now, I don't know if I took my whole 10 minutes.
15 I want to make sure that if the Court has any questions on
16 any of the other aspects of the irreparable harm argued that
17 I do have a chance to address them.

18 THE COURT: I don't.

19 MS. FRIEDEMANN: All right. Then I will leave it
20 at that.

21 THE COURT: All right. Thank you, Ms. Friedemann.
22 I'm sorry to hurry you. As I said, it wasn't your fault.

23 Ms. Norgard, you can have one minute if there is
24 something specific you want to respond to, but then we have
25 to go.

1 MS. NORGDARD: I do, Your Honor. And I'll be
2 brief.

3 First of all, I want to make sure the record is
4 clear. The Guidezilla II is not better than GuideLiner.
5 Guidezilla II is better than Guidezilla I. I just want to
6 make sure that the Court didn't miss -- or that I didn't
7 misstate that. I heard the Court say, well, they thought
8 the Guidezilla is better. No, no, no.

9 THE COURT: You'll have to get the transcript and
10 see what you said. I thought you said it was better than
11 GuideLiner.

12 MS. NORGDARD: Well, let me clarify it now.
13 Guidezilla II is not better than GuideLiner. The difference
14 is, and the reason it matters, is that Guidezilla II is
15 better than GuideLiner I, and that's why the numbers are
16 what they are.

17 Ms. Friedemann talked about it's unusual to get a
18 preliminary injunction in patent cases. This is that
19 unusual case where these patents have already been
20 extraordinarily litigated. We have an admission of
21 infringement. And the Court is well aware this is not the
22 early case -- or the early phase of this case. These
23 patents are well-known to the Court, and this is the exact
24 kind of case where an preliminary injunction is appropriate
25 and oftentimes entered.

1 I would say that the nexus argument is one that I
2 do not see in the case law. I think it's a misunderstanding
3 of the *Apple* case that is cited in Medtronic's briefs. I
4 think there's a confusion there between damages and a
5 preliminary injunction. I'm not aware of any cases really
6 that go to that metaphysical notion.

7 THE COURT: I have tried two patent cases and I've
8 been involved in many others. I've just never heard this
9 argument before. I'm surprised it wouldn't have come up in
10 the two patents cases I've tried, both of which involved
11 your firm. I think you were plaintiffs once and defendants
12 once. I didn't hear it, either side.

13 MS. NORGARD: Right. Right.

14 Finally, Your Honor, I want to clarify an exhibit
15 that Ms. Friedemann had in her presentation. It is a
16 Medtronic document and it's an important one. Forgive me, I
17 had highlighted it for another purpose. This is on
18 Ms. Friedemann's slide, and she was specifically looking at
19 the left hand, the market share side of this, and trying to
20 -- again, these are Medtronic's documents. Medtronic knows
21 exactly what these mean.

22 I'm going to tell the Court what this one means
23 because I don't think it was necessarily clear. This is a
24 worldwide snapshot of what Medtronic is anticipating. And
25 we know this because you can see that the top -- it's not

1 very good in color here -- this top one here (indicating) is
2 what they're associating with VSI. You note that they are
3 at about -- they pin us at about 45 percent market share.
4 This is a worldwide situation, Your Honor. They anticipate
5 the worldwide market share being a different picture.

6 What really shows what's going to happen in the
7 United States are the examples in the charts that I put up
8 in part of our slide presentation with those falling
9 numbers. That's the United States' picture. That's the
10 market share that matters. This is a worldwide situation,
11 which really doesn't apply. This is sort of whitewashing
12 things. And we know that because even Medtronic admits we
13 have far more than 45 percent of the market. So I just
14 wanted to make that clear.

15 THE COURT: Okay. Thank you, Ms. Norgard.

16 Thank you for your help with the case. It's been
17 a long day, I know. There's a lot here for me to digest and
18 to research, so I wouldn't expect anything from me too soon,
19 but we'll obviously do the best we can.

20 Thanks and have a good weekend and a happy new
21 year. You're free to leave. I'm going to have to pack up
22 some stuff up here.

23 (Court adjourned at 5:08 p.m.)

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I, Debra Beauvais, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Certified by: s/Debra Beauvais
Debra Beauvais, RPR-CRR