

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRONT LINE MEDICAL TECHNOLOGIES, INC.,
Petitioner,

v.

PRYTIME MEDICAL DEVICES, INC.,
Patent Owner

PGR2024-00028
Patent 11,857,737 B2

Held: July 16, 2025

Before: JEFFREY N. FREDMAN, SHERIDAN K. SNEDDEN, and
RYAN H. FLAX, *Administrative Patent Judges*.

APPEARANCES:

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The above-entitled matter came on for hearing on July 16, 2025,
commencing at 11:01 a.m., via video teleconference.

P R O C E E D I N G S

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JUDGE FREDMAN: Good morning. This is the final hearing in PGR2024-00028 which relates to U.S. Patent 11,857,737. Petitioner is Front Line Medical Technologies, Inc., and the Patent Owner is Prytime Medical Devices, Inc. The hearing is open to the public, and the full transcript of the hearing will be made part of the record in due course. I'm Judge Fredman. With me in the hearing room is Judge Flax and on the computer is Judge Snedden.

Counsel for Petitioner, would you identify yourself and your colleagues, please?

HEARING ADMINISTRATOR: Mr. Banner, would you please unmute your mic? Thank you.

MR. BANNER: My apologies. Good morning, Your Honors. My name is Brian Banner. I am with the law firm of Slayden Grubert Beard. And I will be presenting on behalf of Petitioner Front Line Medical today. With me today is Asha Parekh from -- the CEO and Co-Founder of Front Line Medical.

JUDGE FREDMAN: Thank you very much. Counsel for Patent Owner, would you kindly identify yourself and your colleagues.

MR. MURRAY: Hi. Good morning, Your Honors. This is Stephen Murray of Panitch Schwarze on behalf of Patent Owner Prytime. With me in the room today is my co-counsel, Ragi Elias. I also may have one or two co-counsel on the public line and one of the representatives from Prytime on the public line as well.

1 JUDGE FREDMAN: Thank you. So as set forth in our June 5th,
2 2025, Order of Setting the Oral Argument, you know almost always get 60
3 minutes to present this case. We will try and do our best to keep track of
4 time. I don't think you can actually see the timer, but we'll try and just tell
5 you when you're running close to time. But we suggest you also pay
6 attention.

7 So Counselor Petitioner, Mr. Banner, would you like to reserve
8 any time for rebuttal?

9 MR. BANNER: Yes, Your Honor. I'd like to reserve, I think, 20
10 minutes for rebuttal.

11 JUDGE FREDMAN: Twenty minutes. And Counsel for Patent
12 Owner, Mr. Murray, would you like to reserve any time for rebuttal?

13 MR. MURRAY: I think I'll reserve 15 minutes, Your Honor.
14 Thank you.

15 JUDGE FREDMAN: Fifteen minutes. Okay. Thank you. So
16 there's a few things we should cover before we begin. Since we're on the
17 video, you know, you don't need to identify each time you speak. I think
18 we'll be able to tell you apart. And hopefully, you won't be speaking over
19 each other. Mute your microphones when you're not speaking, don't
20 interrupt the other party, you can save any objections for your opportunity to
21 speak.

22 We do have Petitioner's demonstratives, even if they're filed a little
23 late. And of course, we have access to the entire record. When you refer to
24 these things, if you could point to them by either slide or page number, that
25 would be helpful to give us time to find it. We will obviously take these

1 under advisement.

2 Petitioner goes first as you begin the -- you bear the burden of
3 showing unpatentability. And Mr. Banner, you can begin.

4 MR. BANNER: Okay. Let me get my -- so I can get the screen up
5 here, the sheet. Okay. So -- oops, sharing -- okay. Are you able to see the
6 slides?

7 JUDGE FREDMAN: Yes, we can.

8 MR. BANNER: Okay. So I have my demonstratives on the
9 screen. May it please the Board? My name is Brian Banner. And I'm here
10 on behalf of Petitioner Front Line Medical Technologies. I want to thank
11 the Board for the opportunity today to present on behalf of the Petitioner and
12 explain why the Board should maintain the findings in the institution
13 decision and find all claims of the '737 Patent to be unpatentable. I plan to
14 walk through the demonstratives that Petitioner filed with the Board on
15 Monday.

16 Slide 2. For the Board's reference, Slide 2 contains a table
17 summarizing the asserted grounds of invalidity. And this is a table that's
18 also found on page 3 of the petition. Slide 3, this is the agenda that I've
19 prepared based on the briefing. I plan to use 40 minutes of my time, and I'd
20 like to reserve the remaining 20 minutes for rebuttal. Unless the Board has
21 specific questions or would like to focus on specific arguments, I plan to
22 start with claim construction, then I'll discuss the person having ordinary
23 skill in the art or PHOSITA.

24 I will then move to the various arguments raised with respect to
25 Grounds 1 through 4, that I use Fogarty as the primary reference, starting

1 with expectation of success, then discussing Fogarty's solid wire, followed
2 by Fogarty's proximal hub and flow valve.

3 I'll then discuss the evidence related to Grounds 1 and 2 and 6 to 7
4 that show that an asymmetrical balloon shape in an occlusion catheter is
5 obvious. And then I'll finish by discussing the arguments raised with respect
6 to Grounds 5 through 9 that have Eliason as a primary reference, starting
7 with Eliason's distal catheter section and ending with Eliason's proximal hub
8 and flow valve.

9 Slide 4, the claim construction. Slide 5, there are essentially five
10 claim construction issues or terms in dispute, all relate to terms in Claim 1. I
11 plan to discuss them in the order shown here in Slide 5. I know that the
12 parties agreed on the construction of the terms proximal and distal as those
13 were construed by the Board in the institution decision. And there does not
14 appear to be any dispute related to the meaning of those two terms.

15 Let's go to Slide 6. So starting with the construction of the term
16 proximal hub, Petitioner proposes a plain meaning construction, which is an
17 element or elements oriented away from the body for connecting other
18 cathetered elements, including for connecting an inflation device to an
19 inflation lumen. The Patent Owner's construction is an element or elements
20 for connecting an inflation device to an inflation lumen.

21 JUDGE FREDMAN: Let me just ask a question here if I can.

22 MR. BANNER: Sure.

23 JUDGE FREDMAN: So when you say proximal oriented away
24 from the body, does that have to be -- is any -- let's say you had multiple
25 hubs and sequentially oriented away from the body, are all of those proximal

1 hubs or is only the most proximal? Is it where the furthest from the body
2 part of the proximal hub?

3 MR. BANNER: Certainly, the one closest to the body is a
4 proximal hub. The '737 Patent isn't entirely clear because it also calls a --
5 the Figure 42A embodiment which has a --

6 JUDGE FREDMAN: Right.

7 MR. BANNER: It calls a proximal hub that's on a sleeve, you
8 know, that sleeve fitting that is not the absolute closest one to the bodies, but
9 it's also called a proximal hub. So I believe that the '737 Patent is not
10 entirely clear. And so I don't think it would be appropriate to construe it in a
11 way that would require it to be the closest hub to the body.

12 JUDGE FREDMAN: Okay.

13 MR. BANNER: Slide 7, so the Patent Owner -- so the proximal
14 hub, Petitioner is arguing that it really has its ordinary meaning, as Dr.
15 Resnick explained in his second declaration at paragraphs 49 to 52. Now,
16 Patent Owner's construction which focuses on the connection to an inflation
17 device is overly narrow because it excludes features that the patent describes
18 the proximal hub also is useful for. For example, the feature of the --
19 allowing connection of a pressure sensor, which is not the same as the
20 passage that is used to connect the inflation lumen with an inflation device.

21 And so we believe that Patent Owner's construction is overly
22 narrow. And Petitioner's construction expressly contemplates the proximal
23 hub connecting an inflation device to inflation lumen among other
24 connection. So Patent Owner's argued in surreply that the Petitioner's
25 definition sort of rules this out, but that's just not the case. Petitioner does

1 not -- Petitioner's -- a plain meaning construction does not exclude that
2 embodiment. Thus, the Board should adopt Petitioner's construction, which
3 encompasses the broad meaning as disclosed in the '737 Patent specification.

4 Of course, I'll note that Patent Owner does not appear to argue that
5 this construction makes any difference in the obviousness analysis. At least,
6 I haven't been able to find how this construction actually makes a difference,
7 so this may actually be a moot point.

8 So let's move to Slide 8, the construction of flow valve configured
9 to selectively fluidly communicate the proximal hub with an inflation
10 device. Petitioner's construction is that they're -- the plain meaning of this
11 term is not ambiguous. It is clear on its -- by the -- by its own text what it
12 means, there's no construction necessary. Patent Owner, on the other hand,
13 proposes a construction of, quote, "a manually or automatically actuatable
14 valve that is opened and closed to permit and block fluid flow, respectively,
15 between the proximal hub and the inflation device." This construction is
16 provided by Patent Owner at Paper 12, pages 28 to 30.

17 Slide 9. So Petitioner's position is the phrase needs no
18 construction. Again, it's not ambiguous. It's not expressly defined in the
19 specification, so lexicography wouldn't apply. In contrast, Patent Owner's
20 construction improperly narrows the scope of this claim. It changes the
21 configured to limitation to a method step of a valve that is opened and
22 closed, so essentially requiring a method step. It also inserts a structural
23 limitation of between, where Patent Owner later argues that the flow valve
24 must be located between the proximal hub and the inflation device.

25 Now, that's not what the language says. This language was

1 carefully selected, and we'll get to this a little bit later when we talk about
2 the prosecution amendments. But it was carefully selected to not actually
3 require that structural relationship. Now, Patent Owner argues --

4 JUDGE FREDMAN: There's this claim --

5 MR. BANNER: Yeah.

6 JUDGE FREDMAN: The original claim actually has the word
7 having, right? In fact, the original claim, as filed in this application, it didn't
8 actually say that these were essentially -- the hub had a flow valve, right?

9 MR. BANNER: Yes. The original claim --

10 JUDGE FREDMAN: The original was being claimed.

11 MR. BANNER: My apology, what was the last thing you said? I
12 didn't mean to interrupt.

13 JUDGE FREDMAN: I'm just saying the original claim said a hub
14 having a flow valve. And I don't think the configured part was even there as
15 the valve.

16 MR. BANNER: Yes. That's what the original claim said. It said
17 proximal hub having a flow valve.

18 JUDGE FREDMAN: Well, clearly, there's support for that idea, at
19 least in the --

20 MR. BANNER: Certainly. That is an embodiment that was
21 disclosed in the original claim, yes. But when we get to that, we'll see why
22 the amendment actually made the claims scope broader.

23 Now, with respect to the specific construction, going back to Slide
24 8, that Patent Owner has offered with respect to this claim, the Patent
25 Owner -- back to Slide 9 -- argues that its definition does not require a

1 method and step but requires a valve. And I'm quoting from the surreply
2 here at page 6, quote, "Is capable of being actuated into opened and closed
3 states," end quote.

4 So, you know, this formulation that shows up in the surreply is
5 actually different than -- again, if we look at Slide 8, what Patent Owner's
6 construction was offered in Paper 12. And so it's a little unclear what Patent
7 Owner is doing or which one it's offering. Certainly, it's backed off a little
8 bit in its surreply with this new construction that is just capable of being
9 opened or closed as opposed to this language from the response which says
10 it is opened and closed. But either way, the -- we believe this is
11 unnecessary -- it's an unnecessary rewriting of the claim which is -- has its
12 plain meaning which is unambiguous. And so we would ask the Board, give
13 this claim term its plain meaning.

14 If we look at Slide 10, so now we're moving on to this other issue
15 of the flow valve being part of the proximal hub. And the Board and its
16 institution decision determined that the -- preliminarily determined that the
17 flow valve and proximal hub may be separate elements or, alternatively, the
18 flow valve may be a sub-element portion of the proximal hub.

19 Patent Owner's sort of implicit construction was that the flow valve
20 and the proximal hub are two separately recited structures with a specifically
21 defined spatial relationship between them, namely, the flow valve sits
22 between the proximal hub and the inflation device in order to provide the
23 selective connection between the two components. And again, we -- this
24 kind of feeds off of the dispute in the prior slide as to whether the word
25 between -- rewriting the claim to include this word between is appropriate or

1 not. And here we see how that plays out.

2 So if we look at what -- so Petitioner, we're basically adopting the
3 Board's construction from the institution decision at 14, that these can be the
4 same element or different elements or in a sub-element/element relationship.
5 And as the Board noted in the institution decision, the '73 Patent
6 specification actually supports this finding because it provides examples of
7 hubs that include valves such as the claimed flow valve.

8 So on Slide 11, there's some examples that's -- this is also in the
9 briefing at the reply at pages 4 to 7 of different valves or flow valves that
10 also double or have a -- or sorry, proximal hubs that have a flow valve. So
11 we see Figure 46A --

12 JUDGE FREDMAN: So let me ask.

13 MR. BANNER: Yeah.

14 JUDGE FREDMAN: Patent owner was going to say, I think I'll
15 probably correctly that 1604 isn't a valve that would be used to inflate the
16 balloon, right? It's intended to connect to the sleeve, not the balloon. So it's
17 not part of the sort of the body as -- it's simply used as a sort of comparative
18 point of what the hub and, you know, valve mean.

19 You also highlight in your Slide 11, a hub with a stopcock valve in
20 Figure 42A. And I'm just curious, is there any basis to say that's a stopcock
21 valve, or is that something you're just sort of saying as attorney argument?
22 Or is there a statement in the record?

23 MR. BANNER: Certainly, Your Honor. And this is where the
24 Resnick declaration at paragraphs 57 to 63, this figure with the annotation
25 comes from Dr. Resnick -- and I can pull that up if you'd like me to pull that

1 up. But that's where this figure comes from. And so Dr. Resnick testified in
2 those paragraphs that, you know, although these elements here on the right
3 of Figure 42A aren't sort of labeled or discussed, these are elements that
4 would be --

5 JUDGE FREDMAN: Which is there -- which Resnick -- I guess is
6 it -- it's not the first Resnick.

7 MR. BANNER: It's the second one, Exhibit 1034, Your Honor.

8 JUDGE FREDMAN: Okay. So he said -- and he says that --

9 MR. BANNER: Correct. And he also -- and so it's not only Dr.
10 Resnick, but, you know, the -- Dr. Cimino, when he was testifying regarding
11 Exhibit 1030, which is also a sort of a marked up version of 42A that was
12 marked up during his deposition, he testified that the unnumbered elements
13 on the right of Figure 42A, he said they are most likely Luer lock fittings
14 with valves. He said that at pages 76 to 78 of his deposition.

15 And the Patent Owner has argued in the surreply that Dr. Cimino,
16 you know, didn't say that. But what Dr. Cimino said was that he wasn't sure
17 because they're not numbered or discussed, but, quote, he said, "That's what
18 they look like." And again, that's Exhibit 1032, that's Dr. Cimino's
19 testimony at 76 -- page 76, lines 1 through 11. And he's referring to Exhibit
20 1030, which is another marked up version of Figure 42A. So there's plenty
21 of record of evidence that that's a hub with a stopcock valve there in Figure
22 42A. And so, you know, that's further evidence that the specification has
23 provided examples of these hubs that have valves.

24 Now, Your Honor asked about 1604. And certainly, the Patent
25 Owner argues that that's not a -- it's not a proximal hub according to the

1 claim. But it is a -- well, I wouldn't necessarily agree with that. 1604 is
2 actually called a proximal hub. It has a valve on it. And so, you know, it
3 goes against Patent Owner's arguments that there's nothing in this patent
4 specification that shows proximal hubs without. I mean, that's just not true,
5 1604 is an example.

6 And even under this idea that the proximal hub is something that
7 allows inflation or communication of the fluids to inflate the balloon, now,
8 that 1604 is a two-way (INDISCERNIBLE) valve that has the lumen -- the
9 inflation lumen that goes through it. So it certainly can be closed off. And
10 so it would -- it'd provide the same function that's discussed with respect to
11 the proximal hub. So --

12 JUDGE FREDMAN: So let me ask one other question if I could.

13 MR. BANNER: Sure.

14 JUDGE FREDMAN: So we have -- in Figure 42A, so we have
15 a -- and I -- maybe we'll go back also to look at Figure 40 for a second if
16 that's possible.

17 MR. BANNER: Okay.

18 JUDGE FREDMAN: So in Figure 42A, we have the two -- the
19 hub that we -- that Dr. Resnick and perhaps Dr. Cimino say it is a hub with a
20 stopcock valve, and we have 1604. Which of those -- I mean, 1604 calls
21 itself a proximal hub. Would the other -- the hub with the stopcock valve
22 also be a proximal hub?

23 MR. BANNER: So I'm just trying to get, sorry, Figure 42 --

24 JUDGE FREDMAN: It's on the proximal side of the lumen, if you
25 will --

1 MR. BANNER: Sure.

2 JUDGE FREDMAN: -- as versus the distal side where the
3 atraumatic tip is.

4 MR. BANNER: Yes. And so --

5 JUDGE FREDMAN: And to some extent, it's more proximal.

6 MR. BANNER: Correct. Yeah. The hub with the stopcock valve
7 may be the more proximal hub, but 1604 is also proximal hub. In fact, it
8 uses the term proximal hub, like, in the specification.

9 JUDGE FREDMAN: We've seen that before, you know. I know,
10 I understand that.

11 MR. BANNER: Yeah.

12 JUDGE FREDMAN: Okay.

13 MR. BANNER: Yeah.

14 JUDGE FREDMAN: And then if we can just look at Figure 40 for
15 a second.

16 MR. BANNER: Yeah.

17 JUDGE FREDMAN: So Figure 40, element 1504, which is very
18 clearly a stopcock -- a valve, right?

19 MR. BANNER: Right.

20 JUDGE FREDMAN: And it's also clearly connected to the
21 syringe. And then it's also connected on the other side to a pressure monitor,
22 I think.

23 MR. BANNER: Yes.

24 JUDGE FREDMAN: Would you read that as a hub even if it
25 isn't -- again, it is a hub, if it's not the hub. That's the kind of the question

1 I'm wondering, what does it mean to be a hub?

2 MR. BANNER: Yeah. I think that the --

3 JUDGE FREDMAN: I'm going to ask Patent Owner the same
4 question.

5 MR. BANNER: You know, I think -- I'm not sure that any of the
6 experts have opined on that, that particular question. It's definitely --

7 JUDGE FREDMAN: Right.

8 MR. BANNER: You know, 1504 is definitely a valve. And I
9 think it's called, if I have it right, the pressure relief -- or no, it's -- well, it's --
10 it has some other name other than a flow valve. It's a -- or maybe it is called
11 a flow valve.

12 And I do think that under Petitioner's construction of proximal hub,
13 that is an element oriented away from the body for connecting other catheter
14 elements that would qualify as a type of hub because it is connecting the
15 syringe with the pressure relief valve and -- the pressure sensor and,
16 ultimately, the inflation lumen.

17 JUDGE FREDMAN: Okay. Thank you. That's fine.

18 JUDGE FLAX: Counsel, this is Judge Flax. I have a question for
19 you. You've been talking a little bit about element 1604 disclosed in the
20 patent --

21 MR. BANNER: Correct.

22 JUDGE FLAX: -- right, which is a hub. And it is also described
23 as a hemostatic valve. So it's a hub and valve, right?

24 MR. BANNER: Correct.

25 JUDGE FLAX: Okay. So considering that embodiment or the

1 embodiments that are disclosed in the prior art where you've got a alleged
2 hub that includes a valve as a part of it, as in Fogarty for example, right?
3 Are you with me at this point?

4 MR. BANNER: Yeah.

5 JUDGE FLAX: Okay. So in a configuration like that where a hub
6 includes a valve, how can that valve be configured to selectively fluidly
7 communicate the hub with an inflation device if they are the same
8 component?

9 MR. BANNER: So certainly the -- when it's open, the valve is
10 allowing the inflation device to fluidly -- selectively fluidly communicate
11 with, you know, the portion of the hub that's on the other side of the valve.
12 And when it's -- for example, in Fogarty -- and here there's -- even on 1604,
13 that valve has -- is, you know, part of that hub. And so part of the -- one
14 side of the hub is going to be on the inflation, the right side, and one side is
15 going to be on the inflation lumen side. And so when it's closed, you have a
16 selective fluid communication with the side that's distal to the actual valve
17 itself.

18 JUDGE FLAX: So in your theory of unpatentability here, you're
19 requiring the Board to segment the hub into a side of the hub that is nearer
20 the inflator and a part of the hub that is further away from the inflator, one
21 side always being in fluid communication with that inflator and one side
22 selectively being in communication with the inflator; is that right?

23 MR. BANNER: I wouldn't say that that's a requirement. I would
24 say that there are two theories here. There's the theory that the flow valve
25 can -- under the construction can be a sub-element of the proximal hub itself.

1 And if that is the case, then, you know, there's -- you don't really need to
2 parse at this level. But then there's the alternative theory under the
3 construction that they can't be in an element/sub-element relationship. And
4 in that case, yes, I would agree with what you just stated as that being the
5 theory of invalidity.

6 JUDGE FLAX: So your alternative that you mentioned first is that
7 all of these elements -- hub, valve, inflator -- potentially could be all one
8 component. And these are subparts of a single component?

9 MR. BANNER: I would not include the inflation device in that. I
10 would just say that the flow valve may be a sub-element of the proximal
11 hub. And the reason is, as shown on this slide, Slide 11, that there's just
12 many examples of valves and flow valves being part of a proximal hub, part
13 of the same structure. And so that's kind of the special specification support.

14 Also, in the institution decision, the Board cited to a couple of
15 other examples in the patent about the pressure relief port and that being --
16 possibly being a -- in the proximal hub, which could be a pop-up valve or
17 other similar devised valve. And we're not arguing that that's the flow valve.
18 But again, it's just further evidence that the patent discloses examples of
19 hubs that include, as a sub-element, valves.

20 And so Patent Owner argued in it's -- and I believe in this Patent
21 Owner response that the '737 Patent specification doesn't disclose anything
22 like this. And that's just not accurate. So the specification does disclose
23 these types of configurations.

24 So moving to Slide 11 -- or sorry, Slide 12, in addition to the
25 specification that the prosecution history also supports the Board's

1 preliminary construction where Original Claim 1 expressly recited and thus
2 disclosed, quote, "a proximal hub having a flow valve," end quote. So on
3 Slide 12, we see Original Claim 1. It's found in Exhibit 1002, that's the file
4 history in PDF page 113.

5 Now, in a surreply -- and so again, this is another example of a
6 disclosure of this element/sub-element relationship where the proximal hub
7 has a flow valve. So that is an expressed recitation or expressed disclosure
8 of that structural relationship which we are saying is the appropriate claim
9 construction here.

10 JUDGE FLAX: Counsel, is it possible that -- this is Judge Flax
11 again.

12 MR. BANNER: Sure.

13 JUDGE FLAX: Is it possible that the claims don't cover every
14 embodiment disclosed in the spec but are more focused on an embodiment
15 where there is a valve actually physically configured between a hub and an
16 inflator? Maybe, like, looking at Figure 20 for example.

17 MR. BANNER: Sure. I mean, certainly, the claim language -- I
18 would agree, as a legal principle, that the claim language does not have to
19 cover all the embodiments. But I believe that in this particular instance,
20 when we look at the claim language, we see that the claim language actually
21 does cover all the embodiments. In fact, it was intentionally amended to be
22 broader than just a hub having a flow valve. And that's what we see here in
23 Slide 12.

24 And in the surreply, you know, Patent Owner argues that this
25 prosecution history did not broaden the claim, but it indicated an intent to

1 claim the element separately and that the valve must be between the
2 proximal hub and the inflation device. But that's just incorrect. So the
3 original claim required the flow valve to be part of the proximal hub,
4 whereas the amended claim does not have that same requirement. So
5 contrary to Patent Owner's argument, the amended claim is carefully crafted
6 to leave open two possibilities; the flow valve can be a part of the proximal
7 hub or it can be a separate element.

8 For example, Patent Owner argues now that the amended claim
9 requires a flow valve to be structurally located between the proximal hub
10 and an inflation device. But Patent Owner could have used that word
11 between when it amended this claim, but Patent Owner didn't. Instead, the
12 amended claim only requires that the flow valve is configured to selectively
13 fluidly communicate the proximal hub, quote, "with an inflation device."

14 So that use of the word "with" instead of "between" was intentional
15 and results in a broader claim than the claim that was originally filed. And
16 you can read the current claim that issued that just has a proximal hub and a
17 flow valve configured, you know, to selectively communicate and ask
18 yourself, would that cover an infringing device that had this element/sub-
19 element relationship and as well as an infringing device that had a separate
20 structure as the flow valve and the proximal hub? And the answer is yes. So
21 that tells us that this was a broadening amendment, contrary to Patent
22 Owner's argument.

23 So, you know, Slide 13, let's talk about the case law. So Patent
24 Owner relies on the *Becton, Dickinson* line of cases to argue that the flow
25 valve and proximal hub must be separate structures. But Becton and its

1 progeny are distinguishable. In *Becton*, the exact same structure was
2 accused for both the hinged arm and the spring means. Here, the flow valve
3 is a sub-element of the proximal hub. It's not the exact same structure.

4 Also, in *Becton*, the claim language required separate structures.
5 The spring means was recited as connected to the hinged arm. The spring
6 means extended between the hinged arm and the mounting means. And as I
7 just discussed, no similar restructure -- structural requirement is recited in
8 Claim 1. Patent Owner had -- the applicant had the ability to use the word
9 between when it made that amendment, but it didn't. It used broad language
10 that does not require separate structures.

11 So the Board correctly found -- so *Becton* doesn't apply here for
12 those reasons. In its surreply, the Patent Owner also argues that the recent
13 *Regeneron Pharmaceuticals v. Mylan* case supports this argument. And
14 that's I think page 7 of the surreply. However, like, *Becton*, *Regeneron* did
15 not have any examples in the intrinsic record of the same structure satisfying
16 both terms. So *Regeneron* is distinguishable from the facts here where we
17 have multiple examples in the intrinsic record, that's both the specification
18 and the prosecution history, of examples where you can have this
19 element/sub-element structural relationship.

20 And so indeed, the facts here are more akin to *Google v.*
21 *EcoFactor*, whereas the Board found at page 12 of its institution decision the
22 specification includes embodiments where the flow valve is a sub-element of
23 the proximal hub and the specification and claims do not require separate
24 elements.

25 So as just discussed, the original claims, Figure 42, are in the

1 intrinsic record. That's the specification of prosecution history. Those
2 embodiments show this element/sub-element relationship, and the
3 amendments of original Claim 1 broaden the claim. And all of these things
4 confirm that the claims do not require separate elements. So *Google v.*
5 *EcoFactor* is on point and should determine the result here. And so the
6 Board should maintain a claim construction from the institution decision.

7 Slide 14, moving on to the construction of a digital catheter
8 section. The Board preliminarily construed this phrase, the pages 7 to 18 of
9 the institution decision. And Petitioner adopts that Board's plain meaning
10 construction, which should be maintained. That plain meaning --

11 JUDGE FREDMAN: Let me ask you a question about this.

12 MR. BANNER: Yeah.

13 JUDGE FREDMAN: We did this -- I think if you look -- the
14 question here is, does the distal portion -- I mean just that of the physical
15 catheter, so the tube itself -- or does it include things essentially parts of the
16 wire which is what Eliason is having that are distal to the catheter, right? Is
17 it distal part of the catheter itself or is it a distal things -- including distal
18 things of the catheter assembly, to use the broader term?

19 And I think if we look at column 23 of the '737 Patent, especially
20 line 65, it says a guiding atraumatic tip 150 is coupled to a distal end section
21 of the third catheter member 120. I mean, that sentence pretty clearly is
22 saying that when they talk about the distal end section of the catheter
23 member, they mean the catheter, they mean the tube, not something further.
24 And that in order to get that atraumatic tip, you have to couple it to the distal
25 end section.

1 So when they say distal end section, they actually mean, it seems
2 like from that disclosure, the catheter itself and not other stuff. How do you
3 respond to that?

4 MR. BANNER: So I would respond -- Slide 15, I certainly don't
5 dispute that that is a disclosure in the -- of an embodiment in the '737 Patent.
6 But, you know, when we're looking at claim construction, Philips tells us to
7 start looking at the claims. And what does the claim say? The claim says a
8 distal catheter section distally terminating with an atraumatic tip. This
9 doesn't say distal catheter section distally terminating at an atraumatic tip. It
10 says with an atraumatic tip. I mean, this literally -- the claim language
11 literally says that the distal catheter section, what is the end of it, it
12 terminates with an atraumatic tip.

13 So I think we have to look at that language. And that language
14 says that when we're talking about the distal catheter section -- which really
15 is just a label, right, it's a label of some portion of this catheter -- what is it?
16 Well, the claim says it's the part that terminates with an atraumatic tip. So
17 while that embodiment, it -- column 23 of specification certainly talks about
18 that section ending at the atraumatic tip, that is different than what the claim
19 language recites here.

20 And so, you know, the other claim language surrounding this talk
21 about the intervening occlusion balloon connecting the proximal catheter
22 section with the distal catheter section is consistent with that understanding.
23 And the solid wire extending into the distal catheter section, again, you
24 know, is consistent with this idea that the distal catheter section, as claimed,
25 is the part that terminates with the atraumatic tip.

1 Now, so Patent Owner --

2 JUDGE FREDMAN: It doesn't have to actually be the catheter.
3 The catheter section doesn't have to be the catheter, it's something else.

4 MR. BANNER: It doesn't have to be this --

5 JUDGE FREDMAN: But that's kind of what you're arguing.

6 MR. BANNER: Well, I don't think that's what we're arguing.
7 Well, I mean, I think --

8 JUDGE FREDMAN: The wire which is the -- which in Eliason,
9 it's the wire that forms the atraumatic tip, right, not the catheter?

10 MR. BANNER: Correct. The Eliason -- well, I would not say -- I
11 think there's a distinction here between catheter and shaft. And so I think
12 Patent Owner is talking about this shaft, which is a tube with a lumen in it.
13 And I think when we're talking about the catheter -- and the '737 Patent does
14 this, Dr. Resnick does this, Dr. Cimino does this, you know, go look through
15 the deposition testimony for both of them even -- and even in the
16 declarations, the catheter is a term that's used to -- when we're looking at
17 42A, Dr. Cimino says that's a catheter, you know.

18 So it's not this -- there's a-- I think there's a distinction between sort
19 of the vernacular of catheter. And Dr. Resnick cleared that up in his
20 deposition where he said, when I talk about the catheter, I'm talking to the
21 entire device itself. And that is -- and so I think you're -- the question
22 depends on whether we're talking about the shaft versus the entire thing.
23 And I think that makes a difference.

24 So when -- and for example, I think the question that was just
25 asked touches on an argument that the Patent Owner made in the surreply at

1 page 9, that talks about Figure 15, and the distal catheter member 520 shows
2 a distal catheter section as a shaft that terminates at the atraumatic tip.

3 And so that's -- let me pull up the patent again there. So that was
4 from column 31 where it's talking about at 61 to 64. Well, this whole
5 paragraph starting at page 55. And I note that this highlighted portion at 61
6 to 63, it also says the distal catheter member is not limited to including the
7 lumen and maybe configures a substantially solid between its proximal and
8 distal end or integrally formed with or fixed to the atraumatic tip.

9 So this is the passage that supports this idea that comes from the
10 claim language that the distal catheter section includes and distally
11 terminates with the atraumatic tip. And it doesn't have to be a shaft. And,
12 again, I don't want to confuse a shaft with catheter. Because I think, you
13 know, catheter is more loosely used in -- to refer to the entire device. So I
14 think that answers the question. If it doesn't, I'd be happy to field any other
15 questions about that.

16 The other one on this issue that I just wanted to touch at -- and
17 we'll get to it with when we talk about Eliason specifically. But in the
18 surreply, Patent Owner argued that the --

19 JUDGE FREDMAN: You got about five minutes, by the way, just
20 to let you know.

21 MR. BANNER: Okay. And in the patent, it's separate from the
22 catheter member that terminates in the atraumatic tip. However, the '737
23 Patent expressly states that the catheter member includes a separate
24 stiffening member such as a nitinol wire. And that's at column 52, 28 to 32.
25 So this idea that the catheter member can't be a wire, it's just not true. The

1 '737 Patent has examples of solid members and also wire members that
2 make up the distal catheter member.

3 So let me get back to the slides here. And I may go over by about
4 five minutes. So let's talk about the claim construction of the solid wire.
5 Again, we think that this is plain meaning, no construction is needed. And
6 Patent Owner essentially tries to rewrite the claim that is not ambiguous at
7 all.

8 Slide 18, the solid wire construction that PO provides, it provides
9 this negative limitation with that an internal lumen. Patent Owner argues in
10 its surreply that this negative limitation is supported by the specification.
11 But the Eko Brands case expressly requires a disclaimer or lexicography.
12 And that's just not found in the '737 Patent. At best, there's a passage that
13 discusses an alternative embodiment and a preference for a wire without a
14 lumen. But again, that's -- it's not -- it does not raise the level disclaimer or
15 lexicography. And so this negative limitation should be rejected.

16 So finally, on this issue of whether a solid wire is secured, Patent
17 Owner narrows the claim scope rewriting secured is fixedly coupled or
18 removably attached, but that contradicts the specification. And that's
19 column 35, lines 4 to 28 where it expressly says, hey, there's this fixedly
20 attachment that uses an adhesive. That's the first highlighted -- that's lines 7
21 through 9. But then it says, that's not the only way you can do this. You can
22 also connect -- you don't have to use adhesive, the fixed attachment. You
23 can do other things. It could be otherwise fastened, secured, or fixed to the
24 proximal hub.

25 So secure does not require a permanent attachment. And it's clear

1 from this section of the '737 Patent that that is the case. So for these reasons,
2 the Board should reject Patent Owner's construction and rely on the
3 unambiguous plain meaning of this term.

4 Let's move on to the PHOSITA Slide 20, a person having ordinary
5 skill in the art. Slide 21 provides different PHOSITA definitions that were
6 proposed, one by the Patent Owner and Dr. Resnick at paragraph 18 of his
7 Exhibit 1003, and the other by Patent -- sorry, that's Petitioner. And the
8 other by Patent Owner and Dr. Cimino at paragraph 25 of his declaration.

9 So let's look at what the -- is basically unrebutted from Dr.
10 Resnick's second declaration, and that's Exhibit 1034. Dr. Resnick, in
11 response to this criticism of him on the PHOSITA, the PHOSITA is only
12 used to sort of discredit Dr. Resnick. There's no substantive arguments that
13 appear to reply on what the definition of PHOSITA is. This is simply an
14 attack on Dr. Resnick.

15 But Dr. Resnick testified in his second declaration in response to
16 this attack that he qualifies as a PHOSITA under either Petitioner's or the
17 Patent Owner's definition. That's unrebutted. He also testified that his first
18 declaration is -- the opinions are unchanged even under the Patent Owner's
19 PHOSITA definition, and that's at paragraphs 44 to 48 of Exhibit 1034.
20 That too is unrebutted.

21 Dr. Resnick testified that the PHOSITA definition should include
22 MDs, and that's at paragraph 25 to 33 of his second declaration. And he
23 gave examples that the prior art is authored and edited by MDs and
24 publications and directed to MDs. And this is under the test of the Federal
25 Circuit of what types of things you look at. Those are the types of things

1 you look at to figure out who the PHOSITA is.

2 So the other thing that --

3 JUDGE FREDMAN: Would --

4 MR. BANNER: Yeah.

5 JUDGE FREDMAN: Would Dr. Resnick exclude people who are
6 not MDs, which sort of seems like the original definition maybe did?

7 MR. BANNER: No. So originally, Dr. Resnick was focused on
8 MDs because that's his -- that's the field. Going back in Exhibit 1034, he
9 looked at the evidence and the other cited -- the arguments that the Patent
10 Owner made. And he agrees that the PHOSITA can include other folks in
11 addition to what he originally defined.

12 So the Petitioner is -- believes that the Board can adopt a definition
13 of PHOSITA that includes both definitions. They're not mutually exclusive
14 and they both have support based on all the factors you look at, based on the
15 case law the Federal Circuit says to look at.

16 And so again, what we think is sort of missing from the Patent
17 Owner's definition and what Dr. Resnick thinks is missing is any reference
18 to an MD, you know. The Patent Owner basically was trying to discredit Dr.
19 Resnick, so they left MDs out of their definition. But everyone agrees that
20 MDs can qualify, and everyone agrees that MDs are an important part of the
21 process. So it's a little odd that that Patent Owner's definition does not even
22 mention MDs.

23 And so finally, this last bullet on Slide 22, an MD with extensive
24 experience using inclusion devices --

25 JUDGE FREDMAN: Your first 20 minutes are up. If you want --

1 MR. BANNER: Okay.

2 JUDGE FREDMAN: Your first 40 minutes, you can run it if you
3 want. You'll be going into your --

4 MR. BANNER: Okay. Yeah. I would be running it here for
5 about five more minutes.

6 JUDGE FREDMAN: Okay.

7 MR. BANNER: So Slide 23, I think, here it is in this -- where Dr.
8 Resnick talks about his experience and -- sorry, this is Dr. Cimino, everyone
9 seems to agree that MDs can be a PHOSITA. So I think I will cut the
10 PHOSITA -- I think that's -- the remaining slides on the PHOSITA, I don't
11 think we need to get into. Unless there's any question on that, I'll get to
12 some of those substantive issues.

13 Again, this issue doesn't go to any of the substantive issues on the
14 PHOSITA. It's simply about the weight to be given to Dr. Resnick. And
15 those things that Dr. Resnick testified to in his second declaration are
16 unrebutted. The Patent Owner didn't even depose him, chose not to depose
17 him. And so there's -- that stands as evidence that's unrebutted.

18 Let's go to Slide 27, Fogarty and the expectation of success. So
19 Slide 28, so the issue is that Fogarty Exhibit 1004 does not indicate the size
20 of the catheter. And there's a limitation in Claim 1 that requires catheter is
21 smaller than 6 French. And Petitioner's petition raised the fact that Fogarty
22 catheter smaller than 6 French were known, for examples of Chengod and
23 Deaton, and provided motivations to size Fogarty's catheter less than 6
24 French. It's just one choice among a limited number of design choices and
25 smaller devices are generally safer.

1 So we provided evidence in Dr. Resnick's initial declaration,
2 paragraphs 90 to 92, that sizing Fogarty's catheter less than 6 French works,
3 as evidenced by Chengod and Deaton. Now, the issue is that the Patent
4 Owner argues that Fogarty catheter cannot size to a 6 French because it has
5 this spring coil, braid, outer tube, and lumen construction. That's the issue.
6 So the Patent Owner says, you didn't show a reasonable expectation of
7 success because you didn't show that these things could be -- a Fogarty
8 catheter with this construction could be sized to 6 French.

9 So in reply, Dr. Resnick at paragraph 96 -- 86 to 95 and 97 of
10 Exhibit 1034 explained this other prior art patent Exhibit 1033 called
11 Yassinzadeh. And it shows a very similar analogous construction that has
12 coils. It has basically two coils or a coil and braid, it has an outer tube and a
13 lumen. And this one can be sized down to below 6 French.

14 And so this is in rebuttal to the arguments made by the Patent
15 Owner. And surreply arguments and new arguments are appropriate in this
16 case when you're replying to arguments made by the Patent Owner. The
17 Patent Owner cites to *Qiagen v. HandyLab* is for saying -- for the
18 proposition that you can't present these reply arguments and evidence. But
19 in that case, the Petitioner was not even replying to an argument. That was
20 just the Petitioner changing its mind or changing its theory.

21 And there's Federal Circuit and the Board has consistently held and
22 that the Petitioner is permitted in reply to introduce new evidence and
23 arguments to show knowledge that a skilled artisan would bring to bear in
24 reading references cited in the petition. And that's exactly what's happening
25 here.

1 And one of Federal Circuit case that says that is *Wildcat Licensing*
2 *v. Atlas*, that's 2024 U.S. App. LEXIS 543. And that is basically what we're
3 relying on here. This is entirely appropriate. And so Fogarty solid wire,
4 there is an expectation of success. None of the theories have changed. None
5 of the explanation has changed. It's just prior art shows that this is doable,
6 this is something that you can do with Fogarty catheter.

7 Slide 31, so Fogarty's stylet, the solid wires are secured within the
8 proximal hub. Slide 32, I mean, Fogarty literally -- so the argument that
9 Patent Owner makes is that the Fogarty's stylet is not secured to the catheter.
10 But Fogarty literally uses the term secured when it's talking about how the
11 proximal end of the stylet is secured in the cap and then secured in the
12 catheter. So this is -- we don't think this is an argument that should be given
13 any weight. It's contrary to what the actual prior art discloses.

14 Slide 33, so this is a -- Patent Owner seeks basically an implicit
15 construction that improperly incorporates specification embodiments.
16 Again, they say it has to be somehow not removable. But that's just not
17 supported by the specification. Dr. Resnick explains that the stylet is not
18 absent during these normal operating conditions because it's used in Fogarty
19 during insertion. And so there's just no -- there's really no sense in Patent
20 Owner's argument here that would say that you can't be secured at one point
21 and then removable later and meet the claim language.

22 Slide 34, so again, the proximal hub and the flow valve. So even
23 under -- you know, if we accept this idea that the proximal hub and flow
24 valve have to be -- or sorry, I apologize, Slide 34 is Fogarty's stylet is
25 secured within the hub under Patent Owner's secured construction, which is

1 unremovably attached. So if you accept that as the claim construction,
2 Fogarty's coil tin is a solid wire that's integrally connected to the tube socket
3 33, which is part of the proximal hub.

4 And so, you know, again, Patent Owner argues that this is a new
5 argument. But *Western Digital Tech v. Viasat* in the PTAB, that's IPR 2022-
6 1171, in December 13, 2023, the Board allowed this kind of evidence saying
7 Petitioner's replies in response to new claim construction. The Federal
8 Circuit is held -- and in addition, the Federal Circuit held the Petitioner must
9 be given an opportunity to respond to these types of new claim
10 constructions.

11 *Axonics v. Medtronic*, that's 75 F.4th 1374, the Patent Office said,
12 we -- or sorry, the Federal Circuit said, we hold that we're a Patent Owner
13 and IPR first proposes a claim construction. And the Patent Owner
14 response, a Petitioner must be given the opportunity and to reply, to argue,
15 and present evidence of anticipation for obviousness under the new
16 construction, at least where it relies on the same embodiments for each
17 invalidity ground as relied on in the petition. So again, all of the claims that
18 the Patent Owner makes about new arguments, they are proper. They're
19 proper under *Axonics* and the Patent -- and the Board's prior decisions, like
20 *Western Digital*. We are responding to arguments that were made by the
21 Patent Owner.

22 Slide 35, Fogarty's proximal hub and flow valve. Slide 36, again,
23 this is under the correct construction where there's a sub-element and
24 element relationship. There's no dispute that these limitations are met. Slide
25 37, even under the incorrect claim construction, you can look at -- like I said,

1 like we discussed before, you can look at the separate pieces and you can
2 kind of separate them out and say the PHOSITA had knowledge of how to --
3 based on Chengod, how to do these separate pieces for the valve and the
4 hub.

5 And Slide 38 shows this in our briefing, the reply 25 to 28. So I
6 think I'll skip to -- unless there are any questions about the proximal hub and
7 flow valve on Fogarty, the --

8 JUDGE FREDMAN: You have about a little more than 10
9 minutes left.

10 MR. BANNER: Yeah. So, I think Grounds 1 through 2 and 6 to
11 7, this is Slide 40, the asymmetrical balloon shape is obvious. This is all
12 explained in the petition, and this is the petition in Exhibit 1034 or 127. The
13 PHOSITA would use a compliant balloon that inflates asymmetrically.
14 There's paragraphs and paragraphs of explanation in the petition and Dr.
15 Resnick's initial declaration that are -- talk about this.

16 And the Patent Owner just ignores that, it just says there's no
17 evidence. They didn't cite anything. But that's just not the case. Saab does
18 not teach away. This is another of Patent Owner's arguments, Saab teaching
19 away from asymmetrical compliant balloons. But again, that is not -- they're
20 not using the right teaching away test. It literally just says, in some cases,
21 you would want to use something other than a compliant balloon.

22 And on Slide 43, that's the *In re Gurley* case. It's just disclosing a
23 preference. It's not teaching away. So Grounds 5 through 9, this is Slide 44,
24 Eliason's distal catheter section, you know, and then in Slide 45, you know,
25 the Patent Owner does not dispute that Eliason discloses it, this -- under the

1 Board's construction.

2 And so, you know, we think that that construction should hold.

3 And therefore, we think that Eliason absolutely discloses the distal catheter
4 section for the reasons in our briefing. It's not limited to the shaft. Again,
5 this is Dr. Resnick testifying. This is quotes from his testimony, that the
6 catheter is the shaft of the device.

7 Typically, I would describe the catheter exceeding from proximal
8 hub to the end of the device distally. Thus, the catheter is the whole device,
9 so from the proximal hub to the end of distal device. And that's the evidence
10 that I was referring to earlier when we were talking about this, about what is
11 the catheter. And that's Exhibit 1034 at 133.

12 So Eliason does have this. And I think that based on that evidence,
13 the Board can find that Eliason discloses the distal catheter section. And
14 Slide 48, Eliason's proximal hub and flow valve, the issues are the same with
15 respect to Fogarty. And for the same reasons, Eliason's proximal hub and
16 flow valve are satisfied.

17 Unless there are any other questions, I will reserve the remaining
18 time for rebuttal.

19 JUDGE FREDMAN: Okay. So you have about eight minutes for
20 rebuttal. Are there any other questions?

21 JUDGE FLAX: None for me.

22 JUDGE FREDMAN: Okay. Then Counsel for Patent Owner, you
23 can begin. Mr. Murray, I think.

24 MR. MURRAY: Yes. Thank you, Your Honor. One second. All
25 right. So I'm going to jump right into the kind of main first issue that

1 occupied a lot of the other part of Mr. Banner's argument, which has to do
2 with the interplay of the proximal hub and the flow valve.

3 And I think it's understood that the Federal Circuit's *Becton*
4 decision and its lineage tell us there is a presumption that separately recited
5 components in a claim are distinct from one another. And that's a
6 presumption, by the way, Petitioner bears the burden to show it has
7 overcome, even though it provided zero argument in that regard in the
8 petition.

9 And I'm going to refer to Petitioner's Slide 11 because there's
10 really where kind of the three main arguments they try to make to show that
11 the '737 specification contains some description.

12 JUDGE FREDMAN: Okay. Let's begin with a question about
13 your spec, though. I'm kind of curious, what is a hub, right? What is it --
14 what exactly does a hub mean? What does that word mean? Do you have a
15 definition in the spec anywhere?

16 MR. MURRAY: To my understanding, there's no formal or
17 explicit definition. I think when you view the specification in context, when
18 it's talking about the hub, or more specifically the proximal hub of this
19 catheter system, specifically we're talking about this piece that is going to
20 connect the injection device or inflation device to the lumen of the catheter.

21 JUDGE FREDMAN: So it's the part that connects the syringe to
22 the catheter.

23 MR. MURRAY: Correct. That's correct.

24 JUDGE FREDMAN: Okay. So we have the Luer lock. And let's
25 just -- for purposes of this, it's probably easier to look at not Figure 42A but

1 Figure 40. Now, if you can see that one. So Figure 42A, we could look at
2 Figure 42A, the hub with the stopcock valve, it's the same difference.

3 We have a part of that hub with the stopcock valve in 42A, and we
4 certainly have that in 1504 on Figure 40, that projects out from the valve and
5 is a part that connects to the syringe, right? Why is that not -- that little bit
6 of it, not the hub, why is the whole thing the hub?

7 MR. MURRAY: I'm sorry, which part --

8 JUDGE FREDMAN: What does that even mean? What --

9 MR. MURRAY: So --

10 JUDGE FREDMAN: If you're looking at 42A or 1504, 1504 has,
11 like, a little part -- has the valve that central portion where the numbers
12 pointing to. Then on the right side of that figure, there's a little extension.
13 And that extension then connects to a tube that is connected to the syringe.
14 So that little section that connects the tube is essentially serving as a hub,
15 right? It's connecting the product to the tube from the syringe to the tube
16 that then connects to this hub -- if I'm calling it that -- to the valve.

17 You similarly see that in Figure 42A, right? There's a little
18 projection on the top that connects that you would put the tube into. And
19 then that below, that is where the valve is. So what -- I mean when you say
20 hub and valve, it's a little unclear what you mean by that. I mean, I
21 understand that you have an embodiment in your spec that seems to separate
22 them. But I don't think you actually show -- maybe I'm wrong -- an actual
23 physical image of a separated one. You show sort of schematics of that.
24 (CROSSTALK) --

25 MR. MURRAY: We don't -- yeah. We don't --

1 JUDGE FREDMAN: You don't actually show an actual
2 embodiment where you show a valve and then separately show a hub; is that
3 true?

4 MR. MURRAY: We do not show a flow valve and a hub in kind
5 of a realistic or, you know, the --

6 JUDGE FREDMAN: It's in a grammatic way, right. I understand
7 what it is. You show it in a --

8 MR. MURRAY: In schematic form.

9 JUDGE FREDMAN: Yes, in schematic form. Okay.

10 MR. MURRAY: And what --

11 JUDGE FREDMAN: So when we're looking at --

12 MR. MURRAY: Go ahead.

13 JUDGE FREDMAN: We're looking at this, like, so the one on the
14 right of Figure 42A or 1504, why is the other -- the portion that's closer to
15 the syringe in both cases not the hub?

16 MR. MURRAY: The portion closer to the syringe, well, the claim
17 language talks about the -- let me pull up the claim.

18 JUDGE FREDMAN: The claim says a proximal hub, a flow valve
19 configured to selectively fluidly communicate the proximal hub with an
20 inflation device. It says nothing about the relationship between the two.
21 The word between as Patent -- as Petitioner raised doesn't appear.

22 MR. MURRAY: So the -- it's correct that the term between does
23 not appear. However, Dr. Cimino did testify that the language of the claim
24 that the -- configured to selectively fluidly communicate the proximal hub
25 with an inflation device, he testified that that imparts the structural flow of

1 how this goes is you have the inflation device, you then have a valve, you
2 then have a proximal hub. He, in fact, during his deposition, he had a hard
3 time being able to reconcile that that, what he understood in that language.

4 JUDGE FREDMAN: I think what you're saying you have -- say
5 that again, you say you have an inflation device, then a valve, then a hub?

6 MR. MURRAY: Then the flow valve, then the proximal hub,
7 correct.

8 JUDGE FREDMAN: The hub is on the other side is distal to the
9 valve?

10 MR. MURRAY: Correct.

11 JUDGE FREDMAN: Is that what you're trying to say?

12 MR. MURRAY: Correct. That is correct. That's what the
13 selectively fluidly communicate the proximal hub with the inflation device
14 imparts. That's the structural detail that it provides.

15 JUDGE FREDMAN: And so one of the questions I have here also
16 is -- so if we take, again, Figure 42A as a simple example, right -- and we've
17 talked about that hub with a stopcock -- now do you dispute that that's a hub
18 with a stopcock valve, in Figure 42A?

19 MR. MURRAY: We dispute that there's adequate evidence to
20 show that's a hub with a stopcock valve. And first of all, it shows --

21 JUDGE FREDMAN: Okay. That's fine. I just -- I was just
22 curious, if you dispute it.

23 MR. MURRAY: Yeah.

24 JUDGE FREDMAN: So we have a valve there, but we also have
25 this idea in Figure 40. Let's look at that for a second where we have

1 essentially this valve and there are things on the proximal end and on the
2 distal end, right? On the distal end, there's also a pressure sensor, right? But
3 there's lots of different things there. What exactly distinguishes a hub from
4 any of these things? What makes a hub a hub?

5 MR. MURRAY: Well, I would point out that --

6 JUDGE FREDMAN: The distal hub connects a tube or something
7 else?

8 MR. MURRAY: Yeah. It connects to -- it connects the inflation
9 device to the lumen. I would say even if you were to assume that the
10 pressure sensor and a coupling 1512 and 1510, in Figure 40, even if you
11 were to say that's a proximal hub, that's a separate piece than the valve 1504
12 that it's connected to there.

13 JUDGE FREDMAN: Absolutely, yeah.

14 MR. MURRAY: So that certainly provides no evidence that the
15 hub is part of -- or the flow valve is part of the proximal hub.

16 JUDGE FREDMAN: But obviously, in 1604, it expressly says
17 that they're together.

18 MR. MURRAY: Well, so 1604 is -- we have to be careful here. It
19 doesn't call 1604 or anything in Figure 42 a proximal hub. It refers to hub
20 members. That's a different component. And it's a component of a sleeve
21 system, not the catheter system. And when you look at -- when the proximal
22 hub is described for the catheter system, it's talked about as performing this
23 function of connecting the inflation device to the lumen, which the hub
24 member, 1604, of the sleeve system does not do. And so that would not be
25 understood by one of ordinary skill in the art to qualify as a proximal hub for

1 purposes of understanding Claim 1.

2 JUDGE FREDMAN: Okay. Even though it calls it a hub and it
3 say it has -- there's a valve in it?

4 MR. MURRAY: It's a hub member and it has a -- what's called a
5 Tuohy Borst valve. And what you see going on here is that this actually
6 slides over the catheter and this -- so when you --

7 JUDGE FREDMAN: I understand it's a different thing; we get
8 that. That's not the question. The question is it's using those terms as two
9 things in the same device, suggesting that a single element can have both a
10 hub property and valve property and a valve property. I mean, that's pretty
11 much --

12 MR. MURRAY: So again --

13 JUDGE FREDMAN: Are you arguing that that doesn't say that?

14 MR. MURRAY: What I'm arguing is that --

15 JUDGE FREDMAN: No. Answer the question, please. Are you
16 arguing that this particular device is not both things at once?

17 MR. MURRAY: It has a valve and what's called a hub member
18 together, I agree with that.

19 JUDGE FREDMAN: Okay. Thank you.

20 MR. MURRAY: However, it's not a flow valve, which is what is
21 in the claim. The claim is not --

22 JUDGE FREDMAN: Yeah. I agree with that. It's not the same
23 kind of valve.

24 MR. MURRAY: Okay. It's not the same kind of valve and it's not
25 the same device that is used in the catheter system. This is for a sleeve

1 system that goes over the catheter. It's a different piece.

2 JUDGE FREDMAN: Totally.

3 MR. MURRAY: So from that perspective, that's why we say that
4 one of ordinary skill in the art would not look at that when trying to
5 determine whether or not the flow valve and proximal hub was cited in the
6 claim should be combined or whether they're separate. It's a different --

7 JUDGE FREDMAN: The question isn't really -- it really isn't a
8 question of what the person of ordinary skill would try and figure out from
9 your patent. It's a question of what does the terms mean, right? When you
10 say a hub and then a flow valve, do those have to be separate elements or
11 not? The answer is no, according to your own specification. The flow
12 valves can or -- valves, not flow valves. The valves can be part of hubs.

13 MR. MURRAY: Valves can be part of hubs. But again, it's a flow
14 valve. It's a very specific type of valve that we're talking about here.

15 JUDGE FREDMAN: The figures, that doesn't -- do you have any
16 place in the spec where it says, definitionally, that those are distinct, there's a
17 between there. It shows it. I'm not seeing their embodiment. I'm asking if
18 there's any definition.

19 MR. MURRAY: There's no explicit definition, no. But I, again,
20 go back to Becton --

21 JUDGE FREDMAN: You're trying to read this into the claim,
22 right? So we are under *Philips*. We aren't trying -- we're not reading it like
23 an examiner would read it right, which --

24 MR. MURRAY: Correct.

25 JUDGE FREDMAN: -- it should have read it that way, probably,

1 but whatever.

2 MR. MURRAY: So correct, we're under *Phillips*, we're trying to
3 read the claim within the context of the specification. We're not trying to
4 read anything in, certainly the express claim language of configured to
5 selectively fluidly communicate the proximal hub with an inflation device,
6 as Dr. Cimino testified provides a structural order to the components and
7 how they're supposed to be arranged. And the idea that a flow valve,
8 specifically, can be combined as part of a proximal hub interferes with that
9 understanding cannot be reconciled.

10 And so when you're reading the claim, first, you look at the claim
11 language. The claim has this expressed description that provides what Dr.
12 Cimino said is that order of components. So you have expressed language
13 that says they shouldn't be combined. You don't have anything in the
14 specification where the flow valve specifically is part of a proximal hub. So
15 you don't have anything that shows exactly what's it's trying to be --

16 JUDGE FREDMAN: The flow valve?

17 MR. MURRAY: Flow valve, correct. If I --

18 JUDGE FREDMAN: You're being specific to flow valve. I
19 understood that.

20 MR. MURRAY: Correct, yes. And the -- and under *Becton*, when
21 you have something recited separately in a claim, there is a presumption that
22 it is separate. And so it is the burden on the Petitioner to show why that
23 presumption is overcome. And I disagree with the characterization of
24 *Becton* in the -- on Slide -- Petitioners slide -- I think it's 13, where it says
25 the exact same structure was accused for both the hinged arm and the spring

1 means.

2 In *Becton*, the hinged arm of the prior art read on the hinged arm in
3 the claim, but then just the hinge was read on the spring means. And so we
4 have something similar here, where you have -- in Fogarty, for example, you
5 have the whole thing was the proximal hub, but then just that valve portion
6 is the valve, even though it's still part of the same device. So *Becton*, I think,
7 is squarely on point with what's going on in Petitioner's analysis.

8 And then with regard to Slide 12, Petitioner's Slide 12, where we're
9 talking about the prosecution history, I think to say that what was done was a
10 broadening amendment, I think disregards the actual facts of the prosecution
11 history. You can see, as was correctly pointed out, the Original Claim 1 said
12 a proximal hub having a flow valve, that was separated. And the language
13 configured to selectively fluidly communicate, which Dr. Cimino says
14 imparts that order of components was added in. And so to us, that
15 amendment narrowed the -- what the claim was intended to mean and what
16 could qualify as a proximal hub and a flow valve.

17 JUDGE FREDMAN: Did the prosecuting attorney give any
18 reason for the amendment?

19 MR. MURRAY: I believe this was a preliminary amendment, so
20 no expressed reason was given.

21 JUDGE FREDMAN: So he just made a change. There's no
22 reason -- we don't understand why he made that at all?

23 MR. MURRAY: There was no -- there is no expressed --

24 JUDGE FREDMAN: No response. It's not responsive to an
25 examiner's action in any way.

1 MR. MURRAY: Correct. I believe this was in a preliminary
2 amendment. That's right, yeah.

3 JUDGE FREDMAN: So in fact -- I mean, it does require -- I think
4 you're right, that it does require it now that there's selectively fluidly
5 communicating the hub with an inflation device, right? So that's what the
6 flow valve has to be able to do. Deleting the word having does mean that it
7 isn't necessarily part of the (INDISCERNIBLE - TECHNICAL
8 DIFFICULTY) as well. I think I agree with you there as well. I don't know
9 that it excludes it, though. That's what you're trying to argue, right? You're
10 trying to argue that it excludes the flow valve part of the proximal hub?

11 MR. MURRAY: Correct. And that --

12 JUDGE FREDMAN: That isn't something that the prosecuting
13 attorney made that argument. We don't have any evidence supporting that
14 position. It's simply an inference you're making correct.

15 MR. MURRAY: And I think Judge Flax asked a question to Mr.
16 Banner that kind of hinted at that, which is how can you, if you have an
17 integrated feature, how can you parse which part of it is a proximal hub
18 that's being fluidly communicated. And Dr. Cimino struggled with that very
19 question in his deposition. And so as I said, that language that's added is
20 what imparts the structural component flow that leads you to the conclusion
21 that the flow valve cannot be part of the proximal hub, or at least supports it.

22 So unless there's any further questions on that, I'll get directly to
23 the Fogarty argument. And actually, yeah, so Fogerty, if the proximal hub
24 and the flow valve cannot read on the same elements, then certainly
25 Petitioner's argument for unpatentability fails. At Petitioner's Slides 37 to

1 39, they have this alternative argument where they're now saying, well, it
2 would be obvious to separate the flow valve and the proximal hub in Fogarty
3 to read on what is in Claim 1 based on Chengod's assembly.

4 And I want to point out, it was -- that we didn't certify -- that's an
5 impermissible change in position. Petitioner's argument initially was
6 Fogarty disclosed these elements and their relationship explicitly. And now,
7 it's switching to the argument that it's no longer present but would have been
8 obvious. You could see direct --

9 JUDGE FREDMAN: So you're saying that it wasn't originally in
10 the petition. I wonder if the argument I think they would make in reply -- I'll
11 make it for them, and then we'll have you respond to it so that we have a full
12 record --

13 MR. MURRAY: Sure.

14 JUDGE FREDMAN: -- is I think they would argue that, well,
15 there wasn't a claim interpretation, so we didn't know what it meant. We
16 didn't know what Petitioner even thought it meant, right -- I mean, Patent
17 Owner thought it meant. They didn't know what you meant when they filed
18 their petition. So now that we know that you mean it as two separate things,
19 they're responding to your position. I don't know that they would agree with
20 that, but that seems to be what they would likely say.

21 MR. MURRAY: I anticipated that would be their argument, and
22 Your Honor's exactly correct. And Mr. Banner can let us know in his
23 rebuttal. But what I would say to that is, firstly, this is not responsive to
24 claim construction, one, because when you have -- when you are reading one
25 component on two different claim features, act and presumption applies.

1 And the onus is on the challenger to say why it is okay to do that. And so
2 their approach from the beginning should have been to address Becton,
3 knowing that's what they were doing.

4 Also, responsive in this case would have been to argue how either
5 our interpretation is wrong, which they've tried to do, or to show why the
6 arrangements in Fogarty or Eliason still disclosed this feature in light of that
7 definition. Instead, they've taken a new direction and approach, which is to
8 say not that these elements are disclosed as claimed but it would have been
9 obvious to make them that way. The trial practice guide, specifically on
10 page 74 says that kind of change in position is making a new contention and
11 it's not properly within the purview of what it means to respond to a
12 preceding brief. And this falls directly within the fact patterns of the *Yita*
13 and *Intelligent Bio-Systems* Federal Circuit cases that we cite in our surreply,
14 pages 20 to 21 and 24.

15 I'll also point out substantively, even if Your Honors were to take
16 up this argument, what they've done here actually creates problems for the
17 rest of their argument. If you look at Petitioner's Slide 38, you can see how
18 they divvy up the valve and proximal hub in Fogarty, according to this new
19 argument. If you separate out the valve the way they've done here, Fogarty
20 has a wire stylet which they've initially in the petition characterized as the
21 solid wire. And the claim says the solid wire has to be secured with a
22 proximal most end in the proximal hub.

23 Well, in -- on Slide 38 from Fogarty's Figure 4, the stylet and its
24 cap would attach to the valve where the syringe is currently attached. And
25 so what you're going to have there, if the valve is to the left of the proximal

1 hub, is now your, quote/unquote, "solid wire" is no longer having its end
2 secured in the proximal hub. It's actually upstream of the proximal hub. So
3 this new theory actually swaps one missing element for another one as part
4 of their analysis. And the same as Mr. Banner said, the same arguments
5 hold true for Eliason, they fail if you properly construe the relationship and
6 the obviousness arguments are new and not well reasoned.

7 If there's no more questions on that, I was going to turn to the
8 distal catheter section.

9 JUDGE FREDMAN: Sure.

10 MR. MURRAY: Okay. And I think, as you've seen earlier today,
11 the fundamental question really is what is the catheter so that we know what
12 is the distal section we're talking about. And the catheter is -- it's a shaft, it's
13 a tube. Dr. Resnick said it multiple times, regardless of how Petitioner
14 wants to spin it in hindsight. And I asked him in his deposition, when you
15 refer to a catheter, what do you mean by that? And his literal answer was
16 the catheter is the shaft of the device. It's page 26 of Exhibit 2002, lines 19
17 to 21.

18 JUDGE FLAX: Counsel, this is Judge Flax.

19 MR. MURRAY: Yes.

20 JUDGE FLAX: Isn't a catheter the entire device that goes inside
21 of a patient?

22 MR. MURRAY: It is not. I think Mr. Banner actually said
23 catheter is -- may loosely be used in that manner. But we're talking about
24 claim construction, and loose usage is not the Philips standard. And when
25 you look at what's in the '737 specification to read the claim in light of the

1 specification, the catheter members, like distal catheter member 520, are all
2 shown as shafts. They're not shown as other pieces, like the wire or other --

3 JUDGE FLAX: So are you saying that the catheter is only the
4 sheath of the device?

5 MR. MURRAY: Correct, yes. Because the claim is a catheter
6 system, the catheter is part of the catheter system, as is the proximal hub, as
7 is the solid wire, et cetera.

8 JUDGE FLAX: So let's take a look at Figure 10 of Eliason. That's
9 Exhibit 1009.

10 MR. MURRAY: Figure 10, you say?

11 JUDGE FLAX: Yes, sir.

12 MR. MURRAY: Okay. I'm there.

13 JUDGE FLAX: Okay. So under your understanding of the term
14 catheter and what a catheter means in the art, where does a catheter end in
15 this device, if you're going from the most proximal to the most distal part?

16 MR. MURRAY: So my understanding under a reading of Claim 1,
17 the catheter likely extends from it looks like the flange 56 up to the balloon.

18 JUDGE FLAX: And the balloon is not part of the catheter?

19 MR. MURRAY: Correct. And I believe even Dr. Resnick
20 described the balloon as being separate from the catheter. And everything
21 you see distally there in Eliason is actually part of the wire. And since we're
22 on Eliason, I'll get to that part.

23 JUDGE FREDMAN: Let me ask a question there, just --

24 MR. MURRAY: Sure.

25 JUDGE FREDMAN: It occurs to me now and it may be may be

1 unreasonable. But the wire is secured, it says, to the catheter. That's pretty
2 clean. So if two things are secured together, are they part of the same thing
3 or not?

4 MR. MURRAY: So if it's -- the wire is secured to the catheter,
5 they together form a catheter system, but the wire doesn't transform into the
6 catheter.

7 JUDGE FREDMAN: It's not the catheter section.

8 MR. MURRAY: Correct.

9 JUDGE FREDMAN: I mean, that's what you're saying, it's not the
10 catheter section?

11 MR. MURRAY: Yeah. It's not the catheter and, therefore, can't
12 be a catheter section because it can't be a section of the catheter.

13 JUDGE FREDMAN: Right.

14 MR. MURRAY: A good analogy I thought of was you have a tire
15 and you have a rim, a tire doesn't become the rim just because it's attached to
16 it. They form a wheel together, but the tire doesn't become the rim, just as
17 the wire here does not become the catheter.

18 JUDGE FREDMAN: Yeah.

19 JUDGE FLAX: So if that's true, why call it a catheter sheath?
20 Why not just call it a catheter?

21 MR. MURRAY: I'm sorry, I don't quite --

22 JUDGE FLAX: You're saying that the sheath is the catheter, no
23 other part of the apparatus that would go inside of a patient's vascular system
24 is the catheter. So why call it a sheath?

25 MR. MURRAY: Why call it a --

1 JUDGE FLAX: Why give it an extra word of nomenclature if that
2 is the catheter? Why call it the catheter sheath?

3 MR. MURRAY: Where is it called a catheter sheath? Are you
4 referring to -

5 JUDGE FLAX: Everywhere in the art it's called the sheath.

6 MR. MURRAY: So I can't speak to why they would add a
7 different word. In the '737, it does not always call it a catheter sheath, if at
8 all. Eliason doesn't use that nomenclature either, as I understand it. We're
9 looking at the specific claim terms in the patent, catheter refers to a specific
10 part of the overall catheter system, which happens to be a shaft or sheath or
11 whatever you want to call it. And other parts of the catheter system aren't
12 part of the catheter itself.

13 And so similarly, the catheter is certainly the main part of the
14 overall system. That's what allows you to get in to perform the necessary
15 operations that need to be performed. Catheter sheath may just be a manner
16 of just clarifying. But we have in the patent claim catheter. Catheter is in
17 the specification shown to be just the shaft of the device. And so the wire or
18 parts of the wire would not be considered as part of the catheter, and so it
19 can't be part of a section of a catheter.

20 JUDGE FREDMAN: I mean, you actually -- at the end of the
21 claim, that's real clear I think too because your proximal catheter section, an
22 inclusion balloon which is therefore not part of the catheter, distal catheter
23 section with a certain size and (INAUDIBLE - TECHNICAL
24 DIFFICULTY) configuration, so.

25 MR. MURRAY: Correct.

1 JUDGE FREDMAN: It sort of also supports that these are
2 different pieces.

3 MR. MURRAY: Right. And then -- and so obviously, what else is
4 driving this whole thing is what's missing from Eliason is the wire extending
5 into the distal catheter section. Because if the wire can be a distal catheter
6 section, it's -- it extends it to itself, which is nonsensical. And because -- the
7 specific issue here is you have these securement beads 24, 26, and wire
8 struts 22, which as part of the institution decision, where couldn't these be
9 considered part of the distal catheter section? But those are all part of the
10 wire.

11 And Dr. Resnick agreed with that. In fact, he, during his
12 deposition, when he was asked about this arrangement, using -- his word
13 was the catheter goes into the body over the wire. So even in his
14 explanation, the catheter and the wire are two separate things. And when
15 you pre-secure it, he was still referring to it as the catheter and the associated
16 wire device in his testimony.

17 So as I mentioned before, the beads and the wire struts aren't going
18 to change what they are part of just to become part of the catheter, just
19 because you're inserting them all together. And so no one of ordinary skill
20 in the art is going to understand these components in Eliason to be a distal
21 catheter section, pre-secured or not. Are there any other questions on that
22 issues, Your Honor?

23 JUDGE FREDMAN: I don't hear any.

24 MR. MURRAY: Okay. I'll move to the solid wire argument then.
25 That's the last of the kind of three claim construction issues. And the -- as

1 you heard briefly from Mr. Banner, the issue really as, well, what does
2 secured mean? Does it have to be fixedly coupled in there, or can it be a
3 removable attachment? If you look at their Slide 19, that shows -- the reason
4 why you have to permanently attach it is because you have these forces in
5 the aorta when this thing is in use that are going to want to collapse the
6 balloon and the catheter in the longitudinal direction if you don't have the
7 right amount of reinforcement.

8 So the claims add this permanently attached wire so you can get
9 the balloon where it needs to be and keep it there for the duration of the
10 procedure. The bottom of the quoted portion from the '737 spec on their
11 Slide 19 explains that that's what's going on here. The assembly is able to
12 withstand the normal operating conditions, and the securement results in a
13 structure able to perform the preferred functions.

14 Mr. Banner was walking through the highlighted sections here.
15 But as you can see, it says the solid wire is fixedly coupled to the proximal
16 hub, preferably using an adhesive. And then the second highlighted portion
17 gets to, well, it doesn't have to be adhesive. It can be other ways to fasten,
18 secure, or fix. And that demonstrates that secured and fixedly coupled are
19 reasonably equivalent.

20 And it's even further reinforced by the prosecution history, if you
21 look at Exhibit 1002, pages 578 to 79, which was cited in our surreply at
22 page 12, it's the - there was an argument made there. And actually, the
23 secured language was added to the claim during prosecution in response to a
24 rejection. There was an argument there based on a piece of prior art that had
25 a guide wire that was configured to be steered and manipulated through the

1 blood vessel and then subsequently removed.

2 And so the argument where -- there is it cannot be secured at a
3 proximal end thereof. So the prosecution history also shows that secured
4 was meant to be a permanent attachment and not something that could be
5 removed prior to the catheter system actually performing the operations it's
6 intended to be used for.

7 And when you get to Fogarty, that's exactly the difference.
8 Fogarty's wire stylet has to come out because you can't inflate the balloon
9 when the stylet is installed. Petitioner did bring up in the reply and in the
10 slides today the new theory that Fogarty's spring coil pin is -- could
11 alternatively be a solid wire.

12 And we argued in our surreply this is a change -- another improper
13 change in position. They are entirely switching the element it -- that they
14 had relied on to satisfy one of the claim elements, which that is
15 impermissible under the Federal Circuit *Ariosa* case. And on that basis
16 alone, you should disregard it. But substantively, the -- this is where the
17 solid wire part of our construction actually comes in.

18 JUDGE FREDMAN: I'm not 100 percent sure even the point you
19 part -- the claim you part -- the part you point to, sorry about that, in your
20 surreply, it talks about (INDISCERNIBLE) therefore cannot be secured at a
21 proximal (INDISCERNIBLE) to the Luer hub 310, right? I mean, that
22 seems to be focused on a particular situation. I'm not sure that it is clearly
23 securing it. It is removable. I don't know that -- you don't have the phrase
24 secured without being removed. You're trying to read that into this claim
25 based on a statement that's a little bit ambiguous. Okay. I'm sure you're

1 saying that.

2 MR. MURRAY: Yeah. So the --

3 JUDGE FREDMAN: Take a look at what the examiner actually
4 did there.

5 MR. MURRAY: Right. But the quoted language we have there is
6 that the guide wire is configured to be steered and manipulated and
7 subsequently removed. And as a result --

8 JUDGE FREDMAN: Do you know where in the prosecution
9 history this is found?

10 MR. MURRAY: Yeah. The quote is from pages 578 to 579.

11 JUDGE FREDMAN: Yeah. Okay.

12 MR. MURRAY: I think that's Exhibit 1002. And they quoted
13 earlier on that page of our surreply, I think, is probably the whole
14 amendment portion, 573 to 580.

15 So just turning quickly to the spring coil argument. The spring
16 coil, we say one of ordinary skill in the art wouldn't understand that to be a
17 solid wire. The specification differentiates the solid wire on the basis that it
18 doesn't have a lumen running through it. And as you can see in Fogarty's
19 spring coil pen gives you the exact lumen that the claim of solid wire is
20 trying to avoid. And so for that reason, we feel that one of ordinary skill in
21 the art wouldn't be looking at this.

22 Mr. Banner touched briefly on the reasonable expectation of
23 success argument. Again, reasonable expectation of success is something a
24 Petitioner has to --

25 JUDGE FREDMAN: Okay. So just looking at -- if I just go back,

1 I'm sorry.

2 MR. MURRAY: Sure.

3 JUDGE FREDMAN: But I'm looking at page 578 where you
4 responded to the examiner. And the full quote is, "Kantor cannot be
5 modified such as the proximal under the guide wire is secured to the Luer
6 hub because it make it inoperable for its intended purpose," right? So that's
7 really not exactly what this says. What it actually is saying is that that
8 particular reference can't have that, not that it's impossible or that that's
9 excluded. So I don't think that that statement says what you think it says.

10 MR. MURRAY: I would disagree with that, but --

11 JUDGE FREDMAN: The Kantor reference is not talking about
12 your claim. So the Kantor reference can't do that, sure, fine. But that
13 doesn't speak to what the claim can do.

14 MR. MURRAY: Again, I would disagree. But, you know, it's up
15 to Your Honor to interpret that, you know.

16 JUDGE FREDMAN: Yeah.

17 MR. MURRAY: We would argue that that passage says that this
18 is intending to differentiate removable hubs. But if Your Honor reads it a
19 different way --

20 JUDGE FREDMAN: It doesn't say that. Kantor can't do it, which
21 is a different thing because Kantor would make it -- it would make Kantor
22 inoperable. That's a different question than could you have removable hubs
23 or not.

24 MR. MURRAY: Well, so --

25 JUDGE FREDMAN: I don't think the argument -- I mean, you

1 might argue that therefore Fogarty is inoperable, I suppose.

2 MR. MURRAY: That's exactly where I was going, Your Honor,
3 very good.

4 JUDGE FREDMAN: Right. But I think that there would need to
5 be evidence supporting that.

6 MR. MURRAY: Right. So yes, Fogarty would be inoperable. I
7 think we've explained that pretty thoroughly in our briefs, that you can't have
8 the wire installed to have it be operable.

9 JUDGE FREDMAN: Well, it's clear that Fogarty can have a
10 removable wire because it is removable, so -- and he has an inflation device,
11 so he clearly can remove it and inflate. So to argue that it's inoperable is
12 saying that what he says he can do he can't do. That seems to be a little bit
13 problematic for a patent that states that, as your presumed operable.

14 MR. MURRAY: Yeah. I mean, if Kantor -- well, I don't have
15 the -- I don't want to dwell on that.

16 JUDGE FREDMAN: Okay. That's fine, let's keep moving then.
17 We have (INDISCERNIBLE).

18 MR. MURRAY: So I was on that reasonable expectation of
19 success that the burden is on the Petitioner to do that. I'll take issue with
20 Slide -- Petitioner's Slide 29, which said we argued Fogarty cannot be a size
21 less than 6 French. What we actually argued was that Petitioner has not
22 shown sufficient evidence that a person skilled in the art would have
23 reasonably expected to successfully reduce Fogarty's specific catheter to that
24 size.

25 And as I think Fogarty is constructed differently from a generic

1 catheter shaft where you just have a single layer of material for a tube.
2 There's additional layers in there. And the reason is to protect that outer
3 tube from being poked by this stylet that goes in and out. And the argument
4 in the petition was just Chengod and Deaton have "Fogerty catheters
5 generically that are less than 6 French" and so it'll work.

6 But they don't understand or know what's going on inside of
7 Chengod and Deaton. And what they're basically doing is saying what you
8 can do for one, quote, "Fogerty catheter" will work for all of them,
9 regardless of any idiosyncrasies of any particular catheter that might impede
10 certain modifications that you could easily make in others. That's
11 conclusory, and that's why we objected to it in our Patent Owner response.

12 Mr. Banner brought up the Yassinzadeh in the reply and today.
13 Again, we argue that's impermissible under the Intelligent Bio-Systems and
14 the trial practice guide because you were completely changing the argument
15 from what it was before. But I also would argue, and it's in our surreply,
16 that Yassinzadeh has a different purpose. And so what goes on in
17 Yassinzadeh is the device goes into a hole in a vessel and just goes to plug it.
18 Whereas Fogerty needs a more robust protection because you have a stylet
19 that's going in and out, and you're going through complex vasculature to
20 remove clots.

21 So yes, Yassinzadeh has a spring and a dilator that are outside of
22 the catheter shaft. And the whole thing, apparently, can fit into 6 French.
23 But because of how different Yassinzadeh is in functionality, it's hard to say
24 a person of ordinary skill in the art would understand that that reference
25 proves you could successfully shrink what Fogarty is doing and retain the

1 main aspects of Fogarty's invention.

2 JUDGE FREDMAN: You're arguing you can't resize something?

3 MR. MURRAY: There's --

4 JUDGE FREDMAN: That's a hard argument, I think. But go
5 ahead, yeah.

6 MR. MURRAY: Understood. But the point is that what's shown
7 in Yassinzadeh is being used for a different purpose, so it may not have the
8 structural rigidity, for example, of what's going on in Fogarty. And so you
9 can't rely on one to say to resize the other would be successful, which is the
10 argument here.

11 JUDGE FREDMAN: You could resize it. You're saying it might
12 not work well. Where it's also --

13 MR. MURRAY: Correct.

14 JUDGE FREDMAN: Also, the question, what's the context, where
15 it's being used, and what, you know, level of pressure? There's lots of
16 different situations.

17 MR. MURRAY: Correct.

18 JUDGE FREDMAN: Some situations may work. Some may not.
19 If you're doing it inside of the baby versus an adult, you might want a
20 slightly smaller size?

21 MR. MURRAY: Correct. And it's -- that's going to vary. And the
22 burden is on the Petitioner to put evidence. And as far as the petition went,
23 we --

24 JUDGE FREDMAN: Well, he has evidence that those sorts of
25 things could be made, yeah.

1 MR. MURRAY: That it would be successful, correct. Yes.
2 Briefly, Claim 2, as Mr. Banner mentioned, there were really two
3 issues here. One is that under Grounds 1 and 5, I believe, the argument was
4 made that asymmetrical balloons exist, and so Fogarty or Eliason's balloons
5 could be designed to inflate asymmetrically. But the Federal Circuit's *Virtek*
6 decision reminds us that's not enough. You can't just show there's two
7 alternatives in the prior art and then say it could have been done. The
8 question has to be whether one of ordinary skill in the art would have done
9 it.

10 And on Slide 41, Mr. Banner was referring to -- it says -- it tries to
11 explain the petition. But if you look all the citations down at the bottom,
12 none of those actually go to the section of the petition on Claim 2. It's all
13 background information, which just reinforces that asymmetrical balloons
14 were known. But they didn't have anything in the petition to show that a
15 person of ordinary skill in the art would have had a reason to modify Fogarty
16 and Eliason specifically in this way.

17 And then Grounds 2 and 7 added the Saab reference to do this.
18 Saab is really an advertisement for high pressure balloons. Petitioner argued
19 that it was just expressing a preference rather than being a teaching away.
20 But on pages 90 to 91, it uses terms like unacceptable and preclude their use,
21 which are hallmark criticisms of teaching away. And obviousness requires
22 you to look at the prior art on the whole. And on the whole, Saab is very
23 critical of these types of balloons. And one of ordinary --

24 JUDGE FREDMAN: I think, obviously, this requires -- I think it's
25 really fair -- *Gurley* is a pretty significant decision that says, you know, non-

1 preferred embodiments are allowed to be used as well, right? Saab shows
2 that you can use both, right, is really what he's showing. He prefers high
3 pressure, there's no doubt. It doesn't really say you can't use them. In
4 certain circumstances, the other ones won't work as well, not that it won't
5 work at all.

6 MR. MURRAY: I would say that Saab overall is trying to
7 encourage the practitioner to use high pressure balloons. It's, I think --

8 JUDGE FREDMAN: I mean, you even quote in your in brief -- in
9 your response at page 59 from Saab, "high-pressure balloons are preferred
10 when precise balloon shape or catheter position is required." That implies
11 that when you don't need a precise balloon shape or catheter position, you
12 don't really need a high-pressure balloon, right? It's really under certain
13 circumstances you want it, and then others you don't. I think that's kind of
14 what the reference says and kind of even what you quote it says.

15 MR. MURRAY: Again, I'll just say I think overall, it's an article
16 that's advertising for high pressure balloons. I think Dr. Cimino takes issue
17 with whether one of ordinary skill in the art would actually look to this as
18 motivation to do a low-pressure balloon. And so the evidence put forward,
19 based on what Dr. Cimino testifies, one of ordinary skill in the art wouldn't
20 look at that.

21 And then I know I probably have about three minutes left in my
22 main argument.

23 JUDGE FREDMAN: You have like five, actually.

24 MR. MURRAY: Oh, even better, my timer's is off. So I'll just --
25 I'll touch on the person of ordinary skill in the art argument. And I think

1 it's -- after Mr. Banner, I think what's clear is really the dispute here is over
2 the definition, whether someone who has a medical degree and experience
3 using these types of catheter systems would qualify as a person of ordinary
4 skill in the art.

5 Usage, though, is not the same as designing or building. Someone
6 who has diabetes, for example, probably uses an insulin pen fairly regularly,
7 so they're going to be familiar with certain components of the pen. That
8 doesn't mean they would know how to design it. When you look at the --

9 JUDGE FREDMAN: Yeah. I think it's a little different than a
10 physician using a catheter. I mean, physicians have to put the catheters
11 together; isn't that correct?

12 MR. MURRAY: Well --

13 JUDGE FREDMAN: The catheters don't come -- they're always
14 preassembled.

15 MR. MURRAY: They have --

16 JUDGE FREDMAN: But generally they don't, I think.

17 MR. MURRAY: They have to assemble pre-made parts, which is
18 what Dr. Resnick testified is -- in his setting, what he's doing is he's taking
19 off-the-shelf components and fitting them together. So he's connecting the
20 valve to the proximal hub. He's doing things like that. What he's not doing
21 and what he testified was he doesn't -- if you can't see it from the outside,
22 he's not sure what's going on inside and where -- one of the things we
23 disagree with Petitioner is about whether a medical doctor can qualify.

24 We don't preclude medical doctors. What we say is that medical
25 doctor has to fit in -- assuming they don't have one of the degrees mentioned

1 in parts one or two of our definition, a medical doctor then has to fit into part
2 three of the definition, which is you need the experience designing and
3 building these things.

4 JUDGE FREDMAN: I mean, I guess one question I have when
5 you say this argument of we need to know what's inside is nothing on your
6 claim is inside, right? You have as your claim a proximal hub, that's visible;
7 a flow valve, that's visible. In fact, those are things that even regular PhDs
8 can actually act when they're putting things together, right? A proximal
9 catheter section, okay, that's a tube. A distal catheter section, another tube
10 into the other end of the tube, an occlusion balloon between those, so that's
11 visible, the balloon.

12 Markings on the exterior, those are visible. Clearly, or there's no
13 point to them. Lumen, okay, you can't actually see the lumen, but the lumen
14 is the inside of the tube. You probably could look at it if you wanted. And
15 the wire -- now, the wire, he's putting the wire into it because that's what he
16 has to do to do his surgery. And then the proximal catheter section -- and
17 you have to have that integrated, we're going to say, atraumatic tip -- that's
18 also visible.

19 So everything you're talking about in this claim is visible. This is
20 not even a situation where there's a hidden spring inside or something that
21 someone couldn't see. This is that -- he has to be able to see every one of
22 these elements. And, indeed, he probably has to put most of them together.

23 MR. MURRAY: Correct. He has to -- in terms of the claim, he
24 has to be able to see it. The visibility issue was more on Fogarty and the fact
25 that Fogarty has some things inside of it that would not be visible to the

1 doctor who is performing the operation. But to -- in order to understand how
2 these parts in the claim fit together, you have to have had experience
3 understanding why you need the solid wire, why certain things are arranged
4 the way they are. To put --

5 JUDGE FREDMAN: So you think a doctor knows why he needs
6 the wire?

7 MR. MURRAY: A doctor would not -- a doctor does not
8 necessarily -- I have to preface that. He's not going to necessarily
9 understand various aspects of the materials and features and different things
10 that are part of what is in these claims. The doctor -- to understand the
11 perspective of the doctor and Dr. Resnick, they're in an operating room, they
12 have a patient on a table, and they're going to use whatever they have
13 available to save a life. And so to him, individual constructions and unique
14 features of specific devices don't matter.

15 And it's not just what's in the claims, you're trying to do an
16 obviousness analysis. You have to consider all of these features of the prior
17 art references as well and how they would combine to render the claim
18 obvious. To Dr. Resnick, it's all going to be obvious because he can use
19 whatever he wants, whenever he wants. He testified at one point he said,
20 any balloon can occlude. But not every balloon is designed for that specific
21 reason. If he has a balloon, he's going to use it. He doesn't live in the world
22 where you have to design features for specific purposes and conditions and
23 you need FDA approval to market a device for a particular procedure, like
24 people of ordinary skill in the field of building and designing catheter
25 systems would. And that's something that should be taken into account. Dr.

1 Resnick is speaking from the experience of --

2 JUDGE FREDMAN: Well, the patent claims don't require that
3 either. We don't -- we're not the FDA. We've been told that many times.
4 Federal circuit's told us that.

5 MR. MURRAY: But the way this claim was put together, as well
6 as the dependent claims. We should also consider that the dependent claims
7 are subsumed within all of this. The way the claims are put together, the
8 way this device was designed was for the specific purpose of aortic
9 occlusion and had to deal with those aortic pulsing forces and being able to
10 withstand those. And this invention is what was come up with to be able to
11 do that.

12 JUDGE FREDMAN: So we're pretty much out of time, unless you
13 want you to keep going if you're --

14 MR. MURRAY: Unless you have any questions, I can reserve the
15 rest of my time.

16 JUDGE FREDMAN: Do my colleagues have any questions?

17 JUDGE FLAX: I don't.

18 MR. MURRAY: Thank you, Your Honors.

19 JUDGE FREDMAN: So let's move to Mr. Banner again. And you
20 have eight minutes.

21 MR. BANNER: Five minutes (INDISCERNIBLE).

22 JUDGE FREDMAN: You need a five-minute recess?

23 MR. BANNER: Yeah.

24 JUDGE FREDMAN: Okay. Let's give everyone a five minute
25 recess. I'm going to pause.

1 (Whereupon, the proceeding went off the record.)

2 JUDGE FREDMAN: So Mr. Banner, I think you have eight
3 minutes. Let's have your rebuttal.

4 MR. BANNER: All right. Thank you, Your Honor. Let me share
5 my screen here. All right. So I want to touch first on the issue of the flow
6 valve and the proximal hub and whether the whether or not those are
7 separate structures. And Mr. Murray talked about the Becton case, about
8 creating presumption, and argued that we have not rebutted that
9 presumption. However, the rebuttal came in the form of talking about
10 *EcoFactor*.

11 And under *EcoFactor*, the fact that there were specific examples of
12 the specification and intrinsic evidence that showed this, the relationship that
13 did not require separate structures, was sufficient rebuttal. And again, so I
14 think we did, in fact, rebut that presumption in *Becton*. And, you know,
15 Patent Owner disagrees that *Becton* -- I said in my initial presentation that
16 *Becton* is further distinguishable because it involved the exact same
17 structure. And Mr. Murray disagreed with that.

18 But although I don't agree, I don't think it matters. *Becton*, again,
19 did not have this situation where -- that we have, like *Google v. EcoFactor*,
20 where there are plenty of examples from the intrinsic evidence that support
21 the structures being in an element/sub-element relationship. So I think the
22 Board can come to the same conclusion and -- that it did in the ID, and that's
23 what we would ask.

24 Now, the final point on this, that Mr. Murray raised on the flow
25 valve and proximal will hub, is that he disputed that there's adequate

1 evidence that Figure 42A actually shows a hub with a stopcock valve. And I
2 would just point the Board to Dr. Resnick's second declaration, that's Exhibit
3 1034 at paragraphs 57 to 63, where he explains this. It's there and that's
4 what it is. Also, again, I refer to this, but Dr. Cimino at pages 76 to 78,
5 where he is discussing Exhibit 1030 of his deposition, that's Exhibit 1032,
6 he's discussing Exhibit 1030 where he says it's most likely a valve.

7 And so let me just show that here. On the screen I have -- this is
8 Exhibit 1030. And again, this is Figure 42A. And the red arrows are the
9 arrows that Dr. Cimino basically annotated with. And if I can go to his
10 testimony, just so I make sure. At 78, I asked, you know, about Exhibit
11 1030, asked if that red arrows reflect where an inflation device might
12 physically connect to the inflation lumen in the catheter depicted in Figure
13 42A. Dr. Cimino said yes.

14 And then that discussion was previous, so page 76. And here's
15 where Dr. Cimino is describing what's in Figure 42. And he said, the most
16 common technology for these types of ports -- or for these types of ends of
17 ports are what's called Luer lock fittings, valves, a whole bunch of
18 directional control devices that have Luer locks that attached to the syringe.
19 And then he says, I'm assuming that those are some form of one of those.
20 And so they have multiple inputs, multiple angles, handles. Now, are those
21 things or not -- I can't say for sure, but that's what they look like.

22 So under a preponderance of the evidence standard, this sure does
23 seem strong to me, that even Dr. Cimino thinks that, hey, that looks like
24 Luer lock fitting and -- with a valve over there on the side. So, you know, I
25 just think that there's plenty of -- given Dr. Resnick's testimony and then Dr.

1 Cimino's deposition testimony, there's plenty of evidence that the patent
2 actually discloses hubs with valves as part of them.

3 Let's talk about Fogarty's proximal hub and flow valve, the
4 argument that we made a new argument on this. As Your Honor may sort of
5 alluded to when Mr. Murray was arguing, this is based on an -- we're making
6 this argument because there was a new claim construction position provided
7 that these are not -- these have to be distinct structures.

8 Now, Mr. Murray cited to the Yita Intelligent Bio-System cases.
9 But those are distinguishable. Those did not deal with cases where there
10 were -- where the reply was simply replying to arguments made by the
11 Patent Owner. That wasn't the case in those cases. And so here, there's a
12 long line of cases, both Federal Circuit and the Patent Office, as I discussed
13 before, that we are entitled to reply to arguments raised by the Patent Owner
14 and its response.

15 That's the *Axiom* case. And if I -- sorry, *Axonics* case -- and I'll put
16 that here up on the screen -- where the Federal Circuit said, where the Patent
17 Owner first proposes a claim construction in a Patent Owner response, a
18 Petitioner must be given the opportunity to reply. So that's what the Federal
19 Circuit said, we must be given the opportunity to reply. And that's what all
20 of the new arguments that we have made in our reply are doing. They're
21 replying to arguments based on Patent Owner's new claim construction
22 positions.

23 On the distal catheter section, Mr. Murray was saying that pre-
24 securing doesn't make the wire somehow part of the catheter. But I think
25 what we have to do here is we have to look at the actual claim language.

1 The distal catheter section terminates with an atraumatic tip. So by the
2 claim's own definition that when the wire is secured to the rest of the
3 catheter and has the atraumatic tip, it is part of the catheter. And Dr. --

4 JUDGE FREDMAN: That's not necessarily the case.

5 MR. BANNER: Yeah.

6 JUDGE FREDMAN: I mean in Fogarty, right, in seems like the
7 catheter does end with atraumatic tip -- or the catheter, the wire is still
8 inside, but the tip is not -- is part of the catheters, the wire doesn't keep going
9 through Fogarty's end, right?

10 MR. BANNER: Right, that's true.

11 JUDGE FREDMAN: So it's not necessarily the case.

12 MR. BANNER: True. Yeah. No, I agree with that. But I do
13 think with respect to Mr. Murray's argument that Dr. Resnick is making
14 some distinction between the wire and the shaft when he or the catheter
15 when he's talking about Eliason, I think Slide 47 of the demonstratives
16 where we -- were I quote Dr. Resnick's second declaration at paragraph 134,
17 he explained that Eliason's catheter when fixed together become a single-
18 unit device, i.e., a single-catheter device. So Mr. Murray is misconstruing
19 what Mr. Resnick actually said -- or Dr. Reznick actually said. And so I
20 think under -- you know, there's plenty of evidence that Eliason has the
21 distal catheter section in the pre-securement body.

22 I know I have about a minute left, so I'll talk -- so on the solid wire
23 construction, does the construction require permanent attachment? I think
24 the Board need only look at the patent, column 35, 4 to 28, to show that Mr.
25 Murray is incorrect that the patent equates secure with physically attached.

1 The applicant used different language and said it can be otherwise fastened.
2 You know, otherwise, something other than a fixable attachment. So we
3 think our solid wire construction should be adopted.

4 And then Mr. Murray made one other argument about the
5 prosecution history, demonstrating that the securement can't be removable.
6 And I think Your Honor kind of caught on to this with the Kantor. That that
7 distinction in the prosecution history was merely that Kantor had this guide
8 wire, the steerable guide wire, and at the proximal end of the guide wire
9 there was a steering mechanism. So if you're -- and so what the examiner
10 was saying there is you're going to attach it, you're going to ruin the ability
11 to steer that guide wire.

12 Finally, on the spring coil as a solid wire, I think that, again, the
13 spec says that the solid wire doesn't have a lumen, and the spring coil also
14 doesn't have a lumen. So I'm not sure why Mr. Murray and the Patent
15 Owner are saying that the solid wire is a lumen. It is certainly coiled. But
16 the claim doesn't require a straight solid wire, just as a solid wire. And
17 there's no dispute that the solid wire or that the spring coil in Fogarty is
18 made up of the solid wire.

19 I think that that in, you know, claims --

20 JUDGE FREDMAN: Your time is up, so let's move on.

21 MR. BANNER: Okay, so with that, the Petitioner request that the
22 claims be determined to be unpatentable. And thank you for your time
23 today.

24 JUDGE FREDMAN: Thank you. Mr. Murray?

25 MR. MURRAY: All right. Thank you, Your Honor.

1 JUDGE FREDMAN: You probably have your 15 minutes, if you
2 want it.

3 MR. MURRAY: Okay. I don't think I'm going to need all of it.
4 But so let me go first back to the issue of Dr. Cimino's testimony regarding
5 that Figure 42A. As you could see that -- what he says there, he doesn't say
6 there's a Luer lock with a valve. He says, Luer locks, valves, et cetera. And
7 he's not entirely clear, again, what's there. He's speculating as to what might
8 be shown. But in -- what he's -- the only thing he suspects is there are ports.
9 And what's shown in those ports, he's not entirely clear. So I don't think the
10 testimony of Dr. Cimino has the type of significance that Mr. Banner is
11 attributing to it.

12 Mr. Banner also argued about new reply arguments, referencing
13 the *Axonics* case. It is true that Petitioners are entitled to respond to Patent
14 Owner arguments, but that is not limitless. I think if you review the *Yita*
15 case that we cited, you have a situation that was very similar to this. The
16 original argument in the petition was that a -- the prior reference disclosed
17 the feature at issue. The Patent Owner argued that that feature was not there.

18 And then the reply switched to say, well, it would have been
19 obvious, based on what was known in the art. And the Federal Circuit said
20 that that was improper scope of reply because it's not responsive to what was
21 argued. The Patent Owner argued only about what the prior art reference
22 taught, not about what a relevant artisan would have found obvious. And
23 similarly here, we argued what *Fogerty* teaches, for example, on that new
24 reply argument, not what a person of ordinary skill in the art would have
25 found obvious to modify about *Fogerty* about those features.

1 And then we have the terminated with an atraumatic tip issue. I'm
2 not really sure why "with" or "at" makes much of a difference at all. The
3 specification shows distal catheter sections referred to mainly as members,
4 and they have atraumatic tips attached to them. I don't understand what the
5 conflict is with our interpretation.

6 JUDGE FREDMAN: Just to clarify that and make sure we
7 understand. Anyway, when you're talking about that, they actually -- I
8 mean, it's a physical sort of -- we'll say (INDISCERNIBLE) the piece that's
9 put on the end of the catheter --

10 MR. MURRAY: It could be --

11 JUDGE FREDMAN: -- the distal catheter.

12 MR. MURRAY: So I agree --

13 JUDGE FREDMAN: So even with that, the distal character could
14 even be bent itself to be closed, essentially --

15 MR. MURRAY: Correct.

16 JUDGE FREDMAN: -- in sort of a rounded shape.

17 MR. MURRAY: That's correct.

18 JUDGE FREDMAN: Like Fogarty, basically. I mean, Fogarty is
19 such a tip.

20 MR. MURRAY: Correct.

21 JUDGE FREDMAN: You wouldn't dispute Fogarty has it -- you
22 wouldn't dispute Fogarty has such a tip. You're not arguing --

23 MR. MURRAY: Oh, no, absolutely not. Absolutely not. Fogarty
24 absolutely has a distal catheter section with an atraumatic tip, absolutely. So
25 I don't know if there's any other question on that.

1 Okay. And then just the last thing, I want to get into the
2 prosecution history with respect to the solid wire being secured. Page 578,
3 does say that the guide wire of Kantor is equated by the examiner with the
4 claim solid wire. The guide wire 302 is not secured to the Luer hub.
5 Moreover, it cannot be modified to include such a feature, and then that gets
6 into some of the reasons why. But it's very clear that Kantor is not secured,
7 nor could it be modified to be secured. And as one of the reasons, because it
8 was (INDISCERNIBLE - TECHNICAL DIFFICULTY).

9 So unless there's any further questions from Your Honors, I think
10 I'm done.

11 JUDGE FREDMAN: I don't have anything. Judge Flax? Is that
12 it?

13 JUDGE FLAX: I don't.

14 MR. MURRAY: Thank you very much, Your Honors.

15 JUDGE FLAX: I don't have any more.

16 JUDGE FREDMAN: Okay. Thank you very much. Well, thank
17 you for your attendance and presentations today. It will be submitted to the
18 panel now for determination and preparation of a final decision. And we are
19 now adjourned. Thank you very much. Have a wonderful afternoon.

20 (Whereupon, the above-entitled matter went off the record at 11:03
21 a.m.)

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