

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

Front Line Medical Technologies, Inc.

V.

Prytime Medical Devices, Inc.

PGR2024-00028

U.S. Patent No. 11,857,737

Petitioner's Oral Argument – July 16, 2025

Asserted Grounds

Ground	Basis	Reference(s)	Challenged Claim(s)
1	§ 103	Fogarty + Chengod + PGK*	1-10
2	§ 103	Fogarty + Chengod + Saab + PGK	2
3	§ 103	Fogarty + Chengod + Sanati + PGK	3-5, 9
4	§ 103	Fogarty + Chengod + Deaton + PGK	8
5	§ 103	Eliason + PGK	1-10
6	§ 103	Eliason + Fogarty + PGK	1-10
7	§ 103	Eliason + Saab + PGK	2
8	§ 103	Eliason + Scott + PGK	3-5, 9
9	§ 103	Eliason + Joe + PGK	8

*PGK = POSITA's General Knowledge

Proposed Discussion Points

- Claim Construction
- Person Having Ordinary Skill in the Art (“PHOSITA”)
- Grounds 1-4: Fogarty & Expectation of Success
- Grounds 1-4: Fogarty’s “Solid Wire...”
- Grounds 1-4: Fogarty’s “Proximal Hub” and “Flow Valve”
- Grounds 1-2, 6-7: Asymmetrical Balloon Shape is Obvious
- Grounds 5-9: Eliason’s “Distal Catheter Section...”
- Grounds 5-9: Eliason’s “Proximal Hub” and “Flow Valve”

Claim Construction

Claim Construction: Terms in dispute

- “proximal hub” (claim 1)
- “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” (claim 1)
- “flow valve” as part of “proximal hub” (claim 1)
- “a distal catheter section” (claim 1)
- “a solid wire, secured at a proximal-most end thereof within the proximal hub” (claim 1)

Claim Construction: “proximal hub”

Petitioner’s Construction	PO’s Construction
Plain meaning: An element (or elements), <u>oriented away from the body, for connecting other catheter elements, including for connecting an inflation device to an inflation lumen.</u>	An element (or elements) for connecting an inflation device to an inflation lumen.

Claim Construction: “proximal hub”

- “Proximal hub” should be interpreted to have its ordinary meaning:
 - Dr. Resnick: An element (or elements), oriented away from the body, for connecting other catheter elements, including for connecting an inflation device to an inflation lumen
- PO’s construction is overly narrow by excluding features other than connecting an inflation device to an inflation lumen
 - E.g., specification describes proximal hub connected to an external pressure sensor. Ex-1034 ¶50 (citing Ex-1001, 26:8-10)

Claim Construction: “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device”

Petitioner’s Construction	PO’s Construction
Plain meaning (no construction necessary)	a manually or automatically actuatable valve that is opened and closed to permit and block fluid flow, respectively, between the proximal hub and the inflation device

Claim Construction: “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device”

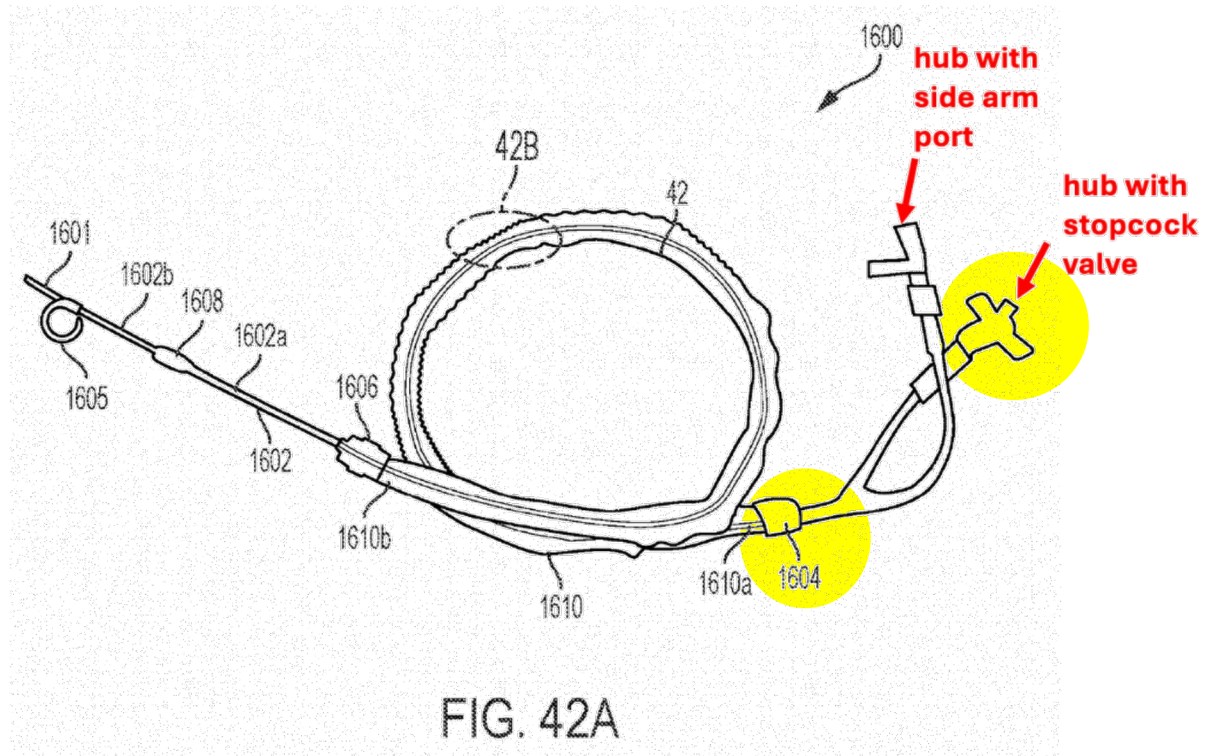
- Phrase needs no construction: not ambiguous and not expressly defined in the specification
- PO’s construction improperly narrows scope:
 - Changes “configured to” limitation to method step of “valve that is opened and closed”
 - Inserts structural limitation of “between” to later argue that the flow valve must be located “between” the proximal hub and the inflation device

Claim Construction: “flow valve” as part of “proximal hub”

Board’s/Petitioner’s Construction	PO’s Implicit Construction
The “flow valve” and “proximal hub” may be separate elements or, alternatively, the “flow valve” may be a sub-element portion of the “proximal hub”	The “flow valve” and “proximal hub” are “two separately recited structures with a specifically defined spatial relationship between them – namely, the flow valve sits between the proximal hub and the inflation device in order to provide the selective connection between the two components”

Claim Construction: “flow valve” as part of “proximal hub”

- Petitioner adopts the Board’s construction (ID at 14)
- The specification supports the Board’s construction:
 - hub with stopcock valve
 - 1604: proximal hub with hemostatic valve
 - See also Ex-1001, 21:27-32 (“proximal hub includes pressure relief port”), 21:9-11 (“pressure relief member may be ... a pop-off valve or other similar biased valve”).



Claim Construction: “flow valve” as part of “proximal hub”

- The prosecution history supports the Board’s construction:

Original Claim 1, limitation [1a]	Amended Claim 1, limitations [1a]-[1b]
a proximal hub having a flow valve;	a proximal hub; a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device;

1. (Currently Amended) An occlusion catheter system comprising:

a proximal hub;~~having~~

a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device;

Ex-1002 (Pros. Hist.), PDF-p.200

Claim Construction: “flow valve” as part of “proximal hub”

- PO’s reliance on *Becton, Dickinson & Co.* is misplaced.
 - In *Becton*, exact same structure was accused for both “hinged arm” and “spring means”
 - Here, “flow valve” is sub-element of “proximal hub,” not exact same structure
 - In *Becton*, claim language required separate structures: “spring means” recited as “connected to” the “hinged arm”; “spring means” “extending between” “hinged arm” and “mounting means”
 - No similar structure requirement recited in claim 1
- Board correctly found that this case is more similar to *Google LLC v. EcoFactor, Inc.*
 - (1) Specification includes embodiments where flow valve is sub-element of proximal hub; and (2) specifications/claims do not require separate elements

Claim Construction: “a distal catheter section”

Board’s/Petitioner’s Construction	PO’s Construction / Implicit Construction
Plain meaning: the distal portion of the claimed catheter, i.e., the portion including the elements located distal of the intervening occlusion balloon	a portion of the catheter shaft itself, and not a portion of the entire catheter system Cannot include a wire

Claim Construction: “a distal catheter section”

- Board’s construction is supported by the claim language:
 - “distal catheter section *distally terminating with an atraumatic tip*”
 - “intervening occlusion balloon connecting the proximal catheter section with *the distal catheter section*”
 - “solid wire ... extending ... *into the distal catheter section*”

Claim Construction: “a distal catheter section”

- PO’s construction improperly narrows scope, limiting “distal catheter section” to a “shaft”
 - Improperly relies on extrinsic testimony from Dr. Resnick’s deposition
 - Contradicts express claim language requiring “distal catheter section” to “terminat[e] with an atraumatic tip”
 - Improperly relies on single embodiment (catheter member 520) as definitional
 - No support for negative limitation ruling out any “non-shaft” portion of a catheter from being part of the “distal catheter section”
 - Implicit construction that “distal catheter section” cannot include a wire contradicts specification embodiments
 - i.e., “nitinol wire” as part of stiffening member and atraumatic tip

Claim Construction: “a solid wire, secured at a proximal-most end thereof within the proximal hub”

Petitioner’s Construction	PO’s Construction
Plain meaning (no construction necessary)	a wire, without an internal lumen, having its end that is positioned furthest away from the patient’s body within and fixedly coupled to the proximal hub

Claim Construction: “a solid wire, secured at a proximal-most end thereof within the proximal hub”

- “solid wire...” phrase is unambiguous
- PO’s negative limitation “without an internal lumen” is unwarranted.

A claim construction may include a negative limitation only “where the limitation is expressly disclaimed or where independent lexicography in the written description justifies adding it.”

Eko Brands, LLC v. Adrian Rivera Maynez Enterprises, Inc.,
946 F.3d 1367, 1381 (Fed. Cir. 2020) (quotations and citations
omitted).

Claim Construction: “a solid wire, secured at a proximal-most end thereof within the proximal hub”

- PO improperly narrows claim scope, rewriting “secured” as “fixedly coupled” or unremovably attached
- PO’s construction contradicts the specification 
- Dr. Resnick testifies that the plain meaning of “secured” does not require a permanent attachment. Ex-1034 ¶¶70-71; Ex-1035-4.

Turning now to FIG. 17, the proximal portion of the balloon catheter system 500 is illustrated. The inflation catheter member 510 is coupled to the proximal hub 590 and the proximal end of the stiffener member or solid wire 530 is fixedly coupled to the proximal hub 590 at a proximal bonding site, preferably using an adhesive 580, to bond an inner wall surface of the proximal hub 590 to an outer wall surface of the solid stiffener member 530. The amount of adhesive 580 used is preferably sufficient to fixedly couple the solid stiffener member 530 to the proximal hub 590. As shown in FIG. 17, the adhesive 580 may fill the entire portion 592 of the proximal hub 590 that holds the stiffener member 530. The proximal end of the stiffener member 530 is not limited to being adhesively bonded to the proximal hub 590 and may be otherwise fastened, secured or fixed to the proximal hub 590, as long as the stiffener member 530 is substantially secured to the proximal hub 590 such that the stiffener member 530 provides stiffness for the balloon catheter system 500, the stiffener member 530 is substantially secured relative to the inflation catheter member 510 and the occlusion balloon 540, the assembly is able to withstand the normal operating conditions of the catheter system 500 and securement results in a structure able to perform the preferred functions of the catheter system 500, as is described herein. Since the solid stiffener member 530

The PHOSITA

The PHOSITA

Petitioner's PHOSITA	PO's PHOSITA
a medical degree and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices. Ex-1003 (1st Resnick Decl.) ¶18.	(i) an undergraduate degree in engineering or physics or material science and at least five years' experience in catheter design and development or laparoscopic/ endoscopic medical device instrumentation design and development; (ii) a graduate degree in engineering or physics or material science and at least three years' experience in catheter design and development or laparoscopic/ endoscopic medical device instrumentation design and development; or (iii) at least six years' experience in catheter design and development. Ex-2001 (Cimino Decl.) ¶25.

The PHOSITA - Dr. Resnick's Second Declaration is Unrebutted

- Dr. Resnick qualifies as a PHOSITA under either Petitioner's or PO's PHOSITA definition (Ex-1002 ¶19, Ex-1034 ¶8)
- Dr. Resnick's 1st Declaration opinions are unchanged even under PO's PHOSITA definition (Ex-1034 ¶¶44-48)
- PHOSITA definition should include MDs (Ex-1034 ¶¶25-33)
 - Prior art authored/edited by MDs in publications directed to MDs
- MD with extensive experience using occlusion devices qualifies as a PHOSITA; design and development experience is not necessary (Ex-1034 ¶¶34-43, 75)

The PHOSITA - PO's Expert Agrees that Petitioner's PHOSITA Qualifies

is entirely too onerous. While the definition I provide above does not preclude an individual with a medical degree and sufficient experience with interventional procedures from qualifying as a PHOSITA, requiring a medical degree excludes

Ex-2001 ¶26

Q. When you gave your keynote speech in 2010, was it common for a team who was designing and developing a medical device to consult with doctors?

* * *

A. MDs are often and frequently and even recommended to be part of a design, development, and commercialization process. And depending on

Ex-1032 58:5-15

The PHOSITA – PO's Criticism of Dr. Resnick is Unwarranted

- PO:

Dr. Resnick instead testified that he never designed a catheter (aside from assembling off-the-shelf components in a surgical setting). Ex. 2002, 14:5-15:16.

Paper 16 (PO Sur-Reply), 4

- Dr. Resnick Response:

characterization of my testimony. At 14:5–15:16 of my deposition testimony, I testified that I did not have any catheter patents, but that I did have experience modifying off-the-shelf catheter products for specific uses and sometimes to improve the device function. At 23:5–24:2 of my deposition testimony, I testified that when I

Ex-1034 (2d Resnick Decl.) ¶76

The PHOSITA – PO's Criticism of Dr. Resnick is Unwarranted

■ Deposition Transcript:

Q Have you ever designed a catheter?

A Am I a patent holder on any catheters?

No.

Q But have you ever designed a catheter?

A So, again, the world of interventional radiology involves using a variety of products. Sometimes off-the-shelf products are modified for specific uses. That's a regular and daily event in our specialty.

Q And when you say "off-the-shelf," you mean something that's purchased as a -- I'll withdraw that.

What do you mean when you say "off-the-shelf"?

A A device or catheter that is available for purchase from the manufacturer.

Q And you said that sometimes, in your field, the off-the-shelf devices require

modification for specific uses.

What do you mean by that?

A To improve efficacy of a device, sometimes we will modify the device in a way to advantageously improve its function.

Q Is that something that's done on a case-by-case basis?

A It is.

Q So you don't hold a meeting, for example, and take a off-the-shelf catheter and decide to modify it in some way?

A No.

Q This is more you have a patient on the table; you have an off-the-shelf catheter; you need to make some kind of modification to it?

A That's correct.

Ex-2022 (Resnick Tr.) 14:5-15:16

The PHOSITA

- Conclusion

Grounds 1-4: Fogarty & Expectation of Success

Grounds 1-4: Fogarty & Expectation of Success

- Fogarty (Ex-1004) does not indicate the catheter size
- Fogarty catheters smaller than 6 Fr were known (e.g., Chengod, Deaton)
- Motivations to size Fogarty's catheter less than 6 Fr:
 - Just one choice among a limited number of design choices
 - Smaller devices are generally safer
- Sizing Fogarty's catheter less than 6 Fr works as evidenced by Chengod & Deaton

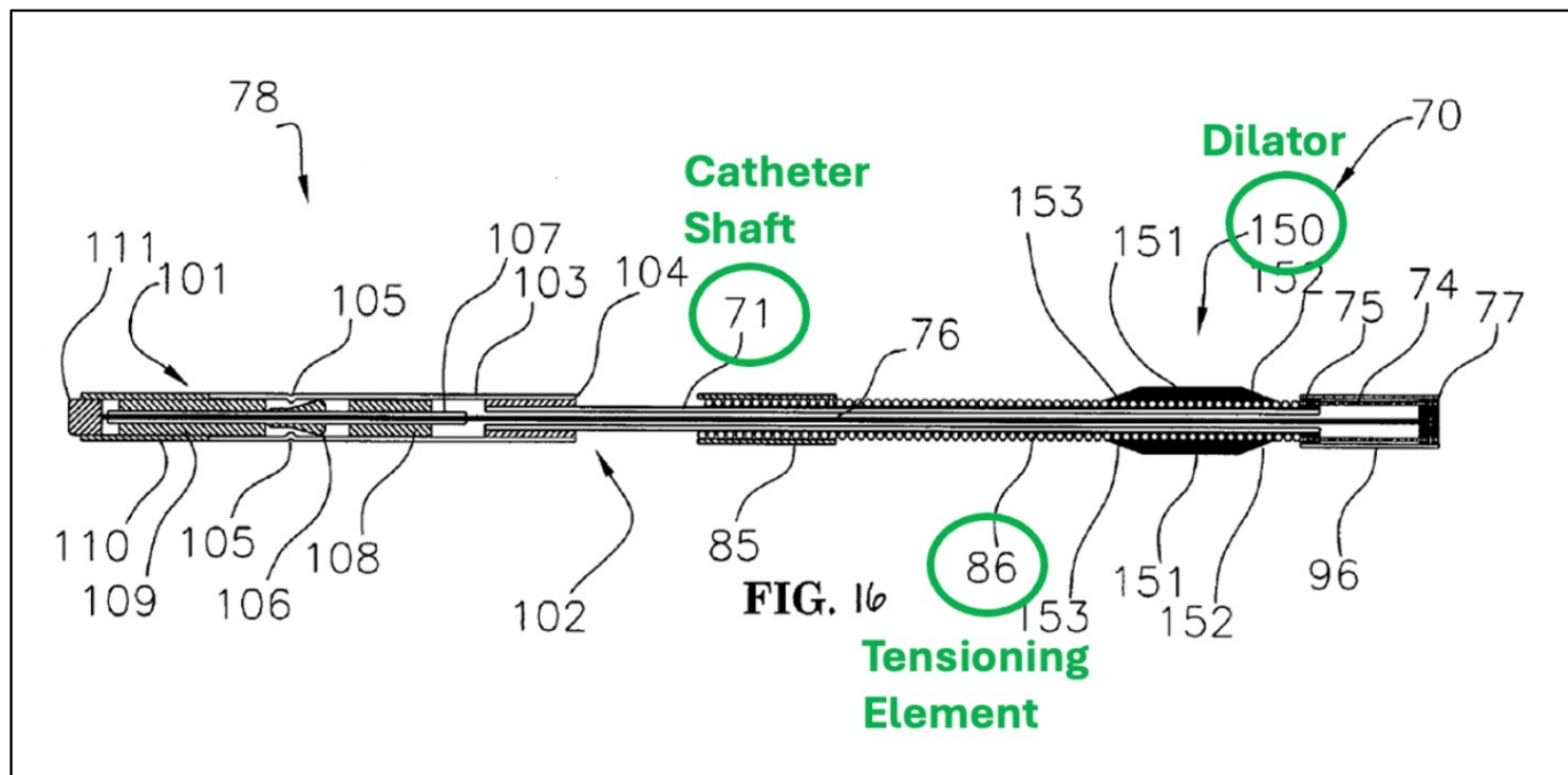
Grounds 1-4: Fogarty & Expectation of Success

- PO argues that Fogarty catheter cannot be sized less than 6 Fr because of its spring coil, braid, outer tube, and lumen.

of the cited Fogarty reference (Ex. 1004). Ex. 2002 at 52:16-57:1. Petitioner has therefore not demonstrated that a PHOSITA would have a reasonable expectation of success in modifying the *particular catheter* taught by the *cited Fogarty patent (Ex. 1004)* to the claimed size when considering the shaft has a spring coil and braid in addition to the outer tube and lumen. For that reason generally, Ground 1 fails.

Grounds 1-4: Fogarty & Expectation of Success

- Yassinzedah: catheter construction is less than 6 Fr and analogous to Fogarty's spring coil, braid, outer tube, and lumen.



Ex-1033, Fig. 16 (annotated)

**Grounds 1-4: Fogarty's "Solid Wire ...
Secured Within the Proximal Hub"**

Grounds 1-4: Fogarty's Stylet is "Secured" Within the Hub Under the Ordinary Meaning of "Secured"

- Fogarty uses the word "secured" to describe the stylet's attachment to the cap/catheter:

The proximal end of stylet 40 is secured in a cap 41 which is equipped with an internal thread 42 to engage hub flange elements 43 on the syringe fitting 32. When valve member 31 is turned to open position, the stylet may be freely inserted through the valve and secured in the catheter. Cap 41 also contains a vent opening 45

Ex-1004, 3:60-65

Grounds 1-4: PO Seeks an Implicit Construction of “Secured” that Improperly Incorporates Specification Embodiments

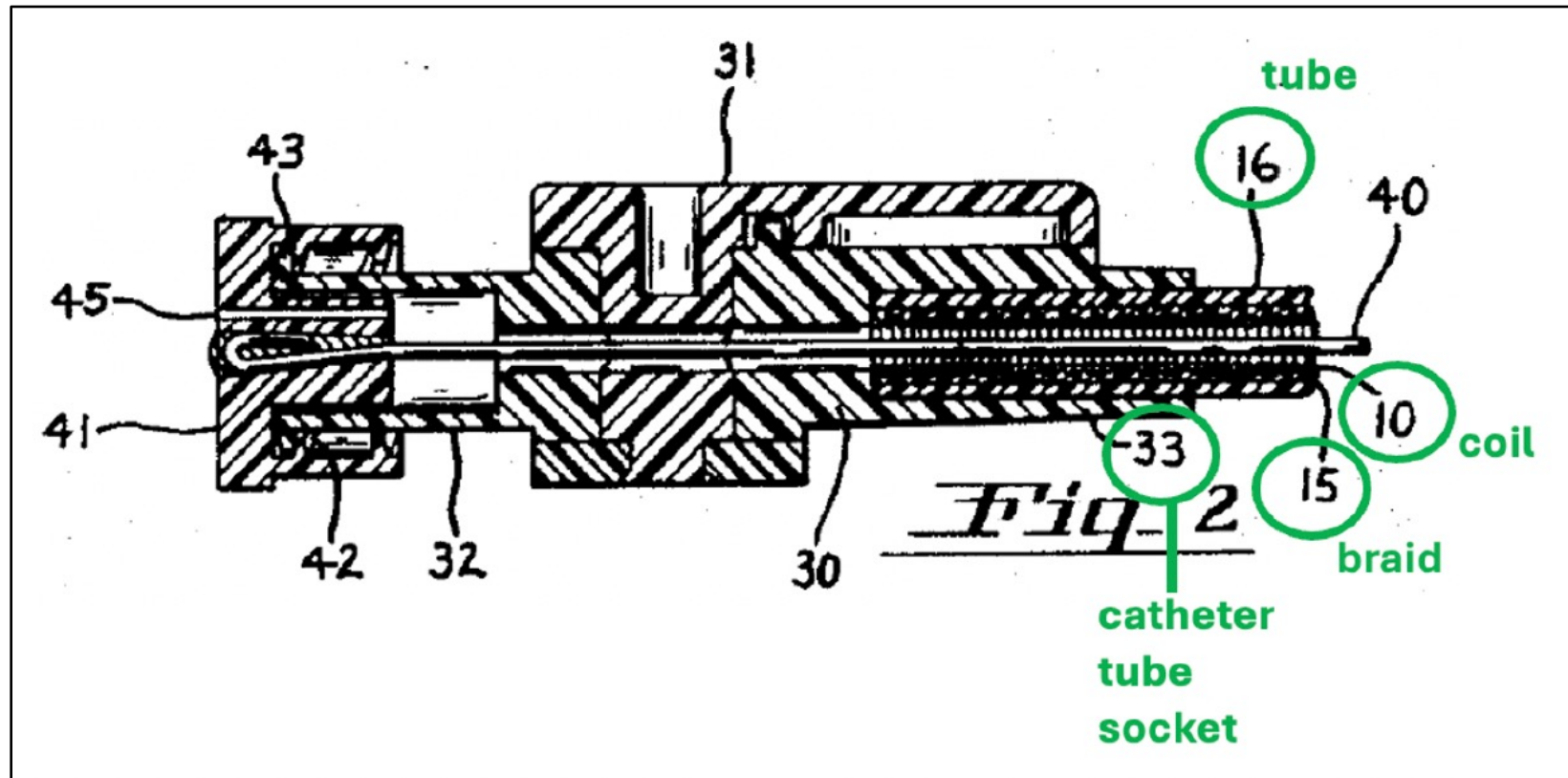
- PO argues: the stylet is not secured because it “must be absent during significant normal operating conditions.” (POR, 39)
 - Improper implicit construction of “secured”
- Dr. Resnick explains that the stylet is not absent during normal operating conditions (i.e., insertion of the catheter):

54. Thus, a PHOSITA understands that the stylet is not absent during Fogarty’s normal operating conditions (i.e., insertion). When the stylet is used to provide added stiffness for insertion, the assembly is, in fact, able to withstand those normal operating conditions. In other words, a PHOSITA understands that Fogarty’s catheter

Ex-1034 ¶102

Grounds 1-4: Fogarty's Stylet is "Secured" Within the Hub Under PO's "Secured" Construction

- Fogarty's coil 10 is a "solid wire" (stainless steel) that is "fixedly coupled to" or "integrally connected" to tube socket 33 (part of the proximal hub)



Ex-1004, Fig. 2 (annotated)

Grounds 1-4: Fogarty's "Proximal Hub" and "Flow Valve"

Grounds 1-4: Fogarty Discloses “Proximal Hub” and “Flow Valve” Under Board’s Correct Claim Construction

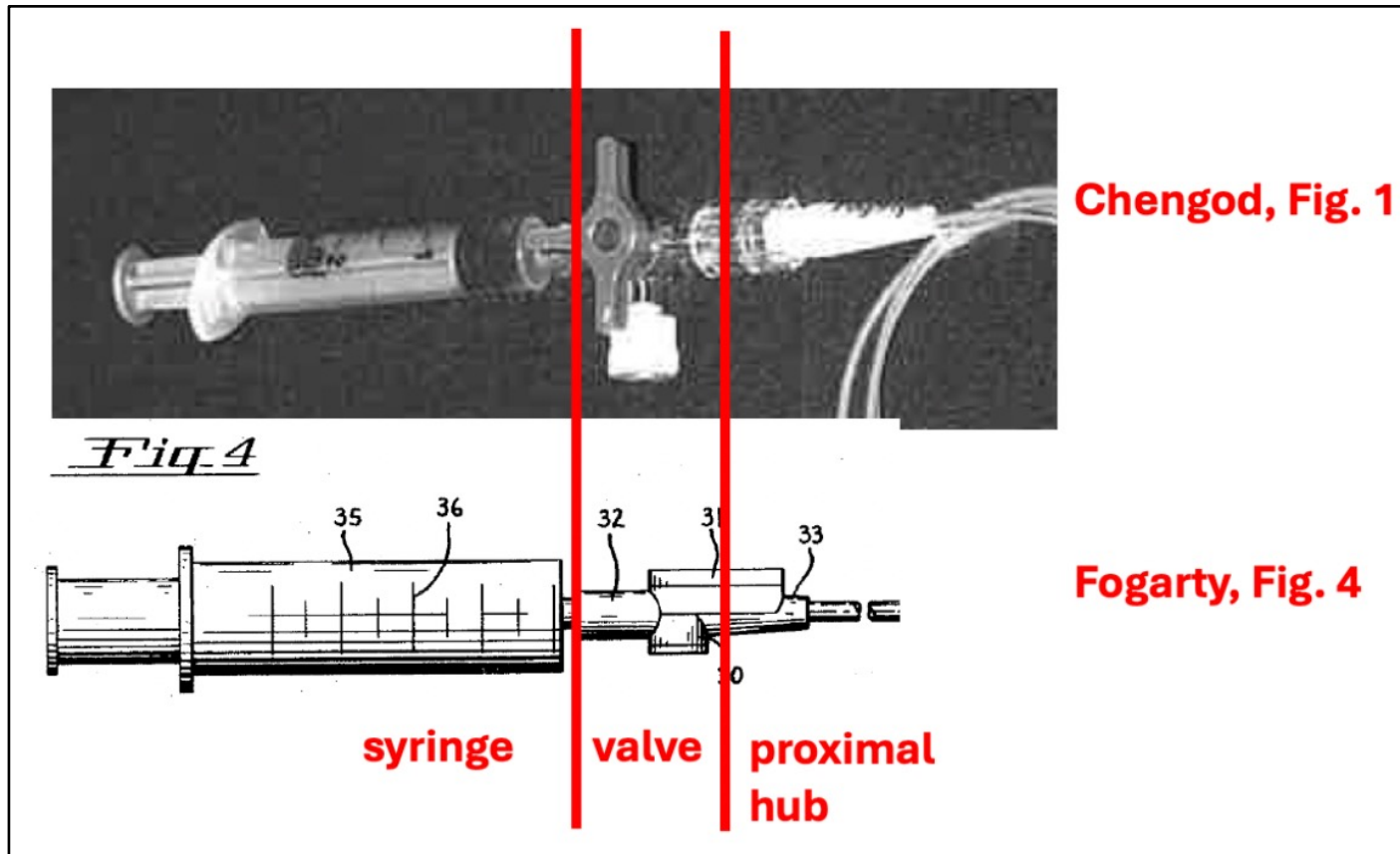
- Board’s correct preliminary construction allows an element/sub-element configuration for “proximal hub” and “flow valve”
 - No dispute that limitations are obvious under Board’s construction

Grounds 1-4: “Proximal Hub” and “Flow Valve” Obvious Under PO’s Incorrect Claim Construction

- Grounds 1-4 based on PHOSITA knowledge:
 - Flow valve as integral part of proximal hub (e.g., Fogarty’s element/sub-element relationship)
 - Flow valve separate from proximal hub (e.g., Chengod’s removably attached valve located between the proximal hub and inflation device)

Grounds 1-4: “Proximal Hub” and “Flow Valve” Obvious Under PO’s Incorrect Claim Construction

- Resulting assemblies are essentially the same:



Ex-1005, Fig. 1 (top, annotated)
Ex-1004, Fig. 4 (bottom, annotated)

Grounds 1-4: “Proximal Hub” and “Flow Valve” Obvious Under PO’s Incorrect Claim Construction

- Fogarty w/ non-integral valve obvious
 - Simple substitution of one known element (hub with valve) for another (separate valve and hub) to obtain predictable results (controlling the flow of fluids with the proximal hub)
 - Finite number of identified, predictable solutions for controlling the flow of fluids with the proximal hub
 - Obvious to try separating the elements found as an integral piece in Fogarty

- Reasonable Expectation of Success
 - Chengod is proof that separating the flow valve from the proximal hub and putting the flow valve between the inflation device and the proximal hub would work as intended

**Grounds 1-2, 6-7: Asymmetrical Balloon
Shape is Obvious**

Grounds 1 & 6: Asymmetrical Balloon Shape is Obvious In View of PHOSITA's General Knowledge

- The Petition explained:
 - Asymmetrical compliant balloons were within the PHOSITA's general knowledge
 - A PHOSITA understands compliant asymmetrical balloons are used in occlusion catheters “to completely fill the body lumen into which it is placed, which is often asymmetrical in shape” (Pet, 21; Ex-1034 ¶ 127)
 - Fogarty's catheter is used for occlusion
 - PHOSITA would use a compliant balloon that inflates asymmetrically to occlude asymmetric vessels in the patent's body
- PO ignores the Petition's explanation and evidence (POR, 48-49; Sur-Reply, 22-23)

Grounds 2 & 7: Saab Does Not Teach Away from Asymmetrical Compliant Balloons

- Saab explains alternative options to elastomeric (compliant) balloons, not that elastomeric balloons are discouraged or should be avoided
- Saab says high-pressure balloons (and not asymmetrical compliant balloons) are desirable “in some cases” – not in “all cases”

Occlusion. Normally, low-pressure, elastomeric balloons are used for occlusion or sealing, but in some cases, when precise sizes or shapes are required, it is desirable to use a high-pressure balloon.

Ex-1006, 91

Grounds 2 & 7: Saab Does Not Teach Away from Asymmetrical Compliant Balloons

- A reference that discloses alternatives and does not discourage one particular alternative does not teach away even if it points out deficiencies in the alternative. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Grounds 5-9: Eliason's "Distal Catheter Section..."

Grounds 5-9: Eliason Discloses a “Distal Catheter Section Distally Terminating with an Atraumatic Tip”

- PO does not dispute that Eliason discloses a “distal catheter section distally terminating with an atraumatic tip” under the Board’s preliminary (correct) construction:

For purposes of this Institution Decision, we preliminarily interpret the term a “distal catheter section” of a catheter as reasonably comprising the elements that are located distal of the “intervening occlusion balloon” that connects the “proximal catheter section with the distal catheter section” of the catheter system, as recited in claim 1.

Paper 7 (ID), 18

Grounds 5-9: Eliason Discloses a “Distal Catheter Section Distally Terminating with an Atraumatic Tip”

- The distal catheter section is not limited to a “shaft”
- Dr. Resnick explains how PO misstates his testimony:

133. Dr. Cimino asserts that, in my deposition, I confirmed his interpretation of “distal catheter section” as being limited to “a portion of the *catheter shaft* itself, rather than of the entire catheter system...” Ex-2001 ¶ 108. I disagree. I testified that “The catheter is the shaft of the device. Typically, I would describe the catheter as extending from the proximal hub to the end of the device distally.” Ex-2002 at 26:21–27:2. Thus, a catheter is the whole device from the proximal hub to the end of the device distally, without qualification, and including all incorporated elements extending to the end of the device.

Ex-1034 ¶133

Grounds 5-9: Eliason Discloses a “Distal Catheter Section Distally Terminating with an Atraumatic Tip”

- Eliason’s catheter is not distinct from the wire when pre-secured
- Dr. Resnick explains how PO misstates his testimony:

134. The POR asserts that, in my First Declaration, I admitted that Eliason’s catheter is distinct from the wire over which it slides. POR at 52. I disagree. At ¶ 144 of my First Declaration, I explained that Eliason’s “occlusion catheter is designed to be fixed to a wire (12) that provides rigidity to the catheter. ... The wire and the rest of the balloon catheter are to be inserted as a single unit or device.” Contrary to the POR’s assertion, this statement literally says that the wire and the other elements of Eliason’s catheter, when fixed together (as in Eliason’s pre-secured embodiment), become a single unit or device (i.e., a single catheter device).

Ex-1034 ¶134

Grounds 5-9: Eliason's “Proximal Hub” and “Flow Valve”

Grounds 5-9: Eliason Discloses “Proximal Hub” and “Flow Valve” Under Board’s Correct Claim Construction

- Board’s correct preliminary construction allows an element/sub-element configuration for “proximal hub” and “flow valve”
 - No dispute that limitations are obvious under Board’s construction

Grounds 5-9: “Proximal Hub” and “Flow Valve” Obvious Under PO’s Incorrect Claim Construction

- Grounds 5-9 based on PHOSITA knowledge:
 - Flow valve as integral part of proximal hub (e.g., Eliason’s element/sub-element relationship)
 - Flow valve separate from proximal hub (e.g., Chengod’s removably attached valve located between the proximal hub and inflation device)
- For same reasons explained for Grounds 1-4, having separate flow valve and hub elements is an obvious variation of Eliason’s integral hub and flow valve

Reserve Remaining Time for Rebuttal