

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

Post Grant Review No. PGR2024-00028

Patent No. 11,857,737

**PETITIONER'S REPLY IN SUPPORT OF POST-GRANT REVIEW
OF U.S. PATENT NO. 11,857,737**

TABLE OF CONTENTS

I. INTRODUCTION	1
II. CLAIM CONSTRUCTION	2
A. “proximal hub”	2
B. “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device”	3
C. “flow valve” as part of the “proximal hub”	4
D. “a distal catheter section”	7
E. “a solid wire, secured at a proximal-most end thereof within the proximal hub”	9
III. PERSON HAVING ORDINARY SKILL IN THE ART (“PHOSITA”).....	10
A. PO’s PHOSITA Definition Does Not Alter Dr. Resnick’s Testimony	11
B. PHOSITA Definition Should Include Medical Degrees.....	11
1. <i>MDs Play a Key Role in Medical Device Design and Development</i>	12
2. <i>Prior Art Solutions and the Educational Level of Workers in the Field Confirm Petitioner’s PHOSITA Definition</i>	13
3. <i>An MD PHOSITA Need Not Have Design Experience if They Have Sufficient Experience Performing Interventional Procedures</i>	14
C. PO’s Other Criticisms of Dr. Resnick and His PHOSITA Definition are Unwarranted	17
IV. GROUND 1: PO’S FOGARTY ARGUMENTS ARE UNAVAILING.....	18
A. The Petition Demonstrates a Reasonable Expectation of Success	19
B. Fogarty Discloses a “Solid Wire ... Secured Within the Proximal Hub”	20
1. <i>Fogarty’s stylet is secured within the proximal hub when “secured” has its ordinary meaning</i>	21
2. <i>Fogarty’s stylet is secured within the proximal hub under PO’s “secured” construction</i>	22

C. Fogarty Teaches or Discloses a Proximal Hub and a Flow Valve Under any Construction	25
D. An Asymmetrical Balloon Shape is Obvious (Claim 2)	28
V. GROUND 5: PO’S ELIASON ARGUMENTS ARE UNAVAILING	29
E. Eliason Discloses “A Distal Catheter Section...”	29
F. Eliason Teaches or Discloses a Proximal Hub and a Flow Valve Under any Construction.....	30
G. An Asymmetrical Balloon Shape is Obvious (Claim 2)	30
VI. GROUNDS 2 & 7: PO’S SAAB ARGUMENTS ARE UNAVAILING	31
VII. CONCLUSION	31

LIST OF EXHIBITS

Ex-1001	U.S. Patent No. 11,857,737 (“the ’737 Patent”)
Ex-1002	Prosecution history of U.S. Patent No. 11,857,737
Ex-1003	Declaration of Dr. Scott A. Resnick
Ex-1004	U.S. Patent Number 3,467,101 (“Fogarty”)
Ex-1005	S. Chengod, MD. et al., <i>Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique</i> , Department of Anesthesiology and Intensive Care, Division of Cardiothoracic and Vascular Anesthesiology and Intensive Care, Amrita Institute of Medical Sciences and Research Center, Kerala, India. (2005) (“Chengod”)
Ex-1006	Mark A. Saab, <i>Applications of High-Pressure Balloons in the Medical Device Industry</i> , Medical Device & Diagnostic Industry Magazine (September 2000) (“Saab”)
Ex-1007	U.S. Patent No. 10,004,622 (“Sanati”)
Ex-1008	Dr. David H. Deaton, <i>Image-Guided Thrombectomy in Vascular Surgery</i> , Endovascular Today (July 2005) (“Deaton”)
Ex-1009	U.S. Patent Number 9,131,874 (“Eliason”)
Ex-1010	Daniel J. Scott, et al., <i>A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock</i> , The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1 (July 2013) (“Scott”)
Ex-1011	U.S. Publication Number 2015/0133892 (“Joe”)
Ex-1012	International Application Number PCT/US2011/033368 (“Eliason PCT Application”)

- Ex-1013 U.S. Patent Pub. No. 2013/0060316 (“Sanati Publication”)
- Ex-1014 X. Gu et al., *A New Technique for Sizing of Atrial Septal Defects*, Catheterization and Cardiovascular Interventions (1999) (“Gu”)
- Ex-1015 Handbook of Endovascular Peripheral Interventions (C.D. Owens & Y. Yeghiazarians eds., Springer 2012)
- Ex-1016 PCT publication number WO 2014/036530 to Bagaoisan (“Bagaoisan”)
- Ex-1017 U.S. Patent No. 8,088,121 to Nishide (“Nishide”)
- Ex-1018 U.S. Patent No. 5,607,394 to Anderson (“Anderson”)
- Ex-1019 U.S. Patent No. 5,779,731 to Leavitt (“Leavitt”)
- Ex-1020 U.S. Patent Publication No. 2008/0188803 by Jang (“Jang”)
- Ex-1021 John M. Mathis, et. al, *Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion*, American Society of Neuroradiology (November 1994) (“Mathis”)
- Ex-1022 U.S. Patent No. 4,846,174 to Willard et al. (“Willard”)
- Ex-1023 Patent Owner’s Infringement Claim Charts filed in *Prytime Medical Devs., Inc. v. Front Line Med. Techs., Inc.*, Case No. 6:24-cv-00001, Dkt. No. 1-3 (W.D. Tex. Jan. 2, 2004)
- Ex-1024 E.P. Gerstenfeld & J. Michele, *Pulmonary vein isolation using a compliant endoscopic laser balloon ablation system in a swine model*, Springer Science+Business Media, LLC (2010) (“Gerstenfeld”)
- Ex-1025 U.S. Patent No. 5,087,246 to Smith (“Smith”)
- Ex-1026 Declaration of Dr. Sylvia Hall-Ellis

- Ex-1027 Patent Owner Prytime Medical Inc. "Leadership" web page (available at <https://prytimemedical.com/prytime-medical/leadership/>) (last visited 05-01-2024)
- Ex-1028 USPTO Assignment Record for U.S. Patent No. 9,131,874 to Eliason (available at <https://patentcenter.uspto.gov/applications/13642465/assignments?application=>) (last visited 05-01-2024)
- Ex-1029 U.S. Patent No. 5,364,352 ("Cimino")
- Ex-1030 Annotated Excerpt from Ex-2001 (Cimino Declaration)
- Ex-1031 "Distal Catheter Section" Excerpts from Ex-2001 (Cimino Declaration)
- Ex-1032 Transcript of Dr. Cimino's deposition held March 20, 2025 ("Cimino Deposition")
- Ex-1033 U.S. Patent No. 7,993,366 to Yassinzadeh ("Yassinzadeh")
- Ex-1034 Second Declaration of Dr. Scott A. Resnick (April 9, 2025)
- Ex-1035 Definition of "Secure," Webster's New Universal Unabridged Dictionary (1996)
- Ex-1036 Printout of <http://www.jcvaonline.com/> (04/09/2025)
- Ex-1037 Printout of <http://evtoday.com/about> (04/09/2025)
- Ex-1038 Printout of <https://journals.lww.com/jtrauma/pages/aboutthejournal.aspx> (04/09/2025)
- Ex-1039 Printout of <https://www.jscai.org/content/aims> (04/09/2025)

Ex-1040

Printout of <https://scai.org/publications/jscai-editorial-board>
(04/09/2025)

I. INTRODUCTION

Petitioner submits this Reply in support of its PGR challenging claims 1-10 of the '737 Patent (Ex-1001) assigned to Patent Owner Prytime Medical Devices ("PO").

PO's Response ("POR") does not undermine Petitioner's showing that claims 1-10 of the '737 Patent would have been obvious. PO's arguments rely on incorrect claim constructions, an artificially narrow definition of a person having ordinary skill in the art ("PHOSITA"), and strained readings of the asserted prior art that are contrary to the Board's findings in the Institution Decision ("ID"). Petitioner's expert, Dr. Resnick, provides detailed rebuttal (Ex-1034) demonstrating a PHOSITA understands the prior art and that it renders the challenged claims obvious—whether under the proper construction of claim terms or under PO's improper constructions.

Nothing in the POR or accompanying expert testimony undermines the Petitioner's demonstration that the claims are unpatentable. To the contrary, PO's expert admitted that every limitation of claim 1 was known by a PHOSITA before the '737 patent was filed. Ex-1032, 163:20-173:7, 175:18-22, 178:21-179:4, 180:2-17, 181:7-21. Claims 1-10 should be cancelled.

II. CLAIM CONSTRUCTION

A. “proximal hub”

PO construes “proximal hub” (POR, 25-27). No construction is needed. Claim terms are generally given their ordinary meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005) (en banc). “There are only two exceptions”: 1) an express definition or 2) disavowal. *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). PO does not allege that “proximal hub” is ambiguous, has been expressly defined, or disavowed. Instead, PO argues Dr. Resnick’s declaration implicitly defines “proximal hub.” POR, 25. That is not a proper *Phillips* analysis. PO’s construction is overly narrow because “proximal hubs” may be configured for functions other than connecting an inflation device to an inflation lumen. Ex-1034 ¶¶49-51. For example, the hub may be connected to a pressure sensor. Ex-1034 ¶50.

“Proximal hub” should be interpreted to have its ordinary meaning. Ex-1034 ¶52. That would include, but is not limited to, an element (or elements), oriented away from the body, for connecting other catheter elements, including for connecting an inflation device to an inflation lumen. Ex-1034 ¶52.

B. “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device”

PO construes this phrase (POR, 28-30), but again, no construction is needed. Ex-1034 ¶53. It is not ambiguous, has not been expressly defined, or disavowed.

PO's construction changes the scope by requiring the valve “is opened and closed” as opposed to merely being “configured to” selectively fluidly communicate. Ex-1034 ¶53. Imposing a method step into a system claim (i.e., requiring opening and closing of the valve) is improper. *See Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002) (patentability of apparatus claim “depends on the claimed structure, not on the use or purpose of that structure”).

PO also improperly adds “between” into the construction to argue “the flow valve must be located *between* the proximal hub and the inflation device.” POR, 41. A PHOSITA would not understand the phrase to require a flow valve structurally located between the hub and the inflation device. Ex-1034 ¶54. PO uses this unsupported structural relationship to recast its argument that the “flow

valve” cannot be a sub-element of the “proximal hub,” an argument already rejected in the ID.¹

C. “flow valve” as part of the “proximal hub”

PO offers an implicit claim construction requiring the “flow valve” and “proximal hub” to be “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...*” POR, 41. The Board rightly rejected PO’s construction in the ID, holding the “proximal hub” and “flow valve” may be separate elements or, alternatively, the “flow valve” may be a sub-element portion of the “proximal hub.” ID, 14.

The specification supports the Board’s construction by disclosing a flow valve as part of a proximal hub. Ex-1034 ¶¶58-63. As Dr. Resnick explains, Figure

¹ The ID construed “flow valve” to address PO’s POPR argument that the flow valve must be operational and cannot include a wire within the proximal hub. ID, 17. The Board’s construction, while consistent with the ordinary meaning (Ex-1034 ¶55), need not be adopted because PO does not make the same argument in the POR. *See* Scheduling Order, Paper 8, at 9 (“[A]rguments not raised in the response may be deemed waived.”).

42A is illustrated having a hub with a “stopcock (flow) valve” for connecting an inflation device:

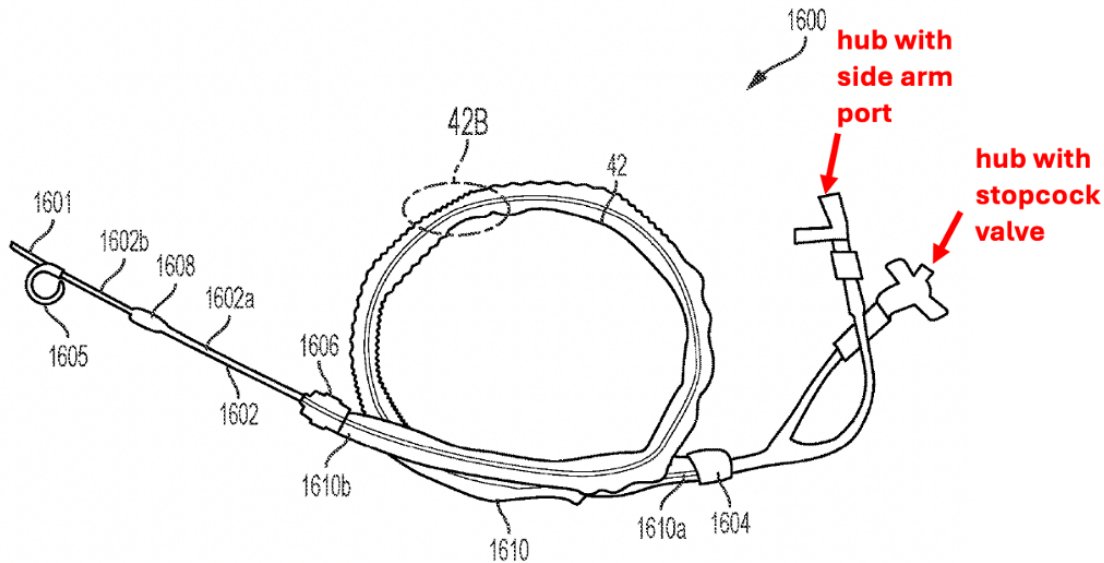


FIG. 42A

Ex-1001, Fig. 42A (annotated); Ex-1034 ¶¶58-59. Dr. Cimino agrees an inflation device would be connected at this location in Figure 42A. Ex-1032, 78:9-22 (discussing Ex-1030).

The specification describes other valves as part of proximal hubs. For example, proximal hub 1604 in Figure 42A “may be configured as any type of hemostatic valve....” Ex-1033 ¶¶60-61; Ex-1001, 60:8-12. Additionally, “the proximal hub includes ... a pressure relief member” (Ex-1001, 21:27-32) which may be “a pop-off valve or other similar biased valve” (Ex-1001, 21:9-11). Ex-1034 ¶62. These hubs with valves (even if they perform different functions)

confirm a PHOSITA understands the “proximal hub” could also include a valve as part of its construction. Ex-1034 ¶¶62-63.

The prosecution history also confirms the flow valve can be a sub-element of the proximal hub. Specifically, original claim 1 recited “a proximal hub having a flow valve.” Ex-1002, PDF-p.113. Although the claim was amended in a preliminary amendment (Ex-1002, PDF-p.200), “original claims are part of the original specification.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010). By amending the claim to recite “a proximal hub” and “a flow valve...” instead of “a proximal hub having a flow valve” (Ex-1002, PDF-p.200), the amendment broadened the original claim so the flow valve did not have to be part of the proximal hub. Thus, the broader amended claim allows for either (1) “a proximal hub having a flow valve” or (2) “a proximal hub” that is separate from “a flow valve”—this aligns with the Board’s ID construction.

Because the specification and prosecution history disclose examples of proximal hubs having valves (including flow valves), *Becton* is inapplicable. As the Board already found, this case is more similar to *Google LLC v. EcoFactor, Inc.*, 92 F.4th 1049 (Fed. Cir. 2024). The *Google* court reversed the Board’s construction requiring separate elements because: (1) the specification included embodiments where separately recited elements were not distinct components, and

(2) “the specification contains no restrictive language and does not explicitly require that the claim [limitations] be separate.” *Id.* at 1058. The same is true here.

Becton is further distinguishable because the *exact same* structure was accused for both the “hinged arm” limitation and the “spring means connected to said hinged arm...” limitation. *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254-55 (Fed. Cir. 2010). Here, Petitioner asserts the flow valve is a sub-element of the proximal hub, not that they are the exact same structures. Ex-1034 ¶¶116-117. Further, in *Becton*, the “spring means” was recited to be (1) “connected to” the “hinged arm,” and (2) “extending between” the “hinged arm” and a mounting means. 616 F.3d at 1255. Thus, the claim language in *Becton* expressly required separate structures. There is no similar *structural* requirement in claim 1. Ex-1034 ¶¶54, 57.

D. “a distal catheter section”

The Board should maintain its plain meaning construction of “a distal catheter section.” ID, 17-18. That construction is consistent with the claim language, i.e., “distal catheter section *distally terminating with an atraumatic tip*,” “intervening occlusion balloon connecting the proximal catheter section with *the distal catheter section*,” and “solid wire ... extending ... *into the distal catheter section*.” Ex-1034 ¶65. Based on this surrounding claim language, a PHOSITA understands the “distal catheter section” is simply the distal portion of the claimed

catheter, i.e., the portion including the elements located distal of the intervening occlusion balloon. ID, 17-18; Ex-1034 ¶¶65-66.

PO's various constructions of "a distal catheter section" (POR, 31; Ex-1031) ignore the intrinsic evidence (claims) and, instead, use extrinsic evidence (Dr. Resnick's deposition testimony) to argue "a distal catheter section" is "a portion of the catheter shaft itself, and not a portion of the entire catheter system." POR, 31 (emphasis removed).² PO's overly-narrow construction contradicts the intrinsic evidence.

First, PO's construction limits the distal catheter section to a shaft and, therefore, contradicts the express claim language requiring the distal catheter section to "terminate[] with an atraumatic tip." Second, PO relies on the "distal catheter member 520" as the only intrinsic evidence supporting its proposed construction and, therefore, improperly regards that embodiment as definitional. POR, 31 (citing Ex-1001, 29:64); Ex-2001 ¶45 (same). The Board should not "confine[] the claims to [disclosed] embodiments." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (*en banc*).

² PO mistakenly states that the Board's construction is "a portion of the **system** that is at the distal end." POR, 31. That was not the Board's construction. ID, 18.

Third, there is no support for PO's proposed negative limitation, which rules out any "non-shaft" portion of a catheter from being part of the "distal catheter section." 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). Neither is present here.

Finally, PO and Dr. Cimino argue "a distal catheter section" cannot include a wire. POR, 52-53; Ex-1032, 157:13–159:11; Ex-2001 ¶¶108-112. This contradicts the specification where (1) a distal catheter section includes a "stiffening member, such as a nitinol wire..." and (2) an atraumatic tip formed by a nitinol wire. Ex-1001, 51:29-33, 52:28-32, 23:66–24:1; Ex-1034 ¶67.

E. "a solid wire, secured at a proximal-most end thereof within the proximal hub"

This phrase should have its ordinary meaning. Ex-1034 ¶¶68-72. PO improperly (1) adds a negative (and unnecessary) limitation "without an internal lumen," and (2) imports limitations from the specification to re-write "secured" as "fixedly coupled." Ex-1034 ¶68. This is contrary to *Phillips*. See, 415 F.3d at 1323.

First, “solid wire” is unambiguous. Ex-1034 ¶69. The negative limitation “without an internal lumen” is unnecessary because it is not germane to any disputed issue. It is also unwarranted. *See Eko Brands*, 946 F.3d at 1381 (negative limitation requires express disclaimer or lexicography).

Second, PO argues “secured” means “fixedly coupled,” which PO later argues means “unremovably attached.” POR, 31-33, 37 (distinguishing Fogarty’s “removable attachment” as not “fixedly coupled”). This is contrary to the specification, which expressly states that “secured” is *not* the same as “fixedly coupled.” Indeed, “fixedly coupled” is “preferably using an adhesive” whereas “the [solid wire] *is not limited to being adhesively bonded ... and may be otherwise* fastened, *secured*, or fixed to the proximal hub...” Ex-1001, 35:4-27 (emphasis added). A PHOSITA understands “fixedly coupled” is not the same as “secured”—the specification describes them as alternatives. Ex-1034 ¶¶71-72.

A PHOSITA understands “secured” to have its plain meaning, which does not require a permanent attachment. Ex-1034 ¶¶70-71; Ex-1035-4.

III. PERSON HAVING ORDINARY SKILL IN THE ART (“PHOSITA”)

PO’s PHOSITA definition does not expressly include an individual with a medical degree (“MD”). POR, 10-14. PO does this to discredit Dr. Resnick’s testimony and exclude him from qualifying as a PHOSITA. POR, 14-18. However, Dr. Resnick qualifies as a PHOSITA under his definition (Ex-1003 ¶17) and PO’s

definition (Ex-1034 ¶8). This likely moots PO's PHOSITA arguments (POR, 10-18) because Dr. Resnick is a PHOSITA under either test. Nevertheless, the Board may adopt a PHOSITA definition that includes Petitioner's PHOSITA *and* PO's PHOSITA. The claims are unpatentable either way.

A. PO's PHOSITA Definition Does Not Alter Dr. Resnick's Testimony

PO's PHOSITA definition does not change Dr. Resnick's unpatentability opinions. Ex-1034 ¶¶44-48. By March 2015, Dr. Resnick had 17 years of experience as a practicing interventionalist and had worked with multiple medical device companies designing and developing catheter-based medical devices. Ex-1034 ¶46. During that time, he worked with engineers who would qualify as a PHOSITA under PO's definition and, thus, understood the level of skill those individuals would have. Ex-1034 ¶46. Dr. Resnick explains that PO's PHOSITA would have the same general knowledge as Petitioner's PHOSITA. Ex-1034 ¶47. And PO's PHOSITA understands claim terms to have the same meaning, and would have found claims 1-10 obvious for the same reasons as Petitioner's PHOSITA. Ex-1034 ¶48.

B. PHOSITA Definition Should Include Medical Degrees

PO's PHOSITA definition lacks a key ingredient, namely, a medical degree. As Dr. Resnick explains, the PHOSITA should either be an MD (Petitioner's PHOSITA) or, if not an MD (PO's PHOSITA) should have consulted or worked

with MDs who have experience with endovascular procedures, as explained below.

Ex-1034 ¶20; *see also id.* ¶¶17-43.

1. MDs Play a Key Role in Medical Device Design and Development

Dr. Resnick is an MD who has worked with medical device companies in device design and development since 2000, including catheter-based devices. Ex-1034 ¶¶8-13. He explains, “MDs are integral to the design and development of any new medical device.” Ex-1034 ¶20. “As active users of medical devices in a clinical setting, MDs ... are the individuals best able not only to identify performance characteristic deficiencies of existing devices for improvement but also to identify gaps in existing device technology as a means of realizing potential new device development opportunities.” Ex-1034 ¶26. Indeed, “omitting participation by MDs from the PHOSITA definition is inconsistent with real world medical device development.” Ex-1034 ¶20. PO’s expert confirms this reality: “MDs are often and frequently and even recommended to be part of a design, development, and commercialization process...” Ex-1032, 58:13–20; *see also* Ex-2001 ¶25 (PO’s definition “does not preclude an individual with a medical degree ... from qualifying as a PHOSITA”).

There is no dispute MDs play a key role in medical device design and development. They should be included in the PHOSITA definition. Ex-1034 ¶¶20, 22, 25, 26.

2. Prior Art Solutions and the Educational Level of Workers in the Field Confirm Petitioner's PHOSITA Definition

PO's PHOSITA definition ignores important evidence of prior art solutions and the educational level of workers in the field, i.e., evidence relevant "in determining level of ordinary skill in the art." *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). In particular, many of the relevant non-patent prior art references are authored and edited by MDs and included in publications that are directed to MDs. Ex-1034 ¶27. These include:

- Chengod (Ex-1005): MD-authored and published in journal edited by MDs and "primarily aimed at anesthesiologists." Ex-1034 ¶28.
- Deaton (Ex-1008): MD-authored and published in journal edited by MDs and targeted to the "endovascular community" composed of MDs. Ex-1034 ¶29.
- Scott (Ex-1010): mostly MD-authored and published in journal sponsored by association made up almost entirely of MDs. Ex-1034 ¶30.

- Gu (Ex-1014): authored by MDs and others and published in journal with predominantly MD-led editorial board. Ex-1034 ¶31.
- Owens (Ex-1015): reference book edited by an MD and directed to MDs. Ex-1034 ¶32.

This evidence confirms a PHOSITA should include individuals with medical degrees and sufficient experience with interventional procedures. Ex-1034 ¶33. It also casts doubt on the absence of MDs in PO's PHOSITA definition.

3. An MD PHOSITA Need Not Have Design Experience if They Have Sufficient Experience Performing Interventional Procedures

PO's PHOSITA definition is overly narrow because it focuses on design and development experience and excludes MDs with hands-on experience performing interventional procedures (i.e., using occlusion catheters). Ex-1034 ¶¶34-43. Dr. Resnick explains: "the clinician who would use the device claimed in the '737 patent ... would be responsible for its safe and effective use" and would be "required ... [to] understand the operation of the devices ... in great detail, including the operation, function, and construction..." Ex-1034 ¶35. That understanding would be achieved through "medical training and obtaining [an] MD, and years of experience using and testing devices." Ex-1035 ¶35. It would also be obtained "through hands-on clinical experience, reviewing instructions for use, attending educational programs and seminars, and studying the scientific

literature.” Ex-1034 ¶42. “[H]aving experience designing and developing catheter devices is not necessary [for an MD] ... as long as the individual has sufficient experience with interventional procedures, i.e., extensive use of [balloon catheters].” Ex-1035 ¶39.

An MD with six years of experience designing and developing catheters (PO's PHOSITA) would also likely qualify under Petitioner's PHOSITA which requires “sufficient experience with interventional procedures...” Ex-1034 ¶38. It would be uncommon for an individual to obtain an MD and then spend six years designing and developing catheter devices for interventional procedures without having practiced in the field and obtained sufficient experience using catheter devices while performing interventional procedures. *Id.* This would be uncommon because medical device companies hire MD consultants based on clinical experience in the relevant field. *Id.* Put differently, it would be atypical (now and in 2015) for companies to engage an MD to help design and develop a product if that MD does not have sufficient clinical experience in the relevant field. Ex-1034 ¶38.

Finally, the problem and alleged solution in the '737 patent confirms an MD with experience *using* relevant devices can be a PHOSITA regardless whether they have experience *designing* those devices. Ex-1034 ¶40. The '737 patent addresses both the *design* of occlusion catheters and the *clinical use* of those catheters. Ex-

1034 ¶75; Ex-1001, 19:65-20:5. The alleged problem relates to reducing hypertension and hypotension during and after a vascular occlusion procedure. Ex-1001, 2:1-3. An MD with extensive experience *using* occlusion devices understands these risks and their effects based on their “personal experience with such blood pressure abnormalities occurring during procedures they performed.” Ex-1034 ¶40.

The alleged solution in the '737 patent, i.e., the claims, “use general terms and do not identify any non-generic design details or tie any design features to the alleged problem.” Ex-1034 ¶41. An individual who had extensively *used* both angioplasty balloons and occlusion devices for performing interventional procedures understands those devices include the generic features found in the '737 patent claims (e.g., “proximal hub,” “flow valve,” “proximal catheter section,” “atraumatic tip,” “occlusion balloon,” etc.). Ex-1034 ¶41. Consequently, that individual would have the skill necessary to understand the operation and clinical effects of the device in claims 1-10 based solely on extensive use of both angioplasty balloons and occlusion devices. Ex-1034 ¶41.

For at least these reasons, an MD with extensive experience using both angioplasty balloons and occlusion devices (and without device design/development experience) would have ordinary skill for considering the problems and solutions relevant to the '737 patent. Ex-1034 ¶¶42-43.

C. PO's Other Criticisms of Dr. Resnick and His PHOSITA Definition are Unwarranted

PO takes testimony out of context to criticize Dr. Resnick and argue his testimony “should be afforded little, if any, weight.” POR, 14-15. These attacks are unwarranted.

First, Dr. Resnick did not admit to having “no experience in catheter design and development.” POR, 15 (citing Ex-2002, 14:5-15:16, 23:5-24:2). Dr. Resnick has worked for over 20 years with medical device companies designing and developing catheter-based interventional devices. Ex-1034 ¶76. His experience includes (1) catheter and interventional device design, (2) prototype creation, and (3) provisional patenting. Ex-1034 ¶76.

Second, Dr. Resnick did not admit he lacked “knowledge of the intricacies” of catheters he has used or that “users are generally unaware of components not visible from the catheter exterior.” POR, 11, 15 (citing Ex-2002, 39:16-40:15, 55:21-57:2). The cited testimony related to specific questions about specific catheters—it was not a general admission about Dr. Resnick's knowledge. Ex-1034 ¶¶77-78.

Third, any suggestion that practicing physicians like Dr. Resnick do not understand the internal structures of catheter systems (POR, 15-16 (citing Ex-2002, 33:11-34:14, 63:7-64:10)) goes too far, especially in view of the generic elements

recited in the '737 patent claims. Ex-1034 ¶¶78-79. Practicing physicians who had extensively used angioplasty balloons and occlusion devices in interventional procedures understands those devices include the generic features recited in the '737 patent claims, understands the operation and clinical effects of those generic features, and understands the prior art that disclosed those generic features. Ex-1034 ¶78.

Finally, Dr. Resnick did not use “vague and confusing references to ‘Fogarty catheters.’” POR, 16-17. For Ground 1, Dr. Resnick explains obviousness in view of the Fogarty catheter disclosed in Fogarty (Ex-1004) and in view of another Fogarty catheter disclosed in Chengod (Ex-1005) and the PHOSITA's knowledge. There is nothing “vague and confusing” about this. Ex-1034 ¶80. And while the term “Fogarty catheters” may, in general, encompass many devices, some of which may have specialized structures, that does not affect Dr. Resnick's analysis because the '737 patent claims recite only generic catheter structures found in many different types of balloon catheters. Ex-1034 ¶81.

IV. GROUND 1: PO'S FOGARTY ARGUMENTS ARE UNAVAILING

PO's Ground 1 arguments rely on incorrect claim constructions and a mistaken conclusion that Petitioner did not demonstrate a reasonable likelihood of success. POR, 35-49.

A. The Petition Demonstrates a Reasonable Expectation of Success

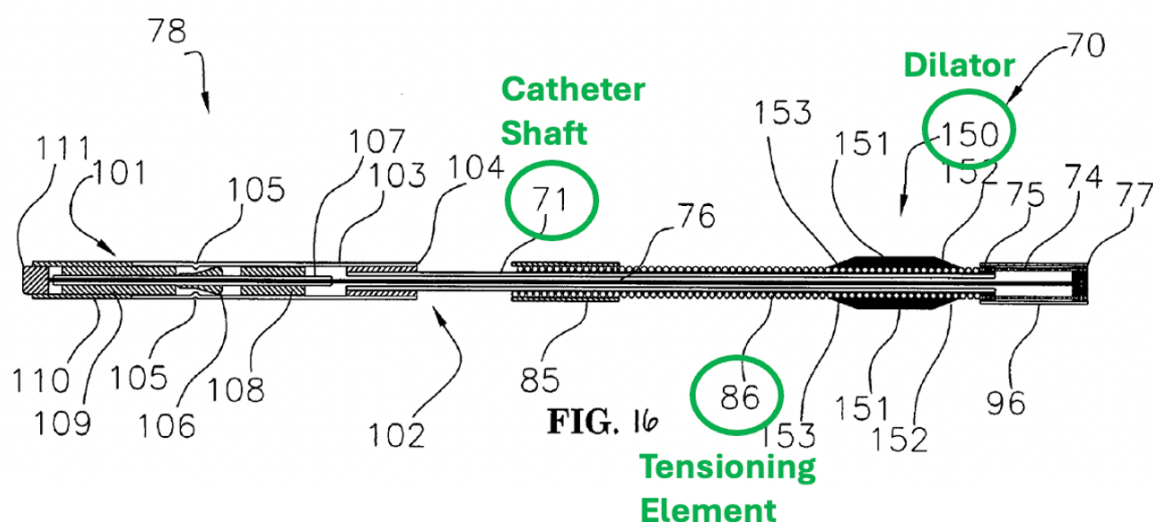
PO ignores the Petition's evidence and explanation of how the prior art and PHOSITA's knowledge, in combination with Fogarty's catheter, renders the "less than 6 Fr" limitation obvious. Petition, 40-41; Ex-1003 ¶¶90-92. The Petition (and Dr. Resnick) explained: (1) Fogarty did not indicate the catheter's size; (2) Fogarty catheters smaller than 6 Fr were known and disclosed in Chengod (and Deaton); and (3) sizing Fogarty's catheter less than 6 Fr would work (i.e., reasonable expectation of success) because it did work. Petition, 40; Ex-1003 ¶¶90-91. In other words, a PHOSITA with knowledge of these references understands the structure of the Fogarty catheters that were smaller than 6 Fr (e.g., Chengod) and, to the extent those structures differed from the device in the Fogarty patent (Ex-1004), the PHOSITA could make the same modifications used to arrive at Chengod and have a reasonable expectation the resulting device will work as intended. Ex-1034 ¶85.

PO suggests Fogarty could not be sized less than 6 Fr because its construction includes a spring coil, braid, outer tube, and lumen. POR, 35-36. PO is wrong. Yassinzedah (Ex-1033) shows a catheter that is less than 6 Fr and that includes a similar spring coil construction as found in the Fogarty patent. Ex-1034 ¶¶86-97. For example, Figure 16 includes a catheter shaft 71 that has a coil spring, tensioning element 86 that is a coil spring, and dilator 150 that surrounds both shaft

71 and tensioning element 86. Ex-1034 ¶¶93-95. Yassinzedah's construction is analogous to Fogarty's spring coil, braid, outer tube, and lumen. Ex-1034 ¶96.

Yassinzedah's dilator 150 has a diameter of either 5 Fr or 6 Fr. Ex-1034 ¶96.

Yassinzedah's analogous construction being less than 6 Fr confirms a PHOSITA would have a reasonable expectation of success in sizing the catheter in Fogarty (Ex-1004) less than 6 Fr. Ex-1034 ¶97.



Ex-1033, Fig.16 (annotated).

B. Fogarty Discloses a “Solid Wire ... Secured Within the Proximal Hub”

PO's "solid wire" argument relies on PO's incorrect construction of "secured" as meaning "fixedly coupled to." As discussed above, that construction is incorrect. When properly construed, Fogarty's solid wire stylet is "secured"

within the proximal hub.³ Even assuming PO's incorrect construction, Fogarty includes a solid wire, i.e., coil 10, that is "fixedly coupled to" the proximal hub.

1. Fogarty's stylet is secured within the proximal hub when "secured" has its ordinary meaning

Fogarty's metal stylet is "secured" within the proximal hub because Fogarty uses the same term, i.e., "secured," to describe the connection: "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.*" Ex-1004 at 3:60-65 (emphasis added); Ex-1034 ¶100. PO incorrectly argues the stylet is "engaged" but not "secured" in the hub, but the second sentence above confirms the stylet is "secured in the catheter." Ex-1004 at 3:62-65; Ex-1034 ¶101. Even if there is a difference between "securement" and "engagement," Fogarty is clear (and a PHOSITA understands) the metal stylet is secured, not merely engaged. Ex-1034 ¶101.

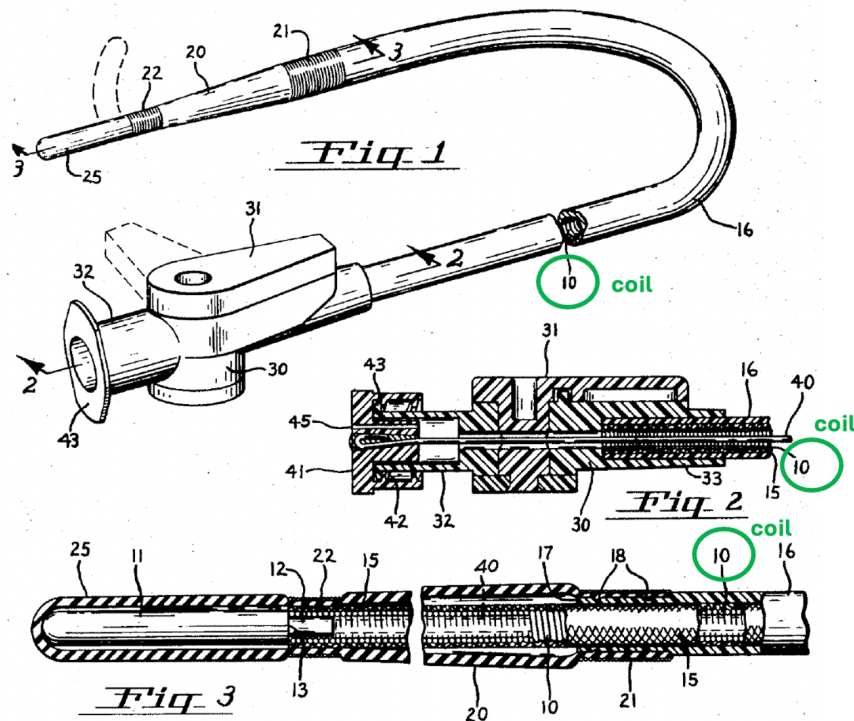
PO next argues Fogarty's stylet is not secured because it "*must be absent* during significant normal operating conditions." POR at 39-40; Ex-2001 ¶¶85-86.

³ PO suggests the stylet is limited to protecting the catheter while not in use. Not so. Ex-1034 ¶83.

This is an implicit construction of “secured” that improperly incorporates limitations from specification embodiments. *See Phillips*, 415 F.3d at (“[W]e have repeatedly warned against confining the claims to [disclosed] embodiments.”). Regardless, PO is wrong because the stylet is not absent during Fogarty’s normal operating conditions (i.e., insertion). Ex-1034 ¶102.

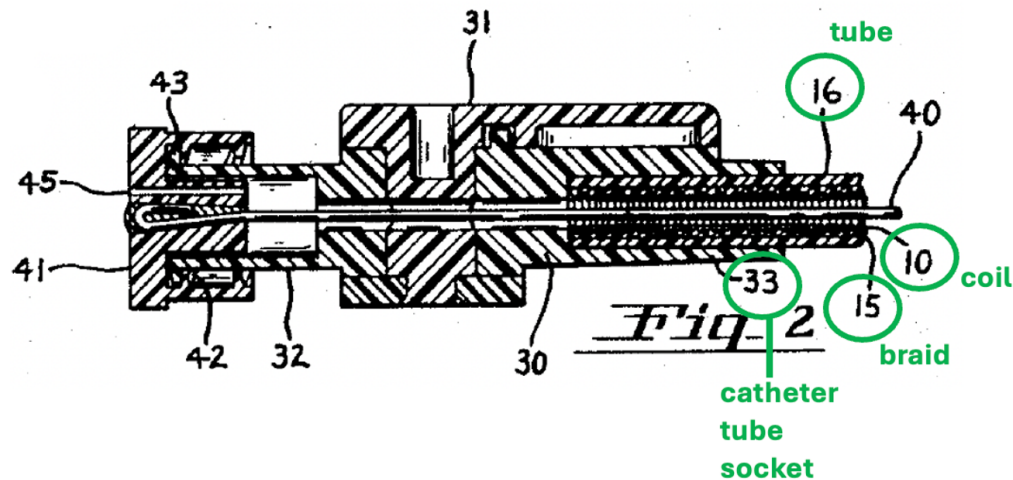
2. Fogarty’s stylet is secured within the proximal hub under PO’s “secured” construction

Even if “secured” means “fixedly coupled to,” Fogarty’s “coil 10” discloses the “solid wire” in claim 1. Ex-1034 ¶¶104-115.



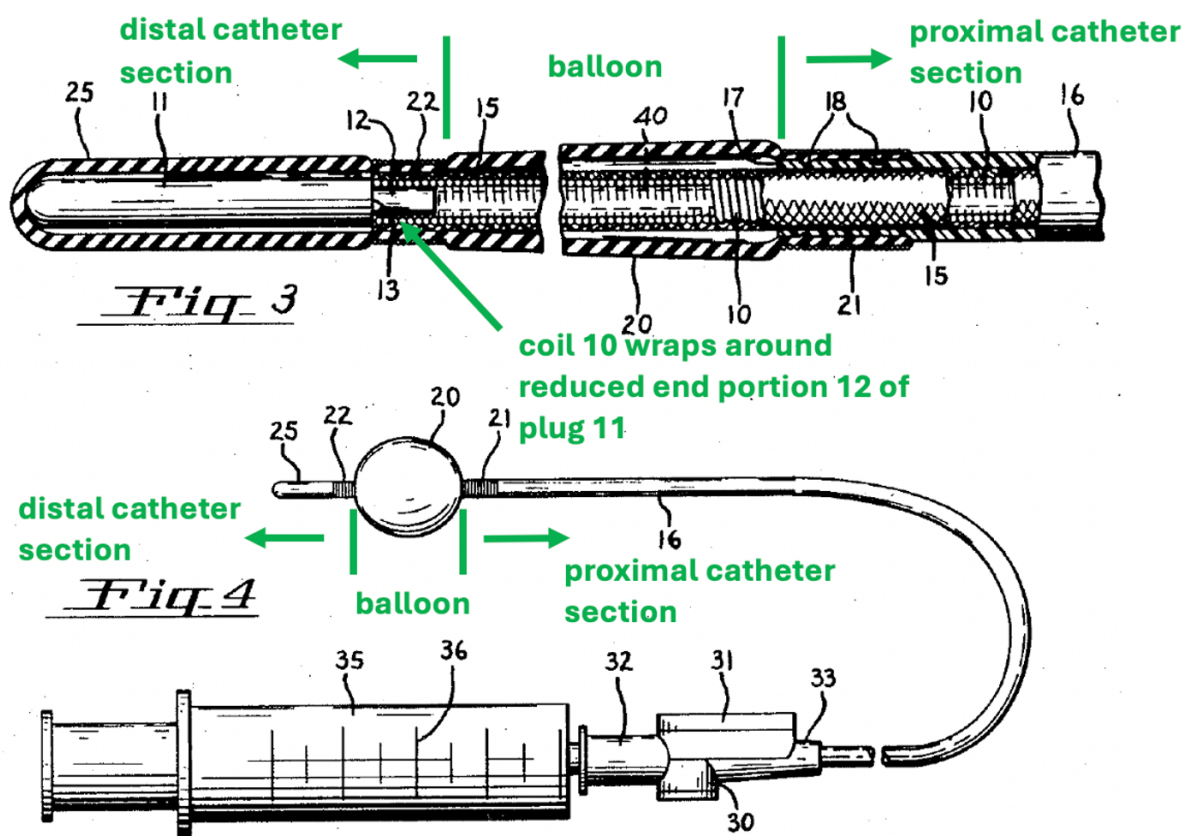
Ex-1004, Figs. 1-3 (annotated); Ex-1034 ¶104. Coil 10 is a solid wire made of stainless steel. Ex-1034 ¶105; Ex-1004, 2:40-41. Figure 2 shows coil 10, along

with braid 15 and tube 16, is connected into catheter tube socket 33 (part of the proximal hub):



Ex-1004, Fig. 2 (annotated), 3:38-42; Ex-1034 ¶105. Although Fogarty does not say how the tube/coil/braid are secured in socket 33, a PHOSITA understands adhesive or epoxy is one design choice for “fixedly coupling” that connection. Ex-1034 ¶106. Alternatively, Fogarty claim 5 describes the connection between the tube (which includes coil 10) and the socket as “integrally connected,” i.e., also “fixedly coupled.” Ex-1034 ¶107.

Coil 10 “extend[s] within the proximal catheter section, the occlusion balloon, and into the distal catheter section,” as shown in the annotated Figures below. Ex-1034 ¶¶108-115.

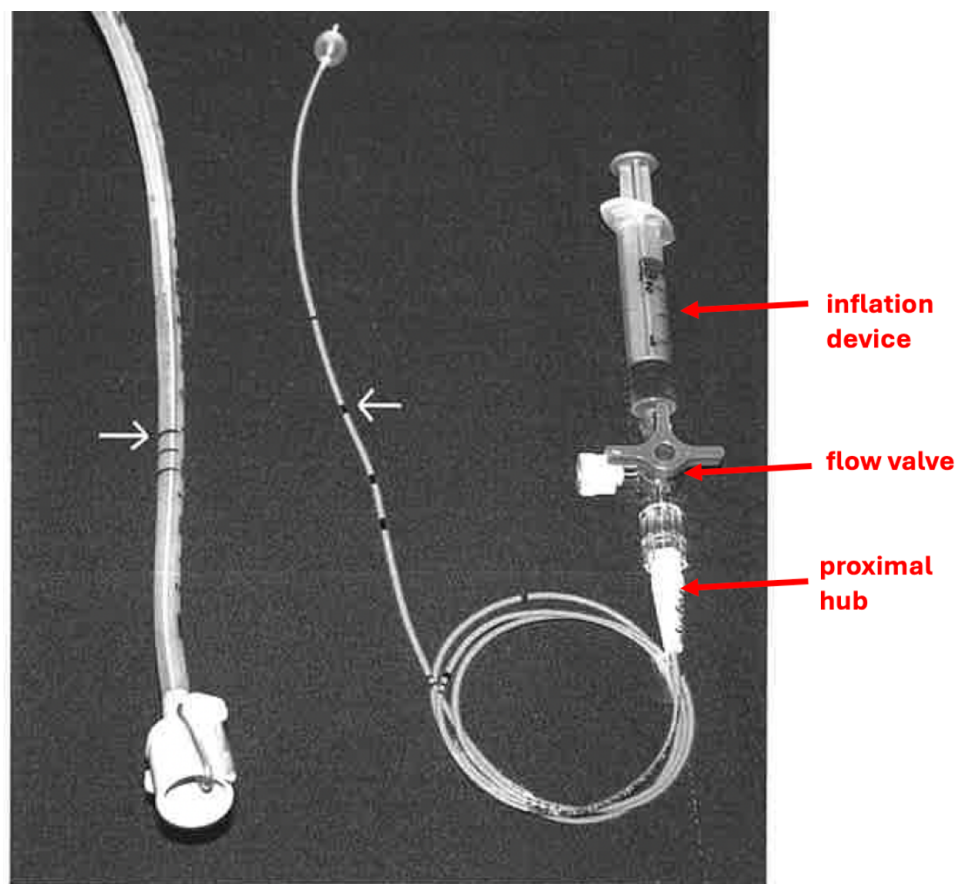


Ex-1004, Figs. 3-4 (annotated). Coil 10 “extends ... into the distal catheter section” under the Board’s construction because coil 10 is epoxied onto the end portion 12 of plug 11, i.e., distal of the intervening occlusion balloon 20. Ex-1034 ¶112. Coil 10 “extends ... into the distal catheter section” under PO’s construction because braid 15, which forms a shaft of the device, extends to shoulder 13; and coil 10 extends within braid 15 to plug 11. Ex-1034 ¶115. Thus, coil 10 extends into the distal catheter section (the distal portion of the shaft made up by braid 15) under PO’s construction of “distal catheter section.” Ex-1034 ¶115.

C. Fogarty Teaches or Discloses a Proximal Hub and a Flow Valve Under any Construction

PO argues the flow valve and proximal hub must be separate components. As discussed above, this claim construction argument fails. There is no dispute Fogarty discloses the proximal hub and flow valve under the Board's preliminary construction that allows an element/sub-element configuration. Ex-1034 ¶¶119-120.

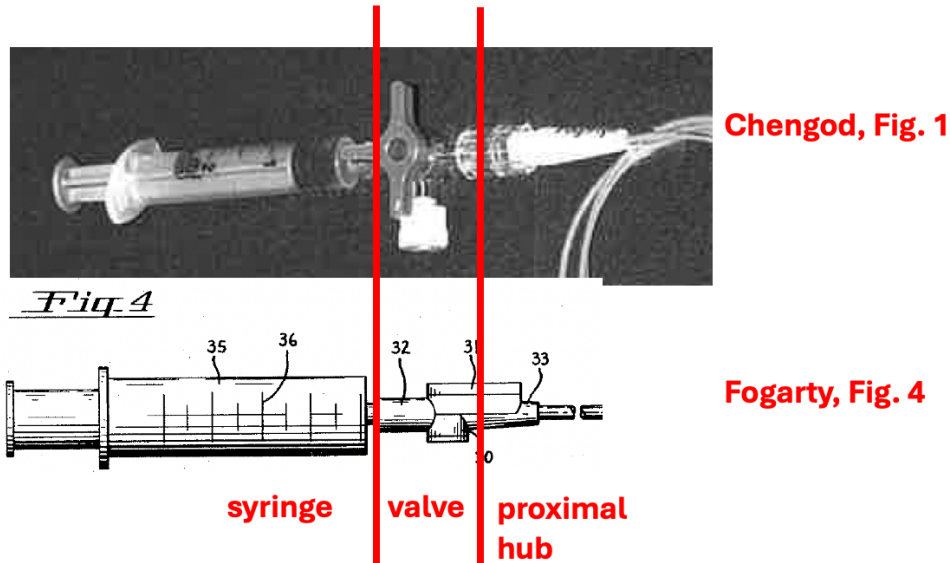
Regardless, the claims are obvious even if the flow valve must be between the proximal hub and the inflation device. Ex-1034 ¶¶121-122. A PHOSITA has knowledge that a flow valve could be an integral part of the proximal hub (i.e., permanently attached in an element/sub-element relationship) or could be separate from a proximal hub (i.e., removably attached and located between the proximal hub and the inflation device). Evidence of this knowledge is found in (1) Fogarty where the flow valve is an integral part of the proximal hub; and (2) Chengod where the flow valve is a separate physical component located between the proximal hub and the inflation device:



Ex-1005, Fig. 1 (annotated). A PHOSITA understands the elements in Chengod are coupled together, likely using luer locks. Ex-1034 ¶122.

Choosing between integral and separate constructions for the hub and valve represents a limited design choice. The pieces can be manufactured integrally or as separate assemblies for coupling together prior to use. The integral assembly typically increases ease of use while the separate assemblies may provide more flexibility for the user. In both cases, the flow valve is “configured to selectively fluidly communicate the proximal hub with an inflation device.” When Chengod’s

separate elements are coupled together, the assembly is essentially the same as Fogarty's integral assembly:



Ex-1005, Fig. 1 (top, annotated); Ex-1004, Fig. 4 (bottom, annotated). The main difference is Chengod's flow valve and proximal hub can be uncoupled from each other. Ex-1034 ¶123.

Claim 1 is obvious in view of Fogarty, Chengod, and the PHOSITA's knowledge even if claim 1 requires a flow valve between the inflation device and the proximal hub. Modifying Fogarty to use a valve that is not integral with the proximal hub represents the 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). The two approaches represent a finite number of identified, predictable solutions for controlling the

flow of fluids with the proximal hub, and a PHOSITA would have found it obvious to try separating the elements found as an integral piece in Fogarty. Success would be reasonably expected because 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. Ex-1034 ¶124.

D. An Asymmetrical Balloon Shape is Obvious (Claim 2)

Contrary to PO's allegations (POR, 48-49), the Petition does, in fact, explain why a PHOSITA would use an asymmetrical balloon in Fogarty's catheter. POR, 48-49. That explanation is in the "earlier passage" that PO mistakenly describes as "describing prior knowledge of allegedly asymmetrical balloon shapes." POR, 49.

The Petition explains that asymmetrical compliant balloons were known to a PHOSITA (Pet., 19-20) and that a PHOSITA knows "an elastomeric [compliant] balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left)" (Pet., 19 (citing to Saab, p. 90 and Fig. 6). Further, "a PHOSITA understands that compliant balloons are often used in occlusion catheters because the balloon can inflate asymmetrically when inside the patient ... to completely fill the body lumen into which it is placed, which is often asymmetrical in shape ..." Pet., 21; Ex-1034 ¶127. The Petition showed that Fogarty's catheter is used for occlusion and that a PHOSITA would use a

compliant balloon that inflates asymmetrically to occlude asymmetrical vessels in the patient's body. Ex-1034 ¶128.

V. GROUND 5: PO'S ELIASON ARGUMENTS ARE UNAVAILING

PO's Ground 5 arguments rely on incorrect claim constructions the Board already rejected. POR, 49-57.

E. Eliason Discloses "A Distal Catheter Section..."

PO argues Eliason does not have "a distal catheter section" because "no part of Eliason's endovascular wire 12 can constitute a distal catheter section." POR, 52. This is a claim construction argument that should be rejected for the reasons discussed above. PO does not attempt to analyze Eliason under the Board's claim construction or refute the Board's conclusion that Eliason discloses the claimed "distal catheter system" as presented in the Petition. Pet., 61-62. Thus, there is no dispute Eliason discloses "a distal catheter section" when it "reasonably compris[es] the elements that are located distal of the 'intervening occlusion balloon'..." ID, 18. Ex-1034 ¶135. When the wire is pre-secured as a "single unit or device" (Ex-1009, 6:5-7), the wire, securement beads, wire struts, and J tip all become part of the catheter that is inserted into the patient's body. Ex-1034 ¶136.

Dr. Resnick did not agree that "catheter" means "the shaft of the device." POR, 51. He testified the catheter is the whole device from the proximal hub to the end of the device distally, without qualification, and the catheter includes all

incorporated elements extending to the end of the device. Ex-1034 ¶133. And Dr. Resnick did not admit the catheter is distinct from the wire over which it slides. POR, 52. He testified the wire and 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.

F. Eliason Teaches or Discloses a Proximal Hub and a Flow Valve Under any Construction

PO repeats its failed argument that Eliason does not have a flow valve because it must be separate and distinct from the proximal hub. There is no dispute Eliason discloses the proximal hub and flow valve limitations under the Board's preliminary construction. Ex-1034 ¶¶139-140.

The claims are obvious even under PO's construction requiring the flow valve to sit between the proximal hub and the inflation device. Ex-1034 ¶141. As explained above for Ground 1 and Fogarty, having separate flow valve and hub elements is an obvious variation of Eliason's integral hub and flow valve. Ex-1034 ¶¶142-144. *See also supra*, Section IV.C.

G. An Asymmetrical Balloon Shape is Obvious (Claim 2)

PO makes the same argument for Ground 5, Claim 2 as it does for Ground 1, Claim 2. PO is incorrect for the same reasons discussed above. *See supra*, Section IV.D.

VI. GROUNDS 2 & 7: PO'S SAAB ARGUMENTS ARE UNAVAILING

Saab (Ex-1006) does not teach away from using asymmetrical elastomeric (compliant) balloons with Fogarty or Eliason. POR, 58-60. 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). A PHOSITA understands Saab as explaining alternative options to elastomeric balloons, not that elastomeric balloons are discouraged or should be avoided. Saab expressly says it is desirable to use high-pressure balloons (and not asymmetrical elastomeric balloons) “in some cases”—not in “all cases.” Thus, in certain instances, i.e., when precise sizes or shapes are required, a PHOSITA understands Saab voices a mere preference for the high-pressure balloons. Ex-1034 ¶¶150-151. This is not teaching away. *In re Gurley*, 27 F.3d at 553.

VII. CONCLUSION

Claims 1-10 are unpatentable.

Respectfully submitted,

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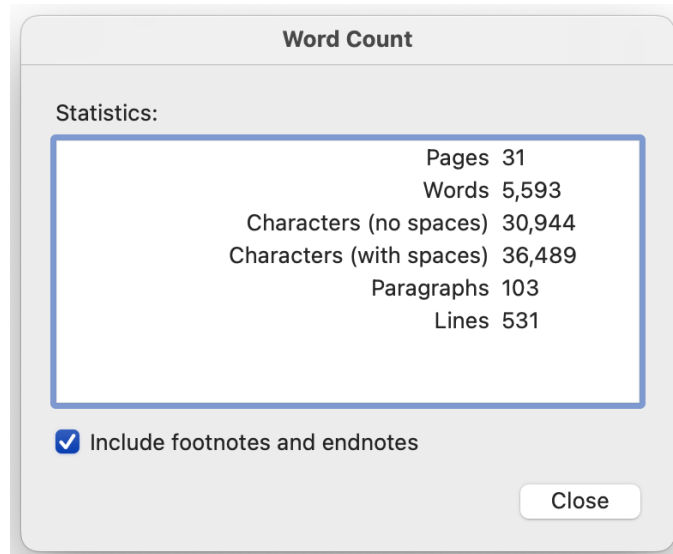
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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing Petition, exclusive of the exempted portions as provided in 37 C.F.R. §42.24(c), contains 5,593 words and complies with the type-volume limitations of 37 C.F.R. §42.24(c)(1) (less than 5,600 for a Reply to Patent Owner Response to Petition).



A screenshot of a 'Word Count' dialog box. The title bar says 'Word Count'. Below the title bar, the word 'Statistics:' is followed by a list of statistics: Pages 31, Words 5,593, Characters (no spaces) 30,944, Characters (with spaces) 36,489, Paragraphs 103, and Lines 531. Below this list is a checkbox labeled 'Include footnotes and endnotes' which is checked. At the bottom right is a 'Close' button.

Statistics:	
Pages	31
Words	5,593
Characters (no spaces)	30,944
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Paragraphs	103
Lines	531

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6(e), the undersigned certifies that the foregoing Petitioner's Reply has been served simultaneously with filing. Service is electronically by consent of the parties and has been sent to the following electronic addresses:

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