Trials@uspto.gov
Tel: 571-272-7822

Paper 24
Date: October 1, 2025

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

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

FREDMAN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 328(a)

I. I. INTRODUCTION

A. Background and Summary

Front Line Medical Technologies, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting post-grant review of claims 1–10 (the "challenged claims") of U.S. Patent No. 11,857,737 B2 (Ex. 1001, "the '737 patent"). Prytime Medical Devices, Inc. ("Patent Owner") filed a preliminary response. Paper 5 ("Prelim. Resp.").

We determined, based on the information presented in the Petition and Preliminary Response, that the '737 patent was eligible for post-grant review, and that at least some of the challenged claims were more likely than not unpatentable at least based on Petitioner's obviousness challenges under 35 U.S.C. § 103. Paper 7 ("Inst. Dec."). Pursuant to 35 U.S.C. § 324, the Board instituted trial on October 16, 2024, of all challenged claims. *Id.*

Following institution, Patent Owner filed a Response to the Petition (Paper 12, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 15, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 16, "PO Sur-Reply"). Both Petitioner and Patent Owner filed deposition transcripts. Exs. 1032, 2002. An oral hearing was held on July 16, 2025, and a transcript has been entered into the record (Paper 21, "Tr.").

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 328(a). Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–10 of the '737 patent are unpatentable.

B. Real Parties-in Interest

Petitioner identifies Front Line Medical Technologies, Inc. as the real party-in-interest. Pet. 97. Patent Owner identifies Prytime Medical Devices, Inc. as the real party-in-interest. Paper 3, 2.

C. Related Proceedings

Petitioner states, regarding related matters, that the '737 patent is part of a family of patents including U.S. Patent 11,672,951 and U.S. Patent 10,149,962, as well as several pending patent applications. Pet. 97–98. Petitioner and Patent Owner each indicates that Patent Owner has asserted the '737 patent against Petitioner in the following lawsuit: *Prytime Medical Devices, Inc. v. Front Line Medical Technologies, Inc.*, filed Jan. 2, 2024, in the United States District Court, Western District of Texas, Case No. 6:24-cv-00001. Pet. 98; Paper 3, 2.

D. The '737 patent (Ex. 1001)

The '737 patent issued January 2, 2024, from U.S. application 17/563,669 filed December 28, 2021. Ex. 1001, codes (45), (21), (22). The '737 patent recites an extensive list of prior applications and provisional applications, including provisional applications US 62/132,528 and US 62/135,603 filed on the earliest claimed priority date of March 19, 2015. *Id.* at code (63), (60).

As background, the '737 patent pertains to "vascular occlusion catheters and methods of vascular pre-conditioning while controlling occlusion and perfusion during an occlusion procedure." Ex. 1001, 1:63–66. The '737 patent describes that, "[t]emporary aortic occlusion as an operative method to increase proximal or central perfusion to the heart and brain in the

setting of shock due to major trauma is generally known." *Id.* at 2:21–24.

The '737 patent describes the desirability of

> a system that intermittently and automatically releases an occlusion by releasing apposition of an occlusive member against the vascular wall and allowing perfusion past the occlusion member in response to a physiological parameter, then re-establishing occlusion in response to potential changes in the physiological parameter, either during a vascular repair procedure to control hypertension or post-repair procedure to control hypotension.

Id. at 2:49–57. Figure 1 of the '737 patent is reproduced below:

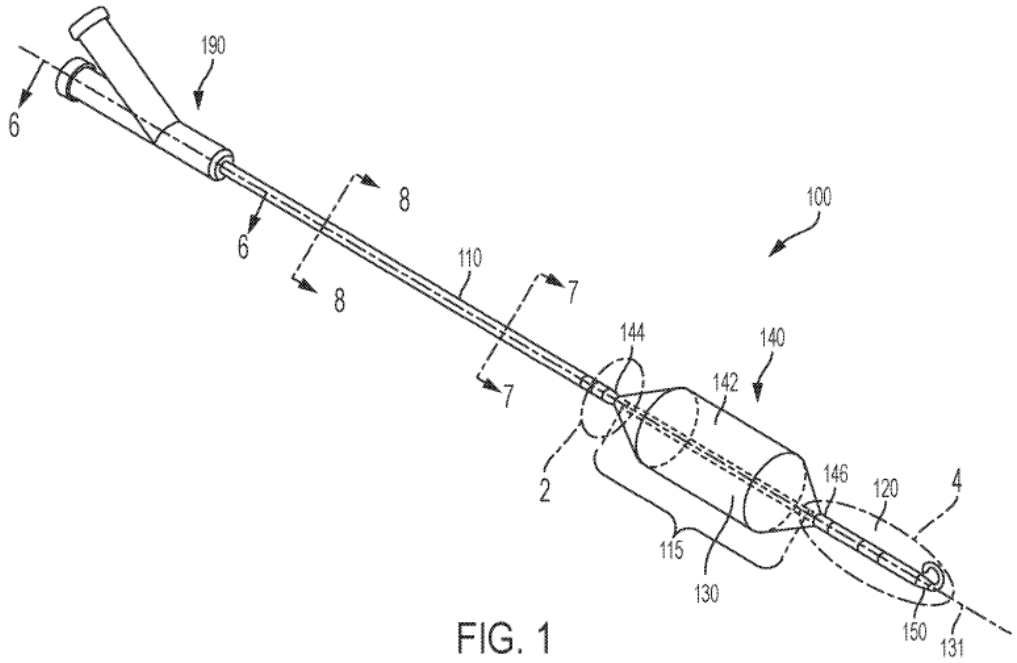


FIG. 1

Figure 1 depicts "the vascular occlusion catheter system **100** generally includes a catheter assembly having a first catheter member **130** having a first lumen **230** . . . an occlusion member **140,** a proximal hub **190** and a guiding atraumatic tip **150**." *Id.* at 21:65–22:4.

E. Challenged Claims

Independent claim 1 is illustrative of the challenged claims in the '737 patent and recites (we include sub-numbering of claim elements for ease of reference, as has Petitioner):

1. [1Preamble] An occlusion catheter system comprising:

[1a] a proximal hub;

[1b] a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device;

[1c] a proximal catheter section in fluid communication with the proximal hub;

[1d] a distal catheter section distally terminating with an atraumatic tip;

[1e] an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being compliant;

[1f] at least one length marking on an exterior of the proximal catheter section to indicate an insertion depth of the occlusion catheter system;

[1g] a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon;

[1h] a solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon and into the distal catheter section; and

[1i] the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration.

Ex. 1001, 66:23–46.

Challenged claims 2–10 depend directly from independent claim 1 and recite additional features of the catheter system. Ex. 1001, 66:47–67.

II. INSTITUTED GROUNDS

We instituted trial based on all of Petitioner's challenges to the patentability of the claims of the '737 patent as presented in the Petition. Pet. 1–3.

Ground	References	Basis	Claims Challenged
1	Fogarty,[1] Chengod[2]	§ 103	1–10
2	Fogarty, Chengod, Saab[3]	§ 103	2
3	Fogarty, Chengod, Sanati[4]	§ 103	3–5, 9
4	Fogarty, Chengod, Deaton[5]	§ 103	8
5	Eliason[6]	§ 103	1–10
6	Eliason, Fogarty	§ 103	1–10
7	Eliason, Saab	§ 103	2
8	Eliason, Scott[7]	§ 103	3–5, 9
9	Eliason, Joe[8]	§ 103	8

Petitioner relies on the Declarations of Scott A. Resnick, M.D. and

[1] Fogarty et al., US 3,467,101, issued Sept. 16, 1969. Ex. 1004.

[2] Chengod et al., *Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique*, 19(5) J. Cardiothoracic and Vascular Anesthesia 636–641 (2005). Ex. 1005.

[3] Saab, M., *Applications of High-Pressure Balloons in the Medical Device Industry*, Medical Devices & Diagnostic Industry 86–97 (Sept. 2000). Ex. 1006.

[4] Sanati et al., US 2013/0060316 A1, published Mar. 7, 2013. Ex. 1013.

[5] Deaton, D., *Image-Guided Thrombectomy in Vascular Surgery*, Insert to Endovascular Today 32–35 (July 2005). Ex. 1008.

[6] Eliason et al., US 9,131,874 B2, published Sept. 15, 2015. Ex. 1009.

[7] Scott et al., *A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock*, 75(1) J. Trauma Acute Care Surg. 122–128 (2013). Ex. 1010.

[8] Joe et al., US 2015/0133892 A1, published May 14, 2015. Ex. 1011.

Sylvia Hall-Ellis, Ph.D. Ex. 1003; Ex. 1026; Ex. 1034. Patent Owner relies on the Declaration of Dr. William Cimino, Ph.D. Ex. 2001.

III. LEVEL OF ORDINARY SKILL IN THE ART

We consider the grounds of unpatentability in view of the understanding of a person having ordinary skill in the art ("PHOSITA") as of the effective filing date of the challenged claims. The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors pertinent to determining the appropriate level of skill in the art include:

> (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. . . . The patent's purpose can also be informative.

Best Med. Int'l, Inc. v. Elekta Inc., 46 F.4th 1346, 1353 (Fed. Cir. 2022) (citations omitted) ("*Elekta*").

A. Petitioner's Position

Petitioner contends that one of ordinary skill in the art would have been someone with

> a medical degree and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices. A busy interventionalist could conceivably acquire an adequate level of experience having a minimum of ten years of post-graduate experience as an interventional radiologist, vascular surgeon, interventional cardiologist, or other endovascular interventionist. Such a person would be familiar with various occlusion balloon catheters and their use in performing vascular occlusion procedures including occlusion

> procedures throughout the vascular system, including occlusion procedures within the aorta.

Pet. 10–11 (citing Ex. 1003 ¶ 18). Petitioner asserts "[t]here is no dispute MDs play a key role in medical device design and development. They should be included in the PHOSITA definition." Pet. Reply 13 (citing Ex. 1034 ¶¶ 20, 22, 25, 26).

Petitioner asserts "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." Pet. Reply 17 (citing Ex. 1034 ¶ 76). Petitioner asserts "Dr. Resnick qualifies as a PHOSITA under his definition (Ex-1003 ¶17) and PO's definition (Ex-1034 ¶8)." *Id.* at 10–11.

B. Patent Owner's Position

Patent Owner asserts that Petitioner's "PHOSITA definition is . . . ultimately improper." PO Resp. 11. Patent Owner asserts that "Dr. Resnick's own testimony shows that catheter use alone does not impart knowledge as to how a particular catheter system is designed or assembled." *Id.* (citing Ex. 2002, 39:16–40:15, 55:21–57:2). Patent Owner asserts "Petitioner's PHOSITA definition leaves no room for individuals without a medical degree to ever qualify." *Id.* at 12 (citing Ex. 2002, 29:4–30:4). Patent Owner asserts that Petitioner's definition would exclude not only the inventors of the '737 patent, but also Thomas Fogarty, inventor of the prior art Fogarty patent. *Id.* at 12–13.

Patent Owner asserts

> Based on the '737 Patent's claims, specification, and prosecution history, a PHOSITA should be an individual having

> (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.

PO Resp. 14 (citing Ex. 2001 ¶ 25).

Patent Owner asserts "[a]n MD, however, does not inherently possess the foundational training needed to design or build a catheter system." PO Sur-Reply 1. Patent Owner asserts "MDs generally raise performance issues and design engineers create solutions" and "Petitioner cannot ignore the difference between using and actually designing/building a device." *Id.* at 3–4. Patent Owner asserts "Dr. Resnick's belated revelation of his 'over 20 years' of design experience should receive little weight since it contradicts Dr. Resnick's own prior testimony." *Id.* at 4.

C. Analysis of Level of Ordinary Skill in the Art

We begin our analysis with the relevant *Elekta* factors.

1. the educational level of the inventor

As to the '737 patent's inventors' educational level, Patent Owner provided the CVs of the inventors. Ex. 2003, Ex. 2004, Ex. 2005. As of the '737 patent's earliest claimed priority date of US provisional 62/135,603 filed March 19, 2015, Curtis Franklin was a mechanical engineer with more than five years of engineering experience in catheter systems, David Spencer was an electrical and computer engineer who managed a number of business enterprises, and Todd Krummenacher had a bachelor's degree in Design and

Visual communications with several years of experience as a technician. *See* Ex. 2003, 1; Ex. 2004, 1; Ex. 2005, 1.

2. type of problems encountered in the art

Dr. Resnick states

> [a]s active users of medical devices in a clinical setting, MDs (as opposed to non-clinician engineers) 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. Dr. Resnick stated in deposition that "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." Ex. 2002, 14:9–13.

Dr. Cimino states "the fundamental concept of understanding the components and the design and the parts and the pieces and how they interact and how they are used in the body, if that's sufficient with this person with six years of experience, there you go." Ex. 1032, 117:7–13.

3. prior art solutions to those problems

As to the prior art, Dr. Cimino states in deposition "what is the relevant prior art from your question? Is it catheter technologies or is it something else? Because clearly I've considered the relevant prior art of catheters, catheter technology, catheter construction, the content of, you know, the things that are outlined and described in the '737." Ex. 1032, 122:6–12.

Dr. Resnick states that a "person with an MD and extensive experience using both angioplasty balloons and occlusion devices in 2015 would understand the risk and effects of hypertension during a vascular

occlusion procedure and the risk and effects of hypotension after a vascular occlusion procedure." Ex. 1034 ¶ 40. Dr. Resnick states:

> Instead of relying solely on design or development experience, clinicians like myself have learned to safely and effectively use a wide range of angioplasty balloons and occlusion devices—including those involving the features found in the '737 patent claims—through hands-on clinical experience, reviewing instructions for use, attending educational programs and seminars, and studying the scientific literature.

Id. ¶ 42.

4. rapidity with which innovations are made

The parties do not identify evidence addressing this factor.

5. sophistication of the technology

Dr. Cimino states "it's absolutely a common and almost ubiquitous aspect of catheters for various fields and different levels -- different levels of occlusion: partial, total, high pressure, low pressure. Balloons have a wide function across the catheter space." Ex. 1032, 132:2–8. Dr. Cimino states that in "the neuro field, in the electrophysiology field, the balloon aspect truly is very common, well-known both from a design standpoint, manufacturing and everything else standpoint." *Id.* at 133:16–19.

Dr. Resnick states

> an individual who had extensively used both angioplasty balloons and occlusion devices for performing interventional procedures would understand those devices include generic features such as the claimed "proximal hub," "flow valve," "proximal catheter section," "distal catheter section," "atraumatic tip," "occlusion balloon," "at least one length marking," "lumen," and "solid wire"—and that these features could be found in catheters having a greatest outer diameter of less than 6 Fr in an uninflated configuration. That individual would also understand catheters include the other generic

> features identified in the '737 patent's dependent claims (e.g., "asymmetrical" [balloon], various other shaped balloons, "solid wire" constructed of metal or stainless steel, proximal and distal radio opaque markers, and syringe). Consequently, that individual would have the skill necessary to understand the operation and clinical effects of the device found in claims 1-10 of the '737 patent based solely on extensive use of both angioplasty balloons and occlusion devices that were available prior to the '737 patent.

Ex. 1034 ¶ 41.

6. educational level of active workers in the field

Dr. Cimino states in deposition that "[a]n educational background founded in design, construction, engineering concepts, materials science that allow somebody to have a fundamental basis . . . on top of that, an experiential actually working in that field of catheter design, construction, and the components." Ex. 1032, 123:3–20. Dr. Cimino answered "yes" when asked whether "a person with a medical degree who had at least six years of experience in catheter design and development would qualify as a PHOSITA." *Id.* at 141:12–16. Dr. Cimino also acknowledged that in his own prior work, "MDs are involved in the process in multiple time points and multiple areas" and "MDs [are] often involved in the entire process." *Id.* at 55:7–9, 56:12–13. Dr. Cimino stated "MDs are often and frequently and even recommended to be part of a design, development, and commercialization process." *Id.* at 58:13–15.

Dr. Resnick states "many of the relevant nonpatent prior art references are authored and edited by MDs and included in publications that are directed to MDs." Ex. 1034 ¶ 27. Dr. Resnick states that many of the authors of Exhibits 1005, 1008, 1010, 1014, and 1015 are medical doctors as are most of the journal editors. *See id.* ¶¶ 28–32.

Dr. Resnick, in deposition, was asked "Would it surprise you to learn Thomas Fogarty invented his first catheter before he received his medical degree?" and answered "I would ask, was he in medicine at the time; such as, in medical school?" Ex. 2002, 32:19–33:1. Exhibit 2013 shows that Dr. Fogarty patented his eponymous surgical catheter device in 1969, four years after completing his surgical residency in 1965. *See* Ex. 2013, 2–3.

Dr. Resnick states "non-MD individuals in Dr. Cimino's definition should have sufficient experience in catheter design and development ***which should include consulting or working with MDs who have experience with endovascular interventional procedures***." Ex. 1034 ¶ 20.

7. Conclusion

Based on the entirety of the record, we determine that a person of ordinary skill in the art at the time of the invention would have possessed either "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 . . . [or] at least six years' experience in catheter design and development" (Ex. 2001 ¶ 25) or "a person with an MD and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices." Ex. 1034 ¶ 22. Such levels of skill in the art are consistent with the '737 patent and the asserted prior art of record.

Regarding Patent Owner's arguments that Dr. Resnick is not a person of ordinary skill in the art and cannot adequately opine on what was known or obvious to a person of ordinary skill in the art about developing catheters

and occlusion devices, we note Patent Owner did not file a Motion to Exclude Dr. Resnick's testimony.

As to Dr. Resnick's qualifications, there can be no dispute that Dr. Resnick meets the educational and experience requirements set forth in our definition. Dr. Resnick received a medical degree, completed a Diagnostic Radiology residency, and a fellowship in Vascular and Interventional Radiology. Ex. 1003 ¶ 8. Dr. Resnick has "extensive experience using both off-the-shelf and purpose-built devices for vascular occlusion in a variety of situations including balloon occlusion devices in patient temporization / stabilization for hemorrhage prior to definitive therapy administration." *Id.* ¶ 13.

> Nor is there any evidence disputing that by March 2015, Dr. Resnick had been in practice for 17 years and had worked with a number of different medical device companies in the design and development of various medical devices, including devices for vascular interventional procedures (which are catheter based). As discussed above, as part of my experience working with medical device companies, I worked with engineers who would qualify as a PHOSITA under Dr. Cimino's definition. For example, I've worked with individuals including the head of engineering, the head of R&D, the CTO, the device lead engineer, and the device team engineers.

Ex. 1034 ¶ 46.

Accordingly, on this record as a whole, we do not agree with Patent Owner's position. Rather, we determine Dr. Resnick qualifies as at least a person of ordinary skill in the art. Thus, we will consider his testimony in this proceeding. We also determine that Dr. Cimino is qualified to provide technical opinions from the perspective of a person of ordinary skill in the

art in this proceeding. *See* Ex. 1003 ¶¶ 7–15; Ex. 1034 ¶¶ 7–13; Ex. 2001 ¶¶ 5–9.

IV. CLAIM CONSTRUCTION

In a *post-grant* review, we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.200(b). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Here, we construe only those claim terms that require analysis to resolve the disputed issues. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'").

Four claim elements' meanings are at issue between the parties: "proximal hub," "flow valve configured to selectively fluidly communicate the proximal hub with an inflation device," "distal catheter section," and "a solid wire, secured at a proximal-most end thereof within the proximal hub." PO Resp. 24–33; Pet. Reply 2–10; PO Sur-Reply 5–12.

A. "proximal hub"

1. Patent Owner's Position

Patent Owner states the "definition of proximal hub as an element (or elements) used to physically connect an inflation device to the inflation

lumen of the catheter is appropriate, based on the claim language and the '737 Patent's specification." PO Resp. 25–26 (citing Ex. 2001 ¶ 37; Ex. 1001, 30:5–30). Patent Owner acknowledges that the catheter ***sleeve system*** 1600 recited in the '737 patent Specification to provide a sterile field also contained the word 'hub'" but asserts that "a PHOSITA would ***not*** consider the catheter sleeve system 1600, and particularly the proximal and distal hub members 1604, 1606 thereof, to inform any understanding of the 'proximal hub' that is recited in the '737 patent claims." *Id.* at 26 (citing Ex. 2001 ¶ 39). Patent Owner asserts that, based on Figure 42A of the '737 patent, "hub members 1604, 1606 of the catheter sleeve system 1600 engage the outer wall of the catheter 1602 and cannot physically connect any component, much less an inflation device, to an inflation lumen of the catheter." *Id.* at 27 (citing Ex. 2001 ¶ 40; Ex. 1001, 59:58–60:12, Figure 42A).

Patent Owner asserts that "the specification and claims *require, at a minimum,* that the proximal hub physically connect an inflation device to the catheter's inflation lumen" and argues that "Petitioner's revised definition contravenes the intrinsic record by making the main purpose of the proximal hub optional." PO Sur-Reply 6.

2. Petitioner's Position

Petitioner asserts "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***.'" Pet. Reply 4.

Petitioner asserts "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." Pet. Reply 2 (citing Ex. 1034 ¶ 50). Petitioner asserts: "'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." *Id.* (citing Ex. 1034 ¶ 52).

Petitioner asserts:

> 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.

Pet. Reply 5–6 (citing Ex. 1034 ¶¶ 62–63) (alterations in original).

Petitioner asserts, regarding Patent Owner's preliminary amendment to the claims upon filing the application which became the '737 patent, that 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." Pet. Reply 6 (alteration in original). Petitioner asserts "[t]hus, 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." *Id.*

3. Analysis

In our claim construction analysis "[w]e begin, as we often do, with the claim language." *Apple Inc. v. Corephotonics, Ltd.*, 81 F.4th 1353, 1358 (Fed. Cir. 2023). For context, claim 1 recites not just "a proximal hub," but also "a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device."[9] Ex. 1001, 66:24–28; *see also id.* at 66:37–39 (also reciting that the proximal hub has a lumen extending therefrom). Claim 1 does not recite any other specific structure of the "proximal hub."

Because "[t]he claims . . . do not stand alone," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005)), we now "turn to the patent's specification for help[, which] . . . provides some useful insight into the claim term's meaning." *Apple*, 81 F.4th at 1358. While the phrase "proximal hub" is not expressly defined in the Specification, the Specification describes

> a proximal hub adapted for connection to a proximal end portion of a balloon catheter shaft wherein a pressure relief port is formed in the proximal hub. In one embodiment, the proximal hub may comprise a plastic body that defines an inflation/deflation lumen and a may or may not include guide wire lumen or a working lumen.

Ex. 1001, 21:17–22. The proximal hub "may be configured to have more than the inflation fluid pathway . . . with each fluid pathway communicating

[9] *See infra* Section IV.B for a discussion of the recited "fluidly communicate" language.

with a different one of any additional lumens in the balloon catheter system." *Id.* at 35:39–43. The '737 patent states a "pressure relief member may be a plastic film, a thin metallic film, a pop-off valve or other similar biased valve." *Id.* at 21:9–11. In another embodiment, the '737 patent describes the "proximal hub 590 includes an inflation connection port 590a with an inflation fluid pathway 594 therein." *Id.* at 30:8–10.

In addition to teaching that the proximal hub may include a pressure relief port (*see also* Ex. 1001, 20:52–56) or an inflation connection port, the Specification describes an embodiment where "system 1600 includes proximal and distal hub members 1604, 1606 that may be constructed and configured as any type of hemostatic valve that permits the catheter 1602 to pass through the valve, such as, for example, without limitation, a Tuohy Borst valve." *Id.* at 60:8–12.

Thus, the Specification expressly contemplates that a proximal hub, whether used for fluid flow to a balloon or as a catheter sleeve, may include subcomponents such as a pressure relief port, fluid pathways, or hemostatic valves. This understanding that a proximal hub may include subcomponents is also consistent with originally filed claim 1 of the '737 patent, which recites "[a]n occlusion catheter system comprising: a proximal hub having a flow valve." Ex. 1002, 113.[10] The aforementioned preliminary amendment modified this element of the claim language to the current language prior to any action by a patent examiner. *Id.* at 200; Tr. 43:1–2. Therefore, no prosecution history is implicated in the interpretation of this claim element.

[10] The original claims in a patent application constitute a part of the "disclosure of the invention" within the meaning of 35 U.S.C. § 132. *See* MPEP § 608.01(a).

Turning to extrinsic evidence, Dr. Resnick states "it is well understood that other functional elements may be included within the proximal hub" and that "a proximal hub may include other elements configured for other functions (e.g., pressure sensing)." Ex. 1034 ¶¶ 49, 51. Dr. Resnick annotates Figure 42A of the '737 patent as shown below:

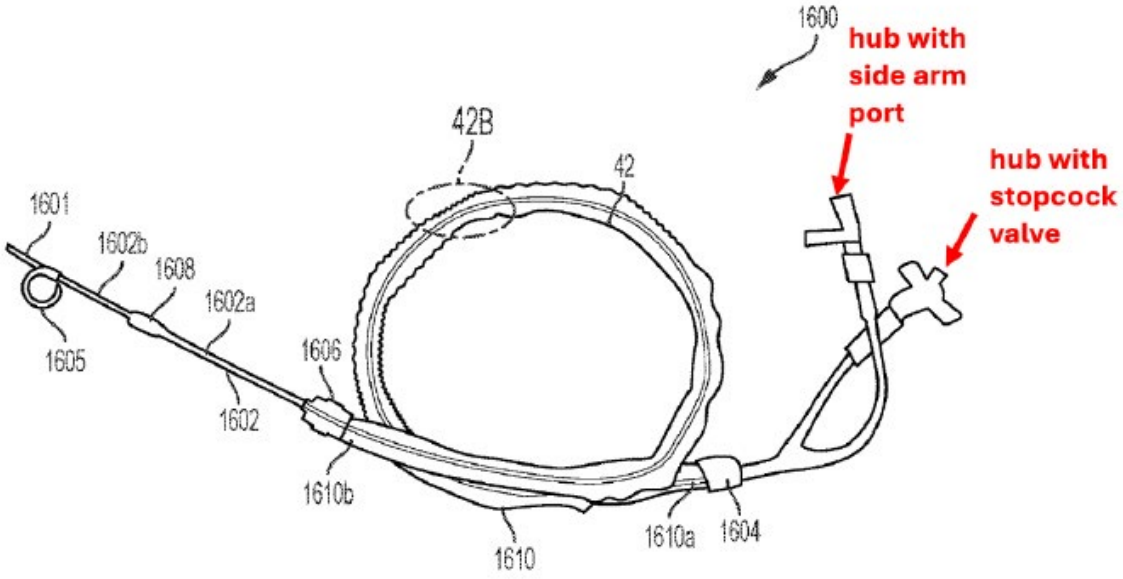


FIG. 42A

Dr. Resnick states that

> a PHOSITA understands the hand-drawn proximal elements to be a hub with a side arm port and a hub with a stopcock valve. Accordingly, Figure 42A also confirms that a "flow valve" can be a sub-element portion of the "proximal hub" because the hub with the stopcock valve would be used to physically connect an inflation device to the inflation lumen of the catheter.

Id. ¶ 59. Dr. Resnick also testifies that, in this figure, "proximal hub member 1604 is a hemostatic valve." *Id.* ¶ 60. Dr. Resnick states the '737 patent "discloses 'the proximal hub includes a pressure relief port . . . [t]he pressure

relief member may be ... a pop-off valve or other similar biased valve.'" *Id.* ¶ 62 (citing Ex. 1001, 21:9–11, 21:27–32) (second alteration in original).

Dr. Resnick concludes that "a PHOSITA would understand the claimed 'proximal hub' can include a flow valve as a sub-element because this configuration is disclosed in the Figure 42A embodiment and because the '737 patent specification includes at least two other examples of hubs that include valves as part of their construction." Ex. 1034 ¶ 63.

Dr. Cimino disagrees, stating that

> hub members 1604, 1606 cannot physically connect any external component, such as an external inflation device, to an inflation lumen of the catheter. This embodiment is not relevant for interpreting "proximal hub" (or what components a proximal hub may or may not include, such as a "flow valve") in the context of these claims.

Ex. 2001 ¶ 40. However, Dr. Cimino does not dispute that the '737 patent teaches a proximal hub 1604 that includes a valve as a sub-element and this was acknowledged by Patent Owner during the oral hearing. Tr. 39:17–18, 40:13; *see, e.g.*, Ex. 1001, 60:8–12. And, the hub and valve configuration recited by claim 1 is not recited to impose any structural limitations other than the flow valve being "configured to selectively fluidly communicate the proximal hub with an inflation device," i.e., no specific positioning is recited. Ex. 1001, 66:24–26.

Moreover, Dr. Cimino acknowledges that "[f]low valves that I knew about prior to 2015 were configured to selectively fluidly communicate one thing to another, in which case they could've been a proximal hub." Ex. 1032, 166:20–167:1.

We find that a preponderance of the evidence, especially the intrinsic evidence in the '737 patent Specification itself, supports an interpretation of

proximal hub as an element that may itself connect an inflation device to the catheter's inflation lumen or that may also comprise sub-elements including valves, pressure relief elements, and inflation connection ports. The associated recited "flow valve" must *selectively fluidly communicate* the proximal hub with such an inflation device, but the record does not support that this requires any specific positioning of the valve in relation to the hub.

We recognize that *Becton* states "[w]here a claim lists elements separately, 'the clear implication of the claim language' is that those elements are 'distinct component[s]' of the patented invention." *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254–55 (Fed. Cir. 2010). However, the instant facts are different than *Becton* where the patent specification "confirm[ed] that the spring means is a separate element from the hinged arm." *Id.* at 1254. The '737 patent Specification, on the other hand, does not confirm that the recited "proximal hub" and "flow valve" must be separate components because the '737 patent identifies and describes several components that may be sub-elements of a proximal hub, notably including "valves." Ex. 1001, 30:8–10, 60:8–12. And, even the original claims in the '737 patent described that sub-element relationship because they expressly recited "[a]n occlusion catheter system comprising: a proximal hub having a flow valve." Ex. 1002, 113. Patent Owner does not identify any statement in the prosecution history suggesting that any claim amendment was made to distinguish proximal hubs *with* flow valves from proximal hubs *without* flow valves. Tr. 43:1–2.

The instant evidence is more similar to that presented in *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011), which addressed claims directed to a device with a "cutting box" and a "dust

collection box." *Powell* held that "the specification teaches that the cutting box may also function as a 'dust collection structure' to collect sawdust and wood chips generated during the wood cutting process. It does not suggest that the claim terms require separate structures." *Id.* at 1231–32. *Powell* further noted, "[n]or are we convinced that the claim language 'in fluid communication' requires that 'cutting box' and 'dust collection structure' be wholly separate structures." *Id.* at 1232. Thus, this precedential case indicates that separately recited claim elements may sometimes refer to parts or sub-parts of one structure (and the common *fluid communication* element is also an illuminating overlap in fact patterns).

Similarly, the Federal Circuit in *Google* addressed a claim with five data inputs into a determination and found the claim was "not limited to [data] inputs that are entirely separate and distinct." *Google LLC v. EcoFactor, Inc.*, 92 F.4th 1049, 1058 (Fed. Cir. 2024). Rather, the *Google* court found that the patent's specification supported a broad reading of the claim language because the language

> places no constraint on the manner in which the [data] inputs are used. A patentee "is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its scope." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012). There is no such redefinition or disavowal here.

Id. Google further states that *Becton* did "not create a *per se* rule that separately listed claim elements are distinct components, regardless of the intrinsic record." *Id.* Like *Google*, the full scope of claim 1 in the '737 patent reasonably encompasses proximal hubs with or without integrated sub-elements such as valves. Ex. 1001, 30:8–10, 60:8–12. A patentee "is free to

choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope." *Thorner*, 669 F.3d at 1367. There is no such redefinition or disavowal here.

Accordingly, we find that a preponderance of the evidence supports an interpretation of the term proximal hub in the '737 patent to encompass proximal hubs that may or may not include sub-elements such as valves.

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

1. Patent Owner's Position

Patent Owner asserts the "ordinary and customary meaning of this claim term, as understood by a PHOSITA, is 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." PO Resp. 28. Patent Owner asserts

> claim 1 does not merely recite a "valve" in isolation. Rather, a ***specific type*** of valve with a ***particular structural relationship*** to other components – a ***flow*** valve that is configured to selectively fluidly communicate ***the proximal hub with an inflation device*** – is claimed. Ex. 2001 at ¶¶ 41-43. A flow valve is commonly understood to be a valve that is opened or closed to selectively permit or block fluid flow therethrough.

Id. at 29 (citing Ex. 2001 ¶ 43; Ex. 1001, 40:27–35). Patent Owner asserts that the "distinction is important because the PTAB disregards this context when attempting to categorize the claimed flow valve as a sub-element of the proximal hub in the Institution Decision to justify Petitioner's arguments." *Id.* (citing Inst. Dec. 10–11; Ex. 2001 ¶¶ 42–44). Patent Owner asserts that a "PHOSITA would not consider a pressure relief member in the

form of a popoff valve or other biased valve to have any relevance, or provide any context, to the claimed flow valve, which is recognized as having an entirely different structure and function from a pop-off valve or other biased valve." *Id.* (citing Ex. 2001 ¶ 42). Patent Owner asserts "[a]ny reliance on the teaching of a pop-off/biased valve to inform this claim term effectively reads 'flow' out of the claim language." *Id.* at 30 (citing Ex. 2001 ¶ 44).

Patent Owner asserts "[c]laim 1 does not recite a generic 'valve' in isolation, but a ***specific type*** of valve with a ***particular structural relationship*** to other components. *Id.* The construction is necessary to differentiate from other valve types with different structural features and capabilities." PO Sur-Reply 6–7 (citing Ex. 2001 ¶¶ 42–44).

2. Petitioner's Position

Petitioner asserts "PO's construction changes the [claim] 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." Pet. Reply 3 (citing *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002)).

Petitioner asserts "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." Pet. Reply 3 (citing Ex. 1034 ¶ 54).

3. Analysis

As above, we begin by focusing on the claim language itself. The phrase "flow valve configured to selectively fluidly communicate the proximal hub with an inflation device" in claim 1 reasonably requires the presence of a flow valve that is capable of allowing or preventing fluid flow through the proximal hub from an inflation device. The ordinary understanding of the word "fluidly" is flowing, not touching, and reasonably means liquid must flow (or not) from the inflation device through the valve and hub. *See* Ex. 1034 ¶ 55 (Dr. Resnick states that he agrees "that the plain meaning of 'a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device' would encompass a 'valve that controls the flow of fluids to a proximal hub.'").

The '737 patent does not use the phrase "configured to selectively fluidly communicate the proximal hub with an inflation device," nor expressly define any of these terms. The '737 patent does provide examples of selective fluid communication, where a "pressure source 1502 has a fluid source contained within the syringe . . . [that] communicates with a free line." Ex. 1001, 57:16–19. A "selectable flow valve 1504 is interposed in the free line and communicates with the regulated line. The selectable flow valve 1504 is operable to select the free line, the regulated line or both the free line and the regulated line." *Id.* at 57:21–25.

The '737 patent explains that "[w]hen the selector valve 1504 is positioned to open the regulated line and close the free line, *fluid is free to flow through* the check valve 1506 to the occlusion catheter and ultimately to the balloon." Ex. 1001, 57:39–42 (emphasis added). Thus, the correct understanding of "fluidly communicate" is that fluid is allowed to flow

through the catheter system between the fluid source to the balloon. This is consistent with our interpretation of a hub with a valve sub-element, as the fluid flows from the fluid source, through a hub (and valve sub-element), until it reaches and inflates the balloon. The valve is configured to selectively allow or disallow this flow (fluidly communicate) at the hub.

Dr. Resnick states a "PHOSITA would not understand this claim phrase to require the specific structural relationship of a flow valve being located ***between*** the hub and the inflation device." Ex. 1034 ¶ 54. Dr. Resnick states:

> the plain meaning of the claim phrase "a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device" is unambiguous and simply requires a flow valve that is configured to select whether to fluidly communicate the proximal hub with the inflation device. Ex-1001, '737 patent at 66:25–26 (claim 1). . . . [T]his claim language encompasses configurations where the flow valve is a sub-element of the hub.

Id.

Dr. Cimino states the "ordinary and customary meaning of this claim term, as understood by a PHOSITA, is a manually or automatically actuatable valve that is opened or closed to permit or block fluid flow between the proximal hub and the inflation device." Ex. 2001 ¶ 41. Dr. Cimino states the "the PTAB appears to focus on the presence of a valve generally on a hub, without appreciating fundamental differences between a flow valve and pressure relief or biased valve." *Id.* ¶ 42. Dr. Cimino contrasts a flow valve with other types of valves, and asserts a "PHOSITA would not consider a pressure relief member in the form of a pop-off valve to have any relevance, or provide any context, to the flow valve recited in the '737 patent claims." *Id.*

However, in deposition, Dr. Cimino acknowledges that, consistent with Figure 42A of the '737 patent, as annotated by Dr. Resnick above regarding the ends of the catheter system, the "most common technology for these types of ends in ports are what's called Luer lock fittings, valves, a whole bunch of directional control devices that have Luer locks that attach to a syringe." Ex. 1032, 76:2–6.

On this issue, we find Dr. Cimino less persuasive and his positions less credible than Dr. Resnick because he apparently failed to understand that point made in the Institution Decision was not that a pop-off valve is functionally identical to a flow valve. Rather the point was that the teaching in the '737 patent of a particular example showing a proximal hub and integrated Tuohy valve is that a hub with an integrated valve of any type provides evidentiary support for a broader interpretation of claim 1 of the '737 patent encompassing situations where a flow valve is a sub-element of a proximal hub.

We agree with Petitioner that "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." Pet. Reply 3. The word "between" is not present in claim 1 of the '737 patent. The Federal Circuit rejected a similar attempt to import limitations into a claim that were not recited in the claim nor provided for by the associated specification, noting "[c]ourts may not rewrite claim language based on what has been omitted from a claim." *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1365 (Fed. Cir. 2003).

Accordingly, we find that a preponderance of the evidence supports an interpretation of the phrase "flow valve configured to selectively fluidly

communicate the proximal hub with an inflation device" in the '737 patent to require a flow valve that allows fluid to flow from an inflation device through a proximal hub and to an occlusion member such as a balloon.

C. "distal catheter section"

1. Patent Owner's Position

Patent Owner asserts that the "ordinary and customary meaning of this claim term, as understood by a PHOSITA, is simply a distal portion of a catheter." PO Resp. 31 (citing Ex. 2001 ¶ 45). Patent Owner asserts "[e]ven Dr. Resnick acknowledges that a catheter is simply 'the shaft of the device.' Ex. 2002 at 26:11-27:3; Ex. 2001 at ¶ 47. Accordingly, a PHOSITA understands that a 'distal catheter section' is a distally-located section of that shaft, not just any distally-located components of an overall system." *Id.* Patent Owner asserts "a PHOSITA would understand that a catheter portion is ***a portion of the catheter shaft itself***, and ***not a portion of the entire catheter system***, which may include other components." *Id.* (citing Ex. 2001 ¶ 46).

2. Petitioner's Position

Petitioner asserts that 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." Pet. Reply 7–8 (citing Ex. 1034 ¶¶ 65–66). Petitioner asserts "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.'" *Id.* at 8. Petitioner asserts:

> 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). . . . 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." . . . 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.

Id. at 8–9 (citing Ex. 1001, 51:29–33, 52:28–32, 23:66–24:1; Ex. 1034 ¶ 67) (first and fourth alterations in original).

3. Analysis

We begin with the claim language, which simply refers to "a distal catheter section," that is, a section of the catheter that is "distal." Turning to the Specification, as we noted in the Institution Decision, the '737 patent states

> when reference is made to the terms "distal" or "distally" it is intended to mean a portion or component of the preferred balloon catheter system that is oriented toward the body into which the system is or is intended to be placed. Thus, for example, the guiding atraumatic tip described hereinafter is located at a distal end of the balloon catheter system.

Ex. 1001, 21:57–62, *quoted in* Inst. Dec. 17.

In one example, the '737 patent states "a guiding atraumatic tip 150 is coupled to a distal end section of the third catheter member 120. The guiding

atraumatic tip 150 may be made of an elastic, shape memory and/or superelastic material, such as a metal or polymer." Ex. 1001, 23:65–24:1.

Dr. Resnick states the "claim term at issue in claim 1 is 'a distal catheter section distally terminating with an atraumatic tip.' A PHOSITA reading this claim language understands the distal catheter section is a portion of the claimed catheter that includes and terminates with the atraumatic tip." Ex. 1034 ¶ 65. Dr. Resnick states that:

> The '737 patent specification discloses that "a third catheter member 1320 of the fourth preferred occlusion catheter system 1300 extends distally relative to the occlusion member 1304 and terminates in an atraumatic tip 1306 or forms a proximal shaft or portion of the atraumatic tip 1306." '737 patent at 51:29–33. Notably, like the claim language at issue, this third catheter member terminates in an atraumatic tip. It is also distal to the occlusion balloon (1304). . . . Thus, a PHOSITA understands from the embodiment that the "distal catheter section" can include a wire. For example, nitinol wire is a metal known for its shape memory that is commonly used in catheters now and in 2015.

Id. ¶ 67.

In deposition, Dr. Resnick answered the question "when you refer to a 'catheter,' what do you mean by that?" with "[t]he 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. The balloon in question is mounted on the catheter." Ex. 2002, 26:19–27:3.

Dr. Cimino states a "PHOSITA would understand, however, that a distal catheter section is a portion of the catheter shaft itself, and not a portion of other components of '***the system***'. Claim 1 recites 'a distal catheter section' and not 'a distal catheter system section.'" Ex. 2001 ¶ 46.

In deposition, Dr. Cimino stated that his declaration was "clarifying that the distal portion of the catheter is the catheter shaft, the distal portion of the catheter shaft, not other components of a catheter; in this case, a guidewire, something that is separable from the catheter." Ex. 1032, 146:15–20. Dr. Cimino states, as an example, that "[i]t would not be correct to call an element of a guidewire a tip, a J tip, a part of the wire, part of the catheter itself. It may extend distally from the end of the catheter, but that does not make it a distal section of the catheter." *Id.* at 159:6–11. In response to a question asking Dr. Cimino about "a distinction between a catheter and a catheter shaft. What is the difference?" Dr. Cimino answers

> I'm using the word "catheter" to include the elements of what is most common a plastic tube with a lumen, with a balloon on it; in this case, the catheter element that has those attributes and could be put on a table or in a package and you could pick it up. And that's the catheter. That is distinct from a guidewire that may be put into the catheter, used separately, but it is not part of that catheter/catheter shaft combination. It never has been.

Id. at 161:4–17.

On this issue, we find Dr. Cimino's positions more credible and more consistent with the disclosure of the '737 patent. The preamble of claim 1 of the '737 patent recites an "occlusion catheter system" and the limitation at issue is drawn to a "distal catheter section." A preponderance of the evidence supports a finding that a "distal catheter section" refers to a portion of the catheter itself and not to the entire "occlusion catheter system" that is the subject of claim 1 of the '737 patent.[11]

[11] We therefore no longer interpret the term "distal catheter section" as in the Institution Decision. *See* Inst. Dec. 17.

In particular, Dr. Cimino's interpretation of the distal end as being an end of a catheter itself rather than the entire catheter system is more consistent with the language in the '737 patent that an "atraumatic tip 150 is coupled to a distal end section of the third catheter member." Ex. 1001, 23:65–66. If the atraumatic tip was the distal catheter section itself, it would make no sense to also state that it was coupled to the distal end section of a catheter member. And in claim 1 of the '737 patent, the "distal catheter section" does not necessarily expressly refer to the entire catheter system. As illustrated in claim 1's preamble, the limitation could have been written to recite a distal catheter *system* section, but was not, also supporting Dr. Cimino's position.

During the hearing, Petitioner stated that "the '737 Patent expressly states that the catheter member includes a separate stiffening member such as a nitinol wire. And that's at column 52, 28 to 32." Tr. 24:22–24. When that embodiment is reviewed in its totality, it begins "[i]n the fourth preferred embodiment of occlusion [catheter] system 1300" and continues to disclose that a "first catheter member 1302, second catheter member 1312 and third catheter member 1320 may also be combined in construction and configuration to have a transitioning stiffness, to include a separate stiffening member, such as a nitinol wire or braided shaft, to have sufficient pushability to have the appropriate amount of column strength." Ex. 1001, 51:59–52:32. This disclosure distinguishes the catheters themselves from the occlusion catheter system, and identifies the stiffening member as a separate element of the occlusion catheter system used to provide column strength to the catheter itself. This further supports Dr. Cimino's distinction between a

distal catheter section and a distal section of the entire occlusion catheter system.

Accordingly, we find that a preponderance of the evidence supports an interpretation of the phrase "distal catheter section" in the '737 patent as drawn to a distal section of a catheter tube and not to a distal section of the entire occlusion catheter system.

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

1. Patent Owner's Position

Patent Owner asserts that the "ordinary and customary meaning of this claim term, as understood by a PHOSITA, is 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." PO Resp. 31–32 (citing Ex. 2001 ¶ 48). Patent Owner asserts that a "PHOSITA understands that the solid wire must be fixedly coupled to and within the proximal hub to add stiffness (and particularly longitudinal stiffness) to the catheter into which the wire extends." *Id.* at 32 (citing Ex. 2001 ¶ 49; Ex. 1001, 35:24–27).

Patent Owner asserts:

> The longitudinal stiffness created by fixing the solid wire to and within the proximal hub supports the catheter against compressive buckling or displacement along the longitudinal axis under the normal operating conditions of the system, *i.e.*, in operation to reach and occlude the target vessel. Ex. 2001 at ¶ 49; Ex. 1001 at 35:24-27. This allows "the assembly [to be] 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."

PO Resp. 32–33 (citing Ex. 2001 ¶ 49).

Patent Owner asserts that a PHOSITA would understand, from the '737 patent disclosure at column 35, lines 4 to 28, that "adhesive bonding or 'otherwise fastened, secured, or fixed' are all ***forms of fixed coupling***, not alternatives." PO Sur-Reply 11–12 (citing Ex. 2001 ¶¶ 48–49). Patent Owner asserts that

> the feature of the solid wire being "secured at a proximal-most end thereof within the proximal hub" was added during prosecution to overcome a rejection. Ex. 1002, 573-580. The prior art was distinguished because its guidewire "is configured to be steered and manipulated through the blood vessel, ***and subsequently removed, and, therefore, cannot be secured*** at a proximal end thereof ***to the luer hub 310***." *Id.*, 578-79 (emphasis added). Accordingly, the prosecution history further demonstrates "secured" was *not* intended to cover removable attachment.

Id. at 12.

2. Petitioner's Position

Petitioner asserts "[t]his 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.'" Pet. Reply 9 (citing Ex. 1034 ¶ 68).

Petitioner asserts "'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* [*LLC v. Adrian Rivera Maynez Enters., Inc.*], 946 F.3d [1367,] 1381 (Fed. Cir. 2020) (negative limitation requires express disclaimer or lexicography)." Pet. Reply 10.

Petitioner asserts:

> 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.

Pet. Reply 10 (alterations in original).

3. Analysis

We begin with the claim language reciting "a solid wire, secured at a proximal-most end thereof within the proximal hub." The issue is what "secured" means. Turning first to the Specification:

> 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.

Ex. 1001, 35:16–27. Thus, while the '737 patent does teach one embodiment where "solid wire 530 is fixedly coupled to the proximal hub 590 . . . preferably using an adhesive 580," the '737 patent expressly contemplates

securing alternatives other than adhesive bonding, that is, other types of fastening methods are included in the term "secured." *See id.* at 35:5–27.

Dr. Cimino states a "PHOSITA understands that the solid wire must be fixedly coupled to and within the proximal hub to add stiffness to the catheter, most specifically longitudinal stiffness which supports the catheter against compressive buckling or displacement along the longitudinal axis under the normal operating conditions of the system." Ex. 2001 ¶ 49.

Dr. Resnick states:

> A PHOSITA would also understand the word "secured" to have its plain meaning, for example, "to make firm or fast, as by attaching: *to secure a rope*." Ex-1035 (Webster's New Universal Unabridged Dictionary (1996)). According to this ordinary meaning, "secure" does not require permanently attaching. Indeed, the example of securing a rope would almost never be a permanent attachment, but instead, would be a knot or other attachment that could be undone.

Ex. 1034 ¶ 70.

"[A]lthough the specification often describes very specific embodiments of the invention, [the Federal Circuit has] repeatedly warned against confining the claims to those embodiments." *Phillips*, 415 F.3d at 1323; *see IQRIS Techs. LLC v. Point Blank Enters., Inc.*, 130 F.4th 998, 1003–04 (Fed. Cir. 2025) ("There is a fine line between reading the claims in light of the specification and importing limitations from the specification into the claims, and here, where there is no evidence suggesting that the ordinary meaning . . . is [so] limited . . . we are not inclined to import limitations from the preferred embodiments into the claimed invention.").

On this issue, we find Dr. Resnick's analysis persuasive and consistent with the disclosure of the '737 patent. We decline to confine the term "secured" in claim 1 to solely meaning "fixedly coupled" when the

specification of the '737 patent itself recognizes that the wire is not limited to adhesive attachment but "may be otherwise fastened, secured or fixed." Ex. 1001, 35:17–19. We agree with Dr. Resnick that the ordinary understanding the word "secured" does not necessarily require a permanent attachment, but would encompass temporary attachments such as ropes knotted but capable of being undone or shoelaces tied securely but capable of being unlaced.

E. Conclusion

We determine that we currently need not expressly construe any other claim terms for the purpose of determining patentability of the challenged claims. *See Nidec*, 868 F.3d at 1017 ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'") (quoting *Vivid Techs.*, 200 F.3d at 803).

V. PATENTABILITY CHALLENGES

A. Principles of Law

In a post-grant review, as in an *inter partes* review, "the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Regarding obviousness, the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). In *KSR*, the Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim

is unpatentable as obvious under 35 U.S.C. § 103 as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art;[12] and (4) considering objective evidence indicating obviousness or non-obviousness.[13] *KSR*, 550 U.S. at 406.

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416. "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417.

> The motivation-to-combine analysis is a flexible one. "*[A]ny* need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed," [but the] . . . analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."

Intel Corp. v. PACT XXP Schweiz AG, 61 F.4th 1373, 1379–80 (Fed. Cir. 2023) (quoting *KSR*, 550 U.S. at 418, 420 (emphasis added)). "[I]f there's a known technique to address a known problem using 'prior art elements according to their established functions,' then there is a motivation to combine," because *KSR* explains that "'if a technique has been used to improve one device [or method], and a person of ordinary skill in the art

[12] *See supra* Section II.A.

[13] There is no asserted evidence pertaining to objective indicia of non-obviousness. *See* PO Resp.

would recognize that it would improve similar devices [or methods] in the same way, using the technique is obvious unless its actual application is beyond his or her skill.'" *Id.* at 1380 (quoting *KSR*, 550 U.S. at 417; and *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 797 (Fed. Cir. 2021)). If addressing a known problem, the prior art combination need not be "the *best* option, only . . . a *suitable* option." *Id.* (quoting *Intel*, 21 F.4th at 800 (emphasis in original)).

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish unpatentability by a preponderance of the evidence.

B. Overview of the Asserted Prior Art

We review and summarize the asserted prior art below. There is no dispute that each asserted reference is prior art.

1. Fogarty (Ex. 1004)

Fogarty is a U.S. patent that issued on September 16, 1969. Ex. 1004, front page. Fogarty discloses that

> a balloon catheter having improved securement for the ends of the inflatable portion of the balloon, to provide a balloon catheter in which the balloon is protected against puncture by the stylet, to provide a catheter having an improved tip construction, to provide a balloon catheter having an integral shut-off valve to maintain the inflation of the balloon.

Id. at 1:57–63. Figure 1 of Fogarty is reproduced below:

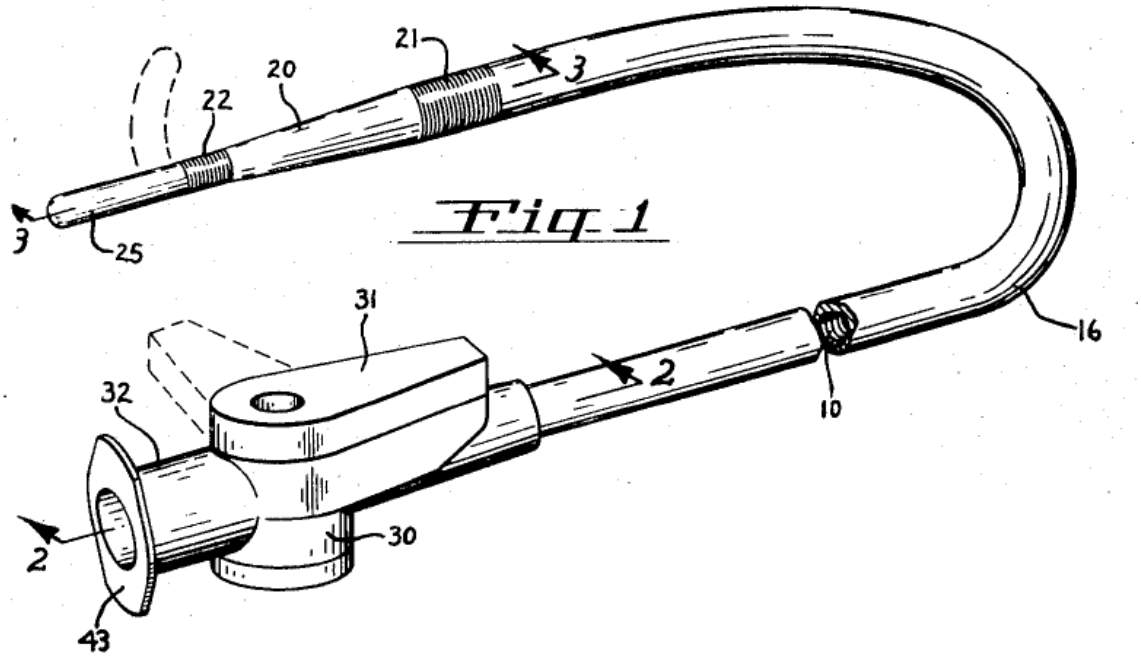


Figure 1 illustrates a catheter "on a core 10 comprising a coil of spring wire . . . covered with a braid 15 of suitable non-reactive and non-hygroscopic material" that is "covered with an outer plastic tube 16 which is drawn on over the braid and positioned with its distal end at 17." *Id.* at 2:40–63. Fogarty states "soft rubber plug 11 of suitable plastic such as neoprene is affixed on the distal end of the coil 10. This plug forms a flexible tip which will readily bend back on itself." *Id.* at 2:43–46. Figure 1 also shows "[e]xtending distally from the winding 22, the balloon [20] has a closed end portion 25 which merely encloses the plug 11 and does not inflate." *Id.* at 3:28–30.

Fogarty states the "proximal end of the catheter tube is secured to a shut-off valve 30 having a rotatable valve member 31. The body of valve 30 is equipped with a conventional fitting 32 in line with the catheter tube socket 33 to receive a syringe 35 for inflating the balloon." Ex. 1004, 3:38–42.

2. Chengod (Ex. 1005)

Chengod is a paper published in a scientific journal. Ex. 1005, 10 (Chengod 636). Chengod teaches, for "surgical management of suppurative lung diseases and bleeding from the lungs," that "a flexible FOB [fiberoptic bronchoscope] that can easily pass even through an SLET [single lumen endotracheal tube] of 3-mm internal diameter is essential for the accurate placement of either the bronchial blocker or the endobronchial tube in the small left bronchus of children." *Id.*

Chengod reviewed two "techniques and compare[d] them with a new technique for the ease of left bronchial intubation and left-lung isolation with the appropriate-size Fogarty catheter, without the help of bronchoscopes." Ex. 1005, 10. Chengod teaches a

> Fogarty catheter was selected, as a bronchial blocker, according to the age of the patient; 4F catheter in the group less than 1 year, 5F in 1 year to 2 years old group, and 6F in the group between 2 years and 4 years. Three markings were made on the Fogarty catheter to aid accurate placement in the left mainstem bronchus.

Id. at 11 (Chengod 637).

Figure 1 of Chengod is reproduced below:

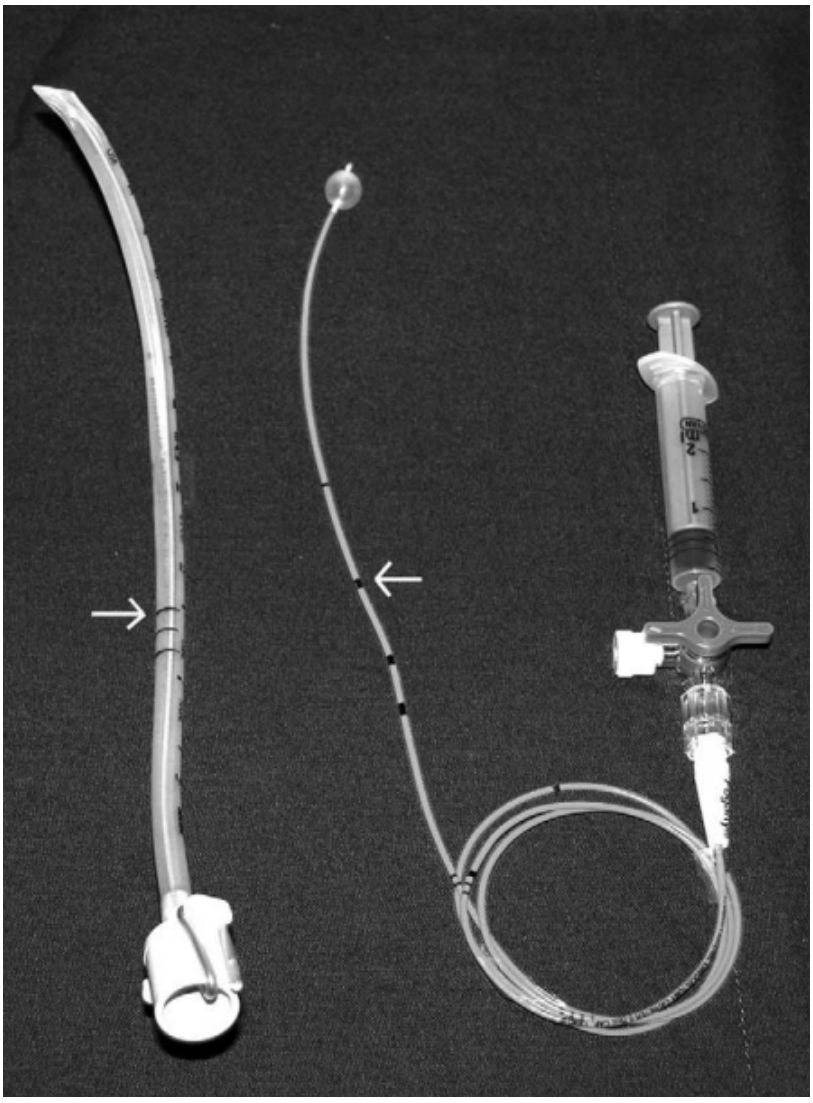


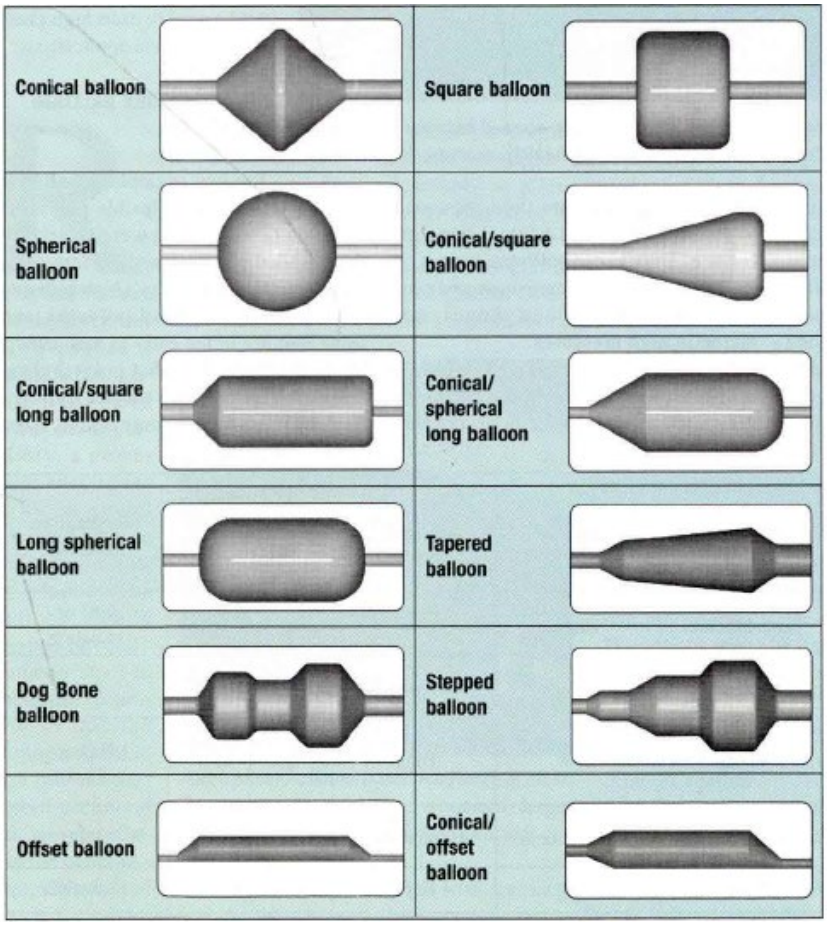
Fig 1. Endotracheal tube modified to resemble a left-sided double-lumen tube with the help of a stylet. Note the bevel of the tube facing toward the right side. Carinal distance is marked on the tube and the catheter as measured from the tip (Arrows). The second and third markings on the catheter, from below upwards, are the carinal distance from the proximal joint of the balloon and 1 cm from the second mark, respectively.

Ex. 1005, 11 (Chengod 637).

3. Saab (Ex. 1006)

Saab is a paper published in a scientific journal in September 2000. Ex. 1006, 7 (Saab 86). Saab teaches "high-pressure medical balloons—with thinner walls, higher strength, and smaller profiles—are well suited for use in a broad range of minimally invasive procedures." *Id.* Saab teaches balloons "can be produced in a variety of lengths, diameters, and shapes, including complex custom shapes for specific applications, and supplied with specialty coatings for added performance." *Id.*

Figure 2 of Saab is reproduced below:



"Figure 2. Examples of high-pressure balloon shapes. A specific shape may be demanded by the particularities of the anatomical site, the[] requirements

of the treatment process, or both. (The designs shown here can be formed in different diameters and lengths.)" Ex. 1006, 9 (Saab 88).

4. Sanati (Ex. 1013)

Sanati is a U.S. patent application publication that was published on March 7, 2013. Ex. 1013, codes (10), (43). Sanati teaches "apparatus and methods for flaring and/or otherwise expanding stents deployed within a body lumen, such as a branch vessel including an ostium extending from another main vessel or trunk." *Id.* ¶ 8. Sanati teaches that, for example, a "first balloon may be expanded to substantially anchor the stent relative to the branch body lumen, and the proximal section of the second balloon may be expanded to flare the first end of the stent within the ostium." *Id.* ¶ 11.

Figure 1b of Sanati is reproduced below:

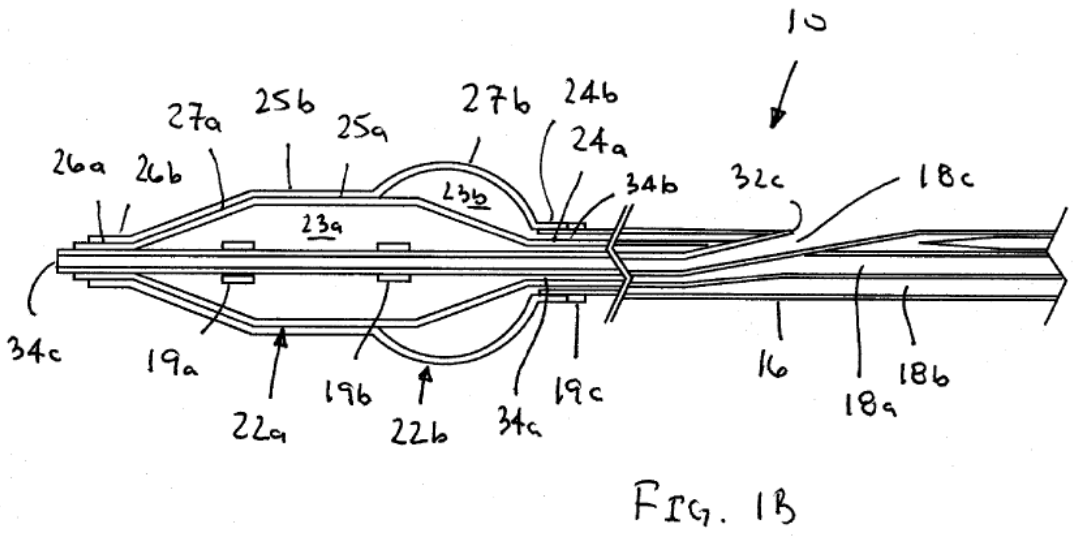


FIG. 1B

Figure 1b shows

> the catheter 12 includes a first or inner balloon 22a and a second or outer balloon 22b on the distal end 16, which are expandable independently of one another . . . The outer balloon 22b includes a first or distal section 25b that extends at least partially over the inner balloon 22a and a second or proximal

> section 27b. For example, the first section 25b may extend entirely over the inner balloon 22a and a distal end 26b of the outer balloon 22b may be attached over or adjacent to the distal end 26a of the inner balloon 22a . . . .

Ex. 1013 ¶¶ 37–38.

5. Deaton (Ex. 1008)

Deaton is a paper published in a scientific journal in July 2005. Ex. 1008, 6 (Deaton 32). Deaton teaches the "addition of fluoroscopy to many operating room environments, and the addition of the guidewire lumen in the Fogarty Thru-Lumen Embolectomy catheter, make possible a far more controlled, reproducible, and accessible technique for thrombectomy and embolectomy." *Id.* Deaton teaches:

> The Fogarty Thru-Lumen Embolectomy Catheter is manufactured in sizes of 3 F to 7 F, which allows the device to accommodate a variety of standard guidewire diameters (.018-, .025-, .035-, and .038-inch). The catheter is available in two lengths-40 cm and 80 cm. Stainless steel bushings located at the proximal and distal ends of the balloon enable accurate visualization under fluoroscopy.

Id.

6. Eliason (Ex. 1009)

Eliason is a U.S. patent that issued on September 15, 2015. Ex. 1009, codes (12), (45). Eliason describes "endovascular resuscitative aortic occlusion systems that are applied rapidly in settings in which fluoroscopy is not available, i.e. fluoroscopy-independent, as a method of occluding the aorta." *Id.* at 1:29–32.

Figure 10 of Eliason is reproduced below:

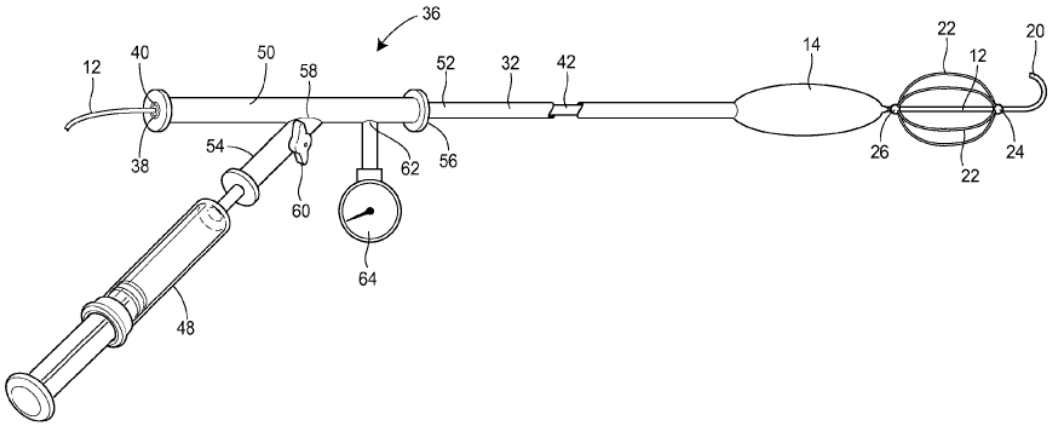


FIG. 10

Figure 10 illustrates

> the aortic occlusion balloon 14 is inflated and deflated via a multi-port and valve assembly 36. The multi-port and valve assembly 36 includes a one-way valve, which is preferably pressure gauge calibrated so as to alert a physician when the aortic occlusion balloon 14 has reached its desired inflation pressure. . . . The endovascular wire 12 can extend through the diaphragm 40, while maintaining fluid-tight communication between the multi-port and valve assembly 36 and the aortic occlusion balloon 14.

Ex. 1009, 10:7–17. Eliason teaches the "self-centering endovascular wire . . . is provided with calibration indicia, such as major length markers in 5 cm increments and minor length markers in 1 cm increments along the shaft." *Id.* at 5:9–12. Eliason teaches the "J tip is provided at a leading (distal) end of the self-centering endovascular wire to prevent vessel perforation." *Id.* at 5:12–14.

7. Scott (Ex. 1010)

Scott is a paper published in a scientific journal in July 2013. Ex. 1010, 7 (Scott 122). Scott teaches "[r]esuscitative endovascular balloon occlusion of the aorta (REBOA) is a potentially lifesaving maneuver in the

setting of hemorrhagic shock." *Id.* Scott teaches "a new, low-profile REBOA system designed to be placed without fluoroscopic guidance." *Id.* at 8 (Scott 123).

Figure 1A of Scott is reproduced below:

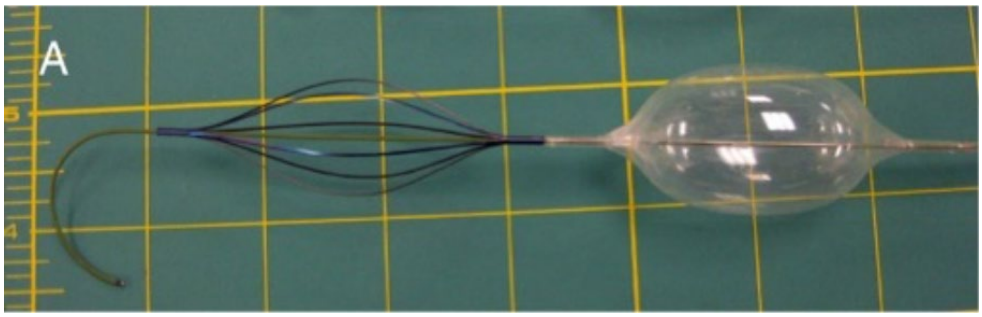


Figure 1A depicts a "[s]ingle component PBS designed to be positioned and inflated without fluoroscopy. The lead or insertion end is a floppy tipped 0.035-inch wire fused to the compliant balloon catheter. A collapsible nitinol rail system is positioned between the floppy tip of the wire and the compliant balloon . . . ." Ex. 1010, 8.

8. Joe (Ex. 1011)

Joe is a U.S. patent application publication that was published on May 14, 2015. Ex. 1011, codes (12), (43). Joe teaches devices "for simultaneous blood flow occlusion and device exchanges in the iliofemoral segment." *Id.* ¶ 13. Joe teaches "introducing a guide wire[,] . . . observing indicia of the presence or absence of a vascular injury[,] . . . retracting the guide wire to position the inflatable balloon adjacent the injury and inflating the balloon to reduce blood flow past the injury." *Id.* ¶ 14. Joe teaches the "balloon 302 may be formed from a soft membrane 304, for example, to provide a compliant balloon." *Id.* ¶ 88. Joe teaches the "balloon 220 and/or portions of the device 202 immediately proximal and distal to the balloon 220 may include one or more radiopaque markers, to facilitate visualization of the

balloon outside a patient's body using radiographic imaging techniques and thus facilitate placement of the balloon 220 in a desired location." *Id.* ¶ 133.

C. Ground 1 – Obviousness over Fogarty and Chengod

Under Ground 1, Petitioner asserts that claims 1–10 are unpatentable as obvious over the combination of Fogarty and Chengod. Pet. 1–2. Petitioner provides a detailed analysis of independent claim 1 and then explains where the claim limitations of dependent claims 2–10 are found within the prior art. *Id.* at 32–45.

We begin with Petitioner's contentions on claim 1, then Patent Owner's Response arguments, Petitioner's Reply and Patent Owner's Sur-Reply, and then move to our analysis, which addresses the arguments in light of the evidence of record. We then separately address claim 2 in the same manner. Although Patent Owner challenges only certain portions of Petitioner's obviousness combination, in light of Petitioner's burden and for completeness we start with Petitioner's evidence for each element of claim 1. We note that Patent Owner has not provided separate argument on the patentability of any of the other challenged dependent claims 3–10 and therefore do not specifically address these claims..

1. Petitioner's Initial Contentions - Claim 1

a. Preamble [1.P]: "An occlusion catheter system comprising"

Petitioner asserts "Fogarty discloses an occlusion catheter system." Pet. 32 (citing Ex. 1004, 1:39–40; Ex. 1003 ¶ 73).

b. Element [1a] – "a proximal hub"

Petitioner asserts "Fogarty discloses this element . . . The proximal hub is the assembly comprising the shut off valve (30), rotatable valve

member (31), syringe fitting (32), and hub flange elements (43)." Pet. 33 (citing Ex. 1004, 3:60–63; Ex. 1003 ¶ 74).

c. Element [1b] – "a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device"

Petitioner asserts:

> Valve fitting (32) may receive a syringe (35) (i.e., an inflation device) for inflating the balloon with a fluid. [Ex. 1004], 3:40-46. Once inflated, closing the valve maintains the inflation of the balloon. *Id.*, 1:54-64, 3:46-48. Thus, the valve (30) is the claimed "flow valve" and is "configured to selectively fluidly communicate the proximal hub with an inflation device" (e.g., the syringe (35)).

Pet. 33–34 (citing Ex. 1004, 3:38–48; Ex. 1003 ¶ 75).

d. Element [1c] – "a proximal catheter section in fluid communication with the proximal hub"

Petitioner asserts "Fogarty states that the proximal end of the catheter tube (16) is secured to the shut-off valve (30) of the hub." Pet. 34 (citing Ex. 1004, 3:38–39). Petitioner asserts that the "inflation fluid in Fogarty passes from the syringe (35) through the hub, the hub's valve (30), and the proximal section of the catheter tube (16) in order to inflate the balloon (20)." *Id.* (citing Ex. 1004, 3:19–27, 3:38–48).

e. Element [1d] – "a distal catheter section distally terminating with an atraumatic tip"

Petitioner asserts "Fogarty includes a distal catheter section that includes a 'soft rubber plug 11' as an atraumatic tip. . . . Fogarty explains that the plug (11) forms a 'flexible tip' that will readily bend back on itself . . . ." Pet. 34 (citing Ex. 1004, 2:43–49, Figure 1; Ex. 1003 ¶ 77).

f. Element [1e] – "an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being compliant"

Petitioner asserts that Fogarty describes a balloon composed of "a strong, elastic material such as latex rubber or a plastic elastomer whereby it will expand to a spherical shape when unconfined and inflated as shown in FIGURE 4." Pet. 35 (citing Ex. 1004, 3:16–19). Petitioner asserts "[i]n Figure 4, the inflated, compliant balloon (20) is shown extending from the closed, distal portion of the catheter (at the closed-end portion of the balloon (25) near plug (11)) to the proximal portion of the catheter tube (16), thus connecting the two catheter sections." *Id.* (citing Ex. 1004, Figure 4; Ex. 1003 ¶ 79).

g. Element [1f] – "at least one length marking on an exterior of the proximal catheter section to indicate an insertion depth of the occlusion catheter system"

Petitioner asserts "Chengod describes not only the use of a catheter with at least one length marking on the exterior of the catheter, but also the significance of these markings for ensuring proper insertion depth of the catheter within the body of the patient." Pet. 36 (citing Ex. 1005, 637).

h. Element [1g] – "a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon"

Petitioner asserts "Fogarty describes the catheter body having a 'hollow inner core' corresponding to the claimed 'lumen.'" Pet. 37 (citing Ex. 1004, 1:66–67). Petitioner asserts "[f]luid flows (fluid communication) from the hub, through the hollow inner core of the proximal catheter section (16), and into the occlusion balloon. Ex-1004, 3:19-25. This fluid

communication allows an inflation mechanism such as the syringe (35) to engage the hub and to inflate the balloon." *Id.* at 37–38 (citing Ex. 1004, 3:38–48; Ex. 1003 ¶¶ 82–83).

i. Element [1h] – "solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon and into the distal catheter section"

Petitioner asserts "Fogarty describes a wire, i.e., metal wire stylet (40), 'to facilitate the insertion of the catheter into a luminal structure within the body.'" Pet. 38 (citing Ex. 1004, 3:48–54). Petitioner asserts "[i]n Figure 3 the metal wire stylet (40) is shown extending through the proximal catheter section (16), the interior of the balloon (20), and ending at the 'reduced portion 12' of the soft rubber tip (11)." *Id.* at 38–39. Petitioner asserts "a PHOSITA understands that a metal wire stylet designed to facilitate the insertion of the catheter into a patient would be solid and not hollow, as a solid wire provides more stability." *Id.* at 39 (citing Ex. 1003 ¶ 89).

j. Element [1i] – "the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration"

Petitioner asserts "Chengod describes use of Fogarty catheters as small as 4 Fr." Pet. 40 (citing Ex. 1005, 637). Petitioner asserts "Chengod expressly discloses four French (4F) and five French (5F) catheters as design choices for an occlusion catheter, where smaller diameter catheters are used for younger patients." *Id.*

k. Motivation to Combine Fogarty and Chengod for Claim 1

Petitioner asserts:

> Even if Chengod had not used an actual Fogarty catheter, it would have been obvious to combine the teachings of Chengod and Fogarty. Fogarty describes an early occlusion balloon catheter. Chengod teaches that such catheters can be made in sizes as small as four French (4 Fr), and that external depth insertion markings can be advantageously used on an occlusion balloon catheter. A PHOSITA would have been motivated by this teaching to make a catheter of the disclosed size and to add depth insertion markings on the catheter described in Fogarty. The PHOSITA would have added depth insertion markings as disclosed in Chengod in order "to aid accurate placement" of the occlusion catheter. Ex-1005, 637. A PHOSITA understands that more accurate placement leads to fewer complications and higher success rates for the intervention procedure. The PHOSITA would have made a Fogarty catheter smaller than 6 Fr because smaller devices are safer (e.g., reduced risk of access site complications). Ex-1003 ¶106.

Pet. 46.

2. Patent Owner's Arguments Concerning Claim 1 and Our Analysis

a. Reasonable Expectation of Success in modifying catheters to less than 6 Fr

Patent Owner asserts "Petitioner has failed to perform a proper obviousness analysis by not adequately demonstrating a reasonable expectation of success in modifying Fogarty." PO Resp. 35. Patent Owner asserts "the category of 'Fogarty catheters' is broad and diverse" and "Dr. Resnick admits he has no idea whether Chengod's or Deaton's catheters have interior constructions similar to that of the cited Fogarty reference." *Id.* at 35–36 (citing Ex. 2002, 52:16–57:1). Patent Owner asserts that

> 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.

Id.

Petitioner responds "(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." Pet. Reply 19. Petitioner asserts that Yassinzadeh "shows a catheter that is less than 6 Fr and that includes a similar spring coil construction as found in the Fogarty patent" where the "dilator 150 has a diameter of either 5 Fr or 6 Fr." *Id.* at 19–20 (citing Ex. 1033 ¶¶ 86–97 ("Yassinzadeh")). Petitioner asserts that Yassinzadeh'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." *Id.* at 20 (citing Ex. 1034 ¶ 97).

Patent Owner responds "Petitioner fails to specify what 'modifications' might be necessary, and ultimately adds no substance to its conclusory assumption that a feature's general existence in the art alone proves a reasonable expectation of success in modifying a particular device." PO Sur-Reply 13 (footnote omitted). Patent Owner asserts that the "PTAB should disregard Yassinzadeh and the related analysis in the Reply and Dr. Resnick's second declaration as improper for not being raised in the Petition." *Id.* at 15. Patent Owner asserts

> Petitioner asserts the mere presence of a particularly-sized tensioning element, dilator, and shaft in Yassinzadeh's catheter

> analogize it to Fogarty. Reply, 19-20. Yassinzadeh, however, is constructed to perform percutaneous sealing of vascular puncture sites (Ex. 1033, 1:18-21) and is not indicated for multiple uses, unlike Fogarty's *reusable* catheter, built with the necessary durability and strength to withstand *repeated* advancement through tortuous vasculature for venous thrombectomy and/or arterial embolectomy procedures.

Id. (citing Ex. 1004, 1:49–51, 2:33–39). Patent Owner asserts that a "PHOSITA would not understand Yassinzadeh's size to be a reasonable barometer as to whether Fogarty's catheter could be similarly reduced while still being capable of performing its intended functions." *Id.*

Our analysis begins with the evidence of record regarding catheter sizing. Dr. Resnick states Fogarty does not address the size of the catheter at issue. *See* Ex. 2002, 51:1–2. Chengod teaches that a "Fogarty catheter was selected, as a bronchial blocker, according to the age of the patient; 4F catheter in the group less than 1 year, 5F in 1 year to 2 years old group, and 6F in the group between 2 years and 4 years." Ex. 1005, 11. Chengod teaches that the "best option for left-sided lung surgeries in this age group would be to place a balloon-tipped bronchial blocker, usually a Fogarty catheter of appropriate size." *Id.* at 13 (citation omitted). Deaton teaches the "Fogarty Thru-Lumen Embolectomy Catheter is manufactured in sizes of 3 F to 7 F, which allows the device to accommodate a variety of standard guidewire diameters." Ex. 1008, 6.

Dr. Resnick states that he "had personal experience with the Fogarty occlusion balloon catheter prior to 2015" and has

> been involved where a Fogarty occlusion balloon was inflated in an artery, vein, or graft for the purpose of vessel occlusion and intraluminal thrombus manipulation. A PHOSITA understands that each of these distinct procedures, wherein vessel occlusion is performed, utilizes a Fogarty device of the

> size appropriate for the vessel caliber in question. Specifically, smaller diameter (typically 4 French) devices would most often be used for vessel occlusion with intraluminal thrombus manipulation, whereas larger catheters (5 Fr or 6 Fr) would be used for embolic delivery manipulation and/or hemorrhage temporization prior to definitive therapy.

Ex. 1003 ¶ 37. Dr. Resnick further states that an ordinary artisan was aware of "Fogarty catheters that were smaller than 6 Fr (Chengod and Deaton) and, to the extent those structures differed from the device in the Fogarty patent (Ex-1004), the PHOSITA could make the same modifications and have a reasonable expectation that the resulting device will work as intended." Ex. 1034 ¶ 85. Dr. Resnick stated "a PHOSITA would understand that a catheter having a spring coil in addition to the other features (braid, outer tube, and lumen) could be constructed in a configuration with a diameter smaller than 6 Fr. This is confirmed by the prior art." *Id.* ¶ 86 (citing Ex. 1033).

Dr. Resnick states that Yassinzadeh[14] (Ex. 1033) provides evidence showing that "catheters could include constructions similar to those found in

[14] We determine that Petitioner's reliance on Yassinzadeh as rebuttal evidence in responsive argument and evidence is not improper. *See* 37 C.F.R. § 42.23(b); *see also* Consolidated Trial Practice Guide at 73 (a "petitioner may file a reply to a patent owner response" and a "party also may submit rebuttal evidence in support of its reply"); 84 Fed. Reg. 64,280 (Nov. 21, 2019) (available at www.uspto.gov/TrialPracticeGuideConsolidated). *See also Genzyme Therapeutic Prods. Ltd. P'ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016)("[T]he introduction of new evidence in the course of the trial is to be expected in . . . trial proceedings and, as long as the opposing party is given notice of the evidence and an opportunity to respond to it, the introduction of such evidence is perfectly permissible under the APA.") Here, Patent Owner had the opportunity to respond in the PO Sur-

the Fogarty patent and have greatest outer diameters less than 6 Fr. This further supports my opinion that a PHOSITA would have a reasonable expectation of success in sizing the catheter in the Fogarty patent (Ex-1004) less than 6 Fr." Ex. 1034 ¶ 97. Yassinzadeh teaches the size of internal components may be optimized for catheter size, specifically explaining that the

> fabricated coil 26 may have a diameter in the range from about 1 mm to about 10 mm. . . . The diameter of the tension coil spring 26 in the preferred embodiment of this invention is chosen to be greater than the inside diameter of an introducer sheath. For example, when a 5 Fr sheath is used the diameter of coil 26 would be greater than 1.75 mm. The greater this difference, the greater the interference between the coil spring 26 and the sheath . . . .

Ex. 1033, 8:64–9:8.

Dr. Cimino does not dispute the use or sizing of Fogarty catheters for intraluminal thrombus manipulation, stating the "embodiment shown in Fogarty is designed for venous thrombectomy procedures, which involves using a balloon to remove a clot (thrombus) by pulling the inflated balloon through the vein with the catheter." Ex. 2001 ¶ 51.

Reply. In addition, Petitioner's use of Yassinzadeh helps explain how a POSA would have understood Fogarty's catheters. *See, e.g.*, *Anacor Pharms., Inc v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018) (after considering whether certain arguments were permissible under the APA, stating: "In addition, the petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner, or if it is used 'to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness.'").

Dr. Cimino states, "the broad class of Fogarty catheters exhibits significant variation in design and construction. The specific details of each Fogarty catheter were designed to address a particular problem(s) related to a specific procedure(s)." Ex. 2001 ¶ 55. Dr. Cimino states a "PHOSITA would have made modifications or changes *to the particular catheter in the cited Fogarty reference* (Ex. 1004) based on knowledge of specific 'Fogarty catheters' that include common design elements for common intended purposes to the cited Fogarty reference." *Id.* (citing Ex. 1004).

In deposition, Dr. Cimino acknowledges that prior to March 2015 "many angioplasty catheters and other cardiac catheters were less than 6 French at that time." Ex. 1032, 181:20–21.

We find that there is substantial evidence of record supporting Petitioner's assertion of a reasonable expectation of success in modifying the size of Fogarty's catheter to smaller dimensions necessary to treat smaller patients. *See, e.g.*, Pet. 40–41 ("PHOSITA would have a reasonable expectation of success in making and using a 6 Fr (or less) sized Fogarty occlusion catheter . . . . [A] basic tenet of endovascular procedures is that the smallest device available that can adequately complete the job is the one that should be used.").

This evidence, including Deaton and Chengod, that demonstrated Fogarty catheters smaller than 6 Fr were known, and the rebuttal reference Yassinzadeh showing that even internal components were known, at the time of invention, to be capable of being designed for catheters smaller than 6 Fr, provides persuasive evidence for a reasonable expectation of success in modifying the Fogarty catheter for use in smaller blood vessels requiring less than 6 Fr size catheters. Ex. 1005, 11; Ex. 1008, 6; Ex. 1033, 8:64–9:5.

Both Dr. Resnick and Dr. Cimino also recognized that catheters with sizes smaller than 6 Fr had been successfully designed in the prior art. Ex. 1034 ¶ 85; Ex. 1032, 181:20–21. "[O]bviousness does not require absolute predictability of success ... *all that is required is a reasonable expectation of success*." *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (second alteration in original).

Accordingly, we find that Petitioner has shown that a preponderance of the evidence supports a reasonable expectation of success in modifying the catheter of Fogarty to a size smaller than 6 Fr in order to function in smaller blood vessels.

b. "secured . . . within the proximal hub"

Based on Patent Owner's interpretation of "secured" in claim 1 of the '737 patent as meaning "fixedly coupled to," Patent Owner asserts: "***It is undisputed that Fogarty's metal wire stylet is not fixedly coupled to the alleged 'proximal hub'***, as even Petitioner acknowledges that Fig. 2 shows the proximal end of the metal wire stylet is ***removably*** engaged '***via cap (41),*** which is ***threaded into the hub flange elements (43)***.'" PO Resp. 37 (citing Pet. 38; Ex. 2001 ¶ 79).

Patent Owner asserts that because Fogarty states "'[t]he proximal end of the 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,'" it is evident that "Fogarty appreciates and differentiates between 'securement', *i.e.*, fixed coupling, and 'engagement', *i.e.*, removable attachment." PO Resp. 37 (citing Ex. 1004, 3:60–62; Ex. 2001 ¶ 79).

Patent Owner asserts that based on the '737 patent, a "PHOSITA understands . . . that the proximal-most end of the solid wire must be fixedly

coupled to, and within, the proximal hub to add longitudinal stiffness to the catheter to combat compressive buckling or displacement." PO Resp. 38–39 (citing Ex. 2001 ¶ 83). Patent Owner also asserts that Fogarty's "stylet 40 ***is not and cannot be present*** during a major aspect of the normal operating conditions encountered by the balloon catheter." *Id.* at 39–40 (citing Ex. 2001 ¶¶ 85–86). Patent Owner asserts that claim 1 of the '737 patent

> is directed to an "occlusion catheter system" utilizing an "occlusion balloon," meaning normal operating conditions of the claimed occlusion catheter system ***necessarily include*** the operation of the catheter to reach ***and occlude*** the target vessel, where significant compressive forces are encountered on the catheter.

Id. at 40 (citing Ex. 2001 ¶¶ 82–84, 87; Ex. 1001, 35:24–27).

Petitioner asserts "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." Pet. Reply 20. Petitioner asserts

> 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***."

Id. at 21 (citing Ex. 1004, 3:60–65; Ex. 1034 ¶ 100).

Petitioner asserts that Patent Owner's assertion that Fogarty's stylet "'*must be absent* during significant normal operating conditions' . . . is wrong because the stylet is not absent during Fogarty's normal operating conditions (i.e., insertion)." Pet. Reply 21–22 (citing PO Resp. 39–40; Ex. 2001 ¶¶ 85–86; Ex. 1034 ¶ 102).

Petitioner also asserts that "Fogarty's 'coil 10' discloses the 'solid wire' in claim 1" because "[c]oil 10 is a solid wire made of stainless steel" that "is connected into catheter tube socket 33 (part of the proximal hub)." Pet. Reply 22–23 (citing Ex. 1034 ¶¶ 104–115; Ex. 1004, 2:40–41, Figure 2, 3:38–42).

Patent Owner responds that in the Petition, "Petitioner never references Fogarty's coil 10 at all, let alone in connection with the claimed solid wire." PO Sur-Reply 16–17 (citing Pet. 38–40). Patent Owner asserts "[s]witching to an entirely different element in Fogarty to complete the obviousness rationale is improper for a reply." *Id.* at 17. Patent Owner asserts that "[e]ven if the argument were timely, Fogarty's 'coil 10' is not a 'solid wire', as claimed." *Id.*

Our analysis begins with the evidence of record regarding "secured . . . within the proximal hub." As discussed above in section IV.D.3., we conclude that the ordinary understanding of the word "secured" to the ordinarily skilled artisan as of the invention date does not necessarily require a permanent attachment, but would reasonably encompass other forms of being secured. We therefore turn to whether Fogarty teaches "a solid wire, secured at a proximal-most end thereof within the proximal hub" as recited in claim 1 of the '737 patent.

Fogarty teaches the catheter is "equipped with a metal wire stylet 40." Ex. 1004, 3:49–50. Fogarty teaches:

> 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.

Id. at 3:60–65. Fogarty teaches "the stylet may be used when desired to facilitate the insertion of the catheter into a lumenal structure within the body. This provides two different pliabilities for the catheter body tube." *Id.* at 3:52–55. Fogarty also teaches the "stylet is also used to protect the catheter when it is not in use. It stiffens the catheter body and prevents acute angulation when the catheter is being handled during sterilization and storage." *Id.* at 3:56–59.

Dr. Resnick states "the Fogarty reference teaches a wire (40), that is secured at a proximal-most end (within flange element 43) thereof within the proximal hub and extends within the proximal catheter section (16) through the occlusion balloon (20), and into the distal catheter section at the soft rubber tip (11)." Ex. 1003 ¶ 88. Dr. Resnick states that a "PHOSITA understands that a metal wire stylet designed to facilitate the insertion of the catheter into a patient would be solid and not hollow, as a solid wire provides more stability. For example, the Bagaoisan, Nishide, and Anders[e]n references disclose solid metal stylets and mandrels." *Id.* ¶ 89 (citing Ex. 1016; Ex. 1017; Ex. 1018).

Dr. Cimino states "Fogarty itself understands and differentiates between 'securement', *i.e.* fixed coupling, and 'engagement', *i.e.*, a removable attachment." Ex. 2001 ¶ 79. Dr. Cimino states "***the stylet 40 is not present during the major aspect of the normal operating conditions encountered by the balloon catheter system of Fogarty.***" *Id.* ¶ 85. Dr. Cimino states "stylet 40 is only secured to the cap 41 during insertion of the Fogarty catheter into the vessel, which cannot be secured in any alleged

proximal hub of Fogarty because the cap 41 and stylet 40 must be removed to perform the procedures with the balloon inflation." *Id.* ¶ 86.

Dr. Resnick responds that "Fogarty's metal stylet is not only used to protect the catheter when not in use, but it may also be used as a stiffening member when inserting the catheter into the body." Ex. 1034 ¶ 83 (citing Ex. 1004, 3:52–54). Dr. Resnick states that "for procedures where the interventionist desires added stiffness when inserting the catheter into the body, the metal stylet can be secured in the cap, which is secured in the catheter's proximal hub by screwing the cap into the syringe fitting 32." *Id.* (citing Ex. 1004, 3:62–65).

In deposition, when asked "[c]an you inflate the balloon in Fogarty with the stylet in place?" Dr. Resnick answered "[o]ne could attach a simple side arm valve, put the stylet through that valve, and inflate with the stylet in place. That's something we do routinely in endovascular procedures, so, yes." Ex. 2002, 43:5–11.

We find that there is substantial evidence of record supporting Petitioner's assertion that Fogarty teaches and suggests "a solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon and into the distal catheter section" as recited in claim 1 of the '737 patent.[15]

Fogarty expressly uses the word "secured" to explain the way in which the wire stylet is attached to the cap that is screwed into a proximal

[15] We need not address Petitioner's belated argument that coil 10 of Fogarty might be interpreted as the solid wire because we find that a preponderance of the evidence of record supports a finding that the metal stylet in Fogarty meets this claim limitation.

hub and, as we have already noted, we do not interpret "secured" as requiring a permanently fixed type of attachment. *See* section IV.D.3 above; Ex. 1004, 3:60–65. We find Dr. Resnick's positions more credible on this point and agree that Fogarty is reasonably understood as teaching a stylet that is secured to the proximal hub. *Id.*; Ex. 1003 ¶ 88.

As to Patent Owner's intended use argument, suggesting that the stylet in Fogarty is not used during surgery (*see* PO Resp. 39), both Dr. Resnick and Dr. Cimino recognized that the stylet in the Fogarty catheter may be fixed to the hub and used during surgery, specifically when inserting the catheter into the patient's body to provide different pliabilities for the catheter. Ex. 1004, 3:52–55; Ex. 1034 ¶ 83; Ex. 2001 ¶ 86. Consequently, even if there were a limitation regarding the use of the stylet, Fogarty addresses this issue.

Accordingly, we find that Petitioner has shown by a preponderance of evidence that Fogarty teaches a catheter system comprising "a solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon and into the distal catheter section" as recited in claim 1 of the '737 patent.

c. "flow valve" and "proximal hub"

Patent Owner asserts "Petitioner and Dr. Resnick . . . equate the same portions of Fogarty with two separately claimed structures, reading their relationship to one another out of independent claim 1 without any semblance of explanation or reasoning for doing so." PO Resp. 43 (citing Ex. 2001 ¶¶ 63–65). Patent Owner also argues the claim interpretation regarding whether a "flow valve" may be a sub-element of a "proximal hub" that we have already addressed in section IV.A.3 above. *See id.* at 41–48.

Petitioner asserts "[t]here is no dispute Fogarty discloses the proximal hub and flow valve under the Board's preliminary construction that allows an element/sub-element configuration." Pet. Reply 25 (citing Ex. 1034 ¶¶ 119–120; Inst. Dec.). Petitioner asserts "the claims are obvious even if the flow valve must be between the proximal hub and the inflation device." *Id.* (citing Ex. 1034 ¶¶ 121–122). Petitioner asserts that

> [c]hoosing 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."

Id. at 26. Petitioner asserts "[m]odifying 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)." *Id.* at 27.[16]

Patent Owner responds to Petitioner's design choice argument, noting the "Petition relied on Fogarty alone as expressly disclosing the proximal hub and flow valve arrangement. Petition, 32-34. This change in theory is

[16] While we find this "design choice" argument by Petitioner a reasonable one on the merits, we agree with Patent Owner that this argument was not presented in the Petition. *See* Pet. 33–34; *see Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1286 (Fed. Cir. 2017) (finding that petitioner's "subsequent arguments amount to an entirely new theory of *prima facie* obviousness absent from the petition"). We therefore do not rely upon Petitioner's "design choice" argument in our analysis, conclusions, or decision.

improper for a reply as it presents a 'meaningfully distinct contention.'" PO Sur-Reply 20.

Patent Owner also asserts

> a PHOSITA would not reconstruct Fogarty's integral shut-off valve 30 into separate and distinct components. While Petitioner broadly contends that choosing between integral and separate constructions represents a limited design choice (Reply, 26), a principal object of Fogarty is to provide a catheter with increased strength and durability to withstand repeated usage, which includes having an *integral* shut-off valve. Ex-1004, 1:49-63. Reconstructing Fogarty's catheter to provide a valve upstream and separate from the "proximal hub" ignores this object by unnecessarily adding potential failure points to a catheter constructed for repeated usage.

Id. at 21. Patent Owner also argues that this "modification to Fogarty would necessarily relocate the connection point of the stylet 40 to the ***inlet of the valve***, *i.e.*, at the same connection point as the syringe in Chengod, and ***not*** within the alleged 'proximal hub.'" *Id.* at 22.

Our analysis begins with the evidence of record regarding "flow valve" and "proximal hub." As discussed above in section IV.A.3., we interpreted "proximal hub" as an element that may connect an inflation device to the catheter's inflation lumen and that may also comprise sub-elements, including a "flow valve."

We therefore turn to whether Fogarty teaches "proximal hub" and a "flow valve" (potentially a sub-element) as encompassed by claim 1 of the '737 patent. Dr. Resnick annotates figure 1 of Fogarty (Ex. 1034 ¶ 117), reproduced below showing a proximal hub with a flow valve circled in green:

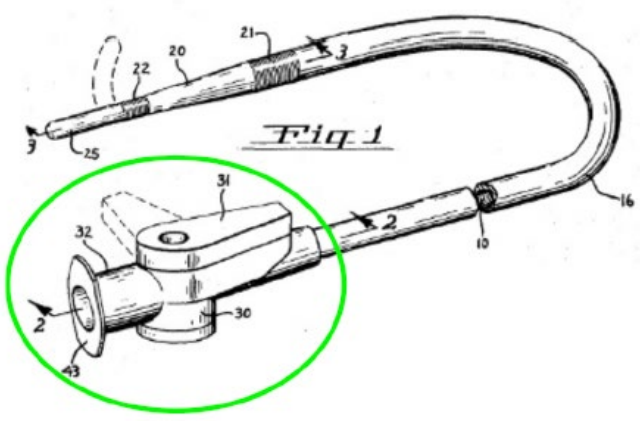


Figure 1 of Fogarty shows the "proximal end of the catheter tube is secured to a shut-off valve 30 having a rotatable valve member 31. The body of valve 30 is equipped with a conventional fitting 32 in line with the catheter tube socket 33 to receive a syringe 35 for inflating the balloon." Ex. 1004, 3:38–42. Thus, Fogarty teaches that the proximal component of the catheter functions both as a hub for connecting a syringe and includes a flow valve allowing fluid to flow between the syringe and an inflation balloon through the hub. *Id.*; *see* Ex. 1034 ¶ 120 ("Fogarty's shut-off valve (30, 31) is a sub-element of the overall proximal hub (30, 31, 32, 33) that is configured to control the flow of fluids from the syringe 35 to the proximal hub (30, 31, 32, 33).").

Dr. Resnick states "it remains my opinion that Fogarty discloses the 'proximal hub' and 'flow valve' limitations of claim 1 under the plain meaning of these claim terms, which would encompass a flow valve as a sub-element of the proximal hub. The basis of my opinion is explained in my First Declaration." Ex. 1034 ¶ 119 (citing Ex. 1003 ¶¶ 74–75).

Dr. Cimino does not disagree, stating that "Dr. Resnick annotates Fogarty's Fig. 1 again for the flow valve feature, and as can be seen below, Dr. Resnick's green circle effectively encompasses the same components as

above for the claimed proximal hub." Ex. 2001 ¶ 64. Although Dr. Cimino does not agree with our claim interpretation as discussed above in section IV.A.3 of this decision, Dr. Cimino does not provide a separate argument disagreeing that Fogarty's device encompasses a proximal hub and flow valve (one that controls whether inflation liquid flows through the hub) in an element/sub-element relationship.

Accordingly, we find that a preponderance of the evidence demonstrates that Fogarty discloses that the proximal component of the catheter functions both as a hub for connecting a syringe and includes a flow valve controlling whether fluids flows between the syringe and an inflation balloon and through the hub.

3. Claim 2 –"asymmetrical" balloon

Petitioner asserts that a "PHOSITA is well aware that compliant balloons such as the type used in the Fogarty catheters as described in Fogarty and Chengod could be designed to inflate asymmetrically." Pet. 41 (citing Ex. 1003 ¶ 93). Petitioner asserts the "use of asymmetrical inflation in compliant balloons was known for many decades and would be known to a PHOSITA. Ex-1003 ¶50. Asymmetrical, complaint balloons were described, for example, in an article by John M. Mathis . . . ." *Id.* at 19 (citing Ex. 1021). Petitioner asserts "a PHOSITA understands that compliant balloons are often used in occlusion catheters because the balloon can inflate asymmetrically when inside the patient." *Id.* at 21 (citing Ex. 1026 ¶¶ 76–83, 99).

Patent Owner asserts "[n]either Petitioner nor Dr. Resnick articulated any reason to substitute an asymmetrical balloon into Fogarty other than to say the balloon 'could be' designed that way." PO Resp. 49 (citing Pet. 41;

Ex. 1003 ¶ 93). Patent Owner asserts that "[w]ith no explanation of why a PHOSITA ***would*** have made the balloon in Fogarty asymmetrical, Petitioner cannot legally sustain its burden to show obviousness of claim 2 over Fogarty, Chengod, and a PHOSITA's knowledge." *Id.*

Petitioner asserts that the Petition explained that "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. Reply 28 (citing Pet. 21; Ex. 1034 ¶ 127) (alterations in original). Petitioner asserts the Petition disclosed that "a PHOSITA would use a compliant balloon that inflates asymmetrically to occlude asymmetrical vessels in the patient's body." *Id.* at 28–29 (citing Ex. 1034 ¶ 128).

Patent Owner responds

> Petitioner merely reiterates that asymmetrical compliant balloons were known (Reply, 28-29), which is insufficient to prove obviousness. *Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 886 (Fed. Cir. 2024). The only difference is Petitioner swapped out "could" for "would." Reply, 28-29. This superficial change does not elevate Petitioner's conclusory analysis to the level of "some articulated reasoning with some rational underpinning" needed to find the claim obvious.

PO Sur-Reply 22–23.

Our analysis begins with the evidence of record regarding asymmetric balloons. Dr. Resnick states Mathis "compared four different low-pressure balloons used for arterial occlusion, and highlight the difference between symmetrical and asymmetrical balloons." Ex. 1003 ¶ 51 (citing Ex. 1021, 3). Dr. Resnick states

> during occlusion procedures, the balloons are used to completely fill the cavity, which often is asymmetrical in shape, resulting in an inflated balloon that is also asymmetrical. For example, X. Gu et al . . . confirms the PHOSITA's knowledge that compliant balloon catheters were often asymmetrical. Gu's catheter includes a "balloon [that] is compliant and made from a very thin stretchable polyurethane membrane." Gu, p. 51 (Ex-1014). Figure 6 depicts a "deployed balloon catheter within the surgically created atrial septal defect" (Gu, p. 54 (Ex-1014)) that is asymmetrical.

Id. ¶ 55 (citing Ex. 1014). Dr. Resnick states "my opinion was (and is) that a PHOSITA would use a compliant balloon in Fogarty that, when inserted into and confined within a lumen in the body, inflates asymmetrically (has an asymmetrical shape) in order to occlude the body lumen." Ex. 1034 ¶ 128.

In deposition, Dr. Resnick states "in practice, the Fogarty balloon, which is a compliant balloon, and other compliant balloons generally inflate in an asymmetric manner." Ex. 2002, 68:19–22.

Dr. Cimino states "Saab clearly teaches, however, that the asymmetric balloon is a ***disadvantage*** and Saab specifically states that the asymmetric balloon '[o]ffer[s] less precision.'" Ex. 2001 ¶ 89 (alterations in original). Dr. Cimino states

> [w]hen considered as a whole, a PHOSITA would understand Saab to be advocating for usage of high-pressure balloons, which do not suffer from the aforementioned problems present in low pressure elastomeric balloons. If a PHOSITA were going to make any modifications to Fogarty or Chengod based on Saab, it would be to transition to a high pressure balloon, not to include the criticized asymmetric balloon . . . .

Id. ¶ 90.

However, Saab states "[b]ecause high-pressure balloons can be precisely shaped, particularly in the transition area, they offer advantages

over elastomeric balloons, whose ends are always spherically shaped." Ex. 1006, 13.

We find that the evidence shows that the ordinary artisan would have had reason to select asymmetrical balloons in certain situations and would have recognized that asymmetrical balloons were known equivalent options for symmetrical balloons.

As to a specific reason to select asymmetrical balloons, both Dr. Resnick and the Saab reference state that when the lumen into which the balloon is being inserted and inflated is asymmetric, the ordinary artisan would select an asymmetric balloon in order to fully occlude the lumen. Ex. 1034 ¶ 128; Ex. 1006, 13.

As to substituting asymmetric balloons for symmetric balloons, *KSR* states that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR*, 550 U.S. at 417. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. Dr. Resnick points to evidence in Saab showing the equivalence of offset balloons and other balloon types for use in patients. *See* Ex. 1003 ¶ 54; Ex. 1006, 9, 11. Dr. Resnick similarly points to both asymmetric and symmetric balloons in Mathis as used equivalently. *See* Ex. 1003 ¶ 51; Ex. 1021, 3.

We recognize Dr. Cimino notes that in certain situations, symmetric balloons may be preferred to asymmetric balloons (Ex. 2001 ¶¶ 89, 91), but a known element "does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Rather, we weigh the

suggestive power of the evidence of record. *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991). Moreover, Dr. Cimino's position that certain situations call for balloon symmetry also supports the converse—certain situations call for asymmetric balloons. On the current evidence, we find Dr. Resnick's positions more credible and more supported by the record as a whole.

Accordingly, we find that a preponderance of the evidence supports a finding that the use of asymmetrical balloons in the Fogarty catheter would have been obvious.

4. Conclusion

On this record, we determine that Petitioner has shown by a preponderance of the evidence that Fogarty and Chengod render claims 1–10 unpatentable as obvious.

D. Ground 2 – Obviousness over Fogarty, Chengod, and Saab

Petitioner argues that claim 2 would have been obvious over Fogarty, Chengod, and Saab. Pet. 47–50; Ex. 1003 ¶¶ 113–118; Ex. 1006, 11.

1. The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical

Petitioner asserts "Saab discloses that asymmetrical balloons made of latex or silicone were known." Pet. 48 (citing Ex. 1006, 11). Petitioner cites to figure 6 of Saab, reproduced below:



"Figure 6. *Offering less precision, an elastomeric balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left)."*

Id. at 49.

Petitioner asserts a

> PHOSITA reading Saab understands that compliant balloons may expand asymmetrically. Ex-1006-11 & Fig. 6 (elastomeric (compliant) balloons "often expand asymmetrically"). Thus, Saab is explaining a behavior that is found in compliant balloons. Alternatively, Saab suggests to a PHOSITA that asymmetrical compliant balloons are a design choice that could be implemented on catheters such as the Fogarty catheter. Either way, a PHOSITA reading Saab would understand that

> asymmetrical inflation of the compliant balloon in the Fogarty catheters is obvious.

Pet. 49 (citing Ex. 1003 ¶ 117).

Patent Owner asserts that a "PHOSITA, however, would not modify Fogarty . . . as proposed, as Saab teaches away from the proposed combination." PO Resp. 58. Patent Owner asserts "Saab elsewhere criticizes the type of low pressure, elastomeric balloon shown in Figure 6." *Id.* at 59.

As we discussed above in our analysis of Ground 1, a known element "does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *Gurley*, 27 F.3d at 553. And, we find the evidence relied upon by Dr. Resnick persuasive that the ordinary artisan would recognize asymmetric balloons as known and obvious alternatives to symmetric balloons. Ex. 1003 ¶¶ 51–57; Ex. 1034 ¶¶ 126–128; Ex. 1006, 13. We also note that claim 2 does not require low pressure occlusion balloons, only asymmetric balloons, and Saab states:

> 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. High-pressure occlusion balloons can be made shorter or longer than elastomeric balloons, thus either reducing or increasing the surface area covered in the vessel or cavity. Because high-pressure balloons can be precisely shaped, particularly in the transition area, they offer advantages over elastomeric balloons, whose ends are always spherically shaped.

Ex. 1006, 12–13. Thus, Saab would have suggested to an ordinary artisan that, even for occlusion balloons, precisely shaping the balloons in non-symmetrical ways would have been advantageous, supporting Petitioner's obviousness position.

2. Conclusion

On this record, we determine that Petitioner has shown by a preponderance of the evidence that Fogarty, Chengod, and Saab render claim 2 unpatentable as obvious.

E. Ground 3 – Obviousness over Fogarty, Chengod, Sanati; and Ground 4 – Obviousness over Fogarty, Chengod, and Deaton

Petitioner asserts that claims 3–5 and 9 would have been obvious over the combination of Fogarty, Chengod, and Sanati. Pet. 50–55. Petitioner further asserts that claim 8 would have been obvious over the combination of Fogarty, Chengod, and Deaton. *Id.* at 56–57.

1. Claim 3 – "The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion"

Petitioner asserts "Sanati Figure 1B shows a balloon with a conically shaped portion facing a spherical portion at element 22b:"

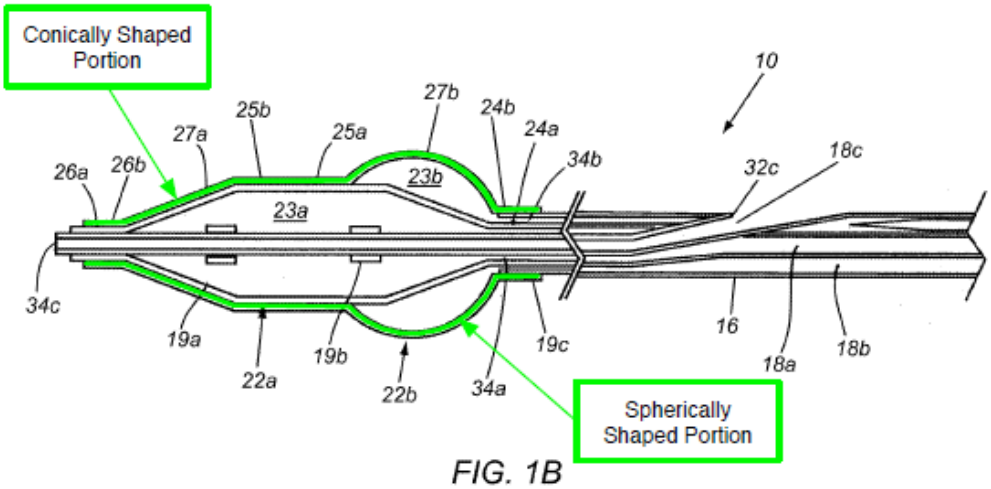


FIG. 1B

Pet. 51 (citing Ex. 1007, Fig 1B as annotated by Petitioner). Petitioner asserts "Sanati describes 'outer balloon 22b' as having a 'substantially spherical' shaped proximal 27b" portion. *Id.* (citing Ex. 1007, 7:25–29).

2. Claim 4 – "The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion"

Petitioner asserts "Sanati's inner balloon 22a has a conically shaped portion facing another conically shaped portion:"

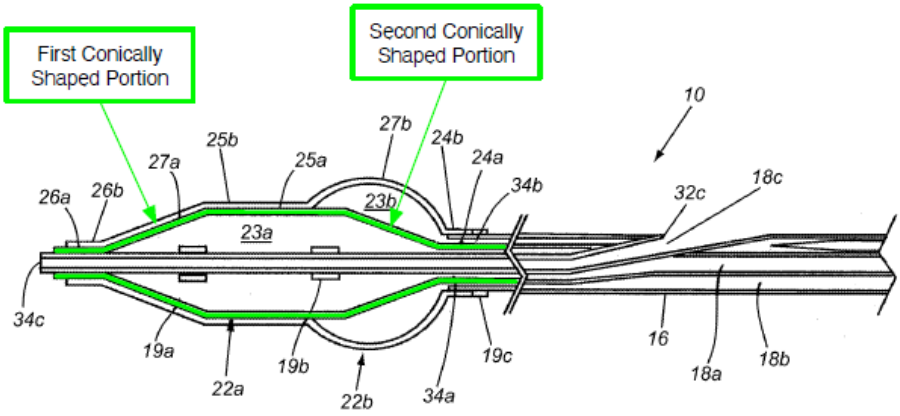


FIG. 1B

Pet. 51–52 (citing Ex. 1007, Figure 1B as annotated by Petitioner). Petitioner asserts "[i]nner balloon 22a has a tapered portion 27a at its distal end and another tapered portion at its proximal end, both forming conical shapes." *Id.* at 52 (citing Ex. 1007, 7:35–47; Ex. 1003 ¶¶ 126–128).

3. Claim 5 – "The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion"

Petitioner asserts "Sanati's balloon 22a has a first conically shaped portion, a second conically shaped portion, and an intervening generally cylindrical portion:"

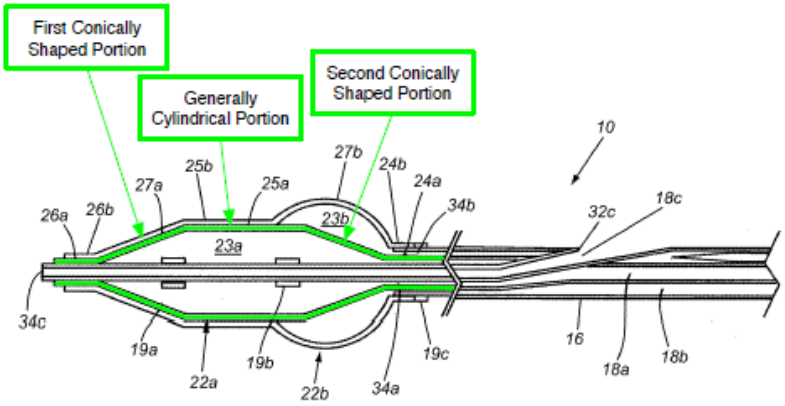


FIG. 1B

Pet. 52–53 (citing Ex. 1007, Fig. 1B as annotated by Petitioner). Petitioner asserts "[t]he inner balloon 22a has a first conically shaped portion facing a second conically shaped portion. Positioned between these two portions is a 'main section 25a' that has 'a substantially uniform diameter.'" Pet. 53 (citing Ex. 1007, 8:50–53; Ex. 1003 ¶¶ 129–130).

4. Claim 9 - "The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions"

Petitioner asserts:

> The term frustoconical describes a conical shape that stops short of reaching a single apex point (i.e., it is truncated before the apex of the cone). The inner balloon 22a of Figure 1B of Sanati teaches two oppositely oriented frustoconical portions in the same manner that it depicts two conically shaped portions facing each other. Ex-1003 ¶94. The conical sections are actually frustoconical because the catheter running through the ends of the balloon results in truncation of a cone:

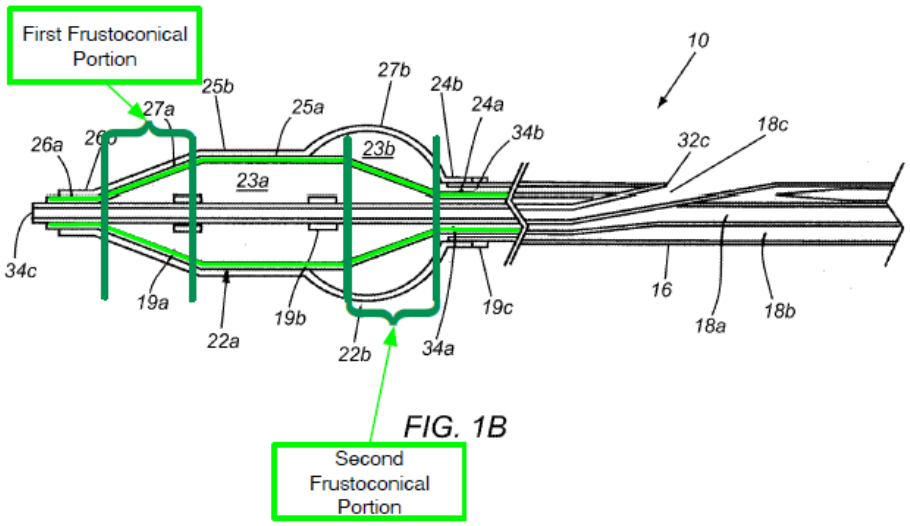


FIG. 1B

Pet. 53–54 (citing Ex. 1007, Figure 1B as annotated by Petitioner; Ex. 1003 ¶¶ 131–132).

5. Motivation for combining Fogarty, Sanati, and Chengod

Petitioner asserts:

> A PHOSITA with knowledge of Sanati and Fogarty would know to use the shape of the balloons shown in Sanati as one of the possible shapes for the balloon used in Fogarty (as modified by Chengod and the PHOSITA's knowledge). A PHOSITA understands that different balloon shapes are necessitated by the variation in human anatomy shape and size and that Sanati is another iteration of an asymmetric balloon using a different mechanism of creating asymmetry in balloon inflation.

Pet. 54–55 (citing Ex. 1003 ¶ 134).

6. Claim 8

Petitioner asserts that Deaton teaches "a version of the Fogarty catheter that was commercially available that included '[s]tainless steel bushings located at the proximal and distal ends of the balloon enable accurate visualization under fluoroscopy.'" Pet. 56 (citing Ex. 1008, 32) (alteration in original). Petitioner asserts that "[s]tainless steel bushings are a

form of radiopaque markers" and therefore "Deaton shows a proximal radio opaque marker proximate a proximal end of an occlusion balloon and a distal radio opaque marker proximate a distal end of an occlusion balloon." *Id.* (citing Ex. 1003 ¶¶ 137–138).

7. Motivation to combine Fogarty, Chengod, and Deaton

Petitioner asserts

> a PHOSITA would have added Deaton's radiopaque markers to the Fogarty catheter of Fogarty and Chengod to increase the usability of those catheters when attempting to locate the balloon under fluoroscopy. Thus, Deaton expressly recognized a reason to combine known elements (a Fogarty catheter as in Fogarty and Chengod with the radiopaque markers of Deaton) in the manner described in the Claim 8 of the '737 Patent.

Pet. 57.

8. Analysis

Patent Owner asserts

> each of Grounds 2–4 fails to compensate for at least the deficiencies described above in Ground 1: (1) a lack of securing the proximal-most end of the solid wire within the proximal hub, and (2) improperly assigning distinct structures of the flow valve and proximal hub to the same components in Fogarty . . . at least because Petitioner utilizes the additional references in Grounds 2–4 solely for other, unrelated claim features.

PO Resp. 60–61 (citing Pet. 48, 51–53, 56; Ex. 2001 ¶¶ 91–92).

We have already addressed both the asserted deficiencies in our analysis above concerning Grounds 1 and 2, finding that Fogarty teaches securing the proximal end of the solid wire within the proximal hub and teaches a proximal hub and flow valve in an element/sub-element relationship. *See supra* IV.A.3; IV.D.3; V.B.2.b; and V.B.2.c. We find that

Petitioner has provided persuasive evidence of obviousness for the specific claims at issue in Grounds 3 and 4 as discussed above.

9. Conclusion

On this record, we determine that Petitioner has shown by a preponderance of the evidence that Fogarty, Chengod, and Sanati render claims 3–5 and 9 unpatentable as obvious. We also determine that Petitioner has shown by a preponderance of the evidence that Fogarty, Chengod, and Deaton render claim 8 unpatentable as obvious.

F. Ground 5 – Obviousness over Eliason

Petitioner asserts that claims 1–10 would have been obvious over Eliason. Pet. 58–72.

1. Petitioner's Initial Contentions – Claim 1

a. Preamble [1.P]: "An occlusion catheter system comprising"

Petitioner asserts that the "title of Eliason references an occlusion system and reference to such systems is made throughout the disclosure (thoracic aortic occlusion system 10)." Pet. 59 (citing Ex. 1009, 1:20–24, 7:33–36; Ex. 1003 ¶ 145).

b. Element [1a] – "a proximal hub"

Petitioner asserts that Eliason discloses that a "proximal hub is shown in Figure 10 as element 36, called the 'multi-port and valve assembly.'" Pet. 60 (citing Ex. 1009, 10:7–9; Ex. 1003 ¶ 146).

c. Element [1b] – "a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device"

Petitioner asserts "Eliason utilizes a valve (60) that is 'actuable between an open condition ... and a closed position' to permit or prevent the passage of inflation fluid from the inflation device (syringe (48)) through the hub (36), to balloon (14)." Pet. 60 (citing Ex. 1009, 10:36–40; Ex. 1003 ¶ 147) (alteration in original).

d. Element [1c] – "a proximal catheter section in fluid communication with the proximal hub"

Petitioner asserts that Eliason discloses that "[p]roximal end (52) of balloon shaft (32) is attached to hub (36)" and that "[h]ub (36) is 'in fluid communication' with both the proximal end of the balloon shaft (32) (proximal catheter section) and the syringe (48)." Pet. 61 (citing Ex. 1009, 10:17–20, Figure 10, 11:33–36; Ex 1003 ¶ 148).

e. Element [1d] – "a distal catheter section distally terminating with an atraumatic tip"

Petitioner asserts that Eliason discloses that the "distal end of the catheter terminates with a 'J tip' (20), which is 'used to minimize trauma to or perforation of the arterial vessels' during use of the catheter." Pet. 61–62 (citing Ex. 1009, 8:47–49, Figure 6, Ex. 1003 ¶ 149).

f. Element [1e] – "an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being compliant"

Petitioner asserts "Eliason describes its balloon as an 'arterial occlusion balloon' and an 'aortic occlusion balloon' (14). Ex-1009, 6:56-63,

9:31-33. Figures 6 and 10 show balloon (14) connecting the proximal section (32) of the catheter with the distal section of the catheter.

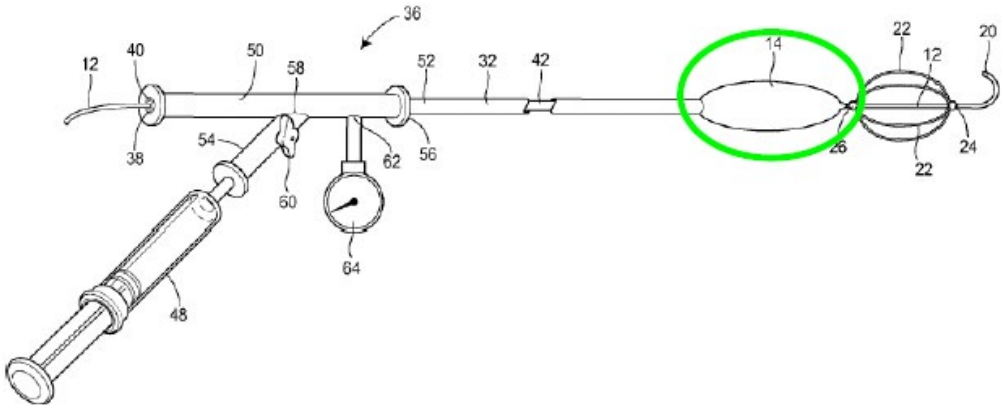


FIG. 10

Ex-1009, Fig. 10 (annotated). Eliason describes balloon (14) as 'sufficiently compliant.'" Pet. 62–63 (citing Ex. 1009, 4:54–61; Ex. 1003 ¶ 150).

g. Element [1f] – "at least one length marking on an exterior of the proximal catheter section to indicate an insertion depth of the occlusion catheter system"

Petitioner asserts "Eliason describes 'pre-calibrated length indicia,' which include both 'minor length markers' (34a) and 'major length markers' (34b) in 5-centimeter increments." Pet. 63 (citing Ex. 1009, 9:31–35). Petitioner asserts that "[w]ith these length markers, a physician can use a correlation chart or 'nomogram' in order to properly position the aortic occlusion balloon at the desired location within the thoracic aorta." *Id.* at 64 (citing Ex. 1009, 10:53–64; Ex. 1003 ¶ 151).

h. Element [1g] – "a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon"

Petitioner asserts that Eliason discloses that "a lumen is used to expand and deflate the balloon; this lumen extends from the fluid source,

namely the syringe (48), to the balloon (14). . . . To extend from the syringe to the balloon, this lumen must extend through the hub (36) and the proximal catheter section." Pet. 64 (citing Ex. 1009, 5:64–6:1, Figure 10; Ex. 1003 ¶ 152).

i. Element [1h] – "solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon and into the distal catheter section"

Petitioner asserts "Eliason describes an 'endovascular wire' (12) that extends from the proximal hub (50), through the proximal catheter section (32), the occlusion balloon (14), and the distal catheter section." Pet. 65 (citing Ex. 1009, 4:49–54, 10:29–32). Petitioner asserts "[a]lthough Eliason does not explicitly state that the wire (12) is solid, a PHOSITA recognizes that a wire that provides rigidity to the catheter would be solid and not hollow." *Id.* at 66 (citing Ex. 1003 ¶ 153).

j. Element [1i] – "the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration"

Petitioner asserts that Eliason discloses that "the various elements of the catheter, including the leading securement bead (24), the trailing securement bead (26), and the unexpanded occlusion balloon (14) are all of sufficiently small cross-sectional dimensions to pass through a sheath (28), which is preferably a six French (Fr) sheath." Pet. 71–72 (citing Ex. 1009, 9:12–27; Ex. 1003 ¶ 161).

k. Motivation to modify Eliason

Petitioner asserts

> a PHOSITA would have been motivated to modify Eliason's pre-securing embodiments to secure the proximal-most end of a wire to the hub because this modification represents known concepts (i.e., Eliason's securing the wire so that it is fixed in place with respect to the hub and the PHOSITA's knowledge that the proximal-most end of the wire could be secured within the proximal hub) combined in familiar ways (i.e., according to Fogarty, Smith, or Nishide), which, when combined, would yield predictable results (i.e., allowing the catheter to be inserted as a single unit or device).

Pet. 70 (citing Ex. 1004; Ex. 1017; Ex. 1025). Petitioner further asserts "[a]n additional benefit would likely be the simplification of manufacturing the device since Eliason's 'fluid-tight' diaphragm connection would no longer be necessary." *Id.* at 71 (citing Ex. 1003 ¶ 160).

2. Claim 1

a. "distal catheter section distally terminating with an atraumatic tip"

Patent Owner asserts "[i]ndependent claim 1 recites and separately names '***a distal catheter section*** distally terminating with an atraumatic tip' and '***a solid wire***, secured at a proximal-most end thereof within the proximal hub, and ***extending*** . . . ***into the distal catheter section***.'" PO Resp. 50 (citing Ex. 1001, claim 1) (second alteration in original). Patent Owner asserts "Petitioner conspicuously does ***not*** identify any reference numerals in Eliason corresponding to the claimed distal catheter section, despite doing so for other claim elements." *Id.*

Patent Owner asserts that a "PHOSITA understands a 'distal catheter section' as being a distally-located section of the catheter shaft itself, ***not*** just

any distally-located components of an overall system." PO Resp. 51 (citing Ex. 2001 ¶¶ 45, 106).

Patent Owner asserts that a "PHOSITA would ***not*** consider any of the components in Eliason's Fig. 6 circled by Petitioner to constitute a 'distal catheter section.'" PO Resp. 52 (citing Ex. 2001 ¶ 109). Patent Owner asserts "Dr. Resnick himself admits that Eliason's catheter is distinct from the endovascular wire over which it slides." *Id.* (citing Ex. 1003 ¶ 144). Patent Owner asserts a "PHOSITA also would not correlate the other circled components highlighted by the PTAB (*i.e.*, the wire struts 22 and securement beads 24, 26) as forming a distal catheter section." *Id.* at 53 (citing Ex. 2001 ¶ 111).

Petitioner asserts

> 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.

Pet. Reply 29 (citing Ex. 1034 ¶ 136) (alterations in original). Petitioner asserts that 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." *Id.* at 29–30 (citing Ex. 1034 ¶ 133).

Patent Owner responds that "***Dr. Resnick's exact testimony states '[t]he catheter is the shaft of the device.'***" PO Sur-Reply 23 (citing Ex. 2002, 26:19–21) (alteration in original). Patent Owner asserts "Dr.

Resnick later referred to 'the catheter' and 'wire' as separate elements when discussing Eliason: 'wherein the device is a single unit and ***the catheter*** and ***associated wire device*** are all attached at the securement bead.'" *Id.* (citing Ex. 2002, 71:13–72:5).

Our analysis begins with the evidence of record regarding "distal catheter section." As discussed above in section IV.C.3., we interpreted "distal catheter section" as drawn to a distal section of a catheter tube and not to a distal section of the entire occlusion catheter system.

> Dr. Resnick states, regarding the "distal catheter section," that
>
> > Eliason discloses this element. The distal end of the catheter terminates with a "J tip" (20), which is "used to minimize trauma to or perforation of the arterial vessels" during use of the catheter. Eliason, 8:47-49 (Ex-1009). Thus, the catheter has a distal section (including the portions with the J tip and the wire struts) terminating with an atraumatic tip.

Ex. 1003 ¶ 149. Dr. Resnick's annotated Figure 6 of Eliason is reproduced below:

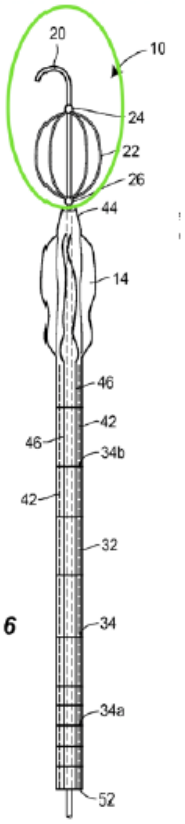


FIG. 6

The annotated Figure 6 shows a green circle around several elements and Eliason states "the J tip 20, the leading securement bead 24, the trailing securement bead 26, and the unexpanded occlusion balloon 14 (which is disposed proximate to the trailing securement bead 26 and illustrated in FIG. 6) are all of sufficiently small cross-sectional dimensions to pass through the sheath 28." Ex. 1009, 9:22–27. Dr. Resnick states that

> when the wire is pre-secured to the rest of the catheter (as in the presecured embodiment) and "inserted as a single unit or device" (Ex-1009 at 6:5–7), the catheter has a distal section (including the portions with the J tip, wire struts, and securement beads) terminating with an atraumatic tip (the J tip).

Ex. 1034 ¶ 135.

Dr. Cimino states "Dr. Resnick conspicuously does ***not*** identify any reference numerals in Eliason corresponding to the claimed distal catheter

section." Ex. 2001 ¶ 105 (citing Ex. 1003 ¶¶ 149, 153). Dr. Cimino states "[c]onsidering the components in Eliason identified by Dr. Resnick as being distally located from the balloon 14, none would be considered by a PHOSITA to constitute a 'distal catheter section.'" *Id.* ¶ 109.

Dr. Cimino states:

> Calling a portion of Eliason's endovascular wire 12 a "distal catheter section" has the added problem of conflicting with the '737 Patent's claim language. The distal catheter section must be separate from a solid wire since the claim calls for the solid wire to extend "into the distal catheter section." A portion of the solid wire being considered as a "distal catheter section" leads to the nonsensical result of the wire extending into itself. For these reasons, no part of Eliason's endovascular wire 12 can be considered as forming a distal catheter section.

Id. ¶ 110. Dr. Cimino states a "PHOSITA also would not consider the wire struts 22, leading securement bead 24, or the trailing securement bead 26 in Eliason as forming a distal catheter section either. Importantly, not only do none of these components meet the standard definition of a catheter, but each of these elements is formed ***on the endovascular wire***." *Id.* ¶ 111. Dr. Cimino further explains that "[a]s Dr. Resnick acknowledges, the J tip 20 is formed by the wire 12 – it is a curved shape introduced into the wire so that the terminal end of the wire 12 does not unintentionally poke a hole in a blood vessel." *Id.* ¶ 112 (citing Ex. 2002, 73:22–74:9; Ex. 1009, 8:45–52).

We find the evidence more persuasively shows that Eliason does not teach a "distal catheter section distally terminating with an atraumatic tip" because we are persuaded by Dr. Cimino's reasoning that a "portion of the solid wire being considered as a 'distal catheter section' leads to the nonsensical result of the wire extending into itself." Ex. 2001 ¶ 110. That is, if the Eliason's endovascular wire 12 that does terminate with an atraumatic

J tip 20 is the distal catheter section, then it cannot satisfy the limitation in claim 1 for "a solid wire . . . extending . . . into the distal catheter section" because that would require the wire to extend into itself. We note that Dr. Resnick does not address or rebut this reasoning directly. And, because we find, as discussed in IV.C.3 above, that the distal catheter section therefore must be part of the catheter itself (rather than catheter system), Eliason does not teach a "distal catheter section distally terminating with an atraumatic tip" as required by claim 1.

Accordingly, we find that Petitioner has not shown by a preponderance of evidence that Eliason teaches or suggests a "distal catheter section distally terminating with an atraumatic tip," as recited in claim 1 of the '737 patent. This, alone, is sufficient to find in favor of Patent Owner on this ground.

b. "flow valve" and "proximal hub"

Patent Owner asserts

> Petitioner contends that in Eliason "[t]he proximal hub is shown in Figure 10 as element 36, called the 'multi-port and valve assembly.'" Pet. at 60; Ex. 2001 at ¶ 94. Petitioner also contends that "Eliason utilizes a valve (60) that is 'actuable between an open condition … and a closed position' to permit or prevent the passage of inflation fluid." *Id.* The name of component 36 ("multi-port ***and valve*** assembly") itself identifies the assembly 36 as including the valve 60.

PO Resp. 54 (citing Ex. 2001 ¶ 94) (alterations in original). Patent Owner asserts "Petitioner, therefore, equates the same portions of Eliason with two separately claimed structures, again reading their relationship to one another out of independent claim 1 without any semblance of explanation or reasoning." *Id.* at 55 (citing Ex. 2001 ¶ 95).

Petitioner asserts "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." Pet. Reply 30.

Our analysis begins with the evidence of record regarding "flow valve" and "proximal hub." As discussed above in section IV.A.3., we interpreted "proximal hub" as an element that may connect an inflation device to the catheter's inflation lumen and that may also comprise sub-elements, including a "flow valve."

We therefore turn to whether Eliason teaches "proximal hub" with a "flow valve" sub-element as encompassed by claim 1 of the '737 patent. Dr. Resnick annotates Figure 10 of Eliason as reproduced below:

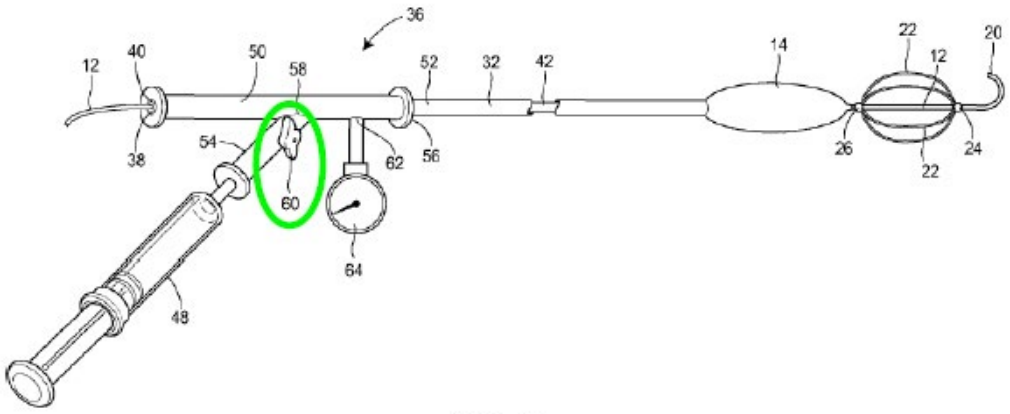


FIG. 10

Dr. Resnick states the "proximal hub in the Eliason catheter is shown in Figure 10 as element 36, which Eliason calls the 'multi-port and valve assembly.'" Ex. 1003 ¶ 146 (citing Ex. 1009, 10:7–9, Figure 10).

Dr. Resnick further states "Eliason utilizes a valve (60) that is 'actuable between an open condition…and a closed position' to permit or prevent the passage of inflation fluid" and valve 60 is circled in green in Figure 10. *Id.* ¶ 147 (citing Ex. 1009, 10:36–40) (alteration in original).

Dr. Cimino disagrees with our claim construction (Ex. 2001 ¶¶ 98–103), but Dr. Cimino also states that a "one-way valve 60, actuatable between open and closed positions to allow or prevent passage of inflation fluid, is provided directly on the branch 54 of the multiport and valve assembly 36." *Id.* ¶ 60.

Accordingly, we find that a preponderance of the evidence demonstrates that Eliason discloses that the proximal component of the catheter functions both as a hub for connecting a syringe and includes a flow valve allowing fluid to flow between the syringe and an inflation device.

3. Conclusion for Claim 1

Accordingly, because we disagree with Petitioner regarding Eliason's teaching of a "distal catheter section distally terminating in an atraumatic tip," we find that Petitioner has not demonstrated that a preponderance of the evidence supports a conclusion that claim 1 is unpatentable as obvious over Eliason.

4. Claim 2

While we find that Eliason does not render claim 2 obvious based on our finding that Eliason fails to teach a "distal catheter section distally terminating in an atraumatic tip" as required by claim 1 of the '737 patent, we recognize that the elements of claim 2 were disclosed in Eliason and the other cited prior art as discussed above for Grounds 2–4.

G. Grounds 6 – 9

As discussed above, we find that Eliason does not render the claims subject to these grounds obvious based on our finding that Eliason fails to teach a "distal catheter section distally terminating in an atraumatic tip" as required by claim 1 of the '737 patent.

VI. CONCLUSION

After considering the evidence and arguments presently before us in the complete trial record, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that Challenged Claims 1–10 are unpatentable.[17]

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not shown Unpatentable
1–10	103	Fogarty, Chengod	1–10	
2	103	Fogarty, Chengod, Saab	2	
3–5, 9	103	Fogarty, Chengod, Sanati	3–5, 9	
8	103	Fogarty, Chengod, Deaton	8	
1–10	103	Eliason		1–10
1–10	103	Eliason, Fogarty		1–10
2	103	Eliason, Saab		2
3–5, 9	103	Eliason, Scott		3–5, 9
8	103	Eliason, Joe		8
Overall Outcome			1–10	

[17] Should Patent Owner wish to pursue amendment of the Challenged Claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding, 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

IV. ORDER

In consideration of the foregoing, it is:

ORDERED that claims 1–10 of U.S. Patent 11,857,737 B2 are determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

FOR PETITIONER:

Brian Banner
SLAYDEN GRUBERT BEARD PLLC
bbanner@sgbfirm.com

James M. Urzedowski
Daniel A. Tysver
FORSGREN FISHER MCCALMONT DEMAREA TYSVER LLP
juredowski@forsgrenfisher.com
dtysver@forsgrenfisher.com

FOR PATENT OWNER:

Stephen E. Murray
John D. Simmons
Dennis J. Butler
Ragi A.I. Elias
PANITCH SCHWARZE BELISARIO & NADEL LLP
smurray@panitchlaw.com
jsimmons@panitchlaw.com
dbutler@panitchlaw.com
relias@panitchlaw.com