

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*.

DECISION
Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

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., filed a preliminary response. Paper 5 (“Prelim. Resp.”).

We have authority to determine whether to institute a post-grant review under 35 U.S.C. § 324. Institution of a post-grant review is authorized by statute when “the information presented in the petition . . . would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a) (2018). Applying that standard on behalf of the Director (37 C.F.R. § 42.4(a)) and in consideration of the Petition, Preliminary Response, and the evidence of record, we determine that the information presented shows that it is more likely than not that Petitioner would prevail in establishing unpatentability of at least one of claims 1–10 of the ’737 patent.

This decision to institute trial is not a final decision as to patentability of claims for which post-grant review is instituted. Our final decision will be based on the full record developed during trial.

II. 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.

III. RELATED PROCEEDINGS

Petitioner states, regarding related matters, that the ’737 patent is part of a family of patents including US 11,672,951 and US 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.

IV. THE ’737 PATENT

A. Background

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.*, 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 postrepair procedure to control hypotension.

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

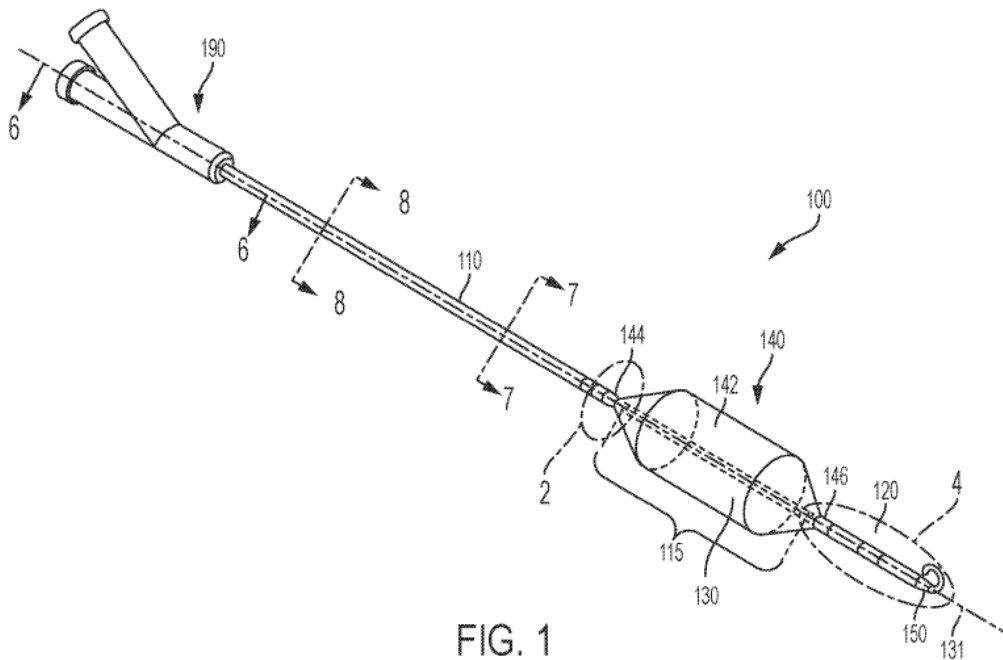


Figure 1 depicts “the vascular occlusion catheter system **100** generally includes a catheter assembly having a first catheter member **130** having a first lumen **230** . . . an occlusion member **140**, a proximal hub **190** and a guiding atraumatic tip **150**.” *Id.* at 21:65–22:4.

B. Post-Grant Review Eligibility

As a threshold issue, we must determine whether the '737 patent is eligible for post-grant review. There are two requirements that must be met for post-grant review to be available. First, post-grant review is only available if the petition is filed within nine months of the issuance of the challenged patent. 35 U.S.C. § 321(c). The petition was filed on May 6, 2024, which is within nine months of the '737 patent's January 2, 2024 issue date. Pet. 1; Ex. 1001, code (45).

Second, post-grant review is available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013 or later. *See* the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”) §§ 3(n)(1), 6(f)(2)(A). The earliest priority date recited for the ’737 patent are provisional applications US 62/135,528 and 62/135,603 filed on Mar. 19, 2015. Ex. 1001, code (60). Thus, the challenged claims all have a priority date after March 16, 2013, and this requirement is met. We apply the AIA version of 35 U.S.C. § 103 for the purposes of this Decision.

V. ILLUSTRATIVE CLAIM

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.

VI. ASSERTED GROUNDS

Petitioner contends that the challenged claims are unpatentable based on a number of grounds, as set forth in the following table. 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

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.

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 Dr. Sylvia Hall-Ellis. Ex. 1003; Ex. 1026.

VII. 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. 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[nd that 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). Patent Owner states that: “***Solely*** for purposes of this Preliminary Response, Patent Owner does not object to Petitioner’s definition of a PHOSITA. Patent Owner reserves the right to assert an alternative definition for a PHOSITA in this or another proceeding involving the ‘737 Patent, where appropriate.” Prelim. Resp. 12.

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.

Because Petitioner’s proposed level of ordinary skill in the art is undisputed and consistent with the cited prior art, we adopt it for purposes of this Decision.

VIII. 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.*

We first address the claim interpretation expressly raised by Petitioner. We then address implicit or inferred claim constructions raised by Patent Owner in their Preliminary Response.

Any claim construction arguments presented during trial should be set forth under a separate heading in the briefing and should not be relegated to or hidden within arguments relating to patentability challenges.

A. Proximal and Distal (recited in claims 1 and 8)

Petitioner submits that the ’737 patent expressly defines the claim terms “proximal” and “distal” as follows:

- “proximal”: “a portion or component of the preferred vascular occlusion catheter system that is oriented away from the body into which the system is or is intended to be placed.” Ex-1001, 21:52-56.
- “distal”: “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.” Ex-1001, 21:56-60.

Pet. 9.

Patent Owner states “at this stage of the proceeding, and *solely* for purposes of this Preliminary Response, Patent Owner does not object to Petitioner’s proposed constructions.” Prelim. Resp. 13.

For purposes of this Institution Decision, we preliminarily accept and adopt Petitioner’s claim interpretation of the terms “proximal” and “distal,” which is based on the express definition of these terms in the ’737 patent specification, as cited in the quoted portion of the Petition, above. As here, “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005).

B. Hub and Flow Valve (recited in claims 1 and 10)

In Patent Owner’s preliminary response, the terms “hub” and “flow valve” are addressed (*see* Paper 5, 18–23). Patent Owner does not expressly identify a specific definition of these terms in the ’737 patent. However, in order to properly analyze these claims in light of the prior art, we perform a preliminary claim interpretation of these terms, which may be changed or supplemented subject to additional evidence and argument as adduced during trial proceedings.

Patent Owner states that claim 1 of the ’737 patent “separately names (i) a **proximal hub** and (ii) a **flow valve** as part of the occlusion catheter system. Ex. 1001 at cl. 1. Claim 1 further recites that the flow valve ‘is configured *to selectively fluidly communicate the proximal hub with an inflation device.*’ *Id.*” Prelim. Resp. 18. Patent Owner cites *Becton* for the proposition that “[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).

Patent Owner notes that Petitioner finds the *proximal hub* is composed of multiple components, specifically quoting Petitioner’s assertion that “[t]he proximal hub is the assembly comprising the ***shut off valve (30)***, rotatable valve member (31), syringe fitting (32), and hub flange elements (43).” Prelim. Resp. 19 (citing Pet. 33).

Patent Owner points to the ’737 patent’s drawings and states “none show or are described as having any type of selectively actuatable valve forming part of the hub itself. *See e.g.*, Ex. 1001 at 25:60-26:12, 31:12-42, 35:4-43, Figs. 1, 6, 12, 17.” Prelim. Resp. 20–21. Patent Owner also states that “examples in the specification of actuatable valves for selectively fluidly communicating the proximal hub to an inflation device (e.g., fluid source) are described as separate from an occlusion catheter (710) containing the proximal hub, rather than coextensive with or as part of the proximal hub.” *Id.* at 21.

We find that the evidence currently of record reasonably supports an interpretation where the claimed *proximal hub* and *flow valve* may be in an element/sub-element relationship where the recited *flow valve* is a portion of the recited *proximal hub*.

We first turn to the ’737 patent specification which is here, as “[i]n most cases, the best source for discerning the proper context of claim terms.” *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004).

The ’737 patent 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 [] may or may not include guide wire lumen or a working lumen.” Ex. 1001, 21:17–22. The ’737 patent describes the “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.

The ’737 patent explains that a “preferred 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.

Based on these statements, the ’737 patent demonstrates that a *proximal hub*, as claimed, may include sub-elements such as a pressure relief member that is a *valve* or an inflation connection port, among other possibilities. Ex. 1001, 21:9–22, 30:8–10. The ’737 patent also describes that a *proximal hub* may itself be configured as a *valve*. *Id.* at 60:8–12.

Citing *Becton*, 616 F.3d at 1254, Patent Owner contends that when a claim lists elements separately, that an accused device cannot infringe that claim if it does not also contain separate elements corresponding to the claimed elements. *See, e.g.*, Prelim. Resp. 19. Here, the disclosure in the ’737 patent specification cuts against Patent Owner’s argument 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 that may be reasonably understood as “flow valves.” Ex. 1001, 30:8–10, 60:8–12.

In *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011), the claims were 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 that “[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 precedent indicates that separately recited claim elements may sometimes refer to parts or sub-parts of one structure.

Similarly in *Google*, the Federal Circuit found the evidence supported a broad reading of the claim language because the language

places no constraint on the manner in which the 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.

Google LLC v. EcoFactor, Inc., 92 F.4th 1049, 1058 (Fed. Cir. 2024).

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.* The facts of *Google* appear similar to those here, where the full scope of claim 1 could encompass a proximal hub with an integrated valve as discussed in the ’737 patent’s specification. Ex. 1001, 30:8–10, 60:8–12.

To reiterate, 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.

Indeed, Figure 42A of the '737 patent contradicts Patent Owner's position that "none [of the figures] show or are described as having any type of selectively actuatable valve forming part of the hub itself." Prelim. Resp. 20–21. To illustrate this, Figure 42A is reproduced below:

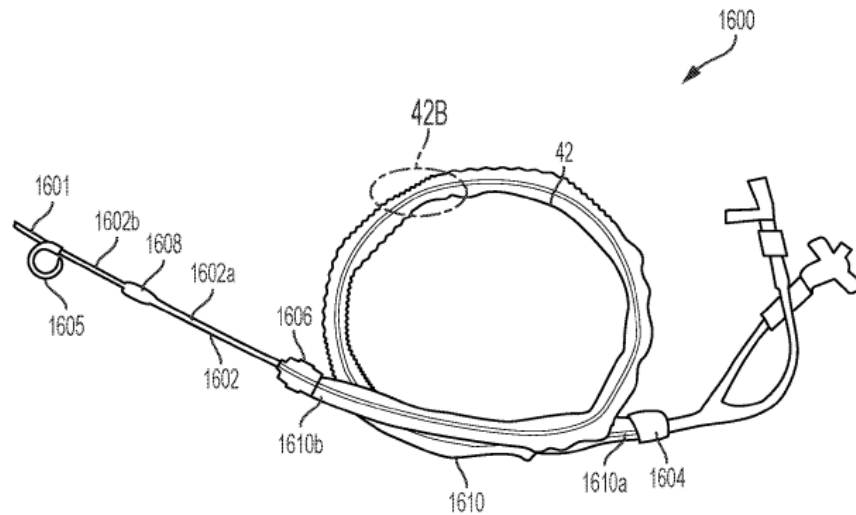


FIG. 42A

Figure 42A of the '737 patent depicts that a “preferred 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.” Ex. 1001, 60:8–12. Figure 42A expressly depicts that a proximal hub member 1604 may also be a hemostatic valve. *Id.*

This understanding of the term “hub” is consistent with Dr. Resnick’s statement that:

A PHOSITA reviewing the Fogarty reference would recognize that the elements 30, 31, 32, and 43 comprise a hub that is on the proximal (away from the patient’s body) end of the catheter. ’737 Patent, 21:52-64 (Ex-1001). A PHOSITA understands these elements are a “hub” because these elements are designed to remain outside the body during use and are used to physically connect an inflation device (e.g., syringe (35)) to the inflation lumen of the catheter.

Ex. 1003 ¶ 74.

For purposes of this Institution Decision, we preliminarily interpret the claim terms “proximal hub” and “flow valve” consistent with the specification of the ’737 patent as broad enough to encompass situations where the “proximal hub” and “flow valve” are separate elements and also where the “flow valve” is a sub-element portion of the “proximal hub.”

C. “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” (recited in claim 1)

In Patent Owner’s preliminary response, the phrase “configured to selectively fluidly communicate the proximal hub” is addressed, even though Patent Owner does not identify a specific definition for any of the terms in the ’737 patent. Prelim. Resp. 14–18. Patent Owner states:

Independent claim 1 of the ’737 patent requires ***both*** ‘a flow valve ***configured to selectively fluidly communicate the proximal hub with an inflation device***’ and ‘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.***” Ex. 1001 at cl. 1.

pathways, 192 and 194. These two fluid entry ports lead to two separate lumens within the catheter, as the '737 patent specification states a “first fluid pathway 192 communicates with the first lumen 230 of the first catheter member and a second fluid pathway 194 communicates with the second lumen 210 of the second catheter member 120.” *Id.* at 26:1–4.

Thus, there is not necessarily incompatibility in a flow valve and a solid wire coexisting, as the wire may extend in one fluid pathway while a flow valve controls the other fluid pathway. We also note that no location for a flow valve is explained with regard to Figure 6. The '737 patent specification shows the use of inflation control systems in Figure 40, which includes selector valve 1504 that “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. Thus, the '737 patent's specification reasonably envisions flow valves not incorporated into the proximal hub at all, but external to the proximal hub.

Furthermore, we do not agree with Patent Owner's use of the word “while” in interpreting the claim limitation. That is, Patent Owner's interpretation requires that the flow valve necessarily be operative at the same time a wire is within the proximal hub. However, Patent Owner's interpretation imposes a method step into a system claim. The patentability of an apparatus claim “depends on the claimed structure, not on the use or purpose of that structure.” *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). Here, the “configured to” language in claim 1 of the '737 patent reasonably encompasses a number of situations, including like that depicted in Figure 6, with a wire in one of multiple flow paths, or where a wire is present before or after a flow valve is operative.

For purposes of this Institution Decision, we preliminarily interpret the claim term “configured to selectively fluidly communicate the proximal hub” consistent with the specification of the ’737 patent to encompass a valve that controls the flow of fluids to a proximal hub during any part of a procedure and that may also, simultaneously or at some different time, include a wire within the proximal hub.

D. “a distal catheter section” (recited in claim 1)

In Patent Owner’s Preliminary Response, the claim term “a distal catheter section” is addressed, although Patent Owner does not identify a specific definition of any of the terms in the ’737 patent. *See* Prelim. Resp. 25–29). Patent Owner states “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***’. Ex. 1001 at cl. 1.” *Id.* at 25. Patent Owner asserts “the claim language further defines a functional relationship between them, *i.e.*, the solid wire extends into the independently listed distal catheter section.” *Id.*

We have already interpreted the claim term “distal” above as the ’737 patent Specification 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. Thus, according to the ’737 patent, “distal catheter section” refers to a portion of the system that is at the distal end.

Our reading of the '737 patent finds the term “distal catheter section” only in the claims. *See generally* Ex. 1001. The '737 patent specification states, “the devices comprise an elongate catheter having a proximal and a distal region An expandable occlusion member, e.g., a balloon, a membrane with or without an expandable frame or an expandable section of the catheter itself, is carried at the distal region of the catheter.” *Id.* at 5:20–26. Thus, this language is reasonably interpreted as meaning that a “section” of the catheter simply refers to any portion of the device as a whole. The plain meaning of the term “section” is “one of the parts that something is divided into.”⁹

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

E. Conclusion

At this point, we interpret only the claim language discussed above. We determine that we currently need not expressly construe any other claim terms for the purpose of deciding whether to institute post-grant review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 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.’”)

⁹ *See* <https://dictionary.cambridge.org/us/dictionary/english/section>. [Accessed Oct. 14, 2024]. Ex. 3002.

(quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Any final written decision entered in this case may include final claim constructions that differ from the preliminary understanding of the claims set forth above. Any final claim constructions will be based on the full trial record.

X. PRELIMINARY ANALYSIS OF PETITIONER'S 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;¹⁰ and (4) considering objective evidence indicating obviousness or non-obviousness.¹¹ *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.” *Id.* 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 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

¹⁰ See *supra* Section II.A.

¹¹ There is no asserted evidence pertaining to objective indicia of non-obviousness. See *generally* Prelim. Resp.

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 original)).

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish that it would more likely than not prevail at trial.

B. Overview of the Asserted Prior Art

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

1. *Fogarty (Ex. 1004)*

Fogarty is a U.S. patent that issued on September 30, 1965. Ex. 1004, front page. Fogarty discloses

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 1:59–63. Figure 1 of Fogarty is reproduced below:

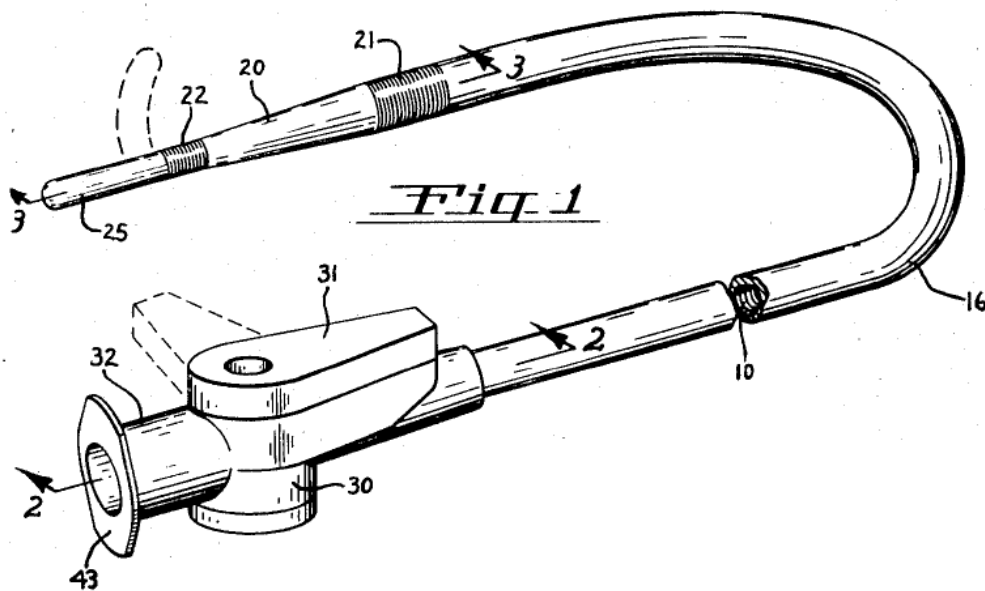


Figure 1 illustrates a catheter “on a core 10 comprising a coil of spring wire . . . covered with a braid 15 of suitable non-reactive and non-hygroscopic material” that is “covered with an outer plastic tube 16 which is drawn on over the braid and positioned with its distal end at 17.” *Id.* at 2:40–63. 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 2:43–47. 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.”

Id. 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:

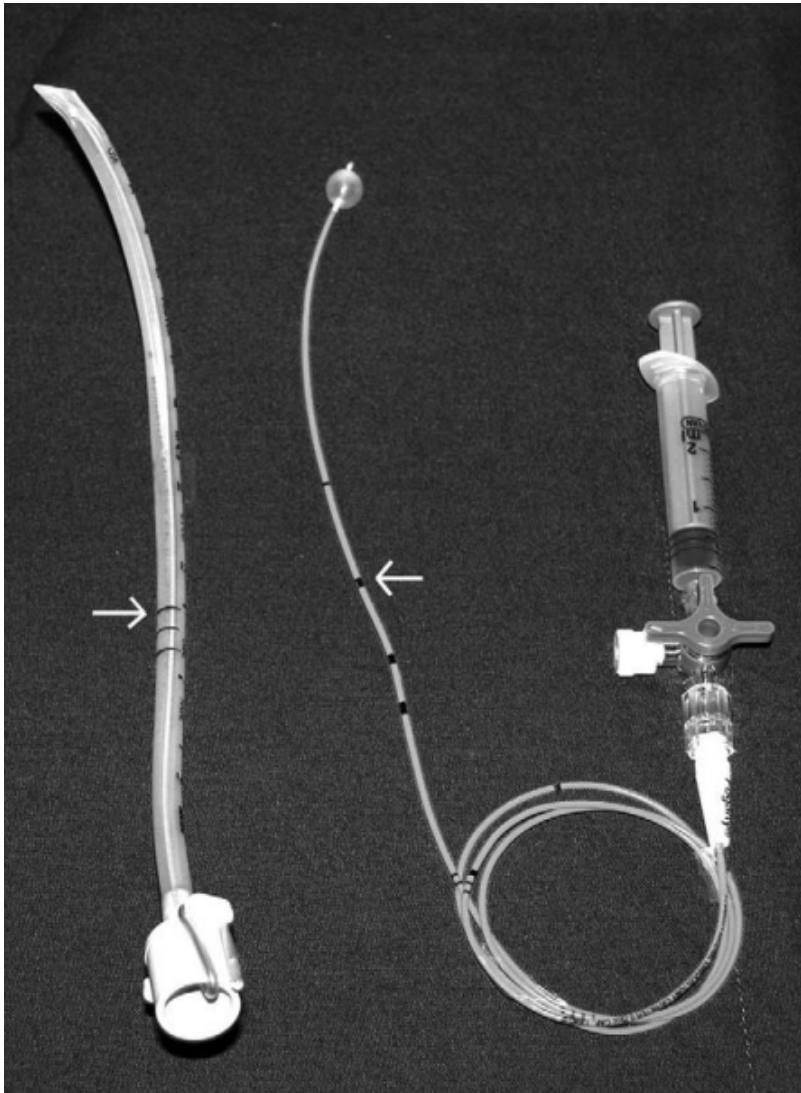


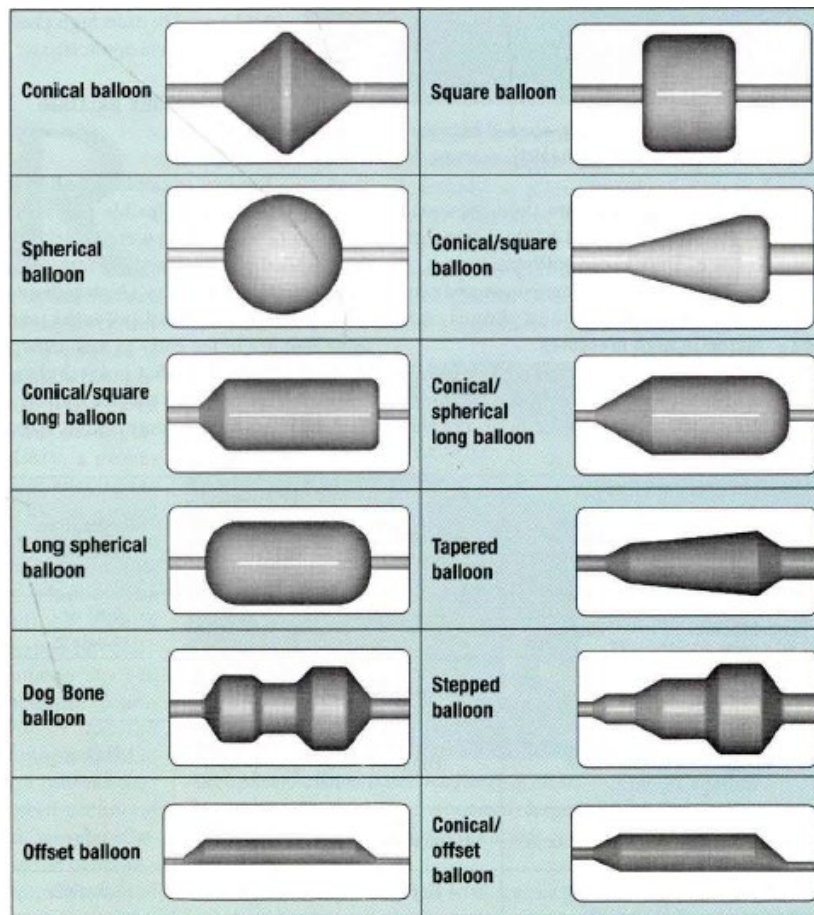
Fig 1. Endotracheal tube modified to resemble a left-sided double-lumen tube with the help of a stylet. Note the bevel of the tube facing toward the right side. Carinal distance is marked on the tube and the catheter as measured from the tip (Arrows). The second and third markings on the catheter, from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

Id. at 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.)” *Id.* at 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:

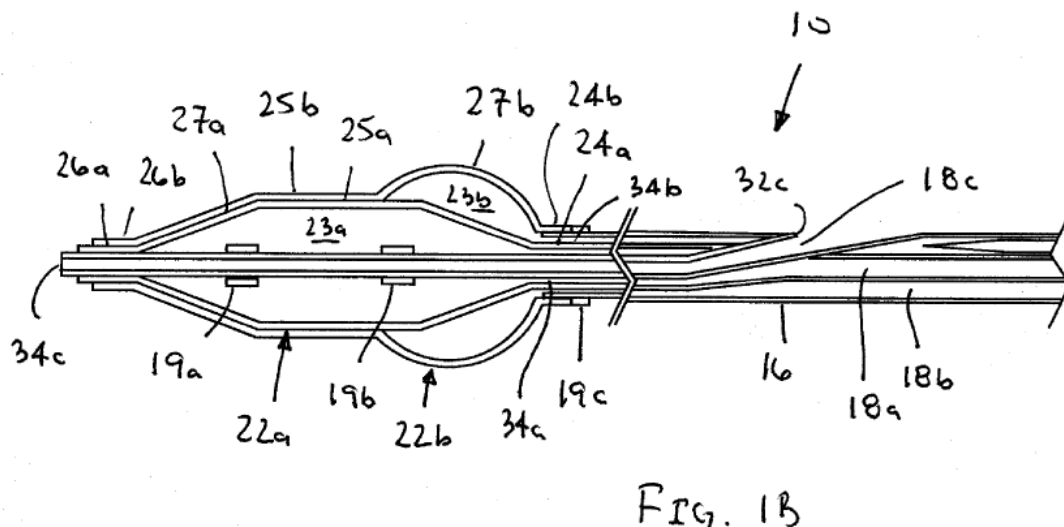


FIG. 1B

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. 1012)*

Eliason is an U.S. patent that issued on September 15, 2015.

Ex. 1009, codes [10], [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.” Ex. 1009, 1:29–32.

Figure 10 of Eliason is reproduced below:

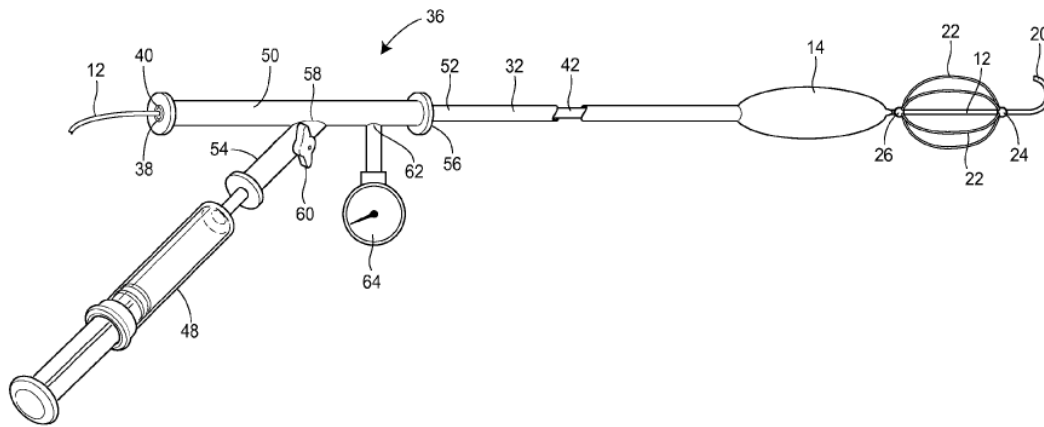


FIG. 10

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.”

Id. at 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:

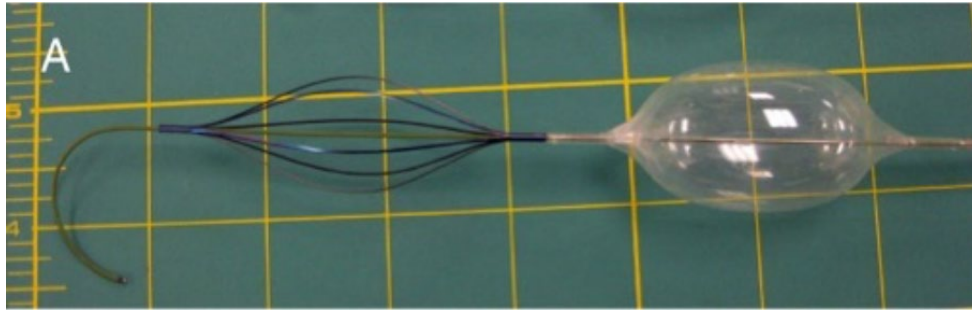


Figure 1A depicts a “[s]ingle component PBS designed to be positioned and inflated without fluoroscopy. The lead or insertion end is a floppy tipped 0.035-inch wire fused to the compliant balloon catheter. A collapsible nitinol rail system is positioned between the floppy tip of the wire and the compliant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

8. *Joe (Ex. 1011)*

Joe is a U.S. patent application publication that was published on May 14, 2015. Ex. 1011, codes [10], [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.

1. 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. *Id.*, 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 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, Fig. 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 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, Fig. 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.” Pet. 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 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. *Analysis of Claim 1*

Based on the preliminary record, Petitioner has met its institution burden and demonstrated that it is more likely than not that it will prevail in showing the claim 1 would have been obvious over Fogarty and Chengod. We address Patent Owner’s arguments below.

a. *Flow valve and wire extending within catheter*

Patent Owner asserts that in Fogarty:

During use of the catheter, the valve 30 can be actuated between the open position (during balloon inflation) and the closed position (for holding the inflation), but during non-use, the valve 30 **must** remain open or else the stylet 40 **cannot be inserted**. Likewise, when the stylet 40 is in the catheter, the valve 30 must remain open and may not close because the stylet 40 blocks rotation of the valve 30.

Prelim. Resp. 16. Patent Owner asserts that “not only is the valve 30 **not selectively actuatable** between open and closed positions when the stylet 40 is present, but Fogarty’s catheter **cannot** utilize the stylet 40 **while also** fluidly connecting to the syringe 35, as both components require availability of the same syringe fitting 32.” *Id.* at 17. Patent Owner asserts “Fogarty does **not** disclose or suggest the valve and wire features as arranged in claim 1.” *Id.* at 17–18.

On the current record, we do not find Patent Owner’s argument persuasive because, based on our preliminary claim construction of the phrase “configured to selectively fluidly communication the proximal hub,” we do not agree that claim 1 of the ’737 patent requires “a functional flow

valve *while* also employing a solid wire extending within the catheter.” *See* Prelim. Resp. 14; *see also supra* claim construction Sections VIII.B and VIII.C. As discussed in our claim construction above, the “configured to” language in claim 1 of the ’737 patent reasonably encompasses a number of situations, including where the wire is present at a time different than when the flow valve is operative.

To be clear, as we interpret the system claim 1 of the ’737 patent on the current record and understand Fogarty, it is the claimed system as a whole that must include a “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” and a “solid wire, secured at a proximal-most end thereof within the proximal hub.” As discussed above, Fogarty appears to teach this as a valve 30 and solid wire stylet 40. *See, e.g.*, Ex. 1004, 3:38–52.

Patent Owner does not dispute that Fogarty teaches both a solid wire and a flow valve, but rather asserts that when the solid wire is inserted, the flow valve cannot operate. But this is not a requirement of claim 1 of the ’737 patent. Claim 1 of the ’737 patent is not a method claim and, therefore, does not require any particular use of the recited components, and specifically, does not require that the solid wire is always present within the proximal hub when the flow valve is operated.

As of the filing date of this application, an ordinary artisan would understand that a “valve” is “a device that opens and closes to control the flow of liquids or gases.”¹² Therefore, the “configured to” “selectively fluidly communicate” language in claim 1 of the ’737 patent “is merely a

¹² *See* <https://dictionary.cambridge.org/us/dictionary/english/valve> [Accessed October 14, 2024]. Ex. 3001.

statement of intended use and does not qualify or distinguish the [] apparatus claimed over the reference.” *In re Sinex*, 309 F.2d 488, 492 (CCPA 1963).

“That rule is grounded in the statutory distinction, in identifying the permissible subject matter of a patent claim, between a physical product (which may be defined in part by its claimed functional capabilities) and activities that constitute a process (which may include a new “use” of a known invention).” *Arctic Cat Inc. v. GEP Power Products, Inc.*, 919 F.3d 1320, 1328 (Fed. Cir. 2019). The rule against giving invention-defining effect to intended-use language “reflects a longstanding substantive aspect of the patent statute—specifically, the ‘well settled’ fundamental principle ‘that the recitation of a new intended use for an old product does not make a claim to that old product patentable.’” *Id.* (citing *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997)).

Therefore, on the current record, we find that Petitioner has shown sufficiently that Fogarty teaches a “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” and a “solid wire, secured at a proximal-most end thereof within the proximal hub.” Pet. 33, 38–39 (citing Ex. 1004, 3:60–63, 43:48–54; Ex. 1003 ¶¶ 74, 89).

b. Single element of Fogarty applied to both proximal hub and flow valve

Patent Owner asserts “[c]laim 1 also recites and separately names (i) a **proximal hub** and (ii) a **flow valve** as part of the occlusion catheter system.

Ex. 1001 at cl. 1.” Paper 5, 18. Patent Owner asserts:

Attempting to apply Fogarty to claim 1, Petitioner contends that “[t]he proximal hub is the assembly comprising the **shut off valve (30)**, rotatable valve member (31), syringe fitting (32), and hub flange elements (43).” Pet. at 33 (emphasis added). Petitioner annotates Fogarty’s Fig. 1 (reproduced below) and

circles the components alleged to constitute the claimed proximal hub, confirming its position that the proximal hub includes the shut off valve 30. *Id.* . . . But Petitioner also contends that “***the [shut off] valve (30)*** is the claimed ‘flow valve’ and is ‘configured to selectively fluidly communicate the proximal hub with an inflation device’.” *Id.* at 33-34 (emphasis added). Thus, Petitioner relies on the shut off valve 30 for ***both*** the proximal hub and the flow valve, which is improper.

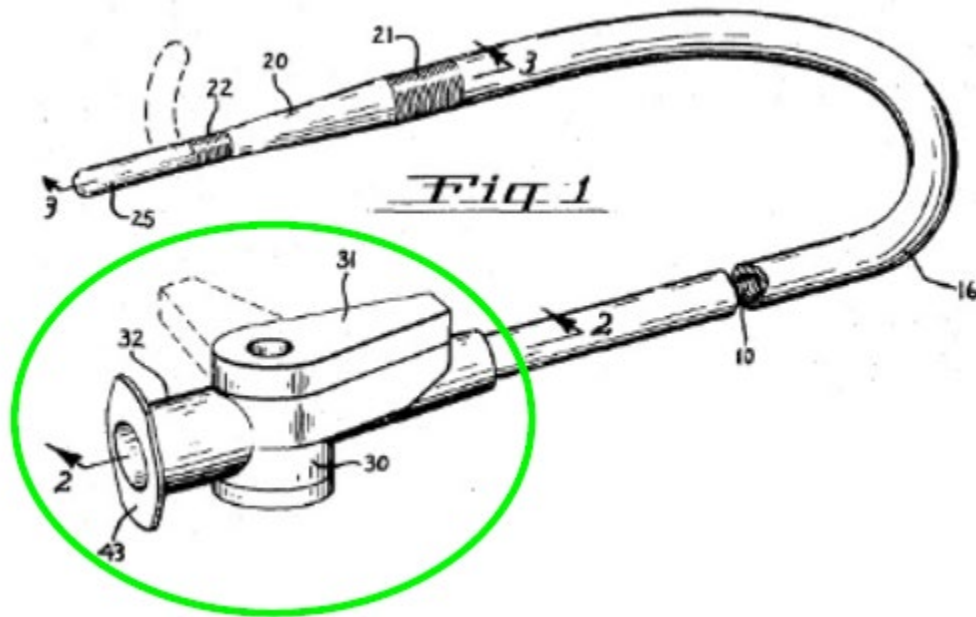
Id. at 19–20.

On the current record, we do not find Patent Owner’s argument persuasive based on our preliminary claim construction of the terms “proximal hub” and “flow valve” discussed above. Specifically, we found that the evidence currently of record reasonably supports an interpretation of a proximal hub and flow valve as being in an element/sub-element relationship where the flow valve is a portion of the hub. In particular, the ’737 patent demonstrates that a proximal hub may include sub-elements such as a pressure relief member that is a valve or an inflation connection port, among other possibilities. Ex. 1001, 21:9–22, 30:8–10. The ’737 patent states that a proximal hub may itself be configured as a valve. *Id.* at 60:8–12. Figure 42A expressly depicts a proximal hub member 1604 may also be a hemostatic valve. *See id.* at 60:8–12.

Our view is bolstered by the analysis of the Federal Circuit of “fluid communication” in *Powell*, which stated “[n]or are we convinced that the claim language ‘in fluid communication’ requires that ‘cutting box’ and ‘dust collection structure’ be wholly separate structures.” *Powell*, 663 F.3d at 1232; *see also supra* at 12–13 (claim construction section).

On the current record, we find that Petitioner has sufficiently shown a proximal hub composed of multiple elements in an element/sub-element

relationship as shown in Petitioner's annotation of Figure 1 of Fogarty reproduced below:



“The proximal hub is the assembly comprising the shut off valve (30), rotatable valve member (31), syringe fitting (32), and hub flange elements (43). A PHOSITA would recognize that the depicted elements comprise a hub positioned on the proximal end of the catheter. Ex-1004, 3:60-63. Ex-1003 ¶74.” Pet. 33.

That is, the proximal hub disclosed in Fogarty is an element composed of four sub-elements: a shut off valve 30, a rotatable valve member 31, a syringe fitting 32 and hub flange elements 43. On the current record, we disagree with Patent Owner's assessment that this reliance on Fogarty's teaching of a hub that contains a valve is improper. In *Becton*, the specification addressed a “hinged arm” and “a spring means” and confirmed “that the spring means is a separate element from the hinged arm.” *Becton*, 616 F.3d at 1254. *Becton* did not address the element/sub-element

relationship of claimed features, while *Powell* found that two claimed components need not be wholly separate structures. *Powell*, 663 F.3d at 1232.

Moreover, the '737 patent specification states that a “preferred 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.” Ex. 1001, 60:8–12. That is, the instant specification recognizes that a hub may incorporate a valve in a similar way to that shown in Fogarty.

Therefore, on the current record, we find that Petitioner has shown that Fogarty teaches a “proximal hub” and a “flow valve” that satisfy the recitations of claim 1 of the '737 patent. Pet. 33–34 (citing Ex. 1004, 3:38–48, 3:60–63; Ex. 1003 ¶¶ 74–75).

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

Patent Owner asserts:

The flow valve in claim 1 of the '737 Patent is specifically “configured to ***selectively*** fluidly communicate the ***proximal hub*** with an inflation device.” Ex. 1001 at cl. 1 (emphasis added). Contrary to Petitioner’s analysis, this language requires ***more*** than just the flow valve being capable of selectively fluidly communicating the inflation device with components of the catheter system ***downstream of the proximal hub***, e.g., the proximal catheter section or any other distal component. Rather, in claim 1 the flow valve must be capable of selectively fluidly communicating the inflation device ***with the proximal***

hub itself as well as fluidly disconnecting the inflation device ***from the proximal hub itself***.

Paper 5, 22. Patent Owner asserts that Fogarty’s “valve fitting 32 (which Petitioner contends forms part of the proximal hub) is fluidly communicating with the syringe 35 (*i.e.*, the inflation device) immediately upon receipt, ***regardless of the condition of the shut off valve 30.***” *Id.* at 23.

On the current record, we find Patent Owner’s interpretation unpersuasive. First, the ’737 patent specification states:

Selective fluid flow through the perfusion openings may be accomplished in a number of alternative manners. For example, a plurality of perfusion lumens may be provided in the catheter. A first perfusion lumen communicating with the perfusion openings distal the first balloon, a second perfusion lumen communicating with the perfusion openings proximal the first balloon and intermediate the second balloon and the first balloon, and a third perfusion lumen communicating with the perfusion openings proximal the proximal balloon.

Ex. 1001, 6:36–45. This disclosure of “selective” fluid flow is referring to selection of which opening in the catheter is being used, and neither the ’737 patent specification nor the claims suggest that no liquid enters a hub including a valve. “[W]e decline to import a negative limitation into the claim that cannot be found in the claim language itself. *See Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1060 (Fed. Cir. 2009) (declining to add negative limitation to claim where ‘there is no basis in the patent specification’).” *Uniloc 2017 LLC v. Sling TV, LLC*, 2024 WL 4038034 *2 (Fed. Cir. 2024). Patent Owner identifies no basis for adding such a negative limitation to the claims that do not expressly recite it.

Second, Fogarty is reasonably understood to selectively allow fluid communication between the valve portion of the hub and any inflation

device, even if some amount of fluid may enter a portion of the hub by Fogarty's valve. Ex. 1004, 3:38–42. Fogarty's valve functions to allow or prevent inflation of the occlusion balloon. *Id.* This reasoning is consistent with that of the Federal Circuit in *Holness*, where a claim to an exercise machine with uninhibited movement was found to be obvious over the prior art because “the distinction [the inventor] seeks to establish is de minimis.” *In re Holness*, 612 Fed. Appx. 999, 1004 (Fed. Cir. 2015).

Third, the situation in Fogarty appears similar to that shown in Figure 42A of the '737 patent, reproduced below:

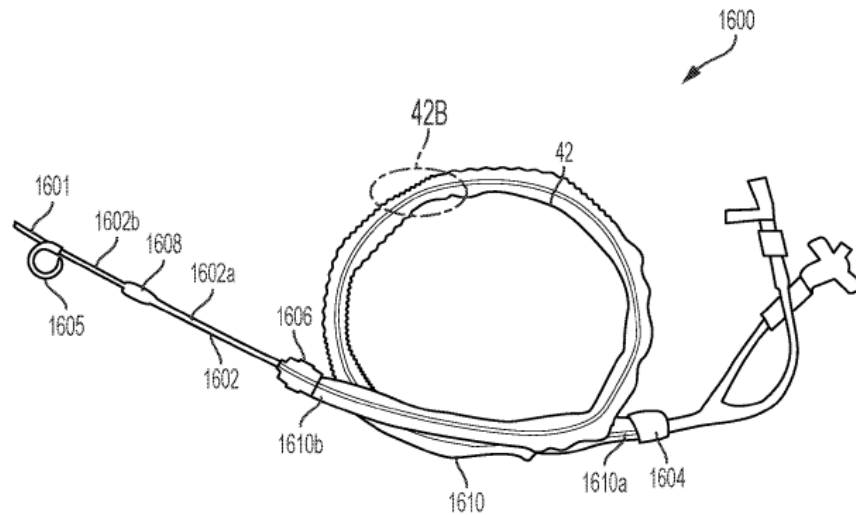


FIG. 42A

Figure 42A identifies hub member 1604 as also functioning as a hemostatic valve. *See* Ex. 1001, 60:8–12. Just as in Fogarty, the current evidence does not show that more than some small amount of inflation fluid could enter the edge of the valve in hub member 1604 prior to being under selective control of the valve itself. More evidence may be submitted during trial to address this question.

Therefore, on the current record, we find that Petitioner has shown that Fogarty teaches a “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” that satisfies the recitation in claim 1 of the ’737 patent. Pet. 33–34 (citing Ex. 1004, 3:38–48, 3:60–63; Ex. 1003 ¶¶ 74–75).

d. Conclusion for Claim 1

Accordingly, Petitioner has demonstrated, on this record, they will more likely than not prevail on their assertion that claim 1 would have been unpatentable as obvious over Fogarty and Chengod.

3. Claims 2–10

We find on this record that Petitioner comes forward with sufficient argument and evidence to show it is more likely than not that claims 2–10 would have been obvious over Fogarty and Chengod. *See* Pet. 41–46. Patent Owner does not, at this time, separately argue any of the dependent claims. *See generally* Prelim. Resp.

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

Under Ground 2, Petitioner challenges the patentability of claim 2 as obvious over Fogarty, Chengod, and Saab. *See* Pet. 2.

1. *Claim 2 – “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).”

Pet. 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.

Id. (citing Ex. 1003 ¶ 117).

Patent Owner does not, at this time, contest Petitioner’s assertions as to Ground 2, other than to raise the points made regarding the same art and Ground 1. *See generally* Prelim. Resp.

2. Conclusion for Claim 2

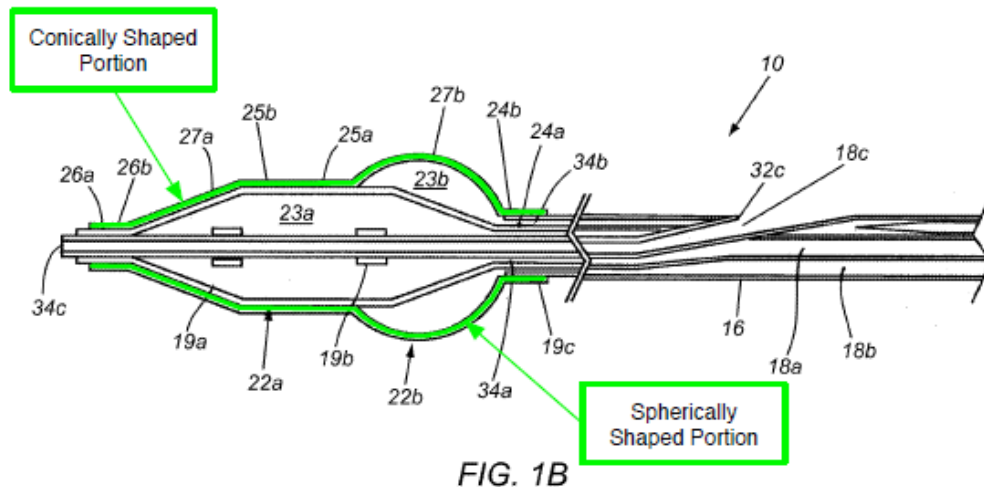
Accordingly, Petitioner has demonstrated, on this record, they will more likely than not prevail on their assertion that claim 2 is unpatentable as obvious over Fogarty, Chengod, and Saab.

E. Ground 3 – Obviousness over Fogarty, Chengod, Sanati

Petitioner asserts that claims 3–5 and 9 would have been obvious over the combination of Fogarty, Chengod, and Santi. Pet. 2.

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

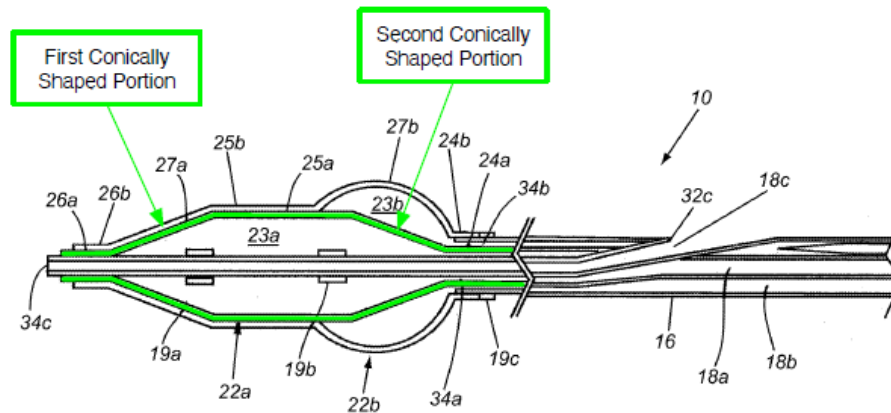
Petitioner asserts “Sanati Figure 1B shows a balloon with a conically shaped portion facing a spherical portion at element 22b:



Pet. 51 (citing Ex. 1007, Fig 1B annotated). 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:



Pet. 51–52 (citing Ex. 1007, Figure 1B annotated). 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:

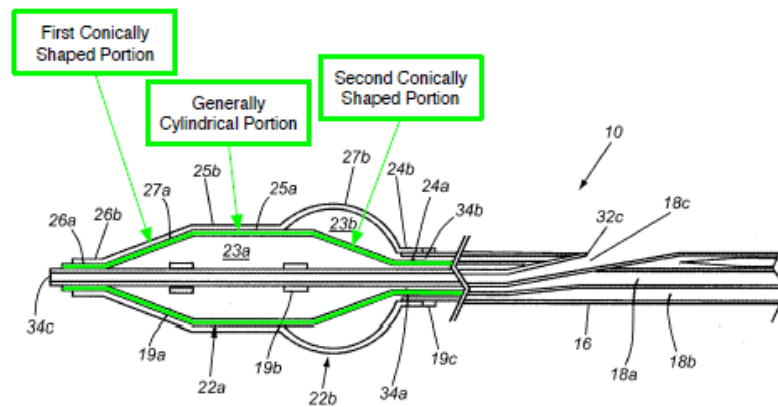


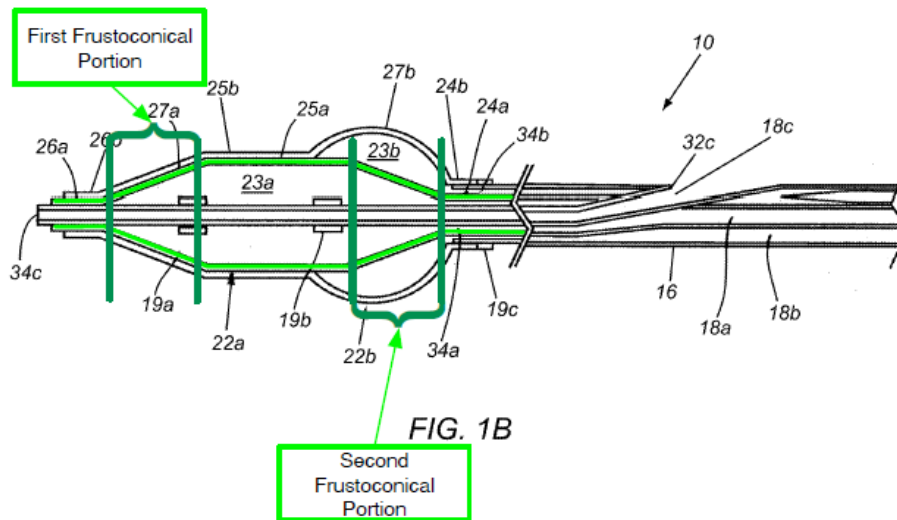
FIG. 1B

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:



Pet. 53–54 (citing Ex. 1007, Figure 1B annotated; Ex. 1003 ¶¶ 131–132). Figure 1B describes a first and second frustoconical portions of a balloon associated with a catheter system. *Id.*

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. *Conclusion for Claims 3–5 and 9*

Accordingly, Petitioner has demonstrated, on this record, they will more likely than not prevail on their assertion that claims 3–5 and 9 would have been unpatentable as obvious over Fogarty, Chengod, and Sanati. Patent Owner does not, at this time, separately argue these claims. *See generally* Prelim. Resp.

F. Ground 4 – Obviousness over Fogarty, Chengod, and Deaton

Petitioner asserts that claim 8 would have been obvious over Fogarty, Chengod, and Deaton. Pet. 2.

1. Claim 8

Petitioner asserts 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 [that] enable accurate visualization under fluoroscopy.’” Pet. 56 (citing Ex. 1008, 32). 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).

2. 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.

3. Conclusion for Claim 8

Accordingly, Petitioner has demonstrated, on this record, they will more likely than not prevail on their assertion that claim 8 is unpatentable as obvious over Fogarty, Chengod, and Deaton. Patent Owner does not, at this time, separately argue claim 8. *See generally* Prelim. Resp.

G. Ground 5 – Obviousness over Eliason

Petitioner asserts that claims 1–10 would have been obvious over Eliason. Pet. 2.

1. Claim 1

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

Petitioner asserts 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 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 ‘actuatable 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).

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

Petitioner asserts 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, Fig. 10, 11:33–36; Ex 1003 ¶ 148).

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

Petitioner asserts 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, Fig. 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.

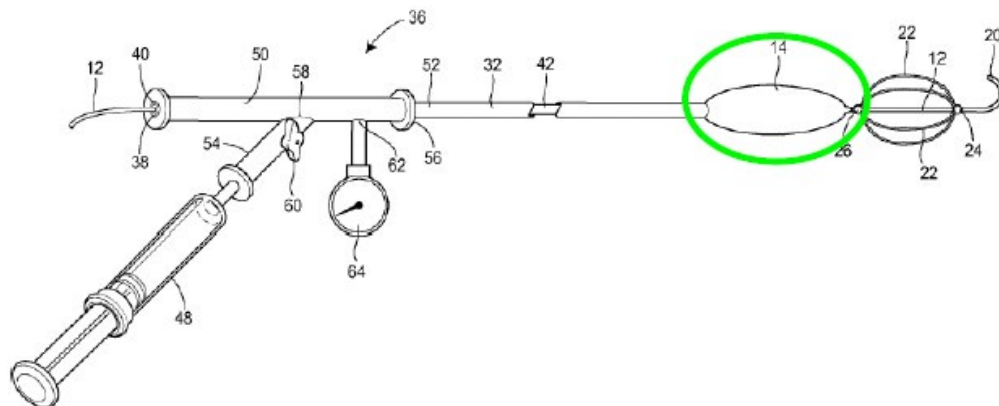


FIG. 10

Ex-1009, Fig. 10 (annotated). Figure 10 depicts an occlusion balloon 14 located between two portions of a catheter. *Id.* 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 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, Fig. 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 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, Smith¹³, or Nishide¹⁴), which, when combined, would yield predictable results (i.e., allowing the catheter to be inserted as a single unit or device).

Pet. 70. Petitioner further asserts “[a]n additional benefit would likely be the simplification of manufacturing the device since Eliason’s ‘fluid-tight’

¹³ Smith, C.E., US 5,087,246 A, issued Feb. 11, 1992. Ex. 1025.

¹⁴ Nishide et al., US 8,088,121 B2, issued Jan. 3, 2012. Ex. 1017.

diaphragm connection would no longer be necessary.” *Id.* at 71 (citing Ex. 1003 ¶ 160).

2. *Analysis of Claim 1*

Based on the preliminary record, Petitioner has met its institution burden and demonstrated that it is more likely than not it will prevail in showing claim 1 would have been obvious over Eliason. We have considered and address Patent Owner’s arguments below, but do not find any persuasive at this stage.

a. “*distal catheter section*” and “*solid wire*”

Patent Owner asserts:

Independent 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***”. Ex. 1001 at cl. 1 (emphasis added). Once again, two structures are not only recited separately from one another, but the claim language further defines a functional relationship between them, *i.e.*, the solid wire extends into the independently listed distal catheter section.

Prelim. Resp. 25.

Patent Owner asserts the “portion of Eliason’s occlusion system 10 that Petitioner equates with the distal catheter section and which terminates in the J-tip 20 ***is the endovascular wire 12 itself.***” *Id.* at 27. Patent Owner asserts that, “[t]herefore, Petitioner improperly equates a single element of Eliason, *i.e.*, the endovascular wire 12, with two separate and distinct elements of the claimed invention: the distal catheter section and the solid wire.” *Id.*

Patent Owner asserts that “[b]y equating the endovascular wire 12 with both the claimed distal catheter section and the claimed solid wire,

Petitioner’s position means the endovascular wire 12 extends into itself, a physical impossibility.” Id.

On the current record, we do not find Patent Owner’s argument persuasive based on our preliminary claim construction of the terms “distal section,” as discussed above. Specifically, we preliminarily interpreted the term “distal catheter section” of a catheter as reasonably comprising all elements that are located distal of the “intervening occlusion balloon” that connects the “proximal catheter section with the distal catheter section” of the catheter system as recited in claim 1.

Petitioner relies upon, in part, Figure 6 of Eliason to show the distal catheter section, which we reproduce below with Petitioner’s annotation. Pet. 61–62.

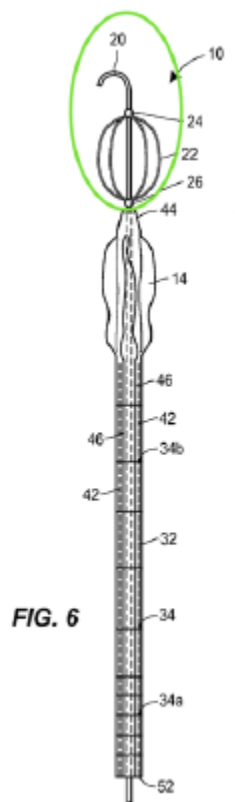


Figure 6 depicts a distal catheter section. *Id.* Petitioner annotates the entire portion distal to the occlusion balloon with a green oval, where Eliason teaches that Figure 6 includes “endovascular wire 12, the J tip 20, the leading securement bead 24, the trailing securement bead 26 . . . the wire struts 22” as elements distal to balloon shaft 44. Ex. 1009, 9:22–30, 53.

When this encircled section is viewed as the entire distal section, and the distal section is not limited to the wire and atraumatic tip alone, Eliason shows endovascular wire extending inside of the securement beads 24 and 26 and the wire struts 22 that also form the distal section of Eliason’s catheter in Figure 6. Ex. 1009, 9:22–30, 53.

We therefore are not persuaded by Patent Owner’s argument that the wire must extend into itself because it extends into other elements within the distal section.

Therefore, on the current record, we find that Petitioner has shown sufficiently that Eliason teaches a “distal catheter section” and “solid wire” where the wire extends into the distal catheter section that satisfies the recitation in claim 1 of the ’737 patent. Pet. 61–62, 65–69 (citing Ex. 1009, 4:49–54, 10:29–32, Fig. 6).

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

Patent Owner asserts

the flow valve in claim 1 is “configured to *selectively* fluidly communicate the *proximal hub* with an inflation device.” Ex. 1001 at cl. 1 (emphasis added). This claim language requires *more* than just the flow valve being capable of selectively fluidly communicating the inflation device with components of the catheter system *downstream of the proximal hub*.

Prelim. Resp. 29. Patent Owner asserts:

As clearly shown in Eliason's Fig. 10, reproduced and annotated below, the syringe 48 (*i.e.*, the inflation device) is fluidly communicated with the branch 54 of the multi-port and valve assembly 36 (which Petitioner contends is the claimed proximal hub) upon engagement therewith, ***irrespective of the condition of the valve 60***, which is downstream of the inlet of the branch 54.

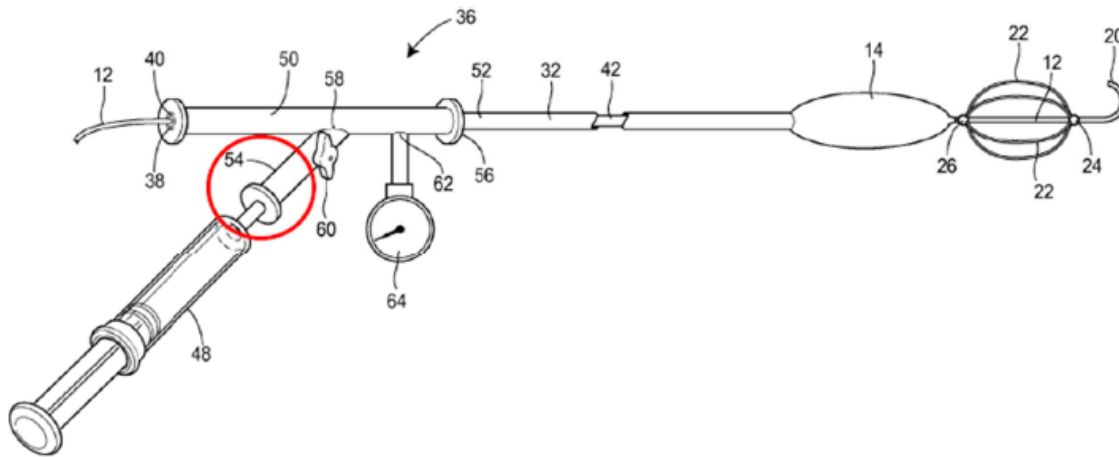


FIG. 10

Prelim. Resp. 30.

On the current record, we find Patent Owner's interpretation unpersuasive. The '737 patent Specification states:

Selective fluid flow through the perfusion openings may be accomplished in a number of alternative manners. For example, a plurality of perfusion lumens may be provided in the catheter. A first perfusion lumen communicating with the perfusion openings distal the first balloon, a second perfusion lumen communicating with the perfusion openings proximal the first balloon and intermediate the second balloon and the first balloon, and a third perfusion lumen communicating with the perfusion openings proximal the proximal balloon.

Ex. 1001, 6:36–45. This disclosure of “selective” fluid flow is referring to selection of which opening in the catheter is being used, and neither the '737 patent Specification nor the claims suggest that literally no liquid enters a hub including a valve. “[W]e decline to import a negative limitation into the

claim that cannot be found in the claim language itself. *See Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1060 (Fed. Cir. 2009) (declining to add negative limitation to claim where ‘there is no basis in the patent specification’).” *Uniloc*, 2024 WL 4038034 *2. Patent Owner identifies no basis for such a negative limitation.

Eliason is reasonably understood to selectively allow fluid communication between the valve portion of the hub and any inflation device, even if some some amount of fluid may enter branch 54 of the hub proximal to Eliason’s valve. Ex. 1004, 3:38–42. Eliason’s valve functions to allow or prevent inflation of the occlusion balloon. *Id. See In re Holness*, 612 Fed. Appx. at 1004.

The situation disclosed in Eliason is similar to that shown in Figure 42A of the ’737 patent, reproduced below:

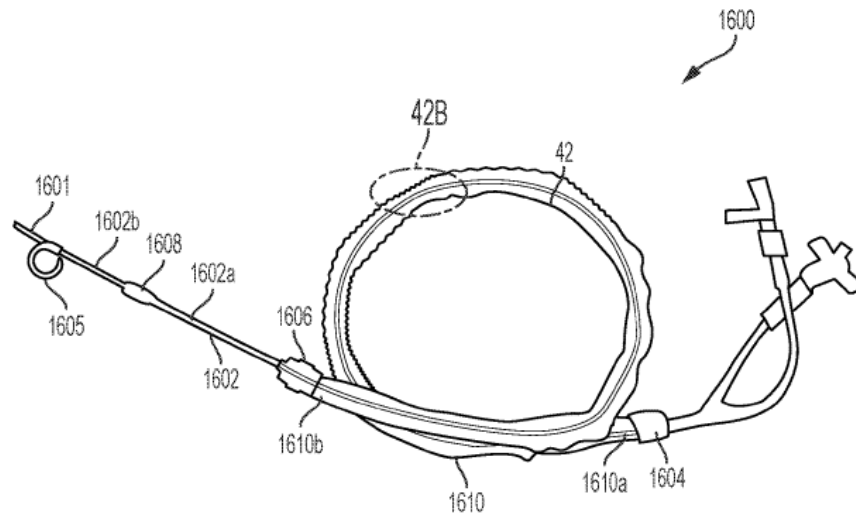


FIG. 42A

Figure 42A identifies hub member 1604 as also functioning as a hemostatic valve. *See Ex. 1001*, 60:8–12. Just as in Eliason, a *de minimis* amount of inflation fluid would enter the edge of the valve in hub member 1604 and the

branch members near it prior to being under selective control of the valve itself.

Therefore, on the current record, we find that Petitioner has shown sufficiently that Eliason teaches a “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” that satisfies the recitation in claim 1 of the ’737 patent. Pet. 60–61 (citing Ex. 1009, 10:36–52; Ex. 1103 ¶ 147).

3. Conclusion for Claim 1

Accordingly, Petitioner has demonstrated, on this record and for the purposes of institution, that they will more likely than not prevail on their assertion that claim 1 is unpatentable as obvious over Eliason.

4. Claims 2–10

We find on this record that Petitioner comes forward with sufficient argument and evidence to show it is more likely than not that claims 2–10 would have been obvious over Eliason. *See* Pet. 72–81. Patent Owner does not, at this time, separately argue any of the dependent claims 2–10. *See generally* Prelim. Resp.

H. Ground 6 – Obviousness over Eliason and Fogarty

Petitioner asserts that claims 1–10 would also would have been obvious over the combination of Eliason and Fogarty. Pet. 2.

- 1. Claims 1–10 – 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 “[t]o the extent that the Eliason reference and the PHOSITA’s knowledge are deemed to not teach that the solid wire (12) is ‘secured at a proximal-most end thereof within the proximal hub’ as recited

in Claim 1, this arrangement is taught by Fogarty.” Pet. 82. Petitioner asserts “Fogarty describes a metal wire stylet (40), ‘to facilitate the insertion of the catheter into a luminal structure within the body.’ Ex-1004, 3:48-54. The metal wire stylet (40) is secured inside the hub by a cap (41) which is threaded into the flange elements (43).” *Id.* (citing Ex. 1009, Figure 2).

2. Motivation to Combine Eliason and Fogarty

Petitioner asserts that

both references describe balloon catheters that can be used for occlusion in the vascular system, and both references use an internal wire that is secured to the catheter body to assist with the insertion of the catheter into the body. Fogarty teaches that this wire stylet can be secured in a cap that is attached to an internal thread of the proximal hub. Eliason would be motivated to use this mechanism as an alternative or improved method to attach the stylet to the balloon shaft.

Pet. 84 (citing Ex. 1003 ¶¶ 184–185).

3. Conclusion for Claims 1–10

We find on this record that Petitioner comes forward with sufficient argument and evidence to show that, more likely than not, claims 1–10 would have been obvious over Eliason and Fogarty. Patent Owner does not, at this time, separately argue these claims. *See* Prelim. Resp. 31–32.

I. Ground 7 – Obviousness over Eliason and Saab

Petitioner asserts that claim 2 would have been obvious over Eliason and Saab. Pet. 3.

1. Claim 2 – “The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.”

Petitioner asserts “Saab explains that compliant balloons (such as the Eliason balloon) can be designed to expand in an asymmetrical manner.”

Pet. 84 (citing Ex. 1006, 11). Petitioner cites to an annotated 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 85 (citing Ex. 1006 Figure 6, annotated). Petitioner asserts “Saab explains that asymmetry is a behavior of compliant balloons or, alternatively, that asymmetrical compliant balloons are a design choice that could be implemented in Eliason’s catheter. Either way, a PHOSITA reading Saab would understand that asymmetrical inflation of the compliant balloon in the Eliason catheter is obvious.” *Id.* (citing Ex. 1003 ¶¶ 190–191).

2. Conclusion for Claim 2

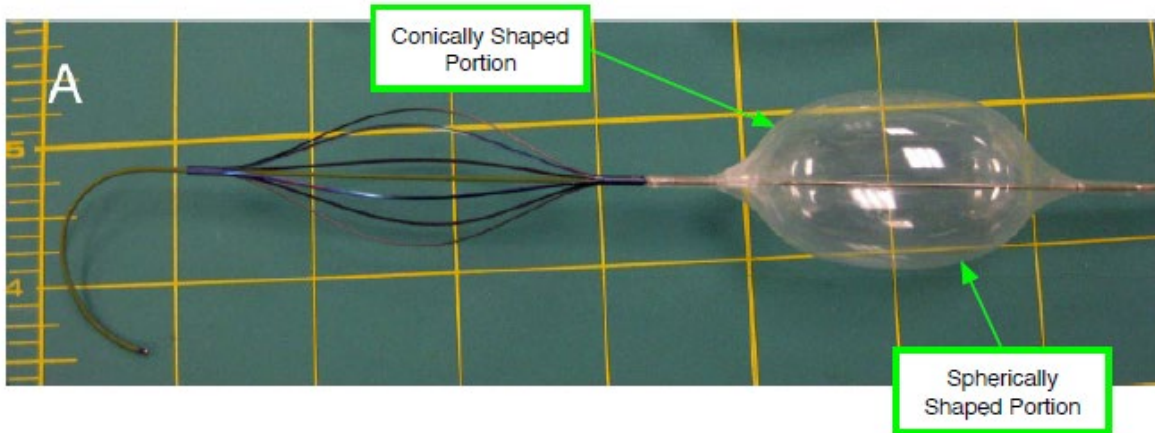
Accordingly, Petitioner has demonstrated, on this record, they will more likely than not prevail on their assertion that claim 2 would have been unpatentable as obvious over Eliason and Saab. Patent Owner does not, at this time, separately argue these claims. *See generally* Prelim. Resp.

J. Ground 8 – Obviousness over Eliason and Scott

Petitioner asserts that claims 3–5 and 9 would have been obvious over Eliason and Scott. Pet. 3.

1. *Claim 3 - “The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion”*

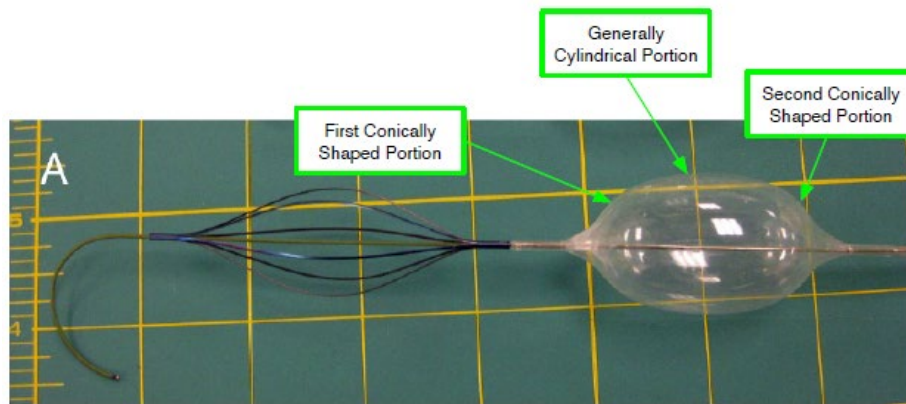
Petitioner asserts “Scott’s balloon has a conically shaped portion facing a spherically shaped portion.” Pet. 87 (citing Ex. 1003 ¶¶ 197–198). Petitioner annotates Figure 1A of Scott, which we reproduce below:



Pet. 88 (citing Ex. 1010, Figure 1A annotated).

2. *Claim 4 - “The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion”*
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”*

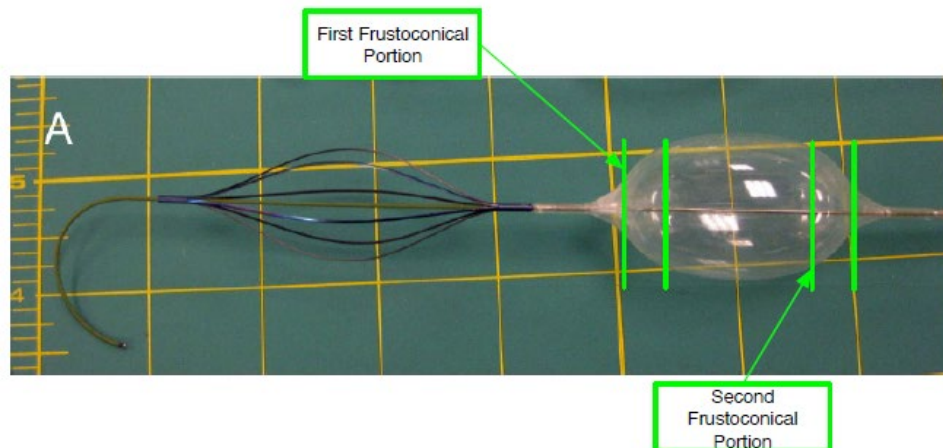
As to claims 4 and 5, Petitioner asserts “Scott Figure 1A teaches a balloon with a conically shaped portion facing another conically shaped portion.” Pet. 88. Petitioner annotates Figure 1A of Scott, reproduced below:



Pet. 89 (citing Ex. 1010, Figure 1A annotated; Ex. 1003 ¶¶ 199–200).

4. *Claim 9 – “The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions”*

Petitioner asserts that Figure 1A of Scott depicts “a balloon with ‘at least two oppositely oriented frustoconical portions.’” Pet. 89 (citing Ex. 1003 ¶ 201). Petitioner annotates Figure 1A of Scott, reproduced below:



Pet. 89 (citing Ex. 1010, Figure 1A annotated; Ex. 1003 ¶ 201).

5. *Motivation to Combine Eliason and Scott*

Petitioner asserts, as to Eliason and Scott:

Both devices include a compliant balloon and a self-centering rail system on a balloon catheter used for the occlusion of the aorta during REBOA like procedures. It would have been

obvious to a PHOSITA that the shape of the balloon shown in Scott could have been used on the device described in Eliason. Because Claims 3-5 and 9 relate to the shape of the compliant balloon, the claims simply apply a known technique (the balloon shapes disclosed in Scott) that had been used to improve a similar device (REBOA balloon catheters having a compliant balloon and a self-centering rail system) in a similar way.

Pet. 90–91 (citing Ex. 1003 ¶ 203).

6. Conclusion for Claims 3–5 and 9

Accordingly, Petitioner has demonstrated, on this record, they will more likely than not prevail on their assertion that claims 3–5 and 9 are unpatentable as obvious over Eliason and Scott. Patent Owner does not, at this time, separately argue these claims. *See generally* Prelim. Resp.

K. Ground 9 – Obviousness over Eliason and Joe

Petitioner asserts that claim 8 would have been obvious over Eliason and Joe. Pet. 3.

1. *Claim 8 – “The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon”*

Petitioner asserts that

Joe indicates that even with low profile occlusion catheters, it is helpful to include radiopaque markers. Ex-1011 ¶0133 (“In some embodiments, 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.”).

Pet. 92 (citing Ex. 1003 ¶ 206).

2. *Motivation to Combine Eliason and Joe*

Petitioner asserts “[b]oth devices can be deployed in the aorta. Joe explains that the utilization of radiopaque markers assists in the visualization of the balloon using radiographic imaging techniques. While Eliason is generally designed for fluoroscopy-free procedures, Figure 12 explicitly describes that in ‘narrow margin procedures,’ fluoroscopy is required.” Pet. 92–93. Petitioner asserts a “PHOSITA understands that including the radio opaque markers would provide a more versatile balloon catheter that could be used for both narrow and wide margin procedures.” *Id.* at 93–94. Petitioner also asserts that a “PHOSITA further understands that inclusion of the radio opaque markers does not interfere with the effective use of the balloon catheter in the fluoroscopy-free (wide margin procedure) setting.” *Id.* at 94 (citing Ex. 1003 ¶ 208).

3. *Conclusion*

Accordingly, Petitioner has demonstrated, on this record, they will more likely than not prevail on their assertion that claim 8 would have been unpatentable as obvious over Eliason and Joe. Patent Owner does not, at this time, separately argue these claims. *See generally* Prelim. Resp.

III. CONCLUSION

Petitioner has, at this stage, established that they would more likely than not prevail in showing that at least one of the challenged claims is unpatentable. This determination is, however, based on a preliminary record and is not final on any issues of patentability. We will make a final determination on the patentability of the challenged claims, applying the preponderance of the evidence standard, based on a fully developed record through trial. *See* 35 U.S.C. § 326(e).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 324(a) post grant review of claims 1–10 of the '737 patent is hereby *instituted* on the grounds set forth in the Petition, commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4(c), notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial will be conducted in accordance with a separately issued Scheduling Order.

PGR2024-00028
Patent 11,857,737 B2

FOR PETITIONER:

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