

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRONT LINE MEDICAL TECHNOLOGIES, INC.
Petitioner

v.

PRYTIME MEDICAL DEVICES, INC.
Patent Owner

Post Grant Review No. PGR2024-00028

Patent No. 11,857,737

**PETITION FOR POST-GRANT REVIEW
OF U.S. PATENT NO. 11,857,737**

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LIST OF EXHIBITS

Ex-1001	U.S. Patent No. 11,857,737 (“the ’737 Patent”)
Ex-1002	Prosecution history of U.S. Patent No. 11,857,737
Ex-1003	Declaration of Dr. Scott A. Resnick
Ex-1004	U.S. Patent Number 3,467,101 (“Fogarty”)
Ex-1005	S. Chengod, MD. et al., <i>Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique</i> , Department of Anesthesiology and Intensive Care, Division of Cardiothoracic and Vascular Anesthesiology and Intensive Care, Amrita Institute of Medical Sciences and Research Center, Kerala, India. (2005) (“Chengod”)
Ex-1006	Mark A. Saab, <i>Applications of High-Pressure Balloons in the Medical Device Industry</i> , Medical Device & Diagnostic Industry Magazine (September 2000) (“Saab”)
Ex-1007	U.S. Patent No. 10,004,622 (“Sanati”)
Ex-1008	Dr. David H. Deaton, <i>Image-Guided Thrombectomy in Vascular Surgery</i> , Endovascular Today (July 2005) (“Deaton”)
Ex-1009	U.S. Patent Number 9,131,874 (“Eliason”)
Ex-1010	Daniel J. Scott, et al., <i>A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock</i> , The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1 (July 2013) (“Scott”)
Ex-1011	U.S. Publication Number 2015/0133892 (“Joe”)
Ex-1012	International Application Number PCT/US2011/033368 (“Eliason PCT Application”)
Ex-1013	U.S. Patent Pub. No. 2013/0060316 (“Sanati Publication”)

- Ex-1014 X. Gu et al., *A New Technique for Sizing of Atrial Septal Defects*, Catheterization and Cardiovascular Interventions (1999) (“Gu”)
- Ex-1015 Handbook of Endovascular Peripheral Interventions (C.D. Owens & Y. Yeghiazarians eds., Springer 2012)
- Ex-1016 PCT publication number WO 2014/036530 to Bagaoisan (“Bagaoisan”)
- Ex-1017 U.S. Patent No. 8,088,121 to Nishide (“Nishide”)
- Ex-1018 U.S. Patent No. 5,607,394 to Anderson (“Anderson”)
- Ex-1019 U.S. Patent No. 5,779,731 to Leavitt (“Leavitt”)
- Ex-1020 U.S. Patent Publication No. 2008/0188803 by Jang (“Jang”)
- Ex-1021 John M. Mathis, et. al, *Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion*, American Society of Neuroradiology (November 1994) (“Mathis”)
- Ex-1022 U.S. Patent No. 4,846,174 to Willard et al. (“Willard”)
- Ex-1023 Patent Owner’s Infringement Claim Charts filed in *Prytime Medical Devs., Inc. v. Front Line Med. Techs., Inc.*, Case No. 6:24-cv-00001, Dkt. No. 1-3 (W.D. Tex. Jan. 2, 2004)
- Ex-1024 E.P. Gerstenfeld & J. Michele, *Pulmonary vein isolation using a compliant endoscopic laser balloon ablation system in a swine model*, Springer Science+Business Media, LLC (2010) (“Gerstenfeld”)
- Ex-1025 U.S. Patent No. 5,087,246 to Smith (“Smith”)
- Ex-1026 Declaration of Dr. Sylvia Hall-Ellis
- Ex-1027 Patent Owner Prytime Medical Inc. “Leadership” web page (available at <https://prytimemedical.com/prytime-medical/leadership/>) (last visited 05-01-2024)
- Ex-1028 USPTO Assignment Record for U.S. Patent No. 9,131,874 to Eliason (available at

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<https://patentcenter.uspto.gov/applications/13642465/assignments?application=>) (last visited 05-01-2024)

I. INTRODUCTION

Front Line Medical Technologies Inc. (“Petitioner” or “Front Line”) petitions for post-grant review (“PGR”) under 35 U.S.C. §§ 321-322 and 37 C.F.R. §42.200 *et seq.* of Claims 1-10 (“Challenged Claims”) of U.S. Patent No. 11,857,737 (“the ’737 Patent”) (Ex-1001), which, on its face, is assigned to Prytime Medical Devices, Inc. (“Patent Owner” or “Prytime”). For the reasons stated below, it is more likely than not that at least one of the Challenged Claims of the ’737 Patent is unpatentable, and as such, the Board should institute review. See 35 U.S.C. §324(a).

II. REQUIRMENTS FOR REVIEW UNDER 37 C.F.R §42.204

A. Standing under 37 C.F.R. §42.204(a)

Petitioner certifies the ’737 Patent is eligible for PGR and Petitioner is not barred or estopped from requesting PGR.

B. Challenged Claims and Statutory Grounds Under 37 C.F.R. §42.204(b)(1-2)

Petitioner requests PGR and respectfully requests review and cancellation of all ten claims of the ’737 Patent (Claims 1-10) on the following grounds.

Ground 1: Claims 1-10 of the ’737 Patent are unpatentable under post-AIA 35 U.S.C. §103(a) as obvious in view of U.S. Patent Number 3,467,101 to Fogarty (“Fogarty”) (Ex-1004); S. Chengod, MD. et al., *Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique*, Department of Anesthesiology and Intensive Care, Division of Cardiothoracic and Vascular

Anesthesiology and Intensive Care, Amrita Institute of Medical Sciences and Research Center, Kerala, India (2005)¹ (“Chengod”) (Ex-1005); and the knowledge of a person having ordinary skill in the art (“PHOSITA”).

Ground 2: Claim 2 of the ’737 Patent is unpatentable under §103(a) as being obvious in view of Fogarty; Chengod; Mark A. Saab, *Applications of High-Pressure Balloons in the Medical Device Industry*, Medical Device & Diagnostic Industry Magazine (September 2000) (“Saab”) (Ex-1006); and a PHOSITA’s knowledge.

Ground 3: Claims 3-5 and 9 of the ’737 Patent are unpatentable under §103(a) as being obvious in view of Fogarty; Chengod; and U.S. Patent No. 10,004,622 to Sanati et al. (“Sanati”) (Ex-1007); and a PHOSITA’s knowledge.

Ground 4: Claim 8 of the ’737 Patent is unpatentable under §103(a) as being obvious over Fogarty; Chengod; and Dr. David H. Deaton, *Image-Guided Thrombectomy in Vascular Surgery*, Endovascular Today (July 2005) (“Deaton”) (Ex-1008); and a PHOSITA’s knowledge.

Ground 5: Claims 1-10 of the ’737 Patent are unpatentable under §103(a) as being obvious in view of U.S. Patent Number 9,131,874 to Eliason et al. (“Eliason”) (Ex-1009) and a PHOSITA’s knowledge.

Ground 6: Claims 1-10 of the ’737 Patent are unpatentable under §103(a) as being obvious in view of Eliason, Fogarty, and a PHOSITA’s knowledge.

¹ Publication dates for non-patent literature are supported by the declaration of Dr. Sylvia Hall-Ellis (Ex-1026 ¶99).

Ground 7: Claim 2 of the '737 Patent is unpatentable under §103(a) as being obvious in view of Eliason, Saab, and a PHOSITA's knowledge.

Ground 8: Claims 3-5 and 9 of the '737 Patent are unpatentable under §103(a) as being obvious in view of Eliason; Daniel J. Scott et al., *A Novel Fluoroscopy-Free, Resuscitative endovascular Aortic Balloon Occlusion system in a Model of Hemorrhagic Shock*, The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1, (July 2013) ("Scott") (Ex-1010); and a PHOSITA's knowledge.

Ground 9: Claim 8 of the '737 Patent is unpatentable under §103(a) as being obvious in view of Eliason; U.S. Pub. No. 2015/0133892 to Joe, et al. ("Joe") (Ex-1011); and a PHOSITA's knowledge.

Summary of Grounds Presented

Ground	Basis	Claim(s)
1	§103(a): Fogarty + Chengod + PHOSITA's Knowledge	1-10
2	§103(a): Fogarty + Chengod + Saab + PHOSITA's Knowledge	2
3	§103(a): Fogarty + Chengod + Sanati + PHOSITA's Knowledge	3-5, 9
4	§103(a): Fogarty + Chengod + Deaton + PHOSITA's Knowledge	8
5	§103(a): Eliason + PHOSITA's Knowledge	1-10
6	§103(a): Eliason + Fogarty + PHOSITA's Knowledge	1-10
7	§103(a): Eliason + Saab + PHOSITA's Knowledge	2
8	§103(a): Eliason + Scott + PHOSITA's Knowledge	3-5, 9
9	§103(a): Eliason + Joe + PHOSITA's Knowledge	8

C. 37 C.F.R. §42.204(b)(4): How the Challenged Claims are Unpatentable

An explanation of how Claims 1-10 are unpatentable is set forth below.

D. 37 C.F.R. §42.204(b)(5): Supporting Evidence

Petitioner relies upon the evidence in the List of Exhibits, including the Declarations of Dr. Scott Resnick, MD, FSIR. (Ex-1003) and Dr. Sylvia Hall-Ellis (Ex-1026).

III. The '737 Patent

A. Overview of the '737 Patent

The '737 Patent is the latest issued patent in a family of patents and applications that include U.S. Patent Number 11,672,951 and U.S. Patent Number 10,149,962. The '737 Patent is entitled "System and Method for Low-Profile Occlusion Balloon Catheter." Ex-1001, [54]. The '737 Patent application (U.S. Patent Application Number 17/563,669) was filed on December 28, 2021, and issued on January 2, 2024. Ex-1001, [21], [22], [45]. The prosecution history of the '737 Patent does not impact the Petition's arguments (Ex-1002).

The '737 Patent generally relates to vascular occlusion catheters and methods of vascular pre-conditioning while controlling occlusion and perfusion during an occlusion procedure. The '737 Patent makes particular note of seeking to provide occlusion catheters for use in resuscitative endovascular balloon occlusion of the

aorta (“REBOA”) procedures. (However, the claims are not so specific, reciting “an occlusion catheter system.” Ex-1001, 66:23-67:7.) As known in the art, REBOA catheters typically include a compliant occlusion balloon carried at a distal aspect of a catheter, and an atraumatic guiding tip forming a distal end of the catheter, wherein the atraumatic tip alleviates the need for a guide wire and allows the catheter to be used in field operations without the need for fluoroscopy or other imaging modality.

IV. THE PRIOR ART

A. Fogarty: U.S. Patent Number 3,467,101 (Ex-1004)

Fogarty is prior art under 35 U.S.C. §102(a)(1-2). It was effectively filed on September 30, 1965. Ex-1004, [cover]. The catheter described in the Fogarty patent was well known and in public use prior to the March 18, 2016, effective filing date of the ’737 Patent. Indeed, these types of catheters became known in the field as a “Fogarty catheter.” *See, e.g.*, Ex-1005 at 1; Ex-1003 ¶69.

B. Chengod: Published Article (Ex-1005)

Chengod, published in 2005, is prior art under 35 U.S.C. §102(a)(1). Chengod is an article entitled: *Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique*, written by Suressh Chengod, MD, et al., and published in the Journal of Cardiothoracic and Vascular Anesthesia in October of 2005 and was publicly available at least by October 24,

2005. Ex-1005, 1. Ex-1026 ¶¶45-52, 99. Chengod describes the use of a Fogarty catheter, a commercialized version of the device described in Fogarty.

C. Saab: Published Article (Ex-1006)

Saab, published in 2000, is prior art under 35 U.S.C. §102(a)(1). Saab is an article written by Mark A. Saab, and entitled: *Applications of High-Pressure Balloons in the Medical Device Industry*. Saab was published in Medical Device & Diagnostic Industry Magazine in September 2000 and was publicly available at least by September 21, 2000. Ex-1006-1; Ex-1026 ¶¶53-60, 99. Saab shows and describes a variety of medical balloon geometries that were known and in use at the time.

D. Sanati: U.S. Patent Number 10,004,622 (Ex-1007)

Sanati is prior art under 35 U.S.C. §102(a)(2). Sanati has an effective filing date of August 31, 2012, because it is a continuation of U.S. Patent App. No. 13/602,074, which was filed on August 31, 2012. Ex-1007, [63]. That application was published on March 7, 2013, as U.S. Patent Pub. No. 2013/0060316 (“Sanati Publication”). Ex-1013. Under 35 U.S.C. § 102(d)(2), Sanati “shall be considered to have been effectively filed ... as of the filing date of the earliest such application that describes the subject matter.” The subject matter of Sanati relied upon in this Petition appears verbatim in the Sanati Publication. Ex-1003 ¶209. Accordingly, Sanati’s effective filing date is the filing date of the Sanati Publication, August 31, 2012.

Sanati describes a balloon catheter having two different expandable balloons which have different shapes and configurations.

E. Deaton: Published Article (Ex-1008)

Deaton, published in 2005, is prior art under 35 U.S.C. §102(a)(1). Deaton is an article published in *Endovascular Today* in July of 2005 and was publicly available at least by September 19, 2005. Ex-1026 ¶¶61-68, 99. The article is entitled *Image-Guided Thrombectomy in Vascular Surgery*, written by Dr. David H. Deaton. The article describes the use of stainless steel bushings, located at the proximal and distal ends of the balloon, in catheters such as the Fogarty balloon catheter, to enable accurate visualization under fluoroscopy.

F. Eliason: U.S. Patent Number 9,131,874 (Ex-1009)

Eliason is prior art under 35 U.S.C. §102(a)(2) because it was effectively filed on April 21, 2011, based on PCT/US2011/033368 (Ex-1012) (“Eliason PCT Application”), which was filed on that date. Under 35 U.S.C. § 102(d)(2), Eliason “shall be considered to have been effectively filed ... as of the filing date of the earliest such application that describes the subject matter.” The subject matter of Eliason relied upon in this Petition is described in the Eliason PCT Application. Ex-1003 ¶210. Accordingly, Eliason’s effective filing date is the filing date of the Eliason PCT Application, April 21, 2011. Eliason describes a fluoroscopy-independent, endovascular aortic occlusion system that appears to be suitable for use in for

performing REBOA procedures. Eliason is listed on the face of the '737 Patent, but was not cited by the Examiner. Ex-1001, [56].

G. Scott: Published Article (Ex-1010)

Scott, published in 2013, is prior art under 35 U.S.C. §102(a)(1). Scott is an article written by Daniel J. Scott, et al. entitled *A Novel Fluoroscopy-Free, Resuscitative Endovascular Aortic Balloon Occlusion System in a Model of Hemorrhagic Shock*. Scott was published in The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1, July 2013 and was publicly available at least by August 1, 2013. Ex-1010, 1. Ex-1026 ¶¶69-75, 99. Scott describes a “new, low-profile REBOA system” including a “fused wire and balloon catheter.” Ex-1010, p.123.

H. Joe: U.S. Publication Number 2015/0133892 (Ex-1011)

Joe is prior art under 35 U.S.C. §102(a)(2) because it was published on May 14, 2015, and was filed on November 14, 2014, before the '737 Patent's March 18, 2015, earliest priority date. Ex-1011. Under 35 U.S.C. § 102(d)(1), Joe's effective filing date is at least the actual filing date, November 14, 2014. Joe describes low profile balloon catheters having compliant balloons suitable for use in occlusion procedures, and which include radiopaque markers.

V. 37 C.F.R. §42.204(b)(3): CLAIM CONSTRUCTION

In a PGR, patent claims are construed using the same claim construction standard that would be used to construe the claim in district court. *See* 37 C.F.R.

§42.200. Thus, for this PGR, the Board applies the claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). See 83 Fed. Reg. 51,340-51,359 (Oct. 11, 2018). Under *Phillips*, claim terms are typically given their ordinary and customary meanings, as would have been understood by a PHOSITA, at the time of the invention, having taken into consideration the claim language, the rest of the specification, and the prosecution history of record. *Phillips*, 415 F.3d at 1313; see also *id.*, 1312-16. Where the specification instructs as to the meaning of a claim term, “the inventor’s lexicography governs.” *Id.* at 1316. The Board, however, construes the claims only when necessary to resolve the underlying controversy. *Toyota Motor Corp. v. Cellport Systems, Inc.*, IPR2015-00633, Paper No. 11 at 16 (Aug. 14, 2015) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner submits 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.

Petitioner believes that no other express constructions of the claims are necessary to assess whether the prior art reads on the Challenged Claims.² All other terms should, therefore, be given their plain meaning. Petitioner reserves the opportunity to respond to constructions offered by Patent Owner, either expressly or impliedly, or adopted by the Board.

VI. LEVEL OF ORDINARY SKILL

A person having ordinary skill in the art (“PHOSITA”) at the time of the alleged invention of the ’737 Patent (March 19, 2015) would have a medical degree and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices. A busy interventionalist could conceivably acquire an adequate level of experience having a minimum of ten years of post-graduate experience as an interventional radiologist, vascular surgeon, interventional cardiologist, or other endovascular interventionist. Such a person would be familiar with various occlusion balloon catheters and their use in performing vascular occlusion

² Petitioner reserves all rights to raise claim-construction and other arguments in district court as relevant and necessary to those proceedings. For example, a comparison of the claims to any accused products may raise controversies that need to be resolved through claim construction that is not necessary here given the similarities between the references and the patent.

procedures including occlusion procedures throughout the vascular system, including occlusion procedures within the aorta. Ex-1003 ¶18.

VII. A PHOSITA'S KNOWLEDGE

The relevant field of the '737 Patent is balloon catheters for use in interventional procedures. Ex-1003 ¶32. Within this field, a PHOSITA at the time the '737 Patent application was filed would have knowledge of many of the features of the Challenged Claims, as evidenced by the prior art.

A. Occlusion Balloon Catheters

By March of 2015, occlusion balloon catheters were well known in the medical profession and to the PHOSITA. An occlusion balloon catheter is a balloon device meant to provide body lumen or vessel occlusion, i.e., to block or obstruct a body lumen or vessel. Indeed, balloon catheters have been in use for decades (the Fogarty patent issued in 1965) and have been used for various procedures including, but not limited to, intravascular and intrabronchial occlusion. Ex-1003 ¶34.

In radiology, different balloon catheters may be used for different procedures. "Balloons can be compliant, non-compliant, or semi-compliant." Ex-1015, 81; Ex-1026 ¶¶84-90, 99 (confirming public availability by March 1, 2012). "Compliant balloon[s] will increase their diameter with increasing pressure. They are typically made of silicone and thermoplastic elastomers, polyethylene, or polyolefin

polymers.” *Id.* “Non-compliant balloons remain at a pre-selected nominal maximum diameter even when the internal balloon pressure is increased beyond what is required to fully inflate the balloon, which facilitates high-pressure inflation. They are made of polyethylene terephthalate or polyamides.” *Id.*; *see also* Ex-1003 ¶49.

Balloon catheters used for angioplasty (intended for vessel dilation) typically include a semi-compliant or non-compliant balloon. In contrast, balloons used primarily for occlusion are typically compliant in nature such that the inflated balloon will conform to the vascular channel and fill the space surrounding the balloon, resulting in an occlusive configuration (e.g., blocking the channel so that blood flow is stopped or mostly stopped). This temporary vessel occlusion can have a number of different therapeutic values depending upon the purpose in question. Deflation of the balloon will resolve the occlusive configuration and allow return of blood flow. Ex-1003 ¶35.

Balloon catheters, including those with compliant balloons and those with semi-compliant or non-compliant balloons, have the effect of occluding blood flow of the patient. These catheters include a lumen through which an inflation fluid would pass to inflate the balloon. Ex-1003 ¶36.

Balloon catheters such as the Fogarty occlusion balloon catheter have been used for a variety of clinical tasks. In addition to regular use of the Fogarty occlusion balloon in the setting of acute hemorrhage, Fogarty balloon catheters can be inflated in an artery for the purpose of controlling embolic material delivery and/or dwell

time, and for the purpose of vessel occlusion and intraluminal thrombus manipulation, for example. A PHOSITA understands that each of these distinct procedures, wherein vessel occlusion is performed, should use a Fogarty device of the size appropriate for the vessel caliber in question. Specifically, smaller diameter (typically 4 French) devices would most often be used for vessel occlusion with intraluminal thrombus manipulation, whereas larger catheters (5 Fr or 6 Fr) would be used for embolic delivery manipulation and/or hemorrhage temporization. Ex-1003 ¶37.

As indicated in the '737 Patent, "REBOA" is an acronym for "Resuscitative Endovascular Balloon Occlusion of the Aorta." The basic REBOA procedure can be used with a variety of different balloon catheters. Prior to the date of the '737 Patent, practitioners performed REBOA-type and similar procedures utilizing large diameter balloon angioplasty catheters wherein the balloon diameter approximated that of the aorta. At the time, such procedures were widely known and routinely performed when the appropriate clinical indication presented itself. The acronym moniker of "REBOA," however, was not in use at the time and the procedure was simply referred to as aortic balloon occlusion. Furthermore, given that interventionalists routinely performed aortic balloon angioplasty for stenotic atherosclerotic lesions, as early as the late 1970s, and that a potential outcome of such angioplasty was acute balloon-induced aortic rupture, every interventionalist needed to be familiar with the concept of aortic balloon occlusion. Ex-1003 ¶38.

While modern interventionalists have a variety of devices available to rapidly manage such acute situations in the interventional suite (graft-covered stents/aortic stent grafts), earlier interventionalists did not have the luxury of such device availability. Prior to the first U.S. aortic stent graft implantation in 1992, and subsequent first aortic stent graft commercial U.S. approval in 1999, the interventional treatment for angioplasty-induced aortic rupture was immediate aortic balloon occlusion followed by definitive surgical repair. Long before the time of the '737 Patent, from the late 1970s when aortic balloon angioplasty was routinely performed without the potential for covered stent bailout in the setting of balloon-induced aortic rupture, until the late 1990s, when aortic stent grafts became commercially available, every interventionalist performing aortic balloon angioplasty was well aware of the above-described facts and methods. Ex-1003 ¶38.

B. Use of Stainless Steel in Balloon Catheter Construction

Care must be taken in the selection of materials that will be used for intravascular catheters. The various available construction materials impart specific performance and reliability characteristics to the device in question. Throughout the history of endovascular devices, a variety of metallurgy has been explored and utilized. This includes stainless steel, nitinol (a nickel-titanium alloy with temperature-determined shape and stiffness memory characteristics), cobalt chromium, titanium, and others. Stainless steel has a long history of use in medical devices due its strength and corrosion resistance. Device performance

characteristics imparted by stainless steel elements are readily manipulable by changing the anatomic configuration of the metal element utilized (diameter, taper, solid configuration, wound configuration etc.). When used in catheter construction, stainless steel imparts substantial strength to the device when compared to similar devices without steel incorporation. Wire windings, incorporated wire elements, and wire stylets are all examples of stainless-steel use in catheter construction. In particular, a PHOSITA at the time of the '737 Patent would be well-aware that a wire stylet for use within a catheter to add longitudinal and rotational stiffness to the catheter could advantageously be constructed of stainless steel. Ex-1003 ¶39.

Evidence of this knowledge is found in the literature. For example, in PCT publication number WO 2014/036530 to Bagaoisan (filed 2013, published March 6, 2014), “FIGS. 1A-1B depict plan and cross sectional views of a first exemplary embodiment of a balloon catheter 100.” Ex-1016 ¶[0094].

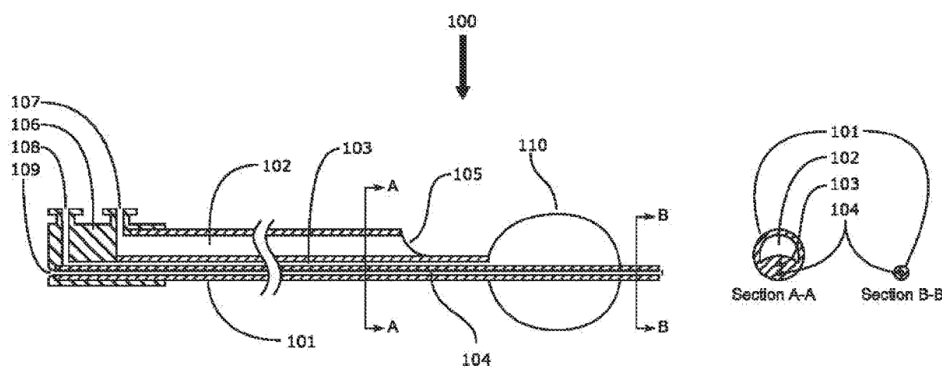


FIGURE 1A

Id., Fig. 1A. Bagaoisan discloses

The elongate member 101 may be fabricated from materials known in the art including, but not limited to Pebax, nylon, urethane, polyester, polyethylene, polyimide, Teflon, Delrin, PEEK, polycarbonate, polypropylene and combinations thereof. **Furthermore, the elongate member 101 may be reinforced with additional materials such as braids, meshes, mandrels, liners, and the like fabricated from materials known in the art including**, but not limited to nitinol, **stainless steel**, titanium, combinations thereof, and the like.

Id. ¶[0095] (emphasis added). A PHOSITA understands Bagaoisan’s description of reinforcing elongate member 101 with stainless steel mandrels (i.e., a cylindrical rods or wires) would increase the longitudinal and rotational stiffness of the catheter. Ex-1003 ¶¶ 40-41.

Another example of using stainless steel in a balloon catheter is U.S. Patent No. 8,088,121 to Nishide (filed 2005, issued 2012). Nishide discloses “a rapid exchange catheter” that takes “a balloon catheter as the primary example.” Ex-1017, 6:49-59. Nishide’s balloon catheter includes a core wire where “[t]he roles of the core wire are to improve the convenience of operation in inserting the catheter into the body along the guide wire, transmit the force applied to the catheter and prevent kink (bend) of the catheter.” *Id.*, 10:30-35. Nishide discloses that “[t]he material for the core wire ... is preferably stainless steel....” *Id.*, 11:48-53; Ex-1003 ¶42.

A final example of using stainless steel in a balloon catheter is U.S. Patent No. 5,607,394 to Anderson (filed 1995, issued 1997). Anderson discloses “a catheter having a stylet that increases columnar strength and axial force transmission (‘pushability’) of the catheter shaft.” Ex-1018, Abstract. In the balloon catheter of

Figure 1, “The stylet is tapered, as shown in FIG. 2, and is preferably made from metal or metal alloy (e.g., stainless steel or Nitinol).” Anderson, 3:8-10; Ex-1003 ¶43.

C. Radiopaque Markers

Prior to March 2015, occlusion balloon catheters utilized radiopaque markers. In fact, a PHOSITA would have intimate knowledge of the fact that balloon catheters (including occlusion balloon catheters) use radiopaque markers to indicate the location of the two sides of a balloon. This follows from the fact that the appropriate identification of balloon positioning within the body is critical to effective therapy using the balloon catheter. Ex-1003 ¶44.

If an occlusion balloon or an angioplasty balloon failed to have radiopaque markers that allow for ready fluoroscopic visualization of the balloon position, the device would be of lesser value for use with image-guided therapy (which is the essence of interventional therapies). This is in contrast to other balloon-type catheters wherein exact device positioning is not critical for therapeutic effect, such as a balloon retention urinary drainage catheter, or a balloon retention intestinal tube (gastrostomy, jejunostomy, etc.). Thus, a PHOSITA would expect an angioplasty or occlusion balloon catheter that could be used in a clinical setting to indicate the balloon location with one or more radiopaque markers. Given the significant potential complications that can occur with balloon inflation in an incorrect location (vessel injury, including overt vessel rupture), exact balloon location identification prior to balloon inflation is critical for safe procedure performance. As such, while

not every intravascular balloon will have two radiopaque markers—one on each end of the balloon, such a configuration affords the most accurate balloon positioning during procedure performance, and as such, nearly every intravascular balloon is configured in such a manner. Ex-1003 ¶45.

Evidence of a PHOSITA's knowledge that two radiopaque markers can be used to indicate the location of the two sides of a balloon in a balloon catheter is found in the literature. For example, *Image-Guided Thrombectomy in Vascular Surgery* by Dr. David H. Deaton (2005) discloses a Fogarty balloon catheter that included “[s]tainless steel bushings located at the proximal and distal ends of the balloon [to] enable accurate visualization under fluoroscopy.” Ex-1008, 32.

Radiopacity is a basic tenet of x-rays. Since the initial discovery of x-rays by Wilhelm Rontgen in 1895 it has been well understood that various materials are more or less visible when radiographically imaged. Basic and known radiopacities include air, soft tissue, fat, bone, metal. Accordingly, a PHOSITA understands Deaton's stainless steel bushings are an example of radiopaque markers on either side of the balloon. Ex-1003 ¶46.

Another example of two radiopaque markers used to indicate the location of the two sides of a balloon in a balloon catheter is U.S. Patent No. 5,779,731 to Leavitt (filed 1996, issued 1998). Leavitt discloses “An intravascular balloon catheter has a balloon near the distal end of a catheter shaft and a pair of radiopaque markers positioned within the balloon interior. The distal marker is disposed on an inner

shaft member and the proximal marker is disposed at the distal end of an outer shaft member. The markers may be positioned to indicate under fluoroscopy the position and working length of the balloon.” Ex-1019, Abstract; Ex-1003 ¶47.

Another example is U.S. Patent Publication No. 2008/0188803 by Jang (published 2008). Jang’s application “relates [] generally to balloon catheters.” Ex-1020, ¶[0003]. Jang’s Figure 1 includes “radiopaque markers 124 and 126 [that] can be positioned at a proximal end of the balloon 100 and at a distal end of the balloon 100, respectively.” Ex-1020 ¶[0034] & Fig. 1; Ex-1003 ¶48.

D. Asymmetrical Balloon Shapes

Most compliant balloons are configured to be inflated symmetrically around the axis of the catheter shaft. However, some compliant balloons are designed to be asymmetrical. The use of asymmetrical inflation in compliant balloons was known for many decades and would be known to a PHOSITA. Ex-1003 ¶50. Asymmetrical, complaint balloons were described, for example, in an article by John M. Mathis, et. al, by the American Society of Neuroradiology, entitled *Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion* (November 1994). Ex-1021. Mathis compared four different compliant arterial occlusion balloons, showing the difference between symmetrical and asymmetrical balloons:

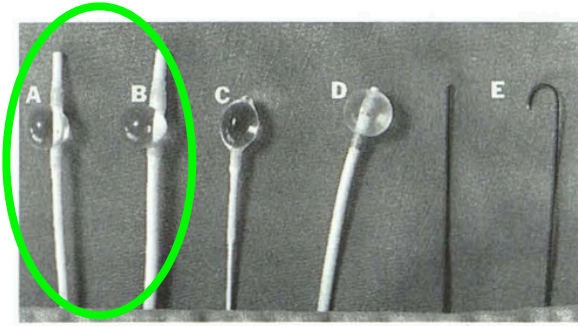


Fig 1. A, 5.0-F Meditech; B, 7.0-F Meditech; C, ITC-NDSB (1509); D, 5.0-F Swan-Ganz; and E, straight and J-tip exchange wires. All balloons are inflated to 5-mm diameter, which approximates working volume for internal carotid occlusion. Note the **asymmetric** balloon inflation of Meditech systems (A and B) relative to the catheter shaft.

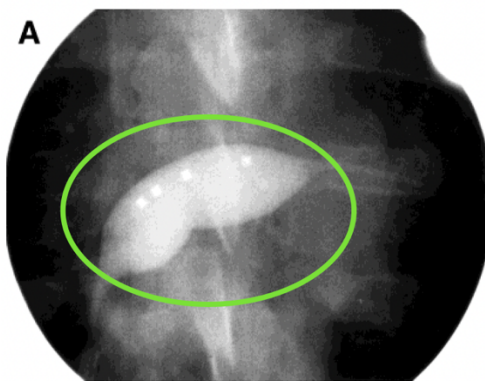
Mathis, 1833 & Fig. 1; Ex-1003 ¶51.

A PHOSITA would be well aware that a compliant balloon used for arterial occlusion could be configured to inflate asymmetrically. Evidence of this knowledge is found in the literature including Mathis. Ex-1003 ¶ 53. Another example is Saab (2000), which confirms the PHOSITA's knowledge: "an elastomeric [compliant] balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left)." Ex-1006-11.



Ex-1006-11, Fig. 6; Ex-1003 ¶54.

Further, a PHOSITA understands that compliant balloons are often used in occlusion catheters because the balloon can inflate asymmetrically when inside the patient. For example, during occlusion procedures, the balloons are used to completely fill the body lumen into which it is placed, which often is asymmetrical in shape, resulting in an inflated balloon that is also asymmetrical. For example, X. Gu et al., *A New Technique for Sizing of Atrial Septal Defects*, Catheterization and Cardiovascular Interventions (1999) (“Gu”) confirms the PHOSITA’s knowledge that compliant balloons can inflate asymmetrically. Ex-1026 ¶¶76-83, 99 (confirming public availability at least by January 15, 1999). Gu’s catheter includes a “balloon [that] is compliant and made from a very thin stretchable polyurethane membrane.” Ex-1014, 51. Figure 6 depicts an asymmetrically inflated balloon: “deployed balloon catheter within the surgically created atrial septal defect”:



Ex-1014, 54 & Fig. 6; Ex-1003 ¶55.

E. Other Compliant Balloon Shapes

1. “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion”

A PHOSITA understands that complaint balloons are typically used in occlusion procedures because the compliance allows the balloon to fill (and thus occlude) the cavity into which it is placed. In practice, this results in compliant balloons that, when inflated inside the body (e.g., intravascularly), are asymmetrical because those body lumens typically have asymmetrical shapes. Nevertheless, due to the way balloon catheters with compliant balloons are typically manufactured (e.g., since the Fogarty catheter was introduced in the 1960s), these compliant balloons have certain shape characteristics (when inflated outside the patient, i.e., not in regular use) that are well-known to a PHOSITA. Ex-1003 ¶¶56-57.

The first such well-known shape includes a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.” This shape characteristic is found throughout the literature. For example, it is shown in Sanati which discloses a balloon catheter that contains two different balloons (inner balloon 22a and outer balloon 22b) made of compliant material. Ex-1007, 7:35-47 & Fig. 1B. Sanati’s inner balloon 22a has this well-known shape:

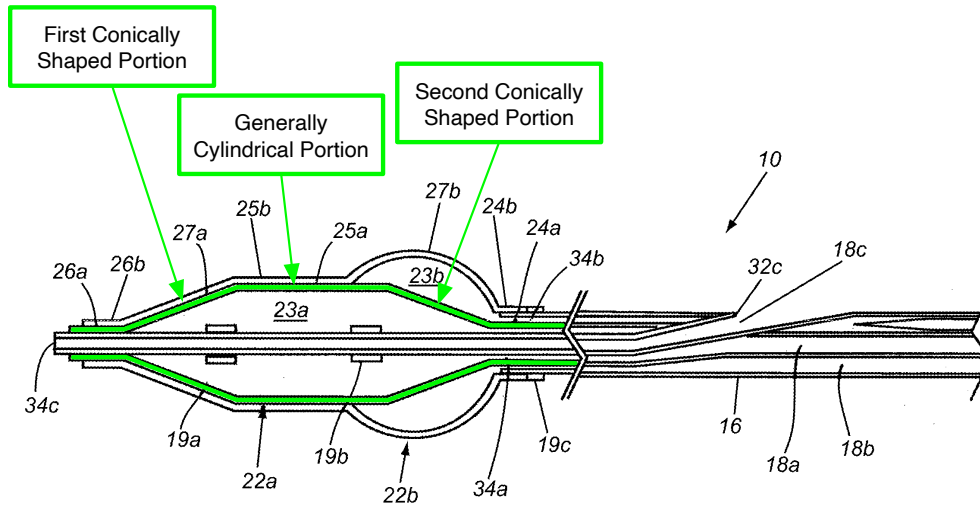


FIG. 1B

Ex-1007, Fig. 1B (annotated); Ex-1003 ¶58.

Eliason also discloses a balloon catheter with a compliant balloon (14) having this well-known shape. Ex-1009, 4:54-6.

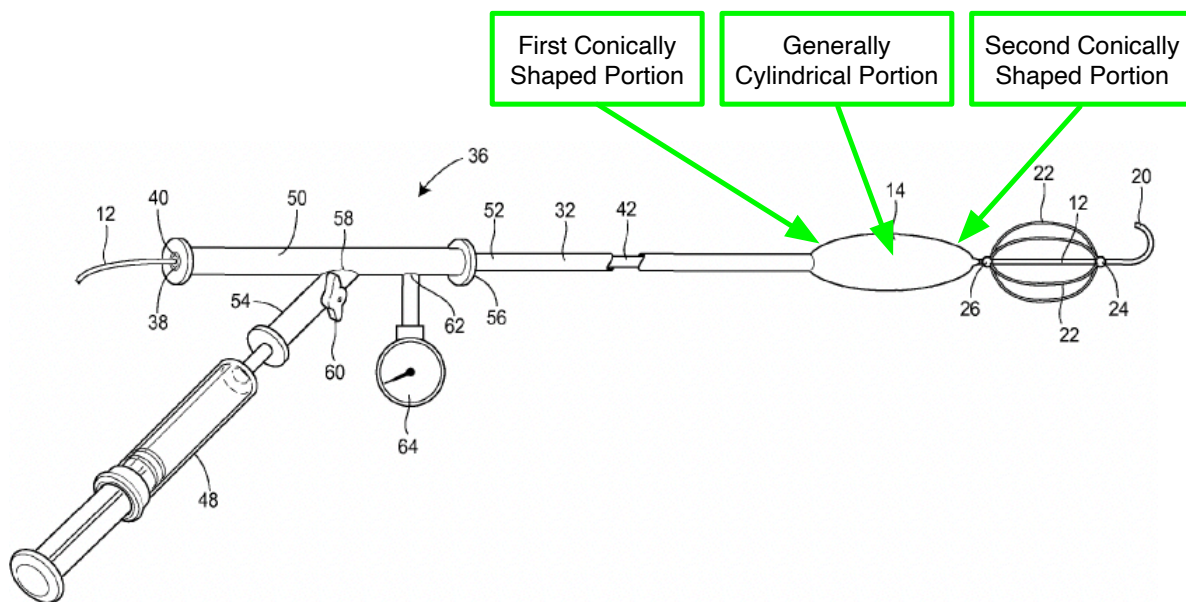
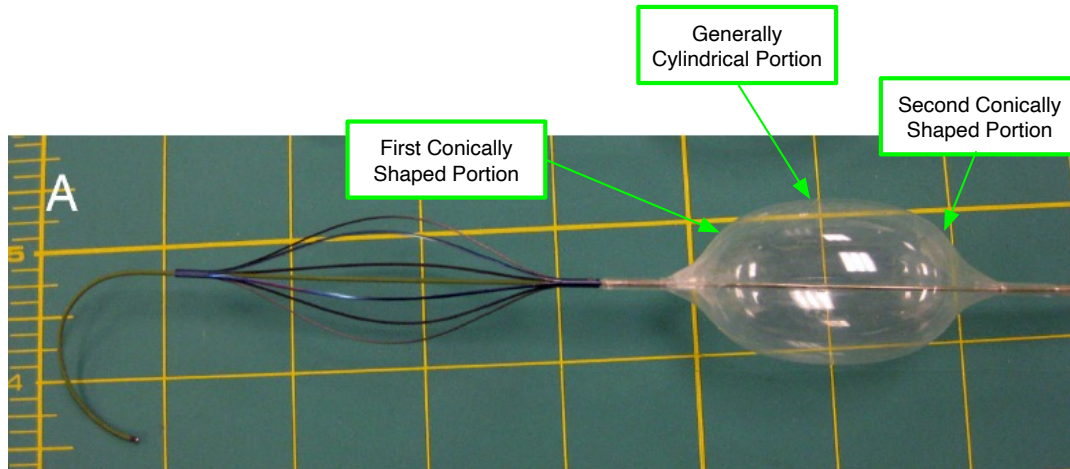


FIG. 10

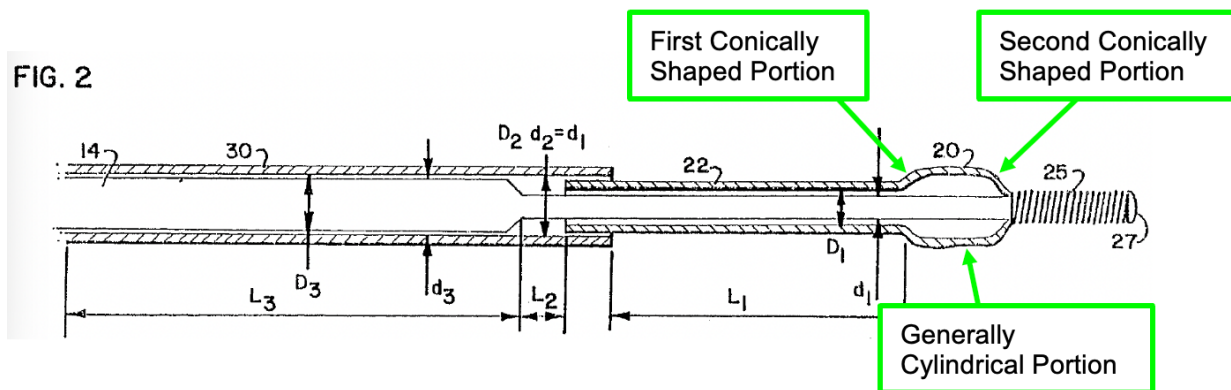
Ex-1009, Fig. 10 (annotated); Ex-1003 ¶58.

Scott also discloses a balloon catheter with a compliant balloon having this well-known shape. Ex-1010, 123.



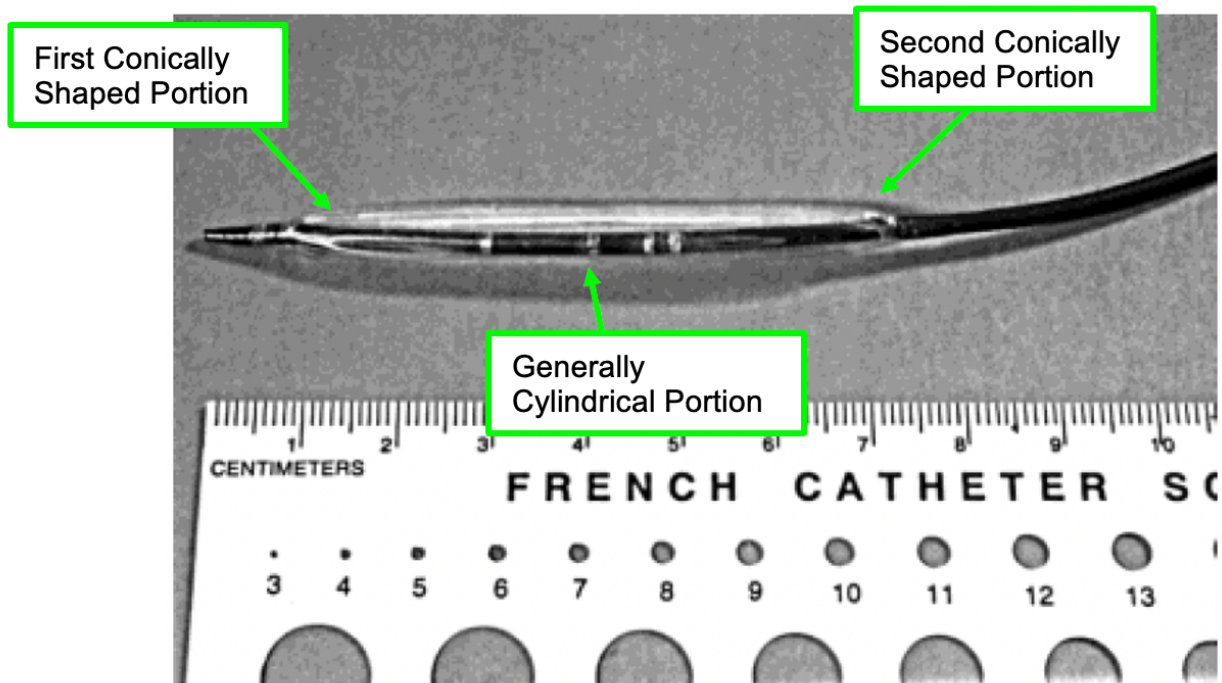
Ex-1010, Fig. 1A (annotated); Ex-1003 ¶58.

U.S. Patent No. 4,846,174 to Willard (issued 1989) discloses a balloon catheter with a compliant balloon 20 that has this well-known shape. Ex-1022, 5:9-11.



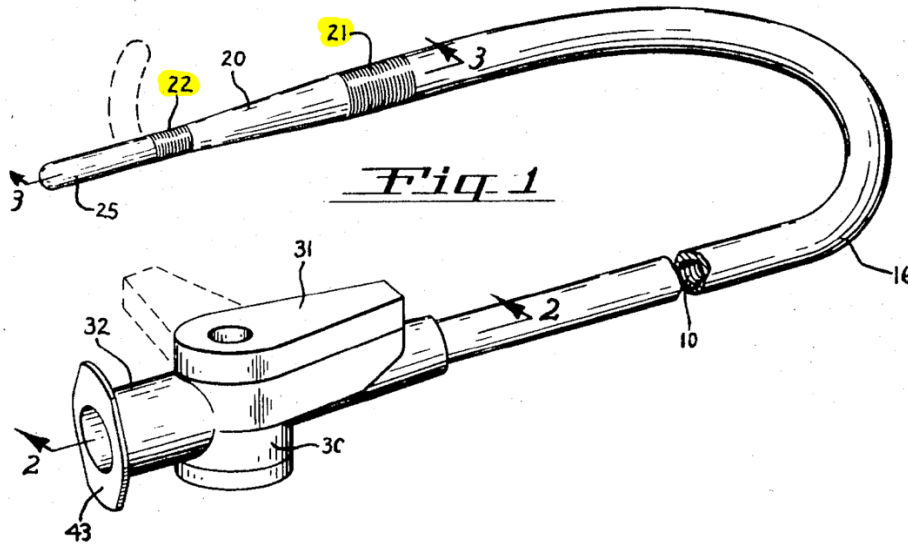
Ex-1022, Fig. 2 (annotated); Ex-1003 ¶58.

Gu (1999) discloses a balloon catheter with a compliant balloon that has this well-known shape. Ex-1014, 51.



Ex-1014, Fig. 1B (annotated); Ex-1003 ¶58.

These references confirm that complaint balloons with a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion” were well known to a PHOSITA by 2015. This shape results from the way the balloon is attached to the underlying catheter body. For example, the balloon can be secured to the catheter body by windings around both distal and proximal ends of the balloon, as described in Fogarty. Ex-1004, 2:71-3:6 (describing balloon 20 is secured to tube 16 by windings 21 at the distal end and by windings 22 and the proximal end).



Ex-1004, Fig. 1 (windings highlighted); Ex-1003 ¶59.

A PHOSITA understands that compliant balloons attached via windings will inflate outside the body into a shape that includes a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.” This is because the center of the compliant balloon can stretch to a larger circumference whereas the portions of the balloon near the windings will tend to taper due to the restriction at the attachment point. Ex-1003 ¶60.

2. “a conically shaped portion facing another conically shaped portion”

A PHOSITA further understands that a balloon having a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion” also has “a conically shaped portion facing another conically shaped portion.” In particular, the “first conically shaped portion” in the above references faces the “second conically shaped portion.” Thus, “a conically shaped portion facing

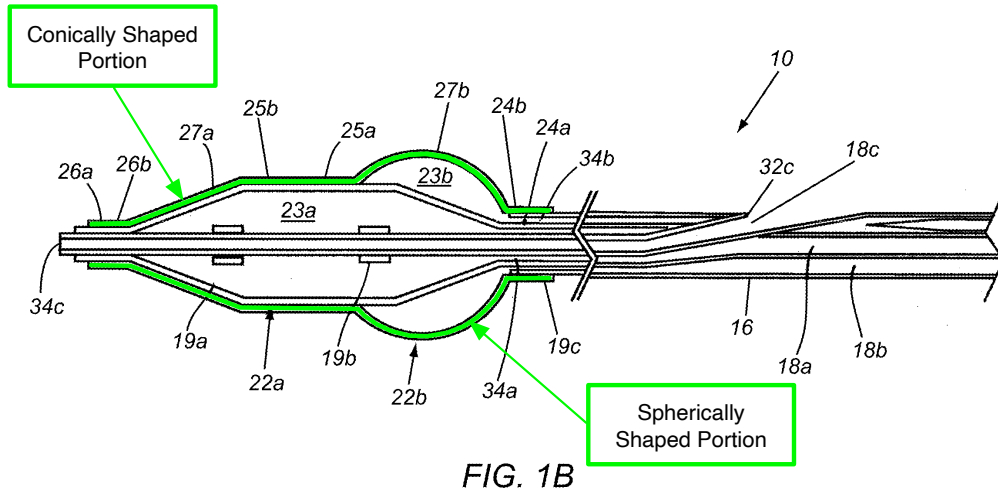
another conically shaped portion,” is also taught by the above references and was well known to a PHOSITA at the time of the ’737 Patent. Ex-1003 ¶62.

3. “at least two oppositely oriented frustoconical portions”

A PHOSITA further understands that a balloon having a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion” also has “at least two oppositely oriented frustoconical portions.” The term “frustoconical” is not a term of art in the medical profession (nor to a PHOSITA). It describes a conical shape that stops short of reaching a single apex point (i.e., it is truncated before the apex of the cone). In the well-known balloon that has a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion,” the conical sections are actually frustoconical because the catheter running through the ends of the balloon results in truncation of the cone (i.e., there is no apex). Accordingly, a PHOSITA in 2015 was well aware that the “first conically shaped portion” and “second conically shaped portion” in the above references are “two oppositely oriented frustoconical portions.” Ex-1003 ¶63.

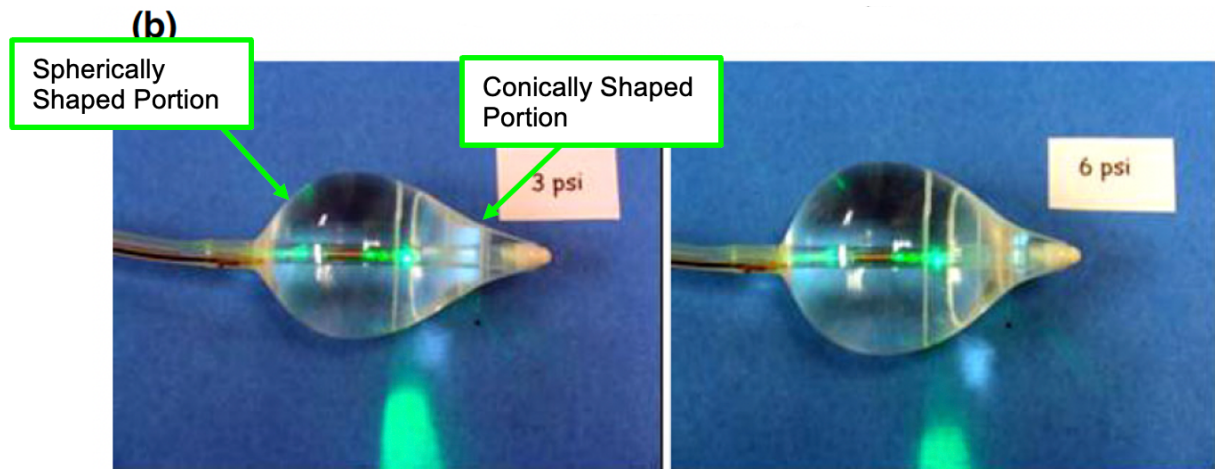
4. “conically shaped portion facing a spherically shaped portion”

The prior art confirms that well-known compliant balloon shapes include a “conically shaped portion facing a spherically shaped portion.” This shape characteristic is found in Sanati, which discloses a balloon catheter where compliant outer balloon 22b has this shape. Ex-1007, 7:35-47.



Ex-1007, Fig. 1B (annotated); Ex-1003 ¶¶66.

E.P. Gerstenfeld & J. Michele, *Pulmonary Vein Isolation Using a Compliant Endoscopic Laser Balloon Ablation System in a Swine Model*, Springer Science+Business Media, LLC (2010) ("Gerstenfeld") also discloses a compliant balloon with a "conically shaped portion facing a spherically shaped portion." Ex-1024, 3; Ex-1026 ¶¶91-99 (confirming public availability by December 22, 2010).



Ex-1024, Fig. 2b (annotated); Ex-1003 ¶¶66.

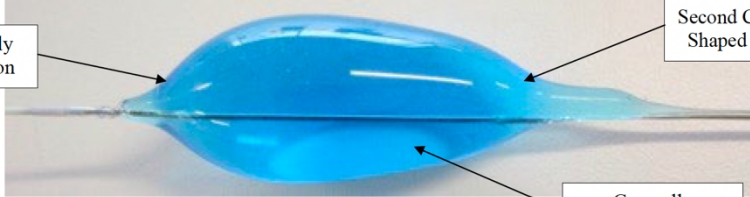
Sanati and Gertenfeld confirm that complaint balloons with a “conically shaped portion facing a spherically shaped portion” were well known to a PHOSITA in 2015. Ex-1003 ¶¶67.

5. Patent Owner’s District Court Complaint Alleges a Standard Compliant Balloon Has the Well-Known Balloon Shapes

Patent Owner submitted an infringement claim chart when it sued Petitioner in district court. Ex-1023. The claim charts allege that a standard compliant balloon meets the various shape limitations of found in the ’737 Patent claims:

4. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.	The compliant offset balloon of the COBRA-OS has a conically shaped portion facing another conically shaped portion at the two ends of the compliant offset balloon.  Conically Shaped Portion Conically Shaped Portion
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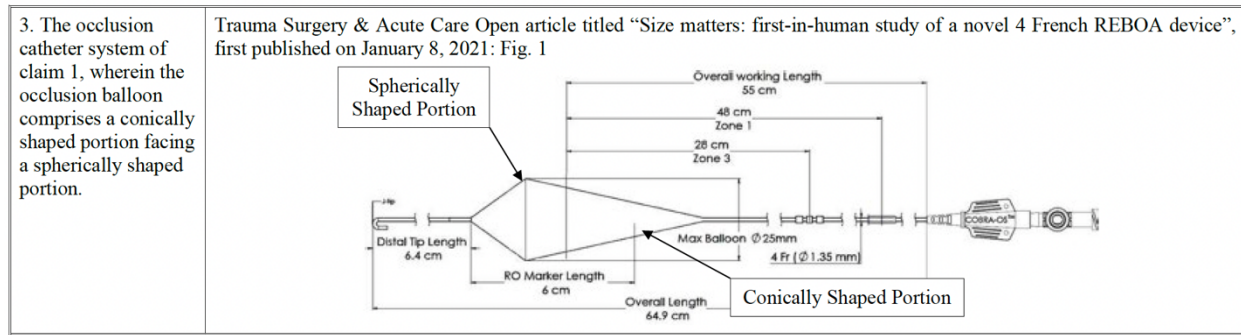
Ex-1023, 13.

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.	The compliant offset balloon of the COBRA-OS includes a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion between the first and second conically shaped portions.  First Conically Shaped Portion Second Conically Shaped Portion Generally Cylindrical Portion
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Ex-1023, 14.

9. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.	The COBRA-OS compliant offset balloon includes two oppositely oriented frustoconical portions  First Frustoconical Portion Second Frustoconical Portion
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Ex-1023, 17.



Ex-1023, 13.

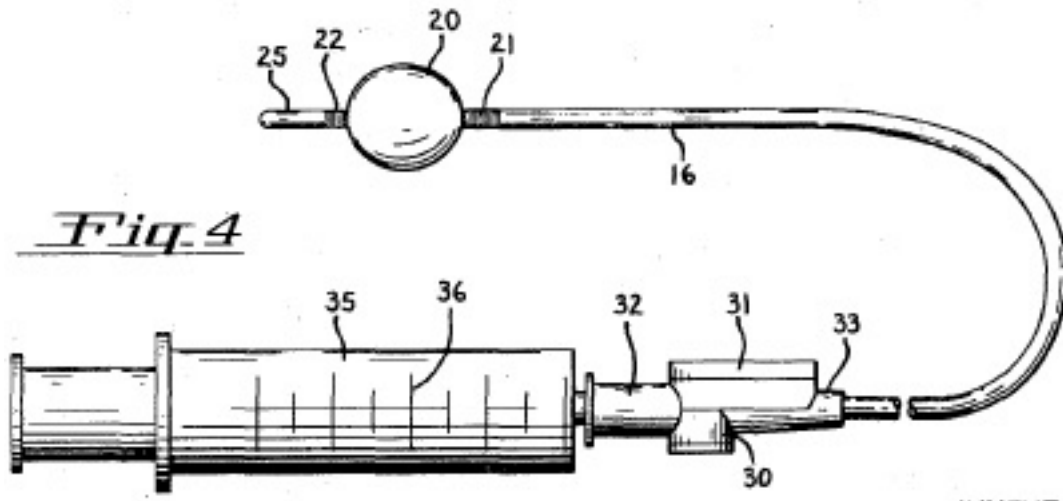
VIII. RECITATION OF THE CHALLENGED CLAIMS

A recitation of the Challenged Claims is provided in Appendix A.

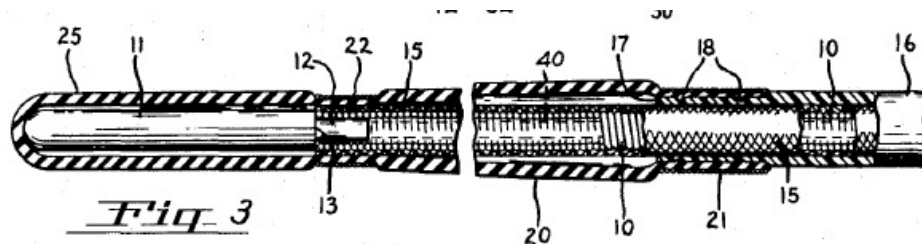
IX. GROUND 1: CLAIMS 1-10 ARE OBVIOUS IN VIEW OF FOGARTY AND CHENGOD AND A PHOSITA'S KNOWLEDGE

A. Overview: Fogarty

Fogarty shows and describes an occlusion catheter system. Ex-1004, 1:39-40. The catheter, as shown in Figure 4, includes a compliant occlusion balloon (20), a proximal end (16) a distal end (the end marked with closed end portion (25) of balloon (20)), a valve (30), and a fitting (32) for receipt of an inflation syringe (35).

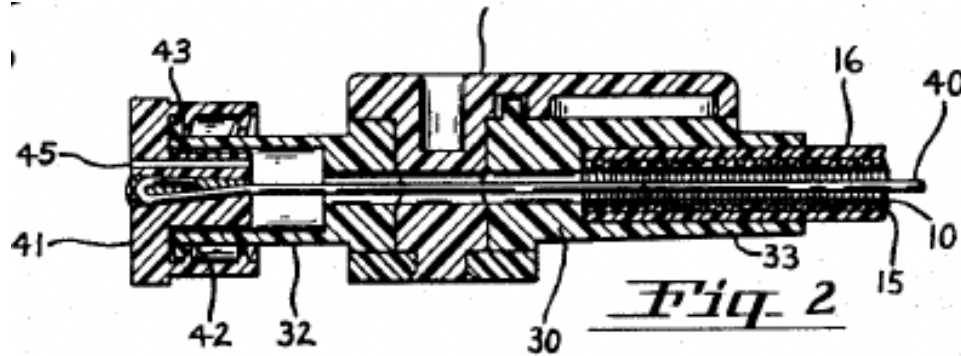


Ex-1004, Fig. 4. The valve (30) and syringe (35) are utilized to inflate and maintain pressure in the compliant balloon (20). Ex-1004, 3:38-48. As shown in Figure 3, the distal section of the catheter terminates at a soft rubber tip (11).



Ex-1004, Fig. 3. Balloon (20) extends between the tip (11) and the proximal catheter section or tube (16). This arrangement is made by inserting the soft rubber tip (11) of the catheter into the open end of balloon (20) until the soft rubber tip (11) contacts the closed end portion (25) of the balloon. Ex-1004, 2:71-3:1. Balloon (20) is then secured to the catheter with windings (21) and (22). Ex-1004, 3:1-6. The catheter is also equipped with a solid metal wire or stylet (40) that extends from the tip (11), as shown in Figure 3, to a cap (41) where it is secured to the proximal end

of the catheter within the hub flange elements (43) in the manner shown in Figure 2.
Ex-1004, 3:60-62.



Ex-1004, Fig. 2.

B. Overview: Chengod

Chengod describes the use of a Fogarty catheter, which is a commercialized version of the device described in Fogarty. Ex-1003 ¶71.

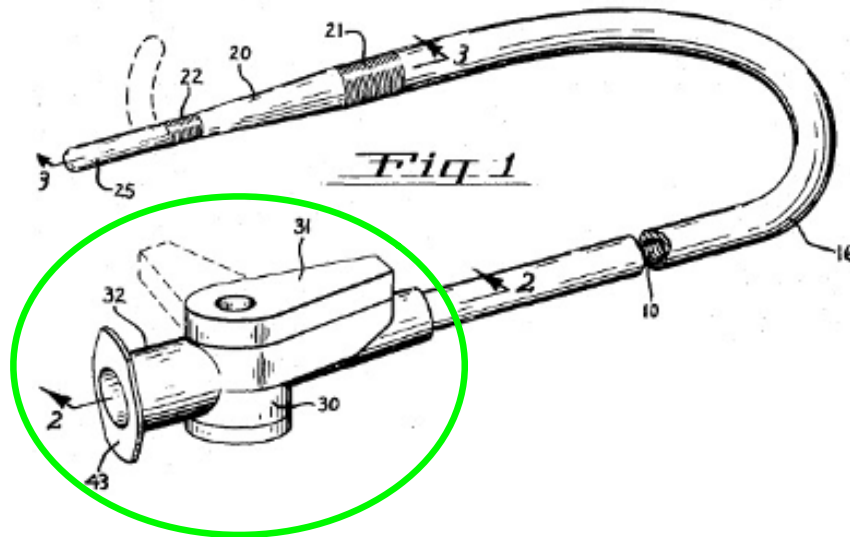
C. Claim 1

Claim 1 is rendered obvious by Fogarty, Chengod, and a PHOSITA's knowledge. Ex-1003 ¶¶68.

1. Element [1Preamble] – “An occlusion catheter system comprising:”

To the extent the preamble is limiting, Fogarty discloses an occlusion catheter system. Ex-1004, 1:39-40. Ex-1003 ¶73.

2. Element [1a] – “a proximal hub”



Ex-1004, Fig. 1 (annotated).

Fogarty discloses this element in Figure 1 and accompanying text. 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.

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

Fogarty discloses this element. Fogarty explains that the “proximal end of the catheter tube is secured to a shut-off valve 30 having a rotatable valve member 31.” Ex-1004, 3:38-39. 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

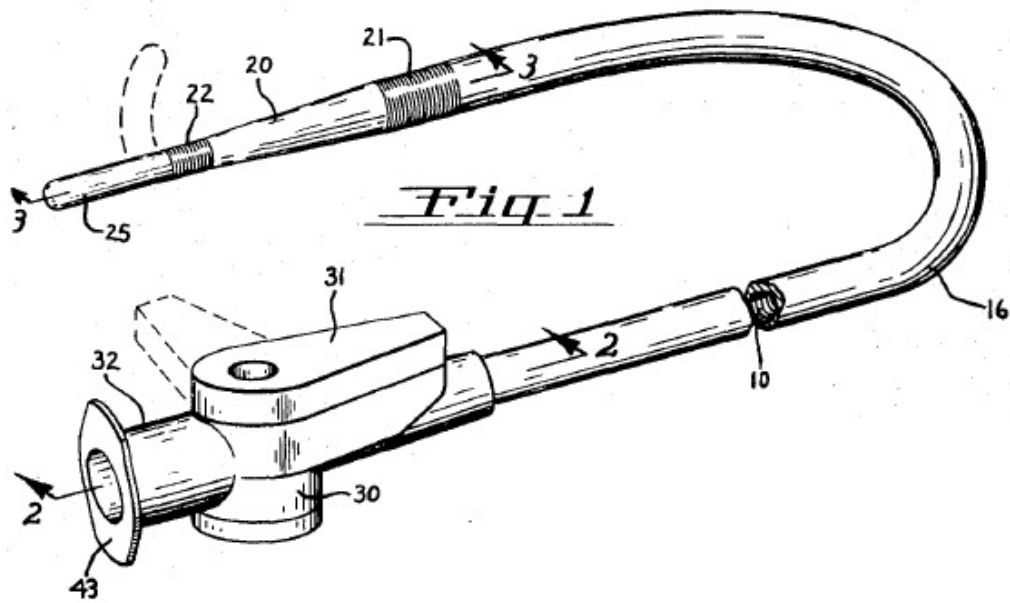
(30) is the claimed “flow valve” and is “configured to selectively fluidly communicate the proximal hub with an inflation device” (e.g., the syringe (35)). Ex-1004, 3:38-48. Ex-1003 ¶75.

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

Fogarty discloses this element. Fogarty states that the proximal end of the catheter tube (16) is secured to the shut-off valve (30) of the hub. Ex-1004, 3:38-39. 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). Ex-1004, 3:19-27, 3:38-48. Thus, the proximal catheter section (16) is in fluid communication with the proximal hub (e.g., via flow valve 30). Ex-1003 ¶76.

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

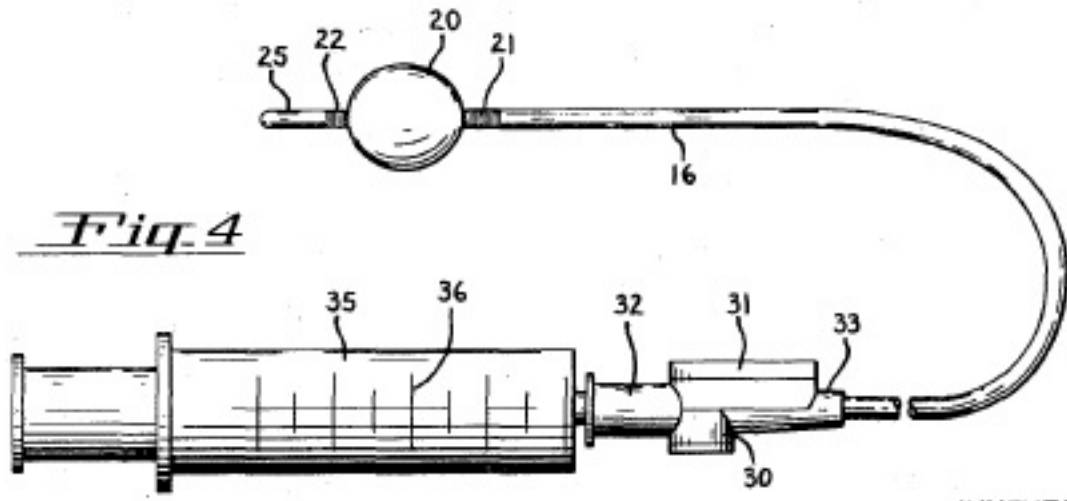
Fogarty discloses this element. Fogarty includes a distal catheter section that includes a “soft rubber plug 11” as an atraumatic tip. The “distal catheter” section is depicted in Figure 1 as the portion including winding (22) and the distal end of the Fogarty catheter. Fogarty explains that the plug (11) forms a “flexible tip” that will readily bend back on itself as shown by the broken lines depicted in Figure 1. Ex-1004, 2:43-49.



Ex-1004, Fig. 1. The soft, flexible nature of the plug (11) makes the tip of the catheter atraumatic. Ex-1003 ¶77.

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

Fogarty discloses this element. Fogarty shows balloon (20) in Figures 1, 3, and 4. The balloon is described as being made 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.” Ex-1004, 3:16-19. Elastomers and latex are compliant materials. Ex-1003 ¶79. In 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. Ex-1003 ¶79.



Ex-1004, Fig. 4.

7. **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”**

Chengod discloses this element. Chengod Figure 1 shows a Fogarty catheter having depth length markings (“carinal distance” markings). Ex-1005, Fig. 1 (below). 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. Ex-1005, 637.

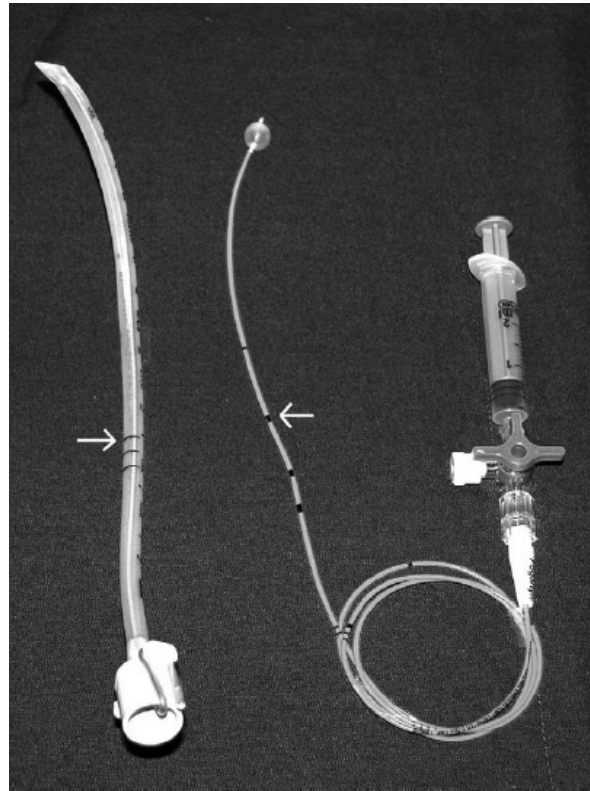


Fig 1. Endotracheal tube modified to resemble a left-sided double-lumen tube with the help of a stylet. Note the bevel of the tube facing toward the right side. Carinal distance is marked on the tube and the catheter as measured from the tip (Arrows). The second and third markings on the catheter, from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

Ex-1005, Fig. 1; Ex-1003 ¶80. Providing a Fogarty catheter with external markings aids in advancing and positioning the catheter into proper position (e.g., the correct insertion depth). Ex-1005, 637, Fig. 1; Ex-1003 ¶¶80-81.

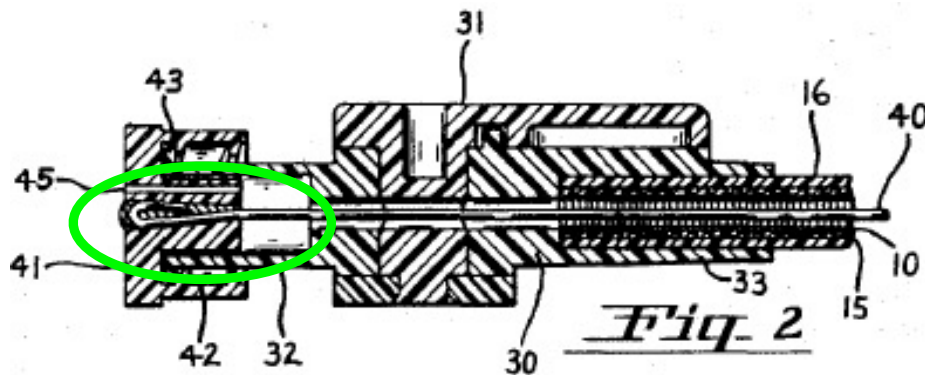
8. Element [1g] – “a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon”

Fogarty discloses this element. Fogarty describes the catheter body having a “hollow inner core” corresponding to the claimed “lumen.” Ex-1004, 1:66-67. The catheter tube (16) (i.e., the “proximal catheter section”) extends from, and is connected to the proximal hub (see Fig. 1 above). Fluid 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 in the manner previously described. Ex-1004, 3:38-48; Ex-1003 ¶¶82-83.

9. Element [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”

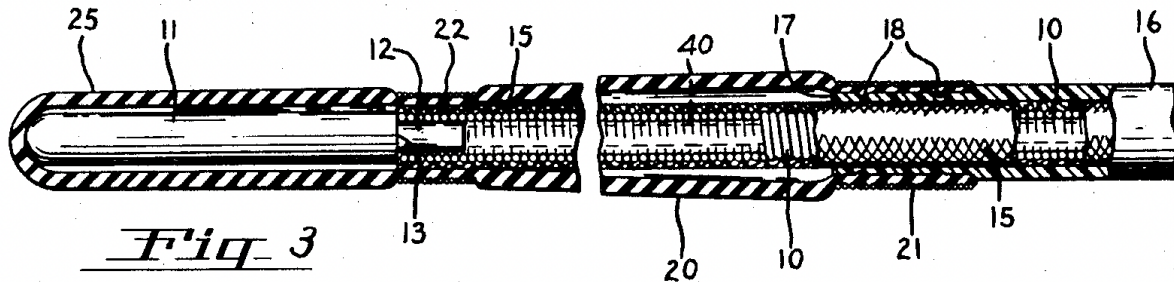
Fogarty discloses and teaches this element. Fogarty describes a wire, i.e., metal wire stylet (40), “to facilitate the insertion of the catheter into a luminal structure within the body.” Ex-1004, 3:48-54. In Figure 2 the proximal end of the metal wire stylet (40) is shown secured within the hub, via cap (41), which is threaded into the hub flange elements (43).



Ex-1004, Fig. 2 (annotated); Ex-1003 ¶¶84-85.

In 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), i.e., ending in the distal catheter section.



Ex-1004, Fig. 3; Ex-1003 ¶¶87-88.

While Fogarty does not explicitly state that the wire stylet (40) is solid, a PHOSITA understands that a metal wire stylet designed to facilitate the insertion of the catheter into a patient would be solid and not hollow, as a solid wire provides more stability. For example, the Bagaoisan, Nishide, and Anderson references disclose solid metal stylets and mandrels. See Section VII.B. A PHOSITA understands those metal stylets and metal mandrels to be the same as a wire. Ex-1003 ¶89.

U.S. Patent No. 5,087,246 to Smith issued in 1992 and includes “elongate wire 34” that is secured to the hub (called the “proximal fitting”) and extends to the “distal tip 38” of the balloon catheter. Ex-1025, 4:17-23. A PHOSITA understands Smith’s disclosure to be a solid metal wire, as depicted in Figure 3. Thus, Smith is additional evidence that wire stylets in balloon catheters are solid metal wires. Moreover, the use of a hollow wire (i.e., a “tube with a lumen, as distinguished in the ’737 Patent (Ex-1001, 30:61-64)) is counter to basic medical device manufacture goals as it would create a larger profile, thus unnecessarily forcing the creation of a

larger medical device. Furthermore, a hollow stylet creates an opportunity for the stylet to kink or collapse upon itself not afforded by a similar device of solid construction. Ex-1003 ¶89.

10. 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”

Chengod discloses this element and it was known to a PHOSITA. Although Fogarty does not indicate a size of the catheter, it was well known to a PHOSITA that Fogarty catheters were available in sizes smaller than 6 Fr. For example, Chengod describes use of Fogarty catheters as small as 4 Fr (Ex-1005, 637) and Deaton discloses Fogarty catheters manufactured as small as 3 Fr (Ex-1008, 32). Ex-1003 ¶90.

Further, a PHOSITA would find it obvious to size a Fogarty catheter less than 6 Fr in diameter (in an uninflated configuration) because a 6 Fr size for an occlusion catheter is simply one of a limited number of known design choices, and a PHOSITA would have a reasonable expectation of success in making and using a 6 Fr (or less) sized Fogarty occlusion catheter in 2015. Again, 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. Ex-1005, 637. Chengod’s disclosure also confirms that there is no question whether a Fogarty catheter with size less than 6 Fr would work. It did. The same is true of Deaton’s Fogarty catheter which was available in sizes of 3 F to 7 F. Ex-1003 ¶91.

A PHOSITA understands that a basic tenet of endovascular procedures is that the smallest device available that can adequately complete the job is the one that should be used. This is because endovascular procedures require devices to be inserted into the blood vessel (artery or vein) thereby creating a hole in that vessel. The larger the device utilized, the larger the hole created. The larger the hole created, the greater the risk for an access site complication (bleeding, pseudoaneurysm formation, arteriovenous fistula formation) to occur. So, practitioners use smaller devices when available because they're generally safer. Ex-1003 ¶¶92.

Thus, it would have been obvious based on Fogarty and Chengod to provide a Fogarty catheter with all sections (proximal section, occlusion balloon, and distal section) having outer dimensions less than 6 Fr in an uninflated configuration to allow the Fogarty catheter to be utilized in narrower vessels. Ex-1003 ¶¶90-92, 105-06.

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

A PHOSITA had knowledge of this claim. Claim 2 depends from claim 1 which is obvious in view of Fogarty, Chengod, and the PHOSITA's knowledge. A PHOSITA is well aware that compliant balloons such as the type used in the Fogarty catheters as described in Fogarty and Chengod could be designed to inflate asymmetrically. *See supra*, Section VII.D; Ex-1003 ¶¶93.

- E. Claims 3-5 – “3. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion” – “4. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.” – “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.”**

A PHOSITA had knowledge of these claims. Claims 3-5 depend from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. A PHOSITA is well aware that compliant balloons such as the type used in the Fogarty catheters as described in Fogarty and Chengod could be designed with the claimed shapes. *See supra*, Section VII.E; Ex-1003 ¶¶94.

- F. Claim 6 – “The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal.”**

Fogarty discloses this claim. Claim 6 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. As discussed above for element 1[h], Fogarty describes use of a “metal wire stylet” (40); thus, the wire is constructed from metal. Ex-1004, 3:48-59. Ex-1003 ¶¶95-96.

- G. Claim 7 – “The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel.”**

Fogarty teaches this claim, which was also well known to a PHOSITA. Claim 7 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. Fogarty explains that wire stylet (40) is constructed of metal. Ex-1004, 3:48-59. As explained above in Section VII.B, a PHOSITA is well aware that metal components used in balloon catheters (including occlusion catheters) can be

made from stainless steel. Thus, for those same reasons, it would be obvious to construct the metal wire stylet of Fogarty out of stainless steel. Ex-1003 ¶¶97-98.

H. 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.”

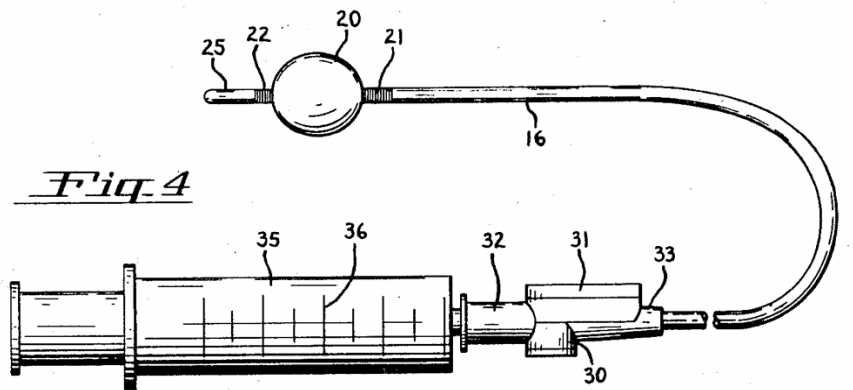
A PHOSITA had knowledge of this claim. Claim 8 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. As explained above in Section VII.C, a PHOSITA is well aware that radio opaque markers are routinely used in balloon catheters, and the position of those markers at either end of the balloon was commonly used in 2015 to identify the location of the balloon under fluoroscopy. Thus, a PHOSITA would find it obvious based on this knowledge to further modify the Fogarty catheter of claim 1 with radio opaque markers. Ex-1003 ¶100.

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

A PHOSITA had knowledge of this claim. Claim 9 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type used in the Fogarty catheters as described in the Fogarty and Chengod references could be designed with the claimed shape. Ex-1003 ¶101.

J. Claim 10 – “An inflation control system kit comprising: the occlusion catheter system of claim 1; and a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.”

Fogarty discloses this claim. Claim 10 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA's knowledge. Fogarty describes the use of a syringe (35) for inflation of the balloon (20). Valve (30) found at the hub has a conventional fitting (32) that can receive the syringe (35) at a tube socket (33). Ex-1004, 3:40-42. The syringe (35) contains a fluid that can be fluidly connected to the valve input of the hub using the fitting (32) and can be used for inflating the balloon. Ex-1004, 3:42-46. Fogarty Figure 4 shows an assemblage (or kit), which includes the occlusion catheter of claim 1 (without markers or size as disclosed in Chengod or known to a PHOSITA), and a syringe (35) containing a fluid that is configured to fluidly connect with an inlet (32) of the proximal hub (30, 31, 32). Ex-1003 ¶¶69-70.



Ex-1004, Fig. 4. Chengod Figure 1 also shows an assemblage (or kit), which includes an occlusion catheter and a syringe containing a fluid that is configured to fluidly connect with an inlet of a proximal hub.

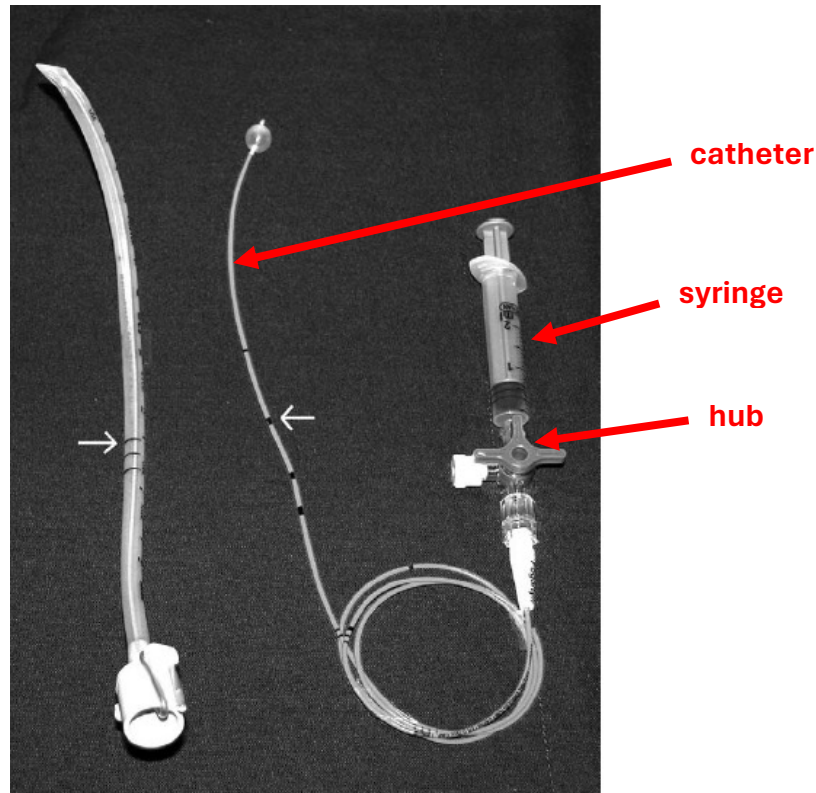


Fig 1. Endotracheal tube modified to resemble a left-sided double-lumen tube with the help of a stylet. Note the bevel of the tube facing toward the right side. Carinal distance is marked on the tube and the catheter as measured from the tip (Arrows). The second and third markings on the catheter, from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

Chengod, Fig. 1 (red annotations added). Thus, Fogarty and Chengod teach the kit of Claim 10. Ex-1003 ¶¶102-104.

K. Motivation to Combine the Fogarty and Chengod References

Chengod provides express motivation to combine its markings and size (less than 6 Fr) with the Fogarty patent because Chengod discloses a Fogarty catheter with the markings and size required by Claim 1 of the '737 Patent. Fogarty is a patent issued on the catheter design of Thomas Fogarty, based on a patent application filed in 1965. Chengod describes the use of the Fogarty catheter in 2005. As explained above for element [1i], the Fogarty catheter has long been available in

small sizes, and Chengod provides proof that the Fogarty catheter design shown in the Fogarty patent was available in a size of six French and smaller. Furthermore, Chengod shows that a Fogarty catheter was actually modified by adding at least one length marking to the exterior of the proximal catheter section. Ex-1003 ¶105.

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.

X. GROUND 2: CLAIM 2 IS OBVIOUS OVER FOGARTY, CHENGOD, SAAB, AND A PHOSITA'S KNOWLEDGE.

A. Overview: Saab

Saab is entitled *Applications of High-Pressure Balloons in the Medical Device Industry*, published in Medical Device & Diagnostic Industry Magazine, in September 2000. Ex-1006-1. Saab describes two basic balloon types, namely high-pressure balloons used to apply force, and low-pressure elastomeric balloons, usually used in occlusion. Ex-1006-7. Saab explains that high pressure balloons typically use noncompliant or low-compliant materials that retain their size and shape, whereas low-pressure balloons “are typically dip molded in a tubular shape.” Ex-1006-8. Low-pressure balloons usually cannot be inflated to precise dimensions and cannot retain well-defined shapes. Ex-1006-8. Saab Figure 2 includes several examples of high-pressure balloons having specific shapes which “may be demanded by the particularities of the anatomical site, the requirements of the treatment process, or both.” Ex-1006-9.

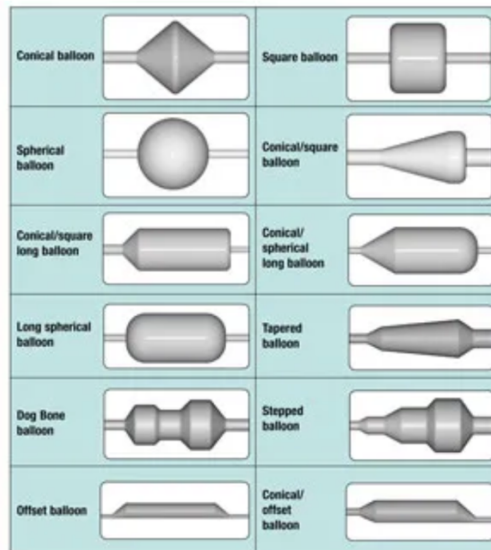


Figure 2. Examples of high-pressure balloon shapes. A specific shape may be demanded by the particularities of the anatomical site, the requirements of the treatment process, or both. (The designs shown here can be formed in different diameters and lengths.)

Ex-1006-9, Fig. 2. A PHOSITA would recognize that Saab is explaining that balloons that are used in balloon catheters can be made in a variety of shapes. Ex-1003

¶¶108-12.

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

Saab discloses this claim. Claim 2 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. Saab discloses that asymmetrical balloons made of latex or silicone were known. Ex-1006-11.



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

Ex-1006-11, Fig. 6; Ex-1003 ¶¶113-15.

C. Motivation to Combine Saab with Fogarty and Chengod

Saab discloses the “endless design possibilities” that were available when designing balloon catheters, focusing almost exclusively on balloon shapes. Ex-1006, 1. 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. Ex-1003 ¶117.

Indeed, a PHOSITA understands that human anatomy is variable, and changes in that anatomy can occur secondary to disease processes (such as atherosclerosis, aneurysms, malignancies, and others). This variation in anatomy shape, size, and course leads to an understanding that in order to occlude a vessel, various balloon sizes and shapes would be required. It's not a "one shape fits all" scenario. Thus, a compliant balloon capability to expand asymmetrically is not only known, but desired in many intervention procedures that would be performed with a Fogarty catheter. Ex-1003 ¶118.

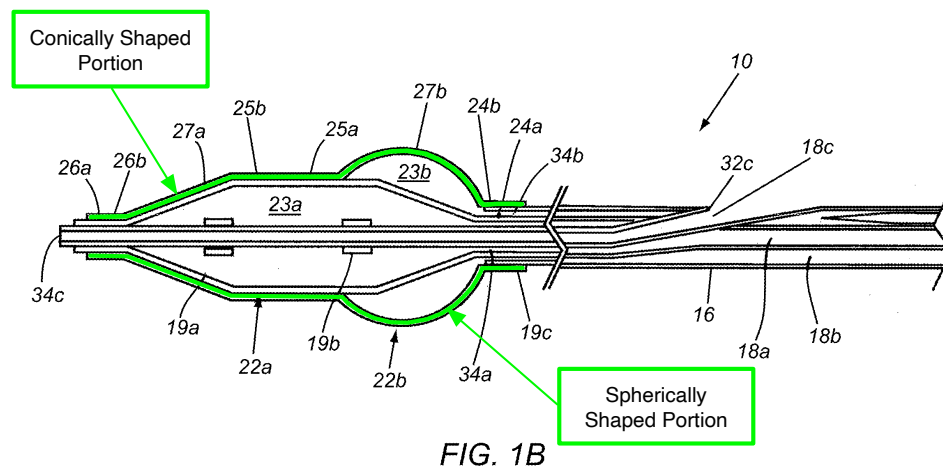
XI. GROUND 3: CLAIMS 3-5, AND 9 ARE OBVIOUS IN VIEW OF FOGARTY, CHENGOD, SANATI, AND A PHOSITA'S KNOWLEDGE

A. Overview: Sanati

Sanati describes a balloon catheter with two balloons: an outer balloon that starts with a tapered, distal end, and then converts to a spherical portion at its proximal end, and an inner balloon that tapers at both ends and is cylindrical in the middle. Ex-1007, Fig. 1B. The balloons of Sanati may be formed from a substantially elastic material such as silicon. Ex-1007, 7:41-47. A PHOSITA understands that silicon balloons are compliant. Ex-1003 ¶122.

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

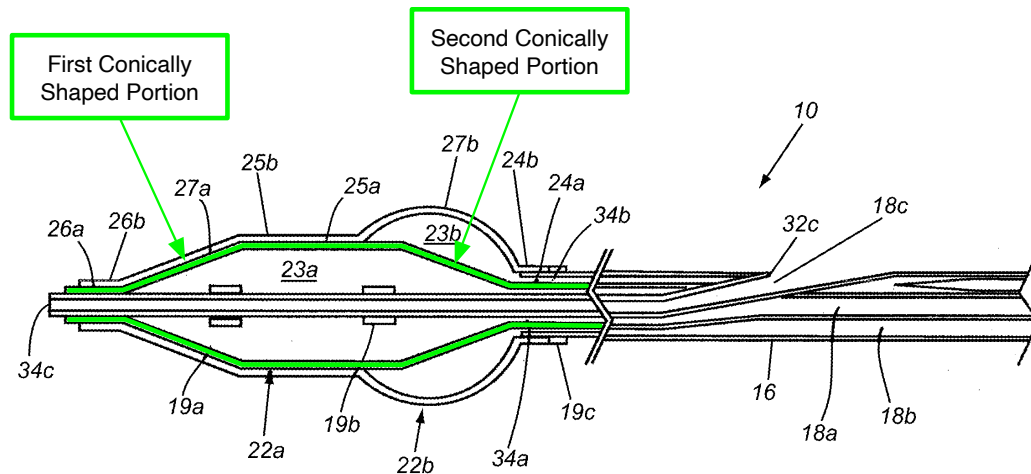
Sanati discloses this claim. Claim 3 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. Sanati Figure 1B shows a balloon with a conically shaped portion facing a spherical portion at element 22b:



Ex-1007, Fig. 1B (annotated). Sanati describes “outer balloon 22b” as having a “substantially spherical” shaped proximal section 27b. Ex-1007, 7:25-29. In Figure 1B, the distal portion of balloon 22b is conically shaped and follows the “tapered” transition portion section 27a. Ex-1007, 8:55-57. Ex-1003 ¶¶124-25.

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

Sanati discloses this claim. Claim 4 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. Sanati’s inner balloon 22a has a conically shaped portion facing another conically shaped portion:



Ex-1007, Fig. 1B (annotated). Inner balloon 22a has a tapered portion 27a at its distal end and another tapered portion at its proximal end, both forming conical shapes. Ex-1007, 7:35-47; Ex-1003 ¶¶126-28.

D. 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”

Sanati discloses this claim. Claim 5 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. Sanati’s balloon 22a has a first conically shaped portion, a second conically shaped portion, and an intervening generally cylindrical portion:

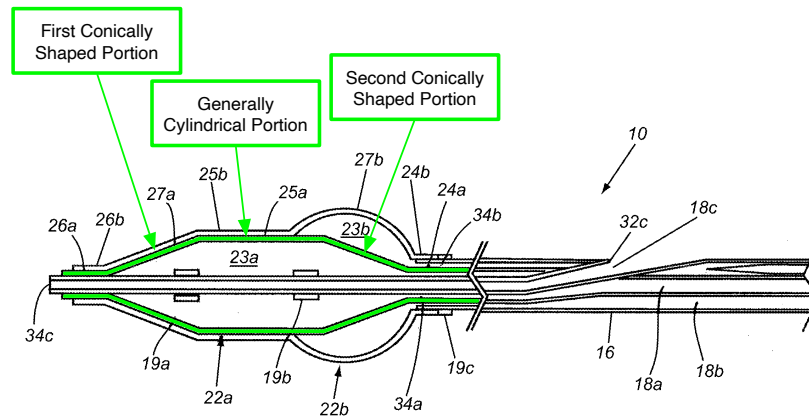


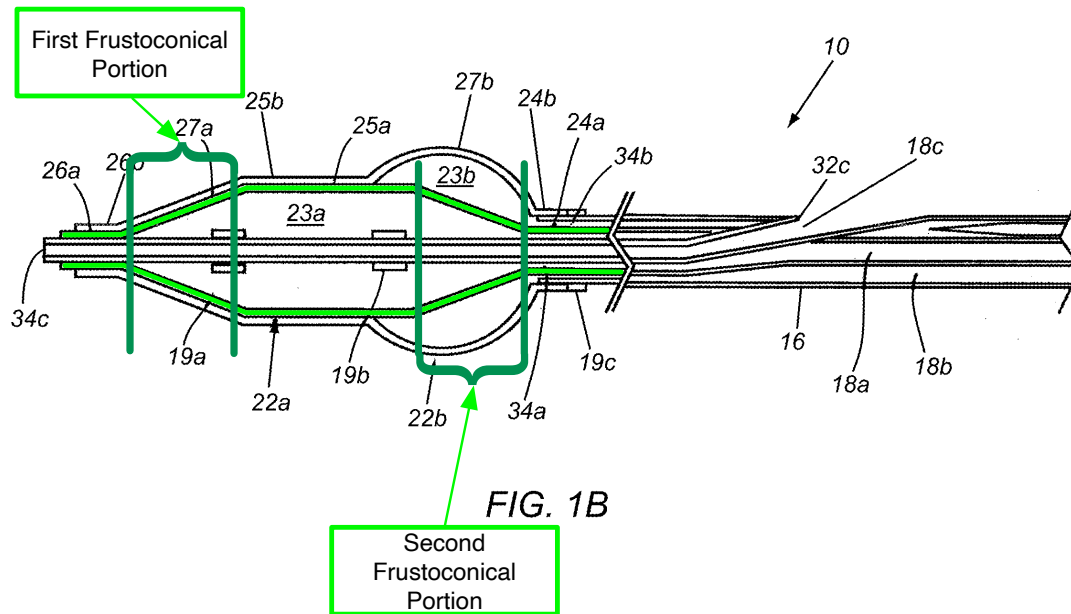
FIG. 1B

Ex-1007, Fig. 1B (annotated). The 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.” Ex-1007, 8:50-53. Sanati further states that the inner balloon has “a substantially cylindrical shape.” Ex-1007, 8:44-49; Ex-1003 ¶¶129-130.

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

Sanati discloses this claim. Claim 9 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge. Santi discloses that inner balloon 22a comprises a conically shaped portion facing another conically shaped portion. 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:



Ex-1007, Fig. 1B (annotated); Ex-1003 ¶¶131-32.

F. Motivation to Combine Sanati with Fogarty and Chengod

A PHOSITA would be motivated to combine Sanati's balloon shapes with the catheter of Fogarty and Chengod. Sanati discloses particular balloon configurations for another compliant balloon catheter. Ex-1007, 7:39-47. A PHOSITA would recognize that both the Fogarty catheter (described in Fogarty and Chengod) and Sanati's catheter utilize compliant balloons that can be used for occlusion catheters, e.g., for blood flow occlusion of the lumens of the vascular system. Ex-1003 ¶¶133.

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. Ex-1003 ¶134.

Sanati's balloon configuration was a known technique that had been used to improve balloon catheters at the time of the '737 Patent. While Sanati does not call its catheter a "Fogarty catheter," a PHOSITA would consider it to be a similar device. Thus, claims 3-5 and 9 of the '737 Patent simply apply a known technique (Sanati's compliant balloon shapes) that had been used to improve a similar device to the Fogarty balloon catheter in a similar way. Furthermore, Sanati teaches that using the disclosed double balloon configuration and shapes allows the operator to "substantially anchor the distal end" of the catheter during the procedure. Ex-1007, 13:6-11. Thus, a PHOSITA would have recognized that anchoring the distal end of the balloon catheter was a reason to apply the teaching of Sanati to the Fogarty catheter described in Fogarty and Chengod. Moreover, a PHOSITA would have a reasonable expectation of success in using Sanati's balloon configuration at least because Sanati discloses its balloon is used for a 1.7mm catheter, which is about a 5.1 French size. (A basic French/mm conversion is that 3 French = 1 mm.) Ex-1003 ¶134.

XII. GROUND 4: CLAIM 8 IS OBVIOUS IN VIEW OF FOGARTY, CHENGOD, DEATON, AND A PHOSITA'S KNOWLEDGE

A. Description of Deaton

Deaton is a published article that was presented as an insert of Endovascular Today in July of 2005. The article is entitled *Image-Guided Thrombectomy in Vascular Surgery*, written by Dr. David H. Deaton. Ex-1008, 32. The article describes the use of stainless steel bushings, located at the proximal and distal ends of the balloon, in catheters such as the Fogarty balloon catheter, to enable accurate visualization under fluoroscopy. Ex-1008, 32.

B. 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"

Deaton discloses this claim. Claim 8 depends from claim 1, which is obvious in view of Fogarty, Chengod, and the PHOSITA's knowledge. Deaton discloses (in July 2005) a version of the Fogarty catheter that was commercially available that included "[s]tainless steel bushings located at the proximal and distal ends of the balloon enable accurate visualization under fluoroscopy." Ex-1008, 32. Stainless steel bushings are a form of radiopaque markers, which is why they enable visualization under fluoroscopy. Thus, 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. Ex-1003 ¶¶137-38.

C. Motivation to Combine Deaton with Fogarty and Chengod

Deaton provides express motivation to combine its markers with Fogarty because Deaton discloses a Fogarty catheter with the claimed radiopaque markings. Deaton specifically mentions the Fogarty catheter history and explains that Deaton's catheter is the "latest iteration" of the Fogarty balloon catheter. Thus, Deaton explains that the changes made are merely a new iteration of the catheter described in Fogarty. In other words, not only is there a motivation to combine the elements, but Deaton also shows an actual, real-life combination in the form of a new iteration of the Fogarty catheter. Ex-1003 ¶140.

Additionally, 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. As explained above in Section VII.C, a PHOSITA would see the benefit in the presence of such markers for balloon catheters used in an image-guided clinical setting, as exact balloon location identification prior to balloon inflation is critical for safe procedure performance. Thus, the addition of the markers of Deaton to the catheter of Fogarty (as modified by Chengod and a PHOSITA's knowledge) would result in a safer device. Ex-1003 ¶¶45, 141.

XIII. GROUND 5: CLAIMS 1- 10 ARE OBVIOUS IN VIEW OF ELIASON AND A PHOSITA'S KNOWLEDGE

A. Description of Eliason

Eliason is U.S. Patent No. 9,131,874, issued to Jonathan L. Eliason and Todd E. Rasmussen on September 15, 2015. As discussed above, Eliason's effective filing date is April 21, 2011. *See supra*, Section IV.F. Mr. Eliason and Mr. Rasmussen are on the Clinical Advisory Board of Prytime Medical Devices, Inc., the owner of the '737 Patent. Ex-1027. Eliason is owned, however, by the University of Michigan, not Patent Owner Prytime Medical Devices, Inc. Ex-1028.

Eliason describes a "[f]luoroscopy-independent, endovascular aortic occlusion system." Eliason describes an occlusion balloon catheter that is designed for performing REBOA type procedures. Ex-1009, 1:29-34. This occlusion catheter is designed to be fixed to a wire (12) that provides rigidity to the catheter. Ex-1009, 9:43-49. The wire (12) passes from the distal end of the catheter distal to the balloon (14), through the shaft (32) and into the hub, where it is secured by diaphragm (40). The wire and the rest of the balloon catheter are to be inserted as a single unit or device. Ex-1009, 6:5-7. The catheter described in Eliason differs from the catheter described in the '737 Patent in the addition of self-expanding wire struts in Eliason. Ex-1009, 8:53-54. These struts (element 22 in Figure 10, below) are located distal to the balloon and are designed to keep the catheter centered in the vasculature. Ex-1009, 5:17-20, 46-52.

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2. Element [1a] – “a proximal hub”

Eliason discloses this element. The proximal hub is shown in Figure 10 as element 36, called the “multi-port and valve assembly.” Ex-1009, 10:7-9. This assembly remains outside the body during use and is used to physically connect the inflation device (syringe) to the inflation lumen of the catheter. Ex-1009, 10:33-36; Ex-1003 ¶146.

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

Eliason discloses this element. The inflation device is syringe (48) attached to hub (36). Ex-1009, 10:33-36. 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). Ex-1009, 10:36-40.

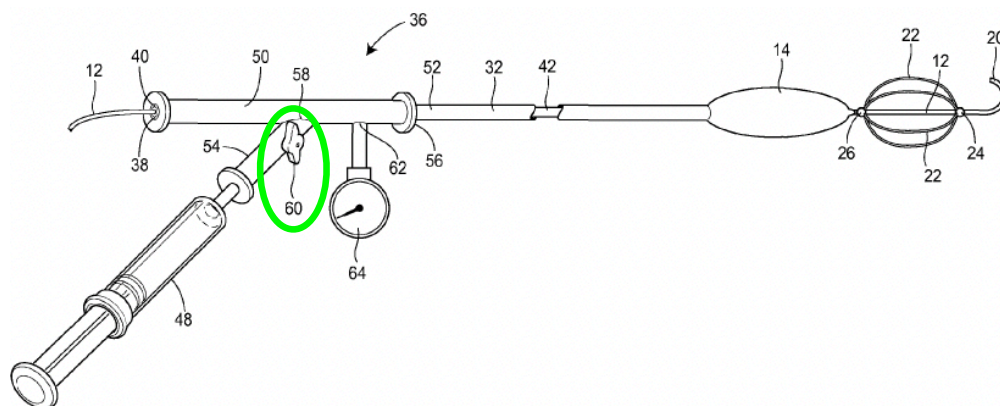


FIG. 10

Ex-1009, Fig. 10 (annotated). The valve (60) is moveable between an open condition and a closed condition, as such, it is configured to selectively fluidly communicate the proximal hub with the inflation device. Ex-1009, 10:36-52; Ex-1103 ¶147.

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

Eliason discloses this element. Proximal end (52) of balloon shaft (32) is attached to hub (36):

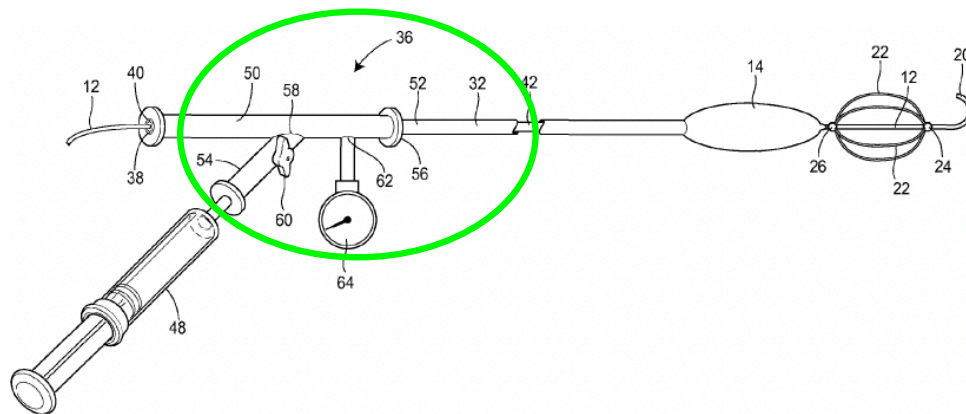


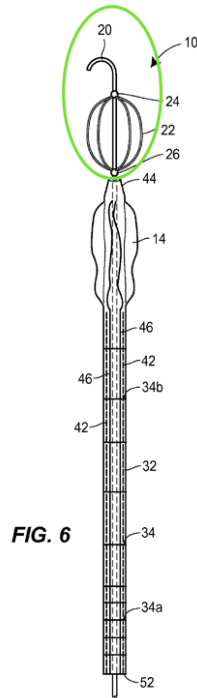
FIG. 10

Ex-1009, 10:17-20 & Fig. 10 (annotated). Hub (36) is “in fluid communication” with both the proximal end of the balloon shaft (32) (proximal catheter section) and the syringe (48). Ex-1009, 11:33-36; Ex-1003 ¶148.

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

Eliason discloses this element. The distal end of the catheter terminates with a “J tip” (20), which is “used to minimize trauma to or perforation of the arterial

vessels” during use of the catheter. Ex-1009, 8:47-49. Thus, the catheter has a distal section terminating with an atraumatic tip:



Ex-1009, Fig. 6 (annotated); *see also*, Fig. 10; Ex-1003 ¶149.

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

Eliason discloses this element. Eliason describes its balloon as an “arterial occlusion balloon” and an “aortic occlusion balloon” (14). Ex-1009, 6:56-63, 9:31-33. Figures 6 and 10 show balloon (14) connecting the proximal section (32) of the catheter with the distal section of the catheter.

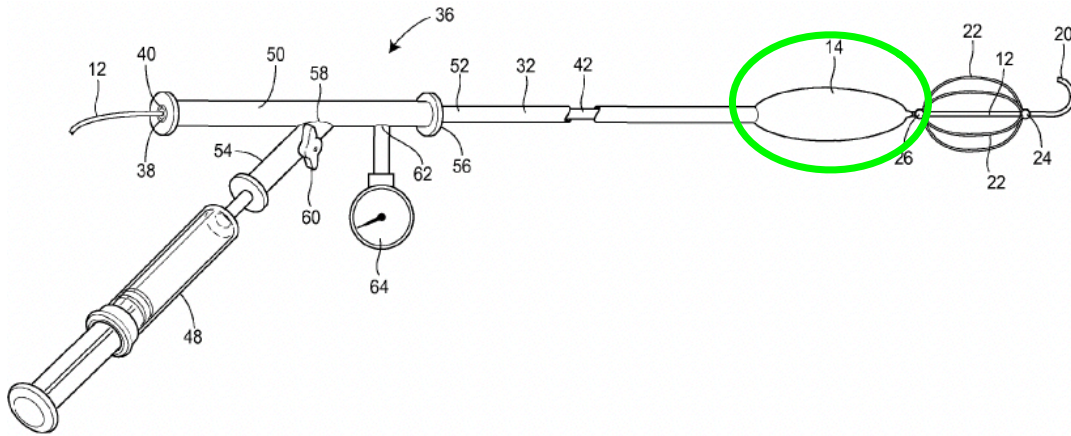
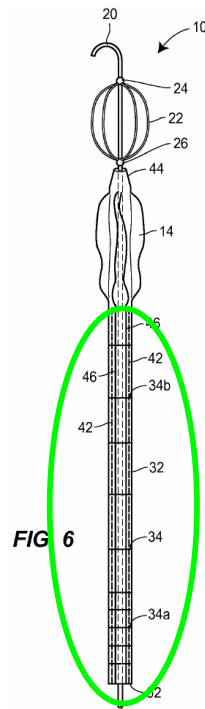


FIG. 10

Ex-1009, Fig. 10 (annotated). Eliason describes balloon (14) as “sufficiently compliant.” Ex-1009, 4:54-61; Ex-1003 ¶150.

7. 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”

Eliason discloses this element. Eliason describes “pre-calibrated length indicia,” which include both “minor length markers” (34a) and “major length markers” (34b) in 5-centimeter increments. Ex-1009, 9:31-35. These markers are found on the exterior of the proximal section of the balloon shaft (32).



Ex-1009, Fig. 6 (annotated). With 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. Ex-1009, 10:53-64. Thus, these markers are used to indicate an insertion depth of the occlusion catheter system. Ex-1003 ¶151.

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

Eliason discloses this element. In Eliason, 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). Ex-1009, 5:64-6:1. To extend from the syringe to the balloon, this lumen must extend through the hub (36) and the proximal catheter section.

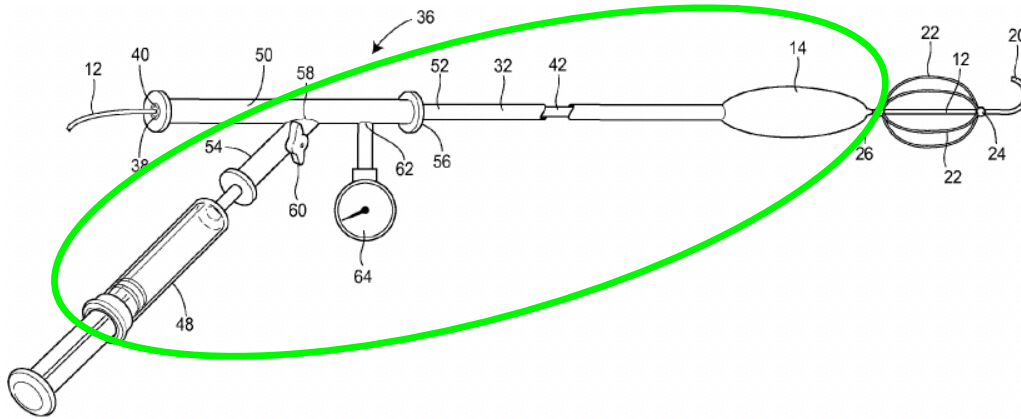


FIG. 10

Ex-1009, Fig. 10 (annotated); Ex-1003 ¶152.

9. **Element[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”**

Eliason teaches this element. 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. Ex-1009, 4:49-54, 10:29-32.

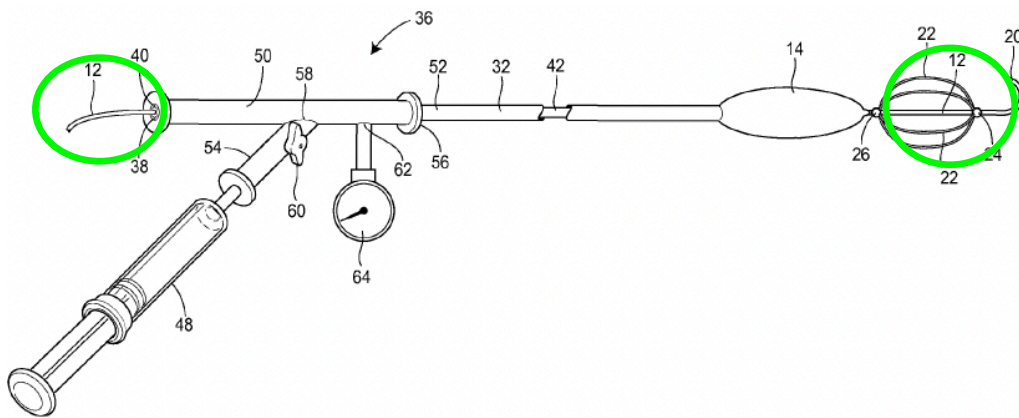


FIG. 10

Ex-1009, Fig. 10 (wire 12 circled). Wire (12) provides rigidity to the catheter. Ex-1009, 9:43-49. Although 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. Ex-1003 ¶153.

In some embodiments of Eliason, the endovascular wire can move separately from the remainder of the catheter through a lumen. In other embodiments, (“pre-securing embodiments”), however, “[t]he self-centering wire and the occlusion balloon may be inserted as a single unit or device.” Ex-1009, 6:5-7. In these embodiments, the wire 12 is “secured” to the remainder of the catheter in two locations. One of these locations is at the trailing securement bead, which is shown as element 26 in Figure 10. Ex-1009, 11:20-23.

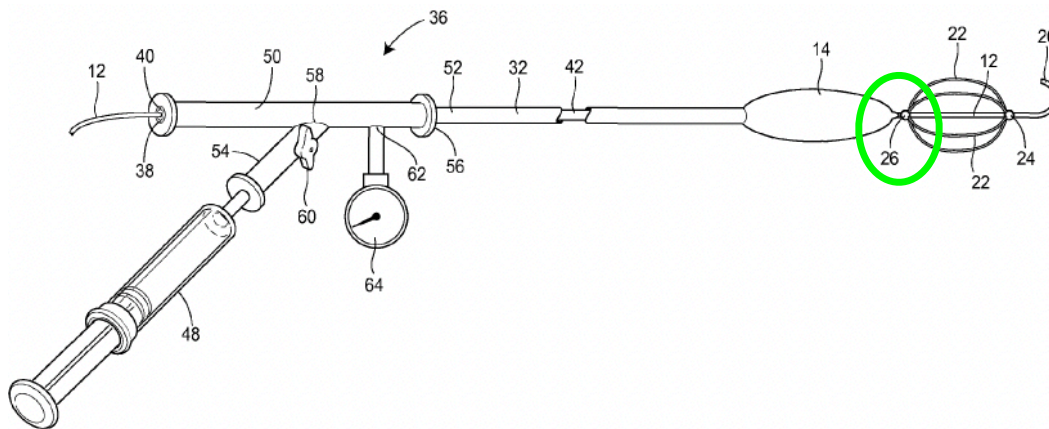


FIG. 10

Ex-1009, Fig. 10 (annotated).

Claim 6 of Eliason discloses “pre-securing the balloon shaft [32] to the endovascular wire proximate a trailing securement bead, allowing the balloon shaft and endovascular wire to be inserted in the patient and delivered as a single unit.”

Ex-1009, 16:41-45 (claim 6). Eliason claim 6 depends from claim 4, which indicates the “pre-securing” method may be performed when “selectively inflating a thoracic aortic balloon” by comparing a pre-measured “distance between the at least two external anatomical landmarks of the patient to a prediction model and calculating a length to which a calibrated endovascular wire and a balloon shaft of the thoracic occlusion system are to be inserted in the patient.” Ex-1009, 16:18-38 (claim 4). According to this method, the catheter can be inserted “independent of fluoroscopy.” Ex-1009, 16:18-38 (claim 4). This “pre-securing” method was described in the published version of the PCT application (PCT/US2011/033368), which was published on October 27, 2011. Ex-1012, cover page. In particular, the “pre-securing” method was described in published claims 8, 56, and 57. Ex-1003 ¶154.

The endovascular wire (12) is also secured at the hub (36) by diaphragm (40), which ensures a “fluid-tight” connection between the hub (36) and the aortic balloon (14). Ex-1009 10:12-17, 10:29-32.

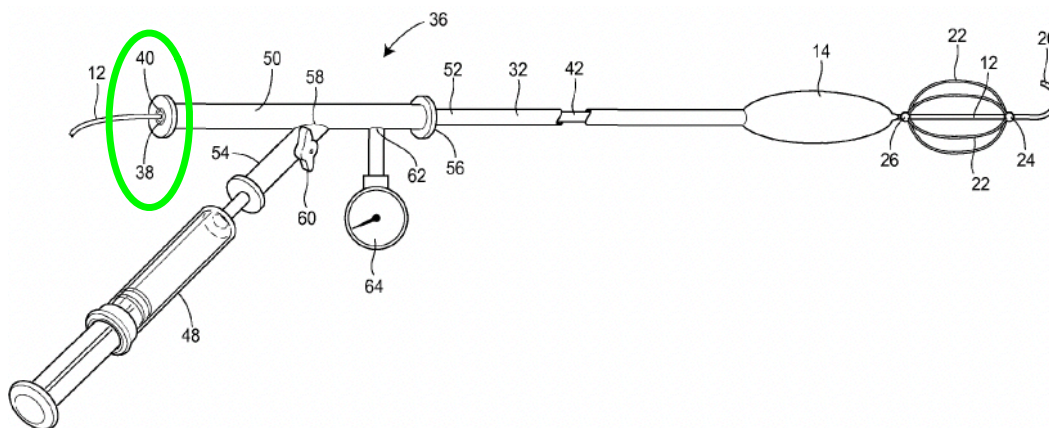


FIG. 10

Ex-1009, Fig. 10 (annotated). Although Eliason states that the diaphragm (40) “can extend” through the diaphragm, a PHOSITA understands that there is no need for the wire (12) to extend any significant distance beyond the diaphragm (40) because the diaphragm maintains a “fluid-tight connection and because the wire (12) does not move with respect to the rest of the catheter. It is, in the words of Eliason, used as a “single unit or device.” Ex-1009, 12:29-32, 6:5-7; Ex-1009 ¶155.

The “fluid-tight connection” (Ex-1009, 10:29-32) made by the wire (12) and the diaphragm (40) secures the proximal-most end of the wire (12) within the hub (36). The wire is “secured” to the proximal hub when it is attached so that it can withstand normal operating conditions and perform the preferred functions (e.g., providing rigidity that resists distal or caudal migration (Ex-1009, 9:43-49)) of the catheter, in this case, where the balloon and wire are used as a “single unit or device.” Ex-1009, 6:5-7; Ex-1003 ¶156.

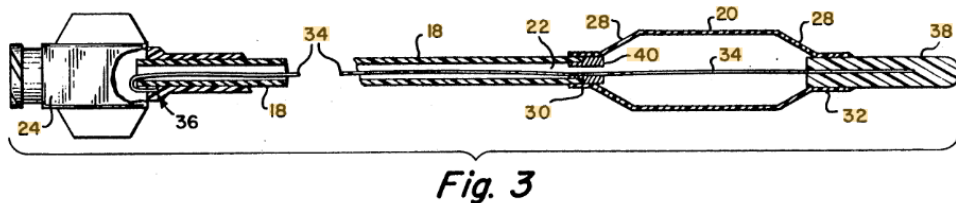
To the extent Patent Owner argues the connection between the diaphragm and the wire does not secure the proximal-most end of the wire to the proximal hub, a PHOSITA would have found it obvious to modify Eliason’s balloon catheter to arrive at this element of the claim. In particular, for the pre-securing embodiments, a PHOSITA understands that there is no need for the wire (12) to extend beyond the proximal hub (multi-port and valve assembly (36)) because the entire balloon catheter is fixed in position on wire 12 so that it can be “inserted as a single unit or device.” Ex-1009, 6:5-7. In contrast, the diaphragm is necessary in other

embodiments (i.e., not the pre-securing embodiments) where the wire is first inserted into the patient, and the balloon shaft is later inserted over the wire until it reaches the trailing securement bead (26). Ex-1009, 9:38-41, 11:20-23. A PHOSITA understands there will be some amount of wire extending beyond the diaphragm in these other embodiments because the interventionist holds onto the wire while passing the balloon shaft over it. Because there is no need for the extra wire length in the pre-securing embodiments, a PHOSITA would have found it obvious to modify those embodiments to secure the wire to the proximal hub so that the wire does not extend beyond the hub. Ex-1003 ¶157.

A PHOSITA would have been motivated to modify Eliason's pre-securing embodiments in this way because this modification represents known concepts combined in familiar ways, which, when combined, would yield predictable results. Eliason teaches the concept of securing the wire so that it is fixed in place with respect to the proximal hub so that the entire balloon catheter can be "inserted as a single unit or device." Ex-1009, 6:5-7. By 2015, a PHOSITA was well aware of the concept that the proximal-most end of a wire (e.g., a stylet or mandrel) could be secured within the proximal hub for a balloon catheter. This knowledge is documented in the literature, including

- Fogarty (Ex-1004) (see Ground 1).

- Smith (Ex-1025): Smith includes “elongate wire 34” that is secured by its proximal-most end (36) to the hub (called the “proximal fitting 24”). Ex-1025, 4:17-23 & Fig. 3.



- Nishide (Ex-1017): Nishide discloses a “catheter ... structure in which the proximal terminal of the stylet terminates at the hub unit.” Ex-1017, 3:5-14.

Ex-1003 ¶ 158.

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

Smith, and Nishide balloon catheters) in a similar way (to allow insertion of the wire and the balloon shaft at the same time). Ex-1003 ¶159.

Additionally, a PHOSITA would find it obvious to modify Eliason's balloon catheter to arrive at this element of Claim 1 because a PHOSITA could implement a predictable variation (i.e., the variation taught in Fogarty, Smith, and Nishide), and would see the benefit of doing so. As for benefits, a PHOSITA would understand that implementing this variation (i.e., modifying Eliason) would likely result in a less costly device due to requiring less metal (i.e., the metal wire would no longer extend past the hub) and no longer requiring the diaphragm. An additional benefit would likely be the simplification of manufacturing the device since Eliason's "fluid-tight" diaphragm connection would no longer be necessary. Ex-1009, 12:29-32. Finally, a PHOSITA would understand that securing the proximal-most end of the wire within the hub as described in Fogarty, Smith, and Nishide would result in a balloon catheter design with the desired rigidity but without the excess wire hanging from the proximal end of the hub. Ex-1009, 9:43-49; Ex-1003 ¶160.

10. 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.”

Eliason discloses this element. In Eliason, 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

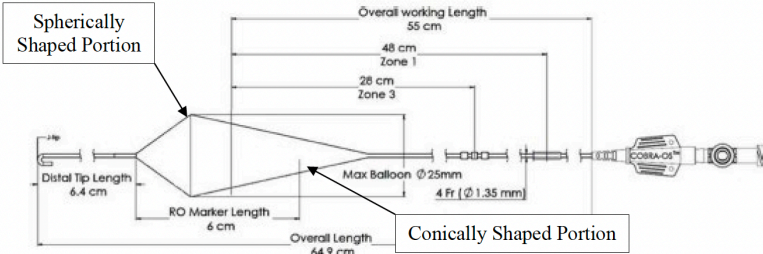
(Fr) sheath. Ex-1009, 9:12-27. Because the unexpanded occlusion balloon must advance through the sheath along with the balloon shaft (32), a PHOSITA would recognize that all of these elements have an outer diameter of less than six Fr if they are to pass through the sheath (28). Ex-1003 ¶161.

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

Eliason teaches this claim which is known to a PHOSITA. Claim 2 depends from claim 1, which is obvious in view of Eliason and the PHOSITA’s knowledge. As explained above in Section VII.D, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate asymmetrically. Since this is the only additional element added by claim 2, this claim is also obvious in view of Eliason and the PHOSITA’s knowledge. Ex-1003 ¶162.

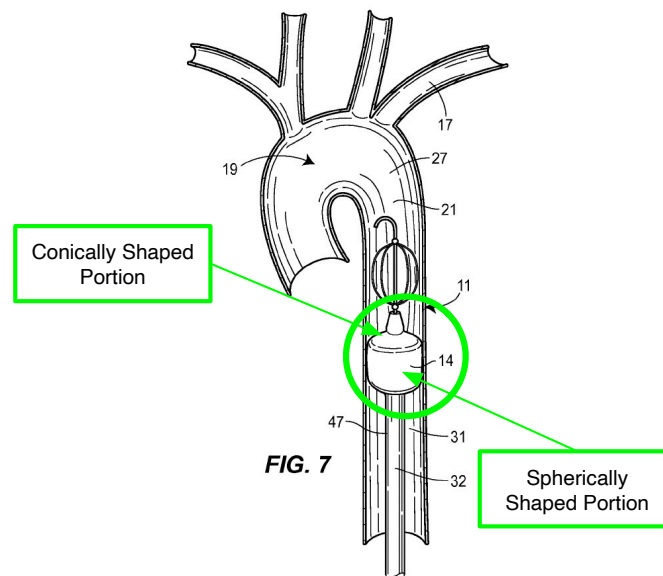
D. Claim 3 – “The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.”

Eliason discloses and teaches this claim. Claim 3 depends from claim 1, which is obvious in view of Eliason and the PHOSITA’s knowledge. Patent Owner alleges in district court that a conical balloon with a circular cross section satisfies the limitation in claim 3 of the ’737 Patent that requires a “spherically shaped portion”:

3. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.	Trauma Surgery & Acute Care Open article titled “Size matters: first-in-human study of a novel 4 French REBOA device”, first published on January 8, 2021: Fig. 1  The diagram shows a catheter system with a distal tip, a conically shaped portion, and a spherically shaped portion. Dimensions include: Distal Tip Length 6.4 cm, RO Marker Length 6 cm, Overall Length 64.9 cm, Overall working Length 55 cm, Zone 1 48 cm, Zone 3 28 cm, Max Balloon ϕ 25mm, and 4 Fr (ϕ 1.35 mm). Labels point to the Spherically Shaped Portion and the Conically Shaped Portion.
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Ex-1023, 13.

Based on the patent owner’s apparent understanding of the claim, Figures 7 and 11 of Eliason show the elements of claim 3, namely a conically shaped portion facing a spherically shaped portion. For example, Eliason Figures 7 and 11 show a particular shape for balloon (14):



Ex-1009, Fig. 7 (annotated).

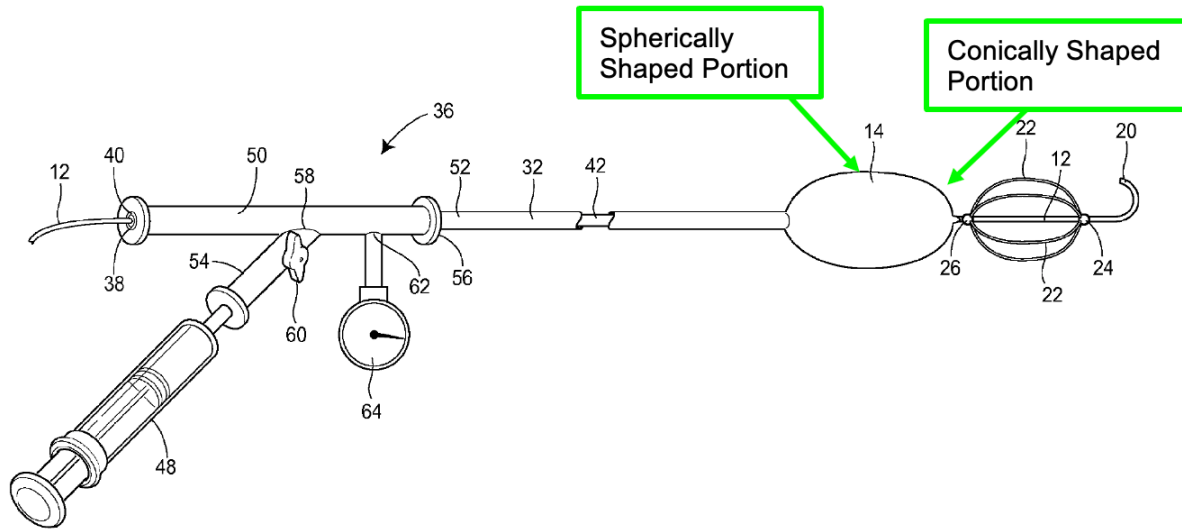


FIG. 11

Ex-1009, Fig. 11 (annotated). In Figure 7, the top of the balloon (14) is shown as a conical shape. The center of the balloon has a circular cross section, similar to what Patent Owner identifies as a “spherically shaped portion.” Thus, consistent with Patent Owner’s allegations, Eliason discloses “a conically shaped portion facing a spherically shaped portion.” Ex-1003 ¶¶163-66.

Alternatively, the balloon shape of claim 3 is obvious based on the PHOSITA’s knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate with “a conically shaped portion facing a spherically shaped portion.” Since this is the only additional element added by Claim 3, this claim is obvious in view of Eliason and the PHOSITA’s knowledge. Ex-1003 ¶167.

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

Eliason discloses and teaches this claim. Claim 4 depends from claim 1, which is obvious in view of Eliason and the PHOSITA's knowledge. A PHOSITA recognizes from Eliason that balloon (14) is symmetrical with both ends having similar conically shaped portions facing each other:

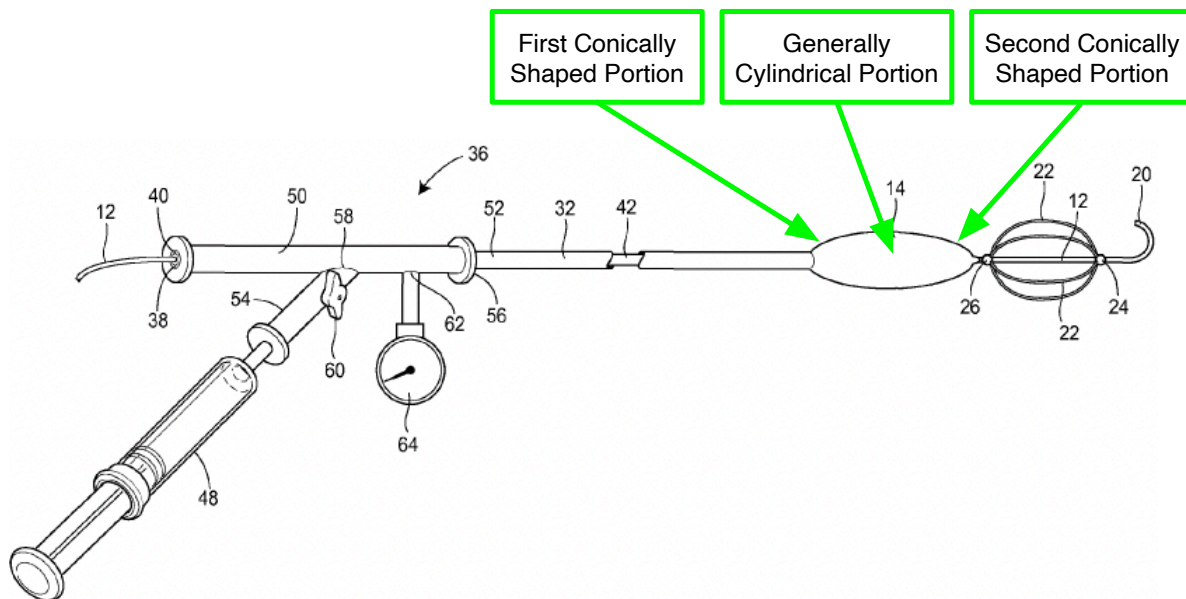


FIG. 10

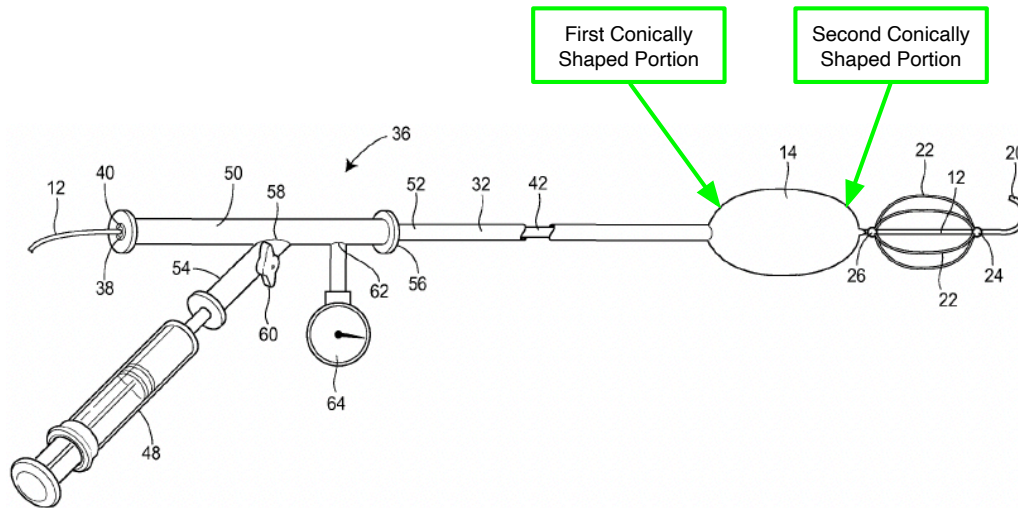


FIG. 11

Ex-1009, Figs. 10-11 (annotated); Ex-1003 ¶168.

Alternatively, the balloon shape of Claim 4 is obvious based on the PHOSITA's knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate with "a conically shaped portion facing another conically shaped portion." Since this is the only additional element added by Claim 4, this claim is obvious in view of Eliason and the PHOSITA's knowledge. Ex-1003 ¶169.

F. 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."

Eliason discloses and teaches this claim. Claim 5 depends from claim 1, which is obvious in view of Eliason and the PHOSITA's knowledge. Each element of claim 1 is found in Eliason. Eliason shows balloon (14) with two conically shaped portions facing one another, and an intervening cylindrical portion:

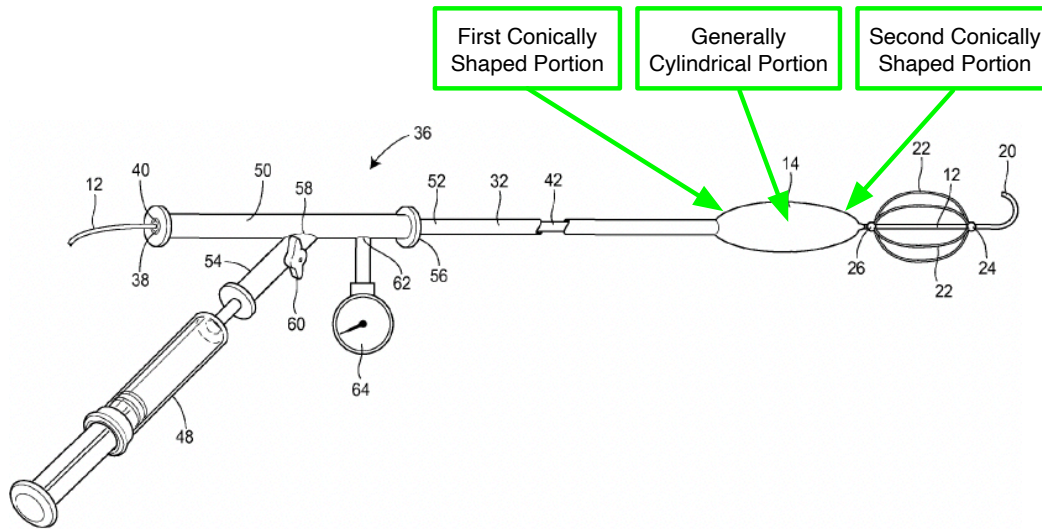


FIG. 10

Ex-1009, Fig. 10 (annotated). Ex-1009 ¶170.

Alternatively, the balloon shape of Claim 5 is obvious based on the PHOSITA's knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate with "a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion." Since this is the only additional element added by Claim 5, this claim is obvious in view of Eliason and the PHOSITA's knowledge. Ex-1003 ¶171.

G. Claims 6 and 7 – "6. The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal." – "7. The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel."

Eliason teaches these claims. Both Claim 6 and Claim 7 depend from Claim 1, which is obvious in view of the Eliason reference and the PHOSITA's knowledge. Claim 6 adds that the solid wire is made of a metal, while Claim 7 adds that the solid

wire is constructed of stainless steel. As explained above in Section VII.B, a PHOSITA is well aware that metal components used in occlusion catheters can be made from stainless steel. In particular, the wire used for rigidity in a balloon catheter can be made from stainless steel. Thus, it would be obvious to construct the endovascular wire (12) of Eliason out of stainless steel. Ex-1003 ¶172.

H. 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.”

A PHOSITA has knowledge of this claim. Claim 8 depends from claim 1, which is obvious in view of Eliason and the PHOSITA’s knowledge. As explained above in Section VII.C, a PHOSITA is well aware that radio opaque markers are routinely used in balloon catheters, and the position of those markers at either end of the balloon is commonly used to identify the location of the balloon under fluoroscopy. While Eliason is generally designed for fluoroscopy-free procedures, Figure 12 explicitly describes that in “narrow margin procedures,” fluoroscopy is required.

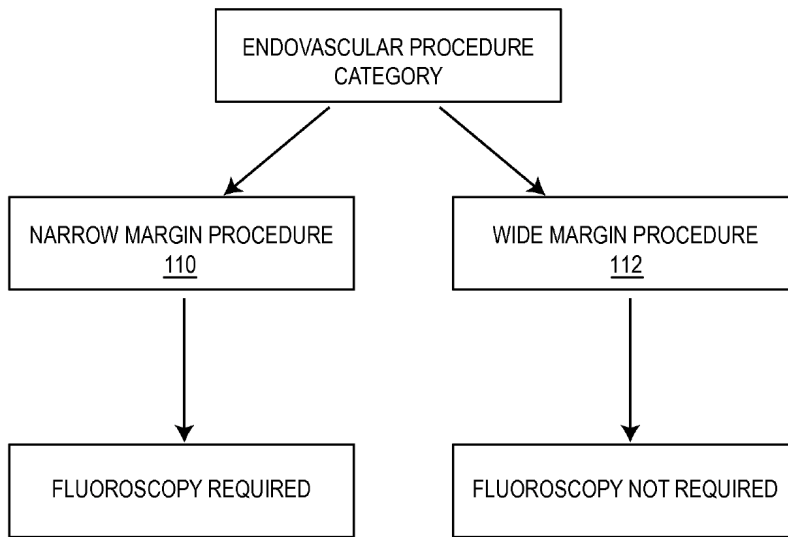


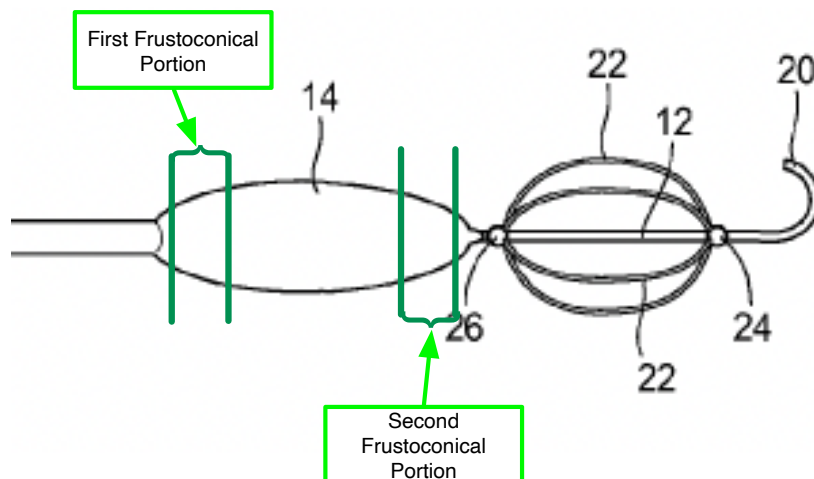
FIG. 12

Ex-1009, Fig. 12 & 11:50-51; Ex-1003 ¶174.

Such narrow margin procedures include endovascular procedures in large axial vessels of the human torso. Ex-1009, 11:43-61. Thus, the addition of the radiopaque markers as well known to a PHOSITA would add the capability to use the device of Eliason in “narrow margin procedures.” A PHOSITA would find it obvious based on this knowledge to further modify the Eliason catheter (as modified based on the PHOSITA’s knowledge) with two radio opaque markers as claimed. 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. 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. Ex-1003 ¶175.

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

Eliason discloses and teaches this claim. Claim 9 depends from claim 1, which is obvious in view of Eliason and the PHOSITA’s knowledge. As discussed in Section VII.E.3, 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 conical sections of the compliant balloon catheters are actually frustoconical because the catheter running through the ends of the balloon results in truncation of a cone. Thus, Figure 10 of Eliason shows two oppositely oriented frustoconical portions.



Ex-1009, Fig. 10 (excerpted and annotated); Ex-1003 ¶176.

Alternatively, the balloon shape of Claim 9 is obvious based on the PHOSITA’s knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate with “at least two oppositely oriented frustoconical portions.” Since this is the only

additional element added by Claim 9, this claim is obvious in view of Eliason and the PHOSITA's knowledge. Ex-1003 ¶177.

J. Claim 10 – “An inflation control system kit comprising: the occlusion catheter system of claim 1; and a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.”

Eliason discloses this claim. Claim 10 depends from claim 1, which is obvious in view of Eliason and the PHOSITA's knowledge. Eliason's Figure 10 depicts the balloon catheter coupled to a syringe, and Eliason explains that the syringe (48) is connected to the hub (36) through the side port (58) and branch (54) of the hub (36). Ex-1009, 10:33-36.

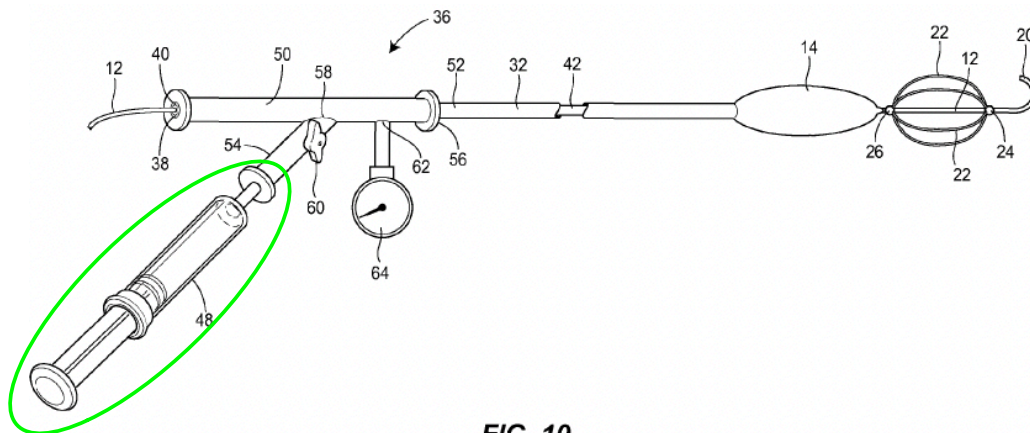


FIG. 10

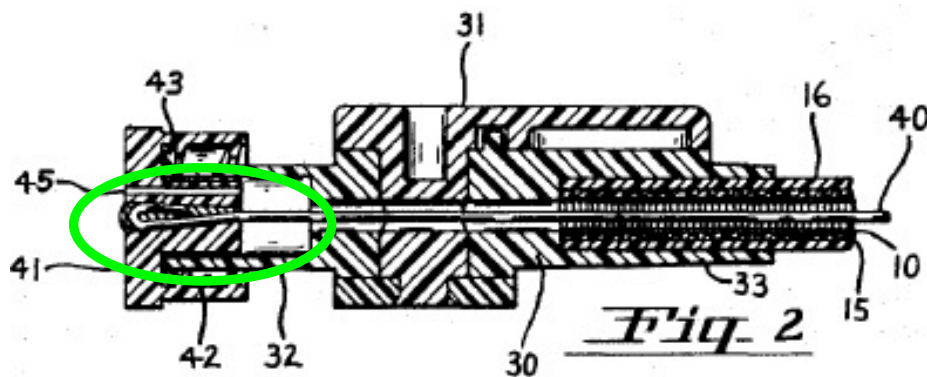
Ex-1009, Fig. 10 (annotated). The syringe (48) is filled with inflation fluid that is then introduced into the hub (36). Ex-1009, 9:67-7:3. Thus, Eliason discloses claim 10. Ex-1003 ¶179.

XIV. GROUND 6: CLAIMS 1- 10 ARE OBVIOUS IN VIEW OF ELIASON, FOGARTY, AND A PHOSITA'S KNOWLEDGE

A. Claims 1-10

As shown in Ground 5, claims 1-10 are obvious in view of the Eliason reference and the PHOSITA's knowledge. To 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, and each of these claims are therefore obvious in view of a combination of Eliason, Fogarty, and the PHOSITA's knowledge. Ex-1003 ¶181.

As discussed for Ground 1, element [1h], 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):



Ex-1009, Fig. 2 (annotated). The "hub flange elements" (43) form part of the proximal hub (elements 30, 31, 32, and 43). The wire (40) is therefore attached

within proximal hub, and this attachment allows the wire and the catheter to withstand normal operating conditions and perform the preferred functions of the catheter. Thus, the Fogarty reference teaches that the metal wire stylet is secured within the hub (30, 31, 32), and this securing occurs at the wire's proximal-most end. As further discussed above, Fogarty teaches its wire is solid, not hollow, and this would be known to a PHOSITA. Ex-1003 ¶182.

B. Motivation to Combine Fogarty and Eliason

Both Eliason and the Fogarty describe compliant balloon catheters that are used for vascular occlusion. Furthermore, both references are designed to use a configuration where the wire does not move with respect to the rest of the balloon catheter. (Eliason's "pre-securing embodiments" are also described in *A Novel Fluoroscopy-Free, Resuscitative Endovascular Aortic Balloon Occlusion System in a Model of Hemorrhagic Shock*, The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1, by D.J. Scott et al. (July 2013) ("Scott"). Scott called these embodiments a "fused wire and balloon catheter scheme" that allows for a "one-pass" method without the need for fluoroscopy. Ex-1010, 123.) Ex-1003 ¶183.

The Eliason reference claims pre-securing the wire (12) to the balloon shaft to allow "the balloon shaft and endovascular wire to be inserted in the patient and delivered as a single unit." Eliason, Claim 6; Eliason PCT Application, Claims 8, 56 & 57. Eliason further describes this ability to insert the self-centering wire and occlusion balloon as a single device. Ex-1009, 6:5-7. Similarly, the Fogarty reference

allows the wire to be secured to the proximal hub of the balloon shaft, with the metal wire stylet helping to “facilitate the insertion of the catheter into a luminal structure within the body.” Ex-1004, 3:49-54. Thus, 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 for the reasons discussed above for Ground 5. Ex-1003 ¶¶184-85.

XV. GROUND 7: CLAIM 2 IS OBVIOUS IN VIEW OF ELIASON, SAAB, AND A PHOSITA’S KNOWLEDGE

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

Saab discloses this claim. Claim 2 depends from claim 1, which is obvious in view of the Eliason reference and the PHOSITA’s knowledge. Saab explains that compliant balloons (such as the Eliason balloon) can be designed to expand in an asymmetrical manner. Ex-1006-11.

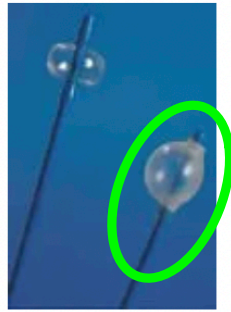


Figure 6. Offering less precision, an elastomeric balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left).

Ex-1006-11, Fig. 6 (annotated). Thus, a PHOSITA would know from Saab that the compliant balloons in the catheters describe by Eliason could be configured to expand asymmetrically. Ex-1003 ¶¶187-89.

B. Motivation to Combine Saab and Eliason

Much like the Fogarty catheters described in Fogarty and Chengod, Eliason describes a compliant balloon that can be used for vascular occlusion. As discussed for Ground 2's motivation to combine, 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. Ex-1003 ¶¶190-91.

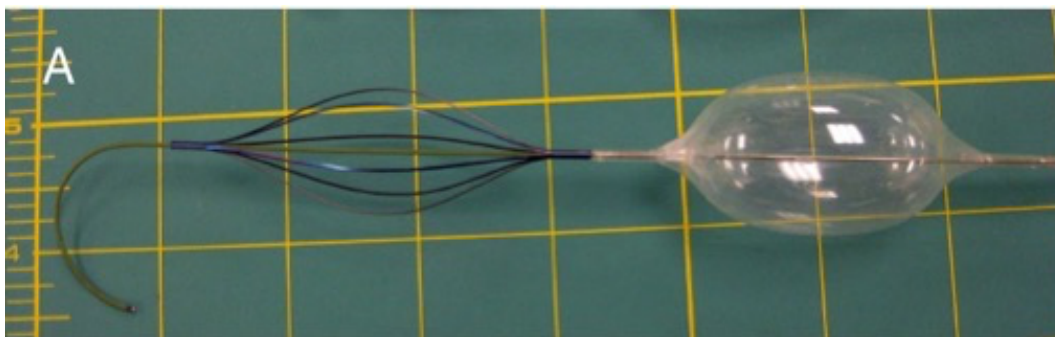
XVI. GROUND 8: CLAIMS 3-5 AND 9 ARE OBVIOUS IN VIEW OF ELIASON, SCOTT, AND THE PHOSITA'S KNOWLEDGE

A. Scott

Scott is a “Poster Paper” presented at the 26th Annual Scientific Assembly of the Eastern Association for the Surgery of Trauma. Ex-1010, 122. That assembly took place in January 2013. Ex-1010, 122. Scott was also published in July 2013 as *A Novel Fluoroscopy-Free, Resuscitative Endovascular Aortic Balloon Occlusion System in a Model of Hemorrhagic Shock* in The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1. Ex-1010, 122.

The authors of this paper are Daniel J. Scott, Jonathan L. Eliason, and others. Ex-1010, 122. Mr. Eliason is the inventor of the Eliason patent (Ex-1009). Mr. Eliason’s co-inventor on the Eliason patent is Mr. Todd E. Rasmussen, who is also an author on Scott. Ex-1010, 122.

Scott describes various test of a “new, low-profile REBOA system.” Ex-1010, 123. Scott describes this device as a “fused wire and balloon catheter” scheme, and shows a portion of it in Figure 1A:



Id.

This figure shows a device that is similar (or identical) to the device described in the Eliason patent (Ex-1009), as shown in Figure 10. Ex-1003 ¶196.

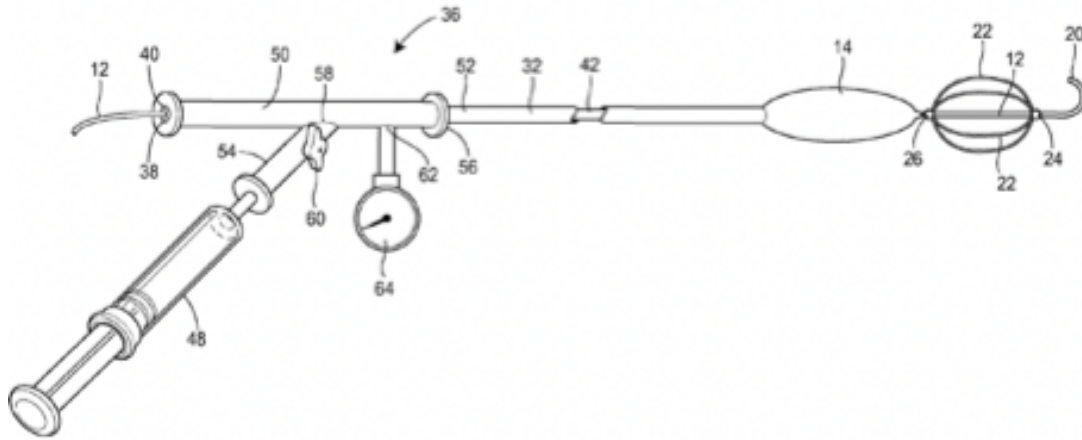
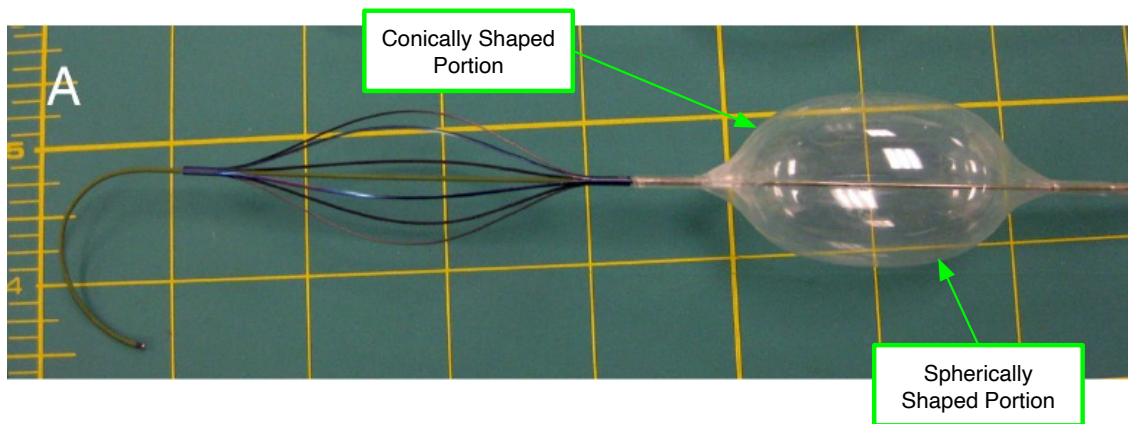


FIG. 10

Ex-1009, Fig. 10.

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

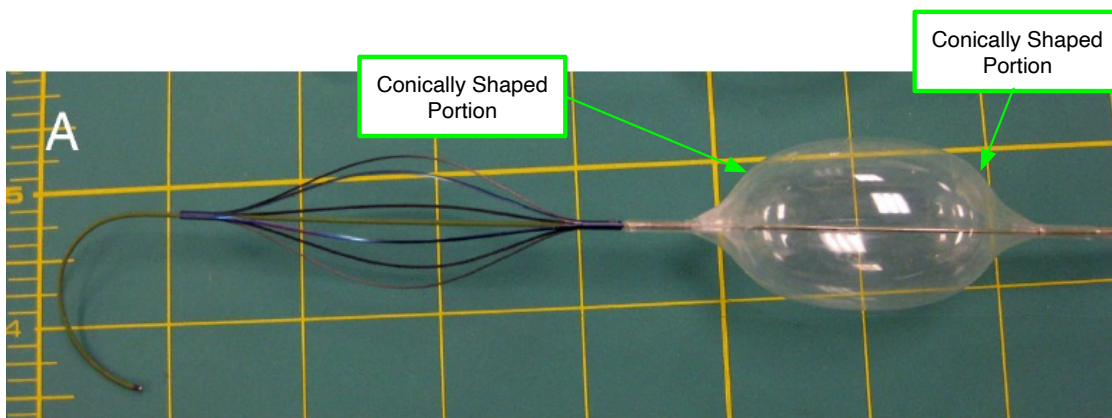
Scott discloses and teaches this claim. Claim 3 depends from claim 1, which is obvious in view of Eliason and a PHOSITA’s knowledge. Scott’s balloon has a conically shaped portion facing a spherically shaped portion. Ex-1003 ¶¶197-98.



Ex-1010, Fig. 1A (annotated).

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

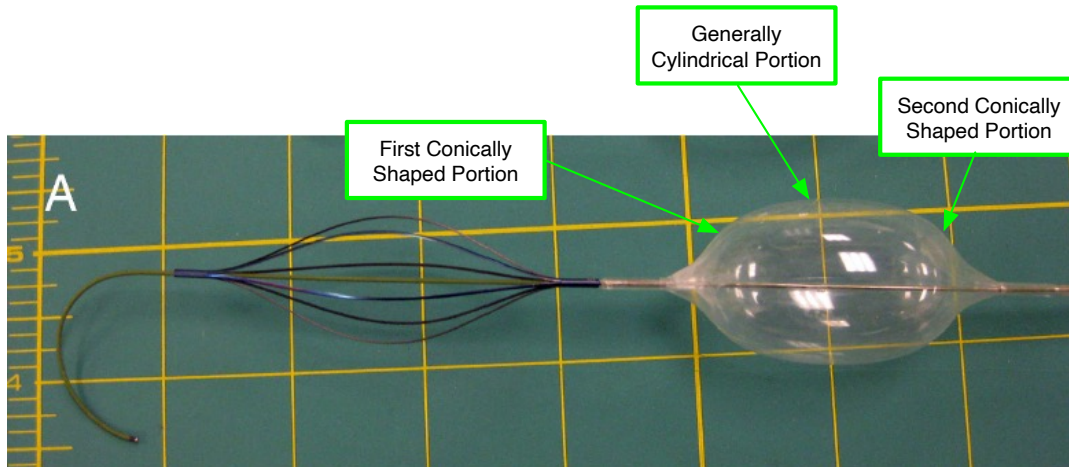
Scott discloses and teaches this claim. Claim 4 depends from claim 1, which is obvious in view of Eliason and a PHOSITA’s knowledge. Scott Figure 1A teaches a balloon with a conically shaped portion facing another conically shaped portion. Ex-1003 ¶199.



Ex-1010, Fig. 1A (annotated).

D. 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”

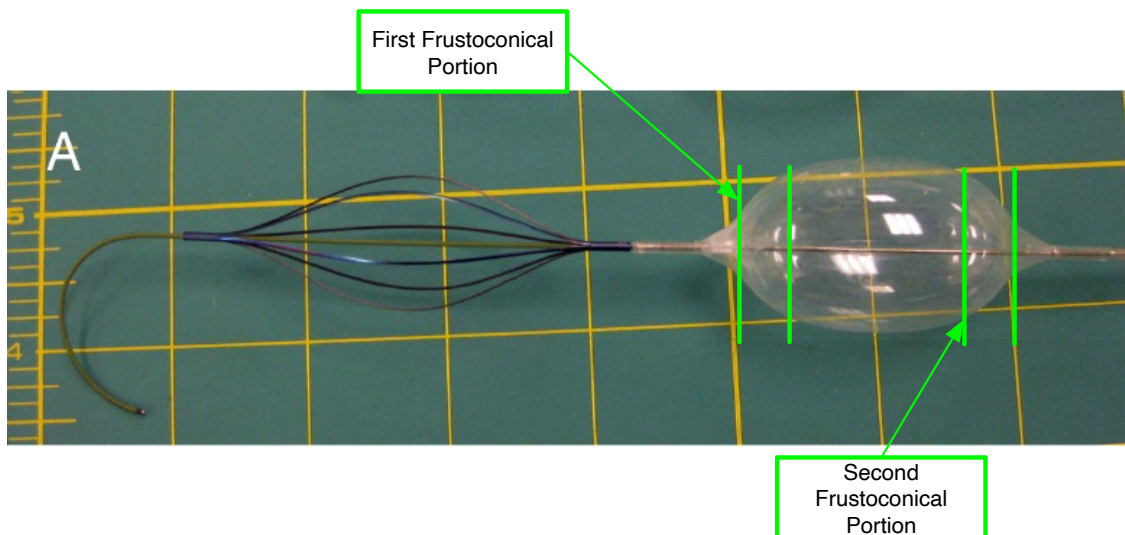
Scott discloses and teaches this claim. Claim 5 depends from claim 1, which is obvious in view of Eliason and a PHOSITA’s knowledge. Scott Figure 1A shows all of the elements of this claim. Ex-1003 ¶200.



Ex-1010, Fig. 1A (annotated).

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

Scott discloses and teaches this claim. Claim 9 depends from claim 1, which is obvious in view of Eliason and a PHOSITA’s knowledge. Scott Figure 1A shows that a balloon with “at least two oppositely oriented frustoconical portions.” Ex-1003 ¶201.



Ex-1010, Fig. 1A (annotated).

F. Motivation to Combine Scott and Eliason

Scott and Eliason describe the same or similar devices. Ex-1003 ¶¶151-152.

Both references describe devices that include a compliant balloon and a self-centering rail system on an occlusion catheter used for the occlusion of the aorta during REBOA like procedures. As such, it would be obvious to combine their teachings as they are both describing and/or showing the same physical device. In other words, the nearly identical features in Scott and Eliason suggest combining the balloon shapes from Scott with Eliason's balloon catheter (as modified based on the PHOSITA's knowledge) to arrive at the shapes claimed in the '737 Patent. In fact, Scott suggests that the combination was actually made as early as January 2013, more than two years before the '737 Patent's March 19, 2015, claimed priority date. Ex-1003 ¶202.

Even if Scott and Eliason were not describing the same physical device, a PHOSITA with knowledge of both references would see the numerous similarities between the devices. 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. Ex-1003 ¶203.

XVII. GROUND 9: CLAIM 8 IS OBVIOUS IN VIEW OF ELIASON JOE, AND A PHOSITA'S KNOWLEDGE

A. Description of Joe

Joe is U.S. Publication No. 2015/0133892, filed on November 13, 2014, and published on May 14, 2015. Ex-1011, [22], [43]. Joe's title discloses a "low-profile occlusion balloon catheter." Ex-1011, [54]. Joe specifies that it uses a soft, compliant balloon. Ex-1011 ¶0088. The catheter in Joe has a balloon (122) that is positioned and inflated at a desired occlusion site to occlude blood flow. Ex-1011 ¶0070.

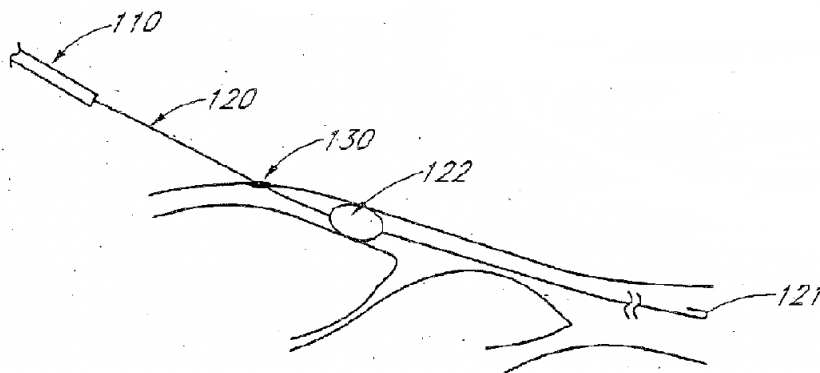


FIG. 1D

Ex-1011, Fig. 1D. Joe states that even with low profile occlusion catheters, it is helpful to include radiopaque markers, and that such markers may be included on areas of the catheter immediately proximal and distal to the balloon in order to

facilitate visualization of the balloon outside a patient's body using radiographic imaging techniques and thus facilitate placement of the balloon in a desired location. 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.”).

B. 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”

Joe teaches this claim. Claim 8 depends from claim 1, which is obvious in view of Eliason and a PHOSITA’s knowledge. 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.”); Ex-1003 ¶206.

C. Motivation to Combine Eliason and Joe

Both Eliason and Joe describe occlusion balloon catheters that use a compliant balloon for occluding blood flow in the arterial system. Both 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.

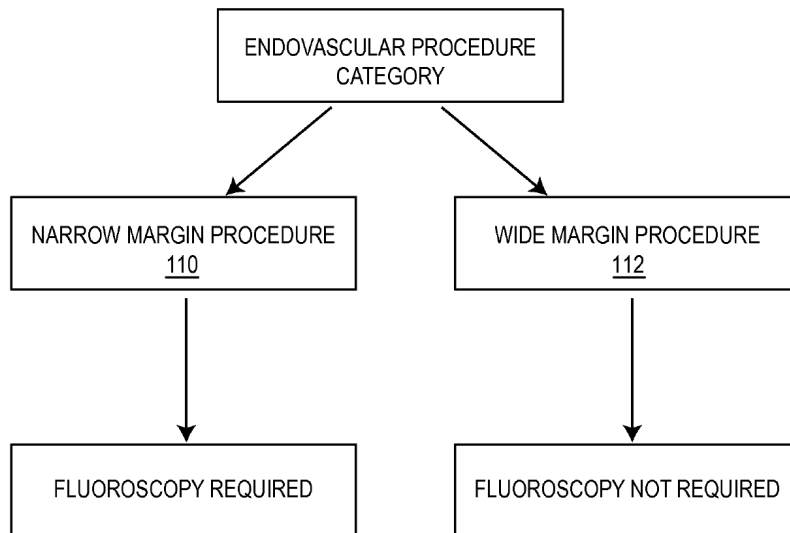


FIG. 12

Ex-1009, Fig. 12 & 11:50-51; Ex-1003 ¶207.

Such narrow margin procedures include endovascular procedures in large axial vessels of the human torso. Ex-1009, 11:43-47. Thus, the addition of the radiopaque markers described in Joe would add the capability to use Eliason’s device in “narrow margin procedures.” Accordingly, a PHOSITA would find it obvious based on Joe to further modify the Eliason catheter (as modified based on the PHOSITA’s knowledge) with radio opaque markers as claimed. 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. 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. Ex-1003 ¶208.

XVIII. DISCRETIONARY DENIAL IS UNWARRANTED

The Board should not exercise its discretion to deny institution.

A. *The Board Should Not Deny Institution Under Fintiv*

The *Apple v. Fintiv* (IPR2020-00019) factors weigh against discretionary denial:

Factors 1-2: The district court action (filed January 2, 2024) is in its infancy, as Petitioner just filed its Answer to Complaint less than a week ago on April 29, 2024. *See Prytime Medical Devices, Inc. v. Front Line Medical Technologies, Inc.*, Case No. 6:24-cv-00001-RP (W.D. Tex.) (D.I. 12). The initial pretrial conference has been set for May 30, 2024. *Id.* (D.I. 13). No trial date has been scheduled. The court (Judge Pitman) typically stays cases after petitions challenging asserted patent(s) have been filed with the PTAB. Thus, a FWD in this PGR is likely to issue prior to the conclusion of a jury trial.

Factor 3: As of the time of this Petition, the parties and the court have made minimal investment in the parallel district court proceedings. Petitioners have

answered the complaint and the court issued an order setting the Initial Pretrial Conference. No discovery has been conducted.

Factor 4: There should be no overlap between this PGR and the district court proceeding.

Factor 6: The unpatentability grounds presented here are strong, and this PGR will resolve issues raised in the district court involving the challenged patent.

B. The Board Should Not Deny Institution Under 35 U.S.C. § 325(d)

To determine whether to exercise its discretion to deny institution “[u]nder § 325(d), the Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate Gmbh*, IPR2019-01469, at 8 (P.T.A.B Feb. 13, 2020) (precedential). An example of a material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims. *Id.* n.9.

This Petition cites to Eliason (Ex-1009) and Smith (Ex-1025), both of which are listed on the face of the '737 Patent. Smith was cited by the examiner as “[t]he closest prior art” in the reasons for allowance. Ex-1002-597. Eliason was not cited

or discussed by the examiner, but was submitted by Patent Owner in an IDS. Ex-1002-160. Thus, [t]here is no evidence ... that the Examiner substantively considered [Eliason] during prosecution.” *Align Tech., Inc. v. Dental Monitoring SAS*, IPR2024-0052, Decision Granting Institution of *Inter Partes* Review, Paper 10, at 11 (P.T.A.B. Apr. 19, 2024).

Smith is cited in this Petition as evidence of the PHOSITA’s knowledge related to a balloon catheter having a “solid wire, secured at a proximal-most end thereof within the proximal hub” (claim 1, element [1h]). In the Examiner’s reasons for allowance, the Examiner did not conclude that Smith failed to show this aspect of the claims. Thus, the Petition does not ask the Board to second-guess an Examiner’s previous determination.

Eliason is cited in this Petition as the primary reference in an obviousness analysis under 35 U.S.C. §. 103(a). Because Eliason was not substantively considered during prosecution, the Petition’s grounds based on Eliason are “a combination of prior art and arguments that are not the same or substantially the same as that considered by the Examiner during prosecution.” *Align Tech., Inc. v. Dental Monitoring SAS*, IPR2024-0052, Decision Granting Institution of *Inter Partes* Review, Paper 10, at 12 (P.T.A.B. Apr. 19, 2024). Indeed, the references relied on in the Petition, including Eliason, are not cumulative to the references applied during examination, as the discussion of the reasons for allowance shows that the elements that the Examiner indicated were missing from the cited art were in fact found in

prior art references reflecting common and readily available balloon catheter devices such as Eliason, Scott, Fogarty, and Chengod. Under these circumstances, the Board should decline to exercise discretion to deny institution under § 325(d). *See id.*

XIX. CONCLUSION

Petitioner respectfully requests a trial be instituted and claims 1-10 of the '737 Patent be canceled.

XX. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. Real party in interest

Petitioner identifies the following as the real parties-in-interest: Front Line Medical Technologies Inc. No other party had access to, control over, or contributed to funding of the preparation or filing of this petition.

Front Line Medical Technologies Inc. is a company organized under the laws of Canada, with its principal place of business at 609 Wellington St. London, Ontario N6A 3R6, Canada.

B. Related matters

The '737 Patent is the latest issued patent in a family of patents and applications that include U.S. Patent Number 11,672,951 and U.S. Patent Number 10,149,962 ("the '962 patent"). The '962 patent is a U.S. National Stage Patent

derived from PCT Application Number PCT/US2016/023223, which was filed on March 18, 2016, and claims subject matter priority to as early as March 19, 2015, based on a series of fourteen provisional patent applications.

Other members of the '737 Patent family include the following pending U.S. Applications:

- U.S. Application Number 17/563,629
- U.S. Application Number 17/717,624

Patent Owner has asserted the '737 Patent against Petitioner in a lawsuit entitled *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. To Petitioner's knowledge, there are no other lawsuits or challenges involving the '737 Patent or the other members of its patent family.

C. Lead and back-up counsel and service information

Lead counsel is Daniel A. Tysver (Reg. No. 35,726). Backup counsel is James M. Urzedowski (Reg. No. 48,596).

D. Service Information

Service information for lead and back-up counsel is:

Forsgren Fisher McCalmont DeMarea Tysver LLP
1500 Capella Tower
222 S. 6th Street
Minneapolis, MN 55402

Phone Number: 612-474-3300
Fax Number: 612-474-3303

Petitioner consents to electronic service by electronic mail at
dtysver@forsgrenfisher.com, juredowski@forsgrenfisher.com.

XXI. PAYMENT OF FEES UNDER 37 C.F.R. § 42.15(a)

The fee for filing this petition requesting the post-grant review under 37
C.F.R. §42.15(b)(1) has been submitted to the USPTO.

Respectfully submitted,

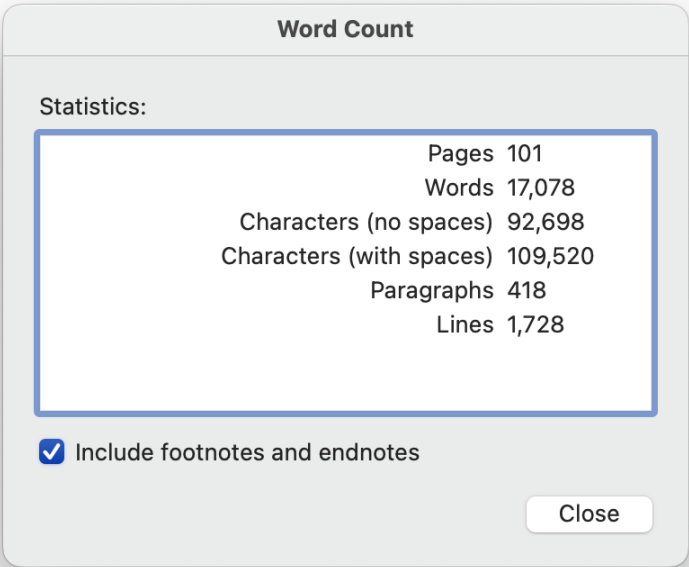
Date: May 6, 2024

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Counsel for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing Petition, exclusive of the exempted portions as provided in 37 C.F.R. §42.24(a), contains 17,078 words and complies with the type-volume limitations of 37 C.F.R. §42.24(a) (less than 18,700 for a PGR).



A screenshot of a 'Word Count' dialog box. The title bar says 'Word Count'. Below the title bar, the word 'Statistics:' is followed by a list of metrics: Pages 101, Words 17,078, Characters (no spaces) 92,698, Characters (with spaces) 109,520, Paragraphs 418, and Lines 1,728. At the bottom left, there is a checked checkbox labeled 'Include footnotes and endnotes'. At the bottom right, there is a 'Close' button.

Statistics:	
Pages	101
Words	17,078
Characters (no spaces)	92,698
Characters (with spaces)	109,520
Paragraphs	418
Lines	1,728

☒ Include footnotes and endnotes

Close

Date: May 6, 2024

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Counsel for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6(e), the undersigned certifies that the foregoing Petition and Exhibits 1001-1028 have been served simultaneously with filing. Service is via FedEx Priority Overnight, which is at least as fast and reliable as Priority Mail Express.

Pursuant to 37 C.F.R. §42.105, service of the petition and supporting evidence has been made on the patent owner at the correspondence address of record for the '737 patent, which is:

570 - PANITCH SCHWARZE BELISARIO & NADEL LLP
TWO COMMERCE SQUARE
2001 MARKET STREET, SUITE 2800
PHILADELPHIA, PA
UNITED STATES

Date: May 6, 2024

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APPENDIX A

Recitation of Challenged Claims

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”
---	--

	[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.”
2	“The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.”
3	“The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.”
4	“The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.”
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.”
6	“The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal.”
7	“The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel.”
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.”
9	“The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.”
10	“An inflation control system kit comprising: the occlusion catheter system of claim 1; and a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.”