

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**FRONT LINE MEDICAL TECHNOLOGIES, INC.**

**Petitioner**

**v.**

**PRYTIME MEDICAL DEVICES, INC.**

**Patent Owner**

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**Case PGR2024-00028**

**Patent No. 11,857,737**

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**DECLARATION OF WILLIAM CIMINO, PH.D.**

## **I. INTRODUCTION**

I, William Cimino, declare as follows:

1. I have been retained by Patent Owner Prytime Medical Devices, Inc. (“Prytime”) to provide expert opinion and testimony in connection with a post-grant review of U.S. Patent No. 11,857,737 (“the ‘737 Patent”) assigned to Prytime.

2. I was retained in this matter by Prytime through its counsel, Panitch Schwarze, as an expert witness in the field of medical device design and medical technology development. I charge a rate of \$ 450 per hour for my services. My compensation in this matter is in no way dependent or contingent on my opinions and testimony or on the ultimate outcome of the case.

3. I have reviewed the ‘737 Patent, as well as the Petition and the references cited therein.

4. In this declaration, I set forth the independent opinions that I have reached and the basis for those opinions using the information currently available to me. Such opinions are based on my education, professional career, and relevant experience in medical device design and medical technology development unless otherwise noted. A list of documents I have reviewed and, in some cases, relied upon in forming my opinions are presented below. I reserve the right to supplement or revise my opinions should additional documents or other information be provided to me.

## II. QUALIFICATIONS

5. My *curriculum vitae* (“CV”), a copy of which is attached hereto, provides details on my education, experience, publications, and other qualifications.

6. I received a Bachelor of Science degree in Aerospace Engineering from the University of Colorado in 1983. I received a Master’s degree in Mechanical Engineering from Purdue University in 1985. I received a Ph.D. in Bioengineering in 1992 from the University of Utah. My dissertation for my Ph.D. was entitled “Active Tip Control for Small Diameter Catheters: Power Transmission and Transduction Requirements.” As part of my dissertation, a 3 French (1 mm OD) cardiac catheter with a 4-way controllable tip was developed and the ability to actively control the tip and direct the catheter in the coronary arteries in an animal model was demonstrated.

7. I was a project lead engineer at Hearth Rhythm Technologies (Temecula, CA) where I was responsible for the design and development of a catheter system for endocardial mapping and ablation. This work directly involved the design and fabrication of catheter shafts, catheter tip steering systems, and electrode configurations on the catheter used for ablation.

8. A current copy of my *curriculum vitae*, attached hereto, provides further information concerning my experience and qualifications, including over 30

years of medical device and medical product design and development and a list of patents and publications that I have authored.

### III. MATERIALS CONSIDERED

9. In forming my opinions expressed in this declaration, I have considered and relied upon my education, background, and experience. In addition, I have reviewed and, in some cases, relied upon the following list of materials in the preparation of this declaration.

| Materials Considered                                                                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| The '737 Patent and its prosecution file history (Exs. 1001, 1002)                                                                                        |
| Front Line Medical Technologies, Inc.'s May 6, 2024, Petition for PGR of the '737 Patent                                                                  |
| Prytime's August 30, 2024, Preliminary Response                                                                                                           |
| Decision Granting Institution of Post-Grant Review on October 16, 2024 "Institution Decision" (Paper 7)                                                   |
| Declaration of Scott Resnick, M.D. ("Dr. Resnick"), FSIR (Ex. 1003)                                                                                       |
| U.S. Patent No. 3,467,101 "Fogarty" (Ex. 1004)                                                                                                            |
| "Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique" by S. Chengod <i>et al.</i> (Ex. 1005) |
| "Applications of High-Pressure Balloons in the Medical Device Industry" by M. Saab (Ex. 1006)                                                             |
| U.S. Patent No. 10,004,622 "Sanati" (Ex. 1007)                                                                                                            |
| "Image-Guided Thrombectomy in Vascular Surgery" by D. Deaton (Ex. 1008)                                                                                   |
| U.S. Patent No. 9,131,874 "Eliason" (Ex. 1009)                                                                                                            |
| "A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock" by D. Scott (Ex. 1010)             |
| U.S. Patent Publication No. 2015/0133892 "Joe" (Ex. 1011)                                                                                                 |
| International Patent Application No. PCT/US2011/033368 (Ex. 1012)                                                                                         |
| U.S. Patent Publication No. 2013/0060316 (Ex. 1013)                                                                                                       |
| "A New Technique for Sizing Atrial Septal Defects" by X. Gu <i>et al.</i> (Ex. 1014)                                                                      |
| Handbook of Endovascular Peripheral Interventions (Ex. 1015)                                                                                              |
| International Patent Publication No. WO 2014/036530 "Bagaoisan" (Ex. 1016)                                                                                |
| U.S. Patent No. 8,088,121 "Nishide" (Ex. 1017)                                                                                                            |

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| U.S. Patent No. 5,607,394 “Anderson” (Ex. 1018)                                                                                                    |
| U.S. Patent No. 5,779,731 “Leavitt” (Ex. 1019)                                                                                                     |
| U.S. Patent Publication No. 2008/0188803 “Jang” (Ex. 1020)                                                                                         |
| “Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion” by J. Mathis <i>et al.</i> (Ex. 1021)           |
| U.S. Patent No. 4,846,174 “Willard” (Ex. 1022)                                                                                                     |
| Patent Owner’s Infringement Claim Charts (Ex. 1023)                                                                                                |
| “Pulmonary vein isolation using a compliant endoscopic laser balloon ablation system in a swine model” by E.P. Gerstenfeld & J. Michele (Ex. 1024) |
| U.S. Patent No. 5,087,246 “Smith” (Ex. 1025)                                                                                                       |
| Declaration of Dr. Sylvia Hall-Ellis (Ex. 1026)                                                                                                    |
| Patent Owner Prytime Medical Inc. “Leadership” web page (Ex. 1027)                                                                                 |
| USPTO Assignment Record for U.S. Patent No. 9,131,874 (Ex. 1028)                                                                                   |
| December 13, 2024 Deposition Transcript of Scott Resnick, M.D. FSIR “Deposition” (Ex. 2002)                                                        |
| U.S. Patent No. 3,435,826                                                                                                                          |
| U.S. Patent No. 3,467,102                                                                                                                          |
| U.S. Patent No. 4,271,839                                                                                                                          |
| U.S. Patent No. 4,338,942                                                                                                                          |
| U.S. Patent No. 4,762,130                                                                                                                          |
| U.S. Patent Publication No. 2018/0263655                                                                                                           |
| U.S. Patent Publication No. 2010/0274189                                                                                                           |

10. Moreover, I am aware of information generally available to, and relied upon by persons of ordinary skill in the art, including technical dictionaries and reference materials, for example, textbooks, manuals, papers, articles, and relevant standards.

#### **IV. UNDERSTANDING OF THE LAW**

11. I am not an attorney, and I am not offering any legal opinions in this declaration nor am I qualified to do so. However, I have been informed by counsel

regarding several legal standards that I am to apply in framing my technical opinions and conclusions.

12. I understand from counsel that the concepts described below require a definition for a person having ordinary skill in the art (“PHOSITA”). I understand that this person is a hypothetical person presumed to have known the relevant prior art within the relevant time frame. I understand that factors for determining the level of skill of this hypothetical person can include sophistication of the technology, the educational level of workers in the field, the types of problems encountered, the prior art solutions to those problems, and the rapidity with which innovations in the field are made.

13. I understand from counsel that claim terms are ordinarily determined to have their ordinary and accepted meaning as would be understood by the PHOSITA at the time of the invention, and in view of the specification and patent prosecution file history. I further understand that a patentee is free to be his or her own lexicographer (*i.e.*, provide his or her own special meaning to any disputed terms), in which case the patentee’s lexicography governs. In making this determination, I understand that the specification and prosecution history must be consulted.

14. I understand from counsel that a patent claim is invalid if the claimed invention would have been obvious to a PHOSITA at the time of the invention. This

means that even if all of the requirements of the claim cannot be found in a single prior art reference, the claim can still be invalid.

15. I understand from counsel that an obviousness analysis involves comparing a claim to the prior art to determine whether the claimed invention would have been obvious to a PHOSITA at the time of the invention in view of the prior art and in light of the general knowledge in the art as a whole.

16. I also understand from counsel that obviousness is ultimately a legal conclusion based on underlying facts of four general types, all of which must be considered: (1) the scope and content of the prior art; (2) the level of the PHOSITA; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of non-obviousness.

17. I also understand from counsel that obviousness may be established by combining or modifying the teachings of the prior art. Specific teachings, suggestions, or motivations to combine any first prior art reference with a second prior art reference can be explicit or implicit, but must have existed before the date of invention. I further understand from counsel that in some circumstances obviousness may be established by a single prior art reference.

18. I understand from counsel that prior art references themselves may be one source of a specific teaching or suggestion to combine features of the prior art, but that such suggestions or motivations to combine art may come from the

knowledge of a PHOSITA. Specifically, a rationale to combine the teachings of references may include logic or common sense available to a PHOSITA.

19. I understand from counsel that a prior art reference may be relied upon for all that it teaches, including uses beyond its primary purpose. I understand that teaching away, *e.g.*, discouragement from making the proposed modification, is strong evidence that the prior art references are not combinable. I also understand from counsel that a disclosure of more than one alternative does not necessarily constitute a teaching away.

20. I understand from counsel that to support a combination of multiple prior art references, there must be a rationale explaining why a skilled artisan would combine the references in the manner claimed and how the proposed combination meets each and every claim element. I understand that it is insufficient to allege obviousness based merely on the fact that alternative arrangements were known in the art.

21. I further understand from counsel that whether there is a reasonable expectation of success from combining prior art references in a particular way is also relevant to the analysis. I understand there may be a number of rationales that may support a conclusion of obviousness, including:

- Combining prior art elements according to known methods to yield predictable results;

- Substitution of one known element for another to obtain predictable results;
- Use of a known technique to improve similar devices (methods, or products) in the same way;
- Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art teachings to arrive at the claimed invention.

22. I understand that it is not proper to use hindsight to combine prior art references or elements of prior art references to reconstruct the invention using the claims as a guide. For example, an obviousness reconstruction should only take into account knowledge within the level of ordinary skill in the art at the time the claimed invention was made, and not utilize knowledge gleaned only from the patent’s disclosure. When it appears hindsight bias is being used, I understand the modification or combination is not considered obvious.

23. I further understand that each prior art reference must be considered in its entirety, including portions which may tend to teach away from the proposed modification or combination. I understand a reference is said to teach away from

the claimed invention where it, for example, criticizes, discredits, or otherwise discourages the solution claimed. I understand that it is improper to combine prior art references where the references teach away from their combination.

24. I understand that so-called objective indicia may be relevant to the determination of whether a claim is obvious should the Patent Owner allege such evidence. Such objective indicia can include evidence of commercial success caused by an invention, evidence of a long-felt need that was solved by an invention, evidence that others copied an invention, or evidence that an invention achieved a surprising result. I understand that such evidence must have a nexus, or causal relationship to the elements of a claim, in order to be relevant to the obviousness or non-obviousness of the claim.

## **V. LEVEL OF ORDINARY SKILL IN THE ART**

25. The '737 Patent is directed to the design and construction of a vascular occlusion catheter deployable in a blood vessel. Accordingly, given the factors identified in paragraph 12 above, and upon my review of the '737 Patent, a PHOSITA at the time of the invention in the '737 Patent (which I understand I am to consider as on or before March 19, 2015) should possess education and/or experience including either: (i) an undergraduate degree in engineering or physics or material science and at least five years' experience in catheter design and development or laparoscopic/endoscopic medical device instrumentation design and

development; (ii) a graduate degree in engineering or physics or material science and at least three years' experience in catheter design and development or laparoscopic/endoscopic medical device instrumentation design and development; or (iii) at least six years' experience in catheter design and development. I believe that this level of education and/or experience enables the PHOSITA to understand designing and building a catheter for a specific purpose or specific procedure.

26. Dr. Resnick proposed that a PHOSITA “must possess a medical degree and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices.” Ex. 1003 at ¶ 18. Dr. Resnick further contends the PHOSITA would need “a minimum of ten years of post-graduate experience in fields such as interventional radiology, vascular surgery, or interventional cardiology, or have other extensive experience as an endovascular interventionist.” Ex. 1003 at ¶ 18. Dr. Resnick also asserts the PHOSITA “would be familiar with various occlusion balloon catheters and their use in performing vascular occlusion procedures throughout the vascular system, including occlusion procedures within the aorta.” Ex. 1003 at ¶ 19. I disagree and believe Dr. Resnick’s assessment of the PHOSITA is entirely too onerous. While the definition I provide above does not preclude an individual with a medical degree and sufficient experience with interventional procedures from qualifying as a PHOSITA, requiring a medical degree excludes

many competent individuals. In my experience, catheters, and medical devices in general, are most often designed by engineers or other similarly educated or trained individuals working in medical product companies who do not have a medical degree. In fact, medical doctors and product design engineers frequently collaborate on medical device design. Dr. Resnick's PHOSITA definition unnecessarily excludes these qualified individuals.

## **VI. THE '737 Patent**

### **A. Background and Summary**

27. The '737 Patent is directed to a vascular occlusion catheter deployable in a blood vessel to increase proximal or central blood circulation to the heart and brain, *e.g.*, in the instance of trauma. Ex. 1001 at 1:63-2:27. The catheter includes an inflatable occlusion balloon configured to partially or completely obstruct the target blood vessel, thereby prioritizing and increasing upstream blood flow, *e.g.*, cerebral blood flow and blood pressure. *Id.* at 5:39-44.

28. Fig. 12 from the '737 Patent (reproduced below) illustrates an example of a portion of the claimed catheter system. The system includes a proximal hub 590 in fluid communication with a proximal catheter section 510, *i.e.*, a proximal section of the catheter shaft. *Id.* at 29:59-65, 35:4-43. The system further includes a distal catheter section 520, *i.e.*, a distal section of the catheter shaft, that distally terminates in an atraumatic tip 550. *Id.* at 29:59-65. Located between the proximal



lumen 610 of the proximal catheter section 510. *Id.* at 35:32-43. The claimed system further has a flow valve located between the external inflation device and the downstream proximal hub, configured to selectively communicate the inflation device with the proximal hub. One example is explained in relation to Fig. 22, where a pressure source 802 (*e.g.*, an inflation device, such as a syringe) connects to a valve 828, which itself is positioned upstream of, and connects to, the occlusion catheter 710 at the proximal hub 590. *Id.* at 30:8-21, 36:57-37:7, 40:18-46. The valve 828 opens and closes to allow pressure from the fluid source 802 to inflate or deflate the balloon 540. *Id.* at 40:27-35.

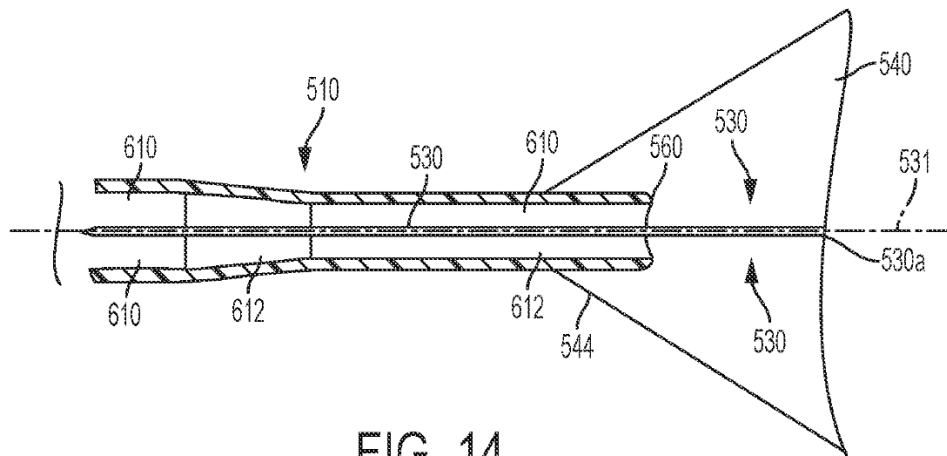
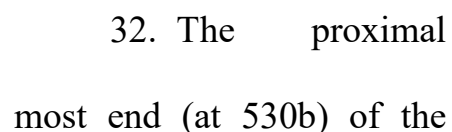


FIG. 14

30. The claimed system also includes a stiffener member that is preferably a solid wire 530 that eliminates the need for a guidewire, *i.e.*, the catheter can be maneuvered through the vasculature to the destination location in the vasculature without requiring a guidewire. *Id.* at 11:46-50, 12:15-17, 13:44-48.

and extends from the proximal hub 590 into the proximal catheter section 510. *Id.* at 30:5-8, 35:5-32.



solid wire 530 is fixedly coupled to and within the proximal hub to add stiffness and strength to the catheter, most specifically longitudinal stiffness which supports the catheter against compressive buckling or displacement along the longitudinal axis under the normal operating conditions of the system, *i.e.*, support against the compressive loading of the catheter shaft when the occlusion balloon is inflated and also support to advance the catheter to reach a target position in the vasculature and to maintain that position. *Id.* at 35: 4-27.

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functions of the catheter system 500.” *Id.* at 35: 24-27. In order to enable the assembly to withstand the aforementioned normal operating conditions encountered during the procedure, including during occlusion when the balloon is inflated, the proximal most-end of the solid wire is required to be fixedly coupled within the proximal hub to support the compressive loading of the catheter shaft.

34. Based on the design of the proximal hub 590, which secures the solid wire 530, fluid from the external inflation device, gated by the flow valve, can enter the proximal hub 590 and thereafter enter the proximal catheter section 510 and the balloon 540. The solid wire 530 is not removed to inflate the balloon. *Id.* at 29:59-30:31, 34:18-43, 35:4-43, 40:18-46. With this claimed design, the occlusion catheter system can be sized to pass through a five to six French (Fr) percutaneous sheath. *Id.* at 30:32-60.

## **VII. CLAIM CONSTRUCTION**

35. I understand that Petitioner only proposed express constructions for the terms “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”) and “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”). As these definitions appear to be derived directly from

the specification (Ex. 1001, 21:52-60), for purposes of my declaration only, I have adopted Petitioner's constructions for the terms "proximal" and "distal".

36. My opinions herein are based, at least in part, on the following additional claim constructions, which are developed in accordance with the ordinary and customary meaning of such claim as understood by a PHOSITA, the '737 Patent specification, and the prosecution history pertaining to the '737 Patent:

37. "proximal hub": Dr. Resnick does not expressly identify a specific definition of the term "proximal hub" in his Declaration, but implicitly provides one within his opinions relating to the present patentability challenges. In equating elements 30, 31, 32, and 43 of Fogarty with the proximal hub of claim 1, Dr. Resnick asserts that "[a] PHOSITA understands that these elements are a 'hub' *because these elements ... are used to physically connect an inflation device (e.g., syringe (35)) to the inflation lumen of the catheter.*" Ex. 1003 at ¶ 74 (emphasis added). Likewise, when he equates the multi-port and valve assembly 36 of Eliason with the proximal hub of claim 1, Dr. Resnick reiterates this interpretation of the multi-port and valve assembly 36 of Eliason, stating that "[t]his assembly ... *is used to physically connect the inflation device (syringe) to the inflation lumen of the catheter.*" *Id.* at ¶ 145 (emphasis added). In view of my understanding from the perspective of one of ordinary skill in this art and the details provided in the specification of the '737 Patent, for the purposes of this PGR proceeding only, I

expressly adopt Dr. Resnick’s definition that a proximal hub is an element (or elements) used to physically connect an inflation device to the inflation lumen of the catheter.

38. I note, however, that when consulting the ‘737 patent specification in connection with the term “proximal hub”, the PTAB in the Institution Decision utilized a particular embodiment, specifically “System 1600” that also used the word “hub” as part of its description. Paper 7 at pg. 11: lines 9-13; pg. 13: lines 7-16. A PHOSITA would not consider *this* utilization of a “hub” to provide any relevance or equivalence to the “proximal hub” recited in the ‘737 patent claims.

39. A PHOSITA would not consider the “System 1600”, and particularly the named proximal and distal hub members 1604, 1606, to have any relevance, or provide any context, to the “proximal hub” recited in the ‘737 patent claims. The “System 1600” is a catheter infection/contamination control system in the form of an external sleeve. The catheter sleeve system comprises an elongate tubular sleeve 1610 providing an internal substantially sterile field for insertion of the catheter 1602 into the sterile lumen thereof during a vascular occlusion procedure. Ex. 1001 at 59:45-65.

40. The catheter sleeve 1610 has hub members 1604, 1606 at the respective proximal and distal sleeve ends 1610a, 1610b that permit the catheter 1602 to extend into and through the catheter sleeve 1600 while generally maintaining hemostasis

and a sterile field within the catheter sleeve 1600. *Id.* at 60:2-8. To summarize, a PHOSITA would understand that the hub members 1604, 1606 shown in Fig. 42A

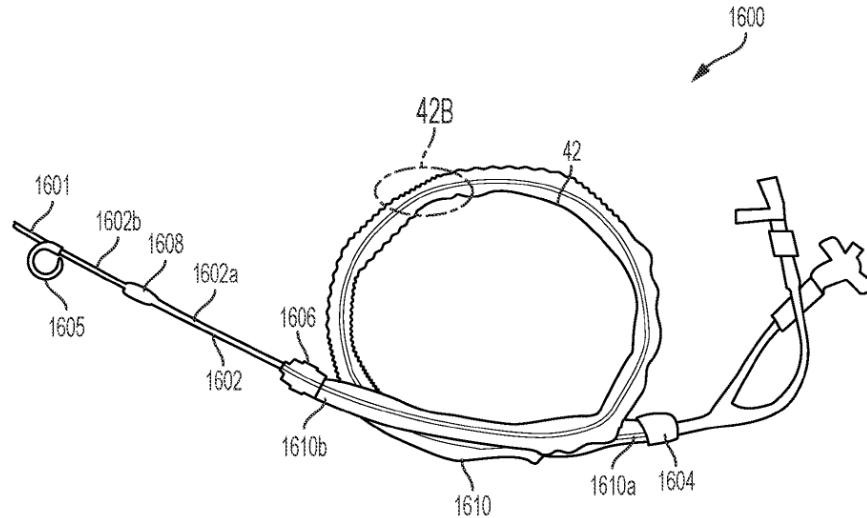


FIG. 42A

are entirely unrelated to an element or elements used to physically connect an inflation device (*e.g.*, syringe) to the inflation lumen of the catheter. Rather, as clearly shown in corresponding Fig. 42A of the '737 patent (shown below), the hub members 1604, 1606 engage the outer wall of the catheter 1602 as hemostatic valves. *Id.* at 60:1-12. The hub members 1604, 1606 cannot physically connect any external component, such as an external inflation device, to an inflation lumen of the catheter. This embodiment is not relevant for interpreting “proximal hub” (or what components a proximal hub may or may not include, such as a “flow valve”) in the context of these claims.

41. “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device”: The ordinary and customary meaning of this claim

term, as understood by a PHOSITA, is a manually or automatically actuatable valve that is opened or closed to permit or block fluid flow between the proximal hub and the inflation device. This construction is supported by the '737 patent as explained in relation to Fig. 22, where a pressure source 802 (*e.g.*, an inflation device, such as a syringe) connects to an actuatable valve 828, which itself is positioned upstream of, and connects to, the proximal hub 590 of the occlusion catheter 710. Ex. 1001 at 30:8-21, 36:57-37:7, 40:18-46. The actuatable valve 828 opens to allow pressure from the fluid source 802 to inflate or deflate the balloon 540 and can also be closed to maintain the balloon 540 in an inflated state or to prevent flow of fluid into the balloon 540. *Id.* at 40:27-35.

42. In the Institution Decision, the PTAB equates a pressure relief member in the form of a pop-off valve or other similar biased valve, disclosed in the '737 Patent specification, with the claimed flow valve. Paper 7 at pg. 10: line 25 – pg. 11: line 6. More specifically, the PTAB appears to focus on the presence of a valve generally on a hub, without appreciating fundamental differences between a flow valve and pressure relief or biased valve. A PHOSITA would not consider a pressure relief member in the form of a pop-off valve to have any relevance, or provide any context, to the flow valve recited in the '737 patent claims. Rather, a PHOSITA would realize that a flow valve has an entirely different structure and function from a pop-off valve or other biased valve.

43. As one example, the flow valve is opened or closed by the user to selectively permit or block fluid flow between the proximal hub and the inflation device (Ex. 1001 at 40:27-35), whereas a pop-off/biased valve is biased to remain in a closed position under normal operative conditions and to open when the pressure on an inlet/upstream side exceeds a threshold pressure to avoid a dangerous or otherwise over-pressurized condition, releasing pressure *from* the inflation/deflation lumen (*see, e.g.*, Ex. 1001 at 2:43-48; 20:47-21:14; U.S. Patent Publication No. 2010/0274189 at Fig. 1, ¶¶ 46, 54). The pop-off/biased valve is typically configured to automatically return to the normally closed position upon relief or dissipation of the upstream pressure to a level beneath the threshold pressure of the relief valve. These types of pressure relief valves provide a safety function, whereas a flow valve is used to selectively control fluid flow.

44. Accordingly, the disclosure in the '737 patent of a proximal hub including a pressure relief member in the form of a pop-off valve or other similar biased valve would not inform a PHOSITA as to the presence of a flow valve on the proximal hub, much less a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device. The PTAB's reliance on the teaching of pressure relief members to inform this claim term effectively reads "flow" out of the claim language. Put another way, if Fogarty or Eliason's alleged "proximal hub" had a pressure relief member, that pressure relief member would not satisfy the claim

feature of a “flow valve...” as recited in claim 1. The pressure relief member disclosure in the ‘737 Patent specification is similarly irrelevant to understanding the claimed “flow valve...”.

45. “a distal catheter section”: The ordinary and customary meaning of this claim term, as understood by a PHOSITA, is simply a distal portion of a catheter. The ‘737 Patent specification discloses, for example, a distal catheter member 520 embodying this concept, in that it is a distally-located portion of a catheter. Ex. 1001 at 29: 64; Figs. 12, 15, 16.

46. The PTAB preliminarily interprets “distal catheter section” as “a portion of the *system* that is at the distal end.” Paper 7 at pg. 17: lines 26-27 (emphasis added). A PHOSITA would understand, however, that a distal catheter section is a portion of the catheter shaft itself, and not a portion of other components of “*the system*”. Claim 1 recites “a distal catheter section” and not “a distal catheter system section.”

47. Dr. Resnick confirms this understanding in his Deposition, stating that a balloon catheter consists of the balloon and the catheter it is mounted on, the catheter being “*the shaft of the device*, typically ... extending from the proximal hub to the end of the device distally”. Ex. 2002 at 26:11-27:3 (emphasis added). A PHOSITA would understand, therefore, that a distal catheter section is a distal

portion *of the shaft* of the device, and not other distally-located components of an overall system, e.g., a guide wire.

48. “a solid wire, secured at a proximal-most end thereof within the proximal hub”: The ordinary and customary meaning of this claim term, as understood by a PHOSITA, is a wire, without an internal lumen, having its end that is positioned furthest away from the patient’s body within and *fixedly coupled to* the proximal hub. This definition is supported by the ‘737 patent, which also explains why this feature is important:

the proximal end of the ... solid wire 530 is *fixedly coupled* to the proximal hub 590 at a proximal bonding site .... The proximal end of the [solid wire] 530 is not limited to being adhesively bonded to the proximal hub 590 and may be otherwise *fastened, secured, or fixed to* the proximal hub 590, as long as the [solid wire] 530 is substantially secured to the proximal hub 590 *such that* the [solid wire] 530 provides stiffness for the balloon catheter system 500, the [solid wire] 530 is substantially secured relative to the inflation catheter member 510 and the occlusion balloon 540, [and] *the assembly is able to withstand normal operation conditions of the catheter system 500*. Ex. 1001 at 35: 4-27 (emphasis added).

49. A PHOSITA understands that the solid wire must be fixedly coupled to and within the proximal hub to add stiffness to the catheter, most specifically longitudinal stiffness which supports the catheter against compressive buckling or displacement along the longitudinal axis under the normal operating conditions of the system, *i.e.*, in operation to reach and occlude the target vessel (the claims are directed to an “occlusion catheter system” utilizing an “occlusion balloon”). As explained by Dr. Resnick in his Deposition, “when you occlude any arterial vessel, you have aortic pulsation forces or cardiac contractile forces ***pushing the balloon forward***. [T]he greater [the] flow that is obstructed, the greater the downward force would be.” Ex. 2002 at 19:20 – 20:8 (emphasis added). That is, normal operating conditions encountering the catheter to reach and occlude the target vessel produce forces acting on the balloon that push on the catheter shaft and the solid wire secured in the catheter shaft. Fixedly coupling the solid wire to and within the proximal hub allows “the assembly [to be] able to withstand the normal operating conditions of the catheter system 500 and securement results in a structure able to perform the preferred functions of the catheter system 500.” Ex. 1001 at 35: 24-27. Naturally, in order to enable the assembly to withstand the aforementioned normal operating conditions encountered during the procedure, including during occlusion, the solid wire is required to be secured within the proximal hub and extending within the

proximal catheter section, the occlusion balloon and into the distal catheter section, as claimed.

## VIII. SUMMARY OF THE PRIOR ART

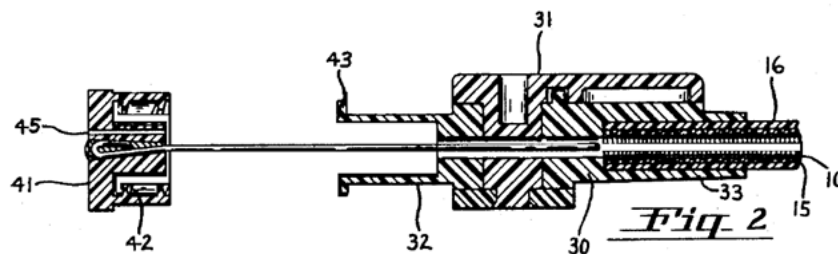
### A. Fogarty

50. Fogarty is directed to a now outdated practice of using catheters repeatedly, *i.e.*, re-using catheters. *See e.g.*, Ex. 1004 at 1:49-51 (“general object of the present invention is, therefore, to increase the durability and strength of the catheter to withstand repeated usage”). To protect the reusable catheter, a metal wire stylet is inserted into the catheter tube when the catheter is not in use to prevent acute angulation of the catheter and to afford a degree of protection. *Id.* at 1:29-35.

51. Fogarty’s catheter includes an outer plastic tube 16 shrunk onto a braid 15 of material covering the outer surface of a spring wire coil 10. *Id.* at 2:40-41, 57-70. The proximal end of the catheter tube 16 is secured, *i.e.*, fixedly coupled, to a shut-off valve having a body 30, a rotatable valve member 31, and a conventional fitting 32 configured to receive a syringe 35 for inflating the balloon 20. *Id.* at 3:38-42. Upon reaching the desired balloon 20 inflation level, the valve 30 may be closed to hold the inflation. *Id.* at 3:46-48. The embodiment shown in Fogarty is designed for venous thrombectomy procedures, which involves using a balloon to remove a clot (thrombus) by pulling the inflated balloon through the vein with the catheter. *Id.* at 2:33-39. Fogarty states that this same catheter, with a shortened tube, may be

used in other areas of the body, such as the genito-urinary tract and the biliary system where the inflated balloon is placed to expand and open a vessel. *Id.* Fogarty also states that most of the important features could be used in an arterial embolectomy, which involves using a balloon to remove a clot that has migrated to another portion of the body (embolus). *Id.* at 2:37-39. None of these procedures require occluding the aorta with the balloon supported by the catheter.

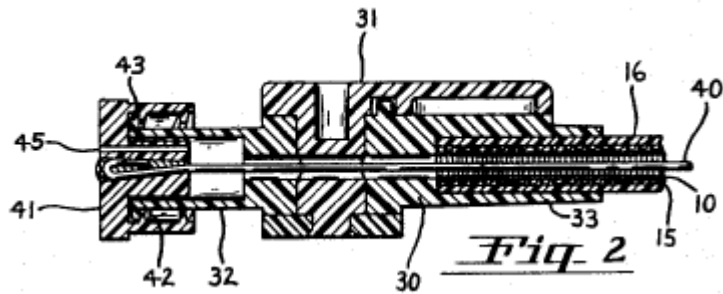
52. The catheter also comes with a separate metal wire stylet 40 “used to protect the catheter *when it is not in use.*” *Id.* at 3:49-59 (emphasis added). As described in Fogarty and shown in an annotated version Fig. 2 of Fogarty (produced below), a proximal-most end of the metal wire stylet 40 is secured, *i.e.*, fixedly coupled, in a cap 41, which itself is selectively engageable with, and disengageable from, the syringe fitting 32. *Id.* at 3:60-62.



53. The stylet 40 may be inserted into the catheter via the syringe fitting 32 “[w]hen the valve member 31 is turned to open position.” *Id.* at 3:62-65. Based on

the above and as can be seen from

Fogarty's Fig. 2 (reproduced at right), the engagement of the cap 41 and the stylet 40 secured



thereto with the syringe fitting 32 prevents connection of a syringe 35 for inflating the balloon 20. The cap 41 and the stylet 40 secured thereto must, therefore, be withdrawn from the catheter for a syringe 35 to be fluidly connected to the catheter via the single syringe fitting 32.

54. Moreover, orienting the valve member 31 in the closed position prevents advancement of the stylet 40 into the catheter tube 16, so whenever the stylet 40 is present in the catheter, the valve member 31 must be in the open position. Absent external modification, when the cap 41 and the stylet 40 secured thereto are present in the catheter, the balloon 20 cannot be inflated, and the catheter cannot function as an occlusion catheter, *i.e.*, the catheter is unable to block any blood flow within the patient.

55. Dr. Resnick refers throughout his declaration to “Fogarty catheters”, which he acknowledged in his deposition generically refers to a class of catheters originally invented by Thomas J. Fogarty. Ex. 2002 at 41:3-42:2; 50: 6-19; 51:6-19; 66:19 – 67:8; 70: 14-20. While the catheter depicted in the Fogarty reference (Exhibit 1004) falls generally within the class of catheters characterized by Dr.

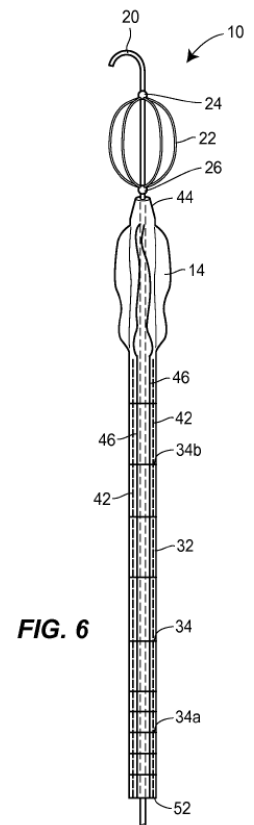
Resnick as “Fogarty catheters,” there are other examples of catheters invented by Thomas J. Fogarty that look and function much differently than what is shown in Ex. 1004: such as in U.S. Patent Nos. 3,435,826 (a basic, single lumen, flexible embolectomy catheter with a balloon attached at its end); 3,467,102 (an embolectomy balloon catheter with a suture material loop 20 at its end for attachment to a leader); 4,271,839 (a dilation catheter with a balloon that is initially inverted in the catheter but becomes everted from the catheter for inflation); 4,338,942 (a dilation catheter with a double lumen tube and inner and outer balloons); and 4,762,130 (an embolectomy catheter having a balloon that forms a helical design when inflated). The Fogarty reference (Exhibit 1004) relied upon by Dr. Resnick specifically incorporates the wire coil 10 and braid structure 15 within the outer plastic tube 16 to protect the tube from damage when inserting or removing the stylet 40. Ex. 1004 at 3:69-73; 4:6-17. None of the other example Fogarty catheters cited above include this structure. Rather, the broad class of Fogarty catheters exhibits significant variation in design and construction. The specific details of each Fogarty catheter were designed to address a particular problem(s) related to a specific procedure(s). Dr. Resnick states that a PHOSITA would have made modifications or changes *to the particular catheter in the cited Fogarty reference* (Ex. 1004) based on knowledge of the broad and diverse class of “Fogarty catheters.” *See, e.g.,* Ex. 1003 at ¶¶ 70, 80, 81, 90, 91. I do not agree. A PHOSITA would have made

modifications or changes *to the particular catheter in the cited Fogarty reference* (Ex. 1004) based on knowledge of specific “Fogarty catheters” that include common design elements for common intended purposes to the cited Fogarty reference (Ex. 1004).

## **B. Eliason**

56. Eliason is directed to a system for deploying and selectively inflating a thoracic aortic balloon at a desired location within the thoracic aorta for resuscitative aortic occlusion. Ex. 1009 at Abstract. Eliason teaches the use of a self-centering, endovascular wire 12 terminating in a J tip 20 with an occlusion balloon 14 and corresponding balloon shaft 32 deployed over the endovascular wire 12. *Id.* at 7:33-57, 8:36-52.

57. The endovascular wire 12 includes a plurality of self-expanding wire struts 22 located proximal to the J tip 20. The struts 22 are mounted upon the shaft of the endovascular wire 12 and extend between a leading securement bead 24 and a trailing securement bead 26, which are each also mounted on the endovascular wire 12. *Id.* at 8:53-57. The struts 22 are collapsed when traversing a transdermal insertion sheath 28, but in an expanded state, shorten in length over the shaft of the endovascular wire 12 between the beads 24, 26 to provide a self-



centering function, keeping the J tip 20 of the wire 12 away from blood vessel sidewalls and preventing unwanted turning down an unintended vessel. *Id.* at 8:61-9:12. As seen in Eliason's Fig. 6 (reproduced at right), no further shafts, tubes or lumens are provided over the endovascular wire 12 between the trailing securement bead 26 and the distal end of the J tip 20.

58. An occlusion balloon 14 is carried on a balloon shaft 32 having an internal lumen 42 that permits the balloon shaft 32 to pass over the endovascular wire 12. *Id.* at 9:31-41. A tapered distal end portion 44 of the balloon shaft 32 prevents the balloon shaft 32 from extending beyond the trailing securement bead 26 on the endovascular wire 12 toward the J tip 20. *Id.* at 9:38-43.

59. The occlusion balloon 14 may be deployed over the endovascular wire 12 outside of the body, and subsequently inserted into the body together as a single unit, or the endovascular wire 12 (and its incorporated structures of the J tip 20, struts 22, and securement beads 24, 26) may be advanced into the body first and the occlusion balloon 14 and balloon shaft 32 subsequently advances over the endovascular wire 12 within the body. *Id.* at 6:5-7, 7:45-52, 8:38-46. In either operation, the balloon shaft 32 only advances over the endovascular wire 12 to the stop surface defined by the trailing securement bead 26.

60. A multi-port and valve assembly 36 includes an elongate tubular barrel section 50 that is affixed to a proximal end of the balloon shaft 32. *Id.* at 10:17-20.

The elongate tubular barrel section 50 includes a terminating port 38 with a diaphragm 40 through which the endovascular wire 12 passes in a fluid-tight manner. *Id.* at 10:7-17. The multi-port valve assembly 36 also includes a side port 58 and a branch 54 that enable a syringe 48 to connect with the elongate tubular barrel section 50, and, in turn, with the proximal end of the balloon shaft 32. *Id.* at 10:33-36. The occlusion balloon 14 is inflated and deflated through the side port 58. A one-way valve 60, actuatable between open and closed positions to allow or prevent passage of inflation fluid, is provided directly on the branch 54 of the multi-port and valve assembly 36. *Id.* at 10:36-44.

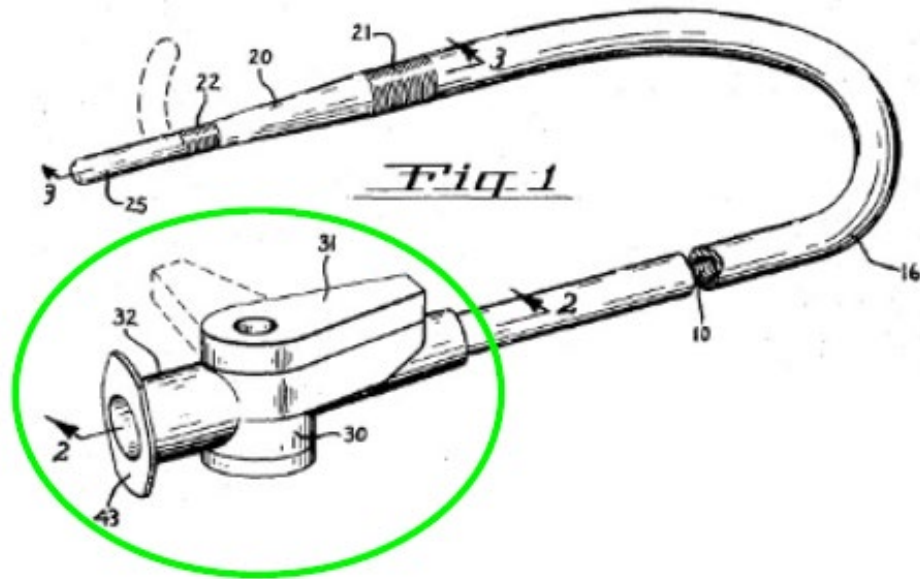
**IX. GROUND 1: CLAIMS 1-10 ARE NOT OBVIOUS OVER FOGARTY, CHENGOD, AND A PHOSITA'S KNOWLEDGE**

**A. Petitioner improperly construes the “flow valve” to be part of the “proximal hub”**

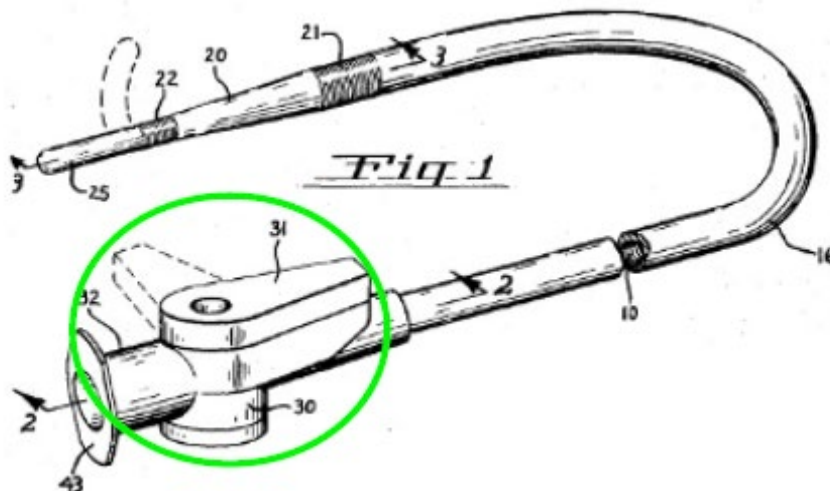
61. Independent claim 1 of the ‘737 Patent recites (i) a *proximal hub and* (ii) a *flow valve* as part of the occlusion catheter system. Ex. 1001 at cl. 1. Claim 1 further recites that the flow valve “is configured *to selectively fluidly communicate the proximal hub with an inflation device.*” *Id.* (emphasis added). These are two separately recited structures with a specifically defined spatial relationship between them. To “selectively fluidly communicate the proximal hub with an inflation device,” the flow valve must be located *between* the proximal hub and the inflation device.

62. An example of this configuration is provided in Fig. 22 of the ‘737 Patent. Actuable valve 828 is located between a pressure source 802 (e.g., an inflation device, such as a syringe) and the rest of the occlusion catheter system 710, which includes the proximal hub 590. *Id.* at 29:59-30:21, 36:57-37:7, 40:18-46. With this configuration, the flow valve is able to selectively fluidly communicate (through opening or closing of the actuable valve 828) a downstream proximal hub 590 with an upstream inflation device 802.

63. Dr. Resnick contends that Fogarty “shows and describes a hub in the form of the *shut off valve 30*, rotatable valve member 31, syringe fitting 32, and hub flange elements 43.” Ex. 1003 at ¶ 74 (emphasis added). Dr. Resnick annotates Fogarty’s Fig. 1 (reproduced below) and circles the components alleged to constitute the claimed proximal hub, confirming his position that the proximal hub includes the shut off valve 30. *Id.*



64. Dr. Resnick also contends that the “shut-off valve 30 having a rotatable valve member 31” and “equipped with a fitting (32) to receive a syringe (35)” constitutes the claimed flow valve. Ex. 1003 at ¶ 75. Dr. Resnick annotates Fogarty’s Fig. 1 again for the flow valve feature, and as can be seen below, Dr. Resnick’s green circle effectively encompasses the same components as above for the claimed proximal hub.



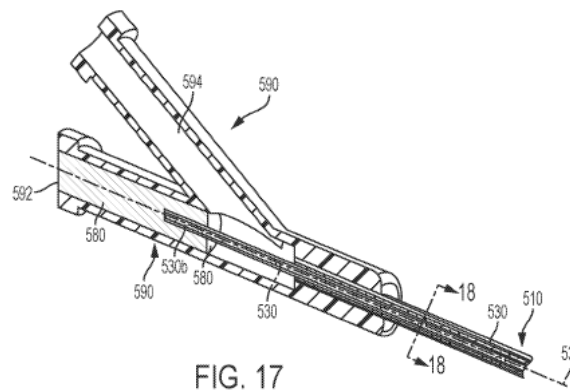
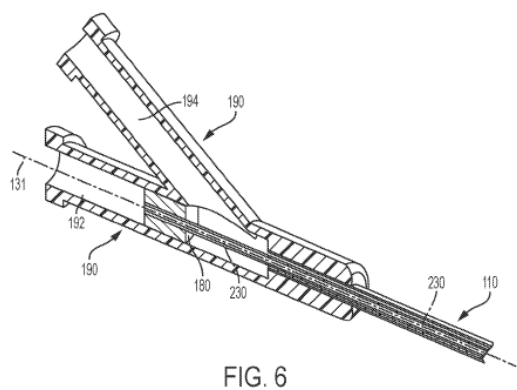
65. Dr. Resnick is therefore using the same portions of Fogarty to cover two separate structures and reads their relationship to one another out of claim 1.

66. As explained above at paragraph 37, ***Dr. Resnick implicitly defined*** the proximal hub as an element (or elements) used to physically connect an inflation device to the inflation lumen of the catheter. The flow valve is a separate, selectively actuatable valve that sits between the proximal hub and the inflation device and is selectively opened or closed to permit or block fluid flow between the two.

67. In relying on the '737 Patent for context and claim interpretation, ***a PHOSITA would understand that the relevant portions of the '737 Patent specification*** (*i.e.*, the portions of the '737 Patent specification describing an element (or elements) used to physically connect an inflation device to the inflation lumen of the catheter, and a manually or automatically actuatable valve that lies between the proximal hub and the inflation device and is selectively opened or closed to permit or block fluid flow between the two, and their relationship with one another) ***confirm that the flow valve is a separate element from the proximal hub and not that the proximal hub and flow valve may be the same component (as Dr. Resnick appears to suggest) or that the proximal hub and flow valve may be in an element/sub-element relationship (as the PTAB argued in the Institution Decision).***

68. For example, the '737 Patent drawings show multiple embodiments of a proximal hub, a sampling of which is reproduced below, none showing or

described the selectively actuatable flow valve as part of the proximal hub itself. *See e.g.*, Ex. 1001 at 25:60-26:12, 31:12-42, 35:4-43, Figs. 1, 6, 12, 17.



69. Likewise, examples in the ‘737 Patent specification of actuatable flow valves that selectively permit or block fluid flow between the proximal hub and the inflation device (*e.g.*, fluid source) are described as separate from an occlusion catheter system (710) containing the proximal hub (*e.g.*, 590), rather than coextensive with or as part of the proximal hub. *See e.g.*, *id.* at 39:38-40:46, Figs. 21-22.

70. Conversely, a PHOSITA would **not** rely upon the portions of ‘737 Patent specification preliminarily relied upon by the PTAB in the Institution Decision, as a PHOSITA would understand that these portions of the ‘737 Patent specification have no relevance, and provide no context, to the “proximal hub” or the “flow valve” recited in the ‘737 Patent claims.

71. Specifically, regarding “proximal hub” and as previously explained in paragraphs 39-40, a PHOSITA would **not** consider the system 1600, and particularly

the proximal and distal hub members 1604, 1606, to have any relevance, or provide any context, to the “proximal hub” recited in the ‘737 patent claims. The infection/contamination control system 1600 is an external sleeve, having an elongate tubular sleeve 1610, to provide an internal substantially sterile field for insertion of the catheter 1602 into the sterile lumen thereof during a vascular occlusion procedure. Hub members 1604, 1606 at the respective proximal and distal sleeve ends 1610a, 1610b permit the catheter 1602 to extend into and through the catheter sleeve 1600 while generally maintaining hemostasis and a sterile field within the catheter sleeve 1600. Ex. 1001 at 59:45-65; 60:2-8.

72. A PHOSITA would understand that the hub members 1604, 1606 are entirely unrelated to an element or elements used to physically connect an inflation device (e.g., syringe) to the inflation lumen of the catheter, but are rather used to engage the *outer wall* of the catheter 1602 and physically *cannot* connect any component, much less an inflation device, to an inflation lumen of the catheter.

73. In relying on the ‘737 Patent for context and claim interpretation, therefore, a PHOSITA would *not* consider the embodiment of the system 1600 as relevant to describing the “proximal hub” in the context of these claims. Accordingly, a PHOSITA would also *not* consider the system 1600 embodiment to understand whether the flow valve is a separate element from the proximal hub or

whether the proximal hub and flow valve may be the same or in an element/sub-element relationship.

74. Likewise, and as previously explained in paragraphs 42-44, a PHOSITA would **not** consider a pop-off valve or other similar biased valve disclosed in the '737 Patent specification to have any relevance, or provide any context, to the "flow valve" recited in the '737 patent claims. A PHOSITA would recognize that a flow valve has an entirely different structure and function from a pop-off valve or other biased valve. As one example, the flow valve is a valve that is opened or closed to selectively permit or block fluid flow therethrough, whereas a pop-off/biased valve is a valve biased to a closed position and will open only when the pressure on an inlet/upstream side thereof exceeds a threshold pressure in order to avoid a dangerous condition, such as overinflating the balloon, and otherwise remains in a closed position under normal operative conditions. These types of pressure relief valves provide a safety-related function, while a flow valve relates to selective control of normal operations for the fluid flow for the catheter.

75. In relying on the '737 Patent for context and claim interpretation, therefore, the disclosure in the '737 patent of a proximal hub including a pressure relief member in the form of a pop-off valve or other similar biased valve would not inform a PHOSITA as to the presence of a flow valve as or part of the proximal hub, much less a flow valve configured to selectively fluidly communicate the proximal

hub with an inflation device as recited in the claims. Accordingly, a PHOSITA would **not** consider the disclosure in the ‘737 patent of a proximal hub including a pressure relief member in the form of a pop-off valve or other similar biased valve to understand whether the flow valve is a separate element from the proximal hub or whether proximal hub and flow valve may be in an element/sub-element relationship.

76. To summarize, in relying on the ‘737 Patent for context and claim interpretation, a PHOSITA would understand that the relevant portions of the ‘737 Patent specification confirm that (i) the flow valve is a separate element from the proximal hub and (ii) a proximal hub and a flow valve may *not* be the same component or in an element/sub-element relationship.

**B. The “proximal-most end” of Fogarty’s stylet is not “secured ... within the proximal hub”**

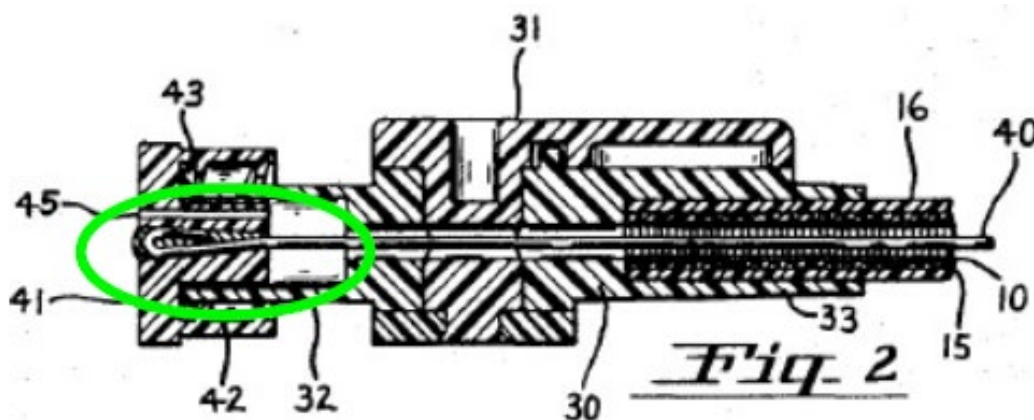
77. Independent claim 1 of the ‘737 Patent also recites “a solid wire, *secured* at a proximal-most end thereof ***within the proximal hub.***” Ex. 1001 at cl. 1 (emphasis added). Fogarty does **not** have a solid wire, secured at a proximal-most end thereof within the proximal hub.

78. Petitioner equates the removable metal wire stylet (40) of Fogarty with the claimed solid wire (stiffener member 530) of the present invention. Petitioner further equates the combination of the shut off valve (30), the rotatable valve

member (31), the syringe fitting (32), and the hub flange elements (43) of Fogarty with the claimed proximal hub. Pet. at 33, 38.

79. Fogarty itself explicitly teaches that “[t]he proximal end of the stylet 40 is **secured** in a cap 41 which is equipped with an internal thread 42 to **engage** hub flange elements 43 on the syringe fitting 32.” Ex. 1004 at 3:60-62 (emphasis added). That is, Fogarty itself differentiates between which component the stylet 40 is “**secured**” to, *i.e.*, the cap 41, versus which component(s) the cap 41 with the stylet 40 is merely “engaged” with, *i.e.*, the syringe fitting 32. Put another way, Fogarty itself understands and differentiates between “securement”, *i.e.* fixed coupling, and “engagement”, *i.e.*, a removable attachment.

80. Nevertheless, Dr. Resnick contends that “the metal wire stylet (40) is secured inside the hub by being secured to a cap (41) which is threaded into the flange elements (43) on the hub.” Ex. 1003 at ¶ 85 (*see also* Dr. Resnick’s annotation of Fogarty’s Fig. 2, reproduced below).



81. Dr. Resnick attempts to back his interpretation by claiming that “[t]he wire stylet (40) is attached within the proximal hub, and ***this attachment allows the wire and the catheter to withstand normal operating conditions and perform the preferred functions of the catheter.***” *Id.* 1003 at ¶ 86 (emphasis added).

82. As previously explained in paragraphs 48, 49 and 52, a PHOSITA would have the same understanding as Fogarty about “securement” – that “secured at a proximal-most end thereof within the proximal hub” requires the proximal-most end of the solid wire be ***fixedly coupled to*** the proximal hub. This definition is also supported by the most pertinent portion of the ‘737 patent, which specifically explains why this feature is important:

the proximal end of the ... solid wire 530 is ***fixedly coupled to*** the proximal hub 590 at a proximal bonding site .... The proximal end of the [solid wire] 530 is not limited to being adhesively bonded to the proximal hub 590 and may be otherwise ***fastened, secured, or fixed to*** the proximal hub 590, as long as the [solid wire] 530 is substantially secured to the proximal hub 590 ***such that*** the [solid wire] 530 provides stiffness for the balloon catheter system 500, the [solid wire] 530 is substantially secured relative to the inflation catheter member 510 and the occlusion balloon 540, ***the assembly***

*is able to withstand normal operation conditions of the catheter*

*system 500.* Ex. 1001 at 35: 4-27 (emphasis added).

83. A PHOSITA understands from this disclosure that the proximal-most end of the solid wire must be fixedly coupled to, and within, the proximal hub to add stiffness to the catheter, most specifically longitudinal stiffness which supports the catheter against compressive buckling or displacement along the longitudinal axis under the normal operating conditions of the system, *i.e.*, in operation to reach and occlude the target vessel when subjected to dynamic blood pressure in the aorta.

84. When the occlusion balloon is inflated in the aorta, normal operating conditions will produce forces acting on the balloon that push on the catheter shaft with embedded and secured wire. *See e.g.* Ex. 1009 at 9:43-49 (describing potential migration that could be caused during balloon inflation by aortic pulsation); U.S. Patent Publication No. 2018/0263655 (describing reinforcement of a REBOA catheter to prevent buckling “in response to the strong axial hemodynamic forces generated in the aorta when flow through is halted”). Fixedly coupling the proximal-most end of the solid wire to and within the proximal hub allows “the assembly [to be] able to withstand the normal operating conditions of the catheter system 500 and securement results in a structure able to perform the preferred functions of the catheter system 500” Ex. 1001 at 35: 24-27.

85. Under normal operation conditions, the stylet 40 of Fogarty must be withdrawn from the syringe fitting 32, i.e., disconnected from the hub flange elements 43 of syringe fitting 32, or else a syringe 35 cannot physically be fluidly connected to the single syringe fitting 32 to inflate the balloon. That is, ***the stylet 40 is not present during the major aspect of the normal operating conditions encountered by the balloon catheter system of Fogarty.***

86. Moreover, the stylet 40 need not be present in Fogarty's stated procedures because the catheter is not intended to resist compressive forces of blood flow when the balloon 20 is inflated to occlude the aortic vessel. Accordingly, the proximal-most end of the stylet (40) ***is not secured*** to the "proximal hub" of Fogarty. The end of the stylet 40 is only secured to the cap 41 during insertion of the Fogarty catheter into the vessel, which cannot be secured in any alleged proximal hub of Fogarty because the cap 41 and stylet 40 must be removed to perform the procedures with the balloon inflation.

87. With respect to the catheter of the '737 Patent, encountering compressive forces resulting from aortic blood pressure during the procedures for which the catheter of the '737 Patent is designed, e.g., vessel occlusion during REBOA, is a normal operating condition for the claimed catheter system. Accordingly, the proximal-most end of the solid wire is fixedly coupled to the proximal hub of the occlusion catheter system of the '737 Patent to provide strength

and stiffness to the catheter to resist the aortic blood pressure encountered during normal operation conditions.

**X. GROUND 2: CLAIM 2 IS NOT OBVIOUS OVER FOGARTY, CHENGOD, SAAB, AND A PHOSITA'S KNOWLEDGE**

88. Claim 2, dependent upon claim 1, recites “wherein the occlusion balloon is asymmetrical.” Dr. Resnick asserts that “Saab explains that low-pressure elastomeric balloons (*i.e.*, compliant balloons) can be designed to expand in an asymmetrical manner” and includes Saab’s Figure 6 and its caption as an example. (Ex. 1003 at ¶ 114). Dr. Resnick takes the position that a PHOSITA would have learned from Saab that the compliant balloon in the catheters described by either or both of the Fogarty and Chengod references could be configured to expand asymmetrally. *Id.* at ¶¶ 115-118.

89. Dr. Resnick’s entire argument is based on the caption for Figure 6. I note that the term “asymmetrical” does not appear anywhere else in Saab. I understand Saab to be promoting the advantages of high-pressure balloons for all different kinds of procedures, including vessel occlusion. Ex. 1006 at 86, 89-96, for example. Saab clearly teaches,

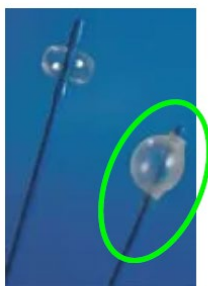


*Figure 6. Offering less precision, an elastomeric balloon (right) will often expand asymmetrally compared with a high-pressure, thin-walled balloon (left).*

however, that the asymmetric balloon is a **disadvantage** and Saab specifically states

that the asymmetric balloon “[o]ffer[s] less precision” In Fig. 6. Saab elsewhere criticizes the type of low pressure, elastomeric balloon shown in Figure 6. For example, Saab states that “*high-pressure balloons are preferred* when a precise balloon shape or catheter position is required. *An elastomeric balloon* can shift and roll, shifting back and forth, which *is unacceptable* in critical positioning applications. *In addition, elastomeric balloons often inflate nonconcentrically and unpredictably, which precludes their use in application demanding extreme accuracy* (Figure 6).” Ex. 1006 at 90-91. Even for occlusion, Saab describes high pressure balloons as offering “advantages over elastomeric balloons.” *Id.* at 91-92.

90. When considered as a whole, a PHOSITA would understand Saab to be advocating for usage of high-pressure balloons, which do not suffer from the aforementioned problems present in low pressure elastomeric balloons. If a PHOSITA were going to make any modifications to Fogarty or Chengod based on Saab, it would be to transition to a high pressure balloon, not to include the criticized asymmetric balloon, which is the change Dr. Resnick suggests. The caption from Figure 6 in Saab that Dr. Resnick relies upon is merely an observation, and one that Saab considers to be a detriment remedied by high pressure balloon usage. Based on my understanding of obviousness, Saab would therefore teach away from the proposed modification to Fogarty for an asymmetrical balloon shape.

**XI. GROUND 3: CLAIMS 3-5 AND 9 ARE NOT OBVIOUS OVER FOGARTY, CHENGOD, SANATI, AND A PHOSITA’S KNOWLEDGE**

91. In reviewing Ground 3, I do not find that Dr. Resnick has added any analysis that addresses the issues I highlight above. Ex. 1003 at ¶¶ 119-134. It is therefore my understanding that because claim 1 is not proved obvious in Ground 1, then dependent claims 3-5 and 9 cannot be obvious in Ground 3 either, for at least the same reasons.

**XII. GROUND 4: CLAIM 8 IS NOT OBVIOUS OVER FOGARTY, CHENGOD, DEATON, AND A PHOSITA’S KNOWLEDGE**

92. In reviewing Ground 4, I do not find that Dr. Resnick has added any analysis that addresses the issues I highlight above. Ex. 1003 at ¶¶ 135-141. It is therefore my understanding that because claim 1 is not proved obvious in Ground 1, then dependent claim 8 cannot be obvious in Ground 4 either, for at least the same reasons.

**XIII. GROUND 5: CLAIMS 1-10 ARE NOT OBVIOUS OVER ELIASON AND A PHOSITA’S KNOWLEDGE**

**A. Petitioner improperly construes the “flow valve” to be part of the “proximal hub”**

93. As described above for Fogarty, independent claim 1 of the ‘737 Patent recites (i) a *proximal hub* and (ii) a *flow valve* as part of the occlusion catheter system. Ex. 1001 at cl. 1. Claim 1 further recites that the flow valve “is configured *to selectively fluidly communicate the proximal hub with an inflation device.*” *Id.* (emphasis added). As previously explained in my analysis of Fogarty, these are two

separately recited structures with a specifically defined spatial relationship between them. To “selectively fluidly communicate the proximal hub with an inflation device,” the flow valve must be located *between* the proximal hub and the inflation device.

94. Dr. Resnick contends that “[t]he proximal hub in the Eliason catheter is shown in Figure 10 as element 36, which Eliason calls the ‘multi-port and valve assembly.’” Ex. 1003 at ¶ 146. Dr. Resnick also contends that “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.” *Id.* at ¶ 147. The name of the multi-port *and valve* assembly 36 is self-identifying that the assembly 36 includes the valve 60. This is also confirmed in Dr. Resnick’s annotated Fig. 10 of Eliason (reproduced) below.

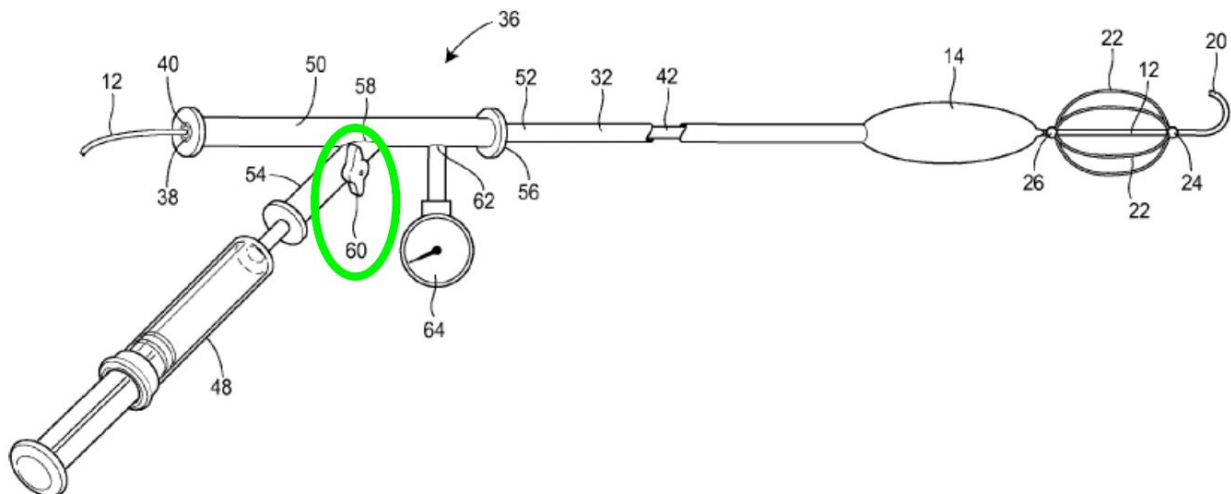


**FIG. 10**

95. Dr. Resnick is therefore using portions of the alleged proximal hub from Eliason to also cover the flow valve structure and read their relationship to one another out of the claim, which a PHOSITA would not do.

96. As explained above at paragraph 37, as well as in my analysis of Fogarty, ***Dr. Resnick himself implicitly defined*** the proximal hub as an element (or elements) used to physically connect an inflation device to the inflation lumen of the catheter. The flow valve is a manually or automatically actuatable valve that sits between the proximal hub and the inflation device and is selectively opened or closed to permit or block fluid flow between the two.

97. In relying on the ‘737 Patent for context and claim interpretation, a PHOSITA would understand that the ***relevant*** portions of the ‘737 Patent specification confirm that the flow valve is a separate element from the proximal hub and ***not*** that the proximal hub and flow valve may be in an element/sub-element relationship.

98. As I explained above, the ‘737 Patent drawings show multiple embodiments of a proximal hub, none showing or describing the selectively actuatable valve forming part of the proximal hub itself. *See e.g.*, Ex. 1001 at 25:60-26:12, 31:12-42, 35:4-43, Figs. 1, 6, 12, 17.

99. Examples in the ‘737 Patent specification of actuatable flow valves that selectively permit or block fluid flow between the proximal hub and the inflation

device are also described as separate from an occlusion catheter system (710) containing the proximal hub (e.g., 590), rather than coextensive with or as part of the proximal hub. *See e.g., Id.* at 39:38-40:46, Figs. 21-22.

100. As previously detailed at paragraphs 38-40, as well as in my analysis of Fogarty, a PHOSITA would **not** rely upon the portions of the ‘737 Patent specification preliminarily relied upon by the PTAB in the Institution Decision, as a PHOSITA would understand that these portions of the ‘737 Patent specification have no relevance, and provide no context, to the “proximal hub” or the “flow valve” recited in the ‘737 Patent claims.

101. More specifically, a PHOSITA would **not** consider the system 1600, and particularly the proximal and distal hub members 1604, 1606, to have any relevance, or provide any context, to the “proximal hub” recited in the ‘737 patent claims. A PHOSITA would understand that the hub members 1604, 1606 are entirely unrelated to an element or elements used to physically connect an inflation device (e.g., syringe) to the inflation lumen of the catheter, but rather engage the **outer wall** of the catheter 1602 and physically **cannot** connect any component, much less an inflation device, to an inflation lumen of the catheter.

102. A PHOSITA also would **not** consider a pop-off valve or other similar biased valve disclosed in the ‘737 Patent specification to have any relevance, or provide any context, to the “flow valve” recited in the ‘737 patent claims. A

PHOSITA would recognize that pressure relief valves provide a safety-related function when a threshold pressure is exceeded and otherwise remain closed, whereas a flow valve relates to selective control of normal operating fluid flow.

103. Therefore, in relying on the ‘737 Patent for context and claim interpretation, a PHOSITA would understand that the relevant portions of the ‘737 Patent specification confirm that the flow valve is a separate element from the proximal hub and not that proximal hub and flow valve may be in an element/sub-element relationship as is the case in Eliason.

**B. Petitioner improperly conflates features of the catheter system of Eliason with the distal section of the catheter of Eliason**

104. Independent claim 1 also recites and separately names “*a distal catheter section* distally terminating with an atraumatic tip” and “*a solid wire*, secured at a proximal-most end thereof within the proximal hub, and *extending ... into the distal catheter section*”. Ex. 1001 at cl. 1 (emphasis added).

105. For the claimed distal catheter section, Dr. Resnick primarily relies upon Eliason's Fig. 6 (Dr. Resnick's annotated version reproduced at right) and circles the portion of the endovascular wire 12 located distally of the occlusion balloon 14, which terminates with a "J tip" 20, as well as the wire struts 22, the leading securement bead 24, and the trailing securement bead 26. Ex. 1003 at ¶ 149. For the claimed solid wire, Dr.

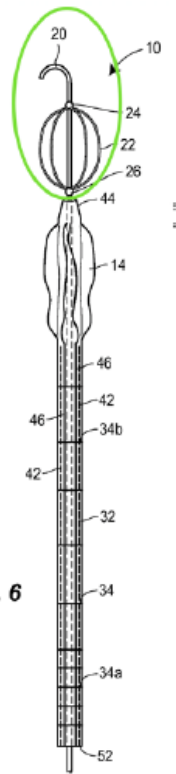


FIG. 6

Resnick cites Eliason's endovascular wire 12 that extends through its tubular barrel section 50, balloon shaft 32, and occlusion balloon 14. Ex. 1003 at ¶ 153; Ex. 1009 at 9:31-10:32, Figs. 6, 10. Dr. Resnick conspicuously does *not* identify any reference numerals in Eliason corresponding to the claimed distal catheter section. Ex. 1003 at ¶¶ 149, 153. Nevertheless, the PTAB in the Institution Decision took the position that "Petitioner annotates the entire portion distal to the occlusion balloon with a green oval, where Eliason teaches that Figure 6 includes 'endovascular wire 12, the J tip 20, the leading securement bead 24, the trailing securement bead 26 ... the wire struts 22' as elements distal to balloon shaft 44" Paper 7 at pg. 54: lines 1-5.

106. As explained above at paragraph 45, the ordinary and customary meaning of the claim term "distal catheter section", as understood by a PHOSITA, is simply a distal portion of a catheter shaft. The '737 Patent specification discloses,

for example, a distal catheter member 520 embodying this concept, in that it is a distally-located portion of a catheter shaft.

107. The PTAB preliminary interprets “distal catheter section” as “a portion of the **system** that is at the distal end.” Paper 7 at pg. 17: lines 26-27 (emphasis added). A PHOSITA would understand, however, that a catheter portion is a portion of the **catheter shaft** itself, rather than of the entire catheter system, which may include other components. Claim 1 recites “a distal catheter section” and **not** “a distal catheter system section.”

108. Notably, Dr. Resnick confirms this understanding in his Deposition, where he states that a balloon catheter consists of the balloon and the catheter it is mounted on, the catheter being “**the shaft of the device**. Typically ... extending from the proximal hub to the end of the device distally”. Ex. 2002 at 26:21-27:3 (emphasis added). A PHOSITA would understand, therefore, that a distal catheter section is a distal portion **of the shaft** of the device, not just any distally-located separate components of an overall system, such as a separate endovascular wire.

109. Considering the components in Eliason identified by Dr. Resnick as being distally located from the balloon 14, none would be considered by a PHOSITA to constitute a “distal catheter section.” First, the endovascular wire 12 –a section of a wire cannot be considered as a section of a catheter shaft since the endovascular wire 12 does not form part of the shaft of the catheter device. For one thing, Dr.

Resnick himself admits that Eliason's endovascular wire is distinct from Eliason's catheter. Ex. 1003 at ¶ 144 (“This occlusion *catheter* is designed to be *fixed to a wire (12)* that provides rigidity to the catheter”) (emphasis added), Ex. 2002 at 71:13-74:14.

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

111. A PHOSITA also would not consider the wire struts 22, leading securement bead 24, or the trailing securement bead 26 in Eliason as forming a distal catheter section either. Importantly, not only do none of these components meet the standard definition of a catheter, but each of these elements is formed *on the endovascular wire*. As an example, Dr. Resnick admits that, in the Eliason embodiment where the endovascular wire 12 is inserted into a patient separately from the catheter, the struts and securement beads are inserted with the wire. Ex. 2002 at 71:13-74:14. Pre-securing the wire 12 to the catheter does not transform these structures into being part of the catheter. Thus, a PHOSITA would not

consider any of the struts 22 or securement beads 24, 26 as forming a “distal catheter section” as claimed.

112. I should also briefly clarify that the J tip 20 seen in Eliason is not a separate element from the endovascular wire 12, either. As Dr. Resnick acknowledges, the J tip 20 is formed by the wire 12 – it is a curved shape introduced into the wire so that the terminal end of the wire 12 does not unintentionally poke a hole in a blood vessel. Ex. 2002 at 73:22 – 74:9; Ex. 1009 at 8:45-52. So to the extent that Dr. Resnick or the PTAB contend that the claimed distal catheter section may be satisfied at all with reference to the J tip, this would also be improper, as the J tip is part of the wire, which as I discussed above, cannot be considered a catheter.

113. Accordingly, Eliason does not disclose that a solid wire extends into a distal catheter section, as claimed.

#### **XIV. GROUND 6: CLAIMS 1-10 ARE NOT OBVIOUS OVER ELIASON, FOGARTY, AND A PHOSITA’S KNOWLEDGE**

114. In reviewing Ground 6, Dr. Resnick modifies his Ground 5 analysis of Eliason and uses Fogarty to allege that Eliason could secure the proximal most end of the wire in the asserted proximal hub. Ex. 1003 at ¶¶ 181-185. I disagree with his analysis, but more importantly, this combination with Fogarty does nothing to address Dr. Resnick’s failure to properly differentiate a “proximal hub” and “flow valve” in Eliason, nor to address his failure to show a solid wire that extends into a

distal catheter section in Eliason. I conclude that Ground 6 fails for at least the same reasons I have described above as Ground 5.

**XV. GROUND 7: CLAIM 2 IS NOT OBVIOUS OVER ELIASON, SAAB, AND A PHOSITA'S KNOWLEDGE**

115. Similar to ground 2, Dr. Resnick takes the position that a PHOSITA would have learned from Saab that the compliant balloon in the catheter described by Eliason could be configured to expand asymmetrically. Ex. 1003 at ¶¶ 187-191. For the same reasons explained above at paragraphs 88-90, Saab teaches away from the proposed modification to Eliason for an asymmetrical balloon shape.

**XVI. GROUND 8: CLAIMS 3-5 AND 9 ARE NOT OBVIOUS OVER ELIASON, SCOTT, AND A PHOSITA'S KNOWLEDGE**

116. In reviewing Ground 8, I do not find that Dr. Resnick has added any analysis that addresses the issues I highlight above in Ground 5. Ex. 1003 at ¶¶ 193-203. It is therefore my understanding that because claim 1 is not proved obvious in Ground 5, then dependent claims 3-5 and 9 cannot be obvious in Ground 8 either, for at least the same reasons.

**XVII. GROUND 9: CLAIM 8 IS NOT OBVIOUS OVER ELIASON, JOE, AND A PHOSITA'S KNOWLEDGE**

117. In reviewing Ground 9, I do not find that Dr. Resnick has added any analysis that addresses the issues I highlight above. Ex. 1003 at ¶¶ 205-208. It is therefore my understanding that because claim 1 is not proved obvious in Ground 5,

then dependent claim 8 cannot be obvious in Ground 9 either, for at least the same reasons.

## **XVIII. CONCLUSION**

118. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the Patent Owner's position in this *Inter Partes* Review proceeding.

Dated: 1/14/2025

  
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William Cimino, Ph.D.

## **William W. Cimino, Ph.D.**

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Home: (303) 666-7675      Cell: (303) 859-4384

**SUMMARY:** Over 35 years of professional medical technology experience, from Senior Engineer to CEO/Chairman, covering all aspects of medical device business including device design and technology development, clinical studies and assessment, regulatory affairs, strategic market development, distribution, business management/growth, and financial/funding requirements. Experience in larger medical device companies and start-ups; with capital products and disposables. Experienced speaker/presenter. Extensive experience with development and prosecution of intellectual property. Education: Ph.D. Bioengineering, M.S. Mechanical Engineering, B.S. Aerospace Engineering.

## **EXPERIENCE**

### ***GID BIO, Inc., Louisville, CO, 2010-present***

#### ***CEO and Board of Directors***

- \* GID BIO was established to provide world-leading technology for cellular therapies for degenerative diseases delivered at point-of-care.
- \* Responsible for the overall financial, legal, scientific, IP and operational development of the company.

### ***Body Beam Research Inc., Superior, CO, 2008-2010***

#### ***President/CEO, Chairman of Board of Directors***

- \* Founded company; generated company business plan and strategies; completed Series A financing with professional venture capital backing.
- \* Generated 1<sup>st</sup>-generation product designs and prototypes.
- \* Established intellectual property platform for Company.
- \* Company acquired 2011.

### ***Sound Surgical Technologies LLC, Louisville, CO, 1998-2008***

#### ***Chairman 1998-2006, CEO or President 1998-2008, Management Committee 1998-2009***

- \* Founded company. Served as the top-ranking executive (CEO) holding full financial accountability and decision-making authority (reporting to the Management Committee).
- \* Elected Chairman of the Management Committee (BOD) 8 consecutive years.
- \* Generated initial company business plan; obtained initial seed financing and several rounds of subsequent financing. Directly involved in all major financing rounds, totaling more than \$25M.
- \* Directed and managed company growth (with management team) from one employee and no revenues to over 50 employees with domestic and international revenues.
- \* Established intellectual property platform for company; over 15 issued patents and trademarks.
- \* Developed, submitted, and obtained 3 FDA 510(k) clearances.
- \* Submitted and obtained UL and CE/MDD approvals for VASER System.
- \* Developed and implemented QSR/ISO compliant quality system for the Company. Served as Management Representative for FDA audit/inspection.
- \* Personally attended or participated in over 500 surgical procedures with Company technology.
- \* Developed and launched two human clinical trials for assessment of a new procedure and a contra-lateral comparison of two different technologies for body contouring.
- \* Company acquired 2010.

### ***National Advisory Council for Bioengineering, University of Utah, 2007-2008, 2008-2009***

## **William W. Cimino, Ph.D.**

- \* Council of leaders from academia, industry, and established alumni to provide guidance on current challenges and new initiatives in bioengineering.

### ***Valleylab, Inc., Boulder, CO, 1993-1998 (division of Pfizer)***

- \* Engineering Manager and Principal Engineer 1998, Principal Engineer 1997-1998. Member of Valleylab's corporate R&D strategy team. Developed university-level specialized training courses in the areas of design, materials, and mechanisms.
- \* Staff Engineer 1993-1997. Responsible for the direction of research teams and product development teams involving new ultrasonic and argon electrosurgery products.
- \* Directed 12+ person product development team which released 4 argon electrosurgical products to market, including RF electronic generator system, disposable tubing set, cart system, and accessories. Product was launched internationally, including 5 languages and CE marking.
- \* Directed 6-person clinical study team which designed, built, and organized a clinical trial (human use, IDE) to investigate ultrasonic tissue dissection and coagulation.

### ***Heart Rhythm Technologies, Temecula, CA, 1992-1993 (division of Eli Lilly)***

- \* Project Lead Engineer. Responsible for the design, development, and future market release of a catheter-based endocardial mapping and ablation system. Provided technical direction for project, schedules, and coordination of regulatory and manufacturing efforts.
- \* Designed and fabricated high-torque catheter shafts, tip steering system, and control mechanisms. Knowledge of biomaterials, extrusion, injection molding, and bonding processes.
- \* Developed animal study protocols and conducted experiments to verify function/safety of product design and (bio)material interactions. Conducted experiments on the influence of electrode size/shape and RF generator output impedance on lesion formation in tissue.

### ***Center for Engineering Design, Univ. of Utah, SLC, UT, 1989-1992***

- \* Research Engineer. Developed 4-way steerable catheter system for cardiac applications.

### ***Boeing Aerospace, Seattle, WA, 1985-1989***

- \* Senior Engineer. Designed control systems for flight vehicles and space vehicles.
- \* Applied multi-variable control theories to systems with multi-modal structural dynamics.
- \* Developed numerical simulations of control systems and interactions with flexible structures.

## **EDUCATION**

### ***Ph.D., Bioengineering, University of Utah, 1992***

- \* Dissertation Title: Active Tip Control for Small Diameter Catheters: Power Transmission and Transduction Requirements. Contributions: The issues of scale pertaining to the design and fabrication of small diameter cardiac catheter systems with actively controllable tip elements were analyzed. A 3 French (1 mm OD) cardiac catheter with a 4-way controllable tip was developed and ability to actively control the tip and direct the catheter in the coronary arteries was demonstrated.
- \* Secondary research area: "Catheter-Based Myocardial Ablation: Electromagnetic and Ultrasonic Energy and Associated Delivery Constraints". Evaluated energy/tissue interaction in terms of energy absorbed per unit volume of tissue as a function of frequency and depth.
- \* Curriculum in electronics and instrumentation, biomechanics, biomaterials, and physiology.
- \* Completed MBA series in financial and management accounting.

## **William W. Cimino, Ph.D.**

### ***M.S., Mechanical Engineering, Purdue University, 1985***

- \* Thesis Title: Kinematic Analysis of General Geometry Positioning and Orienting Mechanisms for Robot Manipulators. Contributions: Analytic solutions to the inverse kinematics problem for general geometry robot manipulator systems were derived. Application to control algorithms for several commercially available robot manipulator systems was demonstrated.
- \* Curriculum in control theory, dynamic system modeling, mechanism design, numerical methods, and microprocessor technology.

### ***B.S., Aerospace Engineering, University of Colorado, 1983***

- \* Curriculum in fluid dynamics, computer science, and flight control theory.

## **PERSONAL/INTERESTS**

- \* Married, two children
- \* Active triathlete, 10+ years of competition
- \* Enjoy reading, skiing, motorcycling (dirt)

## **PATENTS**

- \* U.S. Patent #10,035,004. Implant device, tool, and methods relating to treatment of paranasal sinuses
- \* U.S. Patent #9,950,015. Tissue processing apparatus with fluid suction features and methods relating to collecting and processing human biological material
- \* U.S. Patent #9,909,095. Tissue processing apparatus with filter pierceable to remove product and method for processing adipose tissue
- \* U.S. Patent #9,909,094. Tissue processing apparatus with mixing device and method for processing adipose tissue
- \* U.S. Patent #9,907,883. Method for processing cancellous bone material and related products, methods and uses
- \* U.S. Patent #9,901,721. Method for delivery of treatment formulation to paranasal sinus
- \* U.S. Patent #9,700,459. Apparatuses, tools and kits relating to fluid manipulation treatments of paranasal sinuses
- \* U.S. Patent #9,572,964. Implantation tools, tool assemblies, kits and methods
- \* U.S. Patent #9,561,350. Paranasal sinus access implant devices and related tools, methods and kits
- \* U.S. Patent #9,308,358. Implant device, tool, and methods relating to treatment of paranasal sinuses
- \* U.S. Patent #9,296,984. Tissue processing apparatus and method for processing adipose tissue
- \* U.S. Patent #9,260,697. Apparatus and methods relating to collecting and processing human biological material containing adipose
- \* U.S. Patent #9,206,387. Method and apparatus for processing adipose tissue
- \* U.S. Patent #9,022,967. Implant device, tool, and methods relating to treatment of paranasal sinuses
- \* U.S. Patent #8,298,163. Non-invasive ultrasonic soft-tissue treatment apparatus
- \* U.S. Patent #8,292,835. Non-invasive ultrasonic soft-tissue treatment method
- \* U.S. Patent #7,905,918. Elastic Metallic Replacement Ligament
- \* U.S. Patent #7,361,172. Ultrasonic Device and Method for Tissue Coagulation
- \* U.S. Patent #7,204,825. Surgical System Console
- \* U.S. Patent #6,726,698. Pulsed Ultrasonic Device and Method

## **William W. Cimino, Ph.D.**

- \* U.S. Patent #6,716,194. Surgical Aspiration Device Employing Continuous, Precision Venting
- \* U.S. Patent #6,602,227. Surgical System Console
- \* U.S. Patent #6,585,745. Ultrasonic Cutting and Coagulation Knife Using Transverse Vibrations
- \* U.S. Patent #6,540,713. Vented Aspirator and Method
- \* U.S. Patent #6,391,042. Pulsed Ultrasonic Device and Method
- \* U.S. Patent #6,379,326. Lipoplasty Method
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- \* U.S. Patent #6,224,565. Protective Sheath and Method for Ultrasonic Probes
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- \* U.S. Patent #6,027,515. Pulsed Ultrasonic Device and Method
- \* U.S. Patent #5,857,997. Catheter for Electrophysiological Procedures
- \* U.S. Patent #5,662,606. Catheter for Electrophysiological Procedures
- \* U.S. Patent #5,628,743. Dual Mode Ultrasonic Surgical Apparatus
- \* U.S. Patent #5,382,247. Technique for Electrosurgical Tips and Method of Manufacture/Use
- \* U.S. Patent #5,364,352. Catheter for Electrophysiological Procedures
- \* U.S. Patent #D548,329. Aspiration Canister
- \* U.S. Patent #D539,417. Aspiration Canister
- \* U.S. Patent #D438,952. Console for Surgical Procedures
- \* Various international and EC versions of above-named patents

## **PUBLICATIONS**

### **Journal Publications**

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### **Book Chapters**

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## **William W. Cimino, Ph.D.**

“History of Ultrasound-Assisted Lipoplasty, Revised 2008”, Cimino, W.W., to be published, Editors M.A. Shiffman, M.D. and A. Di Giuseppe, M.D., Springer-Verlag, Berlin, Germany.

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“VASER-Assisted Lipoplasty: Technology and Technique”, Cimino, W.W., *Liposuction: Principles and Practice*, Editors M.A. Shiffman, M.D. and A. Di Giuseppe, M.D., Springer-Verlag, Berlin, Germany, 2006, p 239-244.

“The Physics of Soft Tissue Fragmentation Using Ultrasonic Frequency Vibration of Metal Probes”, Cimino, W.W., *Clinics in Plastic Surgery* on Ultrasound-Assisted Lipoplasty: Part II, Editor Franklin DiSpaltro, W.B. Saunders, Philadelphia, July 1999, p 447-461.

### **Proceedings and Conference Publications**

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Cimino, W.W. “Workspace Analysis of a Six-Revolute Decoupled Robot Manipulator”, Proceeding of the IEEE International Conference on Robotics and Automation, San Francisco, CA, April 7-10, 1986.

Cimino, W.W. and Pennock, G. "Inverse Kinematics of a Six-Revolute General Geometry Robot Manipulator", Proceedings of the 9th Applied Mechanisms Conference, Kansas City, MO, Oct. 28-30, 1985. Award for outstanding paper at conference.

### **Dissertation and Thesis**

Cimino, W.W. *Active Tip Control for Small Diameter Catheters: Power Transmission and Transduction Requirements*, Doctoral dissertation, University of Utah, Salt Lake City, UT, June, 1992.

Cimino, W.W. *Kinematic Analysis of General Geometry Positioning and Orienting Mechanisms for Robot Manipulators*, Master of Science thesis, Purdue University, W. Lafayette, IN, May, 1985.

### **Professional Presentations and Invited Lectures**

## **William W. Cimino, Ph.D.**

Cimino, W.W., “Medical Device Design, Development, and Commercialization in the USA”, invited keynote lecture at conference ‘Critical Pathways for Successful Medical Device Launch in the U.S.’, Taipei, Taiwan, May 20, 2010

Cimino, W.W., “A Multi-center, Prospective, Randomized, Single-blind, Controlled Clinical Study Comparing VAL and SAL”, “Ultrasonic Surgery: Physics and Theory”, “Analysis of VASER Aspirate and Application to AFT”, “Patient Safety and Optimization of Outcomes: Learning from Real-life Examples”, Am. Soc. Aes. Plas. Surg., San Diego, CA, April, 2008.

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Cimino, W.W., “Skin Retraction and the Superficial Subcutaneous Layer”, Bariatric Workshop, Amelia Island, FL, Oct., 2005.

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Cimino, W.W., “Ultrasonic Surgery: Power Quantification and Efficiency Optimization”, Am. Soc. Aes. Plas. Surg. Technology and Innovation Symposium, New York, NY, May 2001.

Cimino, W.W., “Ultrasonic Surgery: Power Quantification and Efficiency Optimization”, Int. Soc. Ultrasonic Surg., Ft. Lauderdale, FL, March, 2001.

Cimino, W.W., “The Art and Science of Vibrating Surgery”, Am. Soc. Plas. Recon. Surg., Los Angeles, CA, Oct., 2000.

Cimino, W.W., “A Physics View”, Lipoplasty Symposium of California Soc. Plas. Surg., Santa Monica, CA, May, 2000.

Cimino, W.W., “Scientific method for Quantifying Performance of Ultrasonic Surgical Probes”, Int. Soc. Ultrasonic Surg., Orlando, FL, May, 2000.

Cimino, W.W., “Ultrasonic Surgery”, Am. Soc. Aes. Plast. Surg. Scientific Program on Biophysics and Long-term Effects of UAL, Dallas, TX, May 1999.