

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRONT LINE MEDICAL TECHNOLOGIES, INC.
Petitioner

v.

PRYTIME MEDICAL DEVICES, INC.
Patent Owner

Patent No. 11,857,737

Post Grant Review No. PGR2024-00028

SECOND DECLARATION OF DR. SCOTT A. RESNICK, M.D.
IN SUPPORT OF PETITIONER'S REPLY IN POST GRANT
REVIEW OF
U.S. PATENT NO. 11,857,737

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 18 U.S.C. § 1001.

Dated:

By: Scott Resnick, MD

Scott Resnick, MD, FSIR

LIST OF EXHIBITS

Ex-1001	U.S. Patent No. 11,857,737 (“the ’737 Patent”)
Ex-1002	Prosecution history of U.S. Patent No. 11,857,737
Ex-1003	Declaration of Dr. Scott A. Resnick, M.D. (May 6, 2024)
Ex-1004	U.S. Patent Number 3,467,101 (“Fogarty”)
Ex-1005	S. Chengod, MD. et al., <i>Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique</i> , Department of Anesthesiology and Intensive Care, Division of Cardiothoracic and Vascular Anesthesiology and Intensive Care, Amrita Institute of Medical Sciences and Research Center, Kerala, India. (2005) (“Chengod”)
Ex-1006	Mark A. Saab, <i>Applications of High-Pressure Balloons in the Medical Device Industry</i> , Medical Device & Diagnostic Industry Magazine (September 2000) (“Saab”)
Ex-1007	U.S. Patent No. 10,004,622 (“Sanati”)
Ex-1008	Dr. David H. Deaton, <i>Image-Guided Thrombectomy in Vascular Surgery</i> , Endovascular Today (July 2005) (“Deaton”)
Ex-1009	U.S. Patent Number 9,131,874 (“Eliason”)
Ex-1010	Daniel J. Scott, et al., <i>A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock</i> , The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1 (July 2013) (“Scott”)
Ex-1011	U.S. Publication Number 2015/0133892 (“Joe”)
Ex-1012	International Application Number PCT/US2011/033368 (“Eliason PCT Application”)
Ex-1013	U.S. Patent Pub. No. 2013/0060316 (“Sanati Publication”)
Ex-1014	X. Gu et al., <i>A New Technique for Sizing of Atrial Septal Defects</i> , Catheterization and Cardiovascular Interventions (1999) (“Gu”)

Ex-1015	Handbook of Endovascular Peripheral Interventions (C.D. Owens & Y. Yeghiazarians eds., Springer 2012)
Ex-1016	PCT publication number WO 2014/036530 to Bagaoisan (“Bagaoisan”)
Ex-1017	U.S. Patent No. 8,088,121 to Nishide (“Nishide”)
Ex-1018	U.S. Patent No. 5,607,394 to Anderson (“Anderson”)
Ex-1019	U.S. Patent No. 5,779,731 to Leavitt (“Leavitt”)
Ex-1020	U.S. Patent Publication No. 2008/0188803 by Jang (“Jang”)
Ex-1021	John M. Mathis, et. al, <i>Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion</i> , American Society of Neuroradiology (November 1994) (“Mathis”)
Ex-1022	U.S. Patent No. 4,846,174 to Willard et al. (“Willard”)
Ex-1023	Patent Owner’s Infringement Claim Charts filed in <i>Prytime Medical Devs., Inc. v. Front Line Med. Techs., Inc.</i> , Case No. 6:24-cv-00001, Dkt. No. 1-3 (W.D. Tex. Jan. 2, 2004)
Ex-1024	E.P. Gerstenfeld & J. Michele, <i>Pulmonary vein isolation using a compliant endoscopic laser balloon ablation system in a swine model</i> , Springer Science+Business Media, LLC (2010) (“Gerstenfeld”)
Ex-1025	U.S. Patent No. 5,087,246 to Smith (“Smith”)
Ex-1026	Declaration of Dr. Sylvia Hall-Ellis
Ex-1027	Patent Owner’s Prytime Medical Inc. “Leadership” web page
Ex-1028	USPTO Assignment Record for U.S. 9,131,874
Ex-1029	U.S. Patent No. 5,364,352 (“Cimino”)
Ex-1030	Annotated Excerpt from Ex-2001 (Cimino Declaration)
Ex-1031	“Distal Catheter Section” Excerpts from Ex-2001 (Cimino Declaration)

Ex-1032	Transcript of Dr. Cimino's deposition held March 20, 2025 ("Cimino Deposition")
Ex-1033	U.S. Patent No. 7,993,366 to Yassinzadeh ("Yassinzadeh")
Ex-1034	Second Declaration of Dr. Scott A. Resnick, M.D. (April 9, 2025)
Ex-1035	Definition of "Secure," Webster's New Universal Unabridged Dictionary (1996)
Ex-1036	Printout of http://www.jcvaonline.com/ (04/09/2025)
Ex-1037	Printout of http://evtoday.com/about (04/09/2025)
Ex-1038	Printout of https://journals.lww.com/jtrauma/pages/aboutthejournal.aspx (04/09/2025)
Ex-1039	Printout of https://www.jscai.org/content/aims (04/09/2025)
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LIST OF APPENDICES

Appendix E List of Materials Considered

I. Introduction

1. I am making this Declaration in support of Petitioner's Reply in the above-captioned Petition for Post Grant Review (PGR) of U.S. Patent No. 11,857,737 (the '737 Patent). I am making this declaration at the request of Front Line Medical Technologies, Inc. as an independent expert consultant in this proceeding before the United States Patent and Trademark Office and to address and respond to the arguments made in the Patent Owner's Patent Owner Response ("POR") and the declaration submitted by Dr. William W. Cimino ("Cimino Declaration") (Ex-2001) in support of the POR. I previously submitted a declaration in support of the Petition, dated May 6, 2024 (Ex-1003) ("First Declaration").

2. As stated in my First Declaration, I am being compensated for my work on this matter at a rate of \$750 per hour. My compensation is in no way contingent on the nature of my findings, the presentation of my findings in testimony, or the outcome of this proceeding. I have no other interest in this proceeding.

3. I have been asked to provide my technical review, analysis, insights, and opinions regarding the prior art references that form the basis for the grounds of rejection set forth in the PGR petition. My opinions are based on my own views and understanding of the prior art, the knowledge of a person having ordinary skill in the art ("PHOSITA"), and the patented technology.

4. Appendix E is a list of documents and other information that I have considered in forming my opinions. Since preparing my First Declaration, I have reviewed the Board's Institution Decision ("ID"), the POR, and the Cimino Declaration. I have also reviewed and considered the documents cited by Dr. Cimino in his declaration and the transcript of Dr. Cimino's deposition held March 20, 2025 ("Cimino Deposition") (Ex-1032). Should additional information become available to me that affects the conclusions or opinions herein, I may supplement or amend this declaration as appropriate.

5. All of my opinions stated in this declaration are based on my own personal knowledge and professional judgment. In forming my opinions, I have relied on my knowledge and experience in the area of Vascular and Interventional Radiology.

II. Professional Qualifications

6. My professional qualifications are listed in my First Declaration and I incorporate those qualifications by reference here. Ex-1003 ¶¶ 7–15.

7. In addition to those qualifications listed in my First Declaration, I also have extensive experience in the design and development of medical products.

8. For example, I work and have worked with a number of different medical device companies (5+) in device design and device development. Such interactions began in 2000 and continue into 2025. This work occurred at various

stages in the design process. Most interventional devices are catheter based and, as such, catheter design and development is an integral part of the device development that I have been involved with. By 2015, I had spent 15 years consulting with various companies on numerous different devices. While this was not a full-time endeavor, the time I spent consulting was substantial and included nights, weekends, academic, and otherwise unassigned time. While Dr. Cimino suggests six years of medical device design and development experience to qualify as a PHOSITA, I believe my aggregated experience between 2000-2015 far exceeds these suggested qualifications.

9. Typical interactions include initial meetings with company leadership to identify areas of unmet need in the interventional medical device space. These discussions will sometimes lead to ideas for new devices, or improvement on existing devices. If so, follow up meetings with engineering/design teams will occur to design/plan/improve the device. Prototypes will be constructed by the engineering team as applicable and as appropriate for review/evaluation. If a decision is made to move forward with device creation, then I am typically involved at various points in the process to a greater or lesser degree depending on my level of input.

10. Not all of the steps noted above involve my (or an MD's) participation in every case, but the above is typical and would have been typical in the March 2015 time frame. My (or any MD's) involvement in the development of a new or improved

medical device can and does begin at any point in the design and development process.

11. I've been told on numerous occasions by both leadership and engineering teams (1) that having actual user (MD) input is invaluable in the process, and (2) that without actual user (MD) input, such leadership and engineering teams feel as if they're operating in a void, without a point of reference. I note that my experience is consistent with Dr. Cimino's deposition testimony, where he confirmed that as early as 2010 and continuing to today, "MDs are often and frequently and even recommended to be part of a design, development, and commercialization process and depending on the product or the direction ... the intent and the regulatory pathway, MDs are often frequently involved in various aspects as it moves through the process. Especially with regard to the use and function in patients." Ex-1032, Cimino Tr. at 58:13–20.

12. The specific types of engineers I've worked with varies broadly and is dependent upon the device in question. Certainly biomedical, material sciences, and plastics engineers would be typical but others may be included as well (thermal, mechanical, etc.). Many of these engineers were Ph.D. level educated and the vast majority of them would fulfill Dr. Cimino's definition of a PHOSITA. It is my opinion, however, that an important aspect of the experience needed to qualify as a PHOSITA includes interaction and consultation with MDs in the relevant field

because the MDs are the ones who actually perform the interventional procedures, who can test the new medical devices, and who are ultimately responsible for the safety of the patients on whom the medical devices are used.

13. Furthermore, I have personal device design experience, independent of that noted above. In particular, I designed a catheter-based medical device, had prototypes built, and filed a provisional patent for the same.

III. Summary of Opinions

14. For the reasons discussed at length in my First Declaration, it is my opinion that there is nothing inventive about claims 1-10 of the '737 patent. As detailed below, it remains my opinion that the prior art and the PHOSITA's knowledge render claims 1-10 of the '737 patent obvious. Nothing in the POR or the Cimino Declaration changes my opinion.

IV. Legal Principles

15. In my First Declaration, I set forth the applicable principles of patent law that counsel provided to me, which I incorporate by reference here. Ex-1003 ¶¶ 16–17, 20–26. I have continued to apply those principles in providing my opinions in this Reply Declaration.

V. Person Having Ordinary Skill in the Art

16. The POR and Dr. Cimino dispute my definition of a PHOSITA. I respond in the following paragraphs.

17. As explained in my First Declaration, a PHOSITA at the relevant time (March 2015) would have had a medical degree and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices.

18. I explained in my First Declaration that *a busy interventionalist* could conceivably acquire an adequate level of experience having 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. The POR and Dr. Cimino take my First Declaration (and my deposition testimony) out of context to argue that a PHOSITA must have a minimum of ten years of post-graduate experience. That argument mischaracterizes my opinion in which I provided the *busy interventionalist* as an example of an MD having sufficient experience with interventional procedures. By giving that example, I did not intend to exclude other MDs with sufficient experience. The specific point to be made is that an MD PHOSITA must accrue sufficient catheter-based procedural experience.

19. Dr. Cimino proposed the following definition of a PHOSITA:

“(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.”

Ex-2001 ¶ 25.

20. I have considered Dr. Cimino's proposed definition of a PHOSITA and the evidence on which he relies in support of that opinion. While I disagree with various aspects of Dr. Cimino's definition (which I discuss below), having considered the new evidence submitted with the POR, I accept for purposes of this proceeding that individuals who did not have a medical degree (“MD”) in March 2015 may qualify as a PHOSITA related to the '737 patent. However, I believe that Dr. Cimino's definition leaves out an important aspect of a non-MD PHOSITA qualification. Specifically, it is my opinion that the non-MD individuals in Dr. Cimino's definition should have sufficient experience in catheter design and development *which should include consulting or working with MDs who have experience with endovascular interventional procedures*. My opinion is based on my experience in the field and my understanding that MDs are integral to the design and

development of any new medical device, as explained below. Indeed, expressly omitting participation by MDs from the PHOSITA definition is inconsistent with real world medical device development and Dr. Cimino's own statements comport with this reality. Dr. Cimino testified in his deposition that "MDs are often and frequently and even recommended to be part of a design, development, and commercialization process ... MDs are often frequently involved in various aspects as it moves through the process [of the design and development of a medical device]." Ex-1032, Cimino Tr. at 58:13–20.

21. The POR refers to my deposition testimony where I confirmed that, "in [my] opinion, a biomedical engineer could never be one of ordinary skill in the art for the '737 patent?" Ex-2002 at 29:4–30:4. I note that discussion was in the context of paragraph 18 of my First Declaration, which defined the PHOSITA as requiring a medical degree. It remains my opinion that a biomedical engineer, without more, would never qualify as a PHOSITA. Dr. Cimino appears to agree with me because his definition of a PHOSITA requires additional experience beyond obtaining a degree in biomedical engineering. Ex-2001 ¶ 25.

22. To be clear, I maintain my opinion that among those qualified as a PHOSITA would be a person with an MD and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices. Thus, I maintain

and stand by the opinions in my First Declaration, and those opinions are unaffected by the fact that non-MDs may qualify as a PHOSITA with the right amount of relevant experience, specifically experience consulting or working with MDs who have experience with endovascular interventional procedures.

23. Dr. Cimino disagrees with aspects of my definition of a PHOSITA. First, Dr. Cimino's definition of a PHOSITA does not expressly include individuals with a medical degree. Second, Dr. Cimino's definition of a PHOSITA is exclusively limited to someone that has designed and developed relevant medical devices (i.e., catheters or laparoscopic/endoscopic medical device instrumentation). I disagree with both aspects of Dr. Cimino's definition, as explained below.

24. As explained in my First Declaration, I understand that factors relevant to determining the level of ordinary skill in the art include the educational level of workers in the field, the sophistication of the technology, and the nature of common problems and solutions within the industry at the time of the alleged invention. The facts in view of the above factors support (1) my original definition of a PHOSITA provided in my First Declaration and (2) the expanded PHOSITA definition that I discuss in this section of this Second Declaration.

A. MDs are PHOSITAs

25. The POR and Dr. Cimino propose a PHOSITA definition that does not expressly include individuals with a medical degree. I disagree.

26. MDs are integral to the design and development of any new medical device. As active users of medical devices in a clinical setting, MDs (as opposed to non-clinician engineers) are the individuals best able not only to identify performance characteristic deficiencies of existing devices for improvement but also to identify gaps in existing device technology as a means of realizing potential new device development opportunities. Thus, expressly omitting MDs (or any input from MDs) from the PHOSITA definition is inconsistent with real world medical device development.

27. Additionally, my review of the prior art solutions to problems in the field and the educational level of active workers in the field confirms my opinion that a PHOSITA would include an individual having a medical degree and sufficient experience with interventional procedures. In particular, many of the relevant non-patent prior art references are authored and edited by MDs and included in publications that are directed to MDs.

28. For example, the Chengod prior art article is found in the Journal of Cardiothoracic and Vascular Anesthesia (Ex-1005). According to its website, the Journal of Cardiothoracic and Vascular Anesthesia “is primarily aimed at anesthesiologists,” i.e., MDs. *See* Ex-1036 (<http://www.jcvaonline.com/>). The Journal’s Editor in Chief and all Associate Editors and Sections Editors are MDs. Ex-1005 at PDF page 4. The author, Suresh Chengod, is also an MD. Ex-1005 at 635.

29. In another example, the Deaton prior art article is found in Endovascular Today. Ex-1008. According to its website, Endovascular Today “is a publication dedicated to bringing you comprehensive coverage of all the latest technology, techniques, and developments in the endovascular field. Our Editorial Advisory Board is composed of the top endovascular specialists, including interventional cardiologists, interventional radiologists, vascular surgeons, neurointerventionists, and vascular medicine practitioners, and our publication is read by an audience of more than 22,000 members of the endovascular community.” *See* Ex-1037 (<http://evtoday.com/about>). Notably, the Editorial Advisory Board is expressly composed of MDs, and I understand based on my experience that the target “endovascular community” would also be composed of MDs. The author, David H. Deaton, is also an MD. Ex-1008 at 32.

30. In yet another example, the Scott prior art article is found in the Journal of Trauma and Acute Care Surgery. Ex-1010. This Journal is sponsored by the American Association for the Surgery of Trauma (*see* Ex-1038 (<https://journals.lww.com/jtrauma/pages/aboutthejournal.aspx>), which is made up almost entirely of MDs (Ex-1010 at PDF page 6). Five of the seven authors, including the first-listed author, Daniel J. Scott, are MDs. Ex-1010 at 122.

31. In another example, the Gu prior art article is found in Catheterization and Cardiovascular Interventions, the Official Journal of the Society for Cardiac

Angiography & Interventions (JSCAI). Ex-1014. According to its website, the “JSCAI is a highly credible and well-balanced reference that highlights practical techniques and pathways of care and delivers high-impact scientific contributions drawn from clinicians and colleagues in interventional cardiology.” *See* Ex-1039 (<https://www.jscai.org/content/aims>). The vast majority of JSCAI’s editorial board are MDs. *See* Ex-1040 (<https://scai.org/publications/jscai-editorial-board>). Three of the seven authors of the Gu article, including the first-listed author, Xiaoping Gu, are MDs. Ex-1014 at 51.

32. In another example, the Owens prior art reference, Handbook of Endovascular Peripheral Interventions is edited by Michael S. Conte, MD, and is directed to medical practitioners (MDs): “I anticipate [the book] will be used widely by students, residents, and fellows – as well as surgeons and interventionalists who are expanding their practice in these areas.” Ex-1015 at vi (PDF page 7).

33. The wealth of relevant prior art references in the field of the ’737 patent that are authored and edited by MDs and directed to MD audiences confirms my opinion that a PHOSITA would include an individual having a medical degree and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices.

B. Sufficient Experience with Interventional Procedures Would Have Provided a Person with Ordinary Skill in the Art

34. As noted above, Dr. Cimino opines that in order to qualify as a person of ordinary skill in the art, an individual would have needed prior experience designing or developing relevant medical devices. Thus, Dr. Cimino's express definition of a PHOSITA suggests that experience *performing* interventional procedures would not have provided a person with ordinary skill. Ex-2001 ¶¶ 25–26. I disagree.

35. As a preliminary matter, each of the opinions I offered in my First Declaration and in this Reply Declaration is based on my experience, which I have detailed at length. More specifically, I am dual board certified in both Diagnostic Radiology and in Vascular and Interventional Radiology, and have myself performed vascular-specific interventional procedures for at least the last twenty-seven years. I routinely used and use balloon catheters like the one described in the '737 patent as part of my clinical practice. An interventional radiologist like myself is the type of clinician who would use the device claimed in the '737 patent and would be responsible for its safe and effective use. As the doctor responsible for the safety of my patients, I was required to and did understand the operation of devices I was using in great detail, including the operation, function, and construction of balloon catheters used to occlude the aorta and other vascular cavities. I gained this understanding in multiple ways, including my medical training and obtaining my MD, and years of experience using and testing devices. I have routinely taught other physicians how to

use balloon catheters throughout my career, including prior to 2015. I consider myself to be an expert on the anatomy of the vascular system and interventional procedures related to the vascular system. And my co-appointment as a full professor in the department of surgery in the division of vascular surgery speaks to this expertise. Based on my experience, including before 2015, I also consider myself to be an expert on catheter devices that are used in the vascular system.

36. Dr. Cimino has not presented in his declaration any disputed issue that is outside the realm of my expertise and experience (or that of a person in 2015 with an MD and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices).

37. I understand that Dr. Cimino addresses the level of ordinary skill in the art from the perspective of an engineer, as that is his background. Although Dr. Cimino does not expressly include individuals with MDs in his definition of a PHOSITA, I note that he appears to agree that an individual with an MD can be a PHOSITA. Specifically, Dr. Cimino states at paragraph 25 of the Cimino Declaration that his PHOSITA definition “does not preclude an individual with a medical degree and sufficient experience with interventional procedures from qualifying as a PHOSITA.” I understand Dr. Cimino’s opinion to be a person with an MD would need at least six years of experience in catheter design and development to qualify as

a PHOSITA—regardless of how much experience that person had performing endovascular procedures using both angioplasty balloons and occlusion devices. Ex-1032, Cimino Tr. at 140:13–141:16.

38. I agree with Dr. Cimino that an individual with an MD and six years of experience designing and developing catheters would qualify as a PHOSITA. Based on my experience both in performing interventional endovascular procedures and in medical device design and development, an individual with an MD and six years of experience designing and developing catheters in 2015 would likely also satisfy my definition of a PHOSITA which requires “sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices.” In other words, it would be the uncommon case for an individual to obtain an MD and subsequently spend six years designing and developing catheter devices for interventional procedures without having actually practiced in the field and obtained sufficient experience using balloon catheters and occlusion devices (i.e., performing interventional procedures). For example, the medical device companies I work with hire me to consult on design/development projects because of my clinical experience in the relevant field. It would be atypical (now and in 2015) for those companies to engage an MD to help design and develop a product if that MD does not have sufficient clinical experience in the relevant field. This makes sense because medical device companies are looking

to consult with experts in the fields, not MDs who are fresh out of medical school or residency training with very little relevant clinical experience.

39. Put differently, it is my opinion that, when discussing individuals with a medical degree, having experience designing and developing catheter devices is not necessary to be a PHOSITA for the '737 patent as long as the individual has sufficient experience with interventional procedures, i.e., extensive use of both angioplasty balloons and occlusion devices in endovascular procedures.

40. In my opinion, the problem and alleged solution of the '737 patent, as well as the challenged claims supports my determination that extensive use of both angioplasty balloons and occlusion devices would qualify a person in March 2015 as a PHOSITA, and that design and development experience would not have been required. The alleged problem identified by the '737 patent relates to reducing and ameliorating both hypertension and hypotension during or after a vascular occlusion procedure. Ex-1001, '737 patent, 2:1–3. A person with an MD and extensive experience using both angioplasty balloons and occlusion devices in 2015 would understand the risk and effects of hypertension during a vascular occlusion procedure and the risk and effects of hypotension after a vascular occlusion procedure because these individuals would have had personal experience with such blood pressure abnormalities occurring during procedures they performed.

41. Additionally, the '737 patent claims use general terms and do not identify any non-generic design details or tie any design features to the alleged problem. Based on my personal experience and my observation of other MDs in the March 2015 time frame, it is my opinion that an individual who had extensively used both angioplasty balloons and occlusion devices for performing interventional procedures would understand those devices include generic features such as the claimed “proximal hub,” “flow valve,” “proximal catheter section,” “distal catheter section,” “atraumatic tip,” “occlusion balloon,” “at least one length marking,” “lumen,” and “solid wire”—and that these features could be found in catheters having a greatest outer diameter of less than 6 Fr in an uninflated configuration. That individual would also understand catheters include the other generic features identified in the '737 patent's dependent claims (e.g., “asymmetrical” balloon, various other shaped balloons, “solid wire” constructed of metal or stainless steel, proximal and distal radio opaque markers, and syringe). Consequently, that individual would have the skill necessary to understand the operation and clinical effects of the device found in claims 1-10 of the '737 patent based solely on extensive use of both angioplasty balloons and occlusion devices that were available prior to the '737 patent.

42. Instead of relying solely on design or development experience, clinicians like myself have learned to safely and effectively use a wide range of angioplasty balloons and occlusion devices—including those involving the features found in the

'737 patent claims—through hands-on clinical experience, reviewing instructions for use, attending educational programs and seminars, and studying the scientific literature. By 2015, vascular occlusion using balloon catheters, including applications in the aorta, had been in use for many years and was frequently covered in the literature, educational courses, and lectures. Scott (Ex-1010) and Eliason (Ex-1009) are two examples of this.

43. Accordingly, it is my opinion that an individual with an MD and extensive experience using both angioplasty balloons and occlusion devices would have ordinary skill for considering the problems and solutions relevant to the '737 patent. In view of my discussion above, including the experience that clinicians like myself had, the problems and solutions in the art, and the lack of sophistication of the '737 patent claims, I disagree with Dr. Cimino that only device design and development experience would provide a person with ordinary skill.

C. Dr. Cimino's PHOSITA Definition Does Not Change My Opinions from My First Declaration

44. Counsel informs me that the POR argues that my First Declaration should be disregarded because my opinions were provided based on my PHOSITA definition, which the POR argues is incorrect. As discussed above, I disagree that my First Declaration's PHOSITA definition is incorrect.

45. Counsel has asked me to evaluate whether any of my opinions in my First Declaration would change if I assume Dr. Cimino's definition of a PHOSITA.

Having done so, I can confirm that Dr. Cimino's PHOSITA definition does not change my opinions from my first declaration.

46. By March 2015, I had been in practice for 17 years and had worked with a number of different medical device companies in the design and development of various medical devices, including devices for vascular interventional procedures (which are catheter based). As discussed above, as part of my experience working with medical device companies, I worked with engineers who would qualify as a PHOSITA under Dr. Cimino's definition. For example, I've worked with individuals including the head of engineering, the head of R&D, the CTO, the device lead engineer, and the device team engineers. Thus, I understand the level of skill those individuals would have based on my experience and my observations while working with them at the relevant time.

47. It is my opinion that Dr. Cimino's PHOSITA would have the same general knowledge as I discuss at ¶¶ 34–67 of my First Declaration, including knowledge of balloon catheter, including occlusion balloon catheters (¶¶ 34–38); use of stainless steel in intravascular catheters (¶¶ 39–43); use of radiopaque markers in balloon catheters (¶¶ 44–48); use of asymmetrical balloon shapes in balloon catheters (¶¶ 49–55); and use of other compliant balloon shapes in balloon catheters (¶¶ 56–67).

48. It is also my opinion that Dr. Cimino's PHOSITA would have found the claims of the '737 patent to be obvious for the same reasons I discuss in my First

Declaration (¶¶ 68–208). An individual who meets Dr. Cimino’s PHOSITA definition would have relevant experience and would understand catheters include generic features such as the claimed “proximal hub,” “flow valve,” “proximal catheter section,” “distal catheter section,” “atraumatic tip,” “occlusion balloon,” “at least one length marking,” “lumen,” “solid wire”—and that these features could be found in catheters having a greatest outer diameter of less than 6 Fr in an uninflated configuration. That PHOSITA would also understand catheters include the other generic features identified in the ’737 patent’s dependent claims (e.g., “asymmetrical” balloon, various other shaped balloons, “solid wire” constructed of metal or stainless steel, proximal and distal radio opaque markers, and syringe). Because these claim terms are general, it is my opinion that Dr. Cimino’s PHOSITA would understand them to have the same ordinary and customary meaning as the PHOSITA I considered in my First Declaration, i.e., as explained next (“Claim Construction”).

VI. Claim Construction

49. **“Proximal hub”**: I understand the POR and Dr. Cimino offer a construction of the claim phrase “proximal hub” as “an element (or elements) used to physically connect an inflation device to the inflation lumen of the catheter.” The POR and Dr. Cimino argue that I gave this definition in my First Declaration. I disagree with that characterization of my First Declaration in which I made clear that, with the exception of the “distal” and “proximal” terms that were defined in the ’737

patent specification, my opinions relied on the ordinary and customary meaning of terms as understood by a PHOSITA. In my opinion, while a “proximal hub” may include “an element (or elements) used to physically connect an inflation device to the inflation lumen of the catheter,” the term “proximal hub” is not limited to this singular functional element. I disagree that a PHOSITA would understand the ordinary meaning of the term “proximal hub” to be so limiting as it is well understood that other functional elements may be included within the proximal hub.

50. For example, the '737 patent describes embodiments that are not limited to “physically connecting an inflation device to the inflation lumen of the catheter.” One such embodiment is described with respect to Figure 6, which includes proximal hub 190 that has two fluid pathways 192 and 194. The '737 patent specification explains that “[t]he first fluid pathway 192 of the proximal hub 190 may be connected to an external pressure sensor...” Ex-1001, '737 patent at 26:8–10.

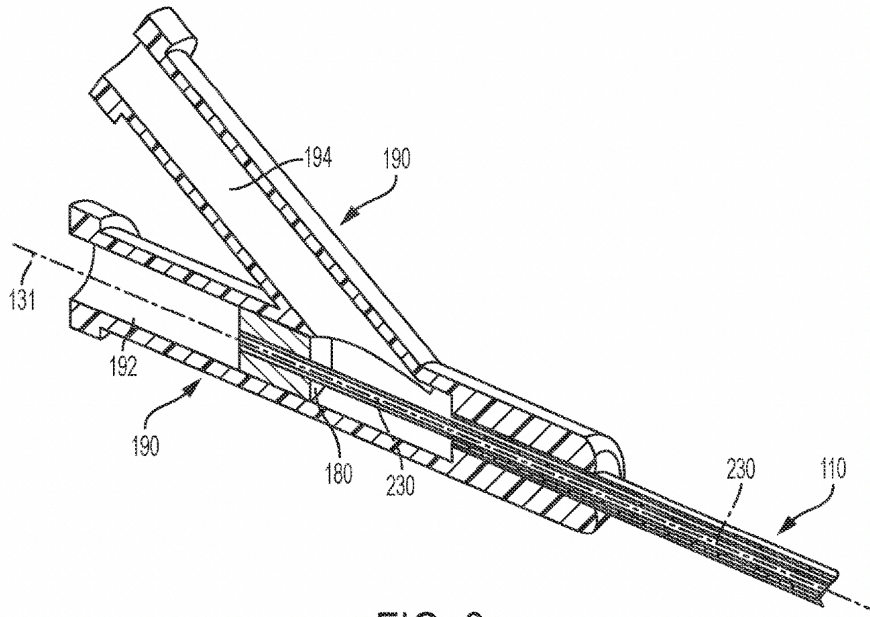


FIG. 6

51. This example from the specification confirms that the ordinary meaning of “proximal hub” is not limited to “an element (or elements) used to physically connect an inflation device to the inflation lumen of the catheter,” but that a proximal hub may include other elements configured for other functions (e.g., pressure sensing).

52. Thus, it is my opinion that a PHOSITA understands the phrase “proximal hub” to have its ordinary meaning, which would include, but is not limited to, an element (or elements), oriented away from the body, for connecting other catheter elements, including for connecting an inflation device to an inflation lumen. While my definition differs from Dr. Cimino’s definition, it is my opinion that the ’737 patent claims are obvious in view of either definition, as discussed below.

53. **“Flow valve configured to selectively fluidly communicate the proximal hub with an inflation device”**: I understand the POR and Dr. Cimino offer a construction of this claim phrase as “a manually or automatically actuatable valve that is opened and closed to permit and block fluid flow, respectively, between the proximal hub and the inflation device.” It is my opinion that a PHOSITA would understand this claim phrase to have its unambiguous plain meaning, and I disagree with the construction offered by the POR and Dr. Cimino as it appears to change the scope of the claim phrase by requiring that the valve “is opened and closed” (i.e., performing the opening and closing operations) as opposed to a valve that is merely “configured to” select whether fluid communication of the proximal hub with the inflation device should occur.

54. In addition, the POR and Dr. Cimino add the word “between” into the construction and later argue that in order “[t]o ‘selectively fluidly communicate the proximal hub with an inflation device,’ the flow valve must be located *between* the proximal hub and the inflation device.” POR at 41; Ex-2001 ¶ 61. I disagree. A PHOSITA would not understand this claim phrase to require the specific structural relationship of a flow valve being located *between* the hub and the inflation device. Rather, the plain meaning of the claim phrase “a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” is unambiguous and simply requires a flow valve that is configured to select whether to fluidly

communicate the proximal hub with the inflation device. Ex-1001, '737 patent at 66:25–26 (claim 1). As explained below, this claim language encompasses configurations where the flow valve is a sub-element of the hub.

55. The Board’s Institution Decision preliminarily interpreted “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” as a “valve that controls the flow of fluids to a proximal hub during any part of a procedure and that may also, simultaneously or at some different time, include a wire within the proximal hub.” Institution Decision, Paper 7 at 17. In general, I agree that the plain meaning of “a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” would encompass a “valve that controls the flow of fluids to a proximal hub during any part of a procedure and that may also, simultaneously or at some different time, include a wire within the proximal hub.” I understand the Board’s preliminary interpretation would not require active “control” of the flow of fluids (i.e., a method step) since the Board rejected “Patent Owner’s interpretation [because it] imposes a method step into a system claim.” Institution Decision, Paper 7 at 16. Rather, under the Board’s interpretation, a PHOSITA would understand that the valve need only *be configured to control* the flow of fluids to a proximal hub during any part of a procedure.

56. While my ordinary meaning definition of “flow valve configured to selectively fluidly communicate the proximal hub with an inflation device” differs

from Dr. Cimino's definition, it is my opinion that the '737 patent claims are obvious in view of either definition as well as the Board's definition, as discussed below.

57. **"Flow valve" as part of the "proximal hub":** I understand the POR and Dr. Cimino construe the phrase "flow valve configured to selectively fluidly communicate the proximal hub with an inflation device" as requiring the flow valve "to be located between the proximal hub and the inflation device." It is my opinion that a PHOSITA would understand this claim phrase to have its unambiguous plain meaning, and I disagree with the construction offered by the POR and Dr. Cimino as it appears to change the scope of the claim phrase by adding a structural limitation that the flow valve is "located between" the proximal hub and the inflation device such that the "flow valve" cannot be a sub-element portion of the "proximal hub."

58. The specification supports my opinion that a PHOSITA would understand that the flow valve can be a sub-element portion of the "proximal hub." For example, Figure 42A in the '737 patent depicts a catheter without an inflation device. A PHOSITA would understand that an inflation device would be connected to either the hub with the side arm port or the hub with the stopcock (flow) valve:

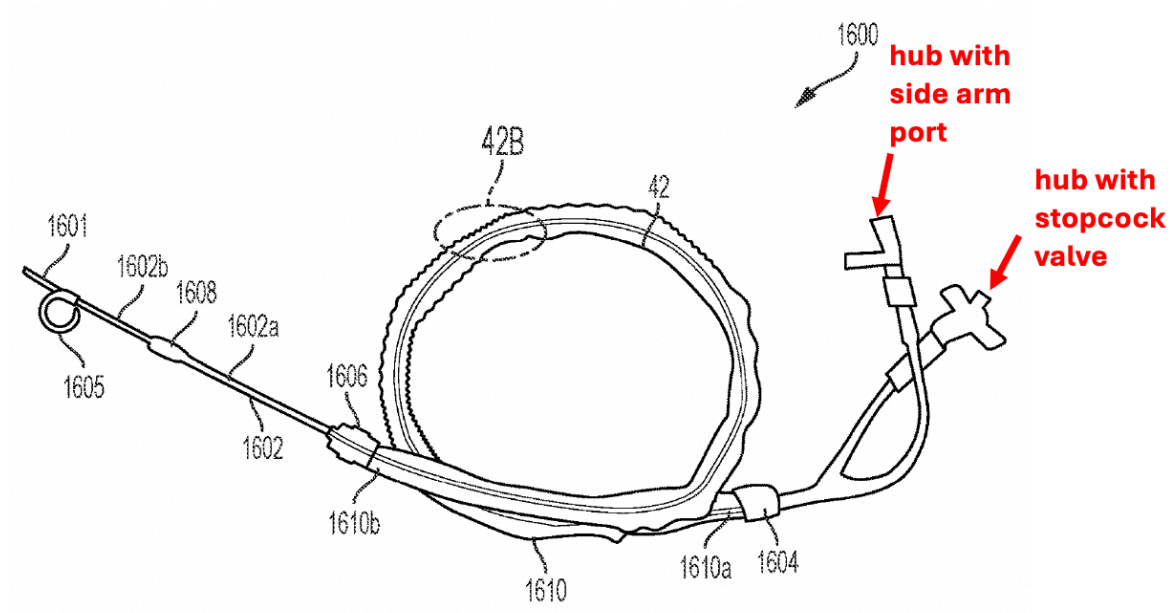


FIG. 42A

Ex-1001, Fig. 42A (annotated). I note that Dr. Cimino agrees that an inflation device would be connected at these locations. Ex-1032 at 78:9–22 (discussing Ex-1030, below).

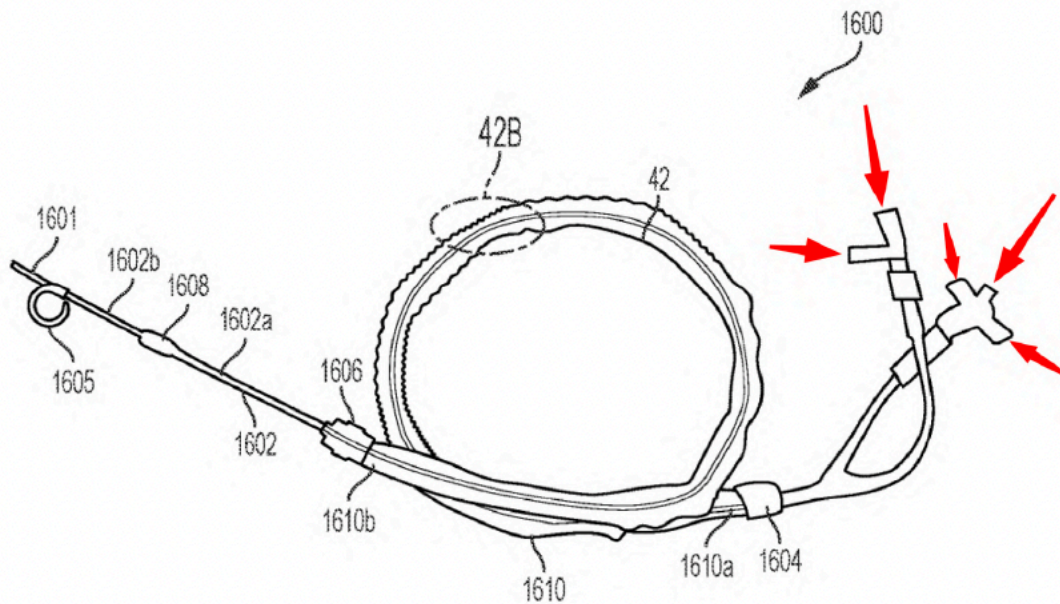


FIG. 42A

Ex-1030 (annotations original as provided by Dr. Cimino in his deposition).

59. Although the proximal elements of the Figure 42A catheter are not labelled, it is my opinion that a PHOSITA understands the hand-drawn proximal elements to be a hub with a side arm port and a hub with a stopcock valve. Accordingly, Figure 42A also confirms that a “flow valve” can be a sub-element portion of the “proximal hub” because the hub with the stopcock valve would be used to physically connect an inflation device to the inflation lumen of the catheter.

60. Additionally, Figure 42A shows “preferred system 1600 [that] includes proximal and distal hub members 1604, 1606 that may be constructed and configured as any type of hemostatic valve that permits the catheter 1602 to pass through the valve, such as, for example, without limitation, a Tuohy Borst valve.” Ex-1001, ’737

patent at 60:8–12. According to this passage, proximal hub member 1604 is a hemostatic valve.

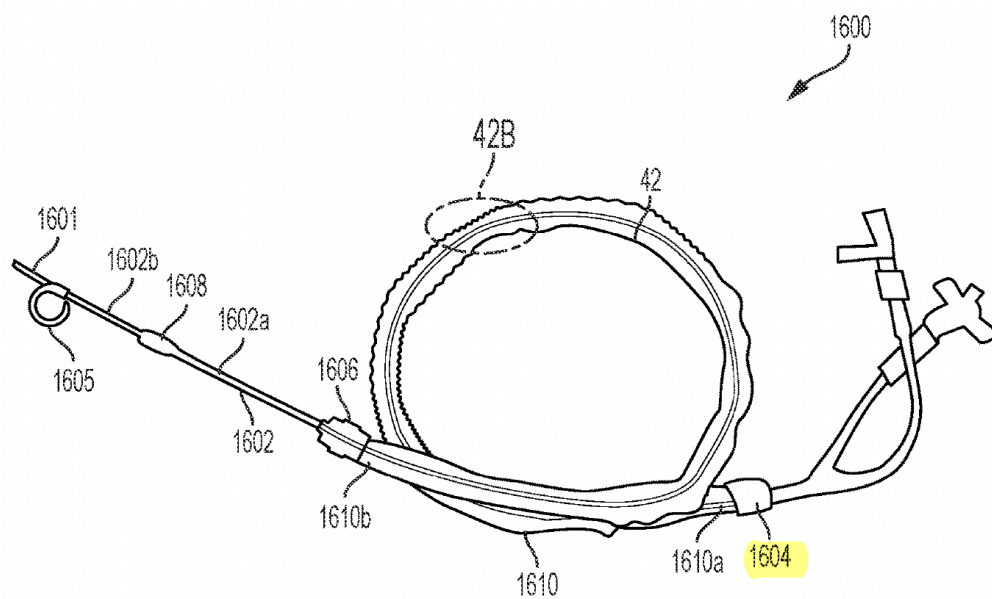


FIG. 42A

61. I understand Dr. Cimino argues that hub 1604 in Figure 42A is unrelated to an element or elements used to physically connect an inflation device to the inflation lumen of a catheter and that this embodiment is not relevant for interpreting the “proximal hub” or what components a proximal hub may or may not include, such as a “flow valve.” Ex-2001 ¶ 40. I disagree. This embodiment, although discussing a different type of hub element, nevertheless confirms that hubs can include valves as part of their construction. Thus, it is my opinion that a PHOSITA would understand, based on this disclosure in the ’737 patent, that the “proximal hub” of claim 1 could also include valves as part of its construction.

62. In another example, the '737 patent specification discloses “the proximal hub includes a pressure relief port ... and a pressure relief member disposed across or in the pressure relief port... The pressure relief member is configured to open or fail (e.g., open, rupture, tear, burst or leak), at a predetermined pressure...” ’737 patent at 21:27–32. The ’737 patent specification discloses that “[t]he pressure relief member may be ... a pop-off valve or other similar biased valve.” ’737 patent at 21:9–11. Thus, a PHOSITA understands from the specification that the proximal hub may include as a sub-element, a valve such as pop-off valve or other similar biased valve. Although a pop-off differs in function from the claimed flow valve, this disclosure is yet another example showing that hubs can include valves as part of their construction.

63. In summary, a PHOSITA would understand the claimed “proximal hub” can include a flow valve as a sub-element because this configuration is disclosed in the Figure 42A embodiment and because the ’737 patent specification includes at least two other examples of hubs that include valves as part of their construction.

64. **“A distal catheter section”:** I understand the POR and Dr. Cimino have offered various constructions of this claim phrase, including “a distal portion of a catheter,” “a portion of the catheter shaft itself, and not a portion of other components of the system,” “a distal portion of the shaft of the device,” and “a distal portion of a catheter shaft.” I disagree that a PHOSITA would understand “a distal catheter

section” to have any of these meanings which introduce the new terms, “shaft” and “catheter shaft,” into the claim.

65. The claim term at issue in claim 1 is “a distal catheter section distally terminating with an atraumatic tip.” A PHOSITA reading this claim language understands the distal catheter section is a portion of the claimed catheter that includes and terminates with the atraumatic tip. Claim 1 also recites other language that describes the “distal catheter section” in relation to other portions of the claimed device, including: “an intervening occlusion balloon connecting the proximal catheter section with the *distal catheter section*” and “a solid wire ... extending within the proximal catheter section, the occlusion balloon and into the *distal catheter section*.” Thus, a PHOSITA reading claim 1 would understand that “a distal catheter section” is simply the distal portion of the claimed catheter, i.e., the portion that includes the elements that are located distal of the intervening occlusion balloon. I note this plain meaning interpretation was adopted by the Board in its Institution Decision. Paper 7 at 18.

66. Dr. Cimino appears to equate the claimed “distal catheter section” with the “distal catheter member” disclosed in the ’737 patent specification. I disagree. As the Board noted in its Institution Decision, the word “section” means “one of the parts that something is divided into.” The ’737 patent specification confirms a PHOSITA would have the same understanding of the word “section.” As examples, the

description of Figure 5 refers to a distal “section” of tip 150, and the description of Figure 10 refers to a flattened distal “section” 454 of the atraumatic tip 450. In these passages, the referred-to “section” is merely one of the parts that the tip 150/450 is divided into.

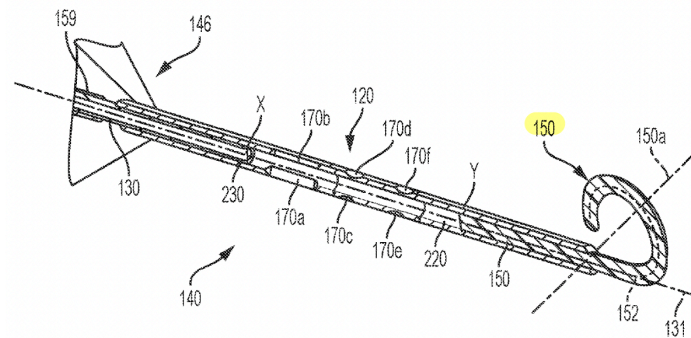


FIG. 5

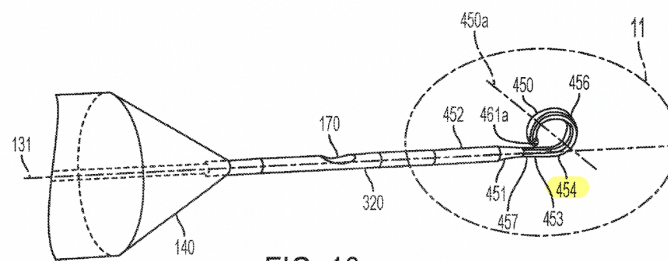


FIG. 10

67. When Dr. Cimino was questioned about his definition of “a distal catheter section” during his deposition, he appears to suggest that the distal catheter section cannot include a wire. Ex-1032 at 157:13–159:11; Ex-2001 ¶¶ 108–112. I disagree. The ’737 patent specification discloses that “a third catheter member 1320 of the fourth preferred occlusion catheter system 1300 extends distally relative to the occlusion member 1304 and terminates in an atraumatic tip 1306 or forms a proximal shaft or portion of the atraumatic tip 1306.” ’737 patent at 51:29–33. Notably, like the

claim language at issue, this third catheter member terminates in an atraumatic tip. It is also distal to the occlusion balloon (1304). The specification goes on to explain that “the third catheter member 1302 may ... include a separate stiffening member, *such as a nitinol wire* or braided shaft, to have sufficient pushability to have the appropriate amount of column strength.” Ex-1001, ’737 patent at 52:28–32 (emphasis added). In addition, the specification indicates that “atraumatic tip 150 may be made of an elastic, shape memory and/or superelastic material, *such as a metal* or polymer.” Ex-1001, ’737 patent, 23:66–24:1 (emphasis added). Thus, a PHOSITA understands from the embodiment that the “distal catheter section” can include a wire. For example, nitinol wire is a metal known for its shape memory that is commonly used in catheters now and in 2015.

68. **“A solid wire, secured at a proximal-most end thereof within the proximal hub”**: I understand the POR and Dr. Cimino offer a construction of this claim phrase as “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.” It is my opinion that a PHOSITA would understand this claim phrase to have its unambiguous plain meaning, and I disagree with the construction offered by the POR and Dr. Cimino as it appears to change the scope of the claim phrase by (1) adding a negative limitation “without an internal lumen” and (2) substituting “secured” with “fixedly coupled to.”

69. A PHOSITA would understand the phrase “a solid wire,” which is an unambiguous term. Thus, in my opinion it is unnecessary to further define “solid wire” as “a wire without an internal lumen.” Of course, this distinction does not appear to be germane to Dr. Cimino’s opinions. This makes sense because neither the Petition nor my First Declaration rely on any wires having a lumen within them to satisfy the “solid wire” limitation of claim 1.

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

71. In my opinion, a PHOSITA reading the ’737 patent claims and specification would understand “secured” consistent with its ordinary dictionary meaning and would not understand “secured” to mean “fixedly coupled to.” For example, the specification draws a distinction between being “secured” and being “fixedly coupled to”:

solid wire 530 is ***fixedly coupled to*** the proximal hub 590 at a proximal bonding site, ***preferably using an adhesive*** 580, to bond an inner wall surface of the proximal hub 590 to an outer wall surface of the solid stiffener member 530. The amount of adhesive 580 used is preferably sufficient to ***fixedly couple*** the solid stiffener member 530 to the proximal hub 590. As shown in FIG. 17, the adhesive 580 may fill the

entire portion 592 of the proximal hub 590 that holds the stiffener member 530. ***The proximal end of the stiffener member 530 is not limited to being adhesively bonded to the proximal hub 590 and may be otherwise fastened, secured or fixed to*** the proximal hub 590, as long as the stiffener member 530 is substantially secured to the proximal hub 590 such that the stiffener member 530 provides stiffness for the balloon catheter system 500, the stiffener member 530 is substantially secured relative to the inflation catheter member 510 and the occlusion balloon 540, the assembly is able to withstand the normal operating conditions of the catheter system 500 and securement results in a structure able to perform the preferred functions of the catheter system 500, as is described herein.

Ex-1001, '737 patent at 35:4–27 (emphasis added).

72. A PHOSITA reading this passage in the '737 patent specification understands that “fixedly coupled to” is described by example of bonding with an adhesive. A PHOSITA reading this passage also understands that being “fastened,” “secured,” or “fixed to” are described as alternatives to being “fixedly coupled to” This passage makes clear that, in the '737 patent, “secured” is not the same as “fixedly coupled to.”

73. While my definition differs from Dr. Cimino’s definition, it is my opinion that the '737 patent claims are obvious in view of either definition, as discussed below.

VII. RESPONSE TO SPECIFIC ALLEGATIONS REGARDING MY PRIOR TESTIMONY

74. The POR and Dr. Cimino make a number of allegations regarding my prior testimony in this proceeding, including testimony in my First Declaration and during my deposition. I now respond to some of those allegations.

75. **First**, the POR asserts that I “incorrectly emphasize experience *using* angioplasty balloons and occlusion devices *in clinical settings* over experience *designing occlusion catheter systems* for occlusion of the aorta, which is what the ’737 patent addresses.” POR at 11. I disagree that the patent is limited to addressing only the design of occlusion catheter systems. The ’737 patent discusses the clinical use of balloon catheter devices (e.g., Ex-1001, ’737 patent at 19:65–20:5 (“...may be used clinically...”)) as well as various aspects of balloon catheter design. Thus, contrary to the POR, a PHOSITA would not understand the ’737 patent to be limited to addressing only the design of occlusion catheter systems.

76. **Second**, the POR asserts that I admitted to having “no experience in catheter system design and development.” POR at 15. I disagree with this characterization of my testimony. At 14:5–15:16 of my deposition testimony, I testified that I did not have any catheter patents, but that I did have experience modifying off-the-shelf catheter products for specific uses and sometimes to improve the device function. At 23:5–24:2 of my deposition testimony, I testified that when I used an angioplasty-intended catheter for a REBOA-type procedure, I did not make

any modifications to the catheter in that instance. These statements are far from an “admission” that I have no experience in catheter system design and development. In fact, as I explained above, over the past 20+ years I have worked with a number of medical device companies in design and development of interventional devices. Most interventional devices are catheter based and, as such, catheter design and development is an integral part of the device development that I have been involved with. Additionally, and as noted previously, I have personal catheter/interventional device design experience with prototypes creation and provisional patenting.

77. **Third**, the POR asserts that I admitted (1) that I lack “knowledge of the intricacies” of the interior construction of catheters that I have used (POR at 15), and (2) that “users are generally unaware of components not visible from the catheter exterior” (POR at 11). Again, I disagree with this characterization of my testimony. At 39:16–40:15 of my deposition testimony, I testified that I was not aware whether the Fogarty catheters I used in the past included a metal coil inside of it, but that I was aware of other elements of those devices. At 55:21–57:2 of my deposition testimony, I again testified that I was not aware if the smaller Fogarty catheters (less than 6 Fr) referenced in my First Declaration included a metal coil spring core. I note that this later testimony had nothing to do with specific catheters that I have used, but rather the smaller Fogarty catheters referenced in my First Declaration, which I understood to include Chengod (Ex-1005) and Deaton (Ex-1008).

78. Further, I disagree with the POR's suggestion that because I was unaware if a catheter I used in the past included a metal coil that all MDs who use catheters have no knowledge of how those catheters are constructed (or at least no knowledge of the non-visible aspects of those catheters). POR at 11. In fact, many interventional MDs (myself included) will routinely deconstruct medical devices (catheters included) for preprocedural device modification or for intraprocedural troubleshooting and, as such, are intimately familiar with internal device design structure and elements. In my opinion, the POR's suggestion goes too far, especially in view of the generic elements recited in the '737 patent claims. As I explain above, an MD in 2015 who had extensively used angioplasty balloons and occlusion devices in interventional procedures would understand those devices include the generic features recited in the '737 patent claims, would understand the operation and clinical effects of those generic features, and would understand the prior art that disclosed those generic features. For example, an MD with extensive experience using these devices would have used catheters both with and without a stiffening member such as a metal stylet and would understand that a catheter with a metal stylet can be inserted without a guide wire in emergency situations where an interventional procedure must be performed quickly, or in other situations where advancement over a guidewire may prove cumbersome or unnecessary. That MD would understand that the metal stylet

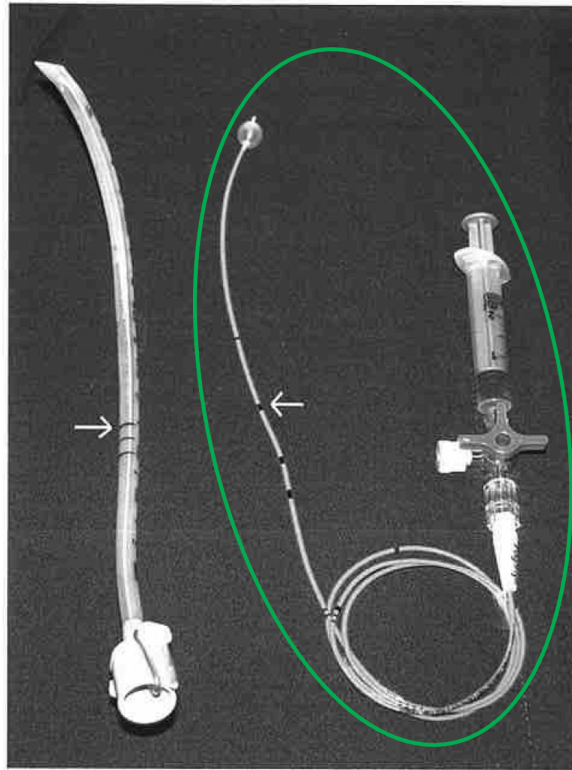
provides stiffness so that the catheter does not buckle as it is guided to the occlusion site.

79. **Fourth**, the POR criticizes my deposition testimony that the “same catheter [in Fogarty (Ex-1004)] can be used for either procedure” (e.g., venous thrombectomy and arterial embolectomy). POR at 15–16. I personally use the same thrombectomy catheter for both arterial and venous thrombectomy in a real world clinical setting on a routine basis (during dialysis graft declotting procedure for instance). I note that Fogarty itself explains that the drawings “illustrate[] a venous thrombectomy catheter” and that “[m]ost of the important features of the invention may also be employed in an arterial embolectomy catheter.” Ex-1004 at 2:33–39. Thus, Fogarty confirms that its catheter can be used for either procedure, as I testified. Accordingly, I disagree with the POR’s criticism of my testimony.

80. **Fifth**, the POR argues that I have used “vague and confusing references to ‘Fogarty catheters’” and that I “fail[] to appreciate that the label ‘Fogarty catheters’ encompasses many devices of high structural diversity, each of which was designed to fit a particular need.” POR at 16. I disagree that my references to Fogarty catheters is vague or confusing or that I have failed to appreciate that there are many types of Fogarty catheters. In my First Declaration, I explain for Ground 1 why the ’737 patent claims are obvious in view of the Fogarty catheter disclosed in Thomas Fogarty’s 1965 patent (Ex-1004) and in view of another Fogarty catheter disclosed in the

Chengod article (Ex-1005) and the PHOSITA's knowledge. Thus, it is unclear why the POR suggests that my references to these catheters are "vague and confusing."

81. While I agree that the term "Fogarty catheters," in general, encompasses many devices, some of which have different structures for particular needs, the existence of specialized catheter structures does not affect my analysis because the '737 patent claims recite only generic catheter structures that are found in many different types of balloon catheters. For example, in Ground 1, I rely on the Fogarty catheter in Chengod as disclosing the "at least one length marking on an exterior of the proximal catheter section to indicate an insertion depth of the occlusion catheter system." Ex-1003 ¶¶ 80–81. The length markers are shown in Figure 1 of Chengod, which also depicts a Fogarty catheter (circled, below right) that includes many of the same features as found in the Fogarty patent (Ex-1004), i.e., a proximal hub with a valve, a syringe (inflation device), a tube with a lumen, a balloon, and an atraumatic tip. My opinion, as explained in my First Declaration, is that a PHOSITA would find it obvious to use the length markings from Chengod's Fogarty catheter on Thomas Fogarty's catheter. Whether Chengod's Fogarty catheter "include[s] the inner coil and braid structure of Fogarty (Ex-1004)" (POR at 17) is irrelevant to my opinion in which I rely on Chengod for its disclosure of length markings.



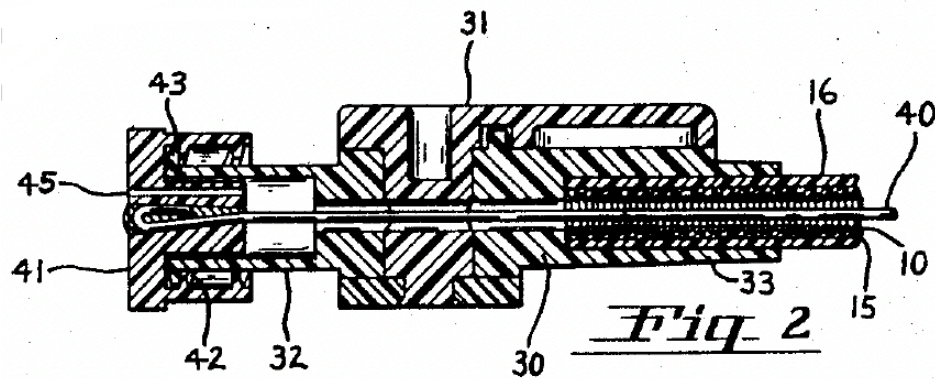
Ex-1005 at 637 (Fig. 1) (annotated).

VIII. RESPONSE IN SUPPORT OF FOGARTY GROUND 1

82. I have reviewed the POR's and Dr. Cimino's arguments against Grounds 1–4 of the Petition, i.e., Grounds based on Fogarty, other references, and the PHOSITA's knowledge. I respond to those arguments next.

83. As an initial matter, both the POR and Dr. Cimino omit an important aspect of Fogarty in their description of Fogarty. Specifically, they explain that Fogarty's metal stylet 40 is provided "to protect the catheter *when it is not in use*" (POR at 20; Ex-1002 ¶ 52), but omit that Fogarty also discloses "the stylet may be used when desired to facilitate the insertion of the catheter into a luminal structure within the body." Ex-1004 at 3:52–54. A PHOSITA understands from this passage

that Fogarty's metal stylet is not only used to protect the catheter when not in use, but it may also be used as a stiffening member when inserting the catheter into the body. In this iteration, a PHOSITA understands Fogarty's stylet 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. "When valve member 31 is turned to open position, the stylet may be freely inserted through the valve and secured in the catheter." Ex-1004 at 3:62–65. In other words, for procedures where the interventionist desires added stiffness when inserting the catheter into the body, the metal stylet can be secured in the cap, which is secured in the catheter's proximal hub by screwing the cap into the syringe fitting 32.



A. Reasonable Expectation of Success

84. The POR argues that "Petitioner has failed to perform a proper obviousness analysis by not adequately demonstrating a reasonable expectation of success in modifying Fogarty" and that "Petitioner has ... not demonstrated that a PHOSITA would have a reasonable expectation of success in modifying the

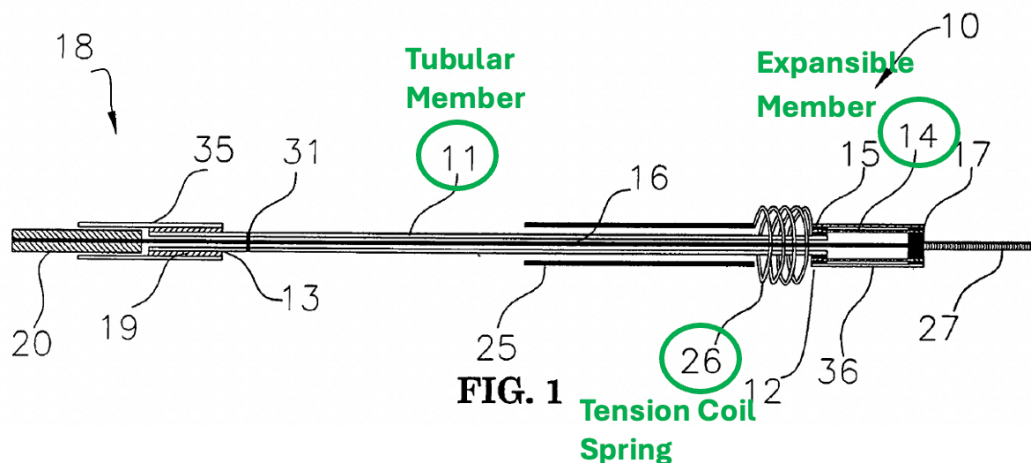
particular catheter taught by the *cited Fogarty patent (Ex. 1004)* to the claimed size [less than 6 Fr maximum diameter] when considering the shaft has a spring coil and braid in addition to the outer tube and lumen.” POR at 35–36. I disagree.

85. In my First Declaration, I explained why a PHOSITA would have a reasonable expectation of success in sizing the Fogarty patent’s catheter to be less than 6 Fr. Ex-1003 ¶¶ 90–92. First, I explained that although the Fogarty patent does not indicate the size of the disclosed catheter, Fogarty catheters smaller than 6 Fr have been known to a PHOSITA long before the ’737 patent (e.g., as expressly disclosed in Chengod and Deaton). Ex-1003 ¶ 90. Thus, a PHOSITA with knowledge of these references would understand the structure of the Fogarty catheters that were smaller than 6 Fr (Chengod and Deaton) and, to the extent those structures differed from the device in the Fogarty patent (Ex-1004), the PHOSITA could make the same modifications and have a reasonable expectation that the resulting device will work as intended. This is just another way of saying that Chengod’s and Deaton’s disclosures “confirm[] that there is no question whether a Fogarty catheter with size less than 6 Fr would work. It did.” Ex-1003 ¶ 91. In other words, there is no hypothetical here. This is why I did not need to determine the internal construction of Chengod or Deaton. Whatever that construction is, a PHOSITA arrived there successfully using Fogarty’s original catheter as a starting point.

86. Of course, to the extent the POR is arguing that the device in the Fogarty patent (Ex-1004) would need to be modified to achieve a 6 Fr size, I disagree. It is my opinion that a PHOSITA would understand that a catheter having a spring coil in addition to the other features (braid, outer tube, and lumen) could be constructed in a configuration with a diameter smaller than 6 Fr. This is confirmed by the prior art, e.g., U.S. Patent No. 7,993,366 (“Yassinzadeh”). Ex-1033.

87. Yassinzadeh is evidence that a PHOSITA would have a reasonable expectation of success in sizing the Fogarty patent’s catheter to have a greatest outer diameter less than 6 Fr because Yassinzadeh shows a catheter that is less than 6 Fr and that includes a similar spring coil construction as found in the Fogarty patent.

88. Yassinzadeh was filed in 2004 (more than a decade before the ’737 patent), issued in 2011, and is titled “Self-Tensioning Vascular Occlusion Device and Method for its Use.” Ex-1033. In Figure 1, Yassinzadeh discloses an occlusion catheter with “tubular member 11,” “expansible member 14,” and “tensioning coil spring 26”:



Ex-1033, Fig. 1 (annotated).

89. Yassinzadeh discloses that “expansible member may comprise a variety of structures including a braided filament, mesh layer, spring, coil, slotted tube, or *balloon*.” Ex-1033 at 3:21–23 (emphasis added).

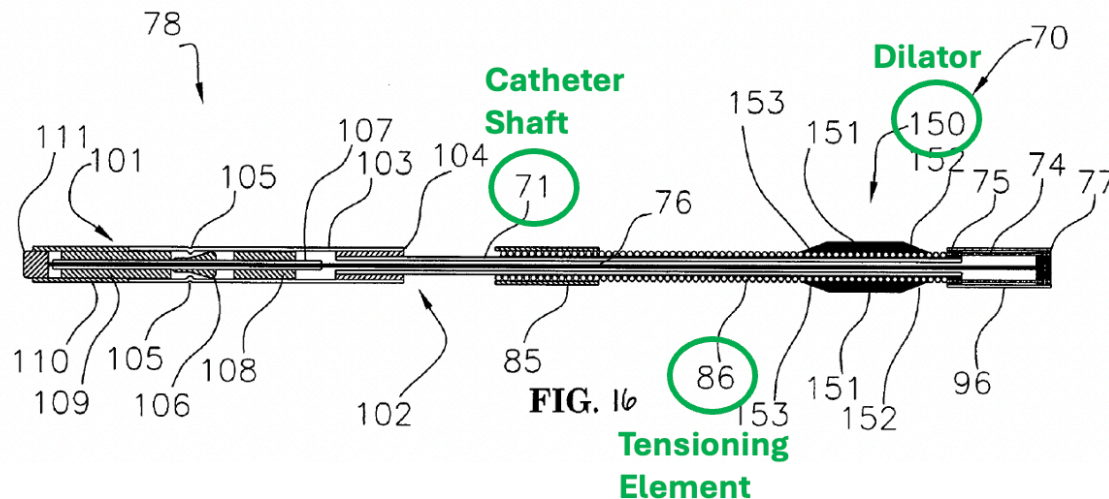
90. Yassinzadeh discloses that “[t]ubular member 11 may be formed from *coiled stainless steel tubing* or polymer materials such as nylon, polyurethane, polyimide, PEEK®, PEBAX®, and the like. Tubular member 11 may have a length in a range from about 10 cm to about 50 cm, preferably in the range from about 15 cm to about 30 cm and *a diameter in the range from about 0.25 mm to about 5 mm, preferably in the range from about 0.5 mm to about 2 mm.*” Ex-1033 at 6:29–36 (emphasis added).

91. Yassinzadeh discloses that “[t]ension coil spring 26 comprises *a helical coil spring* having a central passage *which encompasses first member 11*, wherein its distal end is connected to member 11 proximal the expandable member 14 at

connection point 15.” Yassinzadeh at 8:44–48 (emphasis added). “The fabricated coil 26 may have a diameter in the range from about 1 mm to about 10 mm, *preferably in the range from about 1.5 mm* to about 5 mm in a relaxed state.” Ex-1033 at 8:64–67 (emphasis added).

92. A PHOSITA understands that Yassinzadeh’s Figure 1 occlusion catheter embodiment may be constructed of two coil springs: (1) the smaller tubular member 11 that may be formed from coiled stainless steel tubing, and (2) the larger tension coil spring 26 that surrounds tubular member 11. While not exactly the same, this construction is somewhat analogous to the spring coil and braid structure in the Fogarty patent (Ex-1004). A PHOSITA understands a 6 Fr diameter is 2 mm. The diameter of Yassinzadeh’s smaller tubular member is preferably 0.5 mm (less than 2 Fr) to about 2 mm (6 Fr). The diameter range of the larger tension coil spring 26 preferably starts at 1.5 mm (less than 6 Fr). Thus, Yassinzadeh confirms that catheters could include spring coil construction and have greatest outer diameters less than 6 Fr. This further supports my opinion that a PHOSITA would have a reasonable expectation of success in sizing the catheter in the Fogarty patent (Ex-1004) less than 6 Fr.

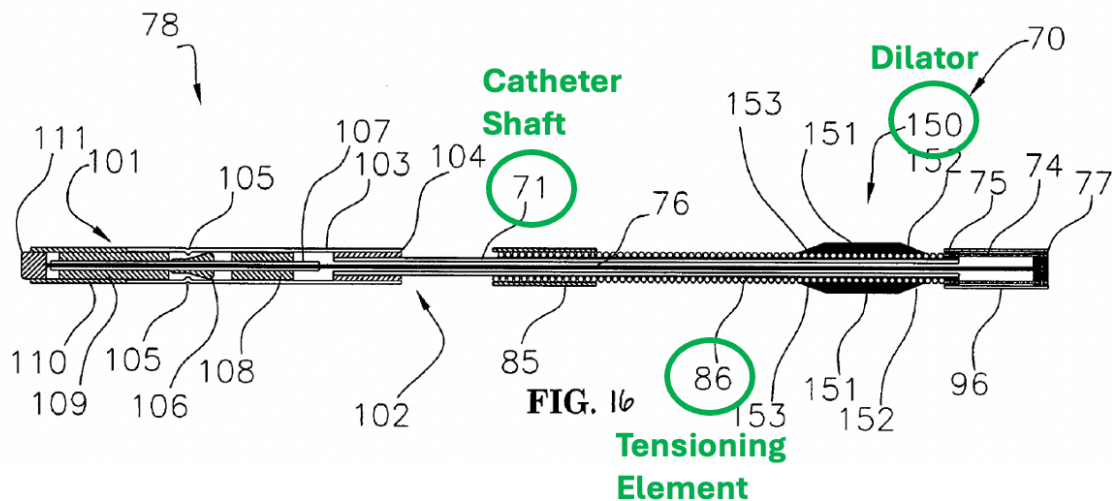
93. In Figure 16, Yassinzadeh discloses another embodiment, device 70:



Ex-1033, Fig. 16 (annotated).

94. “This embodiment is Device 70 is similar in many respects to device 10 of FIG. 1 except in regards to the tensioning element. In particular, the *tensioning element 86* of device 70 *comprises a helical coil spring* which has a smaller diameter that applies tension but does not cause its engagement with the surrounding tissue tract fascia 45, and consequently does not provide means for maintaining the tension.” Ex-1033 at 12:21–28 (emphasis added). Yassinzadeh explains that the catheter shaft 71 is “similar to tubular member 11” of Figure 1. Ex-1033 at 12:45–46. Thus, a PHOSITA understands that Yassinzadeh’s Figure 16 embodiment may be constructed of two coil springs: (1) the smaller catheter shaft 71 that, like tubular member 11, may be formed from coiled stainless steel tubing; and (2) the larger tensioning element 86 that surrounds tubular member 11.

95. In addition to the two coil springs, Yassinzadeh discloses “[d]ilator 150 ... attached at a distal end to the tensioning element 86.” Ex-1033 at 15:55–56. “Dilator 150 comprises leading edges 152 and trailing edges 153 which are tapered and a landing 151 therebetween.” Ex-1033 at 15:64–65. “Dilator 150 may be located proximal to the expansible member 74 and formed from suitable medical grade materials, such as metals (e.g., stainless steel) or preferably polymer materials (e.g., nylon, polyurethane, polyimide, PEEK®, PEBAX®, polyester and the like).” Ex-1033 at 15:44–51.



Ex-1033, Fig. 16 (annotated).

96. While not exactly the same, this construction is somewhat analogous to the spring coil, braid, outer tube, and lumen structure in the Fogarty patent (Ex-1004) (e.g., analogs are the catheter shaft coil, tensioning element, dilator, and catheter shaft lumen, respectively). Dilator 150 has “a diameter of about 0.065 inch for a 5 Fr sheath

and 0.078 inch for a 6 Fr sheath.” Ex-1033 at 15:61–63. A PHOSITA thus understands that the Figure 16 embodiment’s dilator, spring coil tensioning element, and catheter shaft have greatest outer diameters of less than 6 Fr.

97. Thus, Yassinzadeh confirms that catheters could include constructions similar to those found in the Fogarty patent and have greatest outer diameters less than 6 Fr. This further supports my opinion that a PHOSITA would have a reasonable expectation of success in sizing the catheter in the Fogarty patent (Ex-1004) less than 6 Fr.

B. Fogarty has a Solid Wire Secured within the Proximal Hub (Ground 1, Claim 1)

98. The POR and Dr. Cimino argue that Fogarty’s metal stylet is not secured within the proximal hub. POR at 36–41; Ex-2001 ¶¶ 77–87. I disagree.

99. The POR and Dr. Cimino rely on their definition of “secured,” which they argue means “fixedly coupled to” so that it cannot be “removably engaged.” As discussed in the Claim Construction section of this declaration, I disagree with the POR’s and Dr. Cimino’s definition of “secured.”

100. When properly construed to have its plain and ordinary meaning, there is no doubt that Fogarty’s metal stylet is “secured” within the proximal hub. To be sure, Fogarty uses the same term “secured” (according to its ordinary meaning) when describing the metal stylet’s securement within the hub: “The proximal end of stylet 40 *is secured* in a cap 41 which is equipped with an internal thread 42 to engage hub

flange elements 43 on the syringe fitting 32. When valve member 31 is turned to open position, *the stylet* may be freely inserted through the valve *and secured in the catheter.*” Ex-1004 at 3:60–65 (emphasis added). A PHOSITA reading this passage understands that the proximal-most end of Fogarty’s metal stylet is “secured ... within the proximal hub” because Fogarty expressly says so.

101. The POR and Dr. Cimino argue that Fogarty’s disclosure (the first sentence quoted in the immediate paragraph above) differentiates between “securement” and “engagement,” and that Fogarty’s metal stylet is merely “engaged” with the proximal hub. POR at 37; Ex-2001 ¶ 79. I also disagree with this argument because it ignores the second sentence (quoted in the immediate paragraph above) that confirms Fogarty’s metal stylet is “secured in the catheter.” Ex-1004 at 3:62–65. In other words, even if there is a difference between “securement” and “engagement,” Fogarty is clear (and a PHOSITA would understand) that the metal stylet is secured, not merely engaged.

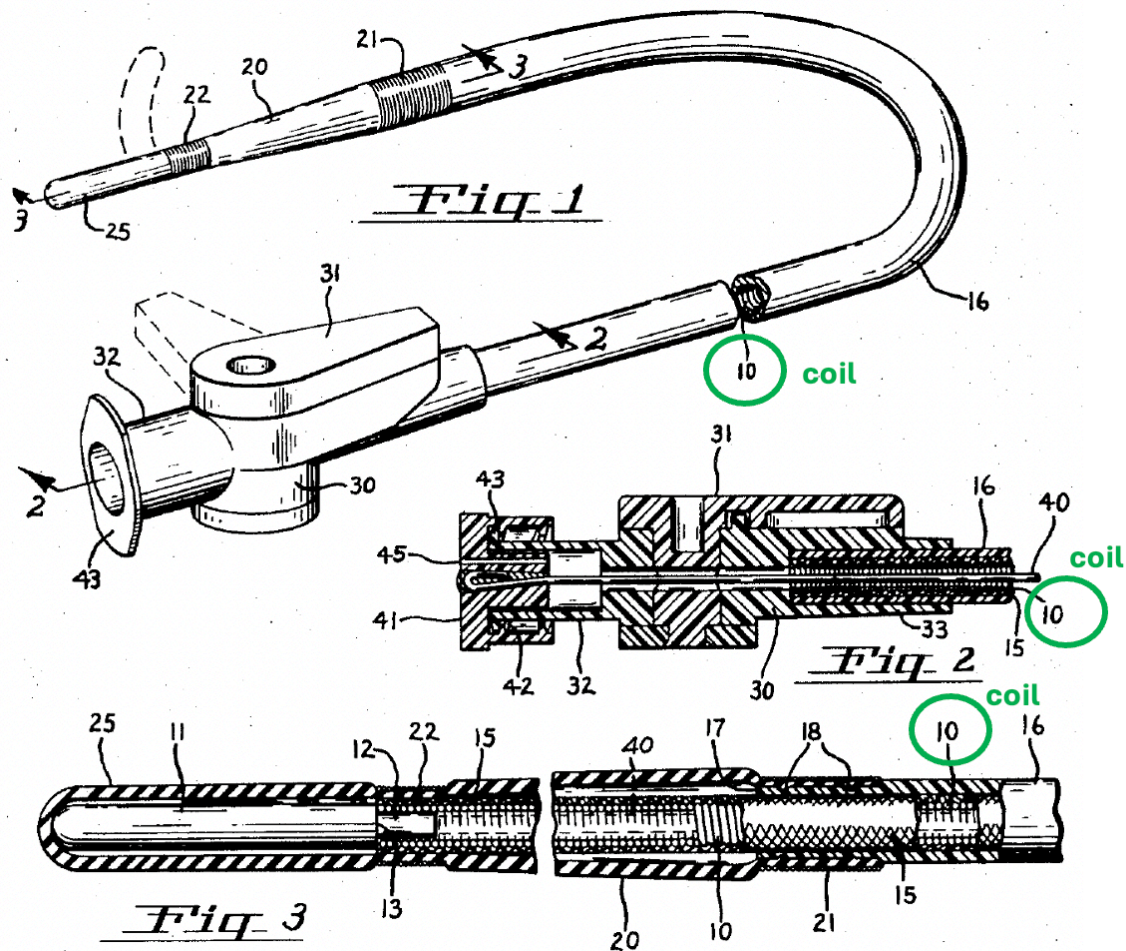
102. The POR and Dr. Cimino next argue that Fogarty’s metal stylet is not secured because it “*must be absent* during significant normal operating conditions.” POR at 39–40; Ex-2001 ¶¶ 85–86. I disagree. This argument appears to rely on a definition of “secured” that requires “the assembly is able to withstand normal operation conditions of the catheter system.” While I disagree that a PHOSITA would understand the term “secured” to have this meaning (i.e., the term should be

given its ordinary meaning), it is my opinion that a PHOSITA would not understand that Fogarty's metal stylet must be absent during significant normal operating conditions. Fogarty discloses "the stylet may be used when desired to facilitate the insertion of the catheter into a luminal structure within the body." Ex-1004 at 3:52–54. Thus, a PHOSITA understands that the stylet is not absent during Fogarty's normal operating conditions (i.e., insertion). When the stylet is used to provide added stiffness for insertion, the assembly is, in fact, able to withstand those normal operating conditions. In other words, a PHOSITA understands that Fogarty's catheter may be used in a manner where the metal stylet is secured to the proximal hub, the catheter is then inserted into the patient's body and directed to the site to be occluded, the metal stylet is then removed, an inflation device is connected to the proximal hub, and the balloon is inflated, resulting in occlusion of the body lumen. Following these steps, the securement of the metal stylet to the proximal hub results in a catheter that is able to operate as intended (i.e., "withstand normal operation conditions of the catheter system").

103. The above discussion shows why, under the plain and ordinary meaning of the term "secured," a PHOSITA would find the "solid wire" limitation of claim 1 obvious in view of Fogarty's metal stylet.

104. In addition, in response to the POR and Dr. Cimino's arguments regarding the "solid wire," it is also my opinion that a PHOSITA would find the

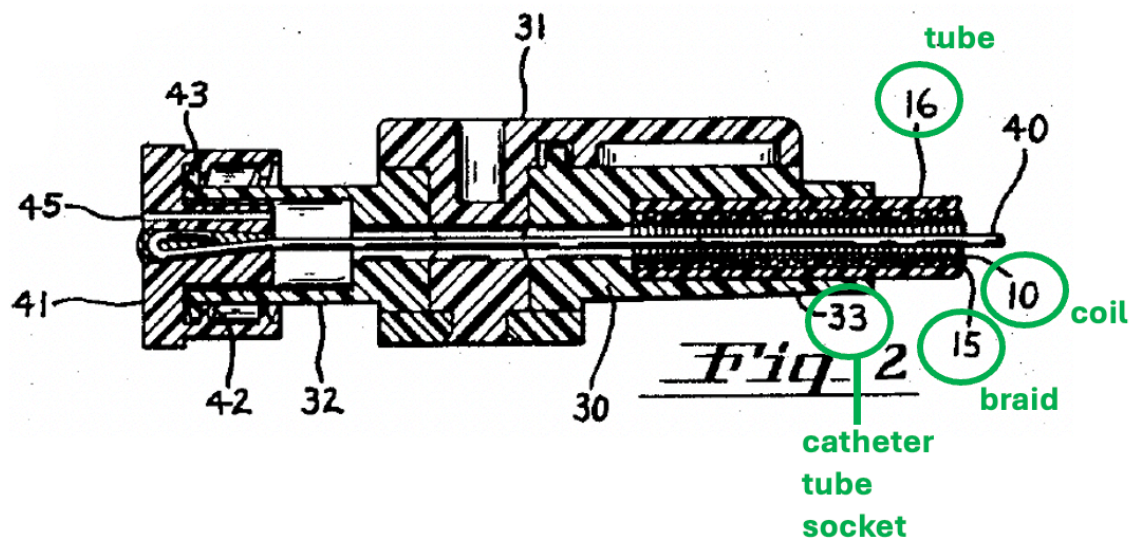
“solid wire” limitation of claim 1 obvious under the POR’s and Dr. Cimino’s definition of “secured” as meaning “fixedly coupled to.” Specifically, the metal stylet was just one example of a “solid wire” in the Fogarty patent. Another solid wire in the same embodiment is the spring wire that makes up coil 10.



Ex-1004, Figs. 1–3 (annotated).

105. Fogarty explains that “[t]he catheter is built on a core 10 comprising a coil of spring wire of suitable material such as stainless steel.” Ex-1004 at 2:40–41. A PHOSITA understands that this spring coil is made of a “solid wire” that does not

have an internal lumen. “A soft rubber plug 11 ... is affixed on the distal end of the coil 10. ... The plug has a reduced end portion 12 which is secured by a suitable cement such as epoxy resin in the end of the coil 10.” Ex-1004 at 2:44–51. Fogarty explains that “[t]he outer surface of coil 10 is covered with a braid 15 of suitable non-reactive and non-hygrosopic material, such as Dacron, Teflon, or the like. This material is braided directly on the body coil 10. ... Then the braid 15 is covered with an outer plastic tube 16, which is drawn on over the braid and positioned with its distal end at 17 a short distance from the plug 11.” Ex-1004 at 2:57–64.



Ex-1004, Fig. 2 (annotated).

106. Fogarty’s Figure 2 depicts the coil/braid/tube catheter elements as they are connected to the “catheter tube socket 33”: “The proximal end of the catheter tube is secured to a shut-off valve 30 having a rotatable valve member 31. The body of valve 30 is equipped with a conventional fitting 32 in line with the catheter tube

socket 33 to receive a syringe 35 for inflating the balloon.” Ex-1004 at 3:38–42.

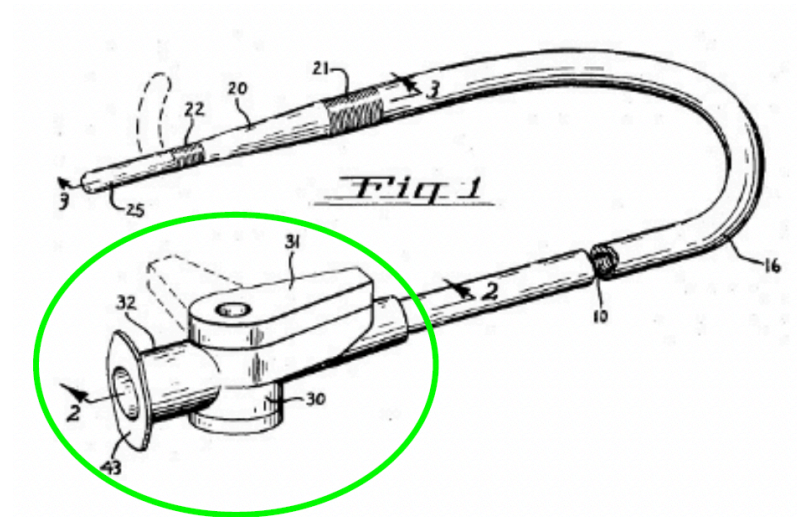
Although Fogarty is silent as to how the tube is secured within catheter tube socket 33, a PHOSITA would understand that one design choice would be to use the same adhesive or epoxy resin that Fogarty uses for other connections in his device. For example, “[t]he plug has a reduced end portion 12 which is secured by a suitable cement such as epoxy resin in the end of the coil 10.” Ex-1004 at 2:49–51. As another example, “the coil 10 is coated with the adhesive on its proximal end portion and in the areas which are to underly the windings 21 and 22 to anchor [the] braid to the coil at these three points.” Ex-1004 at 3:12–15.

107. Moreover, Fogarty claim 5 describes the catheter tube’s connection to the catheter tube socket as “integrally connected”: “A catheter as defined in claim 3 including a plastic shut-off valve having a socket on one end integrally connected with the proximal end of the catheter.” Ex-1004 at 5:6–8. A PHOSITA understands this disclosure to mean the tube (which includes the solid wire core 10) is “fixedly coupled to” the socket so that it cannot be removed. Again, one design option would be to use the same adhesive or epoxy resin to glue the tube into the socket.

108. Based on the foregoing, it is my opinion that Fogarty’s coil 10 discloses and teaches “a solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon, and

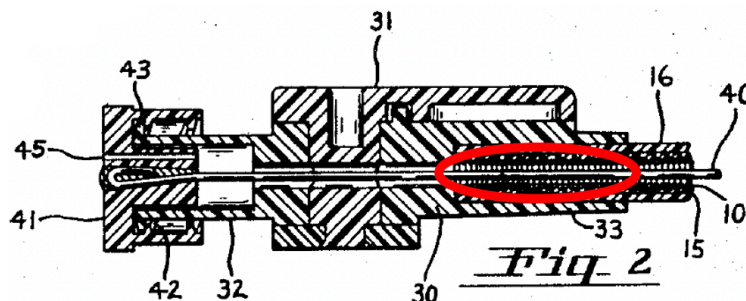
into the distal catheter section,” under both the ordinary meaning of “secured” and the POR’s and Dr. Cimino’s definition of “secured” (i.e., “fixedly coupled”).

109. In my First Declaration, I identified Fogarty’s “proximal hub”: “A PHOSITA ... would recognize that the elements 30, 31, 32, and 43 comprise a hub that is on the proximal ... end of the catheter.” Ex-1003 ¶74.



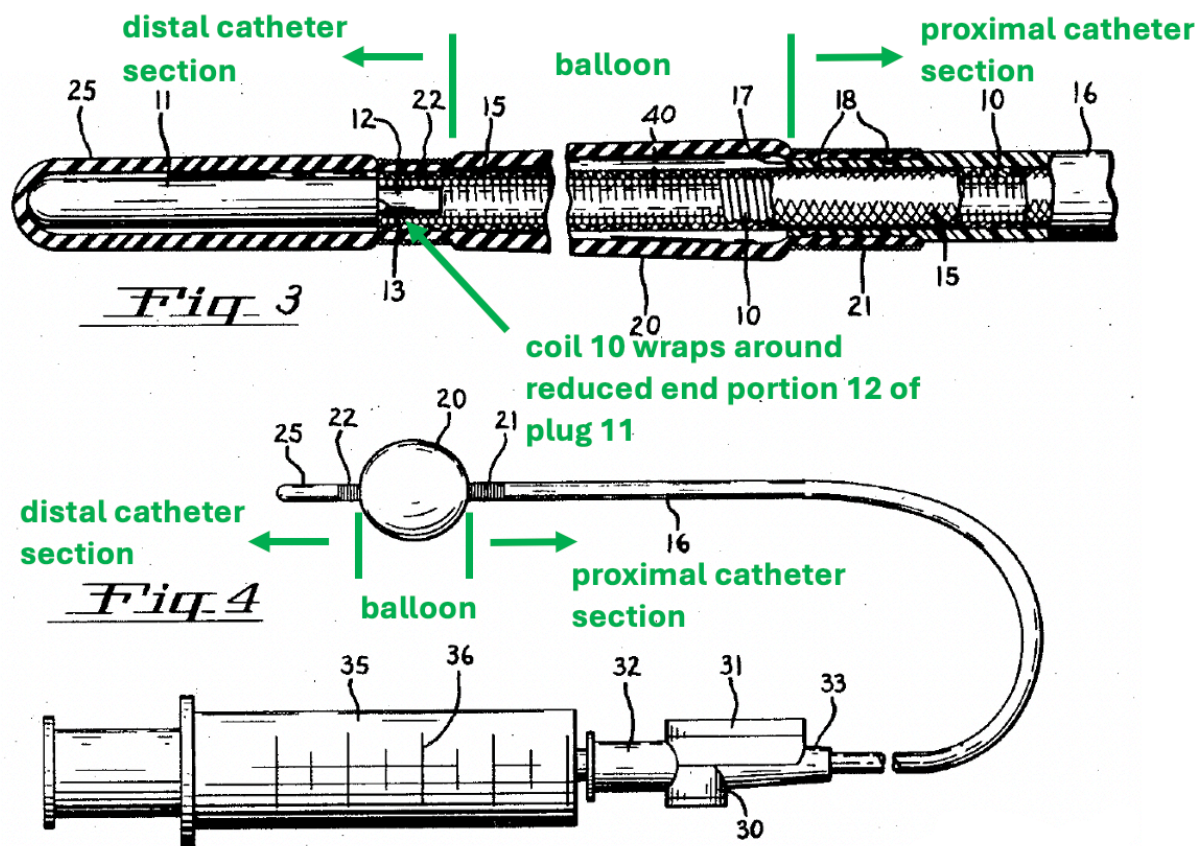
Ex-1004, Fig. 1 (annotated).

110. Fogarty’s coil 10 is a solid wire (e.g., stainless steel) that is wound into a coil shape. Ex-1004 at 2:40–41. It is secured at a proximal-most end thereof within the proximal hub where its proximal-most end interfaces with catheter tube socket 33.



Ex-1004, Fig. 2 (annotated). As discussed above, a PHOSITA would find it obvious to fixedly attach coil 10 (along with tube 16 and braid 15) with adhesive or epoxy, similar to how other members of Fogarty's catheter are attached to each other. In addition, Fogarty's claim 5 expressly discloses that the coil/tube/braid is "integrally connected" to socket 33. A PHOSITA understands this to be "fixedly attached" according to the POR and Dr. Cimino because it is not a removable attachment. Indeed, because it is not removable, it also is "able to withstand normal operation conditions of the catheter system," a requirement under the POR's and Dr. Cimino's definition of "secured."

111. Finally, coil 10 extends within the proximal catheter section, the occlusion balloon, and into the distal catheter section, as shown in annotated Figures 3 and 4 below:



Ex-1004, Figs. 3–4 (annotated).

112. In my opinion, the above annotations reflect a PHOSITA’s understanding of Fogarty regardless of which definition of “distal catheter section” is considered. For example, coil 10 extends into the distal catheter section when “distal catheter section” is given the Board’s (and my) construction, i.e., “comprising the elements that are located distal of the intervening occlusion balloon.” Under this definition, winding 22 and plug 11 are elements located distal of the intervening occlusion balloon. Ex-1004 at 3:28–30. Coil 10 extends into this distal catheter section—it is epoxied onto the end portion 12 of plug 11: “[t]he plug has a reduced end portion 12

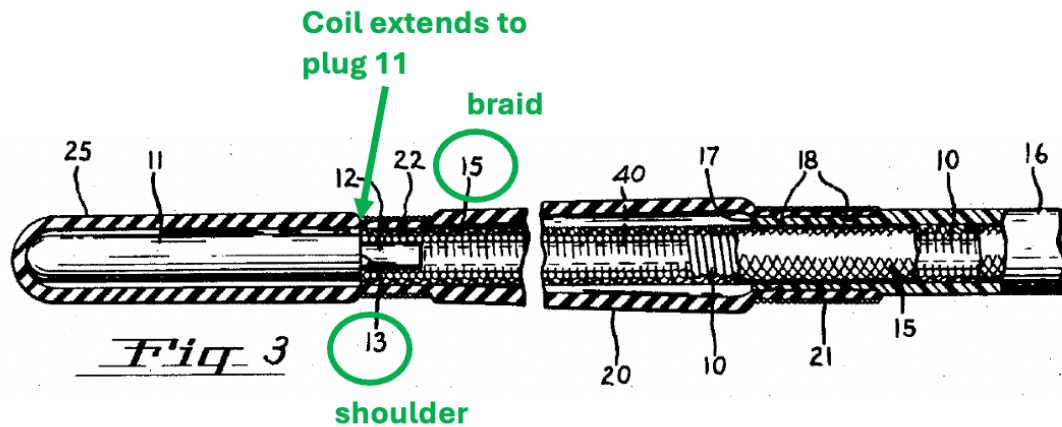
which is secured by a suitable cement such as epoxy resin in the end of the coil 10.”

Ex-1004 at 2:49–51.

113. Patent Owner or Dr. Cimino may argue that plug 11 and winding 22 are not located distal of the intervening occlusion balloon because “the balloon has a closed end portion 25 which merely encloses the plug 11 and does not inflate.” Ex-1004 at 3:28–30. However, a PHOSITA would not understand end portion 25 of balloon to be an “occlusion balloon” because that portion cannot inflate.

Alternatively, Fogarty discloses that instead of a closed end portion of a balloon, the occlusion balloon may be constructed with a sleeve. Specifically, Fogarty claim 8 recites a “sleeve being in fluid communication with said tube through the wall of said coil whereby upon introduction of inflation fluid into said tube, said sleeve will be expanded radially.” Ex-1004 at 6:11–15. Based on this disclosure, a PHOSITA would understand the section of Fogarty that includes winding 22 and plug 11 is the “distal catheter section” that includes elements located distal of the occlusion balloon.

114. In my opinion, the above annotations reflect a PHOSITA’s understanding of Fogarty even under the POR’s and Dr. Cimino’s definition of “distal catheter section,” i.e., “a distal portion of the shaft of the device.”



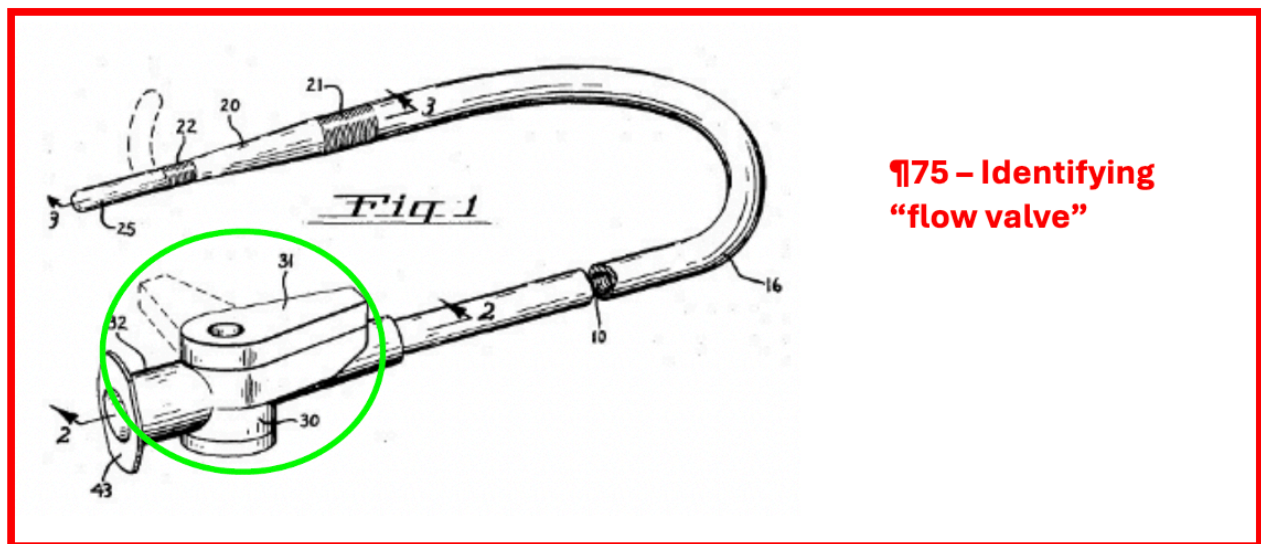
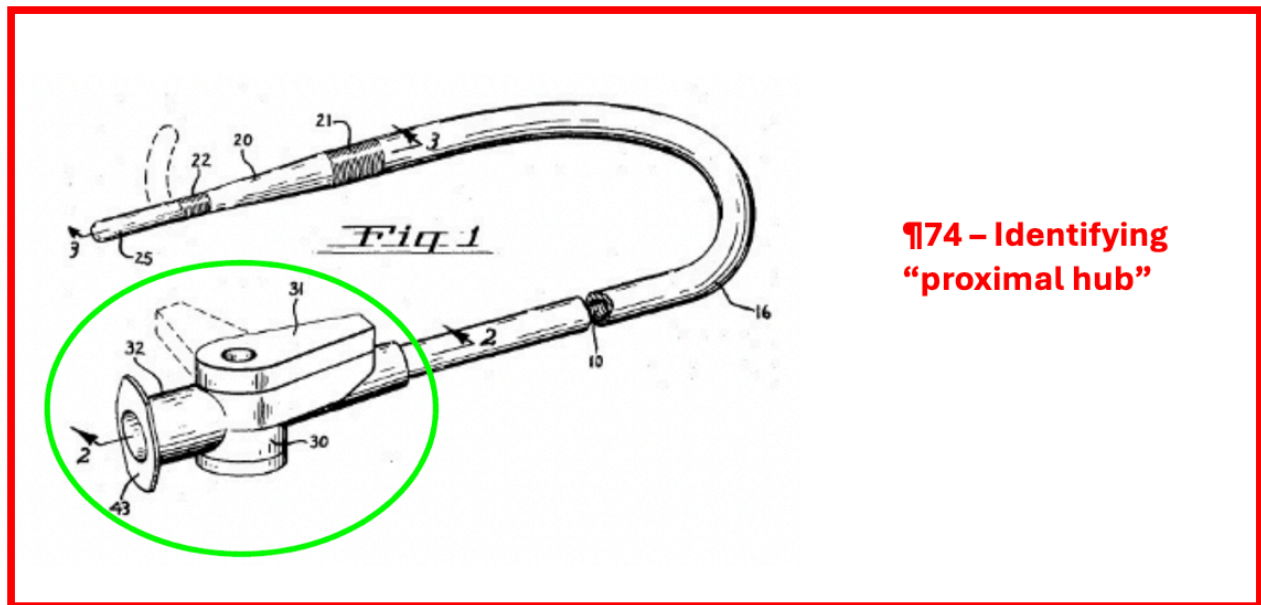
Ex-1004, Fig. 3 (annotated).

115. A PHOSITA understands that braid 15, which forms a shaft of the device, extends to shoulder 13 and that coil 10 extends within braid 15 to plug 11. Ex-1004 at 2:60–61 (“Braid 15 continues in a distal direction to the shoulder 13.”); 2:49–51 (“The plug has a reduced end portion 12 which is secured by a suitable cement such as epoxy resin in the end of the coil 10.”). Both are distal to the occlusion balloon 20. Thus, coil 10 extends into the distal catheter section (the distal portion of the shaft made up by braid 15) under the POR’s and Dr. Cimino’s definition.

C. Fogarty has a Proximal Hub and a Flow Valve, as Claimed (Ground 1, Claim 1)

116. The POR and Dr. Cimino argue that my First Declaration “equate[s] the same portions of Fogarty with two separately claimed structures,” namely, the “proximal hub” and “flow valve” recited in claim 1 of the ’737 patent. I disagree.

117. I expressly identified the “proximal hub” as including “shut off valve 30, rotatable valve member 31, syringe fitting 32, and hub flange elements 43.” Ex-1003 ¶ 74. In contrast, I expressly identified the “flow valve” as “shut-off valve 30 having a rotatable valve member 31.” Ex-1003 ¶ 75. My First Declaration even circled these different portions in Fogarty Figure 1:



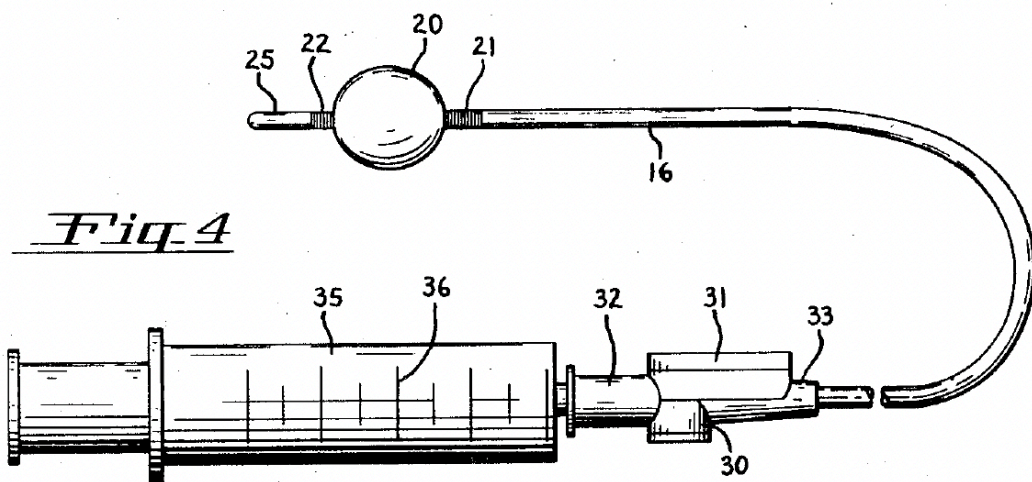
Ex-1003, Fig. 1 (annotated: green circles from First Declaration, red annotation added in this declaration). The different-sized green circle annotations above (and the text that accompanied them) show that I did not equate the same elements in Fogarty for the two different claim limitations. Thus, my opinion, as explained in my First Declaration, is that the valve (30, 31) is a sub-element of the overall proximal hub (30, 31, 32, 33).

118. The POR and Dr. Cimino argue that in order “[t]o ‘selectively fluidly communicate the proximal hub with an inflation device,’ the flow valve must be located *between* the proximal hub and the inflation device.” POR at 41; Ex-2001 ¶ 61. I disagree, as explained in my claim construction discussion above.

119. Thus, it remains my opinion that Fogarty discloses the “proximal hub” and “flow valve” limitations of claim 1 under the plain meaning of these claim terms, which would encompass a flow valve as a sub-element of the proximal hub. The basis of my opinion is explained in my First Declaration. Ex-1003 ¶¶ 74–75.

120. Additionally, it is my opinion that Fogarty discloses the “proximal hub” and “flow valve” limitations of claim 1 under the Board’s preliminary interpretation of these claim terms, which is consistent with their plain meaning. Specifically, the Board found “the claim terms ‘proximal hub’ and ‘flow valve’ ... encompass situations where [they] are separate elements and also where the ‘flow valve’ is a sub-element portion of the ‘proximal hub.’” Institution Decision, Paper 7 at 14. The Board

also found the “flow valve” limitation to “encompass a valve that controls the flow of fluids to a proximal hub during any part of a procedure...” Institution Decision, Paper 7 at 17. Fogarty’s shut-off valve (30, 31) is a sub-element of the overall proximal hub (30, 31, 32, 33) that is configured to control the flow of fluids from the syringe 35 to the proximal hub (30, 31, 32, 33). Ex-1004, 3:38–48.

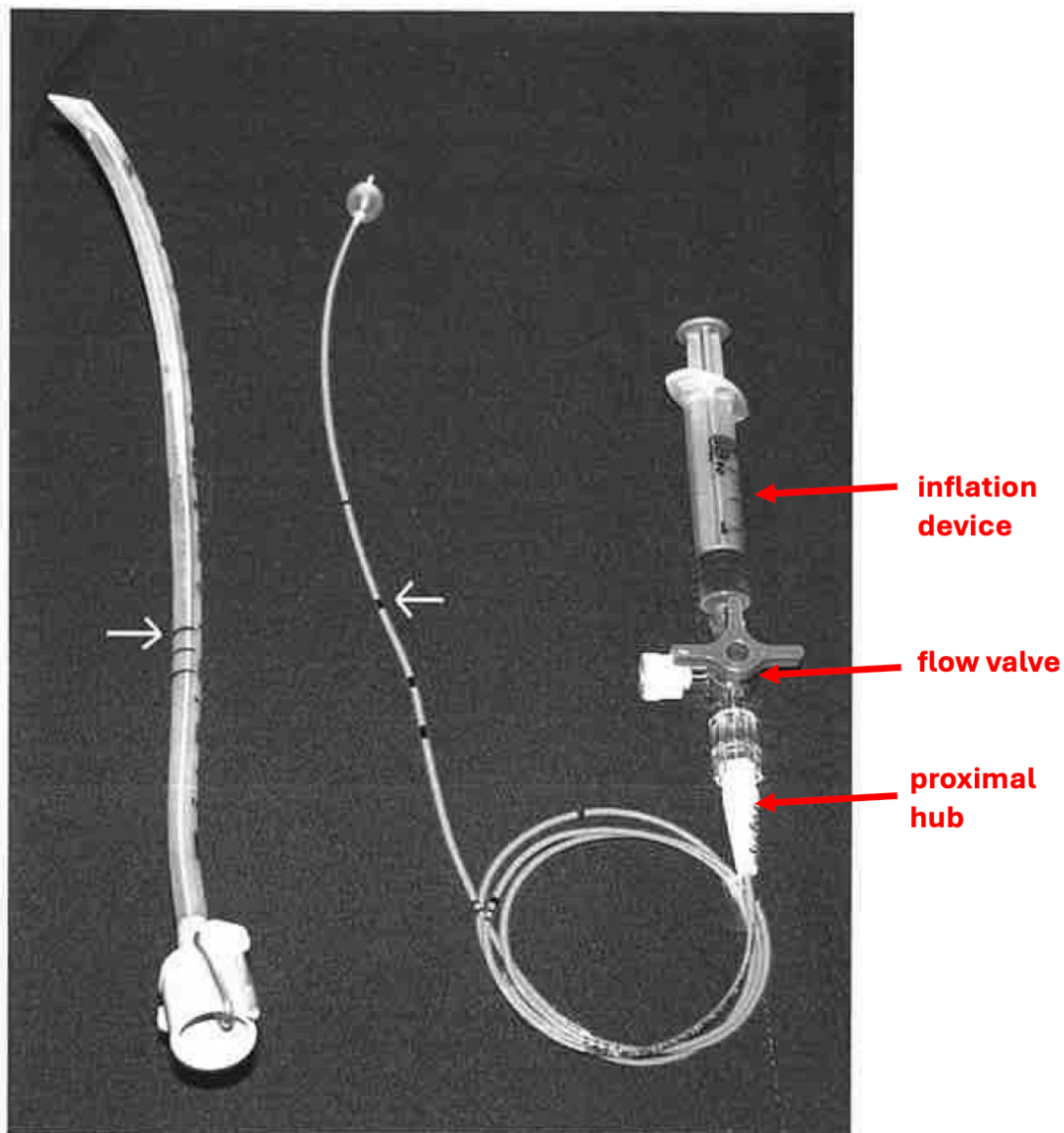


Ex-1004, Fig. 4.

121. Finally, counsel has asked me to consider whether my opinion that claim 1 is unpatentable in view of Ground 1 would change if the Board agrees with the POR and Dr. Cimino that the flow valve must be located *between* the proximal hub and the inflation device. Under this assumption, it is my opinion that a PHOSITA would still find the “flow valve” limitation obvious in view of Fogarty, Chengod, and the PHOSITA’s knowledge.

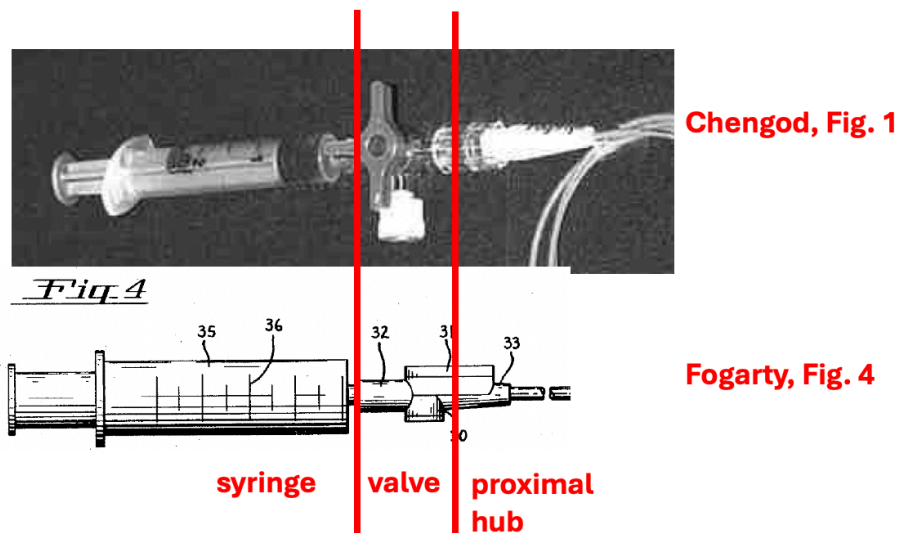
122. A PHOSITA understands based on their knowledge that a flow valve could be an integral part of the proximal hub (i.e., permanently attached in an

element/sub-element relationship) or could be separate from a proximal hub (i.e., removably attached and located between the proximal hub and the inflation device). Evidence of this knowledge is found in (1) Fogarty where the flow valve (30, 31) is an integral part of the proximal hub (30, 31, 32, 33); and (2) Chengod where the flow valve is a separate physical component that is located between the proximal hub and the inflation device:



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

123. In my opinion, the specific configurations of having (1) a valve as part of the proximal hub or (2) a valve separate from the proximal hub represent limited design choices available to a PHOSITA. The pieces can be manufactured as an integral assembly, or manufactured as separate assemblies that are then coupled together prior to use. The integral assembly typically increases ease of use while the separate assemblies may provide more flexibility for the user. In both cases, the flow valve is “configured to selectively fluidly communicate the proximal hub with an inflation device.” Indeed, when Chengod’s separate elements are coupled together, the resulting assembly is essentially the same as Fogarty’s integral assembly:



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

124. Thus, it is my opinion that if claim 1 of the '737 patent requires a flow valve that is between the inflation device and the proximal hub, a PHOSITA would have found that obvious in view of Fogarty, Chengod, and the PHOSITA's knowledge. Modifying Fogarty to use a valve that is not integrally formed with the proximal hub represents the simple substitution of one known element (proximal hub with integral valve) for another (separate valve and hub) to obtain predictable results (controlling the flow of fluids with the proximal hub). Indeed, the two different approaches represent a finite number of identified, predictable solutions for controlling the flow of fluids with the proximal hub, and a PHOSITA would have found it obvious to try separating the elements found as an integral piece in Fogarty. A PHOSITA making this substitution would have a reasonable expectation of success because the PHOSITA knew from catheters such as Chengod that separating the flow valve from the proximal hub and putting the flow valve in between the inflation device and the proximal hub would work as intended.

D. An Asymmetrical Balloon Shape is Obvious (Ground 1, Claim 2)

125. The POR argues that my First Declaration does not adequately explain why a PHOSITA would use an asymmetrical balloon shape in Fogarty's catheter.

POR at 49–49 (“Dr. Resnick’s declaration ... presents the same terse analysis.”). I disagree.

126. In my First Declaration, I explained that Fogarty uses a compliant balloon made of “latex rubber or a plastic elastomer.” Ex-1003 ¶ 79. I also referred to my Section VII.D section as providing evidence that “a PHOSITA is well aware that compliant balloons such as the type used in the Fogarty catheters as described in the Fogarty and Chengod references could be designed to inflate asymmetrically.” Ex-1003 ¶ 93.

127. Based on this statement, the POR argues that I did not “articulate[] any reason to substitute an asymmetrical balloon into Fogarty other than to say the balloon ‘could be’ designed that way.” POR at 49. Again, I disagree. In Section VII.D of my First Declaration (¶¶ 49–55), I explained that asymmetrical compliant balloons were known to a PHOSITA (¶¶ 49–53) and that a PHOSITA would know that “an elastomeric [compliant] balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left)” (¶ 54 (citing to Saab, p. 90 and Fig. 6)). I additionally explained that “a PHOSITA understands that compliant balloons are often used in occlusion catheters because the balloon can inflate asymmetrically when inside the patient ... to completely fill the cavity, which is often asymmetrical in shape ...” Ex-1003 ¶ 55.

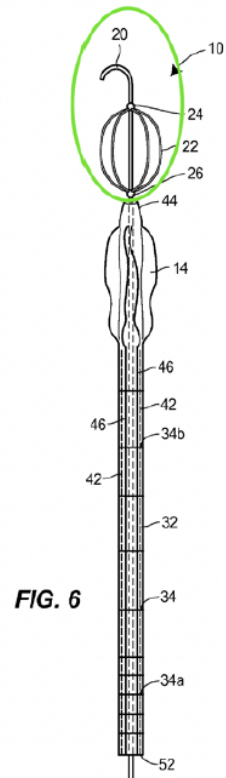
128. Thus, my opinion was (and is) that a PHOSITA would use a compliant balloon in Fogarty that, when inserted into and confined within a lumen in the body, inflates asymmetrically (has an asymmetrical shape) in order to occlude the body lumen. I even included Figure 6 from Gu (Ex-1014) that shows a “deployed [asymmetrical] balloon catheter within the surgically created atrial septal defect.” Ex-1003 ¶ 55. Put differently, Fogarty’s catheter is used for occlusion and a PHOSITA would use a compliant balloon that inflates asymmetrically in order to occlude asymmetrical vessels in the patient’s body. As discussed in Section VII.D of my First Declaration, this option was known to a PHOSITA at the time and a PHOSITA would have found it obvious to use an asymmetrical balloon in Fogarty for the above reasons.

IX. RESPONSE IN SUPPORT OF ELIASON GROUND 5

A. Eliason has a Distal Catheter Section Distally Terminating with an Atraumatic Tip

129. The POR and Dr. Cimino argue that Eliason does not disclose a “distal catheter section.” POR at 50–54; Ex-2001 ¶¶ 104–113. I disagree.

130. First, the POR and Dr. Cimino take issue with the fact that in my discussion of Eliason and the “distal catheter section,” I did “not identify any reference numerals in Eliason corresponding to the claimed distal catheter section.” POR at 50; Ex-2001 ¶ 105. To the extent my First Declaration was unclear, my intent and action was to circle the portion of Eliason’s Figure 6 that included the elements that are located distal to the occlusion balloon (14) (see right excerpt from Ex-1003 ¶ 149).



131. The POR and Dr. Cimino argue that none of the components I identify in Figure 6 would be considered by a PHOSITA to be a “distal catheter section.” POR at 52; Ex-2001 ¶ 109. As an initial matter and for clarity, I did not intend to identify any specific individual component as the “distal catheter section” because this is a label that refers to a portion of the catheter and not any singular component.

132. I understand the POR’s and Dr. Cimon’s argument relies on their interpretation of “distal catheter section” to expressly require a “catheter shaft” and

expressly exclude “a wire.” In the claim construction section above, I explain why I disagree with the POR’s and Dr. Cimino’s interpretation.

133. Dr. Cimino asserts that, in my deposition, I confirmed his interpretation of “distal catheter section” as being limited to “a portion of the *catheter shaft* itself, rather than of the entire catheter system...” Ex-2001 ¶ 108. I disagree. I testified that “The catheter is the shaft of the device. Typically, I would describe the catheter as extending from the proximal hub to the end of the device distally.” Ex-2002 at 26:21–27:2. Thus, a catheter is the whole device from the proximal hub to the end of the device distally, without qualification, and including all incorporated elements extending to the end of the device.

134. The POR asserts that, in my First Declaration, I admitted that Eliason’s catheter is distinct from the wire over which it slides. POR at 52. I disagree. At ¶ 144 of my First Declaration, I explained that Eliason’s “occlusion catheter is designed to be fixed to a wire (12) that provides rigidity to the catheter. ... The wire and the rest of the balloon catheter are to be inserted as a single unit or device.” Contrary to the POR’s assertion, this statement literally says that the wire and the other elements of Eliason’s catheter, when fixed together (as in Eliason’s pre-secured embodiment), become a single unit or device (i.e., a single catheter device).

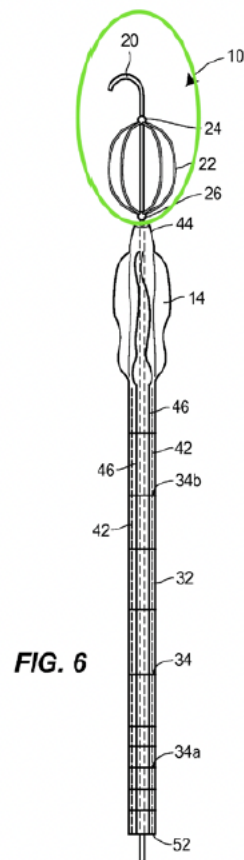
135. I understand the Board preliminarily interpreted “a distal catheter section” as “reasonably comprising the elements that are located distal of the

‘intervening occlusion balloon’ that connects the ‘proximal catheter section with the distal catheter section’ of the catheter system.” Institution Decision, Paper 7 at 18.

This interpretation is consistent with the plain meaning of the term as used in claim 1.

Thus, it is my opinion that Eliason discloses “a distal catheter section” under the Board’s interpretation for the same reason given in my First Declaration (§ 149).

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



Ex-1009, Fig. 6 (annotated).

136. The POR and Dr. Cimino argue that “[p]re-securing the endovascular wire 12 to the catheter ... does not transform these structures into being part of the catheter.” POR at 53; Ex-2001 ¶ 111. I disagree. Eliason expressly teaches that the wire and the other components in Figure 6 are “inserted as a single unit or device” (Ex-1009 at 6:5–7). A PHOSITA understands that when the wire is pre-secured in this “single unit or device” configuration, the wire, securement beads, wire struts, and J tip all become part of the catheter that is inserted into the patient’s body.

B. Eliason has a Proximal Hub and a Flow Valve, as Claimed (Ground 5, Claim 1)

137. The POR and Dr. Cimino argue that Eliason does not disclose the “flow valve” of claim 1. POR at 54–57; Ex-2001 ¶¶ 93–103. The POR and Dr. Cimino based this argument on their claim interpretation that requires the “flow valve” to be a separate structure from the “proximal hub” and that requires the “flow valve” to “*sit// between the proximal hub and the inflation device.*” POR at 54.

138. As I explained in the claim construction discussion above, I disagree that that the flow valve must be a separate structure from the proximal hub and I disagree that the flow valve must be located between the proximal hub and the inflation device.

139. Additionally, it is my opinion that Eliason discloses the “proximal hub” and “flow valve” limitations of claim 1 under the Board’s preliminary interpretation of these claim terms, which is consistent with their plain meaning. Specifically, the

Board found “the claim terms ‘proximal hub’ and ‘flow valve’ ... encompass situations where [they] are separate elements and also where the ‘flow valve’ is a sub-element portion of the ‘proximal hub.’” Institution Decision, Paper 7 at 14. The Board also found the “flow valve” limitation to “encompass a valve that controls the flow of fluids to a proximal hub during any part of a procedure...” Institution Decision, Paper 7 at 17. Eliason’s flow valve (60) is a sub-element of the overall proximal hub (36) that is configured to control the flow of fluids from the syringe (48) to the proximal hub (36). Ex-1009, 10:36–40. The syringe (48) and the valve (60) on assembly 36 can be seen in Figure 10:

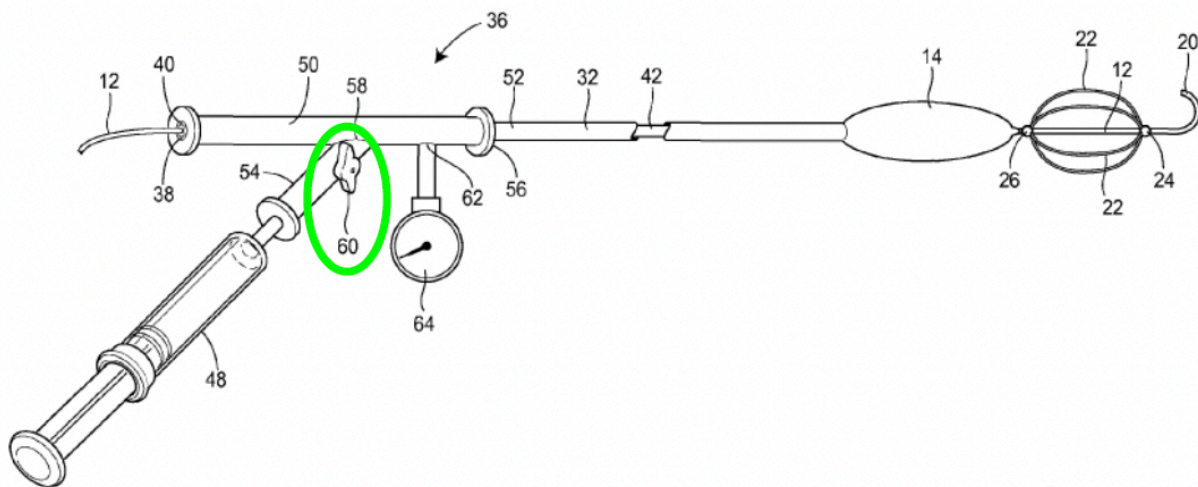


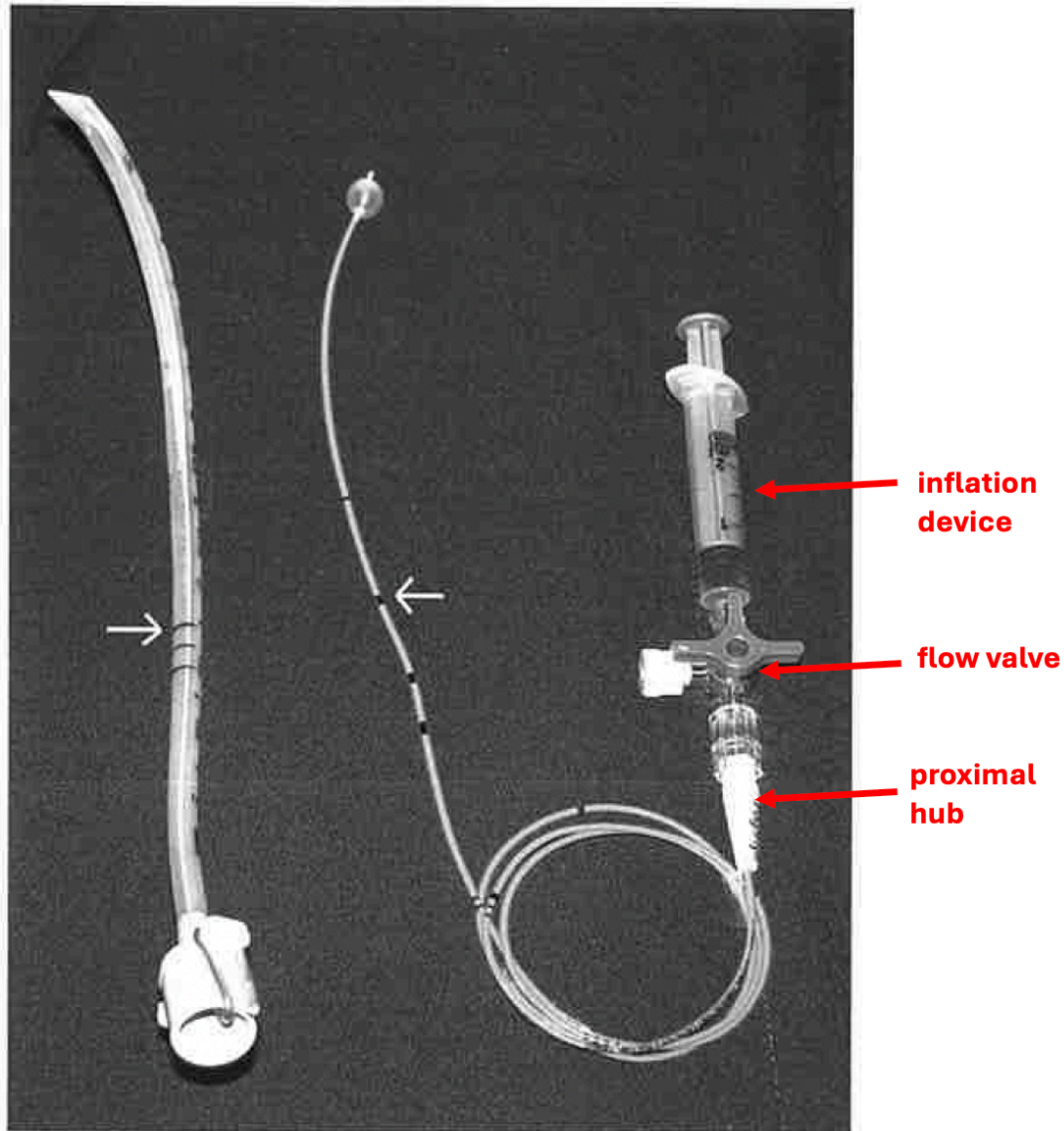
FIG. 10

Ex-1009, Fig. 10 (annotated).

140. Since the valve (6) can move between the open position and the closed position, it is configured to control the flow of fluids from the syringe (48) to the proximal hub (36) during any part of a procedure.

141. Finally, counsel has asked me to consider whether my opinion that claim 1 is unpatentable in view of Ground 5 would change if the Board agrees with the POR and Dr. Cimino that the flow valve must be located *between* the proximal hub and the inflation device. Under this assumption, it is my opinion that a PHOSITA would still find the “flow valve” limitation obvious in view of Eliason and the PHOSITA’s knowledge.

142. As discussed above for Ground 1, a PHOSITA understands based on their knowledge that a flow valve could be an integral part of the proximal hub (i.e., permanently attached in an element/sub-element relationship) or could be separate from a proximal hub (i.e., removably attached and located between the proximal hub and the inflation device). Evidence of this knowledge is found in (1) Eliason where the flow valve (60) is an integral part of the proximal hub (36); and (2) Chengod where the flow valve is a separate physical component that is located between the proximal hub and the inflation device.



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

143. In my opinion, the specific configurations of having (1) a valve as part of the proximal hub or (2) a valve separate from the proximal hub represent limited design choices available to a PHOSITA. The pieces can be manufactured as an integral assembly, or manufactured as separate assemblies that are then coupled

together prior to use. The integral assembly typically increases ease of use while the separate assemblies may provide more flexibility for the user. In both cases, the flow valve is “configured to selectively fluidly communicate the proximal hub with an inflation device.” Indeed, when Chengod’s separate elements are coupled together, the resulting assembly is essentially the same as Eliason’s integral assembly.

144. Thus, it is my opinion that if claim 1 of the ’737 patent requires a flow valve that is between the inflation device and the proximal hub, a PHOSITA would have found that obvious in view of Eliason and the PHOSITA’s knowledge.

Modifying Eliason to use a valve that is not integrally formed with the proximal hub represents the simple substitution of one known element (proximal hub with integral valve) for another (separate valve and hub) to obtain predictable results (controlling the flow of fluids with the proximal hub). Indeed, the two different approaches represent a finite number of identified, predictable solutions for controlling the flow of fluids with the proximal hub, and a PHOSITA would have found it obvious to try separating the elements found as an integral piece in Eliason. A PHOSITA making this substitution would have a reasonable expectation of success because the PHOSITA knew from catheters such as Chengod that separating the flow valve from the proximal hub and putting the flow valve in between the inflation device and the proximal hub would work as intended.

C. An Asymmetrical Balloon Shape is Obvious (Ground 5, Claim 2)

145. The POR argues that my First Declaration does not adequately explain why a PHOSITA would use an asymmetrical balloon shape in Eliason's catheter. POR at 57. I disagree.

146. In my First Declaration, I explained that Eliason uses a "sufficiently compliant balloon." Ex-1003 ¶ 150. I also referred to my Section VII.D section as providing evidence that "a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate asymmetrically." Ex-1003 ¶ 162.

147. In Section VII.D of my First Declaration (¶¶ 49–55), I explained that asymmetrical compliant balloons were known to a PHOSITA (¶¶ 49–53) and that a PHOSITA would know that "an elastomeric [compliant] balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left)" (¶ 54 (citing to Saab, p. 90 and Fig. 6)). I additionally explained that "a PHOSITA understands that compliant balloons are often used in occlusion catheters because the balloon can inflate asymmetrically when inside the patient ... to completely fill the cavity, which is often asymmetrical in shape ..." Ex-1003 ¶ 55.

148. Thus, my opinion was (and is) that a PHOSITA would use a compliant balloon in Eliason that, when inserted into and confined within a lumen in the body, inflates asymmetrically (has an asymmetrical shape) in order to occlude the body

lumen. I even included Figure 6 from Gu (Ex-1014) that shows a “deployed [asymmetrical] balloon catheter within the surgically created atrial septal defect.” Ex-1003 ¶ 55. Put differently, Eliason’s catheter is used for occlusion and a PHOSITA would use a compliant balloon that inflates asymmetrically in order to occlude asymmetrical vessels in the patient’s body. As discussed in Section VII.D of my First Declaration, this option was known to a PHOSITA at the time and a PHOSITA would have found it obvious to use an asymmetrical balloon in Eliason for the above reasons.

X. RESPONSE IN SUPPORT OF SAAB GROUNDS 2 & 7

149. The POR and Dr. Cimino argue that Saab (Ex-1006) teaches away from using an asymmetrical balloon with either Fogarty or Eliason. POR at 58–60; Ex-2001 ¶¶ 88–90, 115. I disagree.

150. In the context of occlusion catheters, Saab explains “Normally, low-pressure, elastomeric balloons are used for occlusion or sealing, but in some cases, when precise sizes or shapes are required, it is desirable to use a high-pressure balloon. High-pressure occlusion balloons can be made shorter or longer than elastomeric balloons, thus either reducing or increasing the surface area covered in the vessel or cavity. Because high-pressure balloons can be precisely shaped, particularly in the transition area, they offer advantages over elastomeric balloons, whose ends are

always spherically shaped. Conical, square, or spherical high-pressure balloons are those typically used for various occlusion applications.” Ex-1006 at 91–92.

151. In my opinion, a PHOSITA reading this passage in Saab would understand that Saab is explaining alternative options to elastomeric balloons, not that elastomeric balloons are discouraged or shouldn’t be used. Indeed, Saab expressly says that it is desirable to use high-pressure balloons (and not asymmetrical elastomeric balloons) “in some cases”—not in “all cases.” Thus, in certain instances, i.e., when precise sizes or shapes are required, a PHOSITA understands Saab to be voicing a mere preference for the high-pressure balloons.

XI. AVAILABILITY FOR CROSS-EXAMINATION

152. In signing this Declaration, I recognize that this declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in this proceeding and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination.

XII. RIGHT TO SUPPLEMENT

153. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner or others raise, and to take into account new information as it becomes available to me.

APPENDIX E – LIST OF MATERIALS CONSIDERED

Ex-1001	U.S. Patent No. 11,857,737 (“the ’737 Patent”)
Ex-1002	Prosecution history of U.S. Patent No. 11,857,737
Ex-1004	U.S. Patent Number 3,467,101 (“Fogarty”)
Ex-1005	S. Chengod, MD. et al., <i>Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique</i> , Department of Anesthesiology and Intensive Care, Division of Cardiothoracic and Vascular Anesthesiology and Intensive Care, Amrita Institute of Medical Sciences and Research Center, Kerala, India. (2005) (“Chengod”)
Ex-1006	Mark A. Saab, <i>Applications of High-Pressure Balloons in the Medical Device Industry</i> , Medical Device & Diagnostic Industry Magazine (September 2000) (“Saab”)
Ex-1007	U.S. Patent No. 10,004,622 (“Sanati”)
Ex-1008	Dr. David H. Deaton, <i>Image-Guided Thrombectomy in Vascular Surgery</i> , Endovascular Today (July 2005) (“Deaton”)
Ex-1009	U.S. Patent Number 9,131,874 (“Eliason”)
Ex-1010	Daniel J. Scott, et al., <i>A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock</i> , The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1 (July 2013) (“Scott”)
Ex-1011	U.S. Publication Number 2015/0133892 (“Joe”)
Ex-1012	International Application Number PCT/US2011/033368 (“Eliason PCT Application”)
Ex-1013	U.S. Patent Pub. No. 2013/0060316 (“Sanati Publication”)
Ex-1014	X. Gu et al., <i>A New Technique for Sizing of Atrial Septal Defects</i> , Catheterization and Cardiovascular Interventions (1999) (“Gu”)
Ex-1015	Handbook of Endovascular Peripheral Interventions (C.D. Owens & Y. Yeghiazarians eds., Springer 2012)

Ex-1016	PCT publication number WO 2014/036530 to Bagaoisan ("Bagaoisan")
Ex-1017	U.S. Patent No. 8,088,121 to Nishide ("Nishide")
Ex-1018	U.S. Patent No. 5,607,394 to Anderson ("Anderson")
Ex-1019	U.S. Patent No. 5,779,731 to Leavitt ("Leavitt")
Ex-1020	U.S. Patent Publication No. 2008/0188803 by Jang ("Jang")
Ex-1021	John M. Mathis, et. al, <i>Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion</i> , American Society of Neuroradiology (November 1994) ("Mathis")
Ex-1022	U.S. Patent No. 4,846,174 to Willard et al. ("Willard")
Ex-1023	Patent Owner's Infringement Claim Charts filed in <i>Prytime Medical Devs., Inc. v. Front Line Med. Techs., Inc.</i> , Case No. 6:24-cv-00001, Dkt. No. 1-3 (W.D. Tex. Jan. 2, 2004)
Ex-1024	E.P. Gerstenfeld & J. Michele, <i>Pulmonary vein isolation using a compliant endoscopic laser balloon ablation system in a swine model</i> , Springer Science+Business Media, LLC (2010) ("Gerstenfeld")
Ex-1025	U.S. Patent No. 5,087,246 to Smith ("Smith")
Ex-1029	U.S. Patent No. 5,364,352 ("Cimino")
Ex-1030	Annotated Excerpt from Ex-2001 (Cimino Declaration)
Ex-1031	"Distal Catheter Section" Excerpts from Ex-2001 (Cimino Declaration)
Ex-1032	Transcript of Dr. Cimino's deposition held March 20, 2025 ("Cimino Deposition")
Ex-1033	U.S. Patent No. 7,993,366 to Yassinzadeh ("Yassinzadeh")
Ex-1035	Definition of "Secure," Webster's New Universal Unabridged Dictionary (1996)
Ex-1036	Printout of http://www.jcvaonline.com/ (04/09/2025)

Ex-1037	Printout of http://evtoday.com/about (04/09/2025)
Ex-1038	Printout of https://journals.lww.com/jtrauma/pages/aboutthejournal.aspx (04/09/2025)
Ex-1039	Printout of https://www.jscai.org/content/aims (04/09/2025)
Ex-1040	Printout of https://scai.org/publications/jscai-editorial-board (04/09/2025)
	Paper 12, Patent Owner's Response
	Paper 7, Institution Decision
	J. Michael Jaeger, et al., <i>Special Purpose Endotracheal Tubes</i> , Respiratory Care in June 1999 (Vol. 44, No. 6)
	https://www.microvention.com/products/scepter
	A. Metzner et al., <i>One-year clinical outcome after pulmonary vein isolation using the novel endoscopic ablation system in patients with paroxysmal atrial fibrillation</i> , Heart Rythm Society (2011)
	P. Neuzil & L. Sediva, <i>Balloon technology for catheter ablation of atrial fibrillation</i> , Cardioloy Dept., Na Homolce Hospital, Prague, Czech Republic, Cor Et Vasa 54 (2012) (available online at www.sciencedirect.com)