

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**FRONT LINE MEDICAL TECHNOLOGIES, INC.**  
**Petitioner**

**v.**

**PRYTIME MEDICAL DEVICES, INC.**  
**Patent Owner**

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**Case PGR2024-00028**

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

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**PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY**

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**EXHIBIT LIST**

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                            |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2001               | Declaration of William Cimino, Ph.D.                                                                                                                                                                          |
| 2002               | December 13, 2024 Deposition Transcript of Scott Resnick, M.D. FSIR                                                                                                                                           |
| 2003               | Curtis Franklin <i>curriculum vitae</i> (downloaded from <a href="http://www.linkedin.com/in/curtis-franklin-50215829">www.linkedin.com/in/curtis-franklin-50215829</a> )                                     |
| 2004               | David Spencer <i>curriculum vitae</i> (downloaded from <a href="http://www.linkedin.com/in/david-spencer-6732b740">www.linkedin.com/in/david-spencer-6732b740</a> )                                           |
| 2005               | Todd Krummenacher <i>curriculum vitae</i> (downloaded from <a href="http://www.linkedin.com/in/todd-krummenacher-36676a72">www.linkedin.com/in/todd-krummenacher-36676a72</a> )                               |
| 2006               | U.S. Patent No. 3,435,826                                                                                                                                                                                     |
| 2007               | U.S. Patent No. 3,467,102                                                                                                                                                                                     |
| 2008               | U.S. Patent No. 4,271,839                                                                                                                                                                                     |
| 2009               | U.S. Patent No. 4,338,942                                                                                                                                                                                     |
| 2010               | U.S. Patent No. 4,762,130                                                                                                                                                                                     |
| 2011               | U.S. Patent Application Publication No. 2018/0263655                                                                                                                                                          |
| 2012               | U.S. Patent Application Publication No. 2010/0274189                                                                                                                                                          |
| 2013               | Silicon Valley Innovations biography web page for Dr. Thomas J. Fogarty (available at <a href="https://svi-inc.com/dr-fogarty-bio/">https://svi-inc.com/dr-fogarty-bio/</a> ) (last visited January 13, 2025) |

## I. INTRODUCTION

Petitioner's Reply does not adequately rectify the Petition's deficiencies. To salvage its expert as a PHOSITA, Petitioner tries to mandate inclusion of MDs on the sole basis of their medical degree, ignoring the fundamental difference between using a medical device and designing or building one. Petitioner even has Dr. Resnick submit *post hoc* allegations of his catheter design experience, contradicting his own earlier testimony. Petitioner's arguments on claim construction and unpatentability vary between being unsupported, mischaracterizing the record in this proceeding, or contradicting the '737 Patent or Petitioner's other evidence and previous positions.

For at least the reasons provided in Patent Owner's Response and in further detail below, the PTAB should find the challenged claims not unpatentable.

## II. PHOSITA

### A. A Medical Degree Does Not Automatically Qualify One as a PHOSITA

Petitioner criticizes Patent Owner's PHOSITA definition for not expressly including individuals with medical degrees. Reply, 10-16. An MD, however, does not inherently possess the foundational training needed to design or build a catheter system.

The '737 Patent claims are directed to “the *design and construction* of a vascular occlusion catheter.” Ex. 2001, ¶ 25 (emphasis added). Dr. Cimino

therefore defined a PHOSITA using educational degrees he believes provide proper foundations in design, construction, materials, interaction, kinematics, and dynamics necessary for this type of device. *See e.g.*, Ex. 1032, 108:14-111:6, 122:19-124:13, 137:19-138:15. At least six years of “hands-on involvement in catheter design and development” can compensate for a lack of degree, as that experience provides “the fundamental concept of understanding the components and the design and the parts and the pieces and how they interact and how they are used in the body.” *Id.*, 112:11-113:8, 116:15-118:6. The parties agree an MD with such experience qualifies as a PHOSITA. POR, 14; Reply, 12. Patent Owner’s definition does not omit MDs based on their degrees – it excludes individuals ***lacking relevant training in catheter device design and development.***

Petitioner suggests MDs should nonetheless automatically qualify as PHOSITAs because they generally consult<sup>1</sup> and are “integral” to the development process. Reply, 12-13. But Dr. Cimino testified that MD involvement is typically limited to testing and evaluating devices and explaining performance needs and usage in patients. Ex. 1032, 39:13-41:6, 54:10-56:13, 57:19-58:20. Even Dr.

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<sup>1</sup> To the extent Petitioner suggests MD consultation should be required in the PHOSITA definition (Reply, 11-12), the parties agree such consultation is routine (*Id.*, 12; POR, 14), meaning it is implicitly covered by the stated experience levels.

Resnick admits that an MD's participation varies case-to-case. Ex. 1034, ¶¶ 9-10. Without specific evidence of an MD's participation level and "hands-on" involvement in actual design, the experience needed for understanding materials, kinematics, and other fundamentals for building the device is not automatically met. There is no need to explicitly recite a medical degree in the PHOSITA definition.

**B. Petitioner Confuses Use with Design**

Petitioner further criticizes Patent Owner's exclusion of catheter users. Reply, 14-16. As mentioned above, the claims recite a catheter system *structure*, not a method of use. See e.g., Ex. 1001, cl. 1 ("An occlusion catheter system comprising..."); Ex. 2001, ¶ 25. The design considers problems encountered by use, such as compressive forces from aortic blood pressure that could undesirably move the catheter, and provides *structural features* to address those concerns, e.g., securing the solid wire's proximal-most end within the proximal hub. Ex. 1001, 29:59-30:31, 35:4-32; Ex. 2001, ¶¶ 31-33. This mirrors the development process described above – MDs generally raise performance issues and design engineers create solutions.

Petitioner notes how several of its own asserted references are publications authored, edited, and directed to MDs. Reply, 13-14. But each listed article<sup>2</sup>

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<sup>2</sup> No patents are listed. *Id.*

concerns *using* a particular device, not detailed structural information. *See e.g.*, Ex. 1005, 636 (“Analysis of a New Technique”); Ex. 1008, 32 (describing expanded surgical capabilities of a new catheter). Dr. Resnick confirmed the references’ lack of structural detail when he admitted not knowing the specifics of Chengod’s or Deaton’s catheters, for example. Ex. 2002, 52:16-54:18. Petitioner cannot ignore the difference between using and actually designing/building a device.

**C. Dr. Resnick’s Belated and Contradictory Experience Disclosure Does Not Resuscitate His Testimony**

Petitioner touts, for the first time on reply, Dr. Resnick’s “over 20 years” of vaguely alleged experience working with medical device companies to design catheters. Reply, 17. Given the opportunity in his deposition to highlight this work, Dr. Resnick instead testified that he never designed a catheter (aside from assembling off-the-shelf components in a surgical setting). Ex. 2002, 14:5-15:16. Dr. Resnick also did not consider this experience important enough to mention in his CV. Ex. 1003, Appendix A. Dr. Resnick’s belated revelation of his “over 20 years” of design experience should receive little weight since it contradicts Dr. Resnick’s own prior testimony.

Petitioner also tries to remedy Dr. Resnick’s statements about what he or other practitioners might know about a catheter’s construction. Reply, 17-18. Dr. Resnick testified that despite using Fogarty catheters “many times,” Fogarty’s spring coil is not an element a user (like him) would be aware of since it is not “visible from the

exterior,” proving *use alone* is insufficient to qualify as a PHOSITA for catheter design and construction.<sup>3</sup> Ex. 2002, 39:7-40:15.

### III. CLAIM CONSTRUCTION

#### A. “proximal hub”

Petitioner alleges “proximal hub” should receive an overly broad “ordinary meaning” because the two exceptions for diverging from that interpretation (“express definition” or “disavowal”) are not met. Reply, 2. But an ordinary meaning is “understood by a person of ordinary skill in the art *when read in the context of the specification and prosecution history.*” *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (emphasis added) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*)). Petitioner ignores this factor in contesting Patent Owner’s interpretation and advancing its own.

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<sup>3</sup> This is not the first time Dr. Resnick has been asked to opine on an issue tangential to his actual training and experience. See e.g., *Luczak v. St. Mary’s Med. Ctr.*, No. A23-1548, 2024 Minn. Dist. LEXIS 338 \*11-13 (Minn. Ct. App., Apr. 29, 2024) (affirming lower court disqualification of Dr. Resnick from opining on standard of care for lacking practical experience in surgical and postsurgical treatment of a particular vascular condition).

Petitioner incorrectly alleges Patent Owner contravened *Phillips*. Reply, 2. Patent Owner only adopted Dr. Resnick’s definition *after finding it consistent with the ‘737 Patent specification and claims*. See POR, 25-26; Ex. 2001, ¶ 37; Ex. 1032, 62:9-13; Ex. 1001, 21:20-22, 22:58-63, 30:5-30. Petitioner further contends that “proximal hubs” may be configured for functions other than connecting an inflation device to an inflation lumen. Reply, 2. Patent Owner’s definition does *not* exclude other functions – as explained above, the specification and claims *require, at a minimum*, that the proximal hub physically connect an inflation device to the catheter’s inflation lumen. Petitioner’s revised definition contravenes the intrinsic record by making the main purpose of the proximal hub optional.

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

Petitioner contends Patent Owner’s “flow valve...” construction improperly imposes a method step by requiring that the valve “is opened and closed,” and that no construction is needed. Reply, 3. Patent Owner’s construction defines a flow valve as a manually or automatically *actuatable* valve that is opened and closed to permit and block fluid flow. POR, 28-29; Ex. 2001, ¶¶ 41-43. That is, the flow valve is *capable* of being actuated into open and closed states, owing to it being “configured to selectively fluidly communicate”. *Id.* Claim 1 does not recite a generic “valve” in isolation, but a *specific type* of valve with a *particular structural relationship* to other components. *Id.* The construction is necessary to differentiate

from other valve types with different structural features and capabilities. Ex. 2001, ¶¶ 42-44.

### C. Relationship between “flow valve” and “proximal hub”

The Federal Circuit recently reaffirmed that “‘where a claim lists elements separately, the *clear implication* of the claim language is that *those elements are distinct components of the patented invention.*’” *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1379 (Fed. Cir. 2025) (quoting *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010)) (emphasis added). “[T]o overcome *Becton*, there must be evidence that shows that the impliedly distinct components, instead, can be satisfied by a single component.” *Regeneron*, 130 F.4th at 1380. Moreover, “[t]he mere fact that there is an alternative embodiment disclosed in [a] patent that is not encompassed by a claim construction *does not outweigh the language of the claim*, especially when the court’s construction is supported by the intrinsic evidence.” *Id.*, 1380-81 (quoting *Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1382 (Fed. Cir. 2022)) (emphasis original). The ‘737 Patent specification supports the clear implication of separateness under *Becton*, despite Petitioner’s reply arguments.

Petitioner first argues that Fig. 42A supports the flow valve being a sub-element of the “proximal hub” because it allegedly discloses a “hub with a ‘stopcock (flow) valve’”. Reply, 4-5. Dr. Cimino testified that although a PHOSITA

understands the highlighted pieces in Fig. 42A are most likely where an inflation device would connect to the catheter lumen, their exact nature is unclear from their schematic depiction, and there is little detail in the specification. Ex. 1032, 64:15-78:22. Conversely, Dr. Resnick concludes these hand-drawn elements definitively show a “stopcock (flow) valve” without any explanation or citation to evidence. Ex. 1034, ¶¶ 58-59. Nothing in the record, besides Dr. Resnick’s conclusory opinion, demonstrates the ‘737 Patent intended to show an integrated proximal hub and flow valve in Fig. 42A.

Petitioner also points to other alleged “hubs with valves” in the specification to support its interpretation. Reply, 5-6. A PHOSITA would not find these unrelated structures relevant to understanding the relationship between the claimed proximal hub and the flow valve, and Petitioner’s analysis effectively reads features out of the claim. POR, 26-30, 46-48; Ex. 2001, ¶¶ 38-44.

Petitioner further contends the prosecution history confirms its position because original claim 1 was “broadened” from “a proximal hub having a flow valve” to “a proximal hub” and “a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device”. Reply, 6. To the contrary, this amendment indicates intent to claim the proximal hub separately from the flow valve. The amendment not only separated the two components but added language establishing a specifically defined spatial relationship – the flow valve must be

between the proximal hub and the inflation device. *See e.g.*, Ex. 2001, ¶¶ 61, 66-67; Ex. 1032, 92:13-94:6. Petitioner’s unsupported “broadening” theory ignores this added language, which is not outweighed by Petitioner’s suggestion of a combined embodiment. *Regeneron*, 130 F.4th at 1380-81; *Kyocera*, 22 F.4th at 1382.

#### D. “a distal catheter section”

Petitioner defends the PTAB’s “distal catheter section” construction (“the portion including the elements located distal of the intervening occlusion balloon”) as “consistent with the claim language.” Reply, 7-8. However, a PHOSITA understands the claim creates a distinction between a catheter and the overall system, which includes other components not considered part of the catheter. POR, 31; Ex. 2001, ¶ 46.

Petitioner also argues, without explanation, that Patent Owner’s construction contradicts the “terminating with an atraumatic tip” language. Reply, 8. The specification shows a distal catheter section as a shaft that terminates in an atraumatic tip. *See, e.g.*, Ex. 1001, 31:54-64;

Fig. 15 (at right). Petitioner further objects to reliance on “distal catheter member 520,”

but *once again* does *not* provide any intrinsic

evidence to the contrary or in support of its own, overbroad interpretation. Reply,

8.

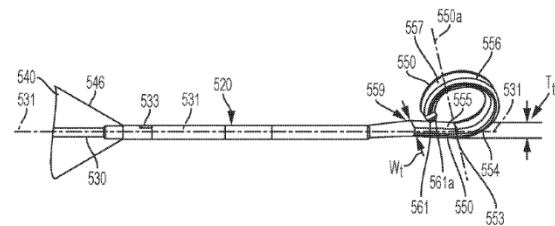


FIG. 15

Petitioner next protests an alleged “negative limitation, which rules out any ‘non-shaft’ portion of a catheter from being part of the ‘distal catheter section.’” Reply, 9. Patent Owner did not propose a negative limitation – the construction is “a distal portion of the catheter.” POR, 31; Ex. 2001, ¶ 45. The remaining discussion relates to what a PHOSITA would understand to be covered or not by that definition, particularly considering the PTAB’s erroneous initial construction incorporating structures that are *not* part of a catheter. POR, 31; Ex. 2001, ¶¶ 45-46.

Petitioner also contends the specification teaches “a distal catheter section includes a ‘stiffening member, such as a nitinol wire.’” Reply, 9. This quote is misleading because Petitioner omits a critical term: “*separate* stiffening member, such as a nitinol wire.” Ex. 1001, 52:28-32 (emphasis added). Petitioner further contends the specification discloses “an atraumatic tip formed by a nitinol wire” (Reply, 9), but the cited passages contain no such teaching. Ex. 1001, 23:66-24:1, 51:29-33, 52:28-32.

**E. “a solid wire, secured at a proximal-most end thereof within the proximal hub”**

Petitioner initially argues construing “without an internal lumen” is unnecessary because “it is not germane to any disputed issue.” Reply, 10. But Petitioner’s Reply makes it an issue by substituting a new component in Fogarty for the stylet as the claimed solid wire. *See* Section IV.B.2, below. Moreover, even if “without an internal lumen” is a “negative limitation,” section IV.B.2 nevertheless

explains why the specification supports such a feature. As such, Patent Owner's proposed definition for "solid wire..." should be adopted.

Petitioner then misconstrues the specification to argue that "secured" is an alternative to, and not the same as, "fixedly coupled." Reply, 10. The specification provides:

The inflation catheter member 510 is coupled to the proximal hub 590 and *the proximal end of the stiffener member or 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. ... *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, 35:4-28 (emphasis added). A PHOSITA understands from this passage that adhesive bonding or “otherwise fastened, secured, or fixed” are all *forms of fixed coupling*, not alternatives. *Id.*; Ex. 2001, ¶¶ 48-49.

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

#### IV. FOGARTY

##### A. Petitioner’s Conclusory and Belated Arguments Do Not Demonstrate a Reasonable Expectation of Success

Petitioner failed to demonstrate that a PHOSITA would have a reasonable expectation of success modifying Fogarty’s multi-component catheter shaft to the claimed diameter. POR, 35-36. The Petition relied on Chengod and Deaton’s mere existence to conclude “there is no question whether *a* Fogarty catheter with size less than 6 Fr would work. It did.” Pet., 40 (emphasis added). Petitioner’s first Reply argument reiterates this bare-bones contention – Chengod and Deaton prove *any Fogarty catheter, regardless of construction*, could successfully be made to fit

within 6 Fr. Reply, 19. Petitioner now adds, “to the extent those structures differed from the device in the Fogarty patent [], the PHOSITA could make the same modifications used to arrive at Chengod and have a reasonable expectation the resulting device will work as intended.” *Id.*

Petitioner fails to specify what “modifications” might be necessary,<sup>4</sup> and ultimately adds no substance to its conclusory assumption that a feature’s general existence in the art alone proves a reasonable expectation of success in modifying a particular device. *See e.g., KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art”). Petitioner cannot satisfy its burden through such cursory statements. *See e.g., In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

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<sup>4</sup> To the extent Petitioner suggests, *e.g.*, removing the coil to facilitate resizing, a modification that would nullify a primary reference’s object is improper. *See e.g., Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, Appeal No. 2013-007786 (PTAB Jan. 17, 2014), 10-12 (*aff’d by Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 Fed. Appx. 755 (Fed. Cir. 2015)). Fogarty’s coil 10 is one of the main features of its invention. Ex. 2001, ¶ 55; Ex. 1004, 1:29-65; 3:69-73; 4:6-17.

Petitioner attempts to remedy this deficiency by citing a new reference, Yassinzadeh, to show “a catheter that is less than 6 Fr and that includes a similar spring coil construction” to Fogarty. Reply, 19-20. Under 37 C.F.R. § 42.23, replies may only respond to the preceding brief, and “respond” “does not mean proceed in a new direction with a new approach as compared to the positions taken in a prior filing.” Consolidated Trial Practice Guide (Nov. 2019), 74.

Examples of indications that a new issue has been raised in a reply include new evidence necessary to make out a *prima facie* case for the patentability or unpatentability of an original or proposed substitute claim, such as newly raised rationale to combine the prior art references that was not expressed in the petition.

*Id.* (citing *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369–70 (Fed. Cir. 2016)). Yassinzadeh is precisely this type of new evidence, as Petitioner bears the burden of showing a reasonable expectation of success. *Intelligent Bio-Sys.*, 821 F.3d at 1367-68. The PTAB previously properly ignored a reply exhibit that could have been submitted with the petition to support expectation of success arguments. *Qiagen N. Am. Holdings, Inc. v. Handylab, Inc.*, 2021 U.S. App. LEXIS 32391, \*9-13 (Fed. Cir. Oct. 29, 2021).

The Petition relied on Chengod and Deaton to support the bare conclusion that “a Fogarty catheter,” not the specific catheter in Fogarty (Ex. 1004), sized less than

6 Fr. “would work.” Pet., 40. Petitioner’s Reply belatedly introduces Yassinzadeh for its revised reasonable expectation of success theory focused on Fogarty’s particular catheter. Reply, 19-20. The PTAB should disregard Yassinzadeh and the related analysis in the Reply and Dr. Resnick’s second declaration as improper for not being raised in the Petition.

Even if presented timely, Yassinzadeh does not provide a PHOSITA with a reasonable expectation that Fogarty could successfully perform its intended procedures if modified to have an uninflated outer diameter less than 6 Fr. Petitioner asserts the mere presence of a particularly-sized tensioning element, dilator, and shaft in Yassinzadeh’s catheter analogize it to Fogarty. Reply, 19-20. Yassinzadeh, however, is constructed to perform percutaneous sealing of vascular puncture sites (Ex. 1033, 1:18-21) and is not indicated for multiple uses, unlike Fogarty’s *reusable* catheter, built with the necessary durability and strength to withstand *repeated* advancement through tortuous vasculature for venous thrombectomy and/or arterial embolectomy procedures (Ex. 1004, 1:49-51, 2:33-39). Yassinzadeh’s single-use catheter advances once through a skin surface opening, fascia tissue tract, and the wall puncture site. Ex. 1033, 10:12-17. A PHOSITA would not understand Yassinzadeh’s size to be a reasonable barometer as to whether Fogarty’s catheter could be similarly reduced while still being capable of performing its intended functions.

**B. Fogarty Lacks the Claimed Solid Wire Under Petitioner’s Original and Latest Theories**

**1. Fogarty’s Stylet Must Be Removed, and is Not “Secured”**

As explained in section III.E, above, the intrinsic record demonstrates the term “secured” was not intended to cover removable attachment. Fogarty’s metal stylet 40 must indisputably be removably attached to the syringe fitting 32, or else the balloon cannot be inflated. POR, 39-40, Ex. 2001, ¶ 85. Petitioner argues this construction of “secured” improperly incorporates limitations from specification embodiments (Reply, 22), but once again fails to provide any intrinsic record support for anything to the contrary.

Petitioner also argues the stylet 40 is not absent during Fogarty’s normal operating conditions because it can be present during insertion. Reply, 22. While Fogarty’s stylet 40 can be used during *preparation*, it must be absent for performing its intended procedure (*e.g.*, venous thrombectomy or arterial embolectomy), when the balloon must be inflated and the normal operating conditions are encountered. POR, 39-40, Ex. 2001, ¶ 85.

**2. Petitioner’s Reliance on Fogarty’s Coil is Late and Does Not Disclose the Claimed Solid Wire**

Petitioner alternatively argues that Fogarty’s “coil 10” discloses the claimed solid wire. Reply, 22-24. The Petitioner never references Fogarty’s coil 10 at all, let alone in connection with the claimed solid wire. *See e.g.*, Pet., 38-40. Dr. Resnick only mentions coil 10 as part of Fogarty’s catheter forming a lumen, not for

the solid wire. Ex. 1003, ¶¶ 82-89. Switching to an entirely different element in Fogarty to complete the obviousness rationale is improper for a reply. *See e.g., Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330-31 (Fed. Cir. 2019) (petitioner “may not raise in reply an entirely new rationale for why a claim would have been obvious”) (internal citations and quotations omitted); *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367-68 (Fed. Cir. 2015) (affirming PTAB’s rejection of reply’s reliance on previously unidentified reference portions to make a meaningfully distinct contention); *Vizio, Inc. v. Polaris PowerLED Techs., LLC*, IPR2024-00073, Paper 32, 32-34 (PTAB Feb. 25, 2025) (rejecting impermissible reply argument that added previously uncited prior art components for relevant claim feature, citing *Henny Penny* and *Ariosa*). The PTAB should disregard this argument in the Reply and the supporting portions of Dr. Resnick’s second declaration as impermissibly changing the obviousness theory and creating a meaningfully distinct contention.

Even if the argument were timely, Fogarty’s “coil 10” is not a “solid wire”, as claimed. The solid wire appears in the embodiment of Figs. 12-18 as a preferred type of stiffener member 530 secured to the proximal hub and extending longitudinally through the inflation catheter member 510 along the longitudinal axis 531 of the stiffener member 530, which substantially comprises the longitudinal axis 531 of the catheter system 500. Ex. 1001, 29:59-30:8. The specification explicitly

recites that “the *alternative* embodiment described herein with reference to Figs. 12-18 includes the stiffener member 530, *preferably the solid wire, instead of a tube with a lumen.*” *Id.*, 30:61-64 (emphasis added).

For example, in the embodiment shown in Figs. 5-6 (reproduced below), a first lumen 230 *extends longitudinally* through the first catheter member 130, which is coupled to the proximal hub 190 and at the third catheter member 120, thereby fluidly communicating a third lumen 220 with the first fluid pathway 192 of the proximal hub 190. *Id.*, 21:65-22:9.

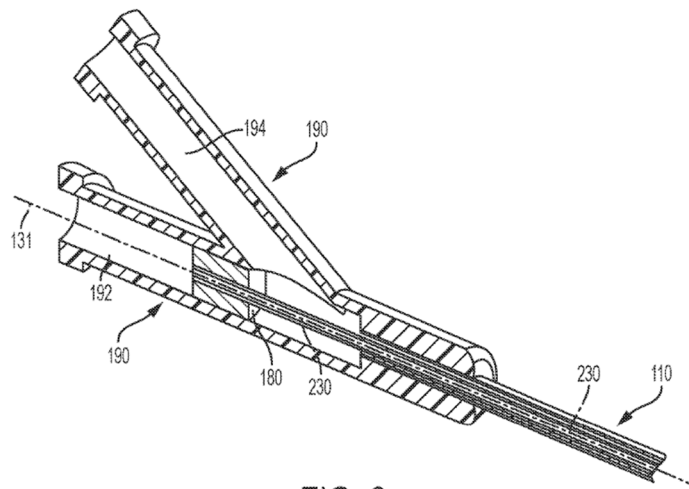


FIG. 6

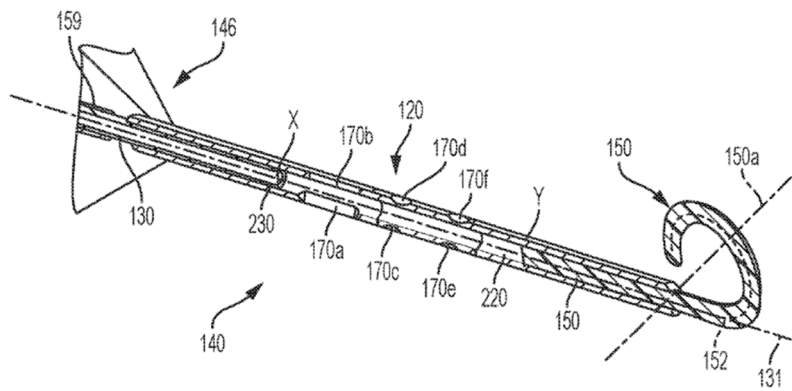


FIG. 5

Conversely, in Figs. 12-18, “[t]he stiffener member 530 implementation ***without a lumen removes the fluid communication with a third lumen.***” *Id.*, 31:6-8 (emphasis added). “Since the solid stiffener member 530 ***has no lumen, no fluid pathway is needed in the portion 592*** that holds the stiffener member 530.” *Id.*, 35:27-30 (emphasis added). Thus, in contrast to earlier-described catheter members having internal lumens extending longitudinally therethrough, the specification teaches that a solid wire does not have an internal lumen extending longitudinally therethrough. Petitioner previously acknowledged this interpretation while arguing that Fogarty’s wire stylet is solid ***and not hollow***. Pet., 39-40 (“the use of a ***hollow wire (i.e., 'tube with a lumen', as distinguished in the '737 Patent*** (Ex-1001, 30:61-64)) is counter to basic medical device manufacture goals as it would create a larger profile .... Furthermore, a hollow stylet creates an opportunity for the stylet to kink or collapse upon itself ***not afforded by a similar device of solid construction***”) (emphasis added).

On the other hand, Fogarty’s coil 10, and more specifically, “the spring wire that makes up the coil 10” (Ex. 1034, ¶ 104) creates the lumen the claimed “solid wire” of the ‘737 Patent specifically avoids. *See e.g.*, Ex. 1004, 1:15-17 (“The catheter ***has a metal lumen comprising a wire coil*** to prevent damage from the repeated insertion of a wire stylet”); 1:66-67 (“The present catheter body has ***a hollow inner core formed of a metal wire coil***”); 3:19-25 (“***an inflating fluid***”

*introduced into the proximal end of the lumen of coil 10* will pass freely through the separated turns and inflate this portion of the balloon as shown”); 4:38 (“A catheter comprising *a wire coil forming a lumen* in the catheter”) (all emphasis added).

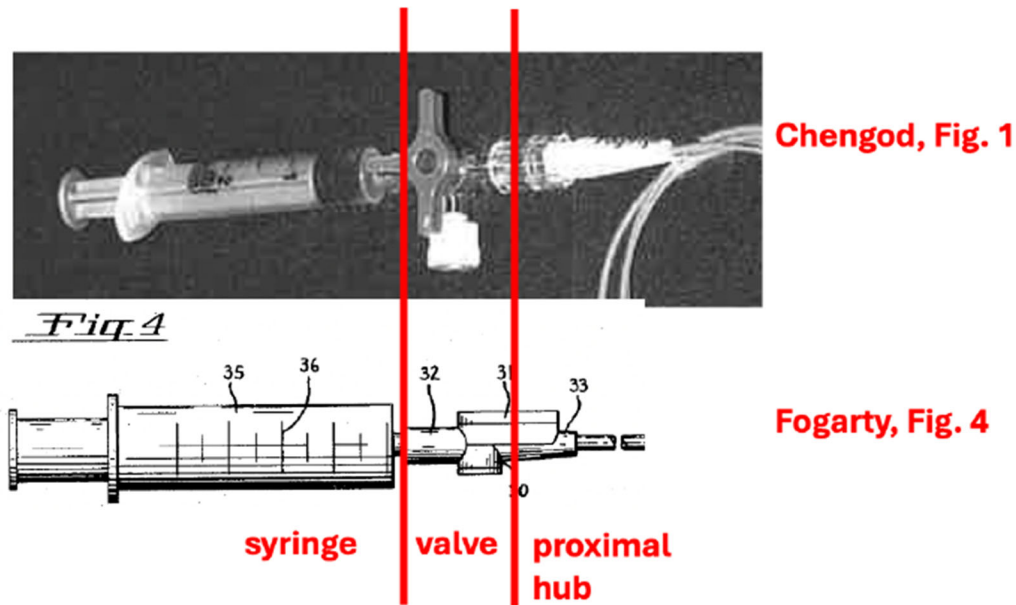
Therefore, a PHOSITA would not equate Fogarty’s coil 10 with the claimed “solid wire.”

**C. Petitioner’s Late Obviousness Argument for Separating the Flow Valve and Proximal Hub Lacks Rational Basis**

Petitioner next argues that even if the flow valve must be between the proximal hub and the inflation device, it now would have been obvious to modify Fogarty to this configuration, based on Chengod. Reply, 25-28. The Petition relied on Fogarty alone as expressly disclosing the proximal hub and flow valve arrangement. Petition, 32-34. This change in theory is improper for a reply as it presents a “meaningfully distinct contention.” *See e.g., Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1366-67 (Fed. Cir. 2023) (affirming disregard of reply argument that it would have been obvious to modify a reference to arrive at the relevant feature when petition previously argued reference disclosed the feature); *Intelligent Bio-Sys.*, 821 F.3d at 1369-70 (affirming disregard of reply argument that it would have been obvious to modify a reference to include relevant feature where petition previously argued reference disclosed that feature); *Colas Sols., Inc. v. Blacklidge Emulsions, Inc.*, 759 Fed. Appx. 986, 991-92 (Fed. Cir. 2019) (affirming disregard

of reply argument that changed unpatentability theory from inherency to “overlapping ranges”); *SMA Solar Tech. Am., LLC v. Tigo Energy, Inc.*, IPR2023-00879, Paper 31, 24-29 (PTAB Oct. 28, 2024) (disregarding reply argument that it was obvious to modify reference to include a limitation when petition argued the reference expressly disclosed the feature). The PTAB should disregard this argument in the Reply and the supporting portions of Dr. Resnick’s second declaration for fundamentally changing the unpatentability theory from the original Petition arguments.

Even if timely presented, a PHOSITA would not reconstruct Fogarty’s integral shut-off valve 30 into separate and distinct components. While Petitioner broadly contends that choosing between integral and separate constructions represents a limited design choice (Reply, 26), a principal object of Fogarty is to provide a catheter with increased strength and durability to withstand repeated usage, which includes having an *integral* shut-off valve. Ex-1004, 1:49-63. Reconstructing Fogarty’s catheter to provide a valve upstream and separate from the “proximal hub” ignores this object by unnecessarily adding potential failure points to a catheter constructed for repeated usage. *Id.*, 1:31-32, 49-63. A PHOSITA would not modify Fogarty in the suggested manner. *See e.g., Plas-Pak*, Appeal No. 2013-007786, 10-12.



Moreover, Petitioner's proposed modification to Fogarty would necessarily relocate the connection point of the stylet 40 to the *inlet of the valve*, *i.e.*, at the same connection point as the syringe in Chengod, and *not* within the alleged "proximal hub." Petitioner has failed to explain how Fogarty could be further modified to teach the claimed "solid wire, *secured at a proximal-most end thereof* within the proximal hub" after separating Fogarty's flow valve and proximal hub in the manner suggested.

#### **D. Petitioner's Conclusory Claim 2 Argument is Substantively Unchanged**

Petitioner's explanation of its claim 2 obviousness argument over Fogarty suffers from the same deficiency as in the Petition. Petitioner merely reiterates that asymmetrical compliant balloons were known (Reply, 28-29), which is insufficient to prove obviousness. *Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97

F.4th 882, 886 (Fed. Cir. 2024). The only difference is Petitioner swapped out “could” for “would.” Reply, 28-29. This superficial change does not elevate Petitioner’s conclusory analysis to the level of “some articulated reasoning with some rational underpinning” needed to find the claim obvious. *KSR*, 550 U.S. at 421; *Virtek*, 97 F.4th at 886-888.

## V. ELIASON

### A. The Wire is Not Considered the Catheter

Petitioner contends there is no dispute Eliason’s wire structures constitute a “distal catheter section” under the PTAB’s construction of that phrase (Reply, 29), but that interpretation is wrong for the reasons set forth above in section III.D. Petitioner then contends “Dr. Resnick did not agree that ‘catheter’ means ‘the shaft of the device.’” *Id.* In contrast, ***Dr. Resnick’s exact testimony states “[t]he catheter is the shaft of the device.”*** Ex. 2002, 26:19-21 (emphasis added). He made no subsequent mention of a wire being part of the catheter and even recited the balloon as a separate element: “The balloon in question is mounted ***on the catheter.***” *Id.*, 26:22-27:3 (emphasis added). Dr. Resnick later referred to “the catheter” and “wire” as separate elements when discussing Eliason: “wherein the device is a single unit and ***the catheter*** and ***associated wire device*** are all attached at the securement bead.” *Id.*, 71:13-72:5 (emphasis added). This is all consistent with Eliason, which describes, *e.g.*, how the lumen that receives the wire “***extends the length of the***

*catheter*,” suggesting the catheter terminates where the lumen ends, while the wire extends further. Ex. 1009, 5:58-64 (emphasis added). Securing a wire to a catheter does not bring the wire into a PHOSITA’s definition of “the catheter.” Ex. 2001, ¶¶ 108-111. Petitioner therefore still has not shown Eliason to have a solid wire extending into a distal catheter section, as claimed.

**B. Petitioner’s Late Obviousness Argument for Separating the Flow Valve and Proximal Hub Lacks Rational Basis**

Petitioner briefly contends that having a separate flow valve and proximal hub is an “obvious variation” of Eliason, referencing the earlier Fogarty argument. Reply, 30. As with the Fogarty ground, the change from the Petition (alleging Eliason discloses the claimed arrangement (Pet., 60-61)), to the meaningfully distinct contention that the arrangement is obvious is improper for a reply. *See* section IV.C, above. The switch is even more egregious in this instance since the new obviousness argument requires Chengod (Reply, 30; Ex. 1034, ¶¶ 142-144), which the Petition never cited in combination with Eliason for claim 1 (Pet., 59-74). The PTAB should therefore disregard this argument in the Reply and the supporting portions of Dr. Resnick’s second declaration. *See* section IV.C, above.

Even if raised timely, Petitioner cited no rationale for relocating Eliason’s one-way valve 60 into a separate and distinct component. Such a modification would unnecessarily add potential failure points to Eliason’s catheter. Obviousness “concerns whether a skilled artisan not only *could have made* but *would have been*

*motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.” *Virtek*, 97 F.4th at 886 (quoting *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)) (emphasis original). Petitioner and Dr. Resnick provide no explanation of why a PHOSITA *would* have modified Eliason to employ separate flow valve and proximal hub elements.

### **C. Petitioner’s Claim 2 Argument is the Same as for Fogarty**

For its contention that claim 2 is obvious over Eliason, Petitioner’s Reply cites back to its Fogarty argument, with no further explanation. Reply, 30. This rebuttal fails for the reasons explained above in section IV.D.

## **VI. PETITIONER UNDERSTATES SAAB’S TEACHING AWAY**

Petitioner correctly summarizes (Reply, 31) that a reference does not teach away by expressing a preference for an alternative and not criticizing, discrediting, or otherwise discouraging investigation into the invention. *UCB, Inc. v. Actavis Labs. UT, Inc.*, 65 F.4th 679, 692 (Fed. Cir. 2023). But Petitioner understates Saab’s criticism of asymmetrical elastomeric balloons. Saab uses phrases like “unacceptable” and “precludes their use” when discussing low pressure balloons. *See e.g.*, Ex. 1006, 90-91. Saab is not advocating a mere preference for high pressure balloons – its overall tenor promotes high pressure balloon usage as superior to low pressure versions. Ex. 2001, ¶¶ 88-90. These criticisms satisfy the standard for “teaching away.”

## VII. CONCLUSION

For at least the reasons recited above and in its January 15, 2025 Response, Patent Owner requests that the PTAB find the challenged claims not unpatentable.

Date: May 21, 2025

Respectfully submitted,

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**CERTIFICATE OF WORD COUNT**

Pursuant to 37 C.F.R. §§ 42.24(c)(4) and 42.24(d), the undersigned certifies that, according to the “Word Count” tool in Microsoft Word, which was used to prepare this paper, the number of words in this Patent Owner’s Sur-Reply to Petitioner’s Reply is 5,400.

/Stephen E. Murray/

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**CERTIFICATE OF SERVICE UNDER 37 CFR § 42.6(e)**

I hereby certify that a true copy of the foregoing PATENT OWNER'S SUR-  
REPLY TO PETITIONER'S REPLY has been served in its entirety this 21<sup>st</sup> day of  
May 2025, by electronic mail on Petitioner's lead and back-up counsel, as follows:

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