

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

Case PGR2024-00028

Patent No. 11,857,737

PATENT OWNER'S PRELIMINARY RESPONSE UNDER
37 C.F.R. § 42.207

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I. INTRODUCTION

All grounds asserted against U.S. Patent No. 11,857,737 (“the ‘737 Patent”) are deficient because Petitioner haphazardly assigns components in the two primary prior art references (Fogarty and Eliason) to elements recited in independent claim 1. Petitioner’s approach fails to account for all of the claim’s elements together at the same time, impermissibly reads multiple claim terms on the same prior art component, and/or ignores key claim language, depending on the ground.

The ‘737 Patent relates to vascular occlusion catheter systems and claim 1 recites structural features, including, *inter alia*, a proximal hub, a flow valve configured to selective fluidly communicate the proximal hub with an inflation device, a distal catheter section distally terminating with an atraumatic tip, and a solid wire that extends from the proximal hub and into the distal catheter section. Petitioner’s grounds all rely on obviousness combinations using either Fogarty or Eliason as the primary reference, but Petitioner’s analysis conflates and/or overlooks the above-identified elements in claim 1 to the point that Petitioner cannot meet its burden to institute a post-grant review for the ‘737 Patent.

Claim 1 calls for ***both*** a flow valve that can selectively place the proximal hub in fluid communication with an inflation device ***and*** a solid wire extending from the proximal hub and into the distal catheter section. Fogarty cannot physically employ these two elements simultaneously, due to its construction where its metal wire stylet

passes through the valve, rendering the valve useless when the metal wire stylet is present within the Fogarty catheter. Fogarty teaches an old and outdated catheter system designed for repeated use. Before or between uses, the metal wire stylet is deployed within the catheter system for protection, but the practitioner must remove the wire before using the catheter system because the metal wire stylet blocks attachment of an inflation device and ***physically prevents the flow valve from being closed*** (*i.e.*, the valve must remain open because the metal wire stylet runs through the valve when present). In other words, during use, Fogarty's catheter system includes the selectively actuatable flow valve but no wire extending into portions of the catheter, while between uses, Fogarty provides the metal wire stylet within the catheter, but the flow valve cannot move. Fogarty does not and cannot employ a functional valve and a wire extending in the catheter system at the same time.

Claim 1 also separately recites the proximal hub and the flow valve, as well as a structural relationship between the two in that the valve selectively enables fluid communication to the proximal hub from an inflation device. Petitioner completely ignores the distinction and relationship between these claimed components when characterizing Fogarty. Petitioner reads Fogarty's valve body 30 ***onto both*** the claimed proximal hub and flow valve. Federal Circuit precedent cautions that separately recited structures in a claim should not be treated as one and the same. Here, Petitioner offers no argument, let alone evidence, to support its position that

Fogarty's valve body 30 may be equated with both the flow valve and the proximal hub.

Petitioner's characterization of Fogarty likewise ignores that the claimed flow valve is configured to "selectively fluidly communicate the proximal hub with an inflation device." Based on Petitioner's interpretation of Fogarty, the alleged "proximal hub" directly connects to an inflation device (a syringe) via a syringe fitting and is, therefore, in fluid communication with the syringe upstream of the valve *regardless of whether the valve is open or closed*. This does not meet claim 1. The remainder of Petitioner's obviousness analyses do not cure any of these deficiencies, and therefore Petitioner cannot show it is more likely than not that any claim of the '737 Patent would have been obvious over any of the Fogarty-based grounds (Grounds 1-4) in the Petition

Petitioner's Eliason grounds suffer from similar defects. For example, claim 1 of the '737 patent separately recites both a solid wire and a distal catheter section while further specifying that the solid wire *extends into* the distal catheter section. Petitioner relies on Eliason's endovascular wire 12 to read on both the solid wire *and* the distal catheter section in claim 1. This interpretation of Eliason is contrary to the Federal Circuit precedent about the presumption afforded to separately recited claim elements and leads to the nonsensical result of the endovascular wire 12 in

Eliason *extending into itself* in attempting to meet claim 1. Petitioner has, accordingly, not demonstrated that Eliason includes these features of claim 1.

Petitioner's characterization of Eliason also ignores the "selectively fluidly communicate the proximal hub with an inflation device" language for the flow valve, which is the same feature that Petitioner overlooked with Fogarty. Based on how Petitioner reads Eliason on claim 1, Eliason's alleged "proximal hub" directly connects to an inflation device (a syringe) in the branch upstream of the flow valve and is, therefore, in fluid communication with the syringe *regardless of whether the valve is open or closed*. As with Fogarty, this characterization of Eliason does not meet claim 1. The remainder of Petitioner's obviousness analyses do not cure any of these deficiencies, and Petitioner cannot show it is more likely than not that any claim of the '737 Patent would have been obvious over any of the Eliason-based grounds (Grounds 5-9) in the Petition.

For at least these reasons, described in further detail below, the Petition should be dismissed.

II. THE INVENTION OF THE '737 PATENT

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

blood vessel, thereby prioritizing and increasing upstream blood flow, *e.g.*, cerebral blood flow and blood pressure. *Id.* at 5:39-44.

The occlusion catheter is low profile to provide several advantages. For example, low profile occlusion catheters facilitate passage of the balloon across severe and remote vascular obstructions, including passage of the catheter through tortuous vasculature to a desired position within the body. *Id.* at 4:63-65, 24:27-45. In addition, the catheter's reduced maximum diameter in an uninflated configuration limits the size of the puncture in a patient's skin during insertion, thereby reducing the clinical requirements for medical professionals performing the procedure. *Id.* at 30:46-57.

Fig. 12 from the '737 Patent (reproduced below) illustrates an example of a portion of the claimed catheter system. The system includes a proximal hub 590 in fluid communication with a proximal catheter section 510. *Id.* at 29:59-65, 35:4-43. The system further includes a distal catheter section 520 that distally terminates in an atraumatic tip 550. *Id.* at 29:59-65. The atraumatic tip 550 may assume a linear configuration for introduction into a patient's blood vessel, but returns to a relaxed, essentially circular profile thereafter to inhibit the catheter's introduction into smaller vessels. *Id.* at 31:43-32:26. The proximal and distal catheter sections 510, 520 are connected to one another via the occlusion balloon 540. *Id.* at 31:43-46. Length markers (not shown) may be printed or etched onto an outside of the

proximal catheter section 510 to indicate to the physician a depth to which the catheter system has been inserted into the patient's body. *Id.* at 36:14-20.

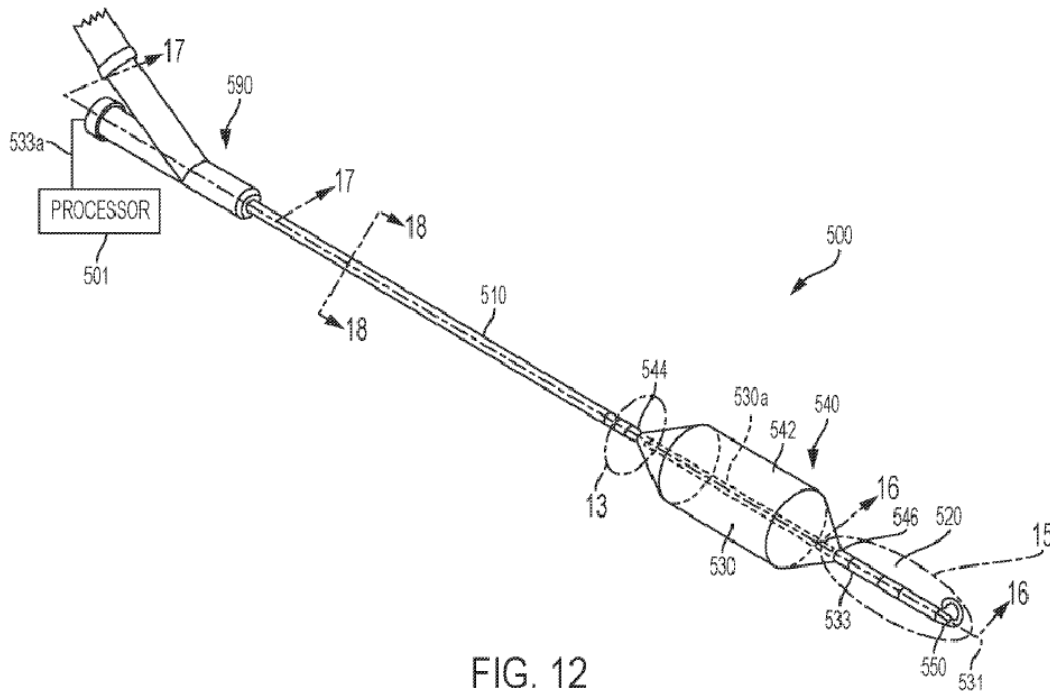


FIG. 12

An inflation lumen 610 extends through the proximal catheter section 510 from the proximal hub 590 to a space defined within the balloon 540 to convey inflation fluid between the balloon 540 and an external inflation device connected to a port of the proximal hub 590. *Id.* at 30:8-21. An example of the proximal hub 590 is shown more closely in Fig. 17 (reproduced below), where an inflation fluid pathway 594 communicates with the lumen 610 of the proximal catheter section 510. *Id.* at 35:32-43. The claimed system further has a flow valve configured to selectively communicate the external inflation device with the proximal hub. One example is explained in relation to Fig. 22, where a pressure source 802 (e.g., an

inflation device, such as a syringe) connects to a valve 828, which itself is positioned upstream of, and connects to, the occlusion catheter 710 at the proximal hub 590. *Id.* at 30:8-21, 36:57-37:7, 40:18-46. The valve 828 opens and closes to allow pressure from the fluid source 802 to blow-up or deflate the balloon 540. *Id.* at 40:27-35.

The claimed system also includes a solid wire 530 that not only allows for a lower profile of the catheter, but provides stiffness and flexibility to replace a

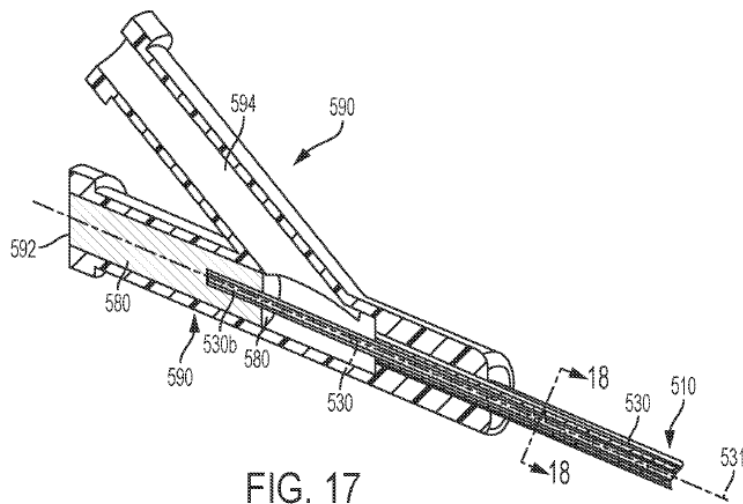


FIG. 17

guidewire, *i.e.*, the catheter can be maneuvered through the vasculature to the destination blood vessel location without requiring a guidewire. *Id.* at 11:46-50,

12:15-17, 13:44-48. As can be seen in Fig. 17 (*see above*), a proximal-most end 530b of the solid wire 530 is secured within the proximal hub 590 and extends from the proximal hub 590 within the proximal catheter section 510. *Id.* at 30:5-8, 35:5-32. Fig. 12 shows the solid wire 530 further extending within the balloon 540 and into the distal catheter section 520. *Id.* at 29:59-30:31. Based on the design of the proximal hub 590 and the placement of the solid wire 530, fluid from the external inflation device, gated by the flow valve, can enter the proximal hub 590 and

thereafter enter the proximal catheter section 510 and the balloon 540 without removal of the solid wire 530. *Id.* at 29:59-30:31, 34:18-43, 35:4-43, 40:18-46. With the claimed design, the occlusion catheter system can be sized to pass through a five to six French (Fr) percutaneous sheath. *Id.* at 30:32-60.

III. RELEVANT ASSERTED PRIOR ART

A. Fogarty

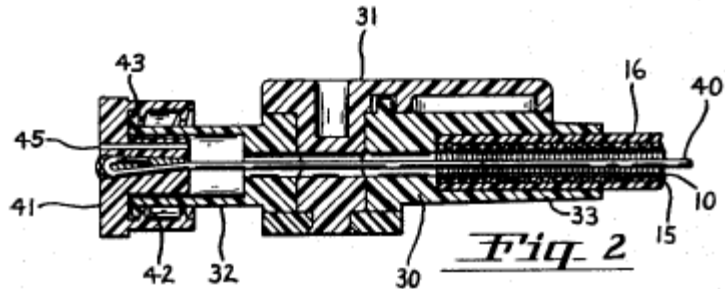
Fogarty issued in 1965 and is directed to an obsolete and now-considered unsanitary practice of using catheters repeatedly, *i.e.*, re-using catheters. *See e.g.*, Ex. 1004 at 1:49-51 (“general object of the present invention is, therefore, to increase the durability and strength of the catheter to withstand repeated usage”). This outdated practice involves inserting a metal wire stylet into the catheter tube during periods of non-use to prevent acute angulation of the catheter and afford a degree of protection. *Id.* at 1:29-35. Repeated introduction of the stylet into the catheter damages the catheter and prevents balloon inflation. *Id.* at 1:35-40. Fogarty’s main invention provides a catheter body tube having a lumen with a flexible metal wall to avoid such damage. *Id.* at 1:15-22, 51-65.

Fogarty’s catheter includes an outer plastic tube 16 shrunk onto a braid 15 of material covering the outer surface of a spring wire coil 10. *Id.* at 2:40-41, 57-70. The proximal end of the catheter tube 16 is secured to a shut-off valve having a body 30, a rotatable valve member 31, and a conventional fitting 32 configured to receive

a syringe 35 for inflating the balloon 20. *Id.* at 3:38-42. Upon reaching the desired balloon 20 inflation level, the valve 30 may be closed to hold the inflation. *Id.* at 3:46-48.

As previously described, the catheter also comes with a metal wire stylet 40 “used to protect the catheter *when it is not in use.*” *Id.* at 3:49-59 (emphasis added). A proximal end of the metal wire stylet 40 is secured in a cap 41, which selectively engages with the syringe fitting 32. *Id.* at 3:60-62. The stylet 40 may be inserted into the catheter via the syringe fitting 32 “[w]hen the valve member 31 is turned to open position.” *Id.* at 3:62-65.

Based on the above and as can be seen from Fogarty’s Fig. 2 (reproduced at right), the presence of the stylet 40 and its associated cap 41 in the syringe fitting 32 prevents connection of a syringe 35 for



inflating the balloon 20. ***The stylet 40 must be withdrawn from the catheter*** for a syringe 35 to be fluidly connected to the catheter via the single syringe fitting 32. Moreover, having the valve member 31 in the closed position prevents insertion of the stylet 40, so whenever the stylet 40 is present in the catheter, the valve member 31 must be in the open position. When the stylet 40 is present in the catheter, the

balloon 20 cannot be inflated, much less remain inflated, and the balloon 20 is unable to block any blood flow within the patient.

B. Eliason

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

The endovascular wire 12 includes a plurality of self-expanding wire struts 22 located proximal of the J tip 20 and extending between a leading securement bead 24 and a trailing securement bead 26, which are each mounted on the endovascular wire 12 for securing the wire struts 22. *Id.* at 8:53-57. The struts 22 are collapsed when traversing a transdermal insertion sheath 28, but in an expanded state, will shorten in length over the endovascular wire 12 between the beads 24, 26 to provide a self-centering function of the endovascular wire 12, keeping the J tip 20 away from blood vessel sidewalls and preventing unwanted turning. *Id.* at 8:61-9:12.

The occlusion balloon 14 is carried on a balloon shaft 32 having an internal lumen 42 that permits the balloon shaft 32 to pass over the endovascular wire 12. *Id.* at 9:31-41. A tapered distal end portion 44 of the balloon shaft 32 prevents the

balloon shaft 32 from extending beyond the trailing securement bead 26 on the endovascular wire 12 toward the J tip 20. *Id.* at 9:38-43.

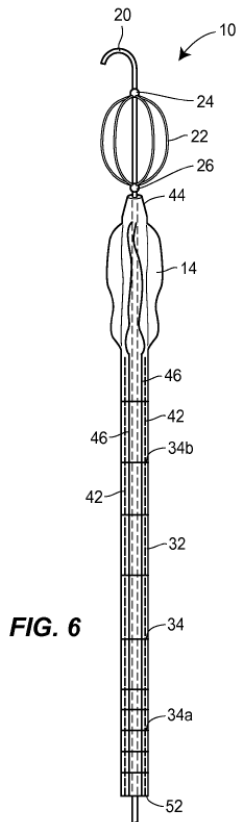


FIG. 6

The occlusion balloon 14 may be deployed over the endovascular wire 12 outside of the body, and subsequently inserted into the body together as a single unit, or the endovascular wire 12 may be advanced into the body first and the occlusion balloon 14 subsequently advances over the endovascular wire 12 within the body. *Id.* at 6:5-7, 7:45-52, 8:38-46. In either operation, the balloon shaft 32 only passes over the endovascular wire 12 to a stop surface defined by the trailing securement bead 26. As seen in Eliason's Fig. 6 (reproduced at left), no further tubes or lumens are provided over

the endovascular wire 12 between the trailing securement bead 26 and the distal end of the J tip 20.

The occlusion balloon 14 is inflated and deflated through a multi-port and valve assembly 36 that includes a terminating port 38 with a diaphragm 40 through which the endovascular wire 12 passes in a fluid-tight manner. *Id.* at 10:7-17. The multi-port valve assembly 36 also includes an elongate tubular barrel section 50 that is affixed to a proximal end of the balloon shaft 32. *Id.* at 10:17-20. The elongate tubular barrel section 50 includes a side port 58 and a branch 54 that enable a syringe

48 to connect with the multi-port and valve assembly 36. *Id.* at 10:33-36. A one-way valve 60 is provided near the side port 58 that is actuatable between open and closed positions to allow or prevent passage of inflation fluid. *Id.* at 10:36-44.

IV. PERSON OF ORDINARY SKILL IN THE ART

Petitioner proposed a definition for a person having ordinary skill in the art (“PHOSITA”) and alleged that the PHOSITA would have had prior knowledge of certain claim features. *See* Pet. at 10-30. ***Solely*** for purposes of this Preliminary Response, Patent Owner does not object to Petitioner’s definition of a PHOSITA. Patent Owner reserves the right to assert an alternative definition for a PHOSITA in this or another proceeding involving the ‘737 Patent, where appropriate. Patent Owner further disputes certain of Petitioner’s allegations regarding which, if any, features of the ‘737 Patent were within the PHOSITA’s knowledge. However, at this stage of the proceeding, such disputes have no bearing on the evidence and arguments presented in this Preliminary Response. Patent Owner reserves the right to rebut any of the arguments presented in section VII of the Petition, in this or another proceeding, where appropriate.

V. CLAIM CONSTRUCTION

Petitioner proposed construing the claim terms “proximal” and “distal” for purposes of this proceeding, but indicated no other express constructions are required to assess the prior art. Pet. at 9-10. While not necessarily agreeing with

these proposed constructions, at this stage of the proceeding, and *solely* for purposes of this Preliminary Response, Patent Owner does not object to Petitioner’s proposed constructions. Patent Owner reserves the right to assert alternative constructions for relevant claim terms in this or another proceeding involving the ‘737 Patent, where appropriate.

VI. PETITIONER CANNOT SHOW IT IS MORE LIKELY THAN NOT THAT AT LEAST ONE CLAIM OF THE ‘737 PATENT IS UNPATENTABLE BECAUSE THE PETITION IS DEFICIENT WITH RESPECT TO AT LEAST ONE ELEMENT OF INDEPENDENT CLAIM 1 FOR EACH GROUND

A petitioner bears the burden to “demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable,” otherwise the “Director may not authorize a post-grant review to be instituted.” 35 U.S.C. § 324(a). Petitioner has failed to meet this burden for at least the reasons described below.

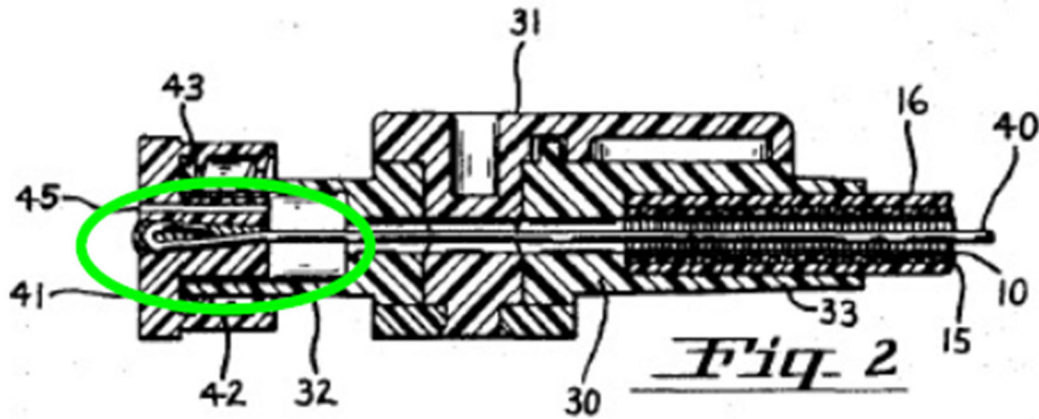
A. Ground 1 is deficient because Fogarty lacks aspects related to the proximal hub, flow valve, and solid wire recited in claim 1

Ground 1 of the Petition alleges that claims 1-10 of the ‘737 Patent would have been obvious over Fogarty, Chengod, and a PHOSITA’s knowledge. To arrive at this conclusion, Petitioner characterizes certain components in Fogarty as disclosing the “proximal hub,” “flow valve,” and “solid wire” recited in independent claim 1. Such characterizations omit key aspects related to these claim elements and improperly blend elements that are structurally distinct from each other.

1. Petitioner fails to demonstrate Fogarty simultaneously includes a functional flow valve and a wire extending within sections of the catheter

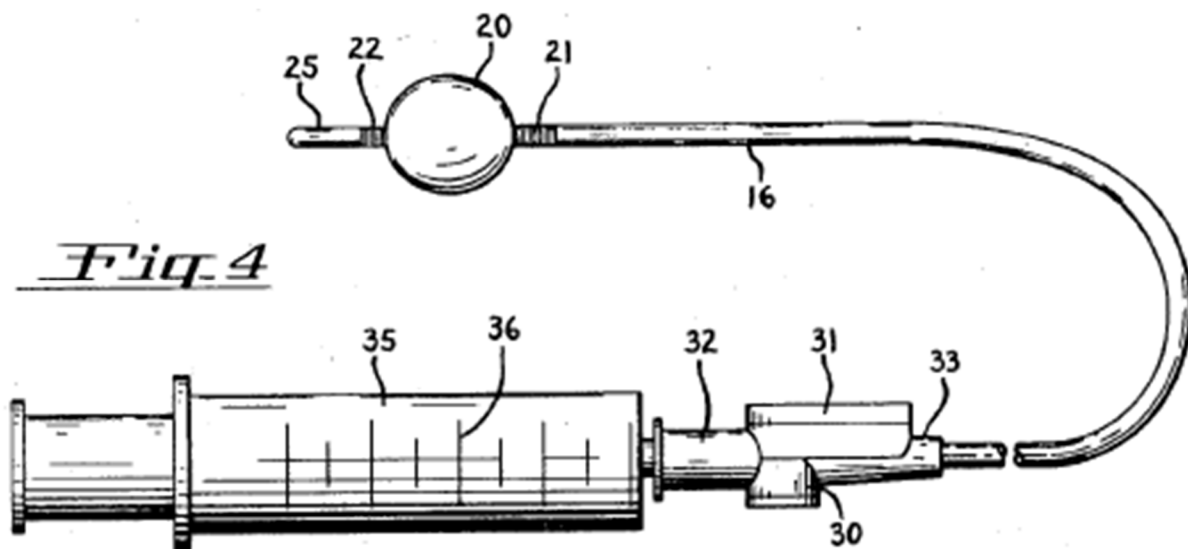
Independent claim 1 of the ‘737 patent requires *both* “a flow valve *configured to selectively fluidly communication the proximal hub with an inflation device*” *and* “a solid wire, secured at a proximal-most end thereof within the proximal hub, and *extending within the proximal catheter section, the occlusion balloon and into the distal catheter section.*” Ex. 1001 at cl. 1 (emphasis added). The claimed device includes a *functional* flow valve *while also* employing a solid wire *extending within the catheter*. This is *not* the case in Fogarty, which teaches multiple configurations of a catheter, none of which includes *both* the functional flow valve and the solid wire secured to the proximal hub simultaneously.

Petitioner alleges that “the [shut off] valve (30) [of Fogarty] is the claimed ‘flow valve’ and is ‘configured to selectively fluidly communicate the proximal hub with an inflation device’.” Pet. at 33-34. Petitioner also equates the metal wire stylet (40) with the claimed solid wire. *Id.* at 38 (*see also* Petitioner’s annotation of Fogarty’s Fig. 2, reproduced below).



Fogarty teaches an outdated practice from the 1960's of using catheters *repeatedly* and to insert a metal wire stylet *during periods of non-use* to prevent acute angulation of the catheter and to afford a degree of protection for the catheter between uses. Ex. 1004 at 1:30-35. An object of Fogarty's antiquated invention is to provide a catheter body which is not damaged by the *repeated insertion and withdrawal of the stylet*. *Id.* at 1:50-56. Petitioner's annotated version of Fogarty's Fig. 2 (above) shows the proximal end of the stylet 40 secured in a cap 41 that removably *engages with the syringe fitting 32 during periods of non-use* of the catheter. *Id.* at 3:60-65. *During such periods of non-use*, the stylet 40 is inserted *through the open valve 30* and secured in the catheter via mounting to the syringe fitting 32. *Id.* In contrast, when the catheter *is in use*, the *stylet 40 must be removed* so that the syringe fitting 32 can receive the syringe 35 to inflate the catheter balloon 20. *Id.* at 3:40-42, 60-65. After the balloon 20 is inflated, *the rotatable valve member 31 may close the valve 30* to hold the inflation, but the stylet cannot be within the catheter or the valve member 31 will not rotate. *Id.* at 3:38-48, Fig. 4

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



Fogarty's claim 4 confirms that the fitting 32 on the valve 30 is configured to **alternately receive a syringe 35** for inflating the balloon and **a cap 41 of the stylet 40**. *Id.* at cl. 4. As a result, during periods of non-use, the valve 30 must remain in the open position so that the stylet 40 can be advanced into the catheter and the cap 41 can be mounted to the syringe fitting 32. The presence of the stylet 40 **physically prevents the valve 30 from being closed**. Conversely, to use the catheter, **the stylet 40 must be completely removed** to allow the syringe 35 to attach to the **same syringe**

fitting 32. Accordingly (and as clearly seen from Fogarty's Fig. 2, above), not only is the valve 30 ***not selectively actuatable*** between open and closed positions when the stylet 40 is present, but Fogarty's catheter ***cannot*** utilize the stylet 40 ***while also*** fluidly connecting to the syringe 35, as both components require availability of the same syringe fitting 32. So, when the stylet 40 is installed, the valve 30 cannot ***selectively*** fluidly communicate anything, since it must remain open. When the valve 30 is selectively actuatable, there is ***no stylet 40 extending through the catheter***.

As part of an obviousness analysis, the prior art must teach or suggest the elements of the claim ***as arranged therein***. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (it is important "to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does"); *cf. Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (prior art reference must disclose elements "arranged as in the claim").¹ As explained above, Fogarty does ***not*** disclose or suggest the valve

¹ Although Ground 1 is based on obviousness and *Net MoneyIN* relates to anticipation, the Petition does not contend the simultaneous presence of a flow valve configured for selective actuation and a wire extending within the catheter was

and wire features as arranged in claim 1. The Petition does not rely on Chengod or the alleged PHOSITA's knowledge to remedy this deficiency. Petitioner only uses Chengod in claim 1 for the length marking and outer diameter features (elements "[1f]" and "[1i]"). Pet. at 36-37, 40-41, 45-46. Similarly, Petitioner only utilizes the alleged PHOSITA's knowledge to modify Fogarty's wire stylet into a solid wire and to assert the outer diameter feature. *Id.* at 39-41.

Petitioner has failed to demonstrate it is more likely than not that claim 1 (or any of claims 2-10 dependent therefrom) would have been obvious over Fogarty, Chengod, and a PHOSITA's knowledge because Fogarty does not disclose a *functional* flow valve *while also* employing a solid wire *extending within the catheter*, as is required by claim 1 of the '737 patent.

2. Petitioner improperly relies on a single element of Fogarty for two different and distinct structural elements in claim 1

Claim 1 also recites and separately names (i) a *proximal hub* and (ii) a *flow valve* as part of the occlusion catheter system. Ex. 1001 at cl. 1. Claim 1 further recites that the flow valve "is configured *to selectively fluidly communicate the proximal hub with an inflation device.*" *Id.* (emphasis added). Not only are these

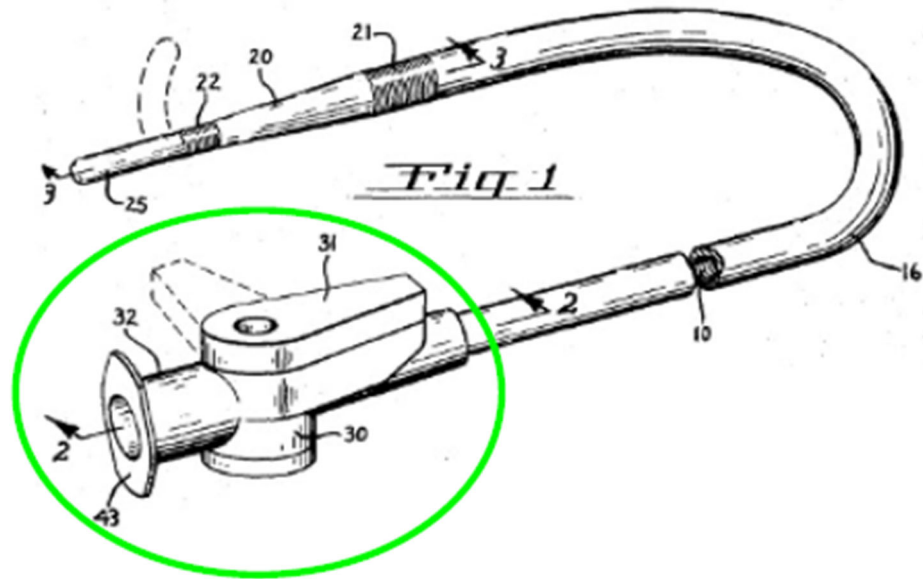
obvious – the Petition alleges "Fogarty *discloses*" these elements. Pet. at 33-34, 38-39 (emphasis added).

two structures recited separately, but the claim defines a specific functional relationship between them.

It is well settled that “[w]here a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.” *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254-55 (Fed. Cir. 2010) (*quoting Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004)); *see also HTC Corp. v. Cellular Communs. Equip., LLC*, 701 F. App’x. 978, 982 (Fed. Cir. 2017) (“separate naming of two structures in the claim strongly implies that the named entities are not one and the same structure”). Absent a properly supported explanation demonstrating to the contrary, Petitioner cannot rely on a common structure to meet two separately recited claim components. *See e.g., Gamber-Johnson LLC v. Nat’l Prods. Inc.*, IPR2021-01159, Paper No. 7 (PTAB Jan. 3, 2022) at 18-19 (“Petitioner offers no explanation or reasoning sufficient for its reliance on the same structure for different elements set forth in the claim”).

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

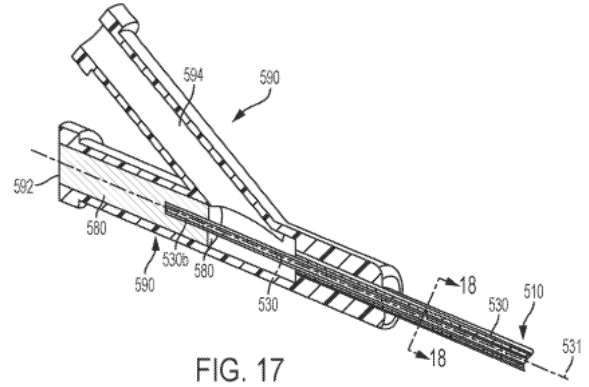
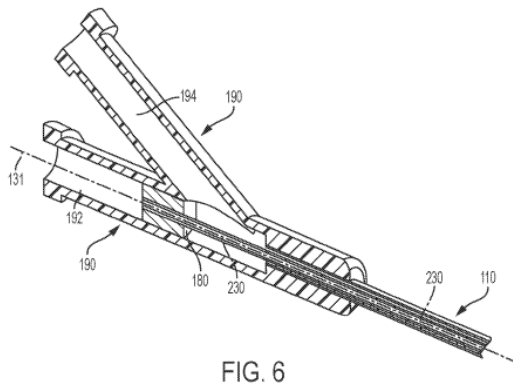
circles the components alleged to constitute the claimed proximal hub, confirming its position that the proximal hub includes the shut off valve 30. *Id.*



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

The Petition offers no explanation or reasoning, in any form, for its reliance on the same structure for different elements set forth in independent claim 1. Nor can it. The ‘737 Patent specification confirms that the flow valve is a separate element from the proximal hub. For example, the ‘737 Patent drawings show multiple embodiments of a proximal hub, a sampling of which is reproduced below, and none show or are described as having any type of selectively actuatable valve

forming part of the hub itself. *See e.g.*, Ex. 1001 at 25:60-26:12, 31:12-42, 35:4-43, Figs. 1, 6, 12, 17.



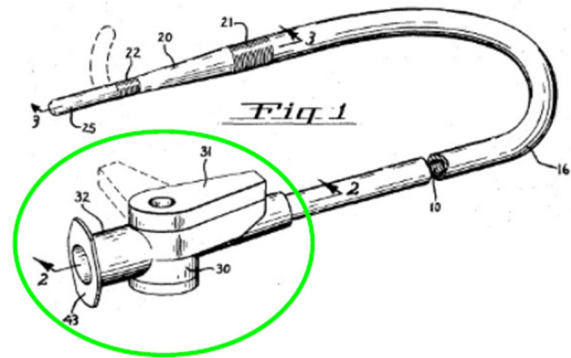
Similarly, examples in the specification of actuatable valves for selectively fluidly communicating the proximal hub to an inflation device (*e.g.*, fluid source) are described as separate from an occlusion catheter (710) containing the proximal hub, rather than coextensive with or as part of the proximal hub. *See e.g., id.* at 39:38-40:46, Figs. 21-22. As before, Petitioner's usage of Chengod and the alleged PHOSITA's knowledge fail to remedy the deficiency created by Petitioner's characterization of Fogarty for the proximal hub and the flow valve. Pet. at 36-37, 39-41, 45-46.

For at least the additional reason that Petitioner is reading Fogarty's valve on two separate and distinct elements in claim 1, Petitioner has failed to demonstrate it is more likely than not that claim 1 (or any of claims 2-10 dependent therefrom) would have been obvious under Ground 1.

3. Fogarty fails to teach or suggest a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device

The flow valve in claim 1 of the '737 Patent is specifically “configured to *selectively* fluidly communicate the *proximal hub* with an inflation device.” Ex. 1001 at cl. 1 (emphasis added). Contrary to Petitioner’s analysis, this language requires *more* than just the flow valve being capable of selectively fluidly communicating the inflation device with components of the catheter system *downstream of the proximal hub*, e.g., the proximal catheter section or any other distal component. Rather, in claim 1 the flow valve must be capable of selectively fluidly communicating the inflation device *with the proximal hub itself* as well as fluidly disconnecting the inflation device *from the proximal hub itself*. Fogarty, as characterized by Petitioner, does not teach the claimed flow valve configuration.

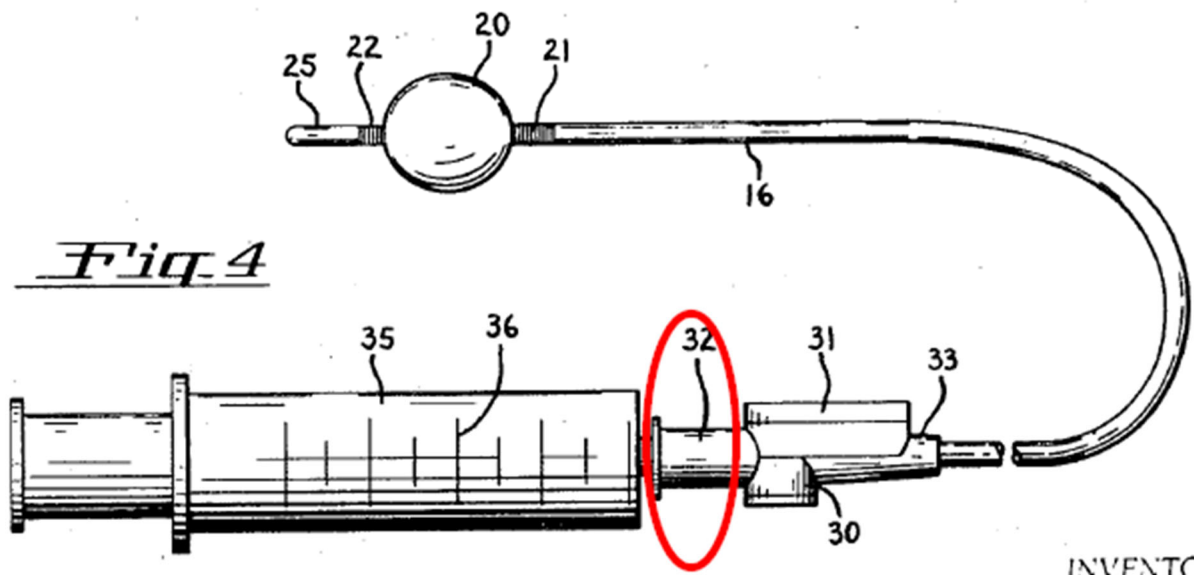
As described above, Petitioner equates the combination of Fogarty’s shut off valve 30, rotatable valve member 31, *syringe fitting (32), and hub flange*



elements (43) with the claimed proximal hub. Pet. at 33; *see also* Petitioner’s annotation to Fogarty’s Fig. 1, reproduced above. Petitioner further equates Fogarty’s shut off valve 30 with the claimed flow valve. Pet. at 33-34. Petitioner

relies upon Fogarty's disclosure that the valve fitting 32 (which Petitioner contends forms part of the proximal hub) "may receive a syringe 35 (i.e., an inflation device) for inflating the balloon... [and] [o]nce inflated, closing the valve maintains the inflation of the balloon" to ***mistakenly conclude*** that Fogarty teaches a flow valve configured to selectively communicate the proximal hub with an inflation device. *Id.*

As clearly shown in Fogarty's Fig. 4 (reproduced and annotated below), however, the valve fitting 32 (which Petitioner contends forms part of the proximal hub) is fluidly communicating with the syringe 35 (i.e., the inflation device) immediately upon receipt, ***regardless of the condition of the shut off valve 30.***



In other words, the shut off valve 30 ***does not and cannot*** control fluid communication between the syringe 35 and the syringe fitting 32, and, therefore the shut off valve 30 cannot ***selectively*** fluidly communicate Fogarty's alleged ***proximal***

hub (*i.e.*, the combination of the shut off valve 30, rotatable valve member 31, syringe fitting 32, and hub flange elements 43) as Petitioner contends, with its inflation device. In the claimed catheter, the flow valve prevents exposure of the proximal hub to any fluid in the inflation device (syringe) until the valve is opened. In contrast, as soon as Fogarty's syringe 35 is attached to the syringe fitting 32, the fluid in the syringe 35 contaminates the alleged "proximal hub" and Fogarty catheter. As before, Petitioner's usage of Chengod and the alleged PHOSITA's knowledge fail to remedy the deficiency created by Petitioner's analysis for the flow valve. Pet. at 36-37, 39-41, 45-46.

For at least the additional reason that Petitioner has not shown Fogarty's shut-off valve is configured for selectively fluidly communicating the proximal hub itself to an inflation device, Petitioner failed to demonstrate it is more likely than not that claim 1 (or any of claims 2-10 dependent therefrom) would have been obvious under Ground 1.

B. Ground 5 is deficient because Petitioner improperly conflates the distal catheter section with the wire and lacks the claimed configuration of the flow valve

Ground 5 of the Petition alleges that claims 1-10 of the '737 Patent would have been obvious over Eliason in view of a PHOSITA's knowledge. This contention relies upon Petitioner's application of Eliason's endovascular wire 12 to both the claimed distal catheter section *and* the solid wire, nonsensically resulting

in the endovascular wire 12 having to *extend into itself* according to claim 1. Petitioner cannot satisfy its burden based on this legal error. In addition, Petitioner's characterization of Eliason's components omits key aspects of the flow valve.

1. Petitioner improperly relies on a single element of Eliason for two different and distinct structural elements in claim 1

Independent claim 1 recites and separately names “*a distal catheter section* distally terminating with an atraumatic tip” and “*a solid wire*, secured at a proximal-most end thereof within the proximal hub, and *extending ... into the distal catheter section*”. Ex. 1001 at cl. 1 (emphasis added). Once again, two structures are not only recited separately from one another, but the claim language further defines a functional relationship between them, *i.e.*, the solid wire extends into the independently listed distal catheter section.

As explained above with respect to Ground 1, “[w]here a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.” *Becton*, 616 F.3d at 1254-55 (quoting *Gaus*, 363 F.3d at 1288); see also *HTC*, 701 F. App'x. at 982. It is improper to rely on a common structure to meet two separately recited claim components absent a properly supported explanation that such a presumption should be overcome. See *e.g.*, *Gamber-Johnson*, IPR2021-01159, Paper No. 7 at 18-19.

For the claimed distal catheter section, Petitioner primarily relies upon Eliason's Fig. 6 (Petitioner's annotated version reproduced at right) and circles the portion of the occlusion system 10 located distally of the occlusion balloon 14, which terminates with a "J tip" 20. Pet. at 61-62. For the claimed solid wire, Petitioner cites Eliason's endovascular wire 12 that extends through its tubular barrel section 50, balloon shaft 32, and occlusion balloon 14. *Id.* at 65; Ex. 1009 at 9:31-10:32, Figs. 6, 10. Petitioner conspicuously does **not** identify a reference numeral in Eliason corresponding to the claimed distal catheter section. Pet. at 61-62, 65.

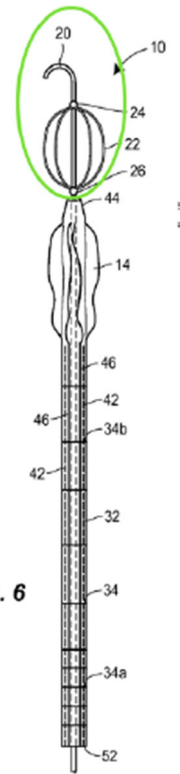


FIG. 6

Eliason explicitly teaches, however, that its occlusion system utilizes a self-centering endovascular wire 12 (with terminating "J tip" 20) that is advanced into the thoracic aorta before ***deploying the occlusion balloon 14 over the endovascular wire 12.*** Ex. 1009 at 7:45-51, 8:36-46. The balloon shaft 32 has an internal lumen 42, permitting the balloon shaft 32 to ***pass over the endovascular wire 12*** until a tapered distal end portion 44 of the balloon shaft 32 abuts the trailing securement bead 26. *Id.* at 9:38-43. As shown in Eliason's Fig. 6, above, and Fig. 10 (reproduced and annotated below), the trailing securement bead 26 is mounted ***on the endovascular wire 12.*** The portion of Eliason's occlusion system 10 that

Petitioner equates with the distal catheter section and which terminates in the J-tip 20 *is the endovascular wire 12 itself*. Therefore, Petitioner improperly equates a single element of Eliason, *i.e.*, the endovascular wire 12, with two separate and distinct elements of the claimed invention: the distal catheter section and the solid wire.

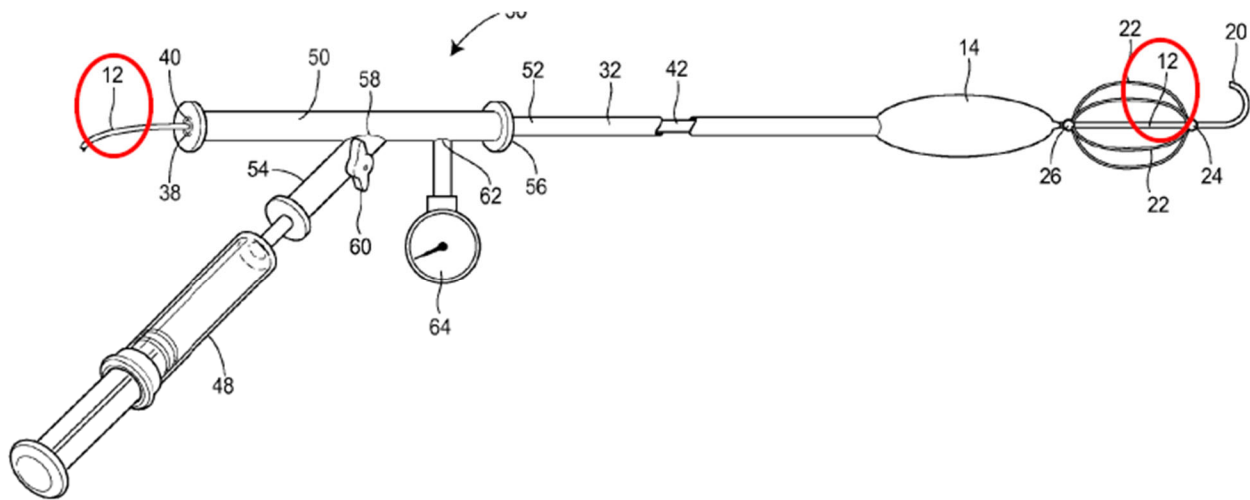
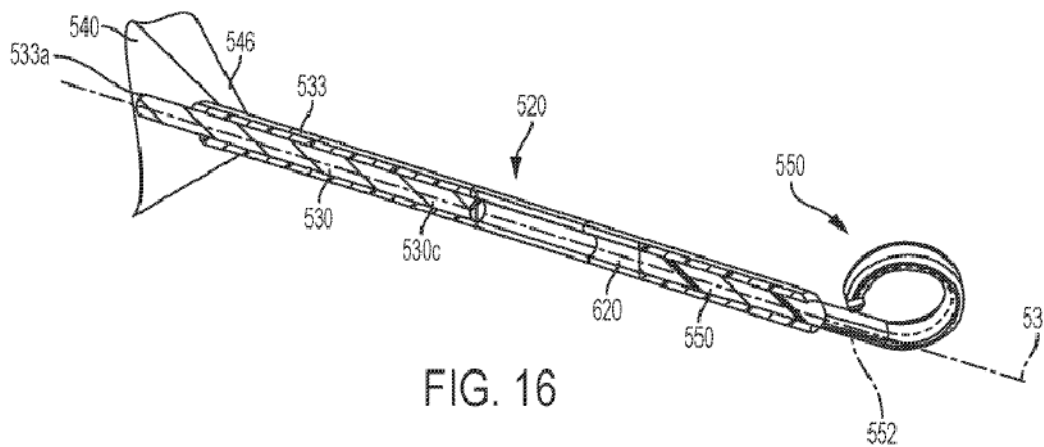


FIG. 10

The Petition offers no explanation or reasoning, in any form, for this structural characterization. First, Petitioner's assertion renders claim 1 nonsensical. By equating the endovascular wire 12 with both the claimed distal catheter section and the claimed solid wire, *Petitioner's position means the endovascular wire 12 extends into itself*, a physical impossibility. See *e.g.*, *Becton*, 616 F.3d at 1255 (rejecting interpretation that "hinged arm" and "spring means" are one and the same where the claim would then require the hinged arm be "'connected to' itself and must 'extend between' itself and a mounting means, a physical impossibility").

Second, the '737 Patent's specification confirms that the distal catheter section is a separate element from the solid wire. An example is visible in Fig. 16 (reproduced below), which shows a stiffener member 530 (*i.e.*, wire) "***coupled*** to at least a portion of the inner surface of ***the second lumen 620***" of ***the distal catheter member***. See *e.g.*, Ex. 1001 at 34:44-64 (emphasis added), 29:59-65, 30:3-31, 31:54-61, Figs. 15-16.



The specification does not portray any embodiment where the stiffener member (or solid wire) constitutes the distal catheter member or section. As explained above, that the wire ***extends into*** the distal catheter section precludes such a possibility.

The Petition does not rely on the alleged PHOSITA's knowledge to remedy this deficiency. Petitioner only utilizes the alleged PHOSITA's knowledge for making Eliason's endovascular wire solid and securing the wire at a proximal-most end within the proximal hub. Pet. at 66-71. For at least the reason that Petitioner is reading Eliason's endovascular wire 12 on two separate and distinct elements in

claim 1, Petitioner fails to demonstrate it is more likely than not that claim 1 (or any of claims 2-10 dependent therefrom) would have been obvious under Ground 5.

2. Eliason fails to teach or suggest a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device

As explained above in section VI.A.3, the flow valve in claim 1 is “configured to *selectively* fluidly communicate the *proximal hub* with an inflation device.” Ex. 1001 at cl. 1 (emphasis added). This claim language requires *more* than just the flow valve being capable of selectively fluidly communicating the inflation device with components of the catheter system *downstream of the proximal hub*. Eliason, as characterized by Petitioner, does not teach the claimed configuration of the flow valve.

Petitioner characterizes Eliason’s multi-port and valve assembly 36 as the claimed proximal hub and Eliason’s syringe 48 as the claimed inflation device. Pet. at 60. Petitioner acknowledges that the assembly 36 physically connects the syringe 48 to the inflation lumen of the catheter. *Id.* The assembly 36 includes an elongate tubular barrel section 50 extending between two ports 38, 56 and further locates a side port 58 and a branch 54 off the elongate tubular barrel section 50. Ex. 1009 at 10:17-36. The syringe 48 attaches to the branch 54. *Id.* at 10:33-36. Petitioner contends Eliason’s one-way valve 60 constitutes the claimed flow valve. Pet. at 60-61. According to Petitioner, “Eliason utilizes a valve (60) that is ‘actuatable between

an open condition ... and a closed position' to permit or prevent the passage of inflation fluid from the inflation device (syringe (48)) through the hub (36), to balloon (14).” *Id.* at 60 (*citing* Ex. 1009 at 10:36-52).

Petitioner erroneously asserts that “[t]he valve (60) is movable between an open condition and a closed condition, as such, it is configured to selectively fluidly communicate the proximal hub with the inflation device.” *Id.* at 61. As clearly shown in Eliason’s Fig. 10, reproduced and annotated below, the syringe 48 (*i.e.*, the inflation device) is fluidly communicated with the branch 54 of the multi-port and valve assembly 36 (which Petitioner contends is the claimed proximal hub) upon engagement therewith, *irrespective of the condition of the valve 60*, which is downstream of the inlet of the branch 54.

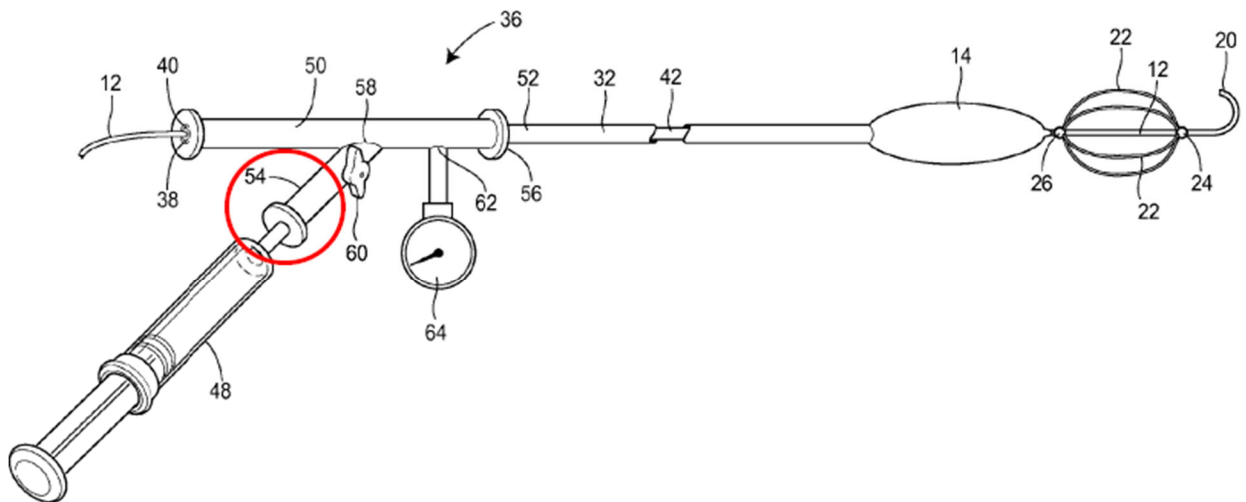


FIG. 10

In other words, the one-way valve 60 *does not and cannot* control fluid communication between the syringe 48 and the branch 54 of the multi-port and valve

assembly 36, and therefore the one-way valve 60 cannot selectively fluidly communicate Eliason's alleged proximal hub (*i.e.*, the multi-port and valve assembly 36) with the inflation device, as claimed. As before, Petitioner's usage of the alleged PHOSITA's knowledge fails to remedy the deficiency created by Petitioner's analysis for the flow valve. Pet. at 66-71.

For at least the additional reason that Petitioner has not shown Eliason's one-way valve is configured for selectively fluidly communicating the proximal hub to an inflation device, Petitioner fails to demonstrate it is more likely than not that claim 1 (or any of claims 2-10 dependent therefrom) would have been obvious under Ground 5.

C. Ground 6 is deficient because it depends on the same errors described above in Petitioner's treatment of Eliason and Fogarty

Ground 6 of the Petition alleges that claims 1-10 of the '737 Patent would have been obvious over Eliason, Fogarty, and the PHOSITA's knowledge. Petitioner relies on the same analysis and conclusions regarding Eliason and the alleged PHOSITA's knowledge as in Ground 5, except Fogarty is added solely to further address securing the solid wire 12 at a proximal-most end thereof within the proximal hub. Pet. at 82-83.

As explained above in section VI.B.1, Petitioner improperly misapplies Eliason's endovascular wire 12 to two separate and distinct claim elements (the distal catheter section and the wire) and does not use the alleged PHOSITA's

knowledge to remedy the deficiency. Fogarty is not used in Ground 6 to address this error in Eliason. Pet. at 82-83. Eliason was also shown (in section VI.B.2, above) to lack a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device – another problem the alleged PHOSITA’s knowledge was not used to correct. Not only does Ground 6 not utilize Fogarty to address this defect (Pet. at 82-83), but Fogarty was shown above to suffer the same deficiency (*see* section VI.A.3). For at least these reasons, Petitioner fails to demonstrate it is more likely than not that claim 1 (or any of claims 2-10 dependent therefrom) would have been obvious under Ground 6.

D. Grounds 2-4 and 7-9 are deficient for at least the same reasons explained above for Grounds 1 and 5

Grounds 2-4 rely on Petitioner’s analysis in Ground 1 for independent claim 1, and simply add the Saab, Sanati, and Deaton references for various features listed in dependent claims 2-5 and 8-9. *See e.g.*, Pet at 48, 51-53, 56. As such, each of Grounds 2-4 fails to compensate for the deficiencies described above in Ground 1 related to (1) simultaneous provision of a functional flow valve and a wire extending within the catheter, (2) distinct structures of the flow valve and proximal hub, and (3) a specific configuration of the flow valve relative to the proximal hub (*see* Sections VI.A.1-VI.A.3, above) at least because Petitioner utilizes the additional references in Grounds 2-4 solely for other, unrelated claim features. Pet at 48, 51-53, 56. For at least these reasons, Petitioner fails to demonstrate it is more likely

than not that any claim of the ‘737 Patent would have been obvious under any of Grounds 2-4.

Likewise, Grounds 7-9 rely on Petitioner’s analysis in Ground 5 for independent claim 1, and add the Saab, Scott, and Joe references for various features listed in dependent claims 2-5 and 8-9. *See e.g.*, Pet at 84, 87-89, 92. As such, each of Grounds 7-9 fails to compensate for the deficiencies described above in Ground 5 related to (1) distinct structures of the wire and distal catheter section and (2) a specific configuration of the flow valve relative to the proximal hub (*see* Sections VI.B.1-VI.B.2, above) at least because Petitioner utilizes the additional references in Grounds 7-9 solely for other, unrelated claim features. Pet at 84, 87-89, 92. For at least these reasons, Petitioner fails to demonstrate it is more likely than not that any claim of the ‘737 Patent would have been obvious under any of Grounds 7-9.

VII. CONCLUSION

For at least the reasons recited above, Patent Owner requests that the PTAB deny institution of the Petition.

Date: August 30, 2024

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. §§ 42.24(a)(1)(ii), 42.24(b)(1), 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 Preliminary Response Under 37 C.F.R. § 42.207 is 6,990.

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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 PRELIMINARY RESPONSE UNDER 37 CFR § 42.207 has been served in its entirety this 30th day of August 2024, by electronic mail on Petitioner's lead and back-up counsel, as follows:

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