

Petitioner Imperative Care's Demonstratives For Oral Argument

January 20, 2026

Imperative Care, Inc. v. Inari Medical, Inc.
IPR2025-00156 (Patent 11,697,012)

Outline of Petitioner's Oral Argument

- ⌚ Overview of IPR Proceedings
- ⌚ Schaffer + Hartley or Eller Render the Challenged Claims Obvious
- ⌚ Schaffer + Garrison or Schaffer + Hartley/Eller + Garrison Renders the Challenged Claims Obvious
- ⌚ Schaffer Anticipates or Renders the Challenged Claims Obvious

Overview of IPR Proceedings

IPR Grounds

Ground	References	Basis	Challenged Claims
1	Schaffer	35 U.S.C. § 102	1-9
2	Schaffer	35 U.S.C. § 103	1-9
3	Schaffer + Hartley	35 U.S.C. § 103	1-9
4	Schaffer + Eller	35 U.S.C. § 103	1-9
5	Schaffer + Garrison	35 U.S.C. § 103	1-9
6	Schaffer + Hartley + Garrison	35 U.S.C. § 103	1-9
7	Schaffer + Eller + Garrison	35 U.S.C. § 103	1-9

Issues In Dispute

Grounds 3-4, 6-7: Schaffer + Hartley or Eller; Schaffer + Hartley or Eller + Garrison

- ⦿ Would a POSITA have been motivated to combine Schaffer + Hartley or Eller?

Grounds 1-2, 5: Schaffer or Schaffer + Garrison

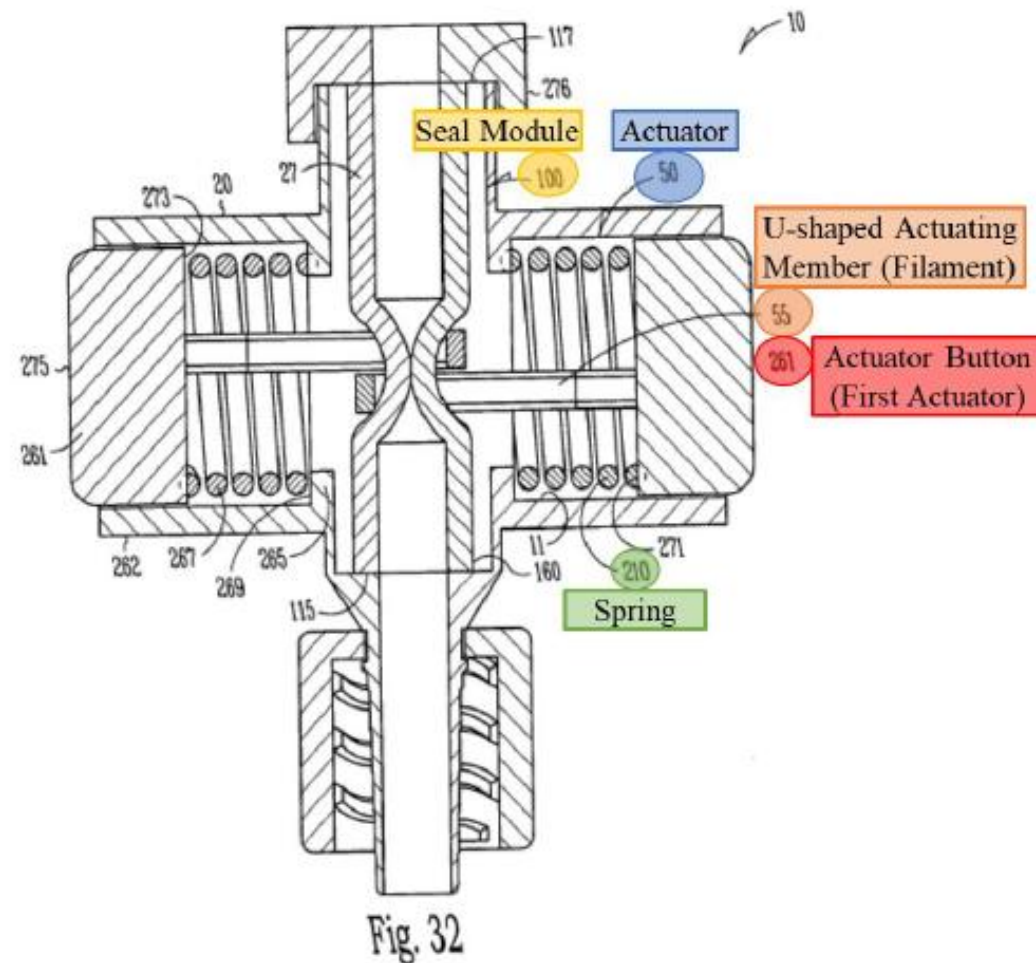
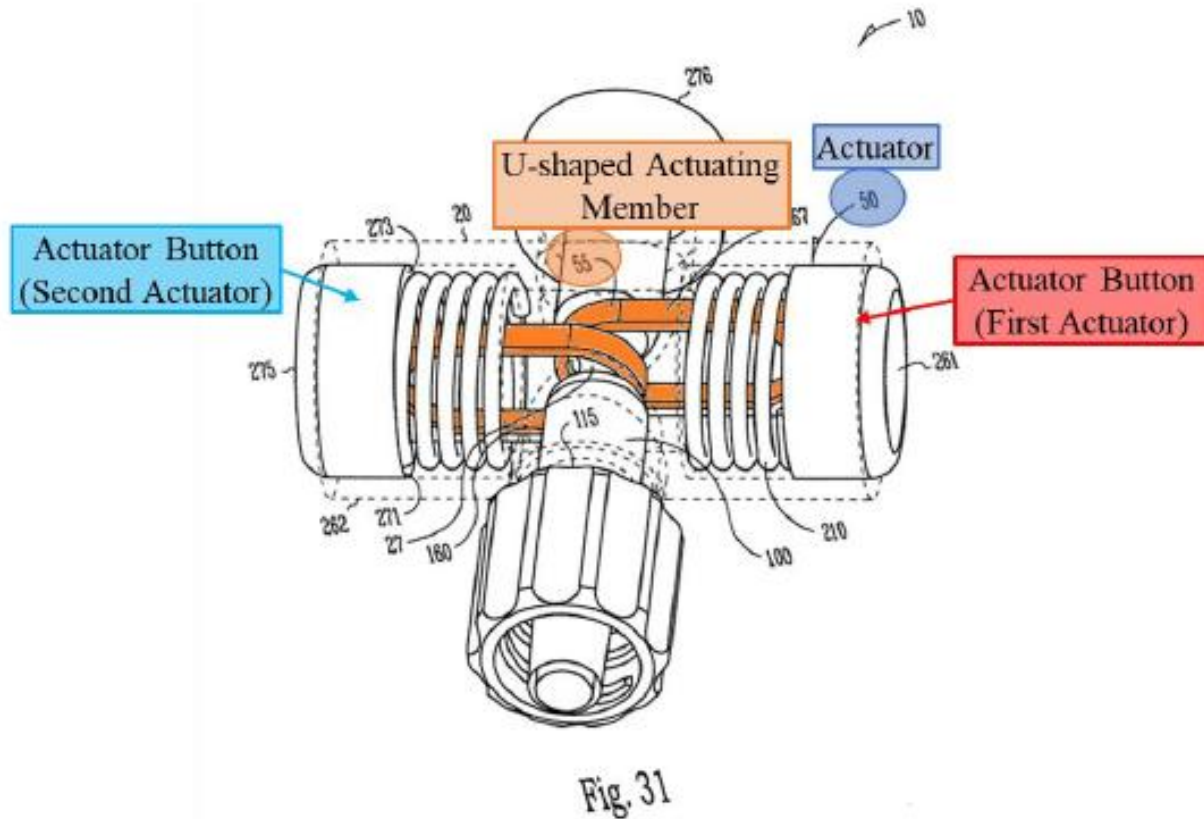
- ⦿ Does the term “filament” require a “thin, flexible length of material”?
- ⦿ Does Schaffer disclose a “filament” regardless of construction?
- ⦿ Do Schaffer’s actuating members form a “loop”?

Issues Not In Dispute

- ⦿ No dispute that Hartley and Eller disclose a “filament” that forms a “loop”
- ⦿ PO raises no arguments concerning Garrison or the combination of Garrison with other references (Grounds 5-7)
- ⦿ PO raises no unique arguments concerning dependent claims 2-9
- ⦿ No dispute that preamble of claim 1 is not limiting
- ⦿ No dispute that Petitioner’s references qualify as prior art
- ⦿ No evidence of secondary considerations of nonobviousness

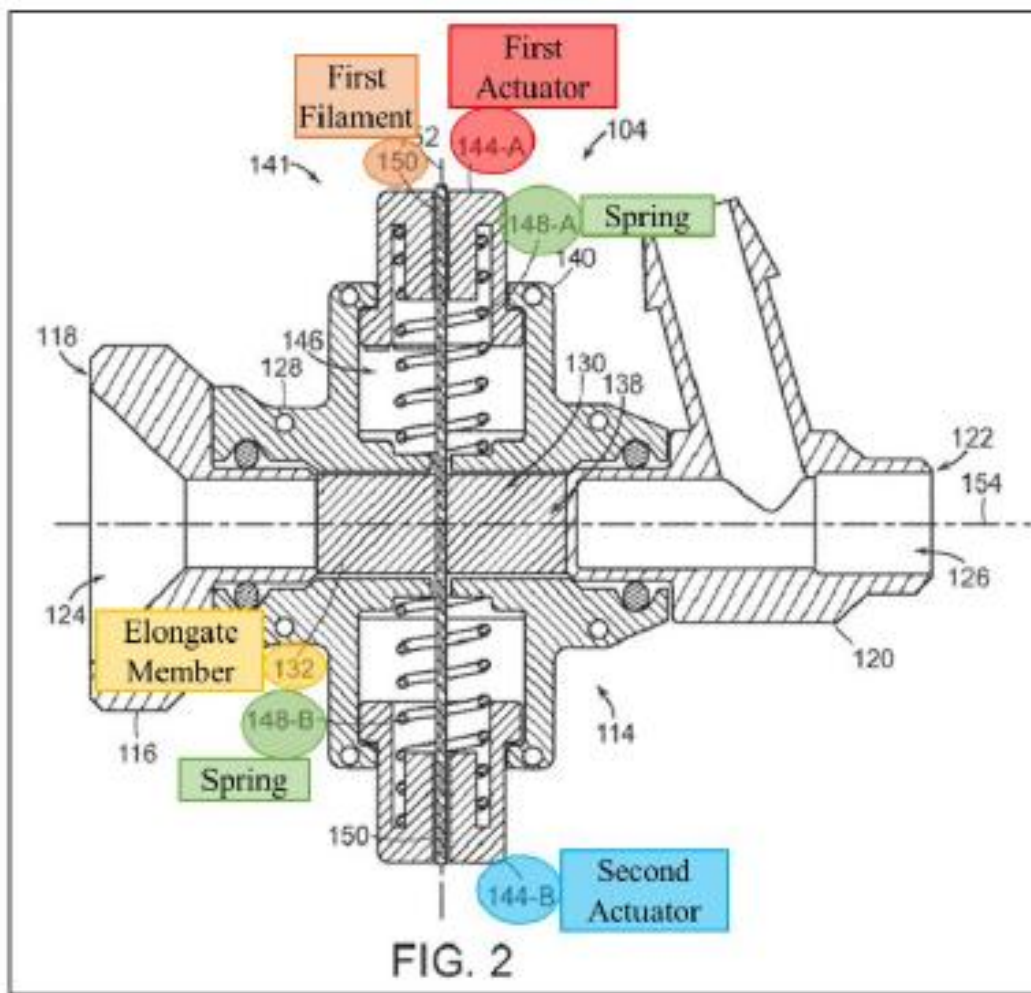
Grounds 3-4: Schaffer + Hartley or Eller Renders the Claims Obvious

Overview of Schaffer

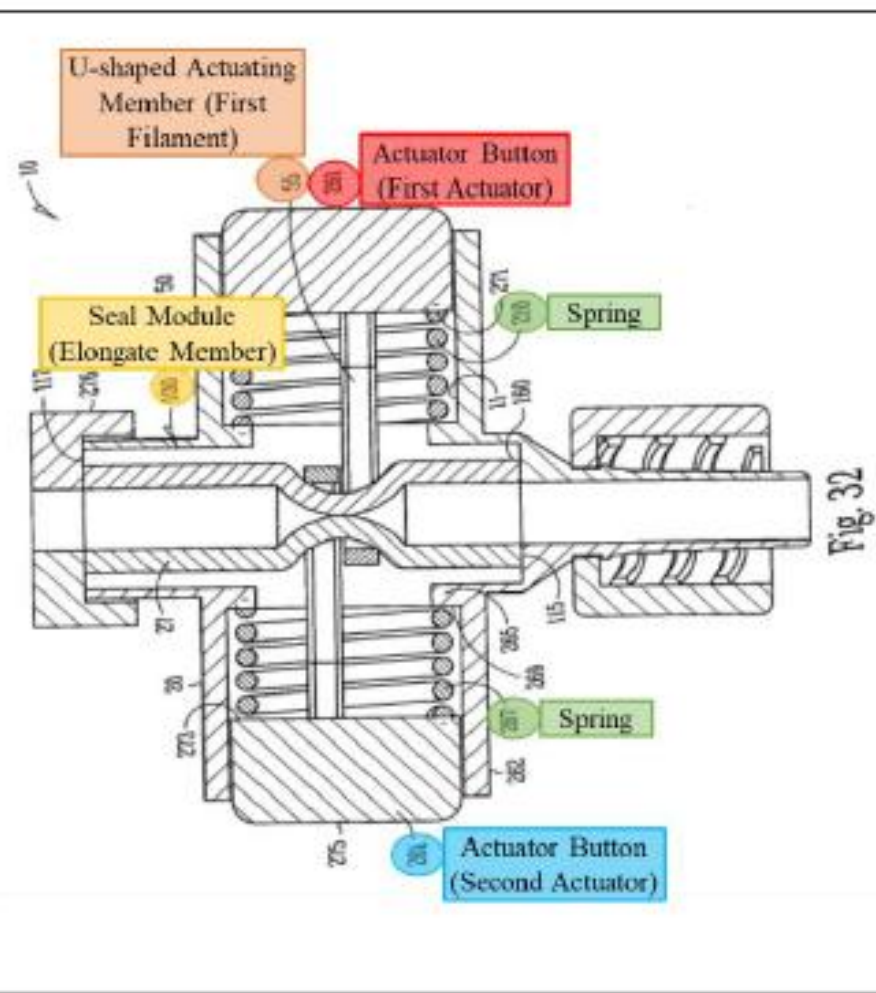


Schaffer Compared To The '012 Patent

'012 Patent



Schaffer



Hartley Discloses a “Filament”

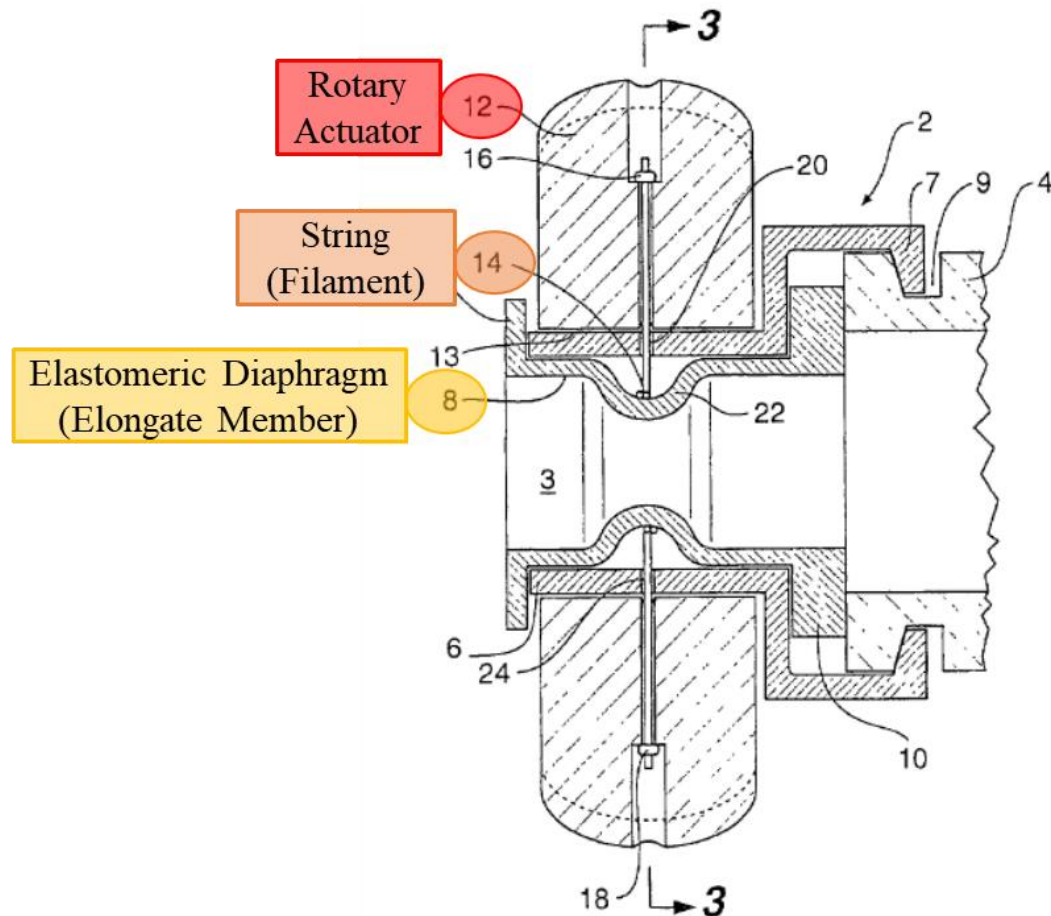


Fig 1

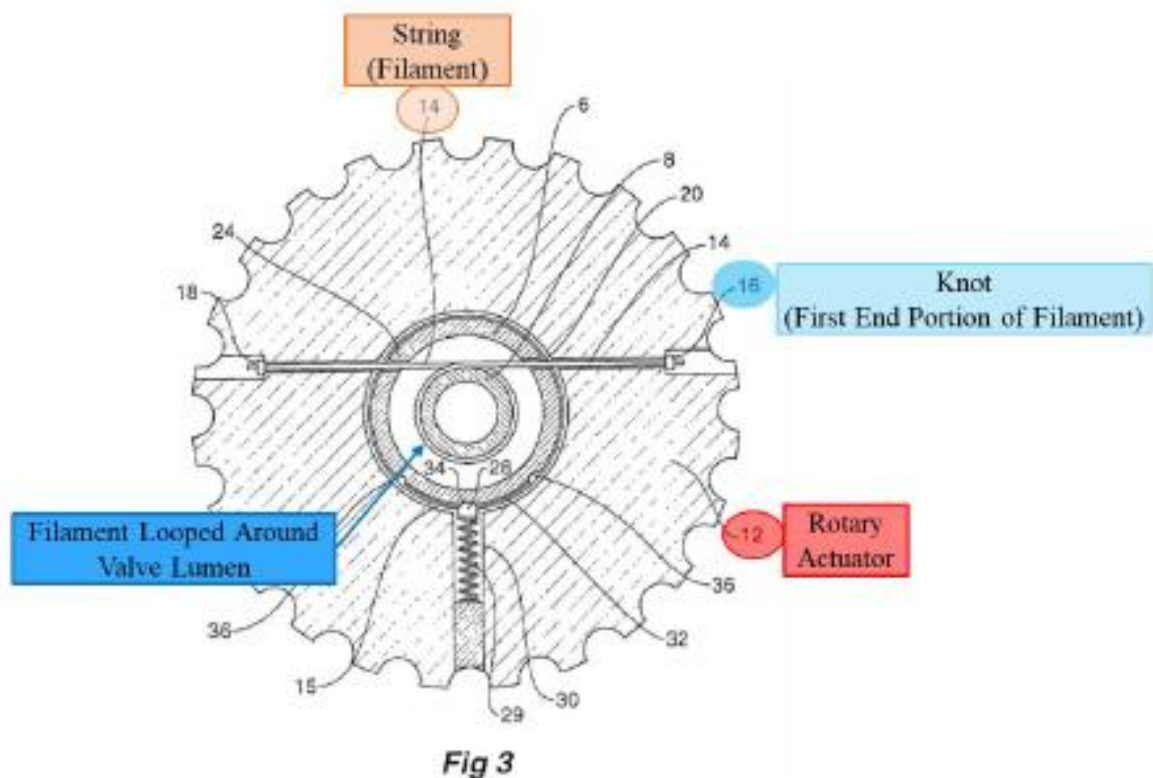
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ABSTRACT

An access valve (2) for a laparoscopic device or a intraluminal deployment device has a cylindrical diaphragm (8) with a longitudinal aperture (3), a flexible member (14) is passed circumferentially around the cylindrical diaphragm and an extension arrangement to pull the flexible member radially and/or tangentially to constrict the diaphragm to at least partially close off the longitudinal aperture. A rotary actuator may be used (12).

[0017] The flexible member may be a string, suture or band or other suitable material.

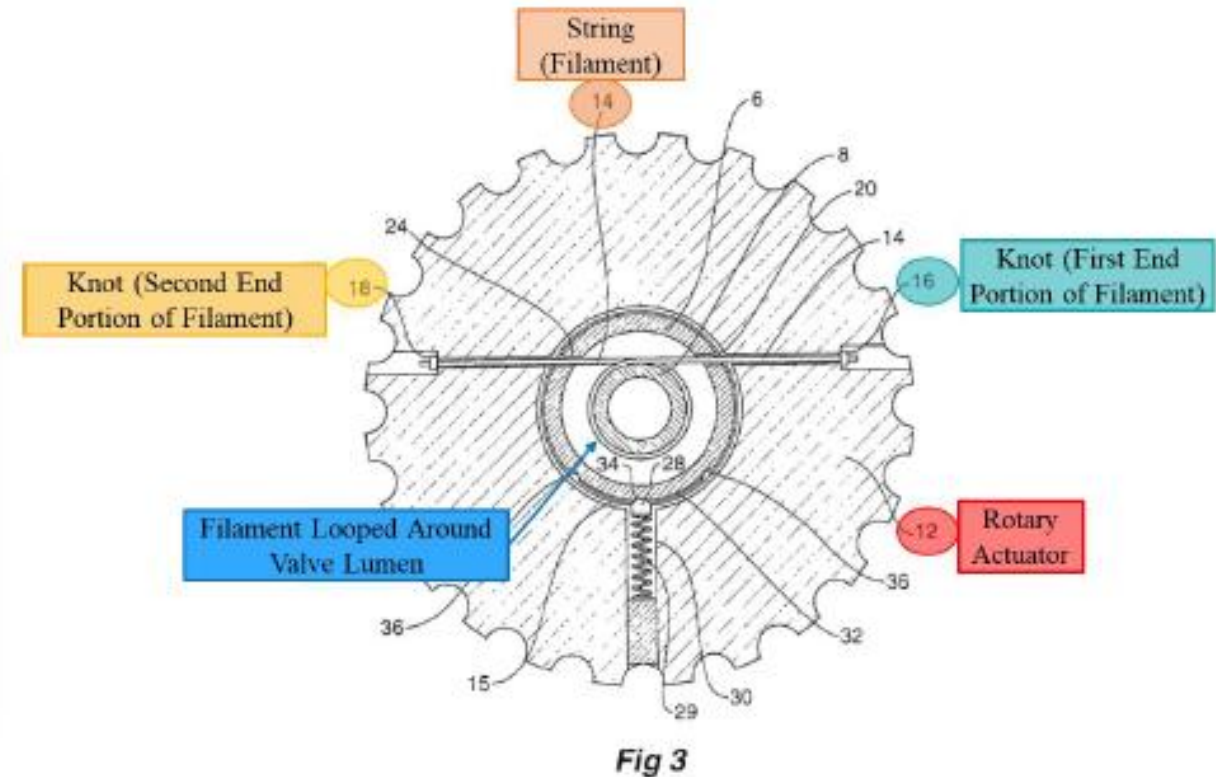
Hartley's Filament Forms a "Loop"



diaphragm. A string 14 is mounted into the rotary actuator with a knot 16 at one end and then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 preferably in a recessed region 22 and then passes through a further aperture 24 in the cylindrical housing before being fixed by knot 18 again in the rotary actuator. Rotation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.

Simple Methods to Attach Hartley's Filament to Actuator

diaphragm. A string 14 is mounted into the rotary actuator with a knot 16 at one end and then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 preferably in a recessed region 22 and then passes through a further aperture 24 in the cylindrical housing before being fixed by knot 18 again in the rotary actuator. Rotation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.



Eller Discloses a “Filament”

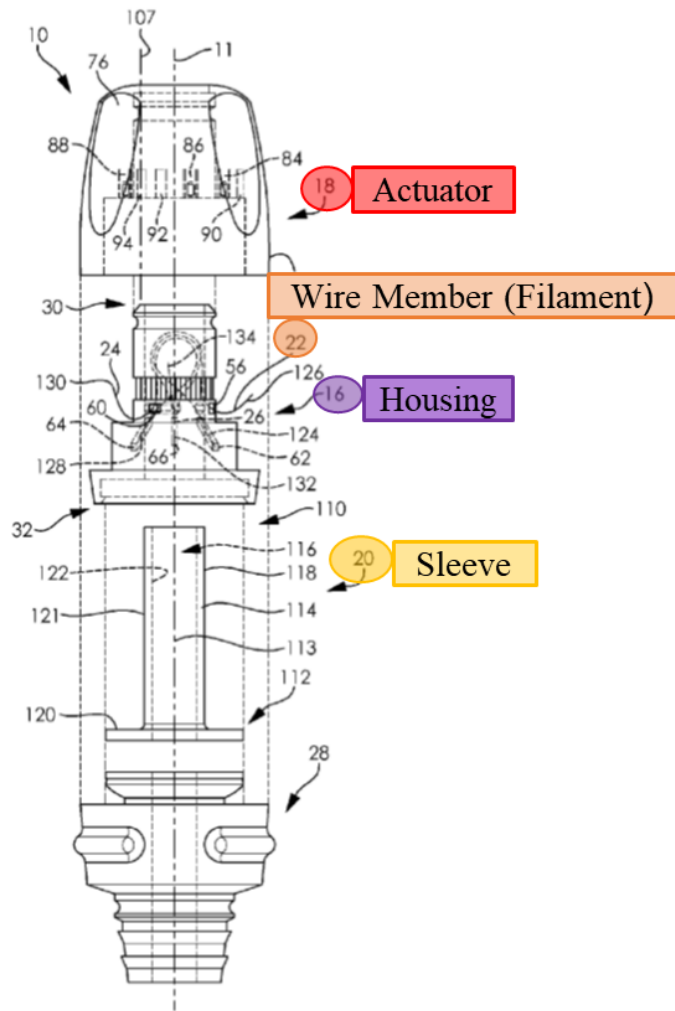


FIG. 2

FIGS. 1, 2, 3, 4, 5, 6, 7, 8A, 8B, 8C, 9A, 9B, 9C, 10A, 10B, and 10C illustrate an embodiment of a selective fluid barrier valve device 10 that has a lengthwise axis 11, a proximal end 12, a distal end 14, a housing 16, an actuator 18, a sleeve 20, a first wire member 22, a second wire member 24, a third wire member 26, and a connector 28. The

ment. Example materials considered suitable to form a wire member include biocompatible materials, materials that can be made biocompatible, braided materials, wound materials, twisted materials, noncompliant materials, metals such as steel, stainless steel, titanium, nickel-titanium alloys, polymers, polypropylene, polyester, Nylon, polyethylene, polyvinyl chloride, polystyrene, compliant materials, flexible materials (e.g., materials that are relatively more flexible than the material that forms the housing), and any other material considered suitable for a particular embodiment.

Eller's Filament Forms a "Loop"

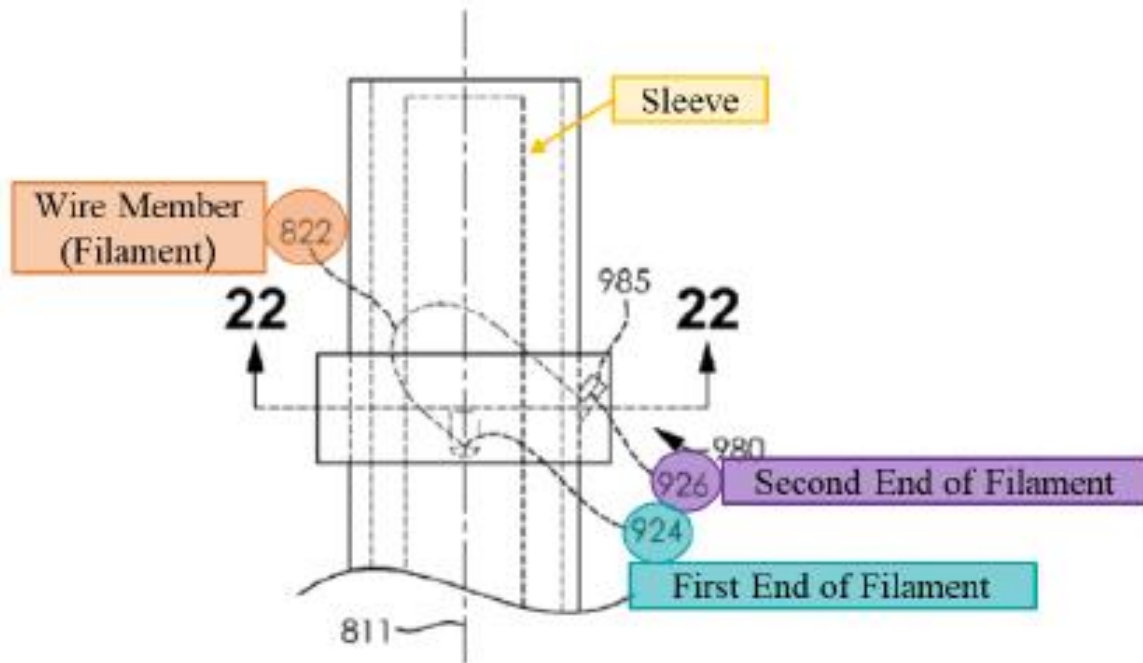
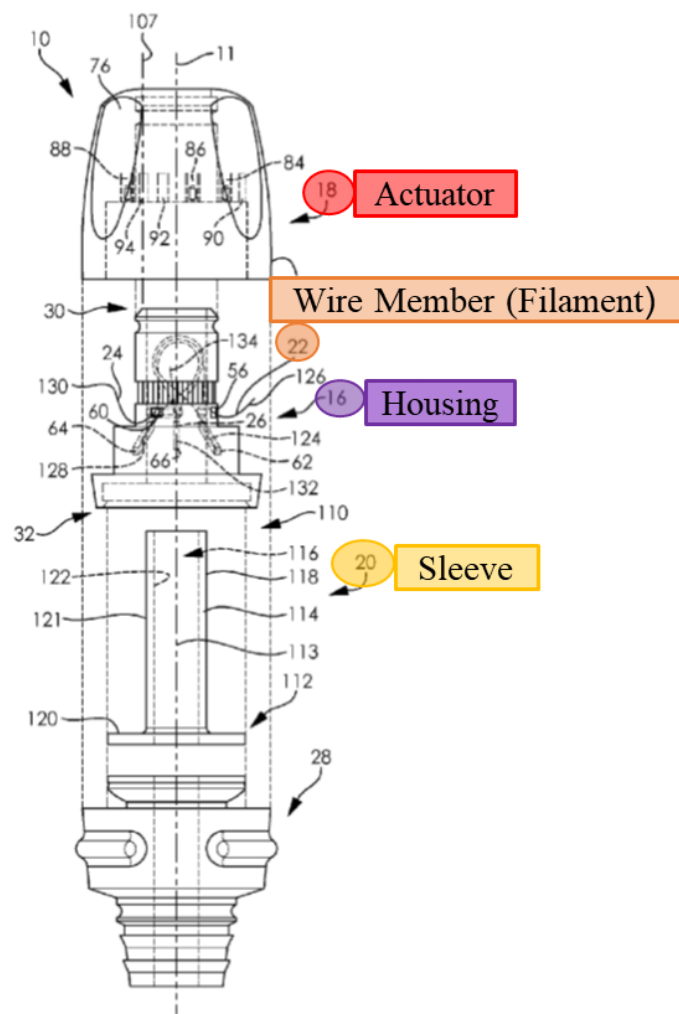


FIG. 21

In the illustrated embodiment, the first wire member 422 is disposed orthogonally relative to the lengthwise axis 411 of the selective fluid barrier valve device 410 (i.e., a plane that contains the lengthwise axis 411 of the selective fluid barrier valve device) and is disposed around more than 50% of the outer surface 521 of the sleeve 422. This provides a mechanism for moving the sleeve 420 from its first configuration to its second configuration. However, alternative embodiments can include a single wire member that is disposed around more than 75% of the outer surface of the sleeve or that is disposed around more than 100% of the outer surface of the sleeve. For example, the wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.

Simple Methods to Attach Eller's Filament to Actuator



Attachment between a wire member and a housing and/or an actuator can be accomplished using any suitable method or technique, and skilled artisans will be able to select a suitable method or technique to attach a wire member to a housing and/or an actuator according to a particular embodiment based on various considerations, including the material(s) that forms the wire member. Example methods and techniques considered suitable to attach a wire member to a housing and/or an actuator include using adhesives, welding, fusing, providing a friction fit between the wire member and the housing and/or actuator, and any other method or technique considered suitable for a particular embodiment. For example, a wire member can have an

First Motivation to Combine Schaffer + Hartley

99. A person of ordinary skill in the art would have been motivated to replace Schaffer's U-shaped actuating members with Hartley's string/flexible member for several reasons. First, a person of ordinary skill in the art would have been motivated by Hartley's disclosure that its valve with the string can "close over a range of diameters of devices passed through the valve or can close completely down to be self sealing." Ex. 1006 at [0037]. A person of ordinary skill in the art would have known that multiple tools of varying sizes could be required for a medical procedure, so Hartley's ability to seal around a range of diameters would have been beneficial. A person of ordinary skill in the art would have also recognized that a hemostasis valve should seal and prevent leakage of

fluid even when no tool is inserted through the valve, such as at the beginning or end of a medical procedure. Thus, Hartley's stated ability of its string to completely close the lumen when no tool is inserted would have also been a valuable benefit to a person of ordinary skill.

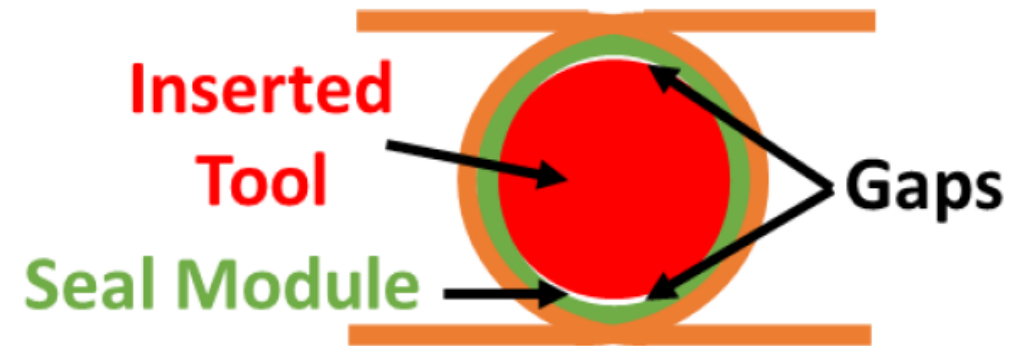
First Motivation to Combine Schaffer + Eller

114. A person of ordinary skill in the art would have found it obvious, and been motivated, to replace Schaffer's U-shaped actuating members with Eller's wire member for several reasons. First, a person of ordinary skill in the art would have been motivated by Eller's description that the wire member can form a seal around one or more medical devices passed through the valve to prevent fluid from leaking around the device. Ex. 1007 (Eller) at 15:21-40, 17:38-43, 18:3-8. A person of ordinary skill in the art would have also recognized that a stasis valve should seal and prevent leakage of fluid when a tool is inserted through the valve during a procedure. Thus, Eller's ability to seal around such devices would have been beneficial to a person of ordinary skill.

Second Motivation to Combine Schaffer + Hartley or Eller

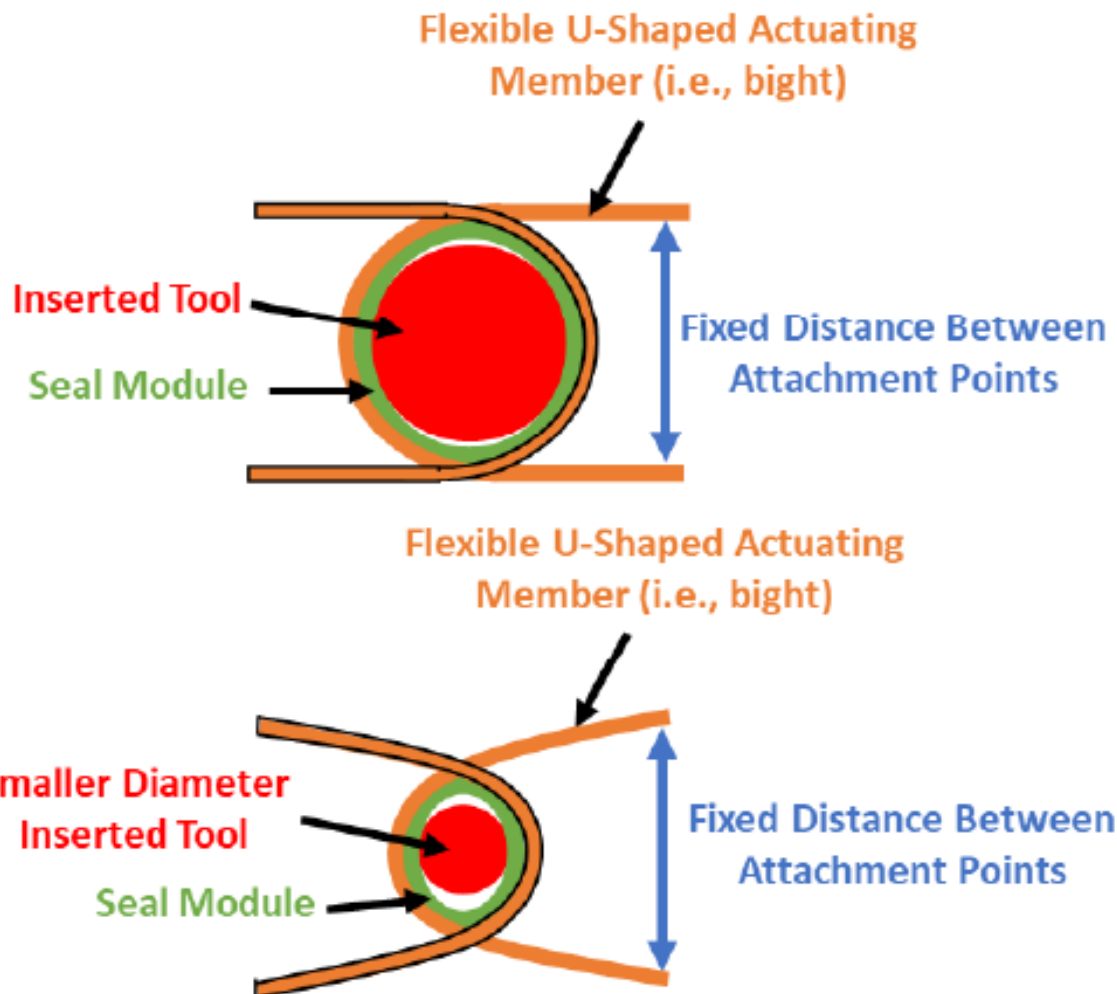
100. Second, a person of ordinary skill in the art would have recognized that Hartley's flexible string may better seal the valve than Schaffer's metallic/plastic U-shaped actuating members depending on the precise dimensions and materials of the actuating members. Hartley's flexible string may better conform to varying diameters or shapes of tools inserted into the valve than Schaffer's U-shaped actuating members. For example, as I discussed above, not all tools will have a round profile and Hartley's flexible string may better conform to the tool than the U-shaped actuating members. A person of ordinary skill in the art would have recognized that if Schaffer's U-shaped actuating members were not sufficiently flexible and conformable to form a perfect seal for a wide range of

tools, small gaps could form between the tool and the valve's lumen, as illustrated in the graphic below:



However, Hartley's string encircles and, depending on the materials, may conform to the size and shape of a wider range of tools used with the valve. This ability to accommodate more tools would have been a highly desirable feature to a person of ordinary skill in September 2017. I note in related proceedings that Patent

Gaps Due to Shape and Attachment to Buttons



Thornton Supp. Decl.

Id. at Fig. 31. Because of this arrangement, even when the U-shaped actuating members (or bights) are relatively flexible, the fixed attachment points to the actuator buttons may prevent the U-shaped actuating members from completely conforming to the exterior of a tool with a smaller diameter than the distance between the attachment points, as I've illustrated below:

PO's Argument Schaffer Would Not Form Small Gaps Lacks Support

PO Response

A. A POSA Would Not Have Been Motivated to modify Schaffer's U-Shaped Members

- 1. Petitioner's stated motivation to combine Schaffer with Hartley/Eller does not exist.**

43, 50. But, every illustrated embodiment of Schaffer discloses a valve that seals across a wide range of instruments without gaps—indeed, that is the purpose of Schaffer. EX2008, ¶¶106-111. More specifically, every illustrated embodiment of Schaffer includes the third seal member 165 that seals without gaps across a wide range of tool/device diameters and shapes. *Id.*

Schaffer Forms a “Nearly Fluid/Gas Tight Seal”

PO Response

Taken together, every embodiment in Schaffer includes the seal member 165, and the seal member—regardless of its specific material construction—forms a complete seal around various instruments or no instruments. Thus, Schaffer does not form gaps. Grounds 3-4 fail for this reason alone: “[a] motivation to combine

Schaffer

[0059] In one embodiment, the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible. Materials 166 include modified vinyl, silicone, polyurethane or a combination thereof. The basic materials are, in one option, modified by compounding them with waxes and/or oils or un-cross-linked modifiers. Such materials are commonly available as “C-Flex” or “Kraton” in the range of 5 to 15 (shore A), as examples. The shore hardness of the material 166 is, in another option, in the range of between 15-20 shore on the “00” scale. This provides a material 166 that is extremely soft and compliant and intrinsically “sticky”. An extremely low shore hardness of the third central seal member 165 material 166 allows the third central seal member 165 to be easily compressed upon itself or upon an inserted instrument. For illustrative purposes only, the nature of the material 166 of the third central seal member 165 can be compared to a gelatinous substance. The material 166 exhibits a “selfclosing” nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal under very light compression.

Figs. 30-34 Do Not Require “Third Seal Member 165”

Schaffer

[0075] FIGS. 30-34 illustrate one embodiment of the stasis valve 10 including a seal module 100 having a lumen sized to allow the passage of fluids or gases. The seal module 100 includes a containment structure 160 with a proximal end 115 and a distal end 117. The seal module 100 is formed of one or more seal members, as discussed above. In another option, the seal module 100 and/or any of its respective seal members can be formed of one or more materials, including their relative properties, as discussed above.

Schaffer

[0076] In one option, two circular actuators 50 are at least partially circumferentially disposed about a portion of the seal module 100 movable from a first position to a second position on opposing sides of the housing 20. The actuators

[0077] In the first position the actuating members 55 of the actuators 50 are, in one option, disposed and at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210). The lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67. In the second position, the actuators 50 are disposed away from the portion 108 of the seal module 100 by a compressive force 67 (e.g. by depressing the distal end 275 of the actuator button 261). As each actuator button 261 is depressed, each actuator 50 slides along the cylindrical interior wall 11 of the housing 20. The

Schaffer Discloses Many Seal Module Materials

Schaffer

seal. In one option, a relatively **high durometer material** is used as the septum material for the first and second seal members **170** and **180** because it provides a low frictional coefficient against most inserted instruments while providing a competent seal. In another embodiment, one or more of the first, second, and third seal members **170**, **180**, and **165** includes **self-lubricating, lubricious or coated septum materials**. Such materials include **specialty silicones, natural latex, various synthetic rubbers** or **elastomeric compounds** of **polyurethane, vinyl** or the like. The low friction nature of the first and second seal members **170**, **180** is in contrast to the highly deformable and compliant nature of the third central seal member **165**.

Thornton Supp. Decl.

[0059]; *see also id.* at [0081]. **Schaffer discloses many other materials that would not be “sticky” or “gelatinous” that could make up that same portion of the valve, such as modified vinyl, silicone, or polyurethane.** *Id.* Nothing in Schaffer suggests that the third valve portion must be made with a “sticky” or “gelatinous” substance in all embodiments.

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A “Sticky” Seal Would Not Work for Figs. 30-34

Schaffer

[0059] In one embodiment, the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible. Materials 166 include modified vinyl, silicone, polyurethane or a combination thereof. The basic materials are, in one option, modified by compounding them with waxes and/or oils or un-cross-linked modifiers. Such materials are commonly available as “C-Flex” or “Kraton” in the range of 5 to 15 (shore A), as examples. The shore hardness of the material 166 is, in another option, in the range of between 15-20 shore on the “00” scale. This provides a material 166 that is extremely soft and compliant and intrinsically “sticky”. An extremely low shore hardness of the third central seal member 165 material 166 allows the third central seal member 165 to be easily compressed upon itself or upon an inserted instrument. For illustrative purposes only, the nature of the material 166 of the third central seal member 165 can be compared to a gelatinous substance. The material 166 exhibits a “selfclosing” nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal under very light compression.

Thornton Supp. Decl.

33. Third, a person of ordinary skill in the art would have recognized that highly “sticky” or “gelatinous” materials would not work well with the seal modules disclosed in Figures 31-34 because those seal modules must “retract to an uncollapsed configuration” when the tension on the module is released by the actuating members. *See id.* at [0077]. A seal module made of very “sticky” or “gelatinous” materials would not have the requisite resilience to return to its uncollapsed configuration. Thus, even if the seal module had some stickiness, a person of ordinary skill in the art would have understood that the seal module cannot be so sticky as to prevent the seal module from retracting to its unsealed state when the constricting force from the actuating members is removed. *See id.*; *see also id.* at [0054] (“The third central seal member 165 is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied.”).

PO Cites No Evidence Petitioner Contradicted the Motivation to Combine

PO Response

Petitioner's expert admitted at deposition in the related '011 IPR that if Schaffer forms a complete seal, there would be no need to modify Schaffer's actuating members:

QUESTION: So **if** [Schaffer's] U-shaped members formed a complete seal around multiple tools, there would be no reason to include Ellers' wire member or Hartley's string in Shafer; isn't that correct?

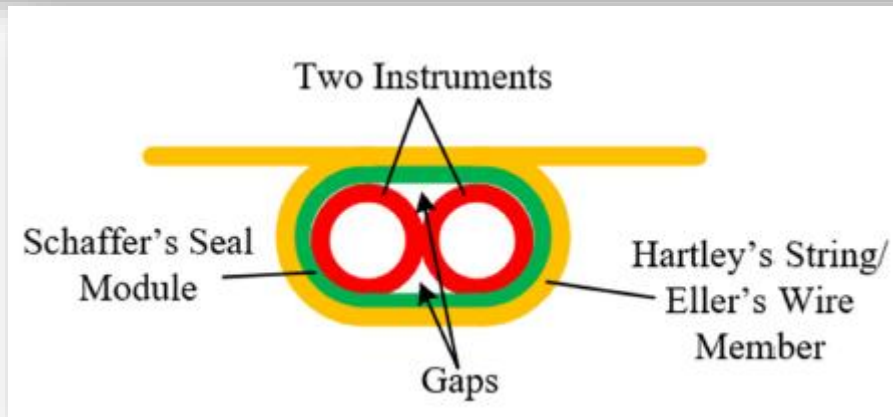
MR. THORNTON: **If it worked perfectly for all the range of tools**, then there probably wouldn't be a need to make adjustments and move to a string-type member.

EX2006, 116:18-117:2. Dr. Zalesky agrees. EX2008, ¶112.

PO's Argument Regarding Two Instruments Not Probative

PO Response

valve is specifically designed to form a seal as explained above. EX2008, ¶118. For example, if two circular instruments were inserted side-by-side through Schaffer's seal module, Hartley's string/Eller's wire in Petitioner's combination (which requires removing the seal member) might not seal the space (e.g., gaps/divots) between the instruments as shown below:



PO Relies on a Different Embodiment for Two Instrument Argument

PO's reliance on this section erroneous because:

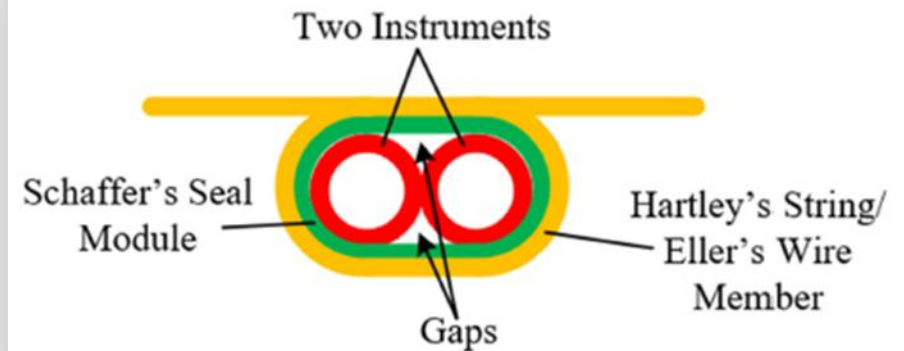
- Disclosure applies to Figs. 12-15
- Disclosure applies to an “embodiment”
- Disclosed embodiment requires three seal members

[0068] In yet another embodiment, two or more instruments 260 are inserted into the valve antegrade, for example, in the distal end 117 of the containment structure 160 while the lumen 193, 190, and 191 of the seal members 165, 170, and 180, are in an open configuration, or in another option, while the lumen 193 of the third central seal member 165 is in a closed configuration. The instruments 260 frictionally engage the lumen 190 of the first seal member 170 and forces it distally away from the second seal member 180 and the third central seal member 165. The first seal member 170 forms a seal against the instruments 260. The back pressure from the retrograde flow 270 against the first seal member 170 forces the first seal member 170 toward the distal end 117 of the containment structure 160 compressing the third central seal member 165 and collapsing it circumferentially against the instruments 260 forming a second, complete seal. The material 166 of the third central seal member 165 is so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped.

PO's Drawing Is Inaccurate

Thornton Supp. Decl.

Patent Owner Response at 52. Patent Owner's illustration does not depict the compliant sealing member described in Schaffer's Paragraph [0068]. The sealing member depicted in Patent Owner's illustration is not "so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped." In addition, Patent Owner does not explain how the illustration would be any different if the string/wire member were replaced with two U-shaped actuating members. Because of the non-compliant seal depicted in the illustration,



Third Motivation to Combine Schaffer + Hartley or Eller

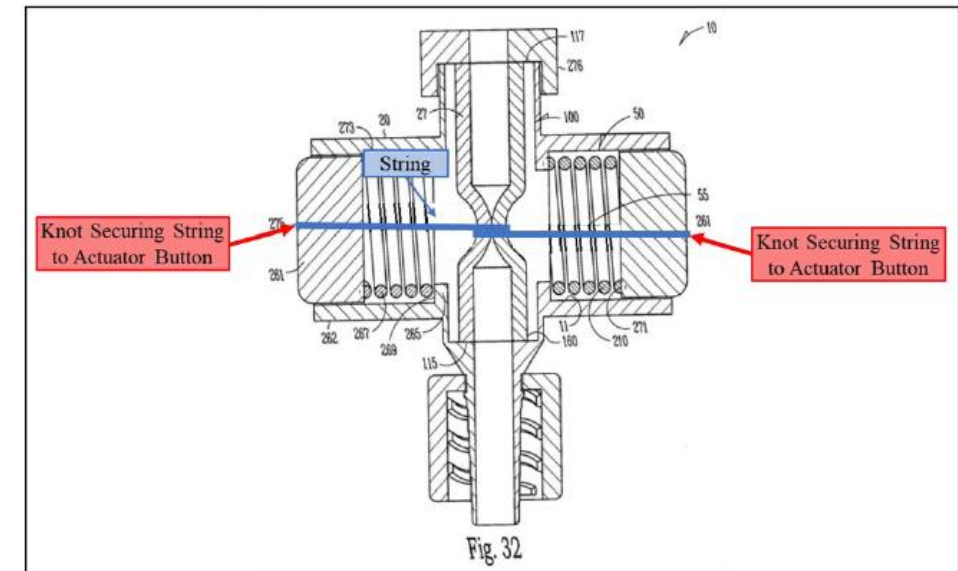
101. Third, the combination of Hartley's string and Schaffer's valve would have merely entailed the substitution of one known element (Hartley's string) for another (Schaffer's U-shaped actuating members) and would have yielded the predictable results of constricting the central lumen of Schaffer's valve to form a seal. I do not see any significant technical challenges that a person of ordinary skill would have confronted in substituting Hartley's string for Schaffer's U-shaped actuating members, and I believe that the substitution would have been well within the level of ordinary skill in September 2017. I note in related

Simple Methods May Be Used to Combine Hartley with Schaffer

Thornton Decl.

104. A person of ordinary skill in the art would have had reasonably expected success in substituting Hartley's string for Schaffer's U-shaped actuating members for multiple reasons. First, Hartley teaches a simple method for attaching its string to an actuator – a knot at the terminal ends of the string. Ex. 1006 (Hartley) at [0031]. A person of ordinary skill in the art would have reasonably expected that this same method could be used to attach Hartley's string to each of Schaffer's actuator buttons. For example, small holes could be made in each of Schaffer's actuator buttons, and each end of the string could be threaded through the hole on the opposite buttons and knotted on the other side. This

Demonstrative Illustration
Schaffer + Hartley's String



Simple Methods May Be Used to Combine Eller with Schaffer

118. A person of ordinary skill in the art would have had reasonably expected success in substituting Eller's wire member for Schaffer's U-shaped actuating members for multiple reasons. First, Eller states that the "[a]ttachment between a wire member and a housing and/or actuator can be accomplished using any suitable method or technique, and skilled artisans will be able to select a suitable method or technique to attach a wire member to a housing and/or an actuator according to a particular embodiment based on various considerations, including the material(s) that forms the wire member." Ex. 1007 (Eller) at 14:37-43. Eller then provides several exemplary ways to secure its wire member to an actuator, "including using adhesive, welding, fusing, providing a friction fit between the wire member and the ... actuator, and any other method or technique considered suitable for a particular embodiment." *Id.* at 14:43-49. Eller's

PO Fails to Explain Why the Combination Is Not Simple

PO Response

In the Institution Decision, the Board asserted that “Schaffer’s two actuating members apply a constricting force to the valve’s seal module when pulled by opposing spring-actuated buttons,” and that “replacing those members with a single string (or wire) would provide substantially the same function.” Institution Decision, p.39. But even if the end function is similar, this does not mean that it would have been simple to redesign Schaffer’s valve to replace the U-shaped actuating members with Harley’s string/Eller’s wire. EX2008, ¶142. Indeed, as Mr. Zalesky explains, “there are many design considerations that a POSITA would need to contemplate if they had been motivated to redesign Schaffer’s valve seal module” that would render it not simple to “have redesigned Schaffer’s valve to accommodate Hartley’s string or Eller’s wire member.” *Id.* Several of these design considerations are discussed below in §V.D.

Fourth Motivation to Combine Schaffer + Hartley or Eller

102. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise “a resilient material in compression within a housing or clamping member.” Ex. 1005 (Schaffer) at [0003]. There were a finite number of ways to compress the resilient material in a hemostasis valve to create a seal in September 2017. Hartley and Schaffer disclose two such methods – Hartley’s single string and Schaffer’s two U-shaped actuating members formed from metal (e.g., aluminum) or plastic. As I discuss in the following section, Eller discloses a third option: one or more wire members. A person of ordinary skill in the art in September 2017 would have found it obvious to select from these finite, predictable options. And as I explain below, they would have had a reasonable expectation of success in implementing them.

PO's Fails to Identify Other Methods to Constrict a Tube

PO Sur-Reply

members.” *Id.*; EX1003, ¶102. But at deposition, Mr. Thornton admitted that there were more than those three ways to constrict a tubular member in a hemostasis valve including those disclosed in Schaffer '616 (EX2007, 105:24-106:4, 106:12-14), Wong (*Id.* at 106:15-19), Kees (*Id.* at 108:14-20, 110:7-19), Myers (*Id.* at 111:9-23), his previous work on a hemostatic-type clamp prototype (*Id.* at 106:20-24), and more (*Id.* at 112:5-114:24).

Mr. Thornton Explained Schaffer/Hartley/Eller Are Different

Thornton Depo. Transcript

Q So is this another finite predictable option to compress the lumen and seal the hemostasis valve?

MR. STOWELL: Objection. Vague.

THE WITNESS: It's still compressing a flexible tube. The mechanism of moving the compressing members is different than the one shown in Schaffer and Schaffer 616 that we've discussed so far.

BY MR. HAMILTON:

Q Is it similar to Schaffer's U-shape member?

A I would characterize it as a different mechanism.

Q Okay. So this is another finite predictable option that's different from Schaffer's two U-shaped

actuating members, Hartley's string, and Eller's wire member, correct?

MR. STOWELL: Objection. Vague.

THE WITNESS: I believe it uses a different mechanism to cause the pinching. The basic point of compressing a tubular member is similar among, really, all of these, all of these design options.

Options Still Finite if Different “Pinch” Valves Included

Thornton Depo. Transcript

Q Okay. So I just want to be clear. On page 74 when you say, These finite predictable options, you're not listing all the options in this paragraph; is that correct?

A Well, as I said earlier, there are a finite number of -- there were a finite number of ways to compress the resilient material in a hemostasis valve. Hartley and Schaffer disclosed two of them, U-shape members versus strings. I would still say that those are, you know -- the few other types that we've talked about today are still a finite number. There's not an infinite number of ways to compress a piece of tubing.

Schaffer's "Principles of Operation" Remain Unchanged

39. Given the similarities in the sealing mechanisms employed by Schaffer, Hartley, and Eller, a person of ordinary skill would have reasonably expected that Schaffer's valve would function with the same principles of operation when the U-shaped actuating members are replaced with Hartley's string or Eller's wire member. When Schaffer's actuator buttons are undepressed, the compression springs would pull each respective end of the string/wire member in opposite directions, causing the string/wire member to constrict Schaffer's seal module and seal the valve. When the actuator buttons are depressed, the tensioning force from the compression springs would be relaxed, allowing the string/wire member to loosen and disengage (i.e., release the constricting force) the seal module, permitting the seal module return to its open, unsealed state.

The String/Wire Permit Forcible Disengagement

Schaffer

the distal end 275 of the actuator button 261). As each actuator button 261 is depressed, each actuator 50 slides along the cylindrical interior wall 11 of the housing 20. The proximal end 273 of each actuator button 261 compresses the distal end 271 of each resilient member 267 which in turn, the proximal end 269 of each resilient member 267 compresses against the inner flange wall 265 of the housing 20. Such movement allows each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough. As the actuator 50 is disposed away from the portion 108 of the seal module 100, the lumen 193 of the third seal member 165 is able to retract in an unsealed configuration.

String/Wire Does Not Compromise “Ease of Manufacturing”

Schaffer

[0083] In an example where the stasis valve 10 includes two actuators 50, the stasis valve 10 is assembled by inserting the actuator button 261 and resilient member 267 (e.g., spring 210) into one side of the housing 20. The actuator button 261 and resilient member 267 (e.g., spring 210) are inserted into an opposing side of the housing 20. Each actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50. Each actuator button is released and the cap 276 secured to the housing 20, for example, with an adhesive. Further, the connecting member 35 is snapped onto the housing. The materials used and the assembly thereof of the stasis valve 10 as described herein can include any of the earlier disclosed embodiments or a combination thereof.

String/Wire Does Not Compromise “Durability”

Zalesky Depo. Tr. (PO’s Expert)

Q. Are you aware of any durable string materials that can be used to manufacture medical devices?

A. So, yeah, polypropylene, polyurethane, suture catgut are amazingly durable.

Q. Are you aware of any durable wires that can be used to manufacture medical devices?

A. There are certain small-braid constructions that are probably more durable than a rolled or drawn small wire. But again, testing would have to confirm that.

Q. And were polypropylene, polyurethane sutures and catgut available prior to 2017?

A. Yes.

Q. And what about the small-braid constructions for the wires that you referred to? Were those available prior to 2017?

A. Yes.

Schaffer + Hartley or Eller Renders Claim 2 Obvious

'012 Patent

2. The aspiration catheter of claim 1 wherein:
the collapsible tubular sidewall comprises a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body;
the constricting mechanism further comprises a second actuator and a second spring coupled to the second actuator; and
the filament further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator, and wherein the first actuator and the second actuator are moveable between (a) a first position wherein the filament circumferentially constricts the valve lumen to create a seal about the elongate, flexible tubular body and (b) a second position wherein the filament is moved to open the valve lumen at least partially.

Schaffer Has First and Second Actuators (Claim 2)

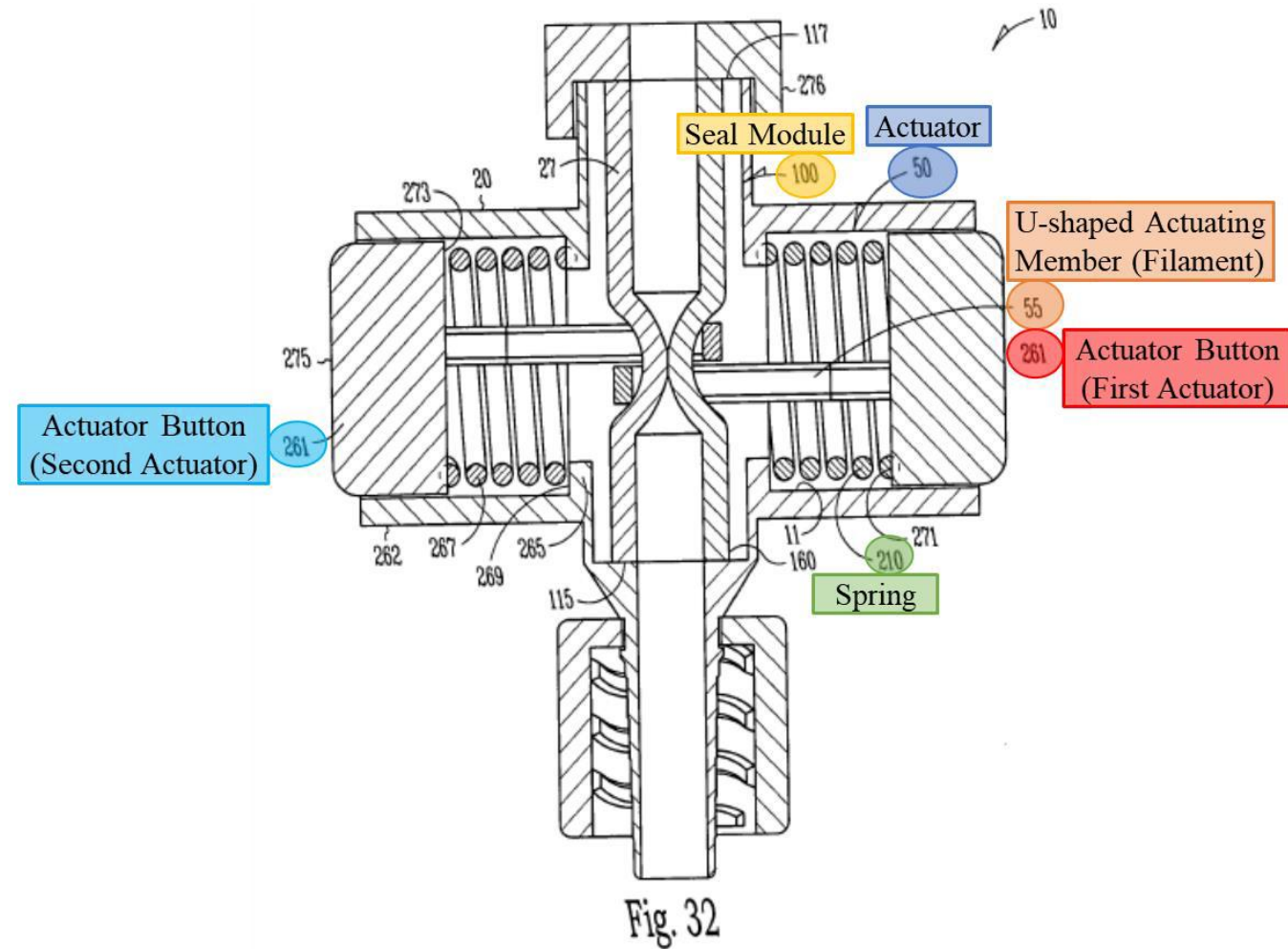
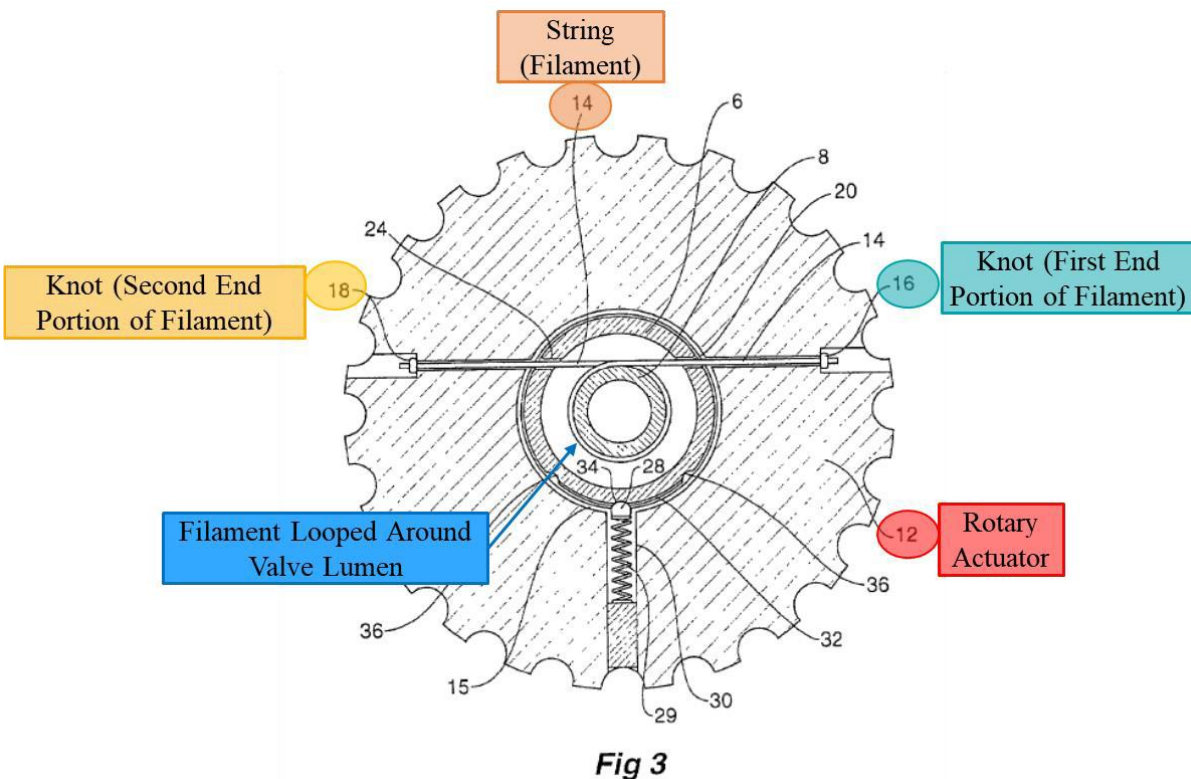
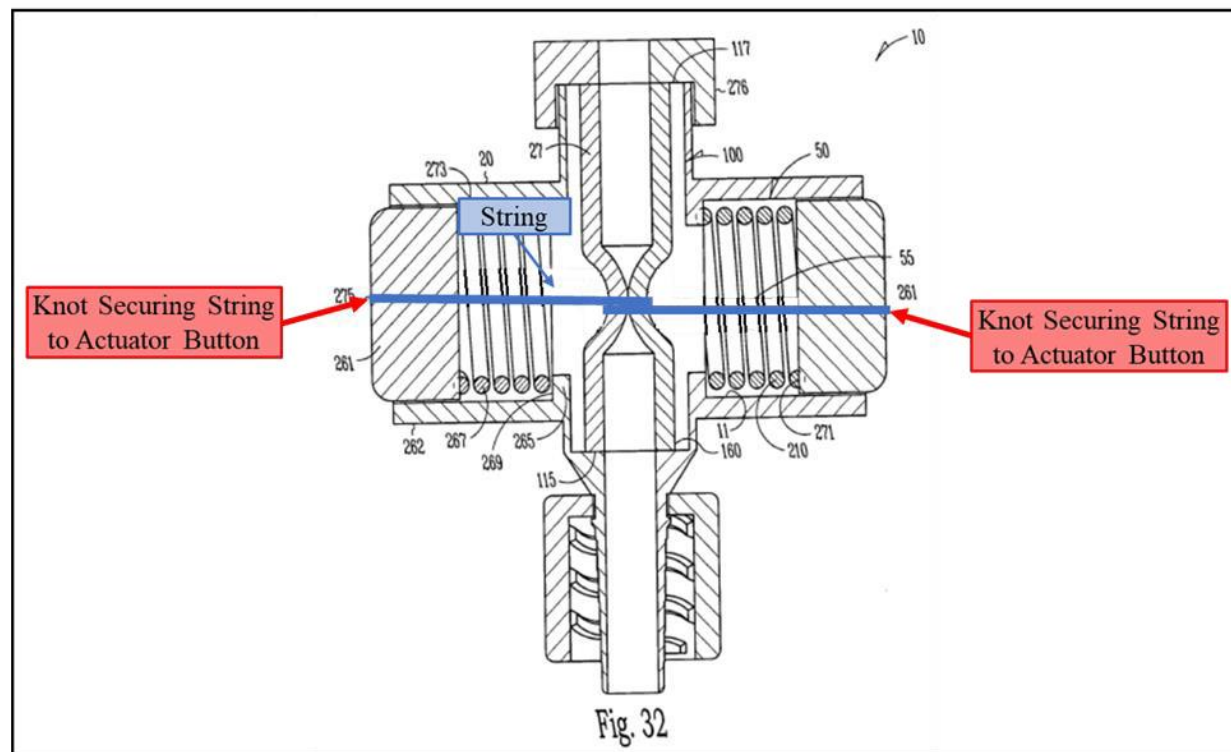


Fig. 32

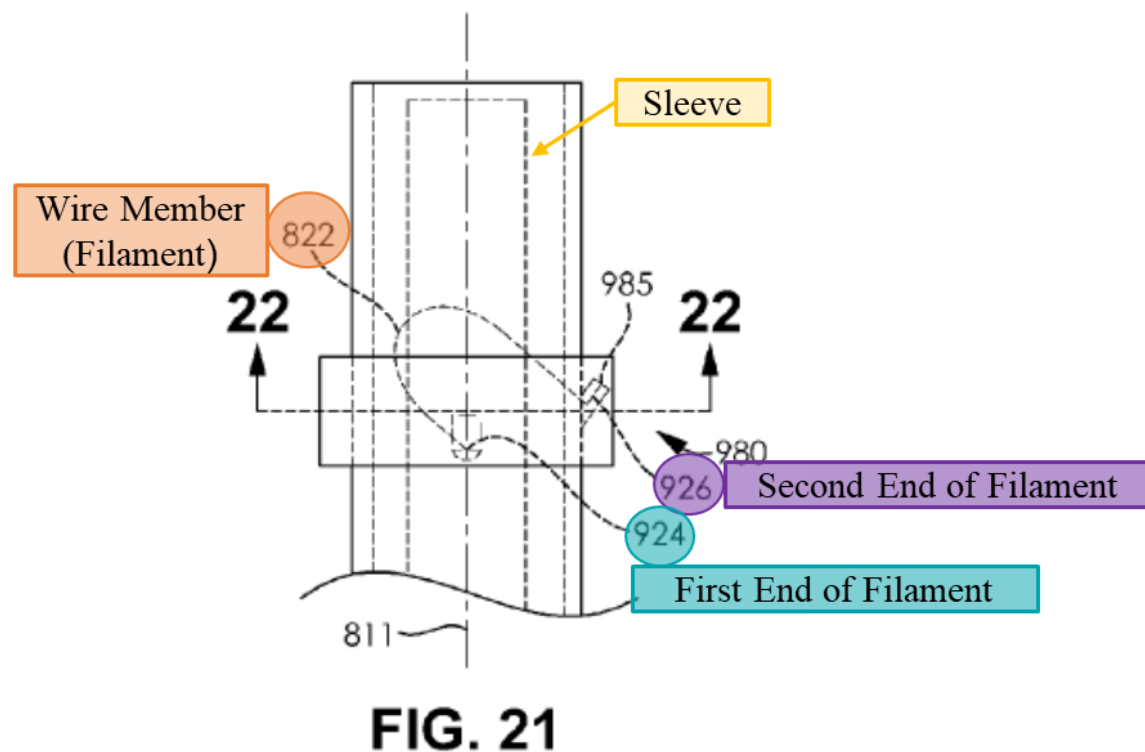
Hartley's String Has First and Second End Portions (Claim 2)



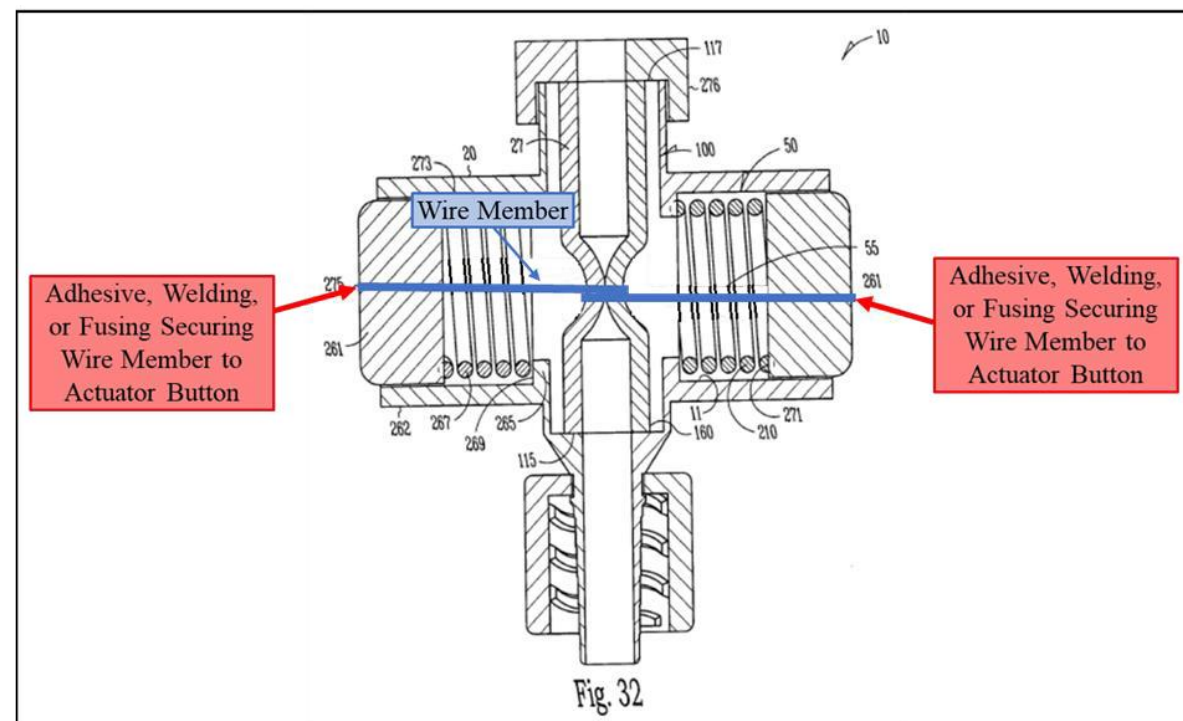
Demonstrative Illustration Schaffer + Hartley's String



Eller's Wire Has First and Second End Portions (Claim 2)



Demonstrative Illustration
Schaffer + Eller's Wire Member



Grounds 5-7: Schaffer + Hartley or Eller + Garrison or Schaffer + Garrison Renders the Claims Obvious

No Dispute That Preamble Is Not Limiting

'012 Patent

1. **An aspiration catheter, comprising:**
an elongate, flexible tubular body, having a proximal end,
a distal end and a central lumen;
a hemostasis valve on the proximal end of the catheter, the
hemostasis valve comprising
 - (a) a collapsible tubular sidewall defining a valve
lumen in communication with the central lumen; and
 - (b) a constricting mechanism having at least a first
actuator, a first filament formed into a loop around
the collapsible tubular sidewall, the filament having
at least a first end portion extending away from the
loop and connected to the first actuator, and a first
spring configured to move the first actuator in a
direction that pulls the first end portion such that a
diameter of the valve lumen decreases in response to
reducing a diameter of the loop.

PO Response

2. Aspiration in the Preamble

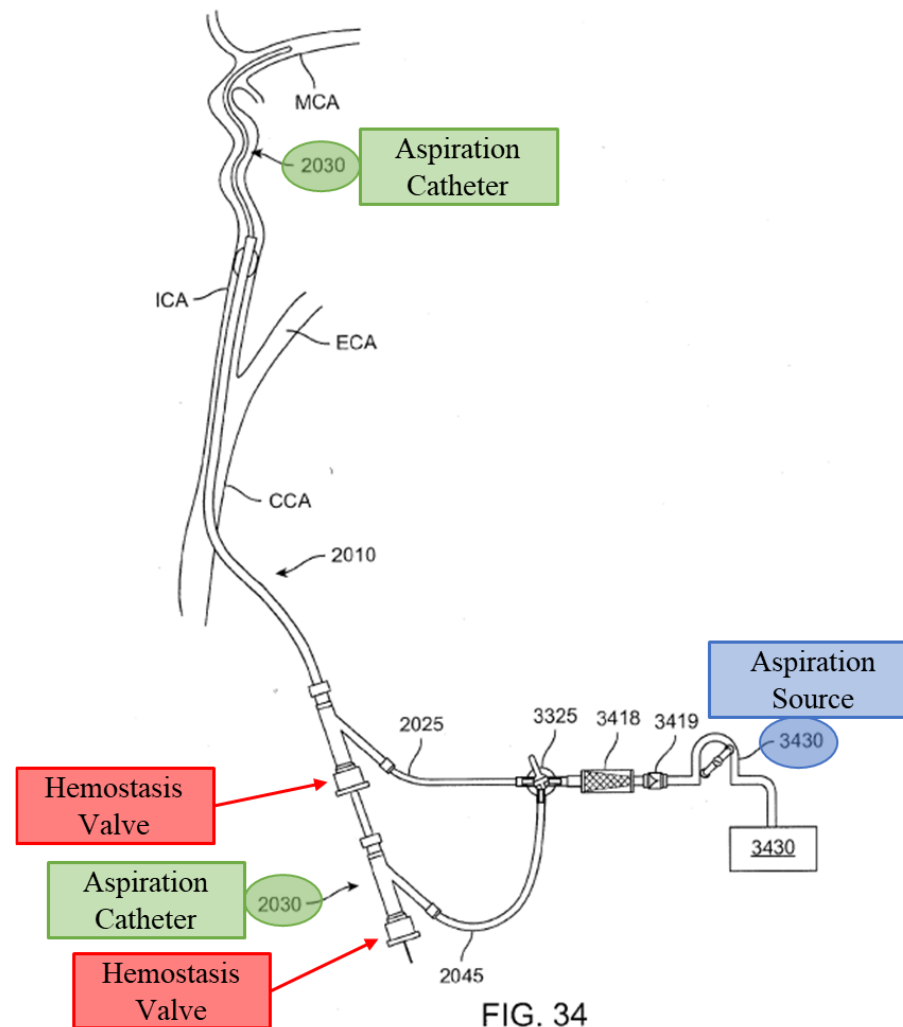
Petitioner proposes that “aspiration” in the preamble of Claim 1 is not limiting. Petition, pp.18-20. **This claim construction issue is not germane to Patent Owner’s arguments here.** Patent Owner reserves the right to contest whether “aspiration” is limiting in this proceeding and other proceedings relating to the '012 Patent and other related patents.

No Disputes Regarding Combination of Garrison with Schaffer/Hartley/Eller

VI. CLAIM 1 IS NOT OBVIOUS OVER THE COMBINATION OF SCHAFFER WITH GARRISON, OR OVER THE COMBINATION OF SCHAFFER, GARRISON AND EITHER OF HARTLEY OR ELLER (GROUNDS 5-7)

Petitioner relies on Garrison for allegedly disclosing the term “aspiration” in the preamble of Claim 1, the “tubular body” of Claim 1, and the “hemostasis valve of” Claim 1. Petition, pp.83-94. However, Petitioner does not rely on Garrison for disclosing any of the hemostasis valve structural limitations of Claim 1 discussed above (e.g., the “constricting mechanism having ... a first filament formed into a loop around the collapsible tubular sidewall ... such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop”). For at least these reasons, Garrison does not remedy the deficiencies in Schaffer, Hartley, and Eller, and Petitioner does not contend that Garrison does.

Garrison Discloses An Aspiration Catheter



Grounds 1-2: Schaffer Anticipates the Claims or Renders Them Obvious

Summary of PO's Arguments

- ⦿ “Filament” limited to a “thin, flexible length of material”
- ⦿ Schaffer’s actuating members are “rigid”
- ⦿ Schaffer’s actuating members do not form a “loop”

Petitioner's Construction of "Filament"

Thornton Decl.

48. Claim 1 requires “a first *filament* formed into a loop around the collapsible tubular sidewall.” I have reviewed the claims, specification, and prosecution history of the '012 patent, and in my opinion, a person of ordinary skill in the art in September 2017 would have understood the term “filament” in the claims of the '012 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

“Filament” Not Limited to Thin, Flexible Materials

'012 Patent

The constricting mechanism **141** can include at least one filament **150** that extends at least partially around the elongate member **132**. In some embodiments, the at least one filament **150** can circumferentially constrict the elongate member **132** to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. The filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal. In some embodiments, the filament **150** can be nylon, stainless steel, nitinol, silicone, or the like. In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament. In some embodiments, the filament **150** can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

PO Has Filed Other Claims Requiring a “Flexible” Filament

PO’s ’384 Patent

1. A valve assembly, comprising:
a tubular member defining a lumen;
a first filament extending in a first loop around the tubular member, wherein the first filament is flexible;
a second filament extending in a second loop around the tubular member, wherein the second filament is flexible;

“Thin” and “Flexible” Inject Ambiguity

Thornton Decl.

(P.T.A.B. Oct. 29, 2024). However, I have reviewed the '012 patent and it does not describe the filaments as “thin” or “flexible.” Moreover, as I explained above, the specification does not provide any measurements for flexibility that would help a person of ordinary skill in the art determine whether a specific material was, in fact, “flexible.” While the '012 patent identifies some potential dimensions for the “filament(s),” the patent states that those dimensions are exemplary, not mandatory. I also believe that Patent Owner’s use of the phrase

PO Does Not Identify Objective Boundaries for “Flexible”

Zalesky Dep. Tr. (PO’s Expert)

Q. How flexible does a material need to be in order to constitute a filament, under your construction?

A. I'm laughing because the word "very" comes to mind. I don't have a quantitative answer to that.

Q. How would you test whether a material has enough of an ability to conform to a structure that it's surrounding to constitute a filament?

A. One way to do it would be simply wrap the filament around a chosen structure, such as a tubular element or a catheter, and observe its compliance and its coaption to the external wall of the device.

Q. How compliant would the material need to be in order to constitute a filament?

A. Again, very. But I think it would be more of a visual observation of its property.

PO's Expert Admits His Definition Depends on Trial and Error

Zalesky Dep. Tr. (PO's Expert)

Q. How would a person of ordinary skill in the art go about determining whether a given material is compliant enough to be a filament or to not be a filament?

MR. HAMILTON: Objection, incomplete hypothetical.

A. Primarily trial and error.

“Flexible” Not Definite Merely Because POSITA Could Make a Working Device

PO Response

And, Petitioner’s expert agrees that a POSA could determine the level of flexibility required. EX2007, 38:22-39:7 (QUESTION: “So that level of flexibility, in this context of a hemostasis valve for an aspiration catheter, one skilled in the art would be able to determine what that level of flexibility is, wouldn’t they?” MR. THORNTON: “I think a person skilled in the art would be able to engineer the right balance of material properties for the filament, the compression tube, or tubular sidewall, the springs, et cetera, in order to make the design work well.”). In other words, a POSA could easily determine how flexible the filament needs be for the hemostasis valve to function as claimed.

“Loop” Limitation Does Not Justify PO’s Construction

Thornton Supp. Decl.

14. I also see that Patent Owner argues that the filament must be flexible to form a loop. However, a person of ordinary skill would have known that a wide range of materials with varying levels of flexibility can be formed into loops. For example, even steel rebar can be made into loops. I also see that Patent

Restriction Requirement Does Not Support PO's Construction

Election/Restriction

This application contains claims directed to the following patentably distinct species:

I) Figs. 1-5

II) Fig. 12

If elected species I, the application further contains distinct sub-species of filament:

IA) Figs. 1-5

IB) Fig. 6

IC) Fig. 7

ID) Fig. 8

IE) Fig. 9

Disposition of Claims*

5) ☒ Claim(s) 1-9 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☐ Claim(s) _____ is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement

Restriction Requirement Does Not Support PO's Construction

Originally Filed Claim 1

1. An aspiration catheter, comprising:
an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;
a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising -
 - (a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and
 - (b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop.

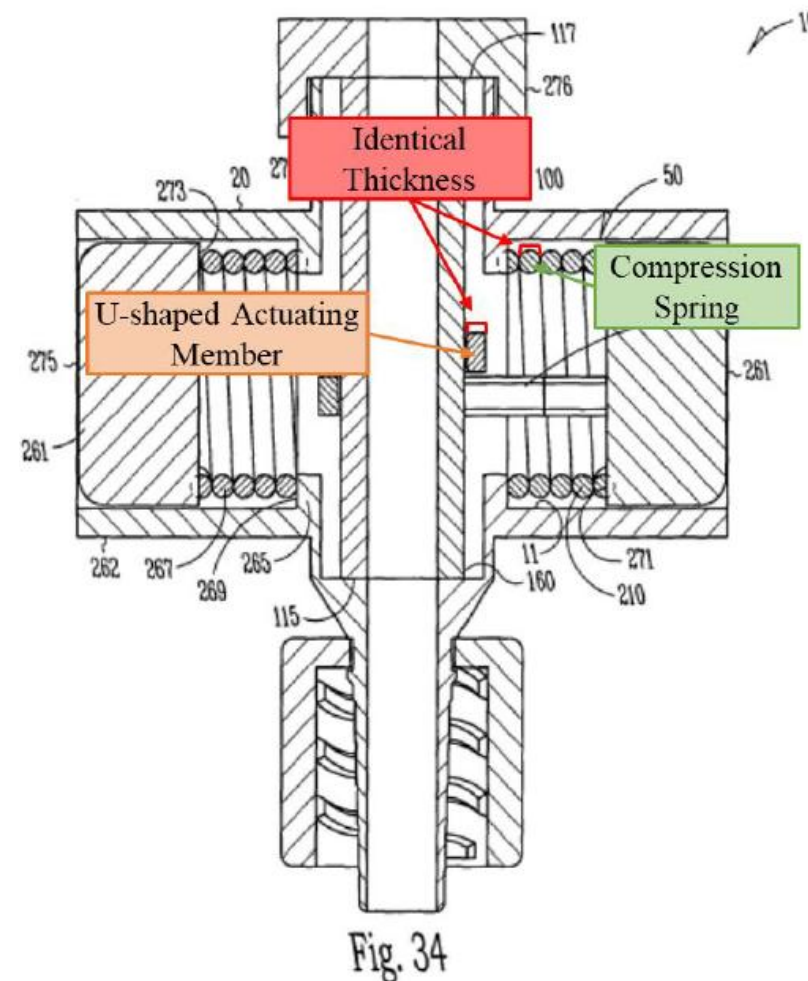
Restriction Requirement Does Not Support PO's Construction

- ⦿ Restriction requirement did not clearly and unambiguously disclaim bight embodiments (Figs. 8 & 9)
- ⦿ Distinction between “loop” and “bight” was not basis for restriction
- ⦿ Examiner recognized that claims were “directed to” Figures 8 and 9
- ⦿ PO did not amend or cancel claims in response to restriction requirement
- ⦿ PO now argues that claims cover more than just the elected subspecies

Schaffer's Actuating Members Are Thin and Flexible

Thornton Supp. Decl.

21. Figures 31-34 of Schaffer also convey to a person of ordinary skill in the art that the U-shaped actuating members are **thin and flexible**. Schaffer's figures illustrate the actuating members as plastic or metal pieces with a thickness that is substantially less than their length. *See* Ex. 1005 (Schaffer) at Figs. 31-34. In addition, although Schaffer does not provide precise dimensions for the U-shaped actuating members, **a person of ordinary skill in the art would have recognized that they would be thin and flexible based on the depiction of the actuating members in relation to the other components of the hemostasis valve.** For example, Schaffer depicts the actuating members having the same thickness as the coils of the compression spring, which must be relatively flexible to function:



Made From Machining Does Not Mean “Rigid”

Thornton Supp. Decl.

23. Patent Owner and Dr. Zalesky also argue that the actuating members in Schaffer are “rigid” based on the following description:

The stasis valve 10, in one option, is made from machining pre-existing amounts of metals and/or plastics. For example, [t]he actuating member 55 and the actuating button 261 is machined from aluminum.

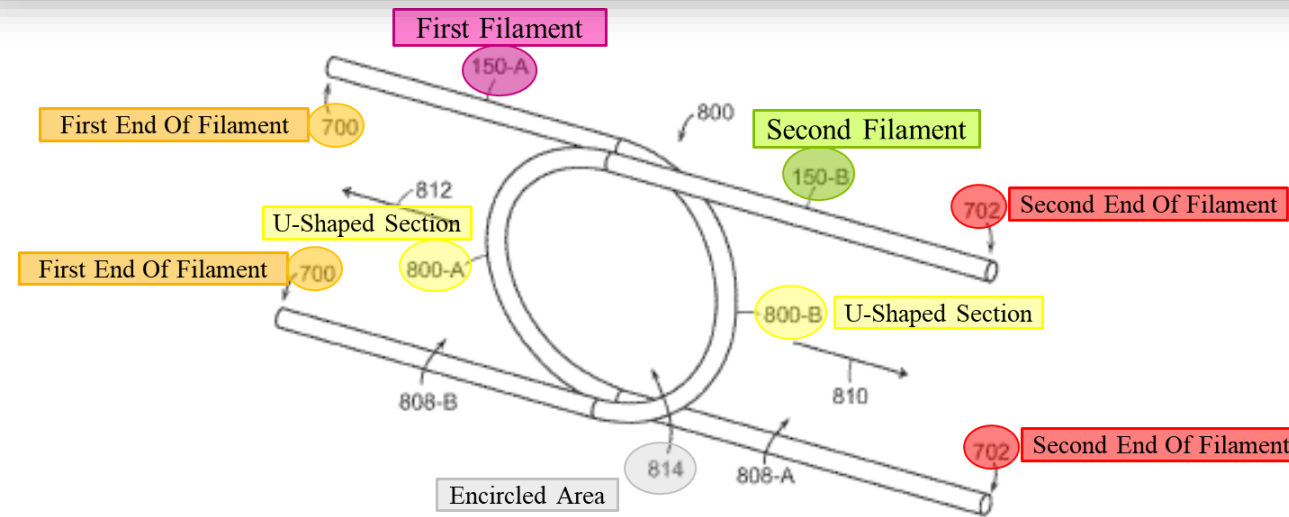
Ex. 1005 (Schaffer) at [0082]. However, the description that a device is “made from machining” is not dispositive of whether the finished product is rigid or flexible. In the case of aluminum, for example, **if enough material is removed during machining, then the final product would not be rigid.** In his deposition, Dr. Zalesky agreed that metallic or polymeric filaments could be manufactured by machining. Ex. 1015 (Zalesky Tr.) at 99:7-17.

Schaffer's Actuating Members Form a Loop

1. An aspiration catheter, comprising:
 - an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;
 - a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising
 - (a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and
 - (b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop.

The “Filament” Can Include Multiple Sub-Filaments

In some embodiments, the filament 150 can comprise multiple filaments, and specifically, as shown in FIGS. 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B. In embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702. The first and second filaments 150-A,



The '012 Patent Says Bights “Encircle” (i.e., Loop)

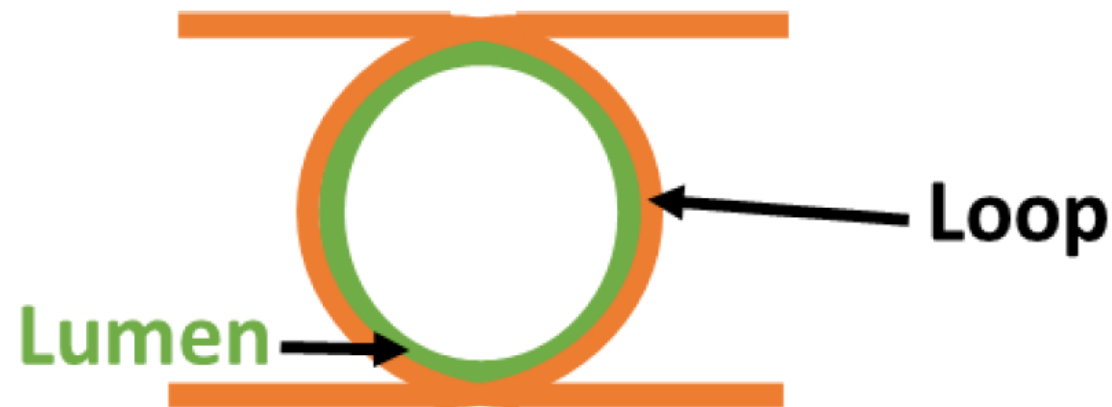
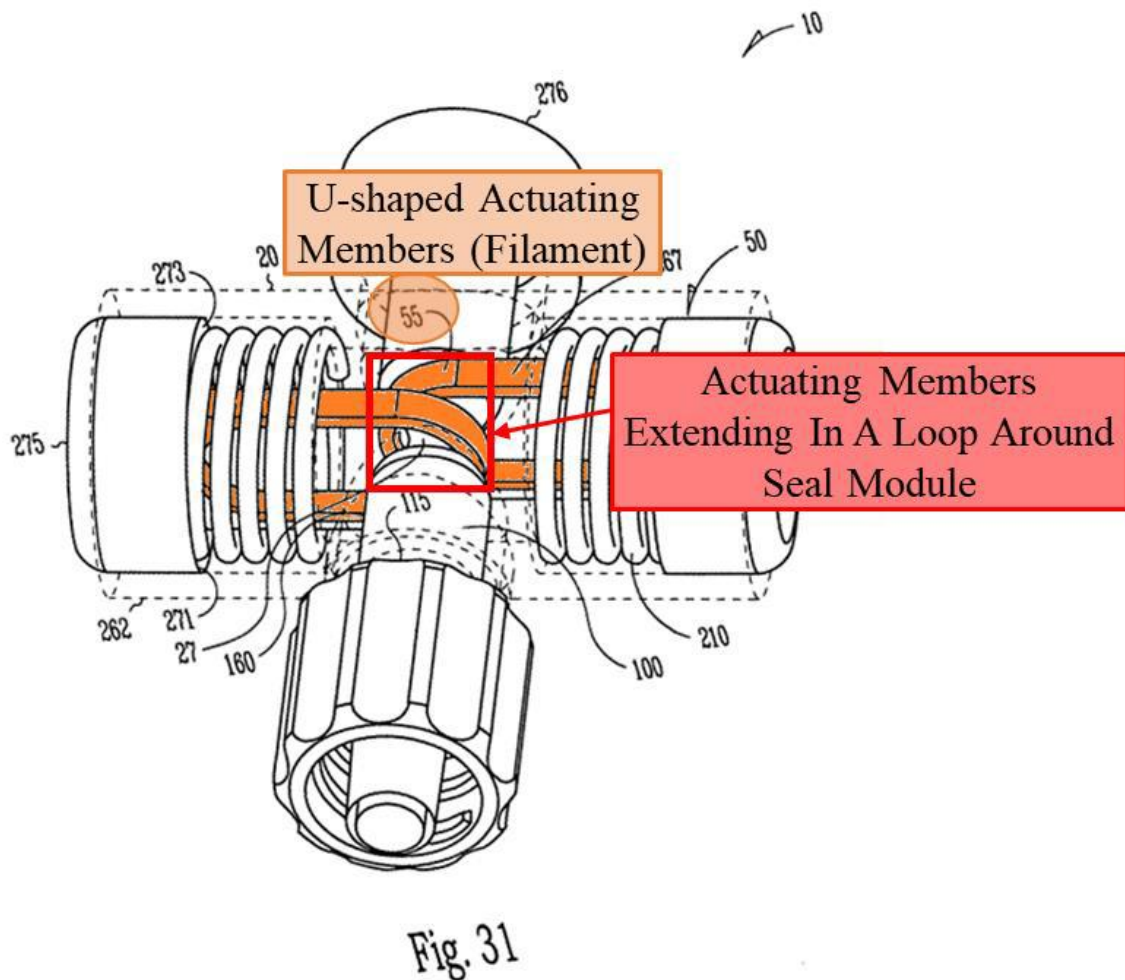
'012 Patent

herein as a constricting area 814. The elongate member 132 can be received within the encircled area 814. In embodiments in which bights 800-A, 800-B overlap to define the encircled area 814, the movement of the constricting mechanism 141 to the first configuration can result in and/or include the first bight 800-A moving in the direction indicated by the arrow 810 and/or the second bight 800-B moving in the direction indicated by the arrow 812, which movement of the bights 800-A, 800-B decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area 814.

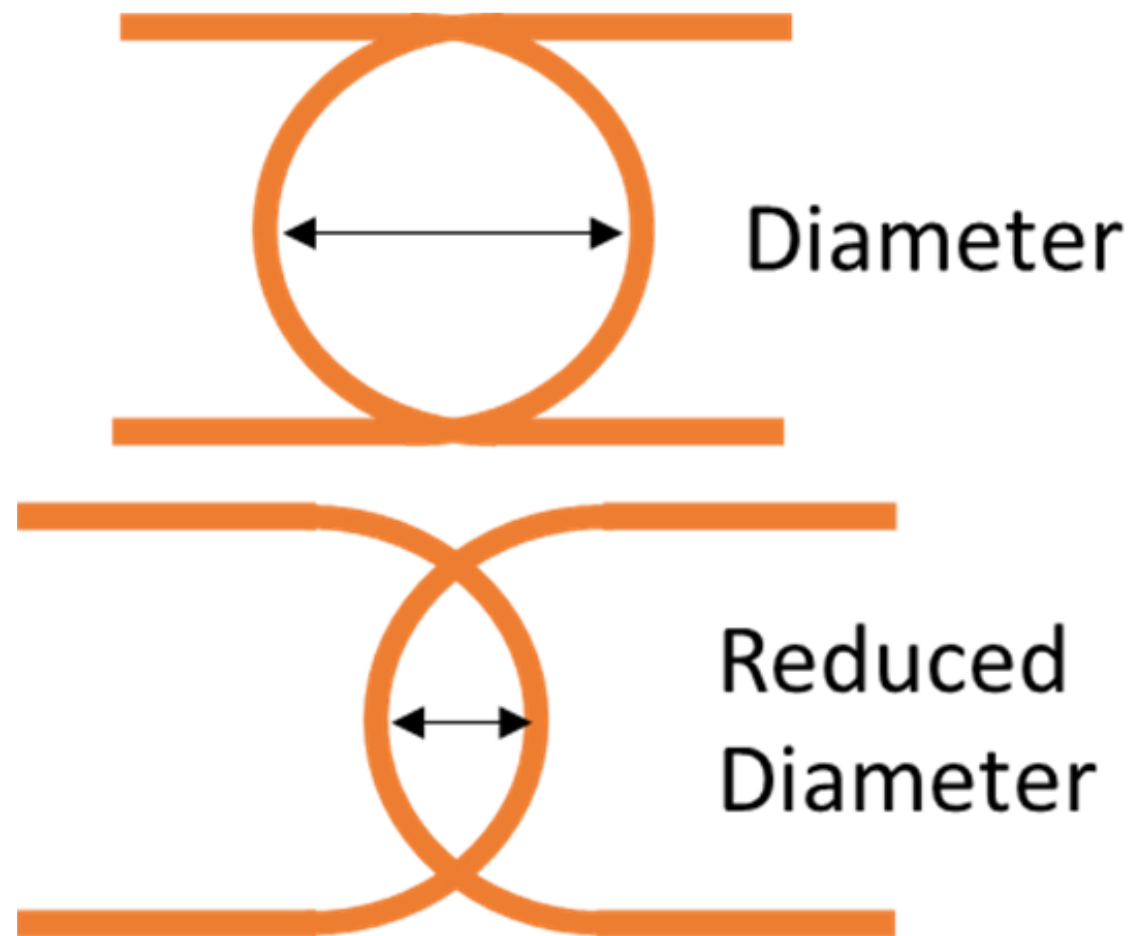
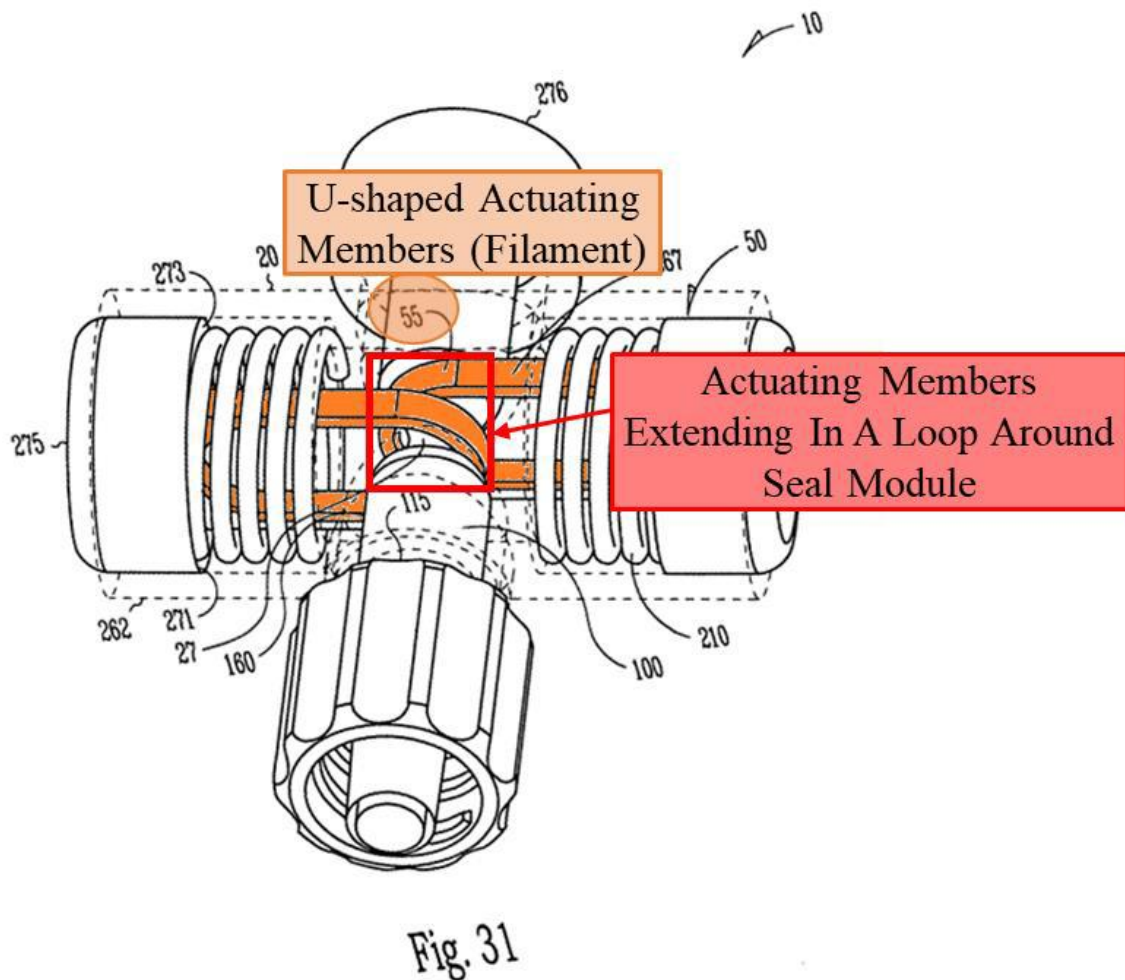
New Oxford Dictionary

loop /lōop/ ► n. 1 a shape produced by a curve that bends around and crosses itself. ■ a length of thread, rope, or similar material, doubled or crossing itself, typically used as a fastening or handle. ■ a curved stroke forming part of a letter
► v. form (something) into a loop or loops; **encircle:** *she looped her arms around his neck.* ■ follow a

Schaffer Forms a Loop



Schaffer's Loop Reduces In Diameter



PO's Requirement for "Single" Filament Unsupported

PO Response

38 (emphasis added). Schaffer's U-shaped actuating members cannot together be construed as the claimed "first filament"—Claim 1 requires **a single** "first filament" by itself "formed into a loop."

'012 Patent

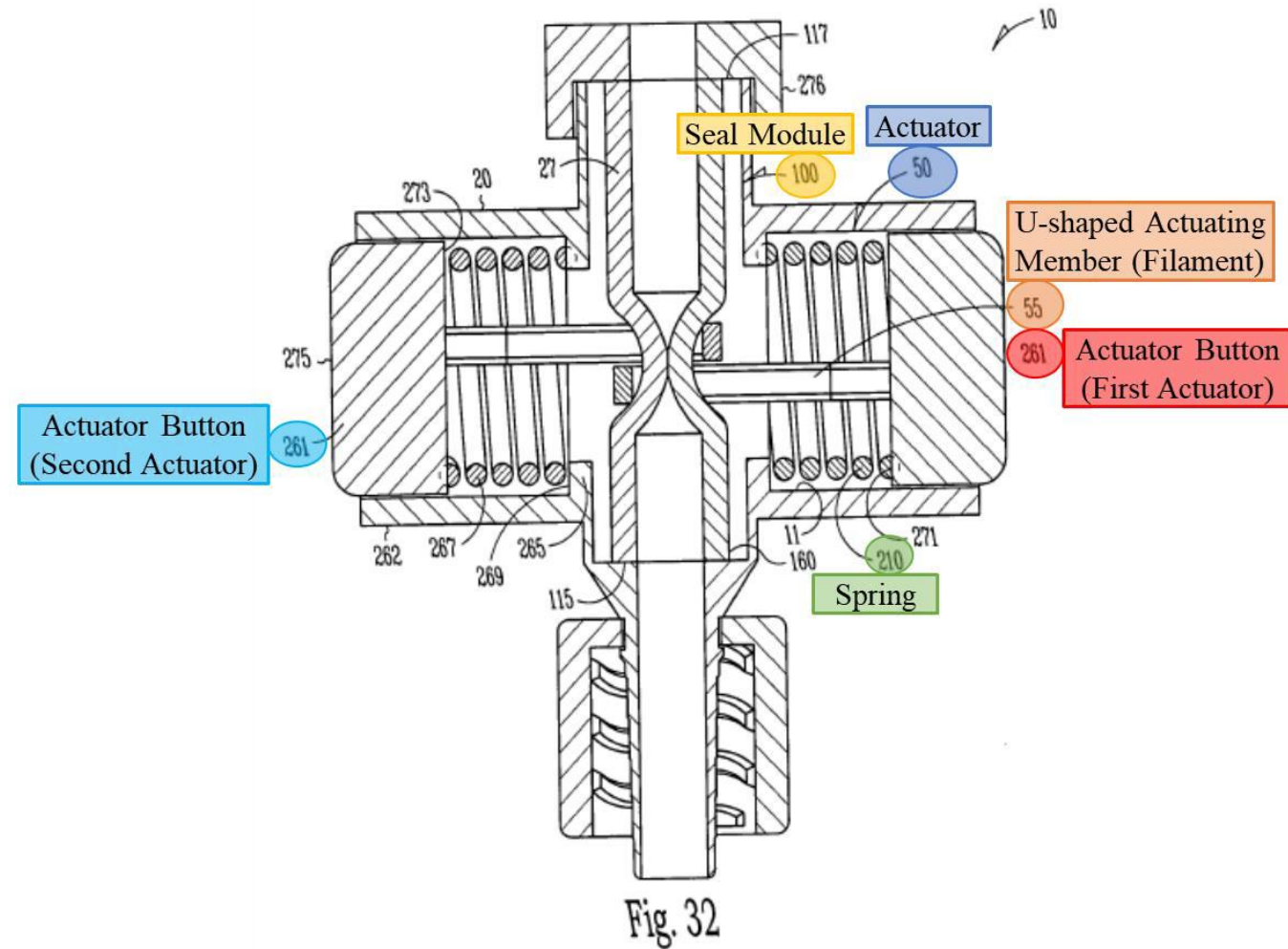
In some embodiments, **the filament 150 can comprise multiple filaments**, and specifically, as shown in FIGS. 7 through 9, the **filament 150 can comprise a first filament 150-A and a second filament 150-B**. In embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702. The first and second filaments 150-A,

Schaffer Anticipates or Renders Claim 2 Obvious

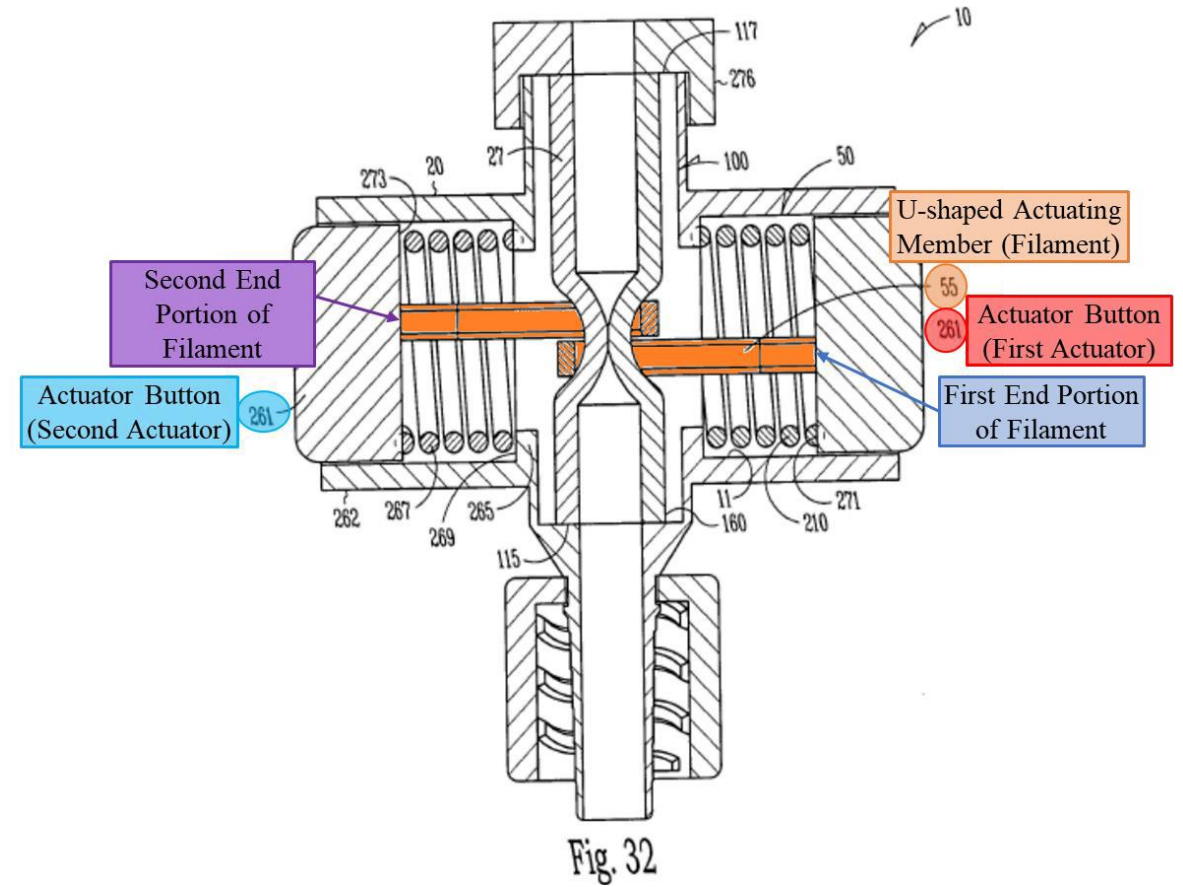
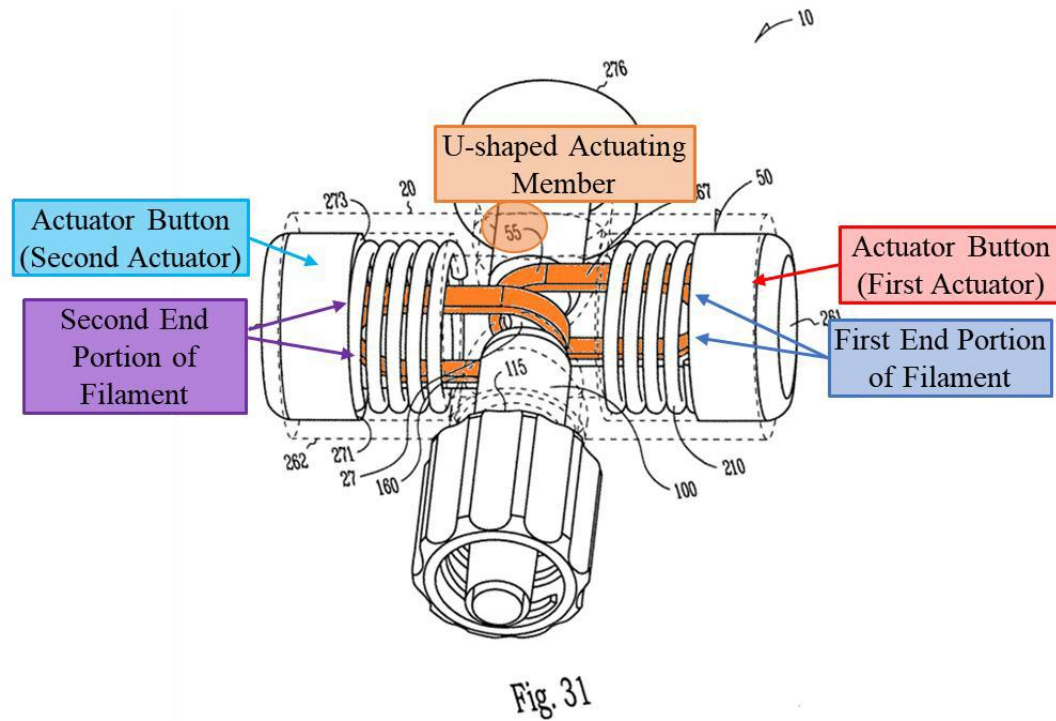
'012 Patent

2. The aspiration catheter of claim 1 wherein:
the collapsible tubular sidewall comprises a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body;
the constricting mechanism further comprises a second actuator and a second spring coupled to the second actuator; and
the filament further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator, and wherein the first actuator and the second actuator are moveable between (a) a first position wherein the filament circumferentially constricts the valve lumen to create a seal about the elongate, flexible tubular body and (b) a second position wherein the filament is moved to open the valve lumen at least partially.

Schaffer Has First and Second Actuators (Claim 2)



Schaffer Has First and Second End Portions (Claim 2)



'012 Patent Says Multiple Filaments Have First and Second End Portions

In some embodiments, the filament 150 can comprise multiple filaments, and specifically, as shown in FIGS. 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B. In embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702. The first and second filaments 150-A,

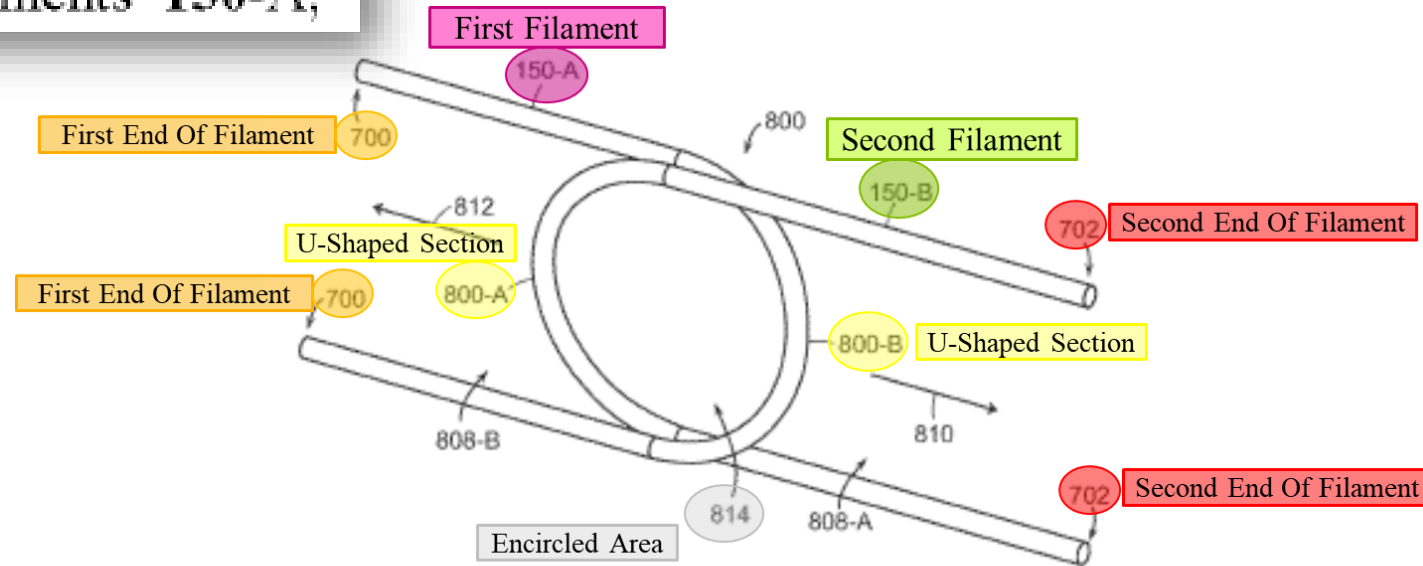


FIG. 8

Mr. Thornton's POSITA Definition Based on Real-World Experience

35. Based on my review of the specification and claims of the '012 patent, it is my opinion that a person of ordinary skill in the art would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience.

36. I can make this assessment because during my career, I had experience assigning engineers to work on mechanical design projects, including projects to design hemostasis valves or incorporate them into catheter-based projects. For such projects, I would assign an engineer with the experience described above.

PO Does Not Identify Basis For POSITA Definition

Zalesky Supp. Decl. (PO's Expert)

76. A POSITA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2 to 4 years of product design or engineering experience designing medical devices in the field of the '012 Patent. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard.

PO's Expert Is Inconsistent

Zalesky Dep. Tr. (PO's Expert)

Q. So a person of ordinary skill in the art does not need to have prior experience designing a hemostasis valve. Is that right?

A. I think that's fair. Yes.

Q. But they wouldn't specifically need experience in designing the devices. Is that correct?

MR. HAMILTON: Objection, asked and answered.

A. Yeah. I think that's correct.

Petitioner Properly Considered Schaffer's Prosecution Drawings (Ex. 1008)

- ⌚ PO does not identify any substantive difference between Schaffer's replacement drawings (Ex. 1008) and published application (Ex. 1005)
- ⌚ No dispute Ex. 1008 authentic and available before priority date
- ⌚ Ex. 1008 is not “extrinsic evidence”
- ⌚ Permissible to consider prosecution history to interpret prior art reference
- ⌚ Permissible to consider “extrinsic evidence” to interpret prior art reference

R.J. Reynolds Does Not Apply Here

- ⌚ Did **not** involve patent figures submitted during prosecution of prior art reference
- ⌚ Board denied institution because prior art articles failed to show prior art device disclosed claim limitations
- ⌚ No holding or suggestion that figures from prosecution of prior art patent publication cannot be considered

