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Petitioner Imperative Care's Demonstratives For Consolidated Oral Argument

July 23, 2026

Imperative Care, Inc. v. Inari Medical, Inc.
IPR2025-00728 (Patent 11,844,921)
IPR2025-00989 (Patent 11,865,291)

Imperative Care v. Inari Medical
IPR2025-00989
Imperative Care Ex. 1050

Outline Of Petitioner's Oral Argument

- Overview of Proceedings

- Disputed Issues
  - Do Schaffer + Hartley or Eller render obvious the "second filament" required by '921 Patent, Claim 10 ('921 Grounds 3-4)?
  - Do Schaffer + Hartley or Eller disclose or render obvious an "actuator having at least a first member movably coupled to the support" ('291 Grounds 3-4)?

- Disputed Issues Previously Resolved by the Board
  - POSITA Qualifications
  - Board found a POSITA would have been motivated to combine Schaffer + Hartley or Eller ('921 Grounds 3-4; '291 Grounds 3-4)
  - Board found a POSITA have been motivated to combine Hartley + Eller ('921 Ground 5)

Issues Not In Dispute

- No dispute that Hartley and Eller disclose a “filament” that forms a “loop”
- PO raises no unique arguments concerning any dependent claims besides ’921 Patent, Claim 10
- No dispute that Petitioner’s references qualify as prior art
- No evidence of secondary considerations of nonobviousness

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Overview Of IPR Proceedings

’921 Patent IPR Grounds

Ground	References	Basis	Challenged Claims
1	Schaffer	35 U.S.C. § 102	1-7, 9-10, 15-18, 20-24
2	Schaffer	35 U.S.C. § 103	1-7, 9-10, 15-18, 20-24
3	Schaffer + Hartley	35 U.S.C. § 103	1-7, 9-10, 15-18, 20-24
4	Schaffer + Eller	35 U.S.C. § 103	1-7, 9-10, 15-18, 20-24
5	Hartley + Eller	35 U.S.C. § 103	1-3, 5-6, 9-10, 15-18, 21-24

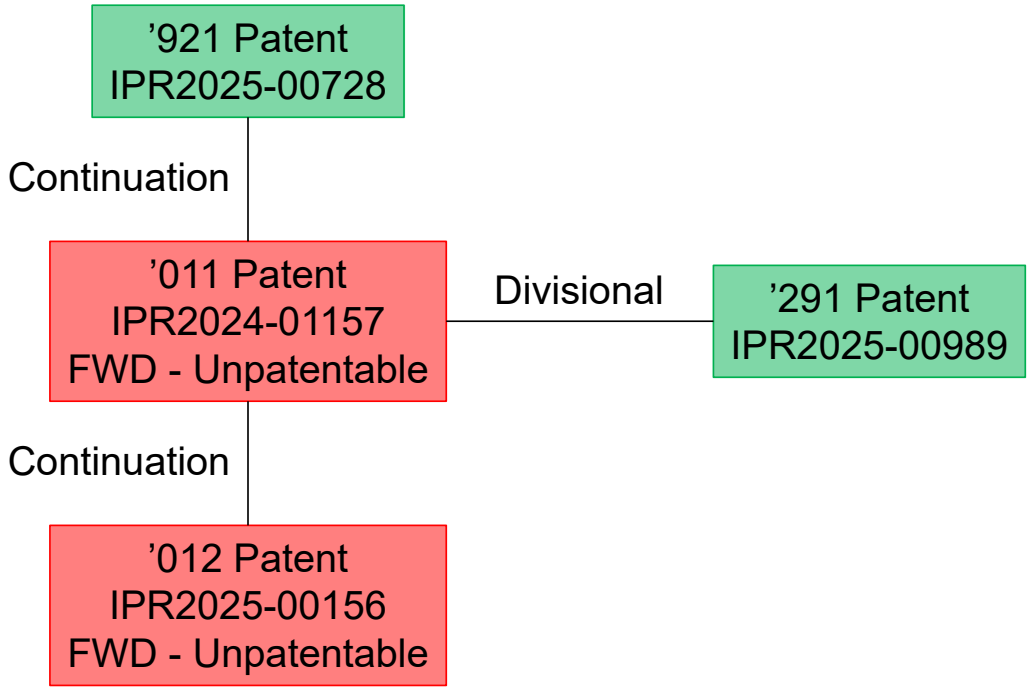
— ’921 Petition (Paper 1) at 20.

’291 Patent IPR Grounds

Ground	References	Basis	Challenged Claims
1	Schaffer	35 U.S.C. § 102	1-3, 5-8, 12-17, 19
2	Schaffer	35 U.S.C. § 103	1-3, 5-8, 12-17, 19
3	Schaffer + Hartley	35 U.S.C. § 103	1-8, 12-17, 19
4	Schaffer + Eller	35 U.S.C. § 103	1-8, 12-17, 19
5	Garrison + Schaffer	35 U.S.C. § 103	18-19
6	Garrison + Schaffer + Hartley	35 U.S.C. § 103	18-19
7	Garrison + Schaffer + Eller	35 U.S.C. § 103	18-19

— ’291 Petition (Paper 1) at 26.

’921 And ’291 Patents Related To Two Unpatentable Patents



— ’921 Ex. 1012 (’011 Pat.); ’921 Ex. 1032 (’012 Pat.); ’921 Ex. 1042 (’011 FWD); ’921 Ex. 1048 (’012 FWD).

’921 Claims Overlap With Unpatentable ’011 Claims

’921 Patent	’011 Patent [Unpatentable]
1. A valve, comprising:	**1.** A valve, comprising:
an elongate member defining a lumen;	a tubular member defining a lumen configured to slidably receive a catheter;
an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and	a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and
a biasing member configured to bias the actuator to the first position.	a biasing system configured to bias the first member and the second member to the first position.

— ’921 Ex. 1001 (’921 Pat.), claim 1; ’921 Ex. 1012 (’011 Pat.), claim 1; ’921 Reply (Paper 22) 3-5.

’921 Claims Overlap With Unpatentable ’012 Claims

’921 Patent

1. A valve, comprising:

an elongate member defining a lumen;

an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and

a biasing member configured to bias the actuator to the first position.

’012 Patent [Unpatentable]

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.

— ’921 Ex. 1001 (’921 Pat.), claim 1; ’921 Ex. 1032 (’012 Pat.), claim 1; ’921 Reply (Paper 22) 3-5.

’291 Claims Overlap With Unpatentable ’011 Claims

’291 Patent

1. A hemostasis valve, comprising:

a support;

an actuator having at least a first member movably coupled to the support;

a collapsible tubular sidewall defining a lumen carried by the support;

a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member, and

a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop.

’011 Patent [Unpatentable]

1. A valve, comprising:

a tubular member defining a lumen configured to slidably receive a catheter;

a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and

a biasing system configured to bias the first member and the second member to the first position.

—’291 Ex. 1001 (’291 Pat.), claim 1; ’291 Ex. 1012 (’011 Pat.), claim 1; ’291 Reply (Paper 19) 2-5.

’291 Claims Overlap With Unpatentable ’012 Claims

’291 Patent

1. A hemostasis valve, comprising:

a support;

an actuator having at least a first member movably coupled to the support;

a collapsible tubular sidewall defining a lumen carried by the support;

a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member, and

a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop.

’012 Patent [Unpatentable]

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.

— ’291 Ex. 1001 (’291 Pat.), claim 1; ’291 Ex. 1022 (’012 Pat.), claim 1; ’291 Reply (Paper 19) 2-5.

District Court-PTAB Make Consistent Preliminary Findings

- Inari asserted ’921 Patent (claims 1 and 10) in preliminary injunction motion
- District Court found Imperative Care raised “substantial question of validity”
  - District Court cited Board’s ’011 Patent institution decision
  - District court found overlap in the ’011 and ’921 patent claims
- District Court found argument that claim 10 is patentable “not persuasive” based on Schaffer

—’921 Ex. 1038 (Order Denying PI) at 15-17.

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Schaffer + Hartley or Eller Render Claim 10 of the ’921 Patent Obvious (’921 Patent, Grounds 3-4)

’921 Patent, Claim 10

- Do Schaffer + Hartley or Eller disclose or render obvious the “second filament” required by Claim 10 (Grounds 3-4)?

> **10**. The valve of claim **1** wherein the actuator is a first actuator, wherein the filament is a first filament, wherein the biasing member is a first biasing member, and wherein the active tensioning mechanism further comprises:
>
> a second actuator coupled to the elongate member via a second filament extending at least partially around the elongate member, wherein the second actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and
>
> a second biasing member configured to bias the second actuator to the first position.

—’921 POR (Paper 18) at 61-66.

Eller Shows That POSITAs Possessed The Skills To Optimize The Number Of Wire Members

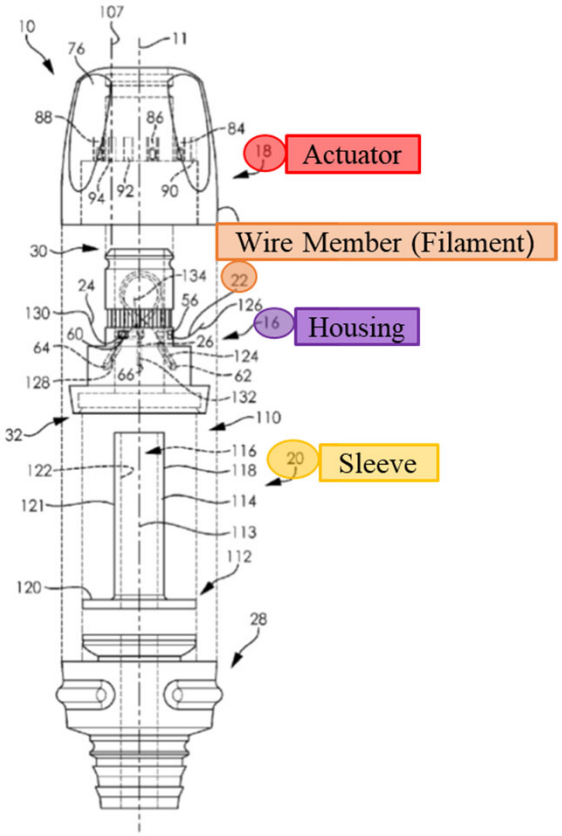


FIG. 2

While the selective fluid barrier valve device **10** has been illustrated as including a first wire member **22**, a second wire member **24**, and a third wire member **26**, a selective fluid barrier valve device can include any suitable number of wire members. Skilled artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the material(s) that forms the sleeve of an embodiment. Example number of wire members considered suitable to include in a selective fluid barrier valve device include one, at least one, two, a plurality, three, four, five, and any other number considered suitable for a particular embodiment.

—'921 Reply (Paper 22) at 19-20; Ex. 1007 (Eller) at 16:7-19, Fig. 2.

Hartley Discloses A String For Constricting A Valve

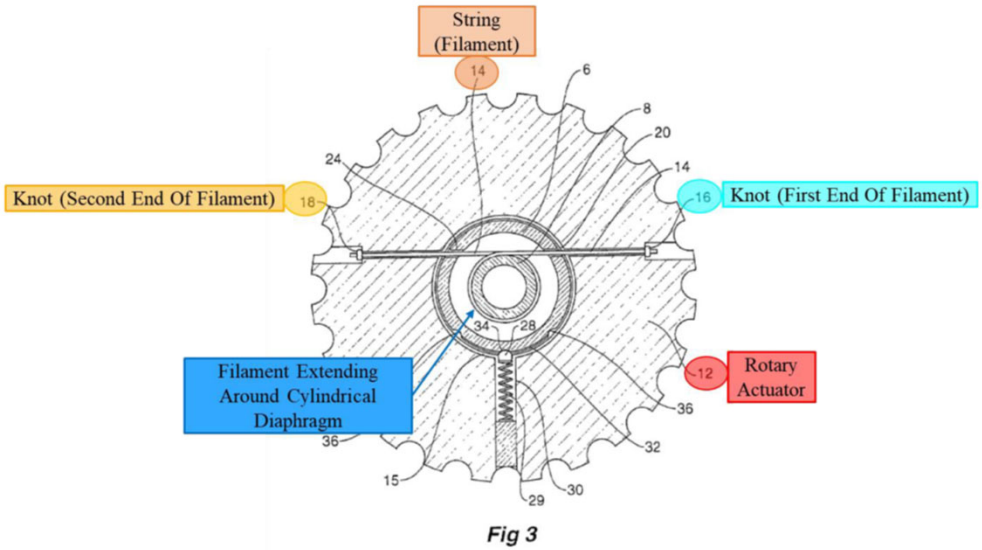


Fig 3

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.

—'921 Petition (Paper 1) at 66; Ex. 1006 (Hartley), [0031], Fig. 3.

No Dispute Hartley's String Includes Multiple Threads

"String" Definition

noun: **string**

1. material consisting of threads of cotton, hemp, or other material twisted together to form a thin length.
   "unwieldy packs tied up with string"

PO's Sur-Reply

theory of obviousness. Pet. Reply, p.13; Petition, pp.66, 70. Patent Owner does not dispute that a single string can "typically include several threads twisted together" or that a single "wire member can include two or more strands or fibers." Petition, pp.66, 70.

—'921 Ex. 1014 (Google Def.); '921 Ex. 1015 (Cambridge Def.); '921 Ex. 1003 (Thornton Decl.) ¶152; '921 Sur-Reply (Paper 23) at 11.

Eller's "Wire Member" Includes Multiple Strands

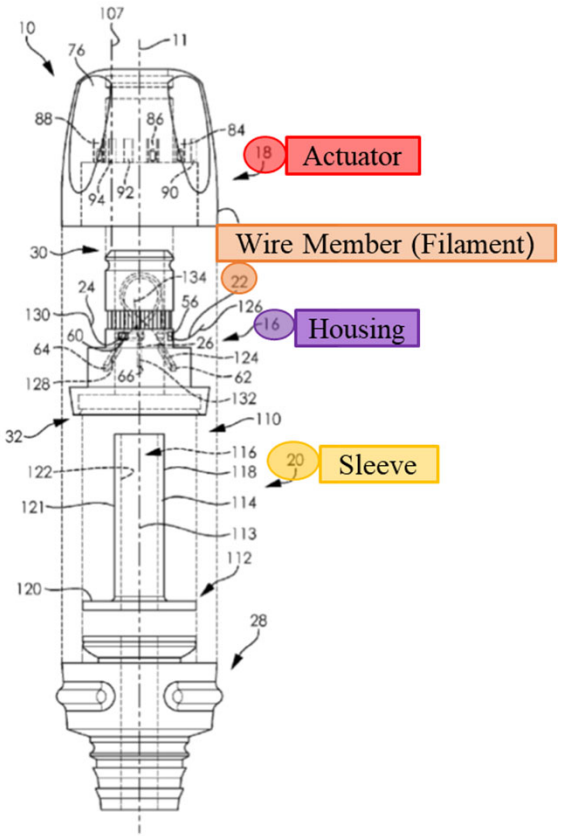


FIG. 2

A wire member, such as the first wire member **22**, the second wire member **24**, and the third wire member **26**, can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted, or otherwise interconnected to one another. For example, a wire member can have a cross-sectional configuration that is round, substantially round, rectangular, square, oval, and any other configuration considered suitable for a particular embodiment and can include any suitable number of strands and/or fibers, such as one, at least one, two, a plurality, three, four, and any other number considered suitable for a particular embodiment. For example, a wire member can comprise a suture or a cable.

—Ex. 1007 (Eller) at 15:61-16:6, Fig. 2.

No Dispute A Thread Or Strand Is A "Filament"

- '921 Patent: "In some embodiments, the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet or tape." – Ex. 1001, 9:15-17

- '011/'012 FWDs: "we agree with Petitioner that a 'filament' as claimed encompasses one or more threads, lines, cords, rope, ribbon, flat wire, sheet, or tape." – Ex. 1042, 17; Ex. 1048, 18.

- PO's Proposed "Filament" Construction: "a thin, flexible length of material formed by one or more strands of material" – POR (Paper 18) at 12-13.

—'921 Petition (Paper 1) at 66-70; '921 Reply (Paper 22) at 13-17.

PO's Expert Agrees Each Thread Is A Filament

Q. So if you had a string comprised of multiple threads and it had sufficient dimension as you understand it to be a filament, and it had an inherent tensile strength that was the ability to withstand force, and it was able to create a very small radius of curvature, would each of the threads within that string be a filament?

MR. MILLER: Objection. Vague. Calls for a legal conclusion.

THE WITNESS: Again, based on the restrictions, each thread if it had those characteristics could be an individual filament.

Q. If you have two threads within the same string, as we just discussed, would each of those threads be a different or a distinct filament?

MR. MILLER: Objection. Vague. Calls for a legal conclusion.

THE WITNESS: If they're wound within or around each other, they constitute a single filament in combination.

Q. Earlier you testified that if you had multiple threads in a string and those threads were unwound, each would be a filament; correct?

MR. MILLER: Objection. Vague. Misstates testimony.

THE WITNESS: Each could be a filament on its own, yes.

—'921 Ex. 1047 (Zaleky Dep. Tr.) at 31:4-32:5.

Hartley's String & Eller's "Wire Member" Include At Least First And Second "Filaments"

fibers that are twisted"). Consequently, a person of ordinary skill in the art would have recognized that Hartley's string 14 encompasses strings having two or more threads, lines, or cords twisted together and therefore includes at least a first and second filament.

157. As I explained above with respect to Hartley, a person of ordinary skill in the art would have found it obvious to use a wire comprised of two filaments (i.e., strands or fibers) that extend from the first actuator button, loop around the elongate member, and terminate at the second actuator button. Eller expressly explains that each wire member can include two or more strands or fibers. Ex. 1007 (Hartley) at 15:61-16:6. In this configuration, the Hartley wire member would include at least two filaments.

—'921 Ex. 1003 (Thornton Decl.) at ¶¶152, 157; '921 Petition (Paper 1) 66-70.

PO Attempts To Import "Separate" Limitation Into Claim 10

POR

simply because of multiple strands twisted together. EX2033, ¶178. A POSA would further understand based on that disclosure that the "first filament" and the "second filament" require separate first and second filaments (whether formed of multiple strands or a single monofilament) rather than a single filament composed of different threads/strands as Petitioner alleges. *Id*. For those reasons Hartley's string or Eller's

—'921 POR (Paper 18) at 63.

No Support For "Separate" Limitation

- "Separate" (or similar term) does not appear in Claim 10
- "Separate" (or similar term) not used in specification to describe first and second filaments
- No argument prosecution history supports a "separate" limitation
- PO identifies no disclaimer or lexicography

—'921 POR (Paper 18) at 61-66; '921 Sur-Reply (Paper 23) at 10-16.

PO Argues Board Should Impermissibly Import "Separate" From Preferred Embodiments

POR

bight 800-B. EX1001; 13:23-29; EX2033, ¶177. A POSA would understand based on that disclosure that the "first filament" and the "second filament" require separate first and second filaments as shown in Figures 7-9 rather than a single filament composed of different threads like Figure 6 as Petitioner alleges. EX2033, ¶177.

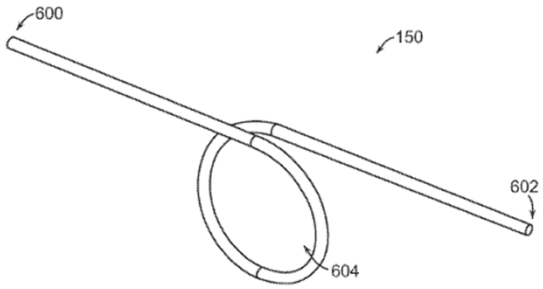


FIG. 6

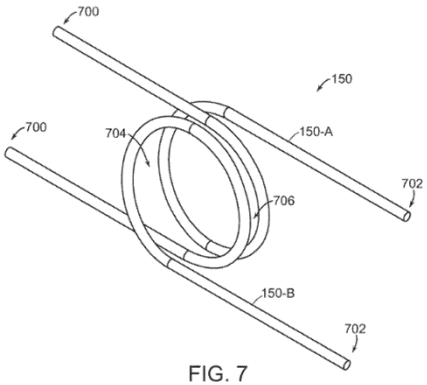


FIG. 7

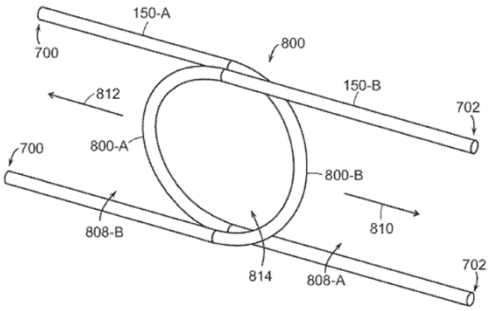


FIG. 8

—'921 Ex. 1001 ('921 Pat.) at 12:54-61, Fig. 7-8; '921 POR (Paper 18) at 62-63.

PO Disregards Specification's Broad Description Of "Filament"

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.

elongate member. In some embodiments, the at least one filament can include a first filament and a second filament. In some embodiments, each of the first filament and the second filament are coupled to the same actuator. In some embodiments, each of the first filament and the second filament are coupled to different actuators. In some embodi-

—'921 Ex. 1001 ('921 Pat.) at 2:65-3:2, 9:1-17; '921 Reply (Paper 22) at 13-17.

PO's Expert Unable To Explain Degree Of Separateness

Q. At what point when they are wound together would they be a single filament rather than separate filaments?

MR. MILLER: Objection. Vague. Calls for a legal conclusion.

THE WITNESS: As soon as they're integrated into a single outside diameter string, that's a single filament.

Q. What constitutes an integrated single outer diameter string?

MR. MILLER: Objection. Vague. Misstates testimony.

THE WITNESS: Two or more threads with the characteristics we just described wound around one another.

Q. So multiple threads comprise a single filament when they are integrated into a single outside diameter; correct?

A. Yes.

Q. And what constitutes integrated is when it's two or more threads that are wound around each other?

MR. MILLER: Objection. Vague. Misstates testimony.

THE WITNESS: Wound or otherwise fashioned in a point so that their constitution leads to a single filament observed with a specific outside diameter.

Q. And how would one observe the single outside diameter?

A. It's visually and mechanically a single component. Its constitution can involve two or more threads that are counter wound, but its function and form are as a single element.

—'921 Ex. 1047 (Zaleky Dep. Tr.) at 32:6-33:14.

Also Obvious To Replace Plastic/Metal U-Shaped Actuating Members With String Or Wire Member

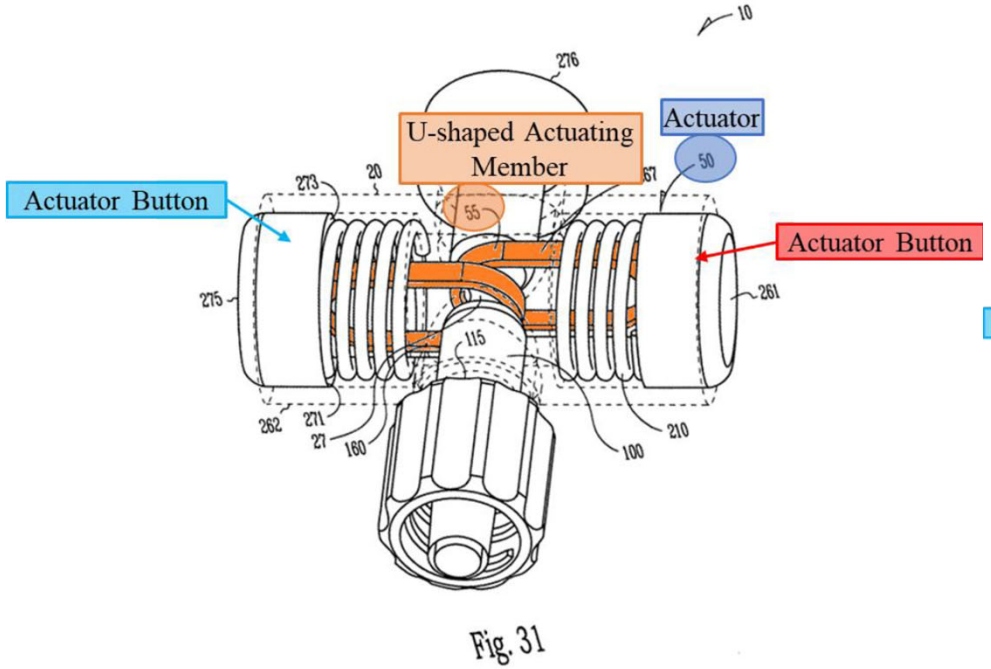


Fig. 31

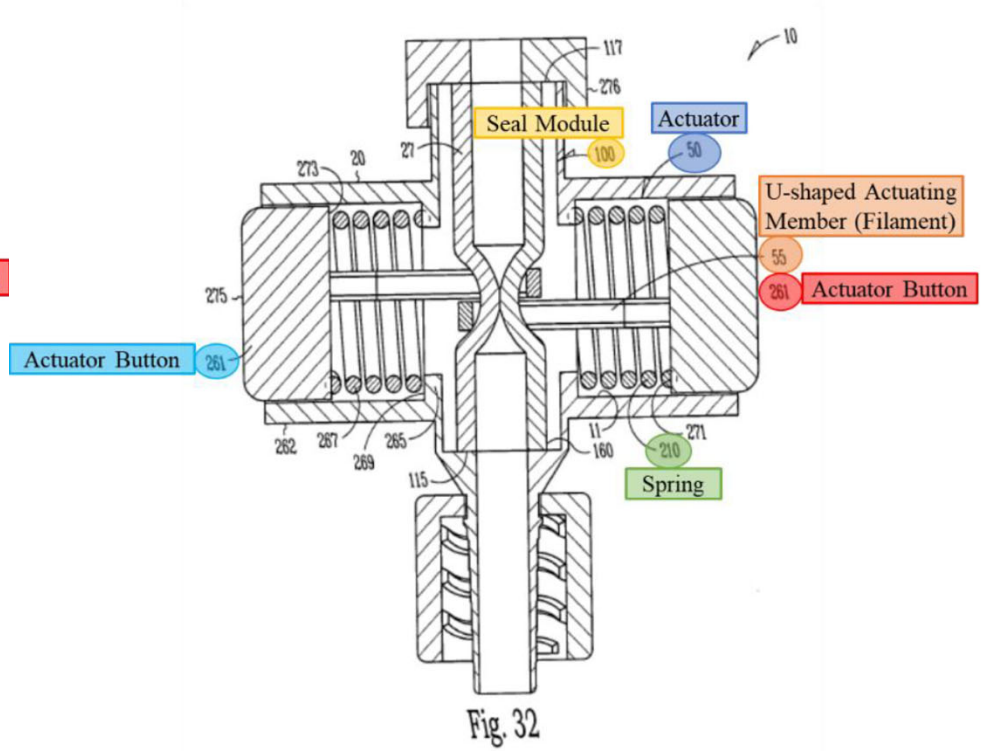


Fig. 32

—'921 Petition (Paper 1) at 68-70; Ex. 1005 (Schaffer), [0075], Figs. 31-32; '921 Ex. 1003 (Thornton Decl.) at ¶¶154-159.

Hartley Discloses a "Filament"

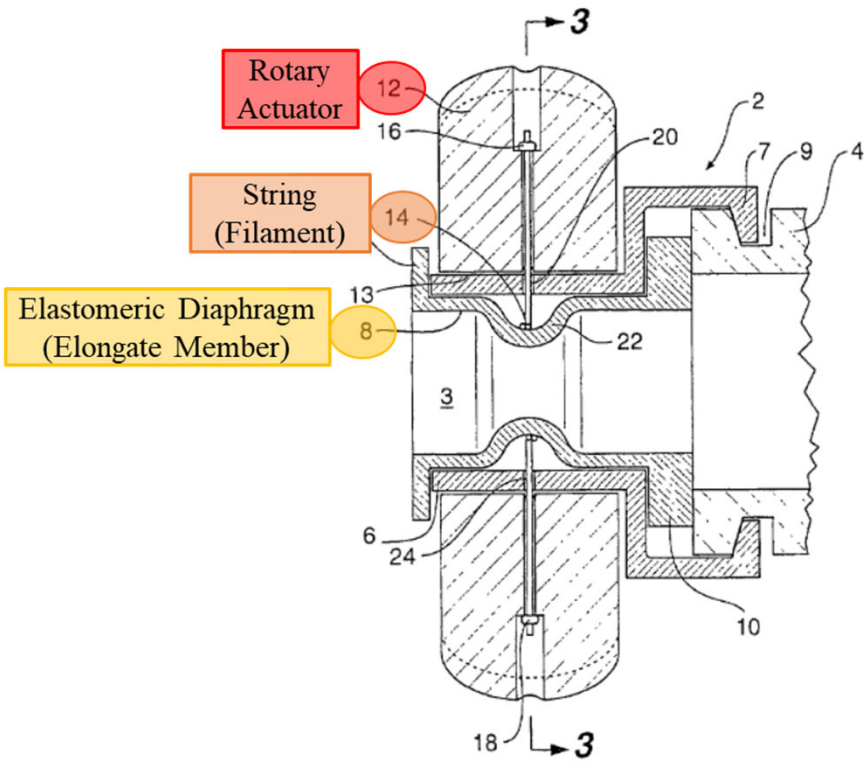


Fig 1

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.

—Ex. 1006 (Hartley), Abstract, [0017], Fig. 1.

Eller Discloses a "Filament"

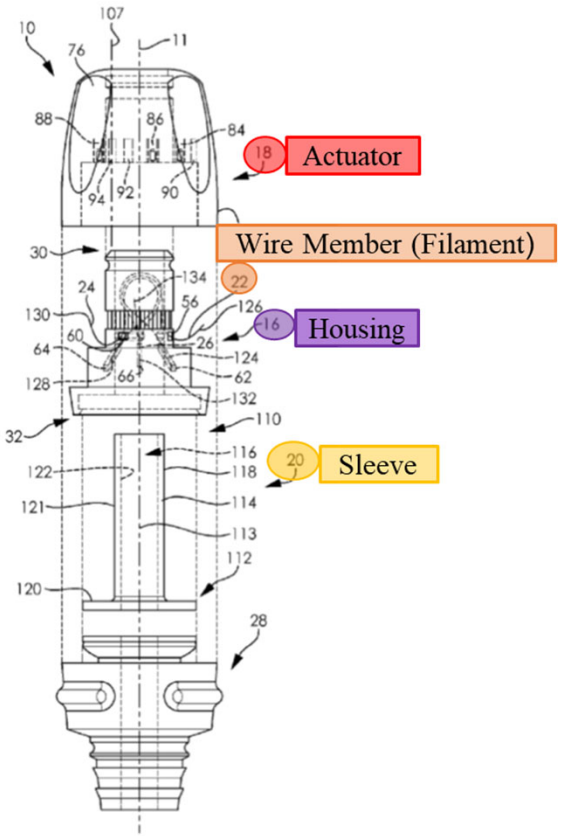


FIG. 2

FIGS. **1**, **2**, **3**, **4**, **5**, **6**, **7**, **8**A, **8**B, **8**C, **9**A, **9**B, **9**C, **10**A, **10**B, and **10**C 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.

—Ex. 1007 (Eller), 5:1-5, 16:7-19, 21:37-22:31, 23:50-25:9, Fig. 2.

Several Undisputed Motivations To Substitute Plastic/Metal U-Shaped Actuating Members With String Or Wire Member

- Hartley/Eller suggest using string/wire member to constrict tube in a valve
- Hartley/Eller disclose string/wire conform to tools of various sizes/shapes
- A finite number of predictable materials existed for use as actuating members including a string and wire member
- This is a substitution of one known element (string/wire member) for another (plastic/metal members) to yield the predictable result of sealing the valve
- Eller discloses POSITAs possessed skills to "select a suitable number of wire members to include in a selective" valve

—'921 Petition (Paper 1) at 68-70; '921 Ex. 1003 (Thornton Decl.) at ¶¶154-159; '921 Reply (Paper 22) at 18-22; Ex. 1007 (Eller) at 16:7-19.

PO Argues Strings/Wire Members Might Interfere

PO Response

they do not repeatedly seal. *Id.*; Petition, pp. 69-70. For example, the two strings or wire members might interfere with one another, especially after Schaffer's actuator buttons are depressed one or more times and if the valve were tilted relative to gravity such that one string/wire members moves toward the other along the seal module. EX2033, ¶182. Specifically, when Schaffer's actuator buttons are depressed one of Hartley's strings or Eller's wire members might move underneath the other, potentially reducing the sealing effectiveness of the valve. *Id.* Indeed, Petitioner's proposed arrangement would increase the cost and complexity of the proposed valve without any of Petitioner's proposed advantages. *Id.*

—'921 POR (Paper 18) at 65; '921 Ex. 2033 (Zalesky Decl.) at ¶182 (same as POR).

’921 Patent Never Describes Methods To Solve Interference

In some embodiments, the filament **150** can be configured to form a bight **800**, which bight **800** can be a single bight or multiple bights. As used herein, a “bight” refers to a U-shaped section between the two ends of the filament **150**. As depicted in FIGS. **8** and **9**, the bight **800** can comprise multiple bights, and specifically a first bight **800**-A and a second bight **800**-B. In some embodiments, the first bight **800**-A can extend through the second bight **800**-B such that the first and second bights **800**-A, **800**-B interlock, whereas in other embodiments, the first and second bights **800**-A, **800**-B can be non-interlocking. Similarly, in embodiments containing the filament **150** having multiple loops, one or several of the multiple loops can be interlocking.

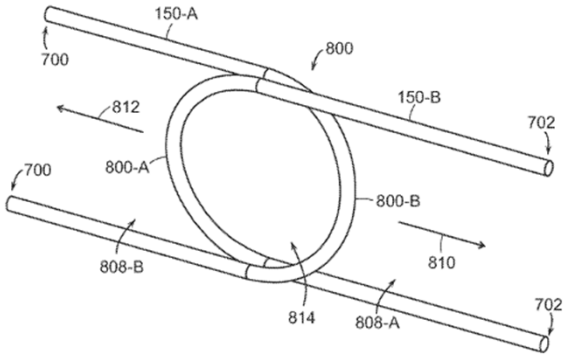


FIG. 8

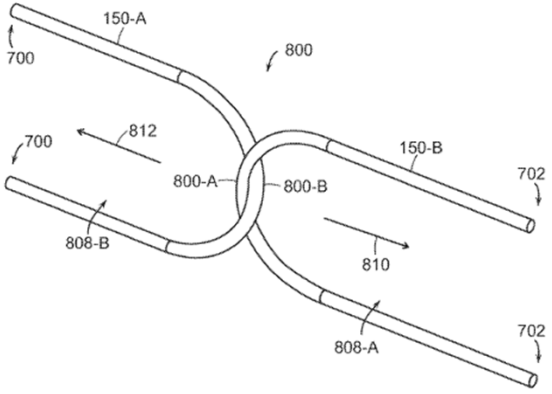


FIG. 9

—’921 Reply (Paper 22) at 19-20; ’921 Ex. 1001 (’921 Pat.) at 13:23-35, Figs. 8-9.

Eller Never Identifies Interference As A Problem

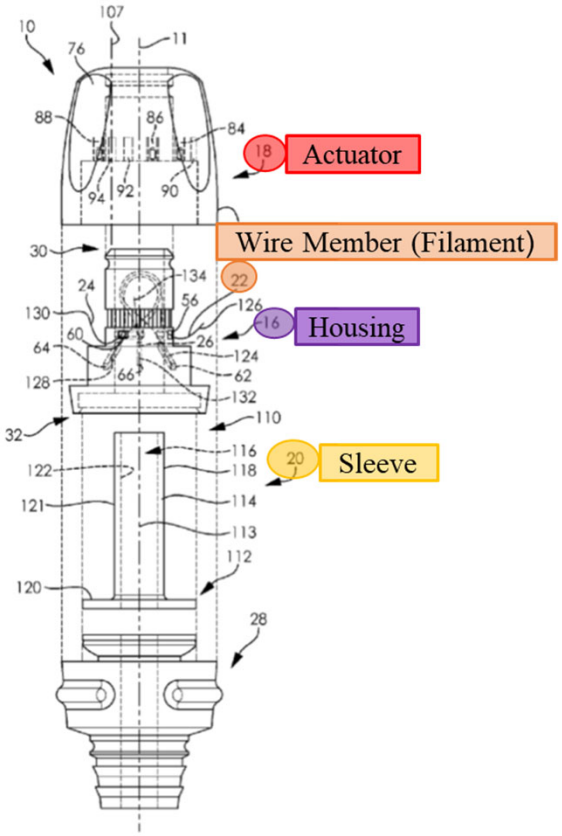


FIG. 2

While the selective fluid barrier valve device **10** has been illustrated as including a first wire member **22**, a second wire member **24**, and a third wire member **26**, a selective fluid barrier valve device can include any suitable number of wire members. Skilled artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the material(s) that forms the sleeve of an embodiment. Example number of wire members considered suitable to include in a selective fluid barrier valve device include one, at least one, two, a plurality, three, four, five, and any other number considered suitable for a particular embodiment.

—'921 Reply (Paper 22) at 19-20; Ex. 1007 (Eller) at 16:7-19, Fig. 2.

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Schaffer + Hartley or Eller Disclose Or Render Obvious "Movably Coupled" ('291 Patent, Grounds 3-4)

’291 Patent, Claim 1

- Do Schaffer + Hartley or Eller disclose or render obvious an “actuator having at least a first member movably coupled to the support” (’291 Grounds 3-4)?

1. A hemostasis valve, comprising:
a support;
an actuator having at least a first member movably coupled to the support;
a collapsible tubular sidewall defining a lumen carried by the support;
a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and
a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop.

—’291 POR (Paper 15) at 36-39, 40 n.3.

No Dispute Schaffer's Housing Is A "Support"

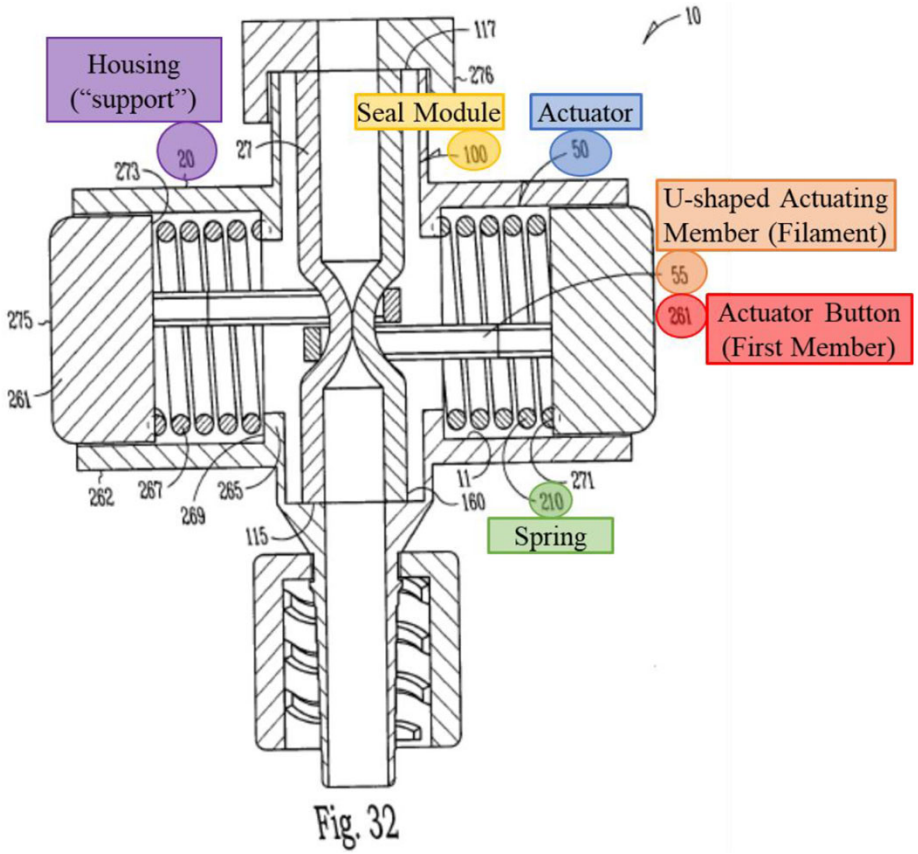


Fig. 32

—'291 Petition (Paper 1) at 31-35; '291 Ex. 1003 (Thornton Decl.) ¶¶83-86; Ex. 1005 (Schaffer) at [0076], Fig. 32.

Schaffer's Actuator Button Is Movably Coupled To The Support

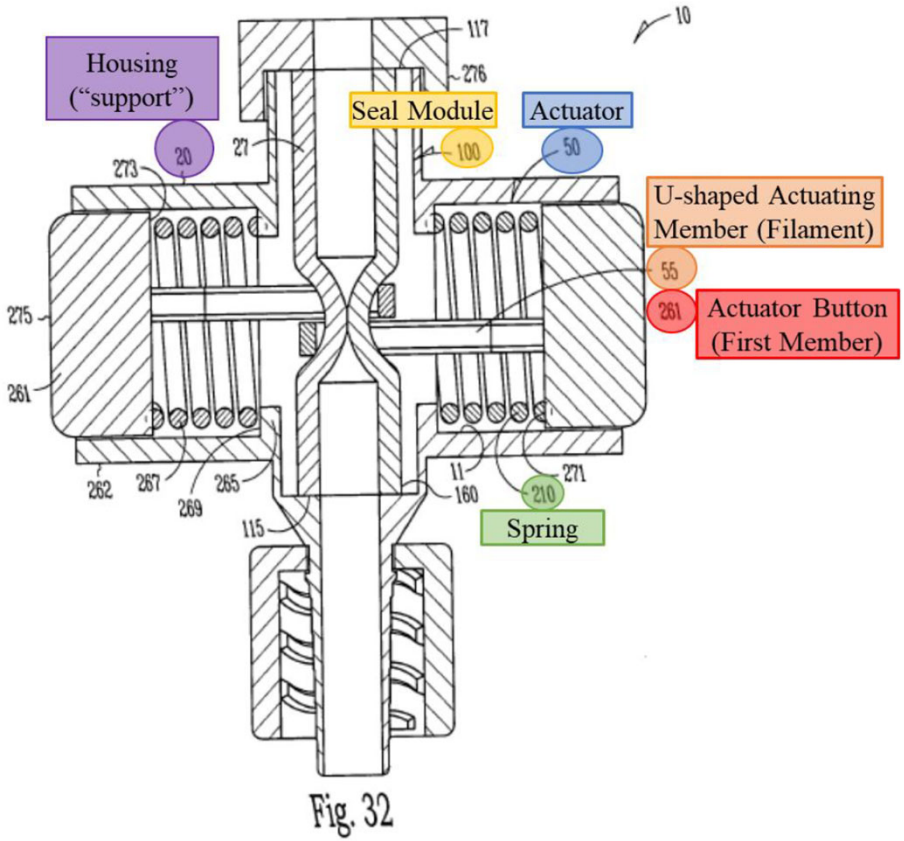


Fig. 32

[0076] In one option, two circular actuators **50** are at least partially circumferencially 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 **50** each include an actuating member **55** which, in one option, is U-shaped. The outer wall **262** of the housing **20** and the inner flange wall **265** of the housing **20** provides opposing support for two resilient members **267** (e.g. spring **210**) disposed within the actuating member **55**. The resilient members **267** include a proximal end **269** and a distal end **271** where the proximal end **269** of the resilient members **267** abut the inner flange wall **265** of the housing **20** and the distal end **271** of the resilient members **267** each abut the proximal end **273** of an actuator button **261**. In one option, the actuators **50** are configured cylindrically to slide along the cylindrical interior wall **11** of the housing **20** from a first position to a second position.

—Ex. 1005 (Schaffer) at [0076]-[0077], Fig. 32; '291 Petition (Paper 1) at 31-35; '291 Ex. 1003 (Thornton Decl.) ¶¶83-86.

Parties Agree Schaffer's Buttons Cannot Be Separated From Support

PO Response

> Instead, Schaffer discloses that its actuator buttons 261 are inserted into opposing sides of the housing 20 and coupled only to actuating members 55 which extend around the seal module 100. *Id.* at ¶98; EX1005, ¶83 ("The actuator button 261 and resilient member 267 (e.g., spring 210) are inserted into an opposing side of the housing 20."). The actuator buttons 261 and the actuating members 55 are held in place only by the resistive force of the seal module 100 against the U-shaped actuating members 55. EX2009, ¶98. Accordingly, Schaffer's actuator buttons 261 are not coupled to the housing 20.

—'291 Patent POR (Paper 15) at 37; *see also id.* at 39 (acknowledging buttons do not "fall out of the housing").

PO's Expert Attempts To Import Additional Limitations Into The Claims

99. Accordingly, the actuator buttons 261 are not coupled at all to the housing 20 but only to the seal module 100. In contrast, for example, the '291 specifically provides that the housing 128 includes "one or several retention features 140" that "engage with and retain all or portions of the constricting mechanism 141 of the valve 104," and more specifically that "retain the actuator 142 and/or can couple the actuator 142 to the housing 128":

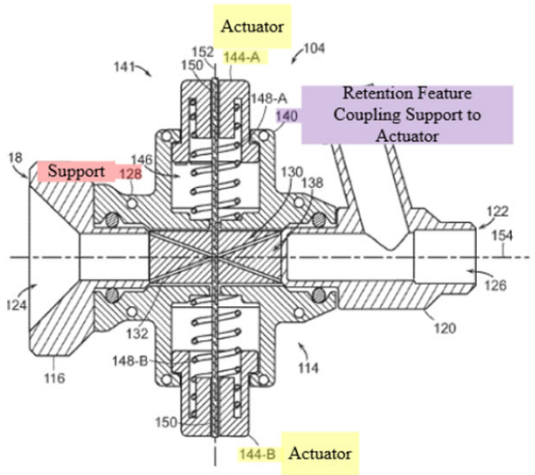


FIG. 2

EX1001, 8:17-23. That is, a POSITA would understand the first member recited in the independent Claims to be "movably coupled" to the support such that it is retained by the support. And, as set forth above, the actuator buttons of Schaffer are not retained or constricted in movement by the housing 20 but simply inserted into the cylindrical openings therein and retained by the seal module via the actuating members 55. If the seal module were not there, Schaffer's actuator buttons 261 would simply pop out of the housing 20. Therefore, Schaffer does not disclose the "first member movably coupled to the support" as recited in independent Claim 1.

—'291 Ex. 2009 (Supp. Zalesky Decl.) at ¶99; *see also* '291 POR (Paper 15) at 36-39 (presenting same argument).

"Coupled" Does Not Require "Directly" Coupled Or "Retention Features 140"

- Claims do not use "directly" coupled or "retention feature" (or similar terms)
- Plain and ordinary meaning of "coupled" includes direct and indirect coupling
  - *See* '291 Reply (Paper 19) at 7-8 (collecting cases)
- No prosecution history support
- '291 Patent specification uses "coupled" to mean direct or indirect coupling

> member **132**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via one or several other components of the valve **104**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via the compression of the reinforcement structure **320** and the elongate member **132** between the housing **128** and one or both of the proximal **116** and the distal **120**.

—'291 Ex. 1001 ('291 Pat.) at 11:35-42; *see also* '291 Reply (Paper 19) at 5-13 (presenting arguments).

“Retention Features 140” Are Optional

The housing **128** can further include one or several retention features **140**. The one or several retention features **140** of the housing can engage with and retain all or portions of the constricting mechanism **141** of the valve **104**. In some embodiments, the one or several retention features **140** of the housing **128** can retain the actuator **142** and/or can couple the actuator **142** to the housing **128**. The actuator **142**

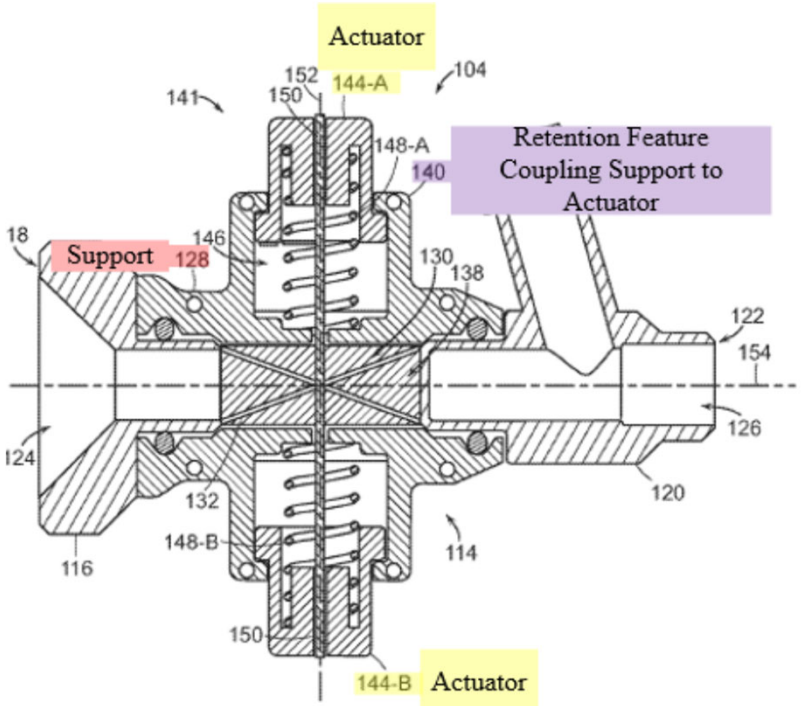


FIG. 2

—’291 Ex. 1001 (’291 Pat.) at 8:17-23; ’291 Ex. 2009 (Supp. Zalesky Decl.) at ¶99; ’291 Reply (Paper 19) at 11-13.

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Issues Previously Resolved By The Board

Disputed Issues Previously Resolved By Board

- POSITA Qualifications

- Board found a POSITA would have been motivated to combine Schaffer + Hartley or Eller (’921 Grounds 3-4; ’291 Grounds 3-4)

- Board found a POSITA would have been motivated to combine Hartley + Eller (’921 Ground 5)

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The POSITA Definition Has Been Resolved

The Board Has Resolved The POSITA Definition

- Parties propose the same POSITA definitions as in ’011 and ’012 Patent IPRs
- Board adopted the same definition in the ’011 and ’012 FWDs:
  - Undergraduate degree in mechanical engineering or a related engineering discipline; and
  - 2-4 years of design or engineering experience related to products in the field of the invention, which involves endovascular devices and the surgical procedures that use such devices
- No dispute Petitioner’s expert qualifies

—’921 Ex. 1042 (’011 FWD) at 13-14; ’921 Ex. 1048 (’012 FWD) at 13-14; ’921 Reply (Paper 22) at 1.

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.

—'921 Ex. 1037 (Zalesky 6/23/25 Dep. Tr.) at 72:21-73:2, 74:18-75:1.

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The Board Found A Motivation To Combine Schaffer + Hartley Or Eller

Evidence Supports A Motivation To Combine Schaffer + Hartley Or Eller

Motivation to Combine	'921/'291 IPRs	'011/'012 FWDs
Hartley/Eller disclose using a string/wire to seal a hemostasis valve	'921 Petition 36, 43; '921 Reply 6-10; '291 Petition 51-52; '291 Reply 13-16	'921 Ex. 1042 ('011 FWD) 52; '921 Ex. 1048 ('012 FWD) 55
Hartley's string or Eller's wire form a better seal than Schaffer's U-shaped actuating members in some circumstances	'921 Petition 36-37, 43; '921 Reply 6-8; '291 Petition 51-52; '291 Reply 13-16	Ex. 1042, 53-55; Ex. 1048, 56-67
Substitution of one known element (Hartley's string/Eller's wire) for another (Schaffer's U-shaped actuating members) to yield predictable results	'921 Petition 35-36, 42-43; '921 Reply 10-12; '291 Petition 51; '291 Reply 18-20	Ex. 1042, 51-53; Ex. 1048, 54-56
Finite number of options for constricting a tubular member in a hemostasis valve in 2017	'921 Petition 37, 43; '921 Reply 12; '291 Petition 52; '291 Reply 20	Ex. 1042, 55-56; Ex. 1048, 57-58

—'921 Ex. 1003 (Thornton Decl.) at ¶¶85-89, 99-102; '291 Ex. 1003 (Thornton Decl.) at ¶¶106-111, 123-126.

Board Agreed Evidence Supported Motivation To Combine

We find, on balance, that a POSA would have considered the modification of Schaffer's valve to include Hartley's string or Eller's wire to involve little more than combining known prior art features according to those features' known functions to yield a predictable result. Hartley's string and Eller's wire were known in the art and used for a similar purpose to Schaffer's U-shaped actuating members—to constrict and collapse a tubular member/lumen and provide a fluid seal in hemostasis valves. *See,*

That Hartley and Eller contemplate use of their respective string and wire for constricting a lumen and providing a seal against leakage of bodily fluids during surgical procedures also suggests that the disclosed strings and wires would have been regarded as suitable and sufficiently durable for medical devices—and hemostasis valves, in particular. *See, e.g.*, Ex. 1007, 1:13–16, 15:41–56 (listing suitable biocompatible materials for the wire member, such as polypropylene, stainless steel, and titanium).

—'921 Ex. 1042 ('011 FWD) at 51-52; '921 Ex. 1048 ('012 FWD) at 54-55.

Board Agreed Evidence Supported Motivation To Combine

> We further agree with Petitioner that a POSA would have considered the proposed modification to be relatively straightforward, and within the ordinary capabilities of the skilled artisan. For example, as proposed by Petitioner, the ends of Hartley's string or Eller's wire could have been (and predictably would have been) attached to Schaffer's opposing actuator buttons according to known techniques, such as knotting or welding.

> Petitioner also persuades us that the proposed modification of Schaffer's valve to include a single flexible string or wire that replaces the two U-shaped actuating members would have been seen by the POSA as potentially advantageous—giving further reason for the POSA to have made that change. Pet. 35–36. We credit Mr. Thornton's testimony that a POSA would have understood that Schaffer's U-shaped actuating members may form small gaps for fluid leakage around the exterior of certain tools inserted into the lumen. Ex. 1003 ¶ 81. On the other hand, a POSA would have

—'921 Ex. 1042 ('011 FWD) at 52-54; '921 Ex. 1048 ('012 FWD) at 55-56.

Board Has Rejected PO's Arguments Against A Motivation To Combine

Argument	'921/'291 IPR	'011/'012 FWDs
Petitioner's motivation to combine does not exist (e.g., Schaffer already seals perfectly)	'921 POR 29-34; '291 POR 41-46	'921 Ex. 1042 ('011 FWD) 57-59; '921 Ex. 1048 ('012 FWD) 58-59
Petitioner's defect would only exist after modifying Schaffer to form an inferior valve	'921 POR 34-38; '291 POR 46-49	Ex. 1042, 59-62; Ex. 1048, 59-63
The combination is not a simple substitution (e.g., Schaffer discloses more plausible solutions)	'921 POR 38-54; '291 POR 50-62	Ex. 1042, 66-68; Ex. 1048, 69-70
The solutions for constricting a tubular member in a hemostasis valve were not finite, identifiable, or known	'921 POR 54-55; '291 POR 64-66	Ex. 1042, 55-56; Ex. 1048, 57
The modifications would change Schaffer's principles of operation (e.g., forcible disengagement, durability, manufacturing)	'921 POR 55-61; '291 POR 66-70	Ex. 1042, 62-66; Ex. 1048, 64-69

—'921 Ex. 1003 (Thornton Decl.) at ¶¶85-89, 99-102; '291 Ex. 1003 (Thornton Decl.) at ¶¶106-111, 123-126.

Schaffer Compared To The ’921 Patent

’921 Patent

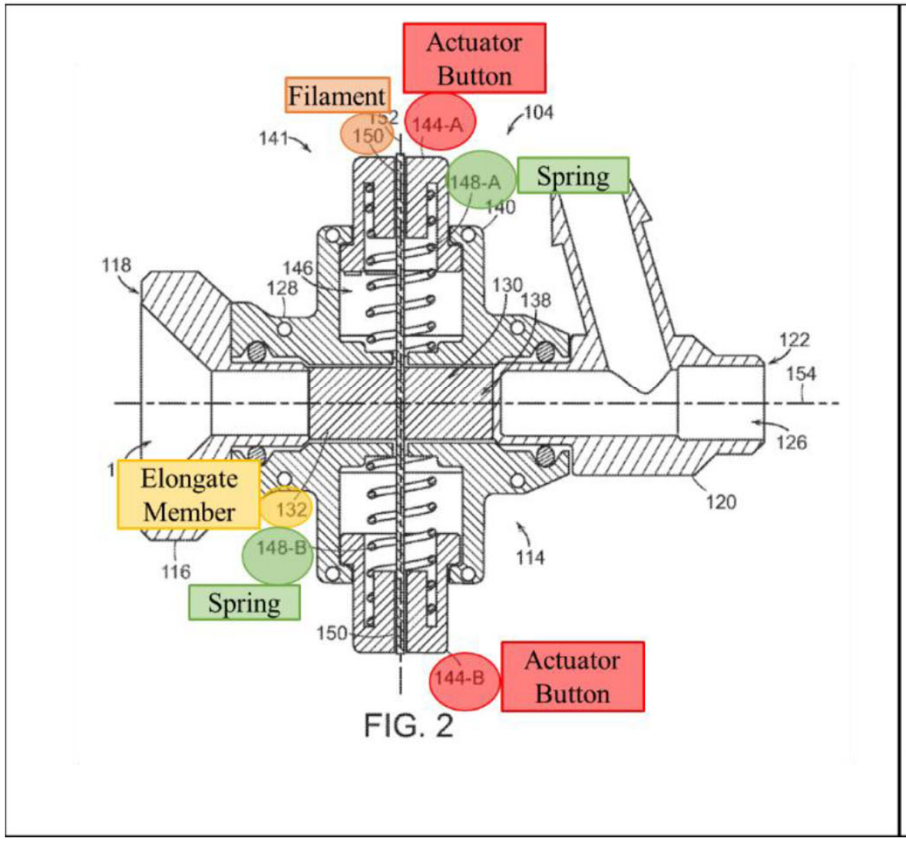


FIG. 2

Schaffer

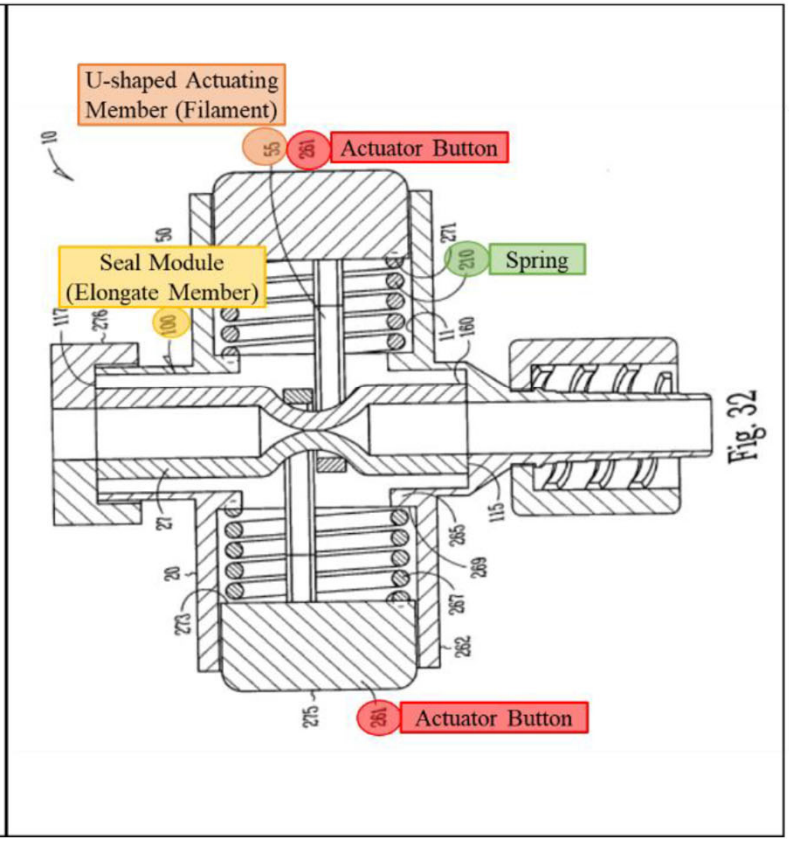


Fig. 32

—’921 Petition (Paper 1) at 5.

Hartley's Filament Forms A "Loop"

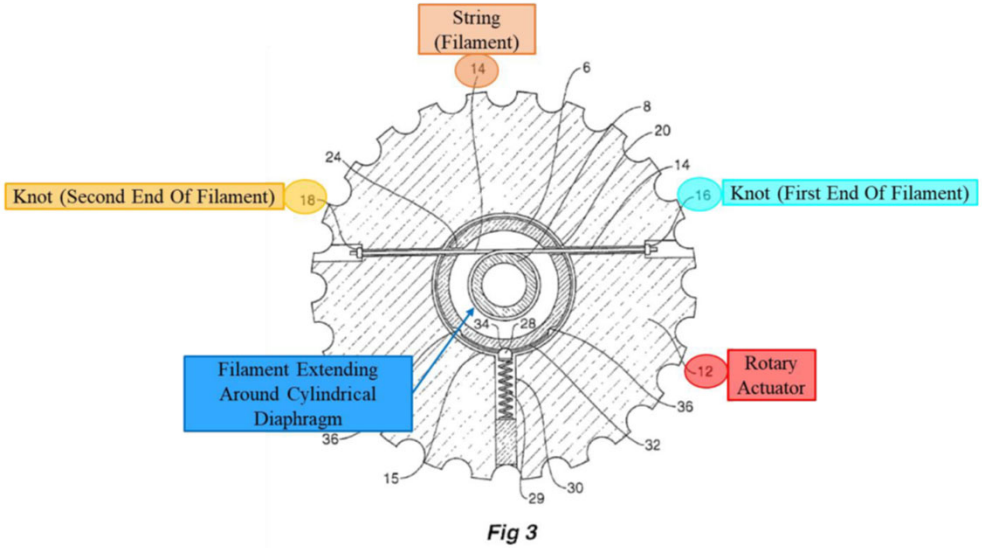


Fig 3

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.

—'921 Petition (Paper 1) at 34-35, 49-50; Ex. 1006 (Hartley), [0031], Fig. 3.

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.

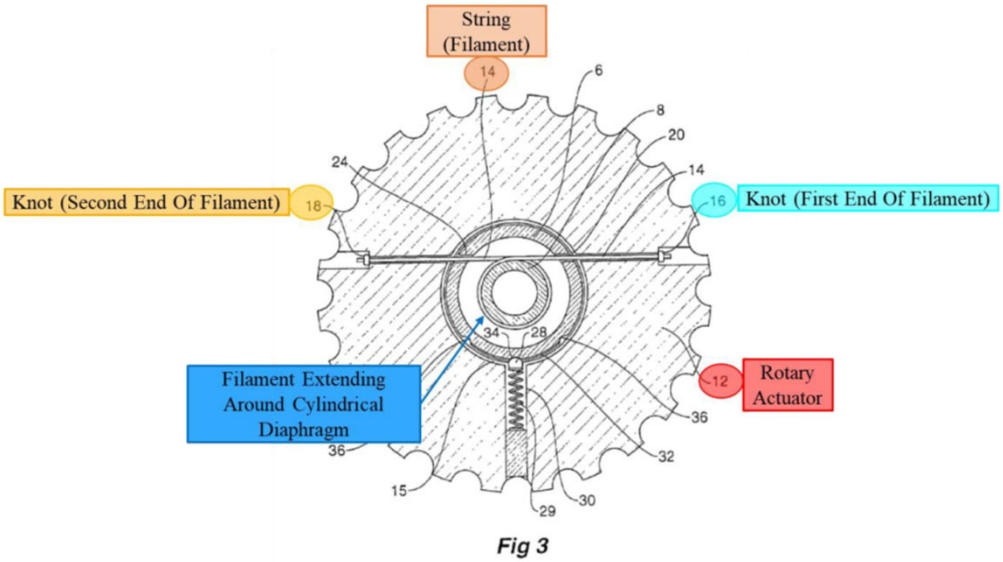


Fig 3

—'921 Petition (Paper 1) at 34-35, 37-38; Ex. 1006 (Hartley), [0031], Fig. 3.

Eller Discloses A "Filament"

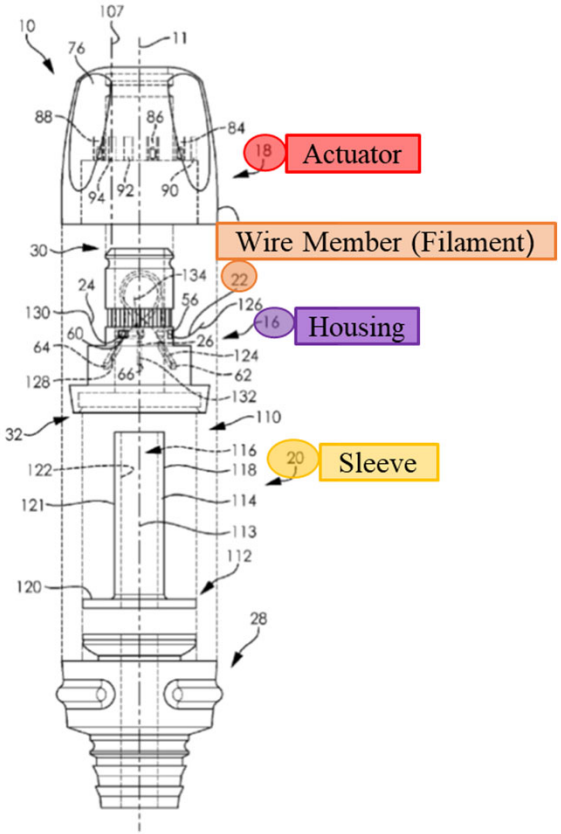


FIG. 2

FIGS. **1**, **2**, **3**, **4**, **5**, **6**, **7**, **8**A, **8**B, **8**C, **9**A, **9**B, **9**C, **10**A, **10**B, and **10**C 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.

—Ex. 1007 (Eller), 5:1-5, 16:7-19, 21:37-22:31, 23:50-25:9, Fig. 2; '921 Petition (Paper 1) at 40-42.

Eller's Filament Forms A "Loop"

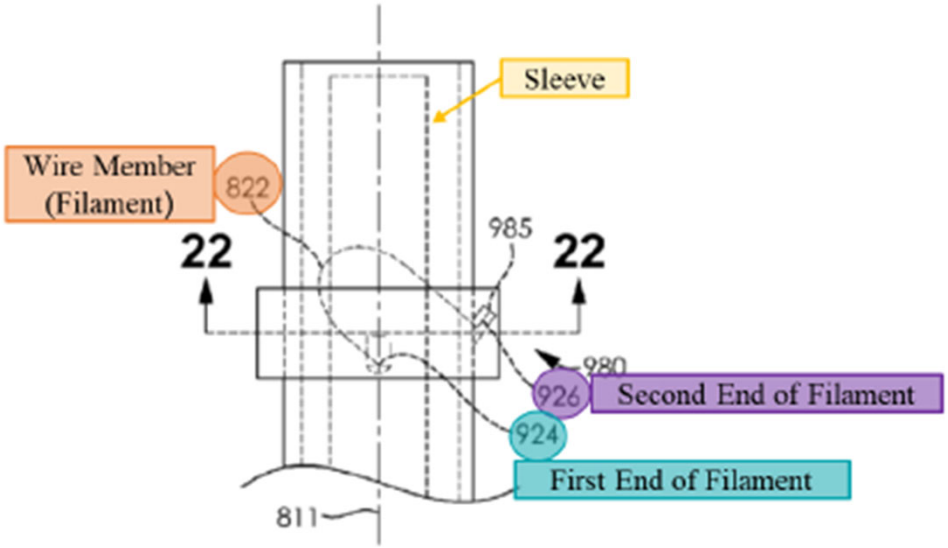


FIG. 21

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.

—Ex. 1007 (Eller), 22:18-24, Fig. 21.

Simple Methods To Attach Eller's Filament To Actuator

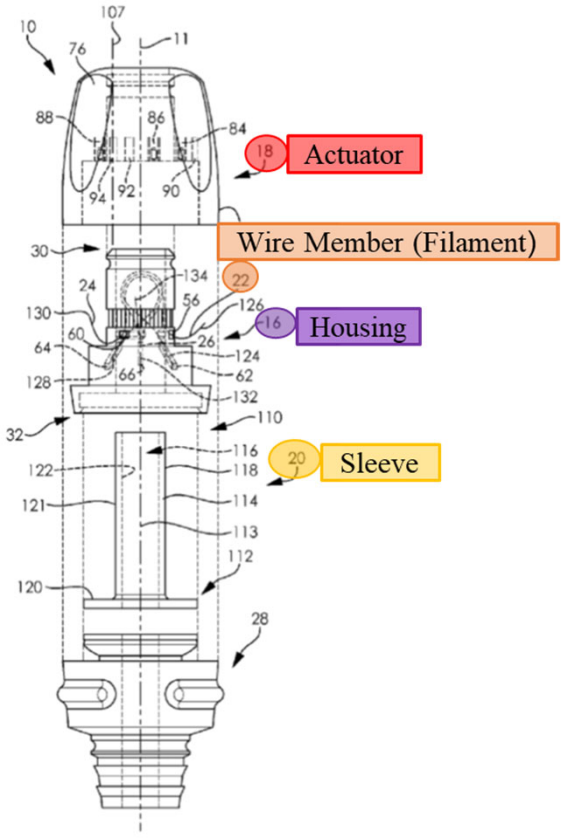


FIG. 2

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 outside diameter that is greater than the inside diameter of a cavity defined by a housing and/or actuator such that a friction fit between the wire member and the housing and/or actuator can be achieved.

—Ex. 1007 (Eller), 14:37-43, Fig. 2; '921 Petition (Paper 1) at 43-45.

First Motivation To Combine Schaffer + Hartley

85. A person of ordinary skill in the art would have found it obvious, and been motivated to, substitute Hartley's string/flexible member for Schaffer's U-shaped actuating members 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 (Hartley) at [0037]. A person of ordinary skill in the art would have known that multiple tools of varying sizes and shapes could be required for a medical procedure, so Hartley's ability to seal around a range of diameters/shapes 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.

—'921 Ex. 1003 (Thornton Decl.) ¶85; '921 Petition (Paper 1) at 35-36; '921 Reply (Paper 22) at 6-7.

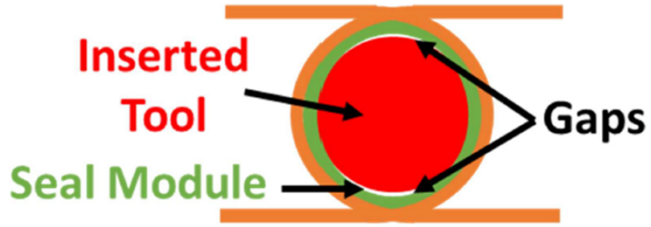
First Motivation To Combine Schaffer + Eller

99. A person of ordinary skill in the art would have found it obvious, and been motivated, to substitute Eller's wire member for Schaffer's U-shaped actuating members 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.

—'921 Ex. 1003 (Thornton Decl.) ¶99; '921 Petition (Paper 1) at 42-43; '921 Reply (Paper 22) at 6-7.

Second Motivation To Combine Schaffer + Hartley Or Eller

86. 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, materials, and mechanical properties 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 Owner

—'921 Ex. 1003 (Thornton Decl.) ¶¶86, 100; '921 Petition (Paper 1) at 36-37; '921 Reply (Paper 22) at 6-8.

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

PO Response

A. A POSA Would Not Have Been Motivated to Substitute Hartley's String/Eller's Wire for Schaffer's Actuating Members

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

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 the teachings of references cannot be based on the alleged existence of a problem that does not exist." *Aruba Networks, Inc. v. Xr Commc'ns LLC*, No. IPR2018-00701, 2018 WL 4090629 at *4 (P.T.A.B. Aug. 27, 2018) (denying institution), citing *In re Schweickert*, 676 F. App'x 988, 996 (Fed. Cir. 2017).

—'921 POR (Paper 18) at 29, 33-34.

Schaffer Forms A "Nearly Fluid/Gas Tight Seal"

PO Response

p.36. Petitioner is wrong. ***Every embodiment*** of Schaffer discloses a valve that seals across a wide range of instruments without gaps via the seal member 165—indeed, that is the purpose of Schaffer. EX2033, ¶¶120-123.

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.

—'921 POR (Paper 18) at 30; Ex. 1005 (Schaffer), [0059].

PO's Expert Agrees Schaffer Would Not Seal Perfectly

Q. And is it your opinion that Schaffer's valve will seal perfectly regardless of the diameter of the device that's inserted through the valve?

MR. HAMILTON: Objection. Incomplete hypothetical.

THE WITNESS: That wasn't really part of my assignment and I certainly wouldn't say perfectly.

—'921 Ex. 1045 (Zalesky Dep.) at 131:17-25.

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 circumferencially 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 circumferencially 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

—Ex. 1005 (Schaffer) [0075]-[0077]; '921 POR (Paper 18) at 30-34; '921 Reply (Paper 22) at 6-8; '921 Ex. 1003 (Thornton Decl.) at ¶86.

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 Decl.

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. Additionally, Schaffer makes

—Ex. 1005 (Schaffer) [0057]; '921 Ex. 1003 (Thornton Decl.) at ¶86.

Figures 30-34 Do Not Identify Item 165

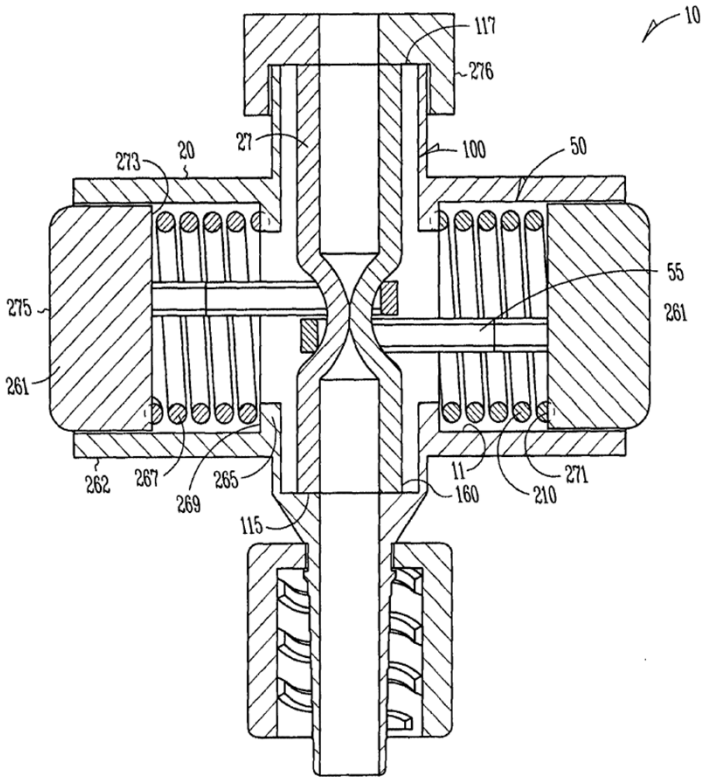


Fig. 32

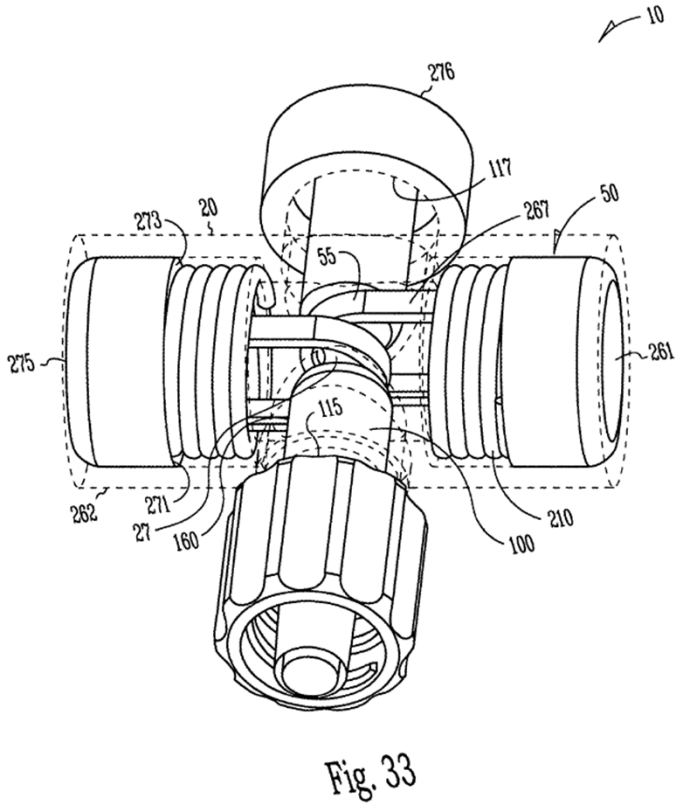


Fig. 33

—Ex. 1005 (Schaffer), Figs. 32-33; '921 Reply (Paper 17) at 6-8; '921 Ex. 1003 (Thornton Decl.) at ¶86.

Board Previously Found Third Seal Member Not Required

We disagree with Patent Owner's argument because, when obviousness is the issue, the prior art's teachings are not limited to the art's examples and preferred embodiments. *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). The third central seal member comprising a highly-compliant material is preferred, but not required, in Schaffer. *See, e.g.*, Ex. 1005 ¶ 59 ("In one embodiment, the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible," and "in one option" such material "is extremely soft and compliant and intrinsically 'sticky'"); *see also id.* (describing the highly-compliant material forming the third central seal member "[f]or illustrative purposes only"). Moreover, in introducing

—'921 Ex. 1042 ('011 FWD) at 58; '921 Ex. 1048 ('012 FWD) at 60.

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 Decl.

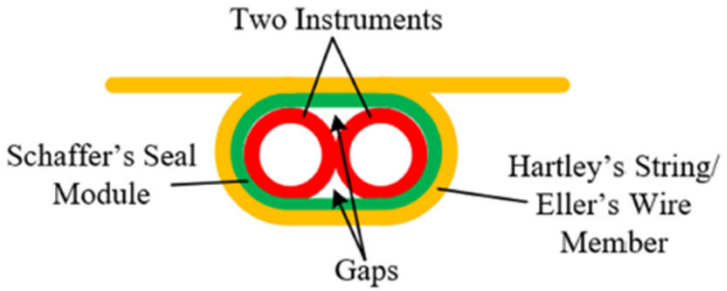
at [0075]. Further, a person of ordinary skill in the art would have recognized that the "sticky" or "gelatinous" materials would not work well with the seal modules disclosed in Figures 31-34 because those seal modules must "retract to an uncollapsed configuration" when the tension on the module is released by the actuating members. A seal module made of the "sticky" or "gelatinous" materials would not easily return to its uncollapsed configuration.

—Ex. 1005 (Schaffer) [0059]; '921 Ex. 1003 (Thornton Decl.) at ¶86.

PO's Argument Regarding Two Instruments Not Probative

PO Response

Schaffer's valve is specifically designed to address. EX2033, ¶130. 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:



—'921 POR (Paper 18) at 37-38; '921 Reply (Paper 22) at 7-8; '921 Ex. 1039 (Thornton Supp. Decl.) at ¶35.

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

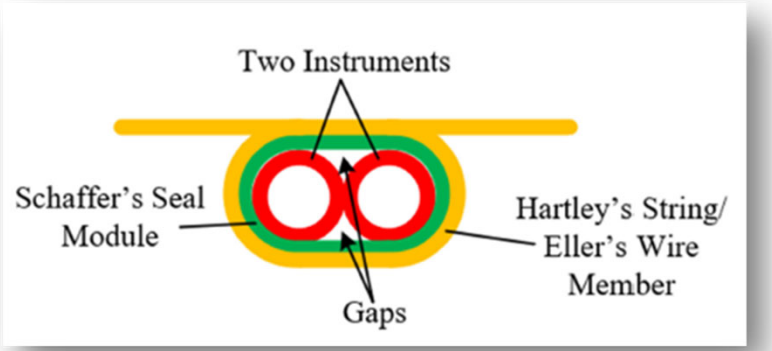
[0068] In yet another embodiment, two or more instruments **260** are inserted into the valve antegrade, for example, in the distal end **117** of the containment structure **160** while the lumen **193**, **190**, and **191** of the seal members **165**, **170**, and **180**, are in an open configuration, or in another option, while the lumen **193** of the third central seal member **165** 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 circumferencially 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.

—Ex. 1005 (Schaffer) at [0068]; '921 Reply (Paper 22) at 7-8; Ex. 1039 (Thornton Supp. Decl.) at ¶35.

PO's Drawing Is Inaccurate

Thornton Supp. Decl.

Patent Owner Response at 60, 70. 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



—'921 Reply (Paper 22) at 7-8; Ex. 1039 (Thornton Supp. Decl.) at ¶35; Ex. 1005 (Schaffer) at [0068].

The Board Previously Rejected This Argument

> Second, Patent Owner's suggestion that Schaffer's valve could provide a better seal in the illustrated two-instrument example presumes that Schaffer's valve includes the highly compliant seal module material that is capable of deforming to fill in those interstices between the two instruments. *Id.* (citing Ex. 1005 ¶ 68). That material is optional, as discussed above. Without that material, it is not evident that Schaffer's two U-shaped actuating members would outperform Hartley's string or Eller's wire in the hypothetical two-instrument scenario. Ex. 1014 ¶ 35 (testifying "Patent

—'921 Ex. 1042 ('011 FWD) at 60; '921 Ex. 1048 ('012 FWD) at 62.

Third Motivation To Combine Schaffer + Hartley Or Eller

87. 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 proceedings that

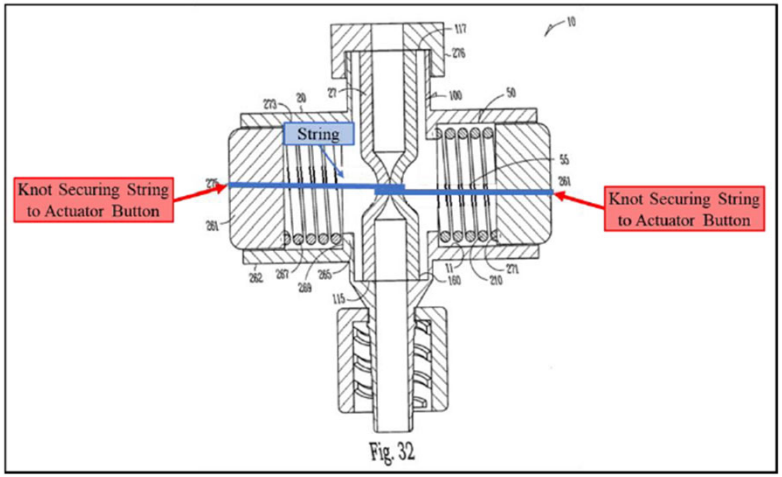
—'921 Ex. 1003 (Thornton Decl.) at ¶¶87, 101; '921 Petition (Paper 1) at 35-36, 43.

Simple Methods May Be Used To Combine Hartley With Schaffer

Thornton Decl.

90. 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 would have been a very simple modification, and a person of ordinary skill in the art would have been fully capable of implementing it in September 2017. The demonstrative illustration that

Demonstrative Illustration
Schaffer + Hartley's String



—'921 Ex. 1003 (Thornton Decl.) at ¶90; '921 Petition (Paper 1) at 37-38.

Simple Methods May Be Used To Combine Eller With Schaffer

Thornton Decl.

103. 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 examples would have been

—'921 Ex. 1003 (Thornton Decl.) at ¶103; '921 Petition (Paper 1) at 43-44.

Fourth Motivation To Combine Schaffer + Hartley Or Eller

Thornton Decl.

88. 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 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.

—'921 Ex. 1003 (Thornton Decl.) at ¶¶88, 102; '921 Petition (Paper 1) at 37, 43.

PO's Fails To Identify Other Methods To Constrict A Tube

PO Response

> But, at deposition in the related '012 IPR, Mr. Thornton admitted that there were more ways to constrict a tubular member in a hemostasis valve including those disclosed in Schaffer '616 (EX2031, 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).

—'921 POR (Paper 18) at 72-73.

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.

—'921 Ex. 2031 (Thornton Dep. Tr.) at 108:14-109:7; '921 Reply (Paper 22) at 12.

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.

—’921 Ex. 2031 (Thornton Dep. Tr.) at 118:4-15.

The Board Found Evidence Shows Four Known Options

In its Sur-reply, Patent Owner argued for the first time that Petitioner's "obvious-to-try" rationale should be rejected because the options for constricting a valve lumen have not been established as "finite, identified, and known." PO Sur-reply 26–28. Patent Owner does not explain why it was late in raising this counterargument. But, even on the merits, Patent Owner's argument is flawed. Through trial in this matter, we find essentially four known options for constricting a hemostasis valve lumen: the U-shaped members of Schaffer; the string or wire of Hartley and Eller; a pressure-assisted collapse valve; and pinch or clamp-type valves like described in references like Wong and Kees (and some other Schaffer embodiments).[22] *Id.* at 27–28; Tr. 19:14–19 (Petitioner arguing "the

—'921 Ex. 1042 ('011 FWD) at 55-56; '921 Ex. 1048 ('012 FWD) at 57.

Schaffer's "Principles Of Operation" Remain Unchanged

Thornton Supp. Decl.

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.

—'921 Ex. 1039 (Supp. Thornton Decl.) at ¶39; '921 Reply (Paper 22) at 8-10.

The Board Previously Rejected This Argument

We also find unpersuasive Patent Owner's argument that the proposed modification of Schaffer changes its principle of operation. PO Resp. 52–60. As an initial matter, Patent Owner never clearly defines what it regards as Schaffer's principle of operation. Patent Owner addresses Schaffer's disclosures related to "forcible disengagement" and further references "durability" and "ease of manufacturing," but does not explain persuasively why those considerations constitute Schaffer's principle of operation. *Id.*; Pet. Reply 8 ("PO presumes that forcible disengagement, easy assembly, and durability define Schaffer's 'principle of operation'" but "PO identifies no part of Schaffer that supports this presumption and none exists"). For reasons discussed below, we define Schaffer's principle of operation differently and, in any event, find that the proposed modification of Schaffer is not materially at odds with the considerations noted by Patent Owner: durability; forcible disengagement; and easy manufacture/assembly.

—'921 Ex. 1042 ('011 FWD) at 63-68; '921 Ex. 1048 ('012 FWD) at 64-68.

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.

—Ex. 1005 (Schaffer), [0077]; '921 Ex. 1020 (Thornton Supp. Decl.) at ¶41; '921 Reply (Paper 22) at 9.

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.

—Ex. 1005 (Schaffer) at [0083]; '921 Ex. 1003 (Thornton Decl.) at ¶87; '921 Reply (Paper 22) at 9-10.

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.

—'921 Ex. 1037 (Zalesky Dep. Tr.) at 169:16-170:11; '921 Ex. 1003 (Thornton Decl.) at ¶87; '921 Reply (Paper 22) at 9-10.

Knobbe Martens
INTELLECTUAL PROPERTY
+ TECHNOLOGY LAW

The Board Found A Motivation to Combine Hartley + Eller
(’921 Patent IPR, Ground 5)

Hartley Discloses A Rotating Valve

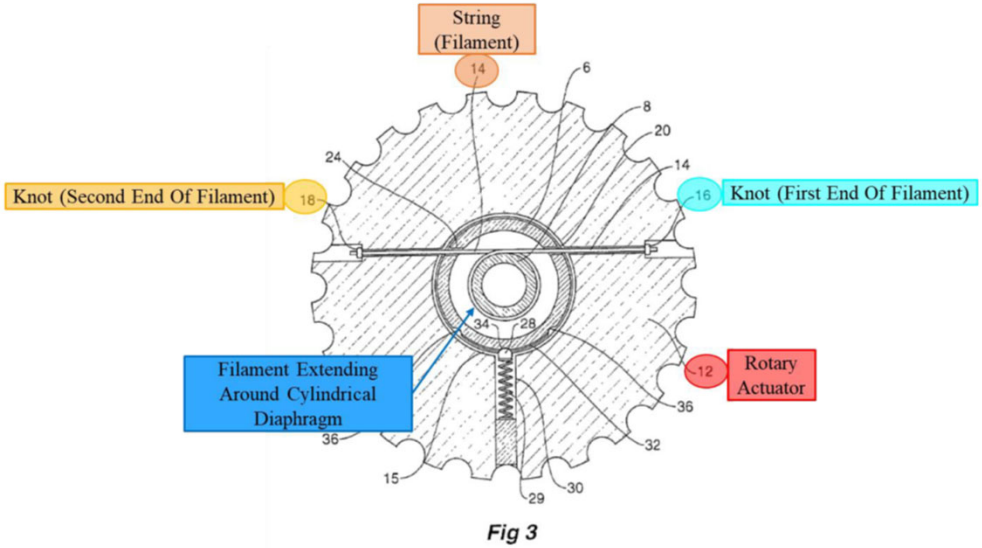


Fig 3

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.

—'921 Petition (Paper 1) at 66; Ex. 1006 (Hartley) at [0031], Fig. 3.

Eller Describes A Biasing System For A Rotating Valve

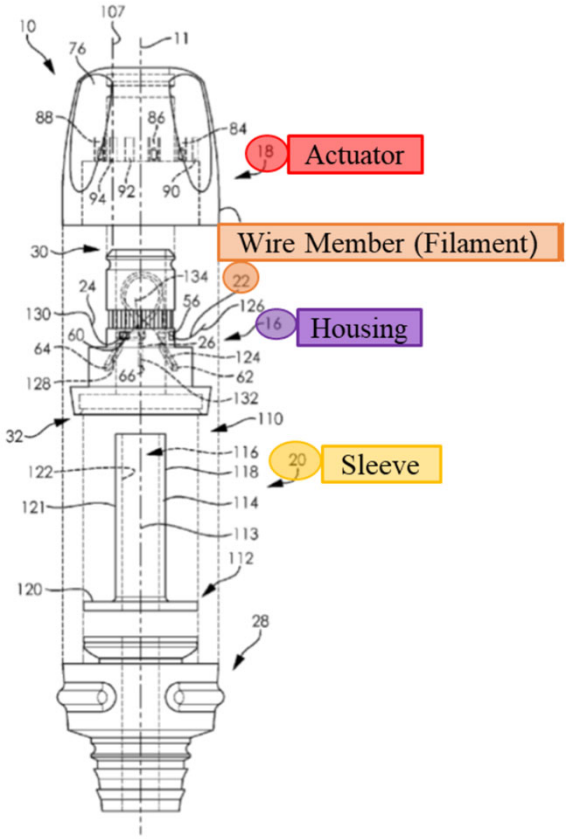


FIG. 2

Optionally, a selective fluid barrier valve device can be biased to the second configuration such that the actuator is biased to the second position. This can be accomplished using any suitable structural configuration or component. For example, a torsion spring can be positioned between the housing and the actuator and can be attached to the housing and the actuator such that when no outside forces are applied to the selective fluid barrier valve device, the spring positions the actuator in the second position.

—Ex. 1007 (Eller) at 19:22-30, Fig. 2; '921 Petition (Paper 1) at 93-97; '921 Ex. 1003 (Thornton Decl.) at ¶¶236-243.

Many Reasons To Combine Eller's Biasing System With Hartley's Valve

- Biasing system ensures that Hartley's valve seals quickly
- Biasing system simplifies operation of Hartley's valve
- Combination of known elements according to known methods to yield predictable results

—'921 Ex. 1003 (Thornton Decl.) at ¶¶238-240; '921 Petition (Paper 1) at 93-97.

POSITA Would Have Had A Reasonable Expectation of Success

- Hartley/Eller from the same field and address the same problem
- The valves share several common features including a string/wire to constrict a tubular member within the valve
- Eller's torsion spring is positioned between rotating components

—'921 Ex. 1003 (Thornton Decl.) at ¶¶241-243; '921 Petition (Paper 1) at 93-97.

The Board Found A Motivation To Combine Hartley + Eller

Patent Owner additionally argues that a POSA would not have been motivated to combine Garrison, Hartley, and Eller as proposed. PO Resp. 79–82. According to Patent Owner, Hartley discloses a valve that uses a "ball and detent system" that retains the rotary actuator on the cylindrical housing and that provides tactile feedback as the actuator is rotated to provide varying opening sizes for the lumen. *Id.* (citing Ex. 1006 ¶¶ 4, 15, 18, 33; Ex. 2026 ¶¶ 198–207). Further, Patent Owner argues, adding Eller's torsion spring as the alleged biasing system "would override the ball and detent system and eliminate Hartley's ability to selectively maintain various opening sizes for the lumen—acting to always seal the valve." *Id.* at 81–82 (arguing the spring could also create resistance to inserted instruments).

We disagree with Patent Owner's counterargument. The ball-and-detent system cited by Patent Owner is clearly an optional feature in Hartley.

—'921 Ex. 1049 ('005 FWD) at ¶¶241-243; '921 Petition (Paper 1) at 93-97.

PO Misidentifies How Hartley's Valve Achieves Its "Objective"

PO Response

> Hartley's objective is to "provide an access valve which can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument." EX1006, ¶[0004]. Hartley achieves that objective through a "detent arrangement" that includes a ball 28 biased by a spring 29 to engage a central recess 34 and end recesses 36 of a housing 6:

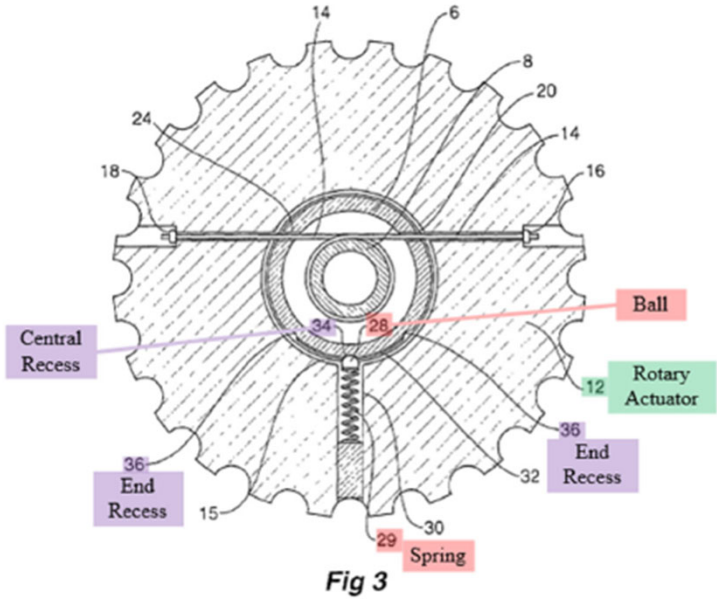


Fig 3

—'921 POR (Paper 22) at 67-68.

The Ball And Detent Are Optional

'005 FWD

We disagree with Patent Owner's counterargument. The ball-and-detent system cited by Patent Owner is clearly an optional feature in Hartley. *See, e.g.*, Ex. 1006 ¶ 15 ("*Alternatively* the rotary actuator may be retained on the cylindrical housing by the ball and detent arrangement discussed in more detail below."), ¶ 18 ("The rotary actuator *may have* a tactile indication of its action by means of a ball or other device acting into detents . . . .") (emphases added). The argument that the ball-and-detent feature is required for Hartley's principle of operation is undercut when the feature is described in the reference itself as optional.[22] Moreover, there would have been a material benefit to adding the torsion spring to Hartley's valve—helping to quickly seal the hemostasis valve and minimize blood loss during surgery. Ex. 1003 ¶¶ 238–239 (testifying, *inter alia*, a torsion spring biasing system would simplify use of Hartley's valve, eliminating the need for manual sealing, and reducing operator error and unwanted blood loss). As explained

Hartley

[0015] The rotary actuator may be retained in position by the flexible member extending from the rotary actuator and through the cylindrical housing. Alternatively the rotary actuator may be retained by a radial flange on the cylindrical housing or the cylindrical diaphragm. Alternatively the rotary actuator may be retained on the cylindrical housing by the ball and detent arrangement discussed in more detail below.

[0018] The rotary actuator may have a tactile indication of its action by means of a ball or other device acting into detents between the actuator and the cylindrical housing. The ball or other device acting into the detents may be spring loaded. The ball or other device may be mounted into the rotary actuator and travel in a circumferential groove in the cylindrical housing. This may also assist with retaining the rotary actuator on the cylindrical housing.

—'921 Ex. 1049 ('005 FWD) at 64-65; Ex. 1006 (Hartley) at [0015], [0018].



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