

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2026-00215
Patent No. 12,239,333

**DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 12,239,333**

<i>Imperative Care v. Inari Medical</i> IPR2026-00215 Imperative Care Ex. 1003
--

TABLE OF CONTENTS

Page No.

I.	INTRODUCTION	1
A.	Engagement	1
B.	Experience and Qualifications	2
C.	Topics of Opinions	4
D.	Materials Considered.....	5
II.	APPLICABLE LEGAL STANDARDS.....	5
A.	Claim Construction.....	6
B.	Anticipation	7
C.	Obviousness.....	7
D.	Person of Ordinary Skill in the Art	11
E.	The Prior Art Is from the Same Field as the 12-'333 Patent.....	13
III.	THE 12-'333 PATENT	14
A.	Summary of the 12-'333 Patent	14
B.	The Challenged Claims	20
C.	Prosecution History	21
IV.	CLAIM CONSTRUCTION	27
V.	SUMMARY OF IPR GROUNDS.....	29
VI.	GROUNDS 1-2: CLAIMS 1, 4-5, 7, 10-11, 13, 15 ANTICIPATED OR OBVIOUS IN VIEW OF GOFF	30
A.	Claim 1	30

TABLE OF CONTENTS **(cont'd)**

Page No.

1.	Preamble - clot collection reservoir	30
2.	a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.....	33
3.	a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber	35
4.	a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber	37
5.	Filter	40
a.	a filter removably positioned within the chamber	40
b.	the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion	40
c.	the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port	42
i.	Goff Discloses This Limitation	42
ii.	Goff Renders This Limitation Obvious.....	43

TABLE OF CONTENTS

(cont'd)

	Page No.
6. the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.....	64
7. the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.....	66
8. the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.....	67
B. Claim 4 – the first filter end portion is curved.....	67
C. Claim 5 – the source of aspiration is configured to generate the negative pressure in the chamber via the second port to draw the clot material against the first filter end portion	68
D. Claim 7 – the first filter end portion is positioned closer to the first housing end portion than the second filter end portion, and wherein the second filter end portion is positioned closer to the second housing end portion than the first filter end portion	71
E. Claim 10	74
1. Preamble – clot treatment system	74
2. an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient.....	74
3. an aspiration source.....	75

TABLE OF CONTENTS

(cont'd)

Page No.

4.	clot collection reservoir.....	75
5.	a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.....	75
6.	a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber	76
7.	a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber	76
8.	a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.....	76
9.	the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.....	77
10.	the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.....	77
11.	the filter is removably positioned within the chamber to provide access to the clot material within the chamber	78

TABLE OF CONTENTS (*cont'd*)

	Page No.
F. Claim 11 – the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region	78
G. Claim 13 – the clot collection reservoir is spaced apart from the aspiration source, and further comprising at least one tube fluidly coupling the second port to the aspiration source	78
H. Claim 15	79
1. a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user actuatable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter.....	80
2. Remaining Limitations.....	81
VII. GROUNDS 3-4: CLAIMS 1, 4-5, 7, 10-11, 13, 15-17, 19-21 RENDERED OBVIOUS BY GARRISON AND GOFF OR LEE	81
A. Claim 1	81
1. Preamble – clot collection reservoir	82
2. a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.....	83
a. Goff.....	83
b. Lee	85

TABLE OF CONTENTS (*cont'd*)

Page No.

3.	a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber	93
a.	Goff.....	93
b.	Lee	93
4.	a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber	95
a.	Goff.....	95
b.	Lee	95
5.	Filter	98
a.	a filter removably positioned within the chamber	98
i.	Goff.....	98
ii.	Lee	98
b.	the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion	99
i.	Goff.....	99
ii.	Lee	99
c.	the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port	100

TABLE OF CONTENTS

(cont'd)

	Page No.
i. Goff.....	100
ii. Lee	100
6. the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.....	101
7. the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.....	103
a. Goff.....	103
b. Lee	104
8. the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.....	104
a. Goff.....	105
b. Lee	105
B. Claim 4 – the first filter end portion is curved.....	106
1. Goff.....	106
2. Lee.....	107
C. Claim 5 – the source of aspiration is configured to generate the negative pressure in the chamber via the second port to draw the clot material against the first filter end portion	107

TABLE OF CONTENTS

(cont'd)

	Page No.
D. Claim 7 – the first filter end portion is positioned closer to the first housing end portion than the second filter end portion, and wherein the second filter end portion is positioned closer to the second housing end portion than the first filter end portion	111
1. Goff	112
2. Lee	112
E. Claim 10	113
1. Preamble – clot treatment system	113
2. an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient.....	115
3. an aspiration source.....	116
4. clot collection reservoir.....	117
5. a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.....	117
6. a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber	117
7. a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber	118

TABLE OF CONTENTS

(cont'd)

	Page No.
8. a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.....	118
9. the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.....	118
10. the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.....	119
11. the filter is removably positioned within the chamber to provide access to the clot material within the chamber	119
F. Claim 11 – the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region	120
G. Claim 13 – the clot collection reservoir is spaced apart from the aspiration source, and further comprising at least one tube fluidly coupling the second port to the aspiration source	120
H. Claim 15	122

TABLE OF CONTENTS

(cont'd)

Page No.

1.	a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user actuatable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter.....	122
2.	Remaining Limitations.....	125
I.	Claim 16 – the aspiration source is configured to generate the negative pressure in the chamber with the valve in the closed position, and wherein the valve is configured to be moved to the open position to apply the negative pressure to the aspiration catheter	125
J.	Claim 17	133
1.	Preamble – clot treatment system	133
2.	an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient.....	133
3.	a hemostasis valve coupled to a proximal portion of the aspiration catheter	133
4.	at least one tube fluidly coupling the first port to a portion of the aspiration catheter distal of the hemostasis valve	137
5.	an aspiration source.....	139
6.	clot collection reservoir.....	139

TABLE OF CONTENTS (*cont'd*)

	Page No.
7. a housing defining a chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion	139
8. a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion.....	139
9. a second port configured to be fluidly coupled to the aspiration source	140
10. a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.....	140
11. the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.....	140
12. the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.....	141
K. Claim 19 – the aspiration source is fluidly couplable to the at least one tube	141
L. Claim 20 – hemostasis valve is configured to receive an instrument therethrough	142

TABLE OF CONTENTS

(cont'd)

	Page No.
M. Claim 21 – the hemostasis valve and the aspiration catheter are configured to receive and route an instrument therethrough	144
VIII. GROUNDS 5-8: CLAIMS 18, 22-25 RENDERED OBVIOUS BY GARRISON AND GOFF OR LEE COMBINED WITH SHAFFER AND HARTLEY OR ELLER.....	145
A. Claim 18	145
1. a tubular member	145
2. a button.....	146
3. a filament coupled to the button and the tubular member, wherein the button is actuatable to loosen the filament to unseal the hemostasis valve	147
a. Hartley	150
b. Eller.....	156
c. Schaffer's Seal Module Would Not Dissuade A Person Of Ordinary Skill From Combining Schaffer With Hartley's String or Eller's Wire.....	168
d. Substituting Schaffer's U-Shaped Actuating Members With Hartley's String Or Eller's Wire Would Not Change Schaffer's Principles Of Operation	173
i. Hartley's String And Eller's Wire Would Not Prevent "Forcible Disengagement" From Schaffer's Seal Module	174
ii. Hartley's String And Eller's Wire Would Not Prevent Assembly Of Schaffer's Valve	175

TABLE OF CONTENTS

(*cont'd*)

	Page No.
iii. Hartley's String Or Eller's Wire Member Would Not Weaken The Durability Of Schaffer's Valve 177 4. Motivation to Combine Garrison with Schaffer and Hartley or Eller..... 178 B. Claim 22 180 1. a tubular member defining a lumen 181 2. a first filament extending in a first loop around the tubular member [and] a second filament extending in a second loop around the tubular member 181 a. Hartley 184 i. Hartley's String Includes Two Filaments 184 ii. A POSITA Would have been Motivated to Use Two of Hartley's Strings..... 187 b. Eller..... 191 i. Eller's Wire Member Includes Two Filaments 191 ii. A POSITA Would have been Motivated to Use Two of Eller's Wire Members 195	

TABLE OF CONTENTS

(cont'd)

Page No.

3.	a pair of actuators biased to circumferentially constrict the first loop and the second loop to elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open.....	198
C.	Claim 23 – the actuators each comprise a button.....	203
D.	Claim 24 – the first filament includes a first portion operably coupled to a first one of the actuators and a second portion operably coupled to a second one of the actuators, and wherein the second filament includes a first portion operably coupled to the first one of the actuators and a second portion operably coupled to the second one of the actuators.....	203
E.	Claim 25 – the first filament is flexible, and wherein the second filament is flexible.....	205
IX.	GROUND 9-10: CLAIMS 26-28 RENDERED OBVIOUS BY GARRISON WITH GOFF OR LEE AND LAUB	206
A.	Claim 26 – the aspiration catheter has a size of at least 16 French.....	206
B.	Claim 27 – the aspiration catheter has a size of at least 20 French.....	215
C.	Claim 28 – the aspiration catheter has a size of at least 22 French.....	216
X.	SECONDARY CONSIDERATIONS	216

TABLE OF CONTENTS
(*cont'd*)

	Page No.
XI. CONCLUSION.....	217

TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 12,239,333 (“the 12-’333 patent”)
1002	12-’333 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1007	U.S. Patent Publication US 2008/0097410 A1 to Lee (“Lee”)
1008	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1009	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1010	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1011	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
1012	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1013	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
1014	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al. (“Garrison ’868”)
1016	U.S. Patent No. 7,998,104 B2 to Chang (“Chang”)
1017	U.S. Patent No. 8,157,760 B2 to Criado et al. (“Criado”)

Exhibit No.	Description
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al. (“Lewis”)
1019	U.S. Provisional Patent Application No. 62/554,931 (the “’931 application”)
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
1021	Exhibit L to Inari’s Supplemental Infringement Contentions for U.S. Patent No. 12,239,333 from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served March 5, 2025)
1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
1023	Resume of Dr. Aquilla Turk, III, D.O.
1024	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1025	U.S. Patent No. 5,197,485 to Grooters (“Grooters”)
1026	U.S. Patent No. 3,785,380 to Brumfield (“Brumfield”)
1027	U.S. Patent No. 3,863,624 to Gram (“Gram”)
1028	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014), definition of “port”
1029	Dorland’s Illustrated Medical Dictionary, 32nd ed. (2012) - Definition of “Port”
1030	Harish Ram et al., “The AngioVac Device and Its Anesthetic Implications,” 31 J. Cardiothoracic and Vascular Anesthesia, 1091-1102 (2017) (“Ram”)
1031	U.S. Patent No. 3,939,078 to Servas (“Servas”)
1032	EP 1 084 722 A2 (“Flamer”)
1033	U.S. Patent No. 3,701,433 to Krakauer (“Krakauer”)

Table of Exhibits 2

Exhibit No.	Description
1034	U.S. Patent No. 4,572,724 to Rosenberg (“Rosenberg”)
1035	U.S. Patent No. 5,618,425 to Mitamura (“Mitamura”)
1036	U.S. Patent No. Re. 32.711 to Dickens (“Dickens”)
1037	U.S. Patent No. 5,788,661 to Japuntich (“Japuntich”)
1038	U.S. Patent No. 5,540,841 to Gsell (“Gsell”)
1039	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated November 7, 2025
1040	Affidavit of Mina Ching regarding WayBack Machine Capture of Paco-Flow Orthopaedic Suction Set Webpage (http://www.pahsco.com.tw/product_detail-138) (Nov. 26, 2025)
1041	Penumbra, Optimizing Direct Aspiration (May 2013)
1042	AXS Universal Aspiration Set Brochure (2017)
1043	Patent Owner’s Response for U.S. Patent No. 11,697,011 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (Apr. 18, 2025)
1044	Supplemental Declaration of Paul Zalesky Ph.D. submitted by Patent Owner as Exhibit 2008 in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157, U.S. Patent No. 11,697,011
1045	Google Dictionary Definition of “String”
1046	Cambridge Dictionary Definition of “String”
1047	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1048	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)

Table of Exhibits 3

Exhibit No.	Description
1049	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 2025)
1050	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,844,921 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. Oct. 10, 2025)
1051	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,865,291 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00989 (P.T.A.B. Oct. 23, 2025)
1052	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,969,333 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Dec. 11, 2025)
1053	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,974,910 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Dec. 11, 2025)
1054	Notice of Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 12,016,580 (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264 (P.T.A.B. Dec. 11, 2025)

Table of Exhibits 4

I, Troy L. Thornton, do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Imperative Care, Inc. (“Imperative Care”) to provide my opinion regarding the patentability of Claims 1, 4-5, 7, 10-11, 13, and 15-28 of U.S. Patent No. 12,239,333 (“the 12-’333 patent”). For the reasons discussed herein, I have concluded that Claims 1, 4-5, 7, 10-11, 13, and 15-28 of the 12-’333 patent are unpatentable because the prior art references anticipate those claims or render them obvious.

2. I understand that this Declaration supports Imperative Care’s Petition for the above-captioned *inter partes* review (“IPR”) of the 12-’333 patent.

3. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me. I also reserve the right to submit a rebuttal declaration in response to any expert declaration(s) submitted on behalf of the owner of the 12-’333 patent, Inari Medical, Inc. (“Inari” or “Patent Owner”).

4. I am being compensated at my customary hourly rate for my work in this matter and I am being reimbursed at cost for my expenses. My compensation in no way depends upon the substance of my opinions or the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding.

B. Experience and Qualifications

5. My experience and qualifications are summarized in my resume, a copy of which is included as Exhibit 1004.

6. I received a Bachelor of Science degree in Engineering Science, with Biomedical Engineering emphasis, in 1985 from Iowa State University. Since then, I have worked as an engineer, executive, and consultant in the medical device industry, particularly in the cardiovascular field. My work has included designing and developing numerous medical devices in the cardiovascular field, including catheters, percutaneous heart valve repair systems, stent grafts, and blood pumps.

7. Since 2015 I have worked as a consultant for various medical device companies, assisting the companies with early design, development, problem-solving, and intellectual property related matters.

8. Before my current consulting business, I was a Program Director for Abbott Ventures from June 2012 through December 2014. My work at Abbott Ventures focused on technical assessment and analysis of potential investments in both cardiovascular and non-cardiovascular medical device technologies.

9. In June 2000, I assumed the position of Director of Research and Development at Evalve, Inc., and in 2001 was promoted to Vice President of Research & Development. I served in that position until June 2012. While at Evalve, I was responsible for managing all aspects of research and development for

a percutaneous mitral valve repair system known as the MitraClip. The MitraClip system included three complex catheters and a permanent mechanical implant, and I led the research and development for all aspects of the product. The MitraClip product received FDA approval in 2013 and is currently available in over 30 countries.

10. From June 1995 through May 2000, I was a Project Manager at Prograft Medical Inc. While at Prograft, I was responsible for the development and commercial launch of a bifurcated, modular stent-graft used in the treatment of abdominal aortic aneurysms known as Excluder. I managed the overall project from its inception through initial commercialization, which involved designing and building initial prototypes, developing physician training materials, assisting with regulatory filings, providing physician training, and supporting physicians during five live case transmissions endovascular symposia.

11. From August 1989 through May 1995, I worked as a Project Group Leader and Senior Engineer for Advanced Cardiovascular Systems at Guidant. My work at Guidant focused on the design and development of percutaneous transluminal coronary angioplasty (PTCA) and perfusion catheters. I was responsible for catheter design, material selection, process development, performance testing, physician evaluation, and animal studies for an elliptical

coronary PTCA catheter that ultimately became the top-selling PTCA in the United States.

12. From 1987 to 1989, I worked as a Manufacturing Engineer at Symbion, Inc. My work at Symbion included developing and improving manufacturing processes for class III medical devices, including a centrifugal blood pump.

13. From 1985 to 1987 I worked as a Process Engineer at Becton-Dickenson, Inc. My work at Becton-Dickenson included validating and implementing manufacturing processes for a thermodilution catheter and conducting cost saving and process improvements for central venous catheter products.

14. In summary, I have more than 35 years of experience in the cardiovascular medical device field, including significant experience designing, developing, testing, and manufacturing catheters and catheter systems for minimally invasive cardiovascular procedures. I am therefore very familiar with the concepts of catheters, catheter systems, and hemostasis valves, and I believe I am well placed to comment on the understanding of a person of ordinary skill in the art in the context of the 12-'333 patent.

C. Topics of Opinions

15. I offer opinions in this Declaration on the following general topics:

- The subject matter described and claimed in the 12-'333 patent;
- The level of ordinary skill in the art pertaining to the 12-'333 patent;
- The teachings of the prior art; and
- Whether Claims 1, 4-5, 7, 10-11, 13, and 15-28 of the 12-'333 patent are anticipated or would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

D. Materials Considered

16. In preparing this Declaration, I have considered the materials referenced in this Declaration and identified in the attached list of exhibits.

17. I have also relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the 12-'333 patent.

II. APPLICABLE LEGAL STANDARDS

18. I am a biomedical engineer by training and profession. The opinions I am expressing in this Declaration involve the application of my education, training, and technical knowledge and experience to the evaluation of certain prior art with respect to the 12-'333 patent.

19. Although I have had some prior exposure to patent matters, I am not an expert in patent law. Therefore, I have been advised of certain principles of

patent law applicable in this matter, which I have used in arriving at my determinations and opinions. The paragraphs below express my understanding of how I must apply these principles in forming my opinions.

A. Claim Construction

20. I understand that the first step in assessing the patentability of a patent claim is to understand the meaning of the words used in the claims. I understand this process of defining, or construing, the claim terms is generally referred to as claim construction. Generally speaking, I understand that I am to apply the ordinary and customary (i.e., plain and ordinary) meaning of each claim term as would have been understood by a person of ordinary skill in the art at the time of the invention, consistent with the specification and prosecution history.

21. I also understand that the patentee may act as its own lexicographer such that they may redefine a claim term to have a meaning that is different from the plain and ordinary meaning. I understand that when a patentee has acted as its own lexicographer, the patentee's definition should be applied instead of the plain and ordinary meaning that the term would have absent the redefinition. I understand that the patentee can redefine a claim term in either the specification or in statements made to the Patent Office during prosecution of the patent. I understand that the patentee's redefinition of a term does not need to be provided in express definitional

format, but rather that the redefinition can be implied through the disclosure of the specification or the patentee's statements during prosecution.

B. Anticipation

22. I understand that a patent claim is unpatentable if it is "anticipated" by a piece of prior art. I have been instructed that a claim is "anticipated" if a prior art reference describes, either expressly or inherently, each limitation of the claim. I understand that this description must be recognizable to a person of ordinary skill in the art at the time of the alleged invention (in this case, January 2018).

23. I understand that an element is "inherent in," and therefore taught by, the prior art, if it necessarily flows from the explicit disclosure of the prior art. The fact that a certain result or characteristic may be present in the prior art is not sufficient to establish inherency. However, if the result or characteristic is necessarily present based upon the explicit disclosure in the prior art, it is inherent in the prior art and is therefore disclosed.

C. Obviousness

24. I understand that a patent claim may also be unpatentable if it is rendered "obvious" by the prior art. I have been instructed that a claim is "obvious" if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. I understand that in considering obviousness I must consider the scope and content of the prior art, the

differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

25. In determining the scope and content of the prior art, I understand that a reference is considered analogous (i.e., appropriate) prior art if it falls within the field of the inventor's endeavor. In addition, a reference is analogous prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering the problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

26. To assess the differences between prior art and the claimed subject matter, I have been instructed that the law requires the claimed invention to be considered as a whole. This "as a whole" assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

27. I am also informed that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include:

- combining prior art elements according to known methods to yield predictable results;
- simple substitution of one known element for another to obtain predictable results;
- a predictable use of prior art elements according to their established functions;
- applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and
- some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

28. A prior art reference may also suggest a limitation of the claims. In that case, even if the prior art reference does not explicitly or inherently disclose the limitation, the motivation to modify the prior art reference to include the limitation may exist within the prior art reference itself. Thus, the limitation would have been obvious over that prior art reference alone. This is the case if a person of ordinary skill in the art would have had a simple design choice or a finite number

of identified, predictable solutions, for example, and if the modification furthers the goals of the prior art reference.

29. I have also been informed that the obviousness analysis must be performed from the perspective of a person of ordinary skill in the art at the time of the alleged invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness; instead, the claims would have been obvious if a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to arrive at the claimed invention and had a reasonable expectation of success in doing so.

30. An obviousness analysis also must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others. I am not aware of any evidence under these factors that would suggest that Claims 1, 4-5, 7, 10-11, 13, and 15-28 of the 12-'333 patent would have been non-obvious, as further explained in Section § X (Heading: "Secondary Considerations") below.

D. Person of Ordinary Skill in the Art

31. It is my understanding that when interpreting the claims of the 12-'333 patent, I must do so based on the perspective of a person of ordinary skill in the art at the relevant priority date. I have been instructed to assume for the purposes of my opinions that the relevant priority date of the 12-'333 patent is January 26, 2018. I have been informed that all of the references relied upon in this Declaration qualify as prior art under that priority date.

32. I am informed that the person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. This is a person of ordinary creativity, not an automaton.

33. I am informed that in determining the level of ordinary skill in the art, several factors are considered. Those factors may include: (i) the type of problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and (v) the educational level of active workers in the field. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

34. Based on my review of the specification and claims of the 12-'333 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 catheter or catheter system design experience and, where necessary, would have consulted with a physician regarding the methods of treatment.

35. I can make this assessment because during my career, I had experience assigning engineers to work on mechanical design projects, including projects to design catheters, sheaths, and related components such as hemostasis valves for use in cardiovascular procedures. For such projects, I would assign an engineer with the experience described above.

36. I am aware that in related IPRs, the Board preliminarily determined that a person of ordinary skill in the art for patents related to the 12-'333 patent would have had an 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." Ex. 1050 ('921 IPR Institution Decision) at 11-12; *see also* Ex. 1051 ('291 Institution Decision) at 12-13. The Board further clarified that "[s]uch devices include, but are not necessarily limited to, hemostasis valves and catheters for minimally-invasive vascular surgeries" and that a person of ordinary skill in the art "need not have had first-hand experience *designing* hemostasis valves." Ex. 1050 ('921 IPR Institution Decision) at 12 (emphasis in original). The Board further stated that a person of ordinary skill in

the art’s “experience related to developing such devices ‘could be as simple as bench testing and looking at clinical data’” and that a person of ordinary skill in the art “would have had an understanding of such devices’ design requirements as determined by the needs of the physician, patient, and procedure, which understanding may be informed by work experience and/or study.” *Id.*

37. The Board’s preliminary decision in the related IPRs aligns with my opinion regarding the qualifications of a person of ordinary skill in the art for the 12-’333 patent, which includes 2-4 years of catheter or catheter component design experience. Accordingly, my opinions regarding the unpatentability of the challenged claims of the 12-’333 patent would not change if the Board’s preliminary definition of a person of ordinary skill in the art from the related IPRs were applied here.

E. The Prior Art Is from the Same Field as the 12-’333 Patent

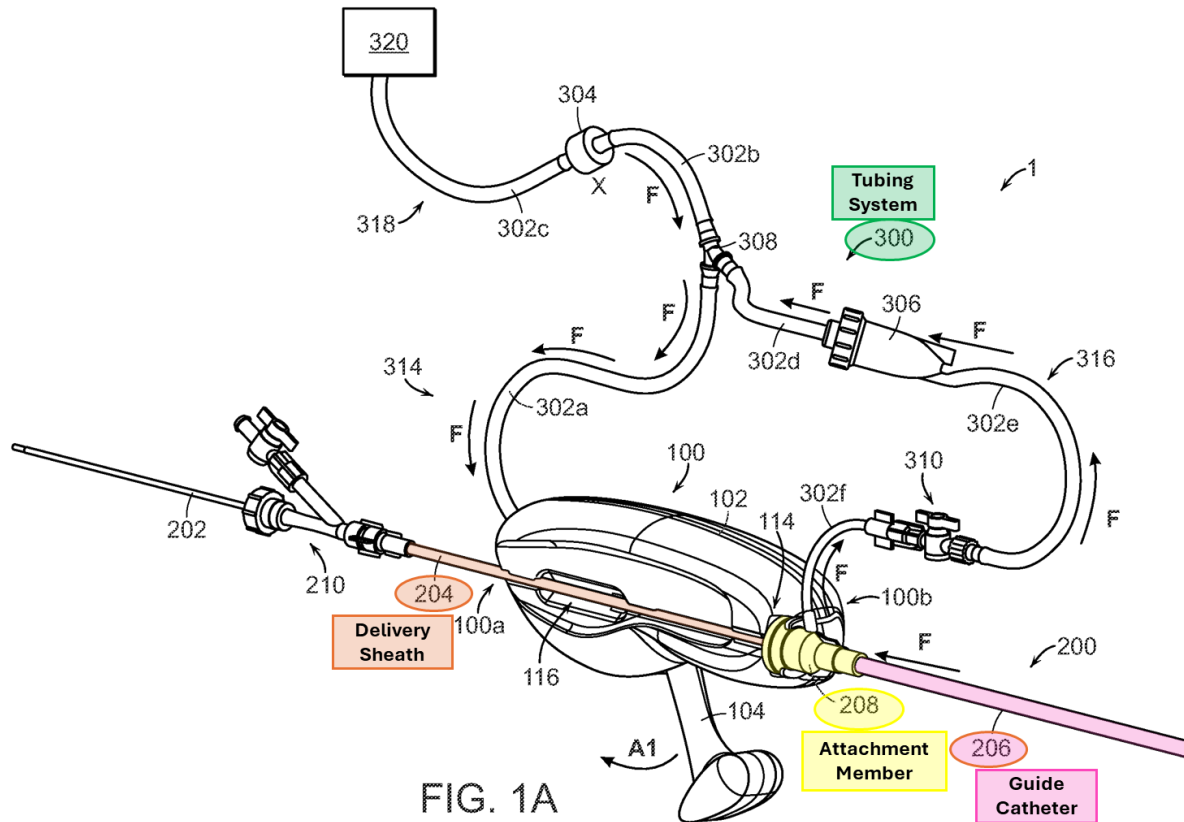
38. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the 12-’333 patent, e.g., devices for aspirating unwanted material from a patient. The references are also pertinent to the problem the inventor was focused on, e.g., aspirating blood and unwanted material from a patient and filtering the unwanted material from the blood.

III. THE 12-'333 PATENT

A. Summary of the 12-'333 Patent

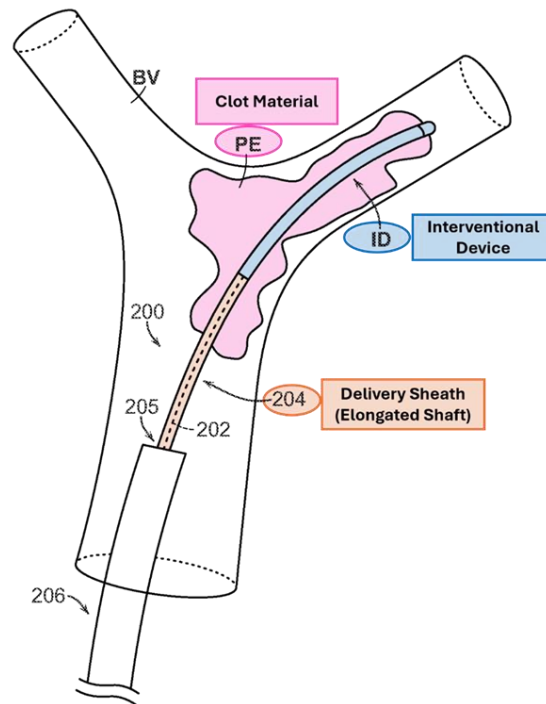
39. The 12-'333 patent is titled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods” and describes a retrieval system for intravascular removal of clot material. Ex. 1001 (12-'333 patent) at 3:53-4:3. The 12-'333 patent explains that the system can treat various clots including pulmonary embolisms (“PE”) and cerebral embolisms. *Id.* at 4:4-10. The retrieval system has a “clot retrieval system 1,” which includes “retraction aspiration device 100 (RA device 100),” “catheter system 200,” and “tubing system 300.” *Id.* at 4:45-51.

40. The catheter system 200 has a guide catheter 206 and a delivery sheath 204 which may “individually comprise an elongated shaft” [orange below]. *Id.* at 5:10-22. The catheter system 200 also includes an “attachment/valve member 208” [yellow below] which can “secure the catheter 200 to the RA device 100” and “fluidly couple an aspiration lumen of the catheter system 200 [...] to the tubing system 300.”



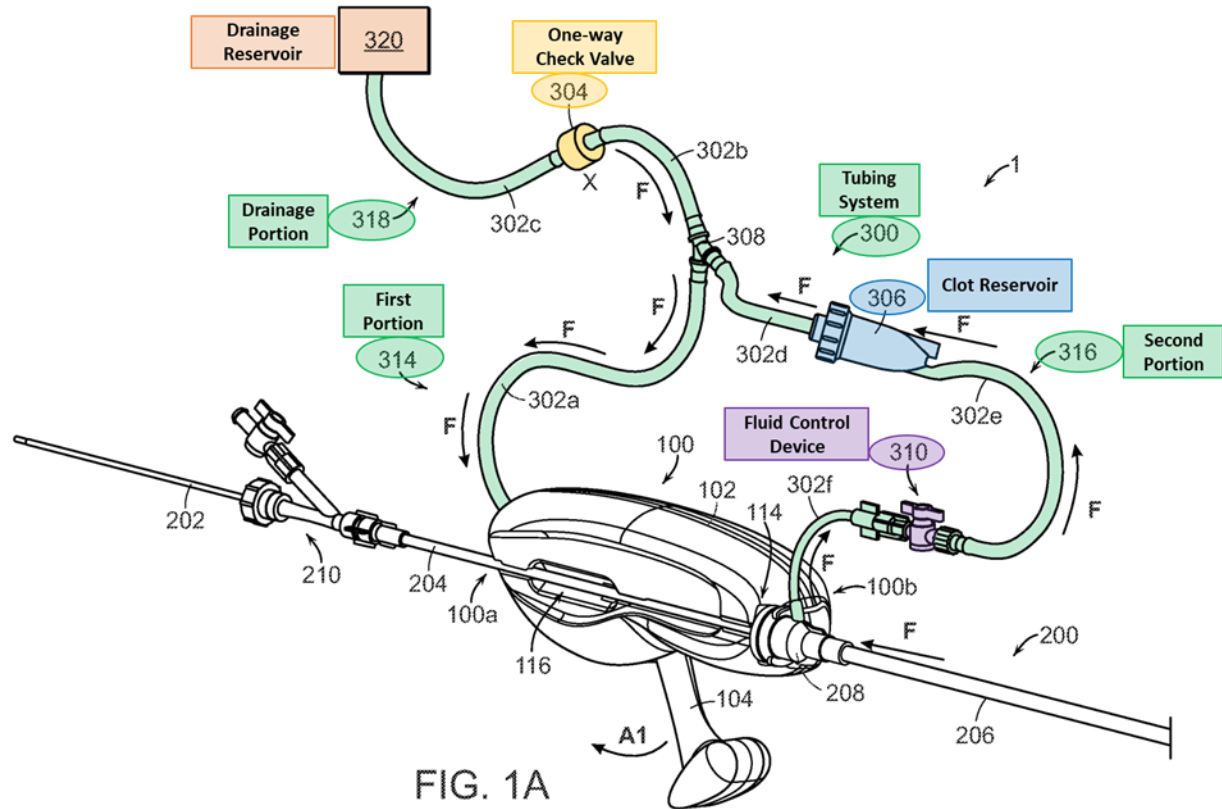
Id. at 6:15-24, Fig. 1A.

41. The 12-'333 patent discloses “an interventional device ID, such as a clot removal and/or clot treatment device” [blue], which can be “housed within delivery sheath 204 [orange]” and “positioned at least partially within the clot material PE” [pink]:



Id. at 5:24-33; Fig. 2A

42. The 12-'333 patent discloses the “tubing system 300 of the clot retrieval system 1 fluidly couples the pressure source of the RA device 100 to the aspiration lumen of the catheter system 200.” *Id.* at 6:55-57. The tubing system 300 has a “first portion 314” coupled to a pressure source and a “second portion 316.” *Id.* at 6:62-65. The second portion 316 has a “clot reservoir 306” [blue] and “second fluid control unit 310” [purple], which may “be a stopcock or a clamp that is externally operated to regulate the flow of liquid through the second portion 316 of the tubing system 300”:



Id., 7:10-25, Fig. 1A. The tubing system also includes a “drainage portion” 318 connected to a reservoir 320 (e.g., a vinyl bag) and a “first fluid control unit 304” that can be a “one-way valve (e.g., a check valve) that only allows fluid flow from the first portion 314 and/or second portion 316 to the drainage portion 318 (and not vice-versa).” *Id.* at 6:62-7:17.

43. The 12-’333 patent further discloses that the “clot reservoir 306 includes a housing 322 [blue]” and “a filter 321 [brown] configured to be positioned within the housing 322”:

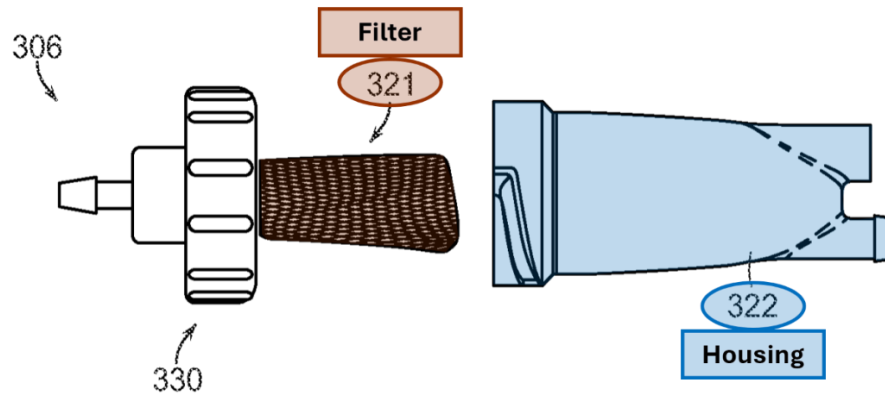


FIG. 3C

Id. at 9:1-5; Fig. 3C. The housing can further include “a port 324 [orange] configured to be removably, fluidly coupled to the catheter system 200” and a “fluid connector (e.g., a barbed outlet) 332 [green] for connecting to the tubing system 300”:

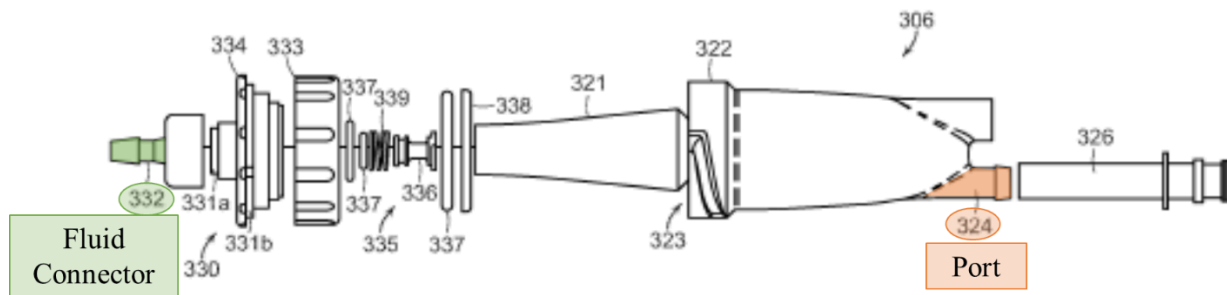


FIG. 3A

Id. at 9:5-22, Fig. 3A

44. The 12-'333 patent discloses that the attachment member 408 “can be, for example, a hemostasis valve configured to maintain hemostasis [...] as the

delivery sheath 204, the pull member 202, the guidewire, the interventional device ID, and/or other components of the catheter system 200 are inserted through the valve 445.” *Id.* at 11:3-13; Fig. 7A. The 12-’333 patent describes a valve having a “tubular member (e.g., an elongate member) 1372” that extends through the valve. *Id.* at 18:12-15. The tubular member has a “thin-walled compliant tubular structure” that facilitates “the uniform collapse of the tubular member 1372 and the sealing of the tubular member 1372”:

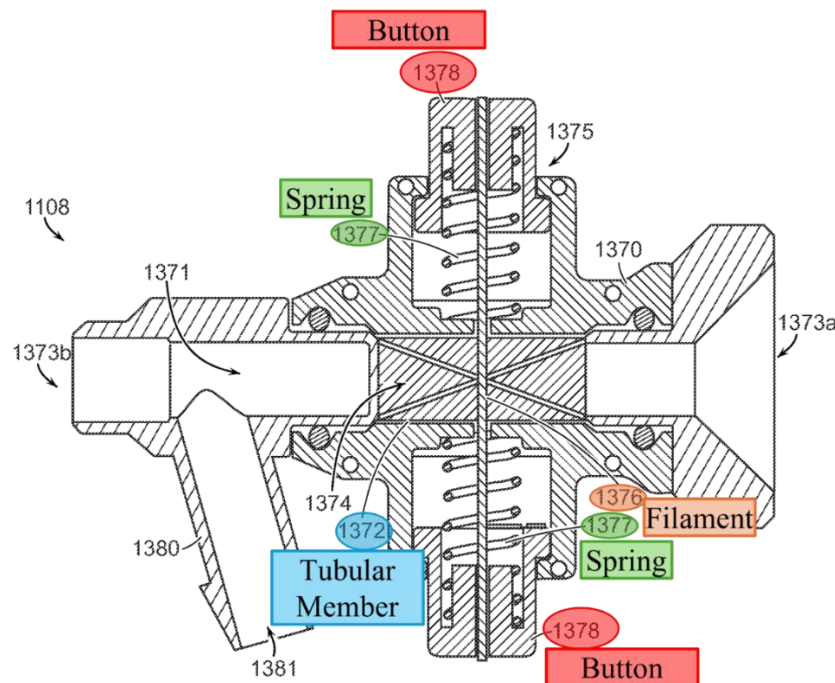


FIG. 13A

Id., 18:15-21, Fig. 13A.

45. The valve disclosed in the 12-’333 patent also includes an “actuation mechanism 1375” that can “collapse and seal the tubular member 1372 via compression and/or constriction of one or more filaments 1376.” *Id.* at 18:21-26.

The actuation mechanism “can be a manual actuator such as one or several buttons 1378.” *Id.* at 18:27-29. The “actuation mechanism 1375 can tighten the filament 1376 to constrict or compress the tubular member 1372 to seal the central lumen 1374 of the tubular member 1372.” *Id.* at 18:41-44. The valve also includes a bias feature, such as a spring, that biases the actuator toward the open or closed configuration. *Id.* at 18:38-41.

46. The 12-’333 patent also allegedly incorporates by reference U.S. Patent Application No. 62/554,931 titled “Hemostasis Valves and Methods of Use.” *Id.* at 17:56-62. The ’931 application is Exhibit 1019 and includes additional descriptions of the hemostasis valve.

B. The Challenged Claims

47. The challenged claims include Claims 1, 4-5, 7, 10-11, 13, and 15-28 of the 12-’333 patent. Claims 1, 10, 15, and 17 are independent claims.

48. Claim 1 is illustrative (but not representative) of some of the limitations in the challenged claims. Claim 1 states:

1. A clot collection reservoir, comprising:
 - housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;
 - a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;
 - a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber; and

a filter removably positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port;

wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;

wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and

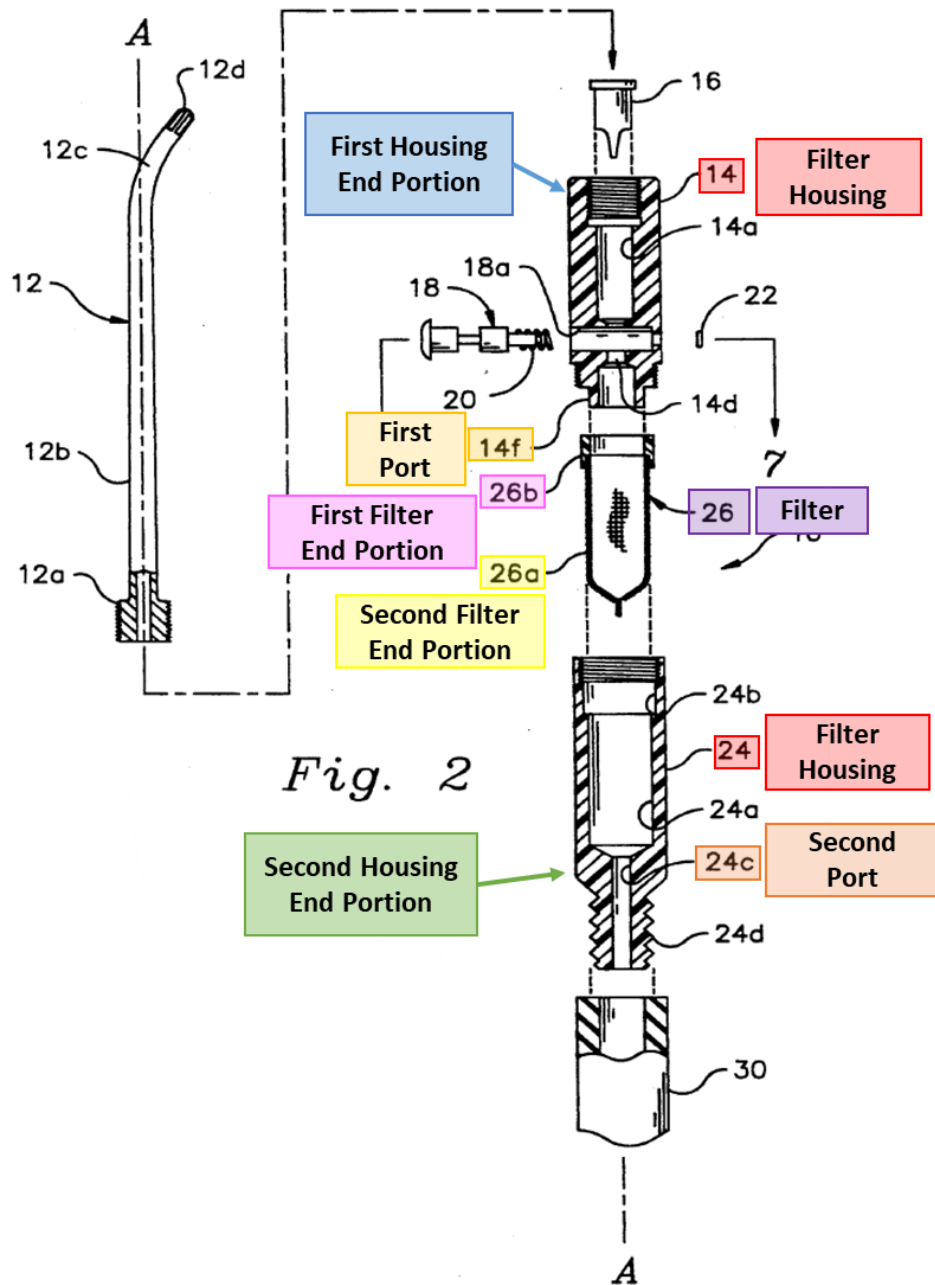
wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.

Ex. 1001 (12-'333 patent) at Claim 1.

C. Prosecution History

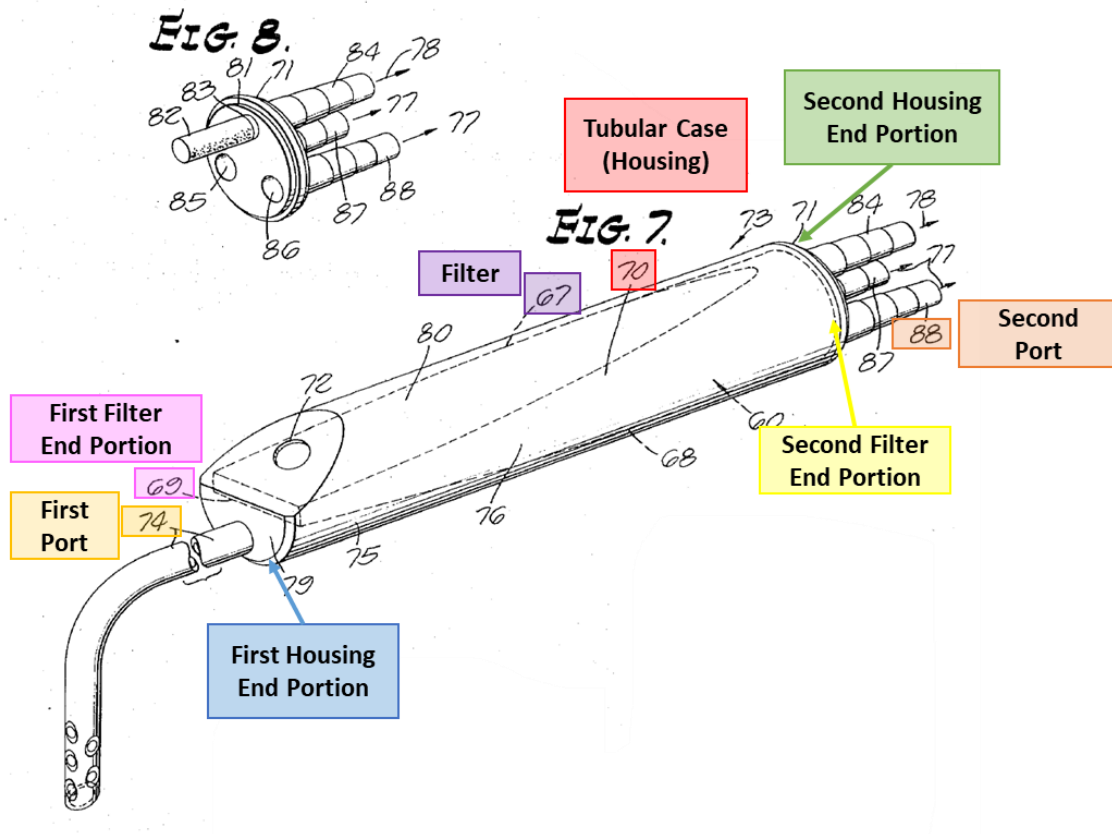
49. I have reviewed the 12-'333 patent's prosecution history. I see that the Examiner issued two Non-final Rejections during prosecution of the 12-'333 patent. In the first Non-final Rejection, issued on January 3, 2024, the Examiner objected to several claims for typographical issues, rejected claims 1-3, 7-8, 10-14, and 16-17 as anticipated by Grooters (U.S. Patent No. 5,197,485 (Ex. 1025)), and rejected claim 9 as obvious over Grooters. Ex. 1002 (12-'333 Prosecution History) at 260-268. The Examiner focused on Figure 2 of Grooters and found that Figure 2 disclosed every limitation of pending claim 1, including: a clot collection reservoir having a housing [red] with a first housing end portion [blue] and a second housing end portion [green], a first port [gold] proximate to the first housing end portion

configured to be fluidly coupled to an aspiration catheter, a second port [orange] configured to be fluidly coupled to an aspiration source, and a cylindrical filter [purple] extending from a first filter end portion [pink] to a second filter end portion [yellow]:



Id. at 264; *see also* Ex. 1025 (Grooters) at Fig. 2. The Examiner further found that Grooters' filter "extends continuously about the first filter end portion such that the filter body encloses an interior region around the second port 24c-24d (the region between outer surface of filter body and inner surface of chamber 24a and above the entrance of second port 24c as shown in Fig. 2)." Ex. 1002 (12-'333 Prosecution History) at 264.

50. After the first Non-final Rejection, the applicant conducted an interview with the Examiner on March 29, 2024. *Id.* at 243-244. According to the Examiner's Interview Summary, the "Applicant argued that the orientation of the filter trap 26 of Grooters is opposite to the orientation of the filter as recited in the claims," and the "Examiner agreed with applicant's arguments." *Id.* However, the Examiner also discussed Brumfield (U.S. Patent No. 3,785,380 (Ex. 1026)) and stated that Figures 7-8 of Brumfield read on pending claims 1 and 11:

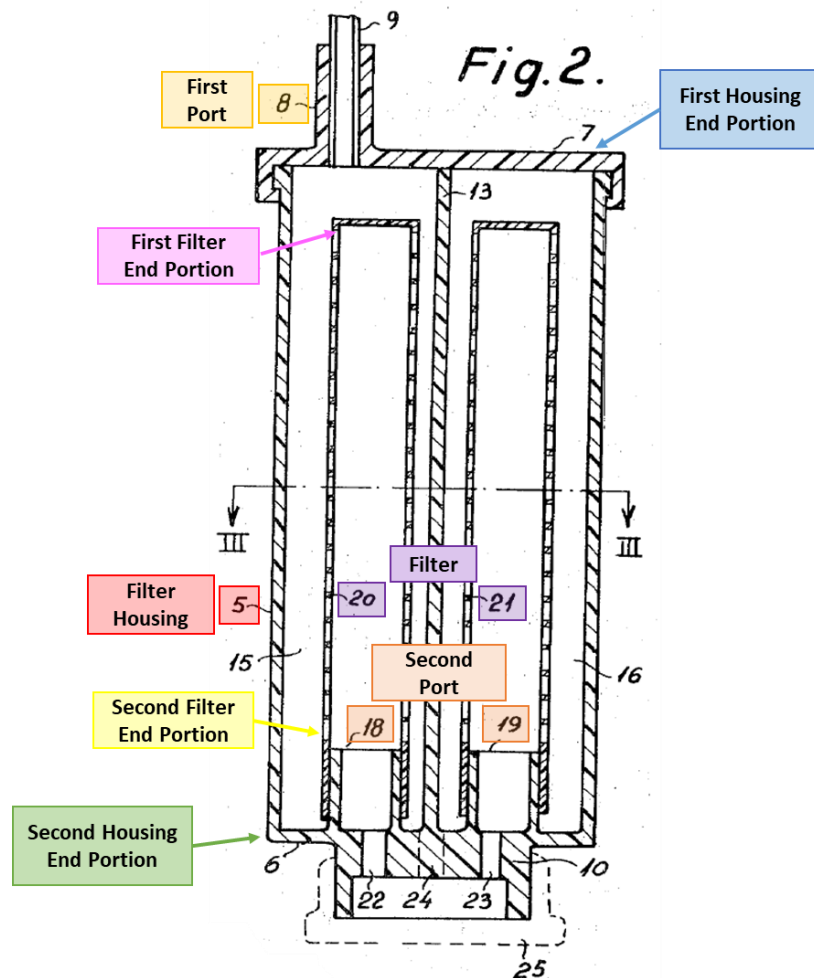


Id.; see also Ex. 1026 (Brumfield) at Figs. 7-8.

51. The Applicant then amended the claims following the March 26 interview to address the typographical issues the Examiner had identified and to amend claims 1 and 11 to require that the first port “provides a first fluid path to the chamber” and the second port “provides a second fluid path from the chamber.” Ex. 1002 (12-’333 Prosecution History) at 216-222. The Applicant repeated its argument from the interview that Grooter’s filter did not “enclose[] an interior region around the second port.” *Id.* at 224. The Applicant also stated that during the interview, “the Examiner provisionally agreed, pending further search and

consideration, that independent claims 1 and 11 would patentably distinguish over Grooters and Brumfield if amended as set forth herein.” *Id.* at 223.

52. Following the amendment, the Examiner issued a second Non-final Rejection on April 26, 2024. *Id.* at 190-200. The Examiner rejected claims 11 and 14 as anticipated by Gram (U.S. Patent No. 3,863,624 (Ex. 1027)) and rejected claims 1-2, 7-10, and 12 as obvious over Gram and Grooters. *Id.* at 192-198. The Examiner focused on Figure 2 of Gram and found that Figure 2 disclosed every limitation of claims 11 and 14, including: a clot collection reservoir having a housing [red] with a first housing end portion [blue] and a second housing end portion [green], a first port [gold] proximate to the first housing end portion configured to be fluidly coupled to an aspiration catheter, a second port [orange] configured to be fluidly coupled to an aspiration source, and a cylindrical filter [purple] extending from a first filter end portion [pink] to a second filter end portion [yellow]:



Id. at 192-193; Ex. 1027 (Gram) at Fig. 2. The Examiner further found that Gram’s filter “extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.” Ex. 1002 (12-’333 Prosecution History) at 193. For claims 1-2, 4, 7-10, and 12, the Examiner found that it would have been obvious to form Gram’s housing from a transparent material in view of Grooters. *Id.* at 194-198. The Examiner also stated that claims 18-19 and 21-30 would be allowable if claim 18 were amended to change “the filter body” to “the filter,” and stated that claims 3, 5-6, and 13-17 would be allowable if rewritten in

independent form. *Id.* at 199. The Examiner did not explain the reasoning for these findings. *Id.*

53. Following the second Non-final Rejection, the Applicant amended the claims on June 3, 2024, cancelling rejected claims 1 and 11, amending claim 18 to recite “the filter” instead of “the filter body,” and amending claims 3, 5, 6, 13, 15, and 16 into independent form. *Id.* at 174-184.

54. The Examiner allowed the claims of the 12-’333 patent following the June 3 amendment. *Id.* at 114-120. In the Notice of Allowance, the Examiner simply stated that the prior art did not teach the limitations of pending independent claims, listing all of the limitations for each independent claim. *Id.* The Examiner did not discuss any particular prior art references in the Notice of Allowance. *Id.*

55. Goff, Garrison, Schaffer, Hartley, Eller, and Laub were cited on Information Disclosure Statements by the Applicant during prosecution of the 12-’333 patent. *Id.* at 88, 227, 372, 382-383, 393. However, neither the Applicant nor the Examiner discussed any of the prior art references that are part of Petitioner’s invalidity grounds during prosecution of the 12-’333 patent. Lee was not cited to the Examiner during prosecution.

IV. CLAIM CONSTRUCTION

56. Claims 18 and 22-25 of the 12-’333 patent require a hemostasis valve having one or more “filaments.” Ex. 1001 (12-’333 patent) at Claims 18, 22-25. I

have offered a construction for “filament” in previous IPRs involving Patent Owner and Petitioner, including IPRs for U.S. Patent Nos. 11,697,011, 11,697,012, 11,554,005, 11,969,333, 11,844,921, 11,865,291, 12,016,580, and 12,156,669. In those IPRs, I opined that that a person of ordinary skill in the art would have understood the term “filament” to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.” In the previous IPRs, Patent Owner has argued that my construction of “filament” is incomplete because I did not limit the claims to “flexible” filaments.

57. Although I maintain my opinions regarding the meaning of “filament” from the previous IPRs, the dispute about whether the “filaments” claimed in the 12-’333 patent must be “flexible” does not impact my opinions set forth herein. The invalidity Grounds that cover Claims 18 and 22-25 (Grounds 5-8) in my below analysis, rely upon Hartley and Eller for the “filament” limitations.” *Infra* §VIII. Patent Owner has not disputed that Hartley or Eller describe “flexible” filaments. As the Board preliminarily found in the Institution Decisions for the ’011,’012, ’005, ’921, and ’291 Patents, Hartley includes a “filament,” regardless of whether the claims are limited to “flexible” filaments. The Board specifically found that Patent Owner “does not dispute that Hartley ... disclose[s] a flexible filament (e.g., flexible string or flexible wire).” Ex. 1048 (’012 Institution Decision) at 21, n.13. The Board also preliminarily found that a person of ordinary skill in the art would

have found it obvious to combine Hartley's filament with Schaffer's valve. Additionally, Eller expressly states that its wire members can be formed from "flexible materials." Ex. 1010 (Eller) at 15:41-60. Therefore, Schaffer in combination with Hartley or Eller renders the claimed "filament" limitations obvious regardless of whether the Board construes "filament" to require flexibility.

V. SUMMARY OF IPR GROUNDS

58. I have identified the following grounds of unpatentability in this Declaration:

Ground	Reference(s)	35 U.S.C. Section	Challenged Claims
1	Goff	§ 102	1, 4-5, 7, 10-11, 13, 15
2	Goff	§ 103	1, 4-5, 7, 10-11, 13, 15
3	Garrison + Goff	§ 103	1, 4-5, 7, 10-11, 13, 15-17, 19-21
4	Garrison + Lee	§ 103	1, 4-5, 7, 10-11, 13, 15-17, 19-21
5	Garrison + Goff + Schaffer + Hartley	§ 103	18, 22-25
6	Garrison + Goff + Schaffer + Eller	§ 103	18, 22-25
7	Garrison + Lee + Schaffer + Hartley	§ 103	18, 22-25
8	Garrison + Lee + Schaffer + Eller	§ 103	18, 22-25
9	Garrison + Goff + Laub	§ 103	26-28
10	Garrison + Lee + Laub	§ 103	26-28

VI. GROUNDS 1-2: CLAIMS 1, 4-5, 7, 10-11, 13, 15 ANTICIPATED OR OBVIOUS IN VIEW OF GOFF

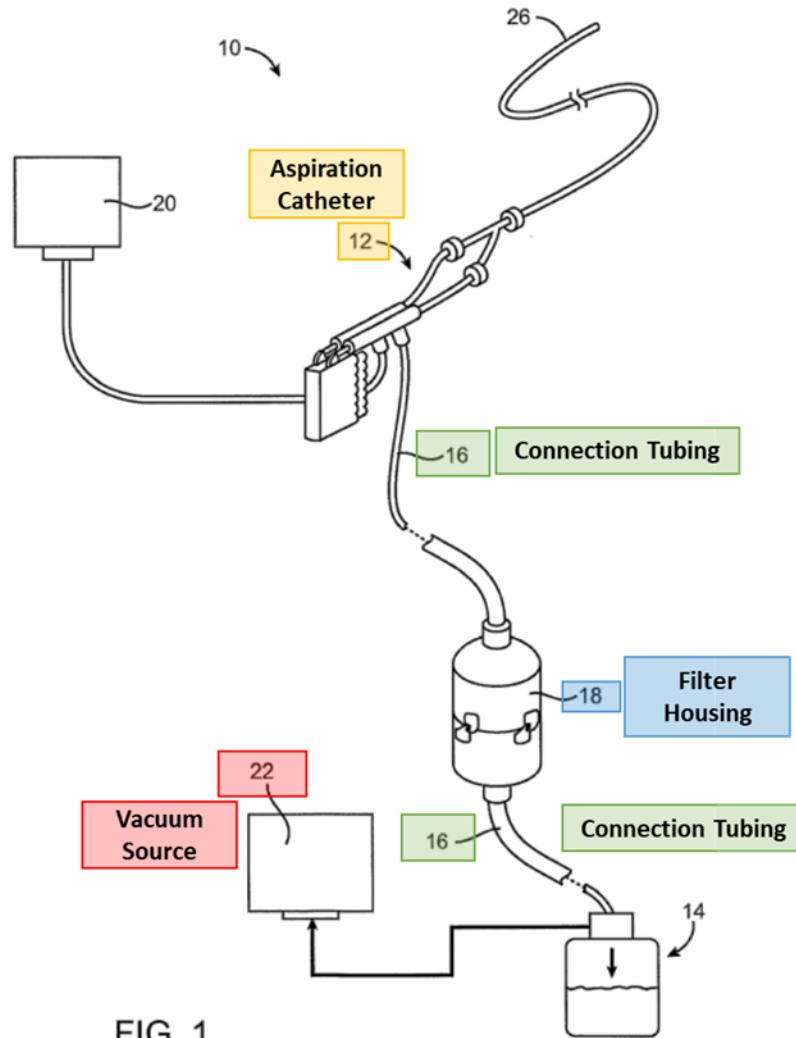
A. Claim 1

59. In my opinion, Claim 1 is anticipated or rendered obvious by Goff.

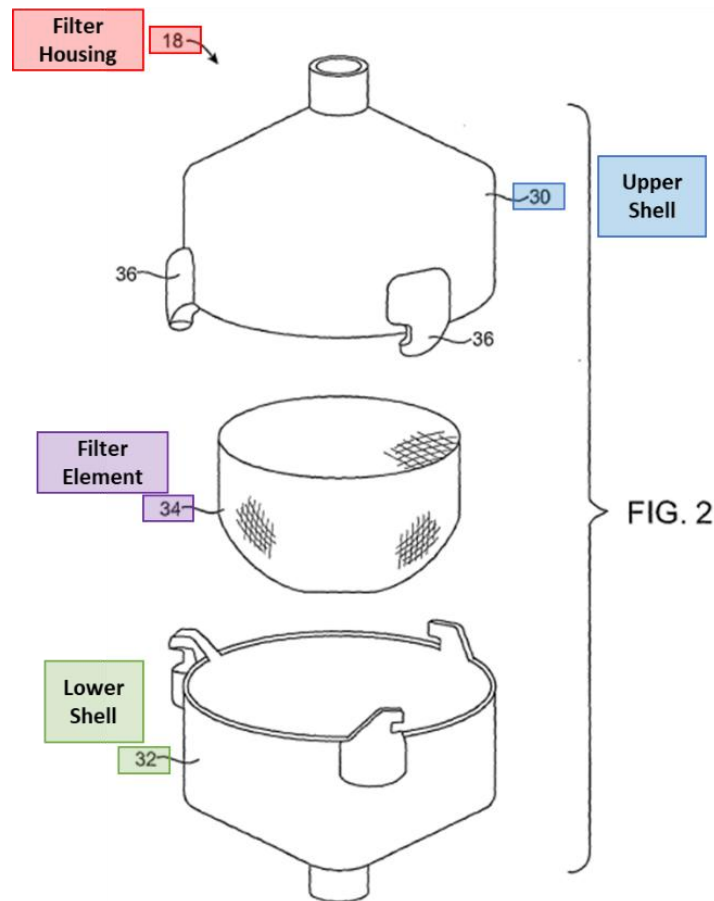
1. Preamble - clot collection reservoir

60. The preamble of Claim 1 recites a “clot collection reservoir.” If this preamble is limiting, Goff discloses this limitation.

61. Goff is titled “methods and systems for filtering aspirated material.” Ex. 1005 (Goff) at Title. Goff discloses an aspiration system that includes a “filter housing 18” that is located between an aspiration catheter and a vacuum source:



Id. at [0025], Fig. 1. Goff’s filter housing (red) includes an upper shell (blue), a lower shell (green), and a filter element (purple) within the housing:



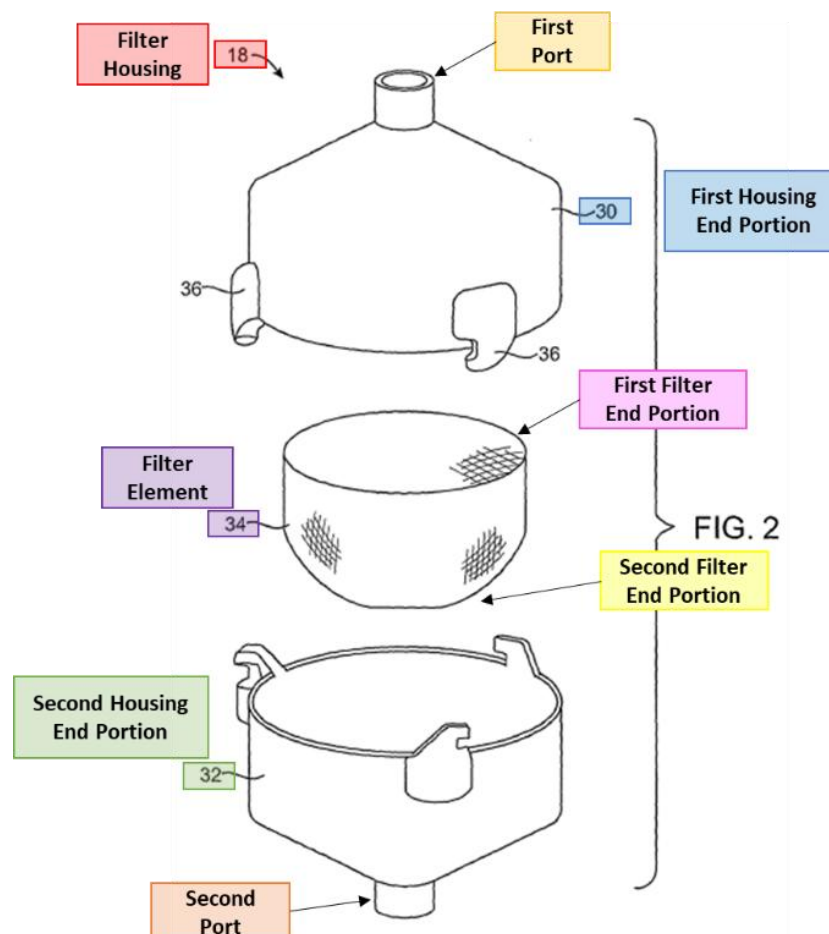
Id. at [0015], [0025], Fig. 2. Goff's filter "remove[s] solid materials from the aspirate before the remaining liquid phase of the aspirate flows to the aspirate receptacle" and "collect[s] solids within the filter element 34 as the aspiration progresses." *Id.* at [0011], [0025]. Goff also explains that its system is "intended for introduction to a blood vessel for introducing a thrombolytic agent in order to disrupt clot," and "the solid material aspirated by the catheter will frequently comprise disrupted clot, thrombus, and/ or plaque." *Id.* at [0024]. Goff's filter is

therefore a “clot collection reservoir” at least because it traps and “collect[s] solids [e.g., disrupted clot] ... as the aspiration progresses.”

2. **a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion**

62. Claim 1 next recites: “a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.” Goff discloses this limitation.

63. Goff’s filter assembly includes a filter housing 18 comprised of an upper shell 30 (blue) and a lower shell 32 (green):



Ex. 1005 (Goff) at [0015], [0025], Fig. 2. As shown in Figure 2 above, the upper shell 30 of the housing is a first housing end portion, and the lower shell 32 is a second housing end portion that is opposite from the first housing end portion. *Id.*

64. As also shown in Figure 2, Goff's housing includes mating connectors 36 to secure the shell portions and form a sealed filter chamber. *Id.*, [0025]. Figure 1 below also shows that Goff's filter housing defines a sealed chamber:

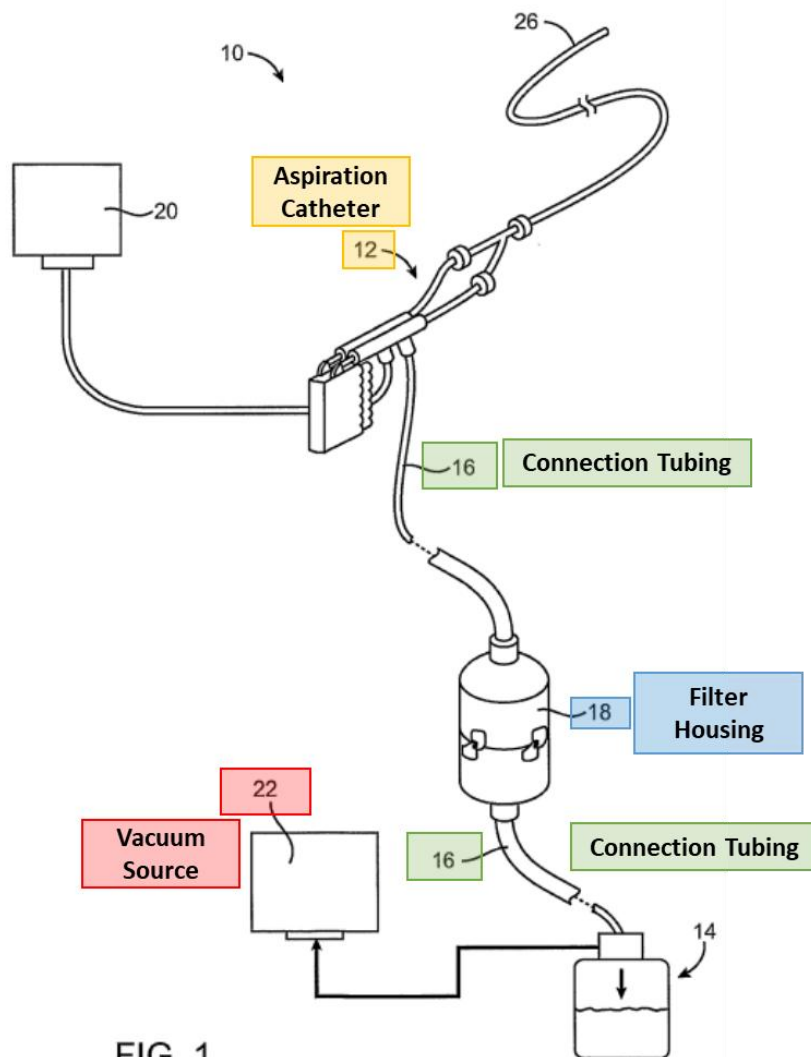


FIG. 1

Id. at Fig. 1. A person of ordinary skill in the art would have recognized that Goff's filter housing must be sealed, otherwise blood would leak from the filter during aspiration procedures.

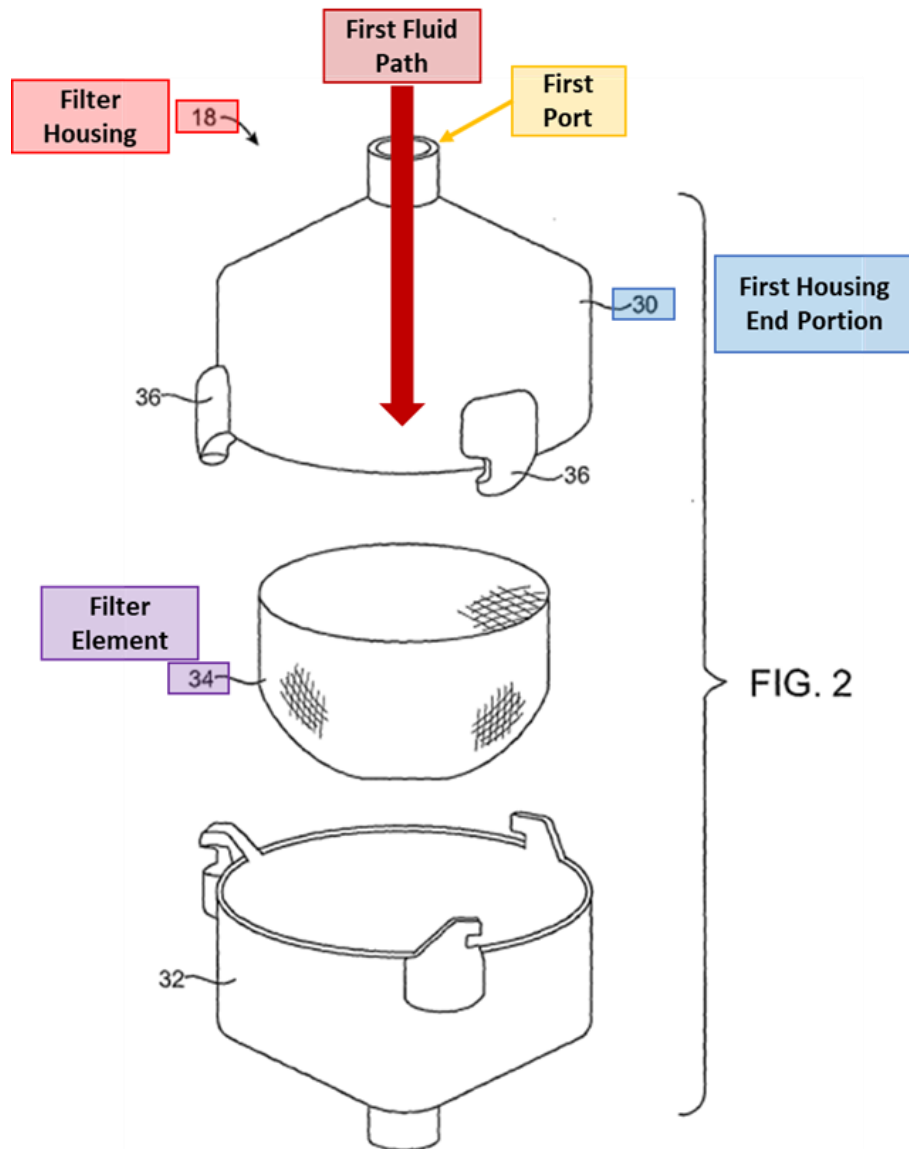
3. **a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber**

65. Claim 1 next recites: "a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber." Goff discloses this limitation.

66. A person of ordinary skill in the art would have understood that the plain and ordinary meaning of "port" is simply an opening for intake or exhaust of a fluid. *See, e.g.*, Ex. 1028 (Merriam Webster); Ex. 1029 (Dorland's). Claim 1 does not specify any features or structure for the "port" aside from requiring that it is "positioned proximate to the first housing end portion and provides a first fluid path to the chamber." The specification of the 12-'333 patent similarly lacks any description of specific features or structures for the "port 324" aside from stating that it is "configured to be removably, fluidly coupled to the catheter system 200." Ex. 1001 (12-'333 patent) at 9:5-7.

67. Goff states that its filter "housing will further have conventional connectors to permit connection at an upper end to the aspiration catheter and at a

lower end to the aspirate receptacle.” Ex. 1005 (Goff) at [0015]. The connectors on the housing are shown in Figure 2 below, which also shows that the connector on the upper shell is positioned proximate to the first housing end portion and provides a first fluid path into the filter chamber:

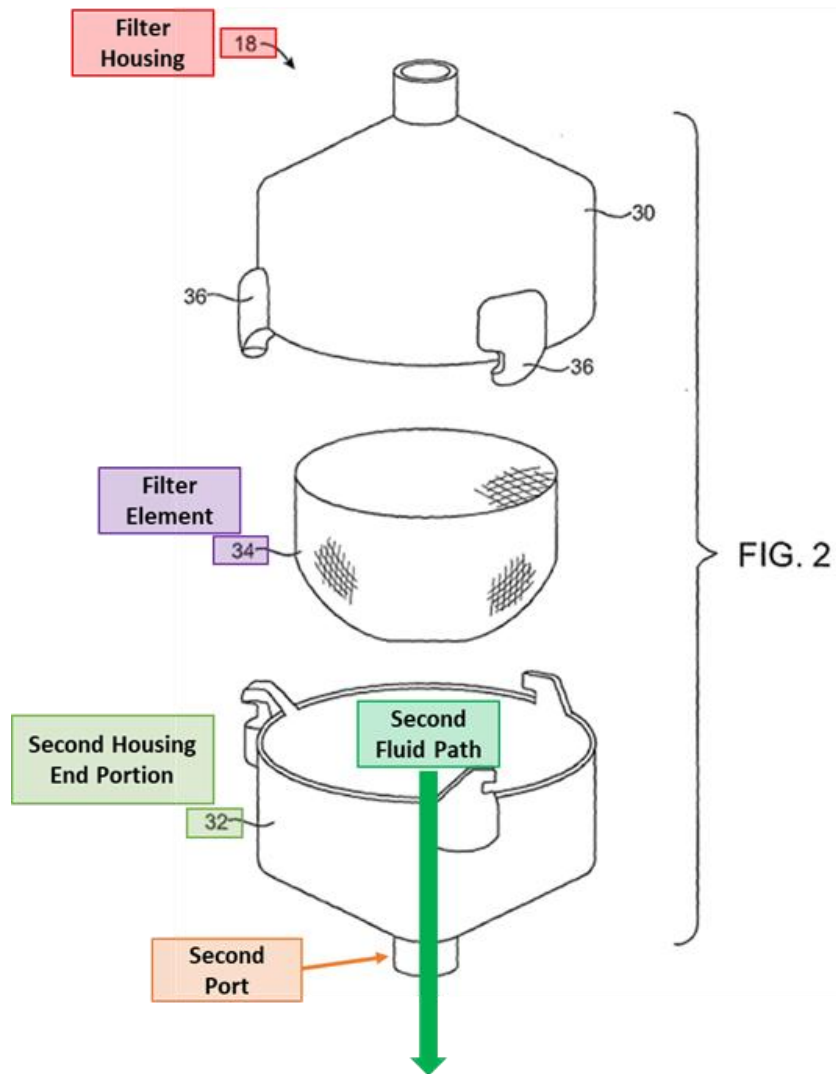


Id. at Fig. 2. Accordingly, the connector at the upper end of Goff’s filter housing is a first “port” as recited in Claim 1.

4. **a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber**

68. Claim 1 next recites: “a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber.” Goff discloses this limitation.

69. As I explained above, Goff’s filter housing includes “conventional connectors to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle.” Ex. 1005 (Goff) at [0015]. As shown in Figure 2 below, the connector on the lower shell 32 on Goff’s filter housing provides a second fluid path exiting the filter chamber:



Id. at Fig. 2.

70. Goff also discloses that its aspiration system may include “a separate vacuum source 22 which may be connected to or through the catheter 12 and/or aspirate receptacle 14.” *Id.* at [0023]. As shown in Figure 1 below, the connector on the lower shell of Goff’s filter housing is fluidly coupled to the vacuum source 22 in Goff’s system:

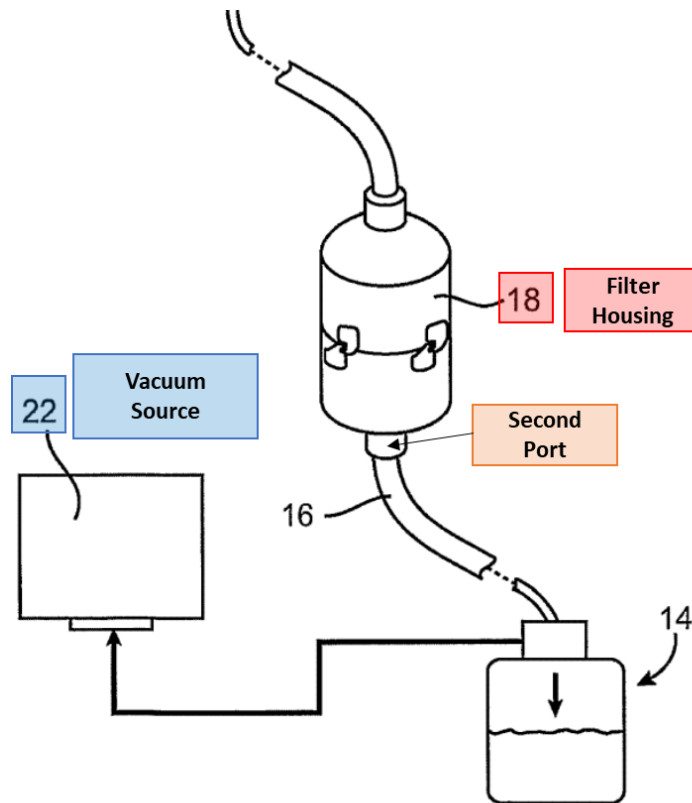


FIG. 1

Id. at Fig. 1 (excerpt). Although Figure 1 illustrates a receptacle between the filter and the vacuum source, a person of ordinary skill in the art would have understood that the receptacle is optional given Goff’s disclosure that the vacuum source can be “connected to or through the catheter 12 and/or aspirate receptacle 14.” *Id.* at [0023] (emphases added). In addition, a person of ordinary skill in the art would have understood that Goff’s vacuum source is fluidly coupled to the second port of the filter through the receptacle even in embodiments that include the receptacle. If there was not such a fluid connection, the negative pressure generated by the vacuum source would not be able to reach the aspiration catheter to remove

unwanted material. The connector on the lower shell of Goff's filter housing is therefore a "second port" as recited in Claim 1.

5. Filter

71. Claim 1 next recites: "a filter removably positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port." Goff discloses these limitations or renders them obvious.

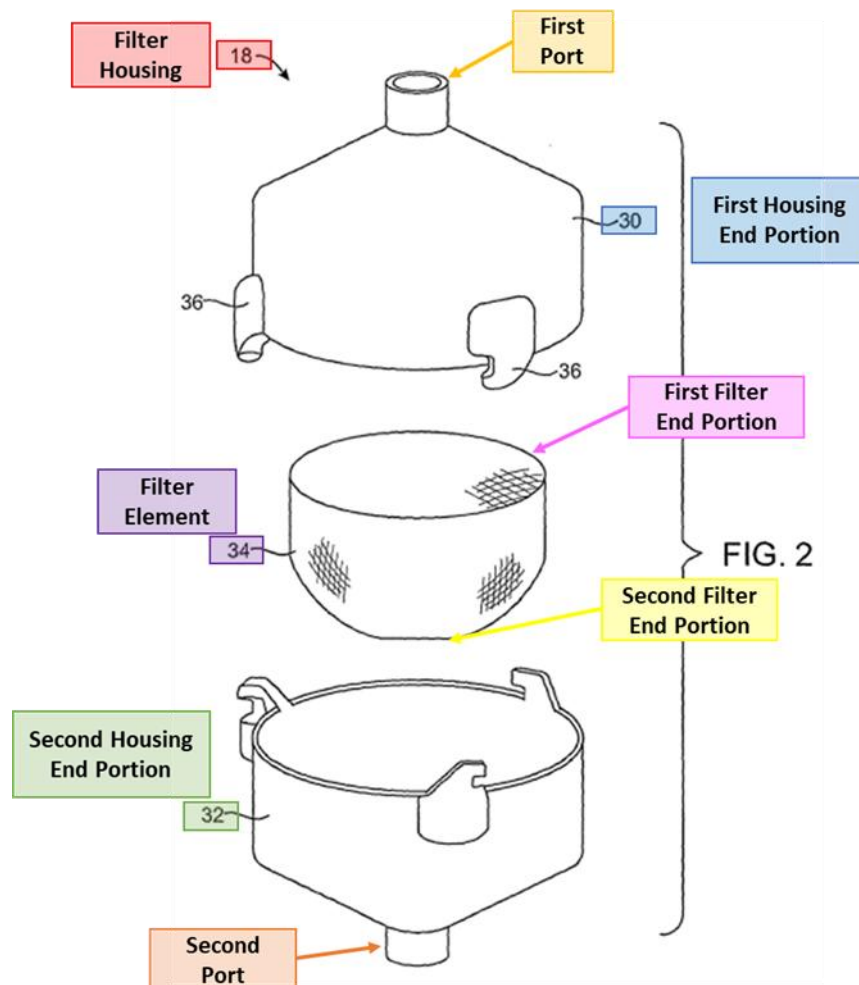
a. a filter removably positioned within the chamber

72. Goff's filter assembly includes a "filter element 34 that may be disposed within the interior of the shells." Ex. 1005 (Goff) at [0025]. Goff also states that its upper and lower shells "may be taken apart to permit introduction, removal, and replacement of the filter element in the interior of the housing." *Id.* at [0015]. Goff's filter element 34 is therefore "removably positioned within the chamber" defined by the filter housing.

b. the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion

73. Goff states that its filter element "may have any one of a variety of geometries including cup-shaped, conical and the filter could be inclined or slanted in the filter-housing to spread the filtrate over the filter to permit differentiation of

the filtrate material.” *Id.* at [0011]. Goff explains that the “geometries in which the filter elements 34 are arranged will depend in large part on the construction of the remainder of the filter assembly.” *Id.* at [0026]. The filter element disclosed in Goff’s Figure 2 has a generally cylindrical shape that extends from a first filter end portion to a second filter end portion:



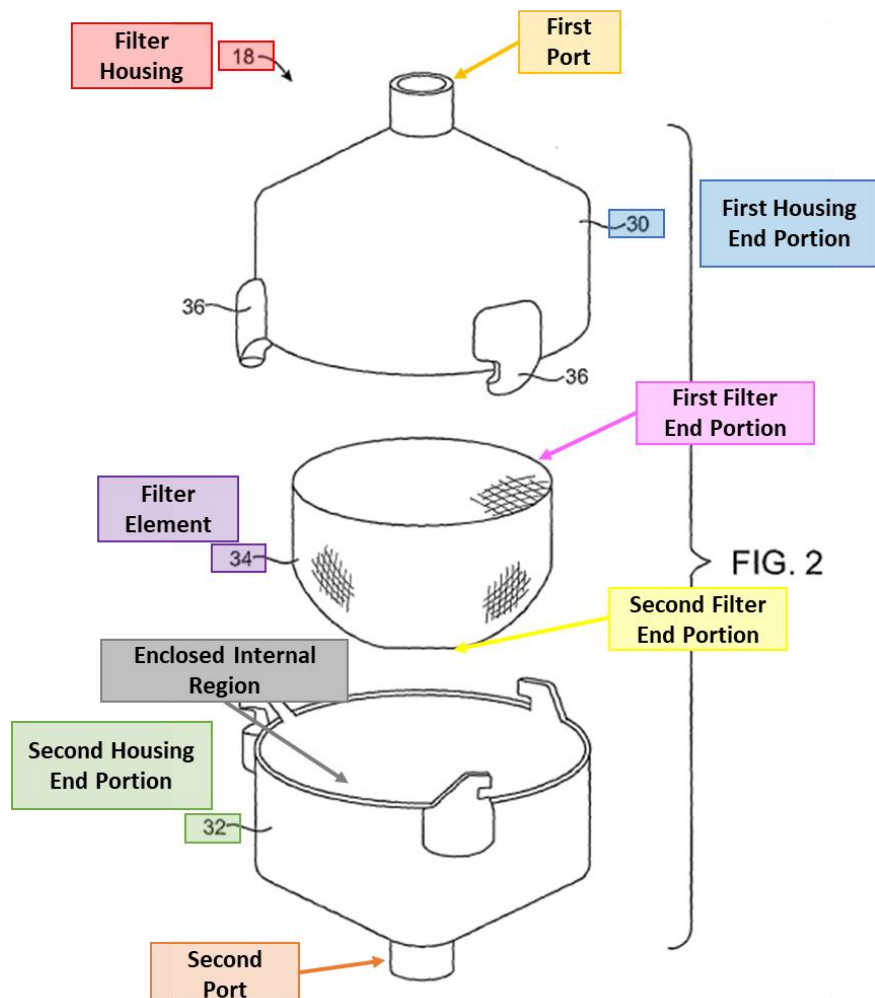
Id. at Fig. 2.

- c. the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port

74. Goff discloses or renders obvious the limitation requiring that “the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.”

i. Goff Discloses This Limitation

75. As shown in Figure 2 below, Goff’s filter element extends in a continuous circle about the first filter end portion:

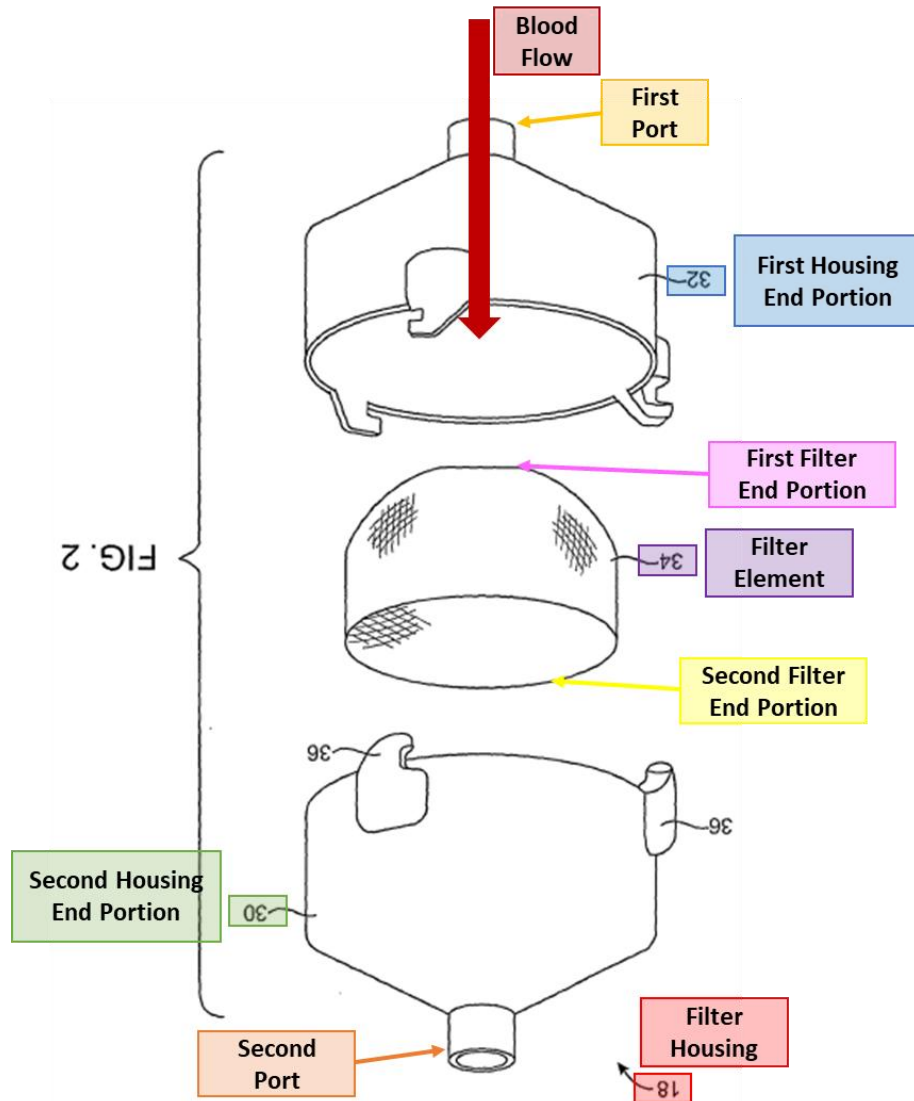


Id. at Fig. 2. The filter element therefore encloses an interior region within the filter chamber between the exterior of the filter element and the wall of the lower shell 32. *Id.* This enclosed interior region is “around the second port” as shown in figure 2 above.

ii. Goff Renders This Limitation Obvious

76. If the Board determines that Goff’s Figure 2 does not disclose this limitation due to the orientation of the filter element 34 in Figure 32, this limitation would have nonetheless been obvious in view of Goff in two ways.

77. **First**, a person of ordinary skill in the art would have found it obvious to simply rotate Goff’s filter housing 180 degrees such that the port on the upper shell 30 connects to the aspiration source and the port on the lower shell 32 connects to the aspiration catheter:



Id. at Fig. 2. In this orientation, blood would flow into the filter chamber through the port on the lower shell 32 (i.e., the “first port”) and out of the filter chamber through the port on the upper shell 30 (i.e., the “second port”). The enclosed end of Goff’s cylindrical filter element would constitute the “first filter end portion,” which extends continuously to enclose an interior region within the filter element around the port on the upper shell 30 (i.e., the “second port”).

78. A person of ordinary skill in the art would have reasonably expected success in rotating the orientation of Goff's filter housing in this manner. Goff explains that the ports on the ends of the filter housing are "conventional connectors" which connect the housing to the aspiration catheter and the vacuum source via standard medical tubing:

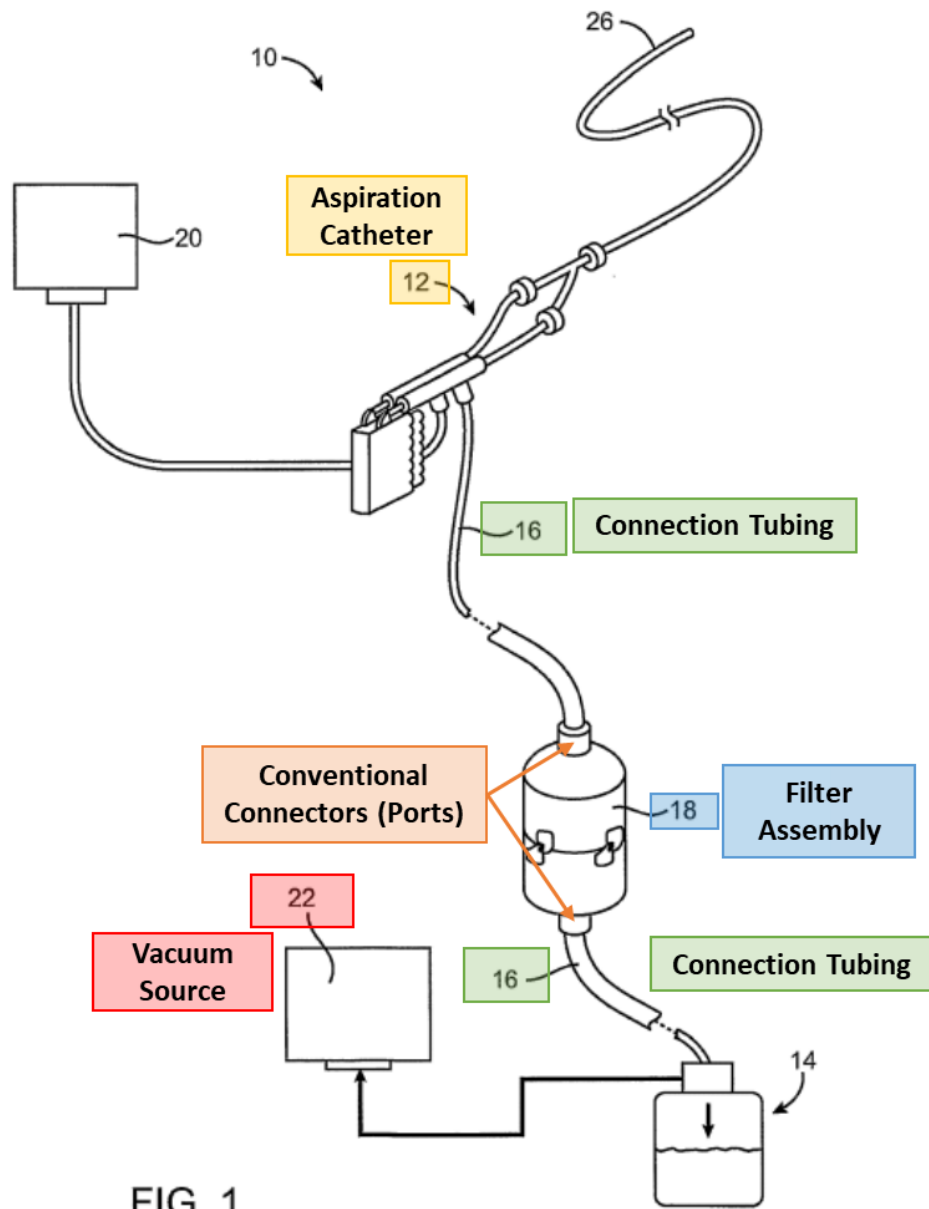
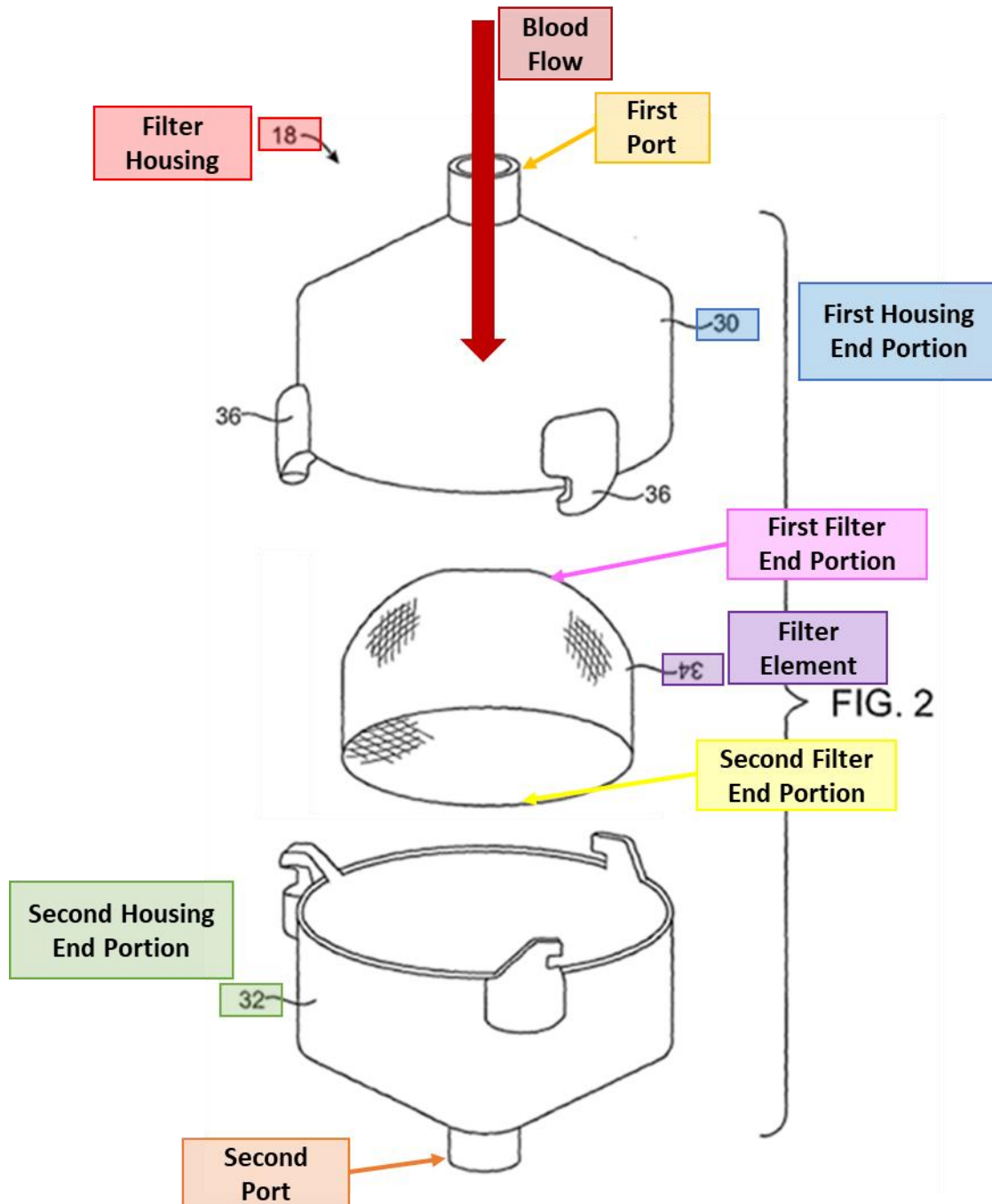


FIG. 1

Id. at [0015], [0022], Fig. 1. Goff does not differentiate between the structure of the “conventional connectors” on the upper and lower shells of the filter housing, nor the connection tubing 16 that is fluidly coupled to each of the connectors. A person of ordinary skill in the art would have therefore understood that rotating the orientation of Goff’s filter housing would not have required any structural changes to the filter housing, the ports (i.e., “conventional connectors”), or the connection tubing. It would have merely required rotating the filter housing before coupling the connectors to the connection tubing, which would have been well within the abilities of a person of ordinary skill in the art.

79. **Second**, a person of ordinary skill in the art would have found it obvious to simply rotate Goff’s filter element 34 within the filter housing so that the open end of the filter element is oriented toward the lower shell 32, as I’ve illustrated in the modified version of Figure 2 below:



Id. at Fig. 2 (modified by Petitioner). As shown above, in this orientation the enclosed end of Goff’s cylindrical filter element would constitute the “first filter end portion,” which extends continuously to enclose an interior region within the filter element around the port on the lower shell 32 (i.e., the “second port”).

80. A person of ordinary skill in the art would have reasonably expected success in rotating Goff's filter element 34 within the filter housing. Goff explains that the "geometries in which the filter elements 34 are arranged will depend in large part on the construction of the remainder of the filter assembly" and also states that while Figure 2 shows the filter element nesting in the lower shell 32, a "wide variety of other geometries would also be suitable." *Id.* at [0026]. Thus, Goff expressly suggests using different filter geometries and conveys that they would be suitable with its housing and filter assembly. Moreover, a person of ordinary skill in the art would have recognized that the purpose of Goff's filter element is to provide a filter that allows the passage of blood while preventing the passage of larger solid particles, particularly aspirated clot material. A person of ordinary skill would have further recognized that the filter element would perform that purpose in either orientation because aspirated blood would pass through the filter's pores, while aspirated clot material would not. *See id.* at [0011] ("The filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff.").

81. A person of ordinary skill in the art would have been motivated to orient Goff's filter in this manner (i.e., with the open end of the filter element facing toward the outflow or "second" port) via either option above for several reasons.

82. First, the orientation of Goff's filter would have presented a person of ordinary skill in the art with a simple binary choice. The enclosed end of the cylindrical filter element can be oriented closer to the inflow port or closer to the outflow port. A person of ordinary skill in the art would have found it obvious to try both of these finite, predictable options, and as I explained above, they would have reasonably expected success in doing so. *Supra* ¶¶[77]-[81]. In fact, a person of ordinary skill would have been aware that cylindrical clot filters enclosing an interior region around an outflow port had been known in the art for decades prior to 2018. There were numerous examples of such filters in the prior art.

83. For example, the AngioVac System was developed by AngioDynamics in 2008 and received FDA approval in 2009. Ex. 1030 (Ram) at 1093. The AngioVac System included an in-line clot filter with a generally cylindrical filter element that enclosed an interior region around the outflow port of a transparent housing:

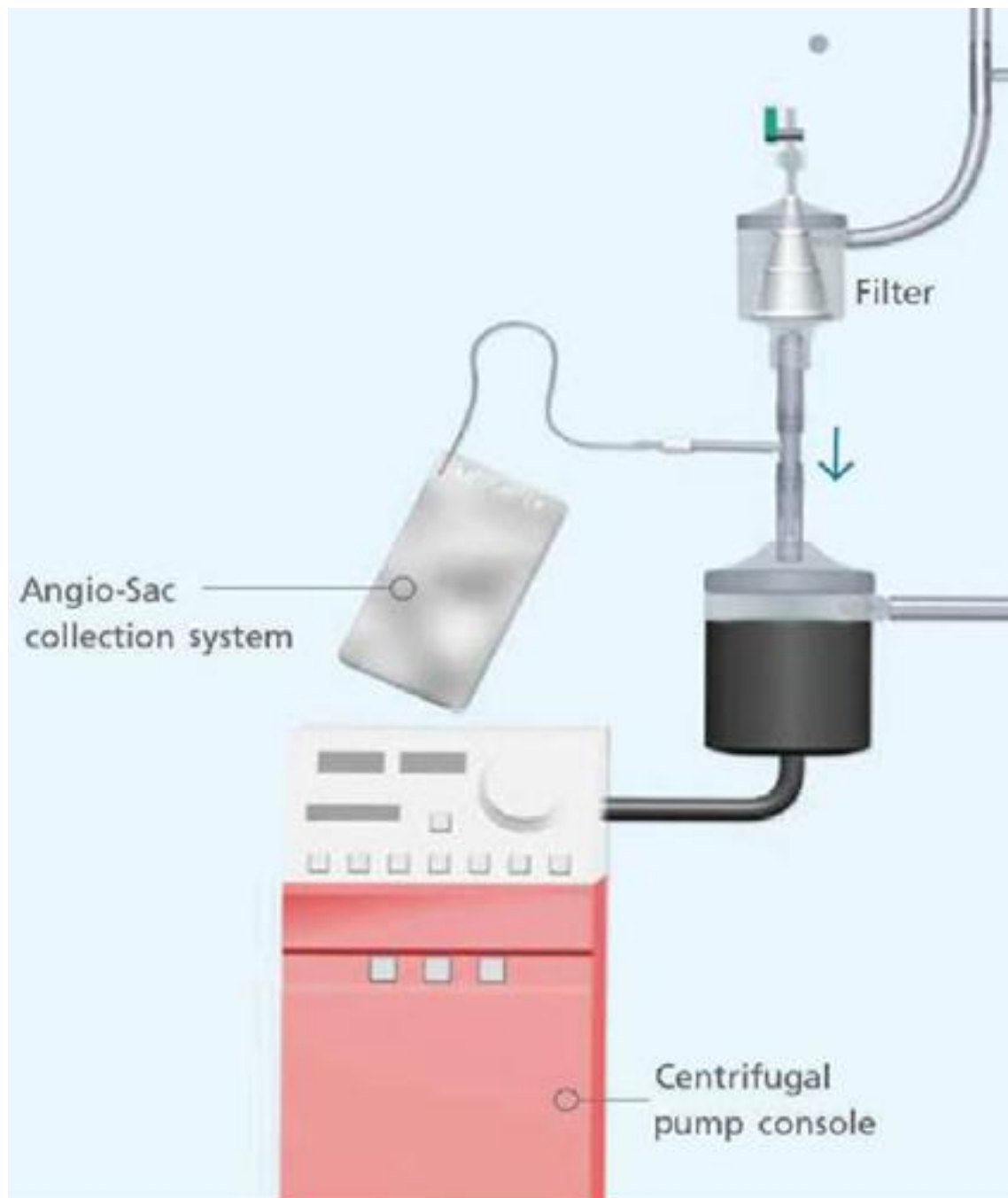
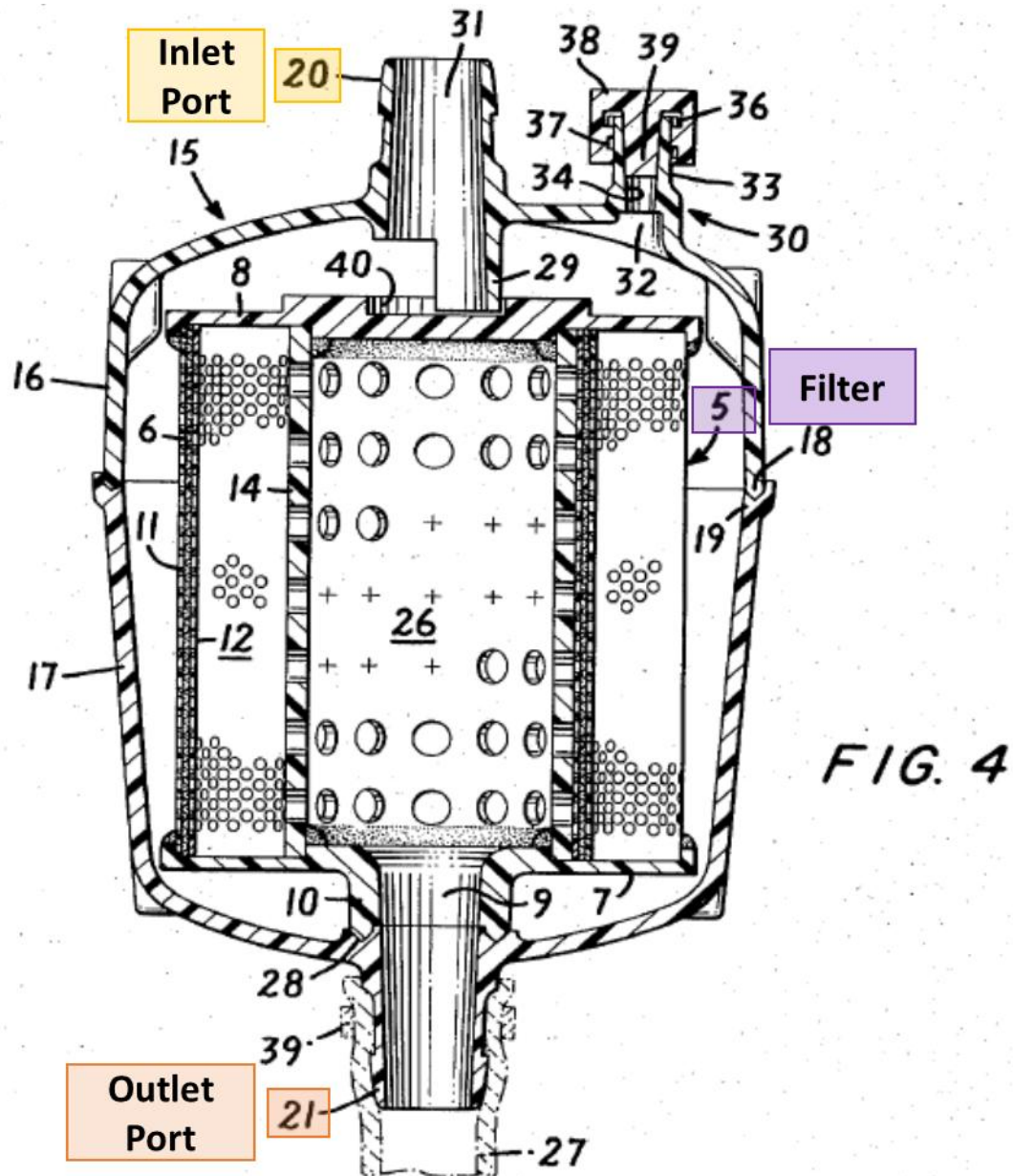




Fig 3. Procedure results, all demonstrating various intravascular material trapped by the inline filter.

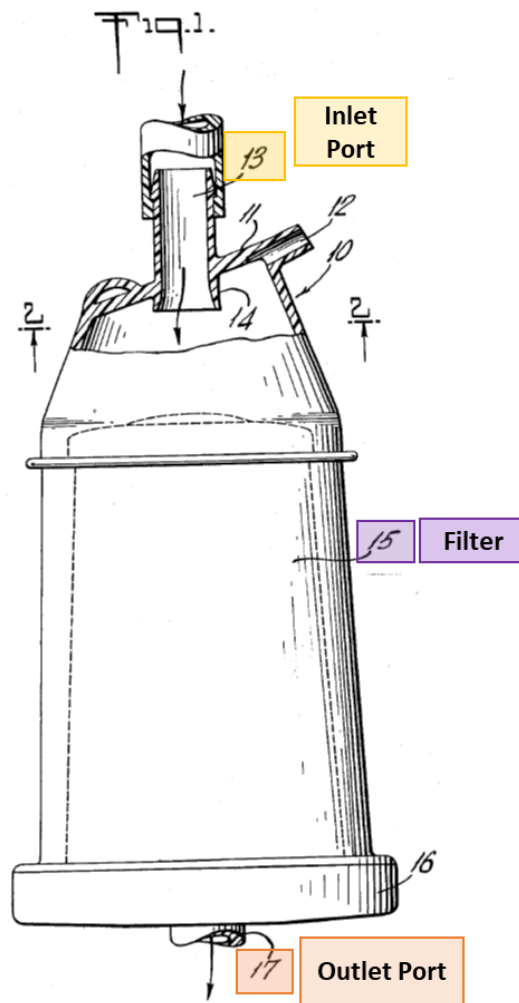
Id. at Figs. 1, 3. As shown in Figure 3 of the Ram article above, the AngioVac System's filter surrounded and enclosed the outflow port such that blood would flow through the filter into the interior region around the outflow port, while aspirated clot material would be trapped outside of the filter within the housing. *Id.*

84. Krakauer, a U.S. Patent that issued in 1972, discloses a blood filter for use in cardiopulmonary bypass procedures that includes a cylindrical filter 5 enclosing an interior region around an outlet port 21 within a filter housing:



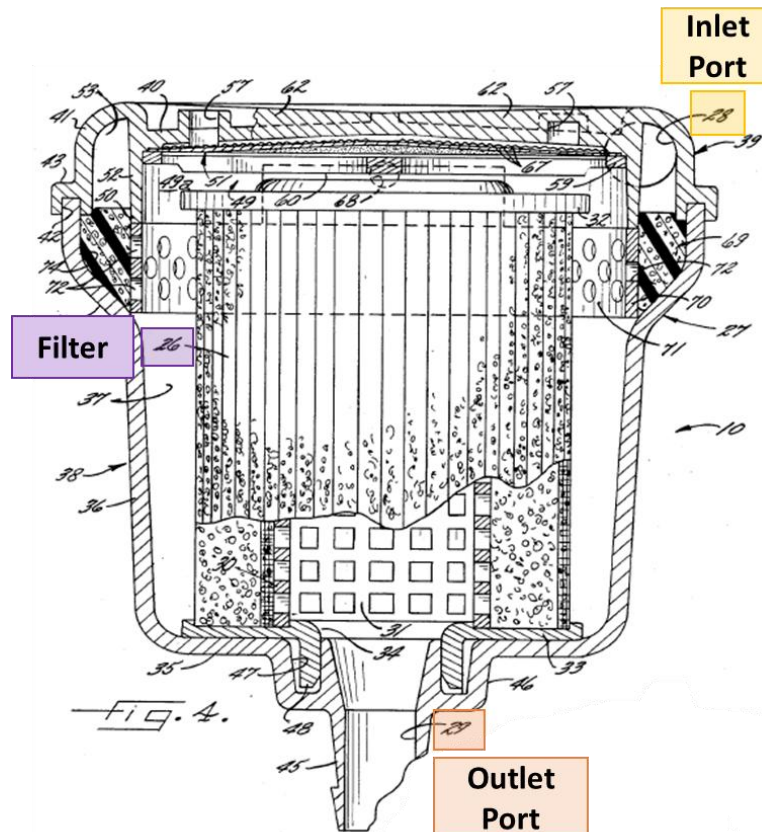
Ex. 1033 (Krakauer) at 4:11-61, Fig. 4. Krakauer explains that the purpose of its filter is to remove microemboli from blood during cardiopulmonary bypass procedures. *Id.* at 3:3-5.

85. Servas, a U.S. Patent that issued in 1976, discloses a “filter for use in extracorporeal blood circulation” that includes a cylindrical filter media 15 that encloses an interior region around a blood outlet 17 within a sealed housing chamber:



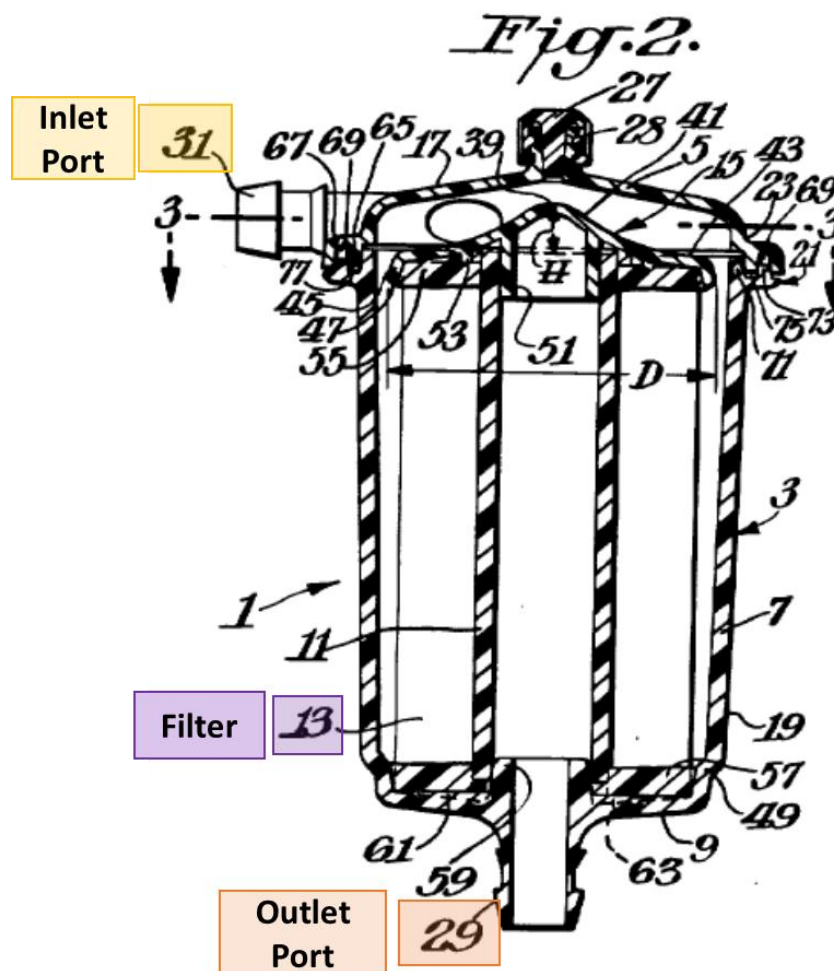
Ex. 1031 (Servas) at 1:59-2:8, Fig. 1. Servas expressly discloses that the top of its filter “is capped and sealed and the bottom of the [filter] media is sealed into the bottom portion 16 of the filter” and the blood outlet is located “[i]n the center of the bottom portion.” *Id.* at 2:2-5. Servas explains that its filter media “may be any standard sieve type or depth type filter medias” and the “specific media will be dependent on where the filter is to be used and the type of solid or liquid particles to be removed from the blood.” *Id.* at 2:45-51.

86. Rosenberg, a U.S. Patent issued in 1986, discloses a blood filter for use in cardiopulmonary bypass procedures that includes a cylindrical filter element 26 that encloses an interior region around an outlet port 29:



Ex. 1034 (Rosenberg) at 3:16-41, Fig. 4. Rosenberg's filter "removes microemboli including gas or air bubbles, fat emboli and aggregates formed from platelets, white blood cells, red blood cells, and other debris" from aspirated blood. *Id.* at 2:62-67.

87. Dickens, a U.S. Patent issued in 1988, discloses an arterial blood filter for use in cardiopulmonary bypass operations that includes a cylindrical filter element 13 that encloses an interior region within a housing around the outlet port 29:

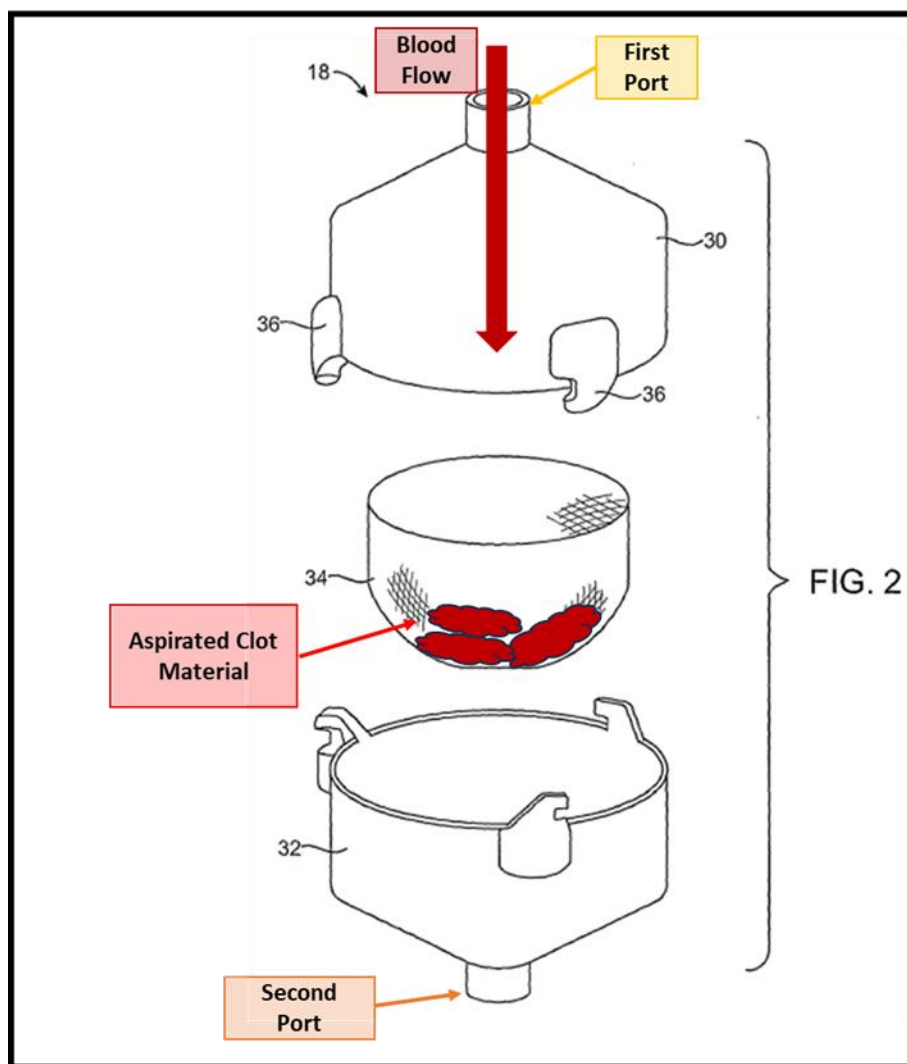


Ex. 1036 (Dickens) at Abstract, 3:20-65, Figs. 1-2. Dickens explains that its filter element “serves to trap any solid debris that may be present in the blood.” *Id.* at 3:63-65.

88. These many examples of prior art blood filters demonstrate that a generally cylindrical filtering element enclosing an interior region around an outlet port was a commonly used orientation throughout the prior art. A person of ordinary skill in the art in 2018 would have been aware of these examples, and they would have given the person of ordinary skill even further motivation to use a similar orientation with Goff’s filter. The common use of this orientation would have also reinforced the person of skill’s reasonable expectation of success in using it for Goff’s filter.

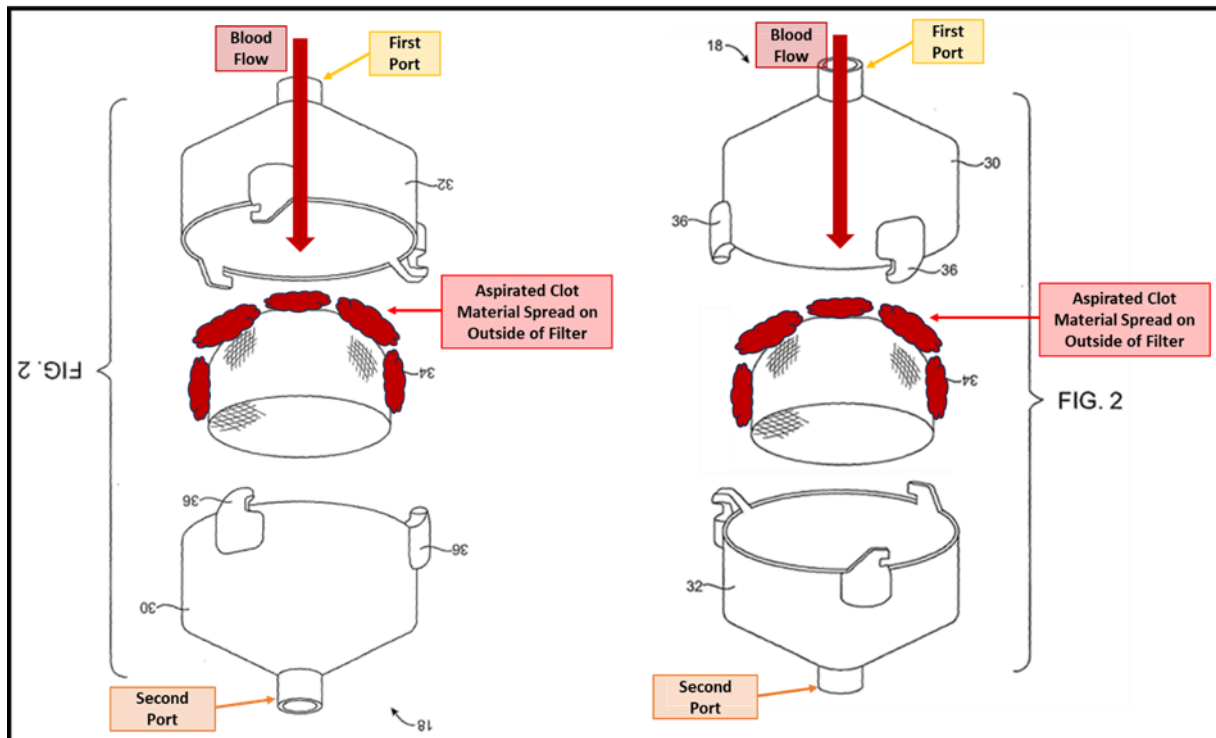
89. Second, a person of ordinary skill in the art would have been motivated to orient Goff’s filter element with the open end facing toward the outflow port so that clot material would be collected on the exterior surface of the filter element, which would make it easier to visualize the clot material. A person of ordinary skill would have recognized that if the open portion of the filter faces the inflow port, clot material would collect within the filter element, and the material making up the filter element may obscure visualization of the clot material:

Orientation 1



Ex. 1005 (Goff) at Fig. 2. In contrast, orienting the open end of the cylindrical filter toward the outflow port would spread the aspirated clot material on the outside surface of the filter:

Orientation 2



Id. (modified by Petitioner). A person of ordinary skill in the art would have recognized that this would make it easier for the operator to visualize and inspect the aspirated clot material within the filter canister because the clot material would not be obstructed by the filter material. This benefit is demonstrated by the real-world clinical use of the AngioVac System, which trapped clot material on the outside of the filter making it easily visible:

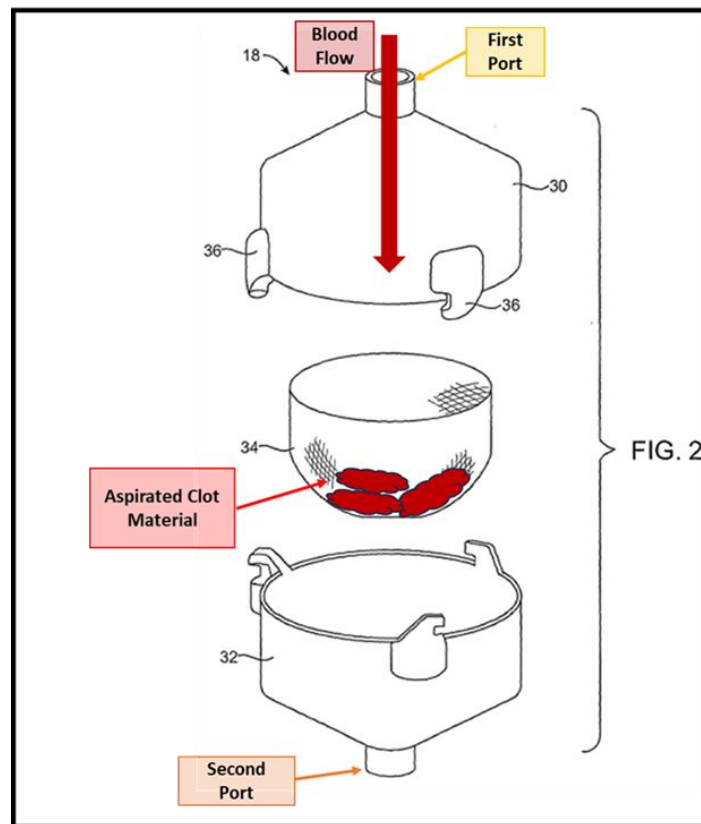


Fig 3. Procedure results, all demonstrating various intravascular material trapped by the inline filter.

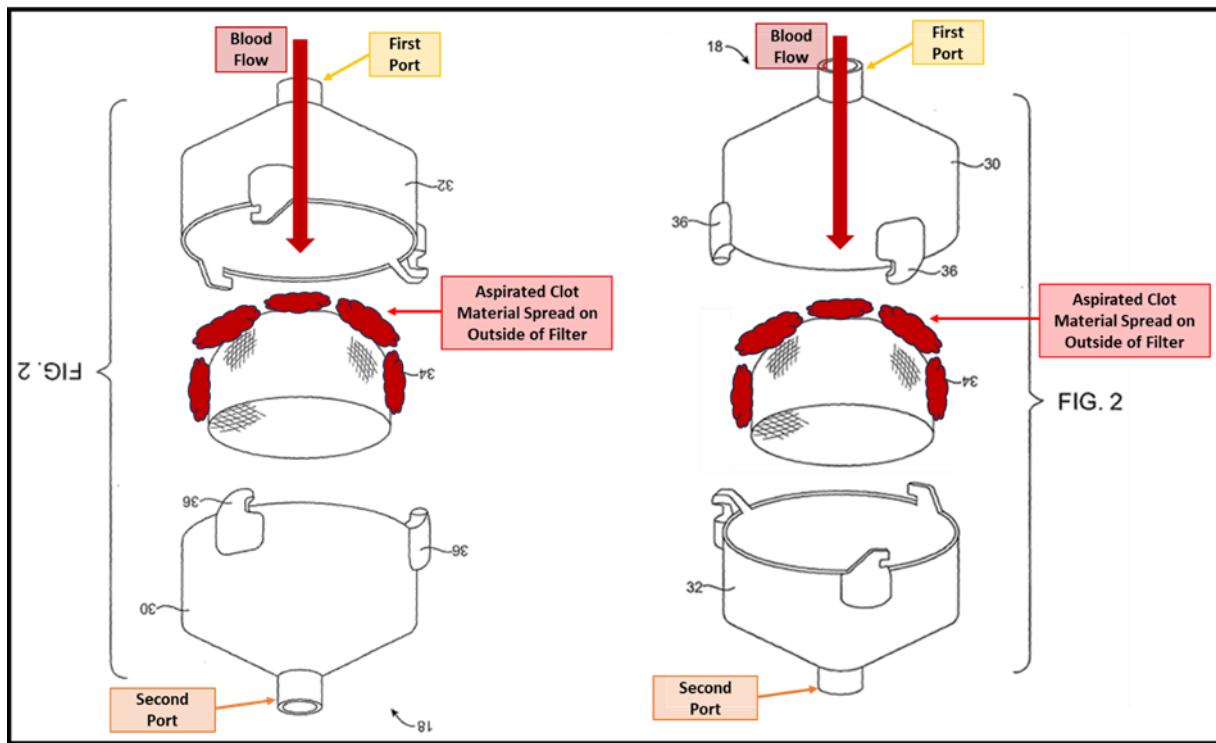
Ex. 1030 (Ram) at Fig. 3. In addition, Goff discloses that its filter assembly “may be at least partially transparent to permit observation of the solid materials as they collect,” which underscores the importance of the enhanced visualization that would be provided by this arrangement. Ex. 1005 (Goff) at [0015].

90. Third, Goff's disclosure that "the filter could be inclined or slanted in the filter-housing to spread the filtrate over the filter to permit differentiation of the filtrate material" would have further motivated a person of skill to orient the open end of the filter element toward the outflow port. Ex. 1005 (Goff) at [0011]. As I explained above, a person of ordinary skill would have recognized that orienting the open end of Goff's cylindrical filter toward the outflow port would be more likely to "spread the filtrate over the filter to permit differentiation of the filtrate material" because it would prevent filtrate from collecting in the enclosed end of the filter:

Orientation 1



Orientation 2

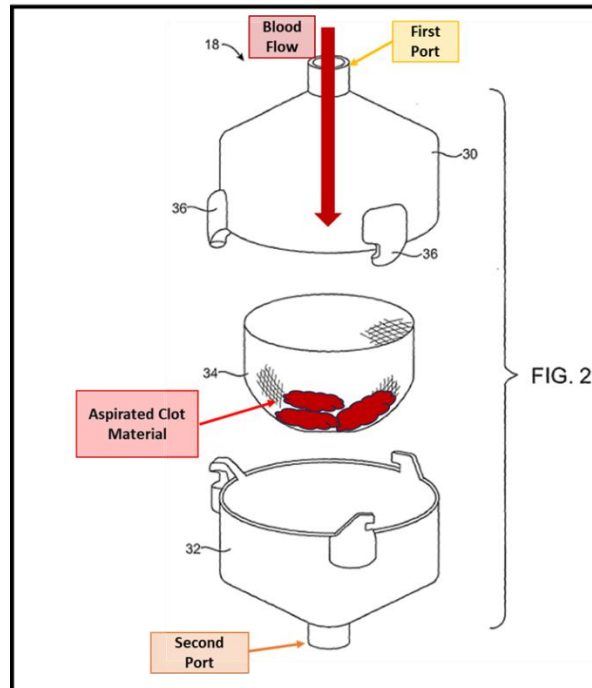


In contrast, orienting the open-end of the cylindrical filter toward the inflow port would likely collect clot material within the enclosed end of the cylindrical filter, making it more difficult to visualize, differentiate, and remove the material.

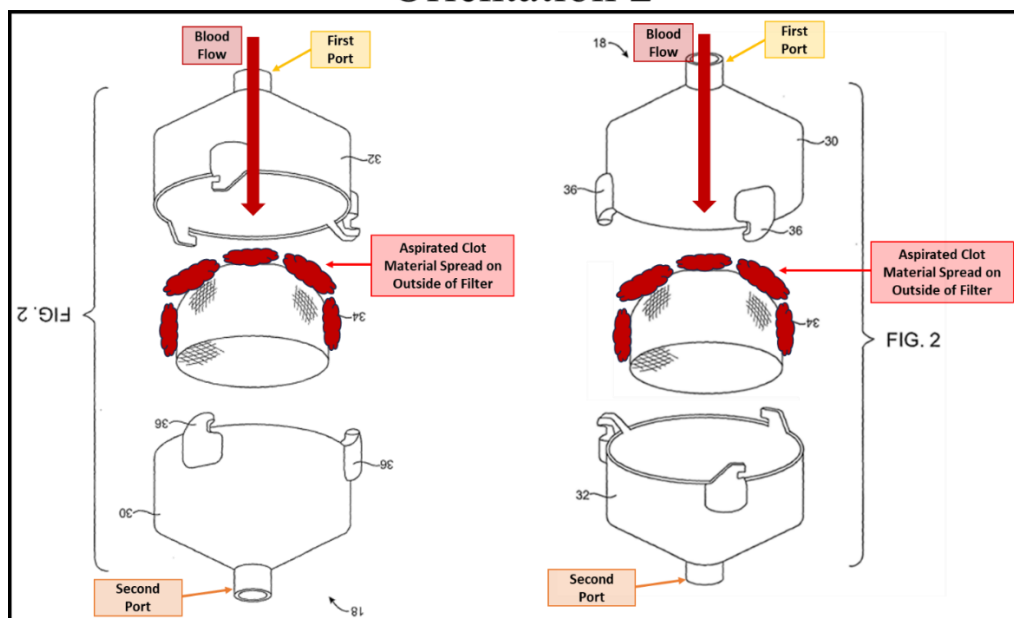
91. Fourth, Goff's disclosure that "[p]referably, the filter element will allow the separated solid materials to collect on an exposed surface so that the solid materials will be easily removed and/or absorbed" would have further motivated a person of skill to orient the open end of the filter element toward the outflow port. Ex. 1005 (Goff) at [0011]. As I explained above, a person of ordinary skill would have recognized that orienting the open end of Goff's cylindrical filter toward the

outflow port would be more likely to “allow the separated solid materials to collect on an exposed surface [i.e., the outer surface of the filter element] so that the solid materials will be easily removed and/or absorbed”:

Orientation 1



Orientation 2



Id. at [0011], Fig. 2 (modified by Petitioner). In contrast, orienting the open-end of the cylindrical filter toward the inflow port would likely collect clot material within the enclosed end of the cylindrical filter, making it more difficult to visualize, differentiate, and remove the material. Again, Figure 3 of the Ram article demonstrates this benefit in practice with the prior art AngioVac System filter:



Fig 3. Procedure results, all demonstrating various intravascular material trapped by the inline filter.

Ex. 1030 (Ram) at Fig. 3.

6. **the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port**

92. Claim 1 next recites: “wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.” Goff discloses this limitation.

93. Goff states that a “syringe, vacuum connection, or other conventional vacuum source may be connected at or through the catheter and/or the aspiration receptacle in order to aspirate the fluid from the hollow body structure, through the aspiration catheter, and into the aspirate receptacle,” as depicted in Figure 1 below:

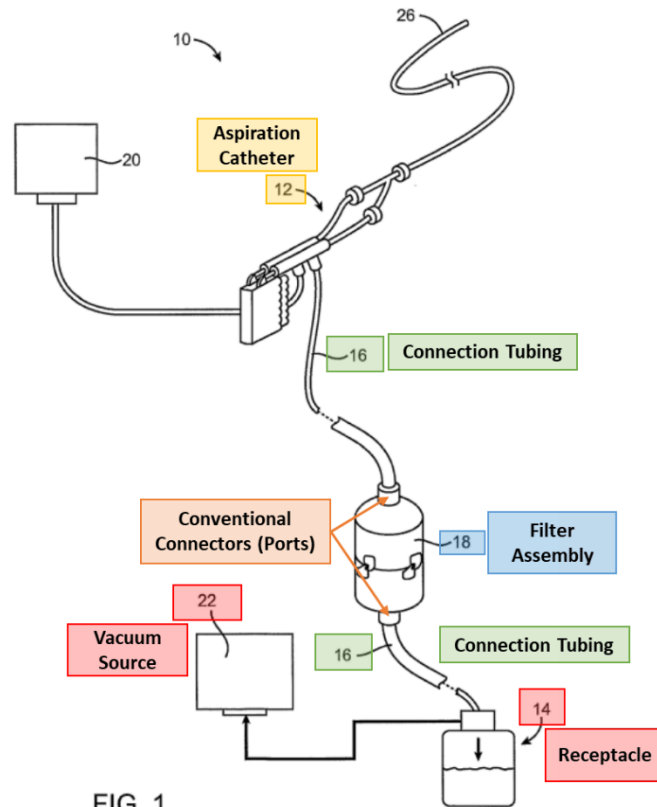


FIG. 1

Ex. 1005 (Goff) at [0010]. Goff also states that “at least one filter assembly including a filter housing and a removable (and replaceable) filter element is placed between the aspiration catheter and the aspirate receptacle in order to remove solid materials from the aspirate before the remaining liquid phase of the aspirate flows to the aspirate receptacle.” *Id.* at [0011]. A person of ordinary skill would have therefore understood that Goff’s vacuum source generates negative vacuum pressure in the filter housing’s chamber via the second port that is fluidly coupled to the vacuum source as shown in Figure 1 above. *Id.* at Fig. 1. A person of ordinary skill would have further understood that the negative pressure in the chamber would draw blood and clot material into the chamber where the filter element would

“remove solid materials from the aspirate before the remaining liquid phase of the aspirate [i.e., filtered blood] flows” into the interior region and ultimately exits the chamber through the outflow port.

7. **the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port**

94. Claim 1 next recites: “wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.” Goff discloses this limitation.

95. Goff states that its “filter assembly include[es] a filter housing and a removable (and replaceable) filter element [] placed between the aspiration catheter and the aspirate receptacle in order to remove solid materials from the aspirate before the remaining liquid phase of the aspirate flows to the aspirate receptacle.” Ex. 1005 (Goff) at [0011]. Goff further explains that the “filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff,” and discloses exemplary pore sizes ranging from 1µm to 5mm. *Id.* Accordingly, Goff’s filter element is “configured to inhibit the clot material from passing through the filter into the interior region and through the second port” as recited in Claim 1.

8. **the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region**

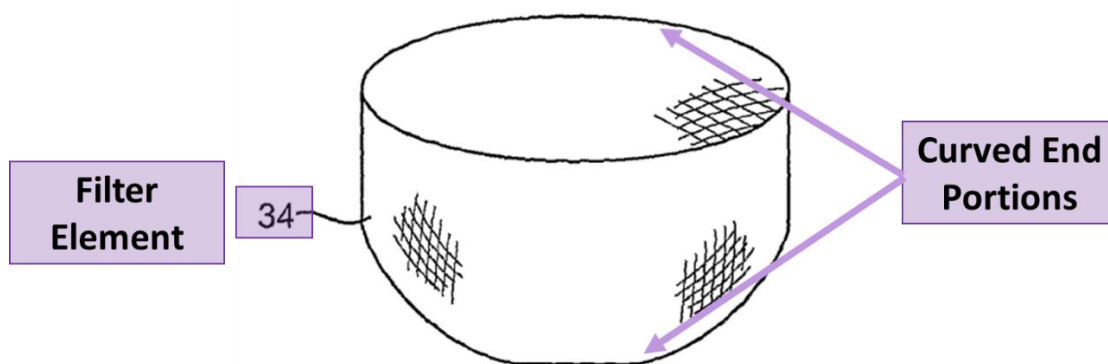
96. Claim 1 finally recites: “wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.” Goff discloses this limitation.

97. Goff states that its “filter housing and optionally filter element may be at least partially transparent to permit observation of the solid materials as they collect.” Ex. 1005 (Goff) at [0015].

B. **Claim 4 – the first filter end portion is curved**

98. Claim 4 recites the “the “clot collection reservoir of claim 1 wherein the first filter end portion is curved.” Goff anticipates Claim 4 or renders it obvious.

99. As illustrated in Figure 2, both ends of Goff’s cylindrical filter element are “curved”:



Ex. 1005 (Goff) at Fig. 2 (excerpt). The open end of the filter has circular shape that is curved, and the enclosed end of the filter is also curved. *Id.* Therefore, the

“first end portion” of Goff’s cylindrical filter element is curved in both of the orientations of the filter that I discussed above for Claim 1. *Supra* §VI.A.5.

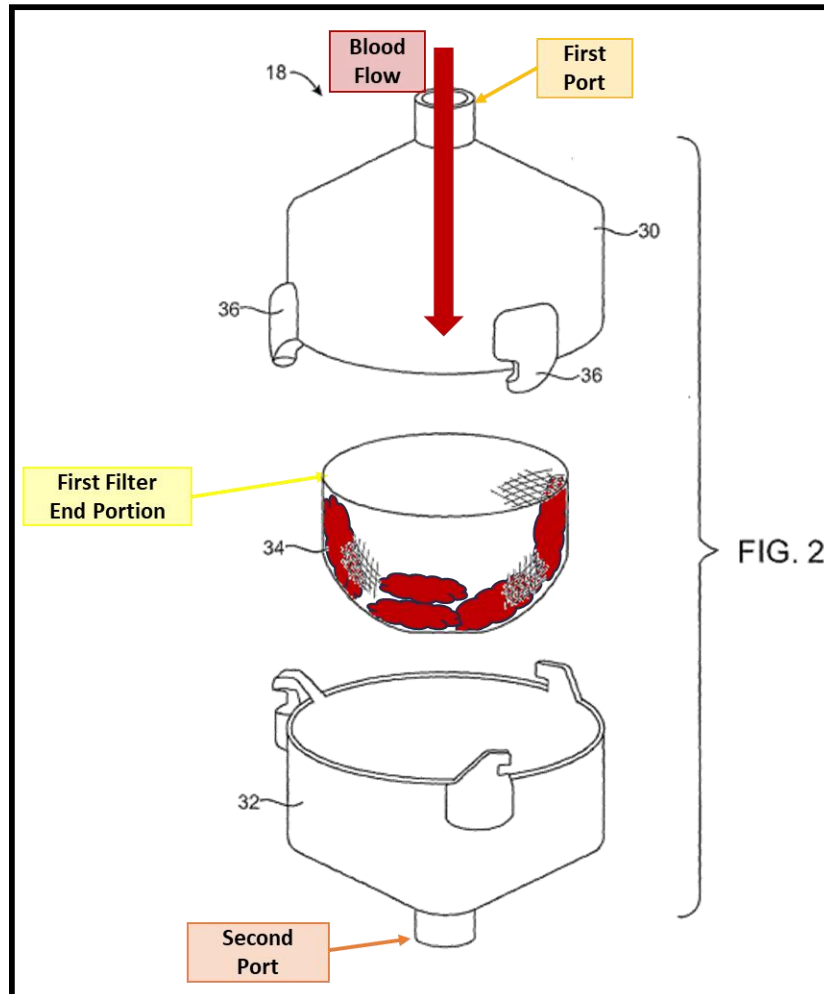
C. **Claim 5 – the source of aspiration is configured to generate the negative pressure in the chamber via the second port to draw the clot material against the first filter end portion**

100. Claim 5 recites the “clot collection reservoir of claim 1 wherein the source of aspiration is configured to generate the negative pressure in the chamber via the second port to draw the clot material against the first filter end portion.” Goff anticipates claim 5 or renders it obvious.

101. As I explained previously for Claim 1, Goff discloses an aspiration source that generates negative pressure in the filter housing that draws aspirated blood and clot material into the housing via the first (inflow port), and then the filter element separates the clot material from the blood. *Supra* §VI.A. A person of ordinary skill would have understood that the aspirated clot material would be drawn against the “first filter end portion” of Goff’s filter in both of the orientations of the filter that I discussed for Claim 1.

102. As I’ve illustrated below, aspirated clot would be drawn against all sides of Goff’s cylindrical filter element in the first orientation, including the first filter end portion, as clot material filled the filter:

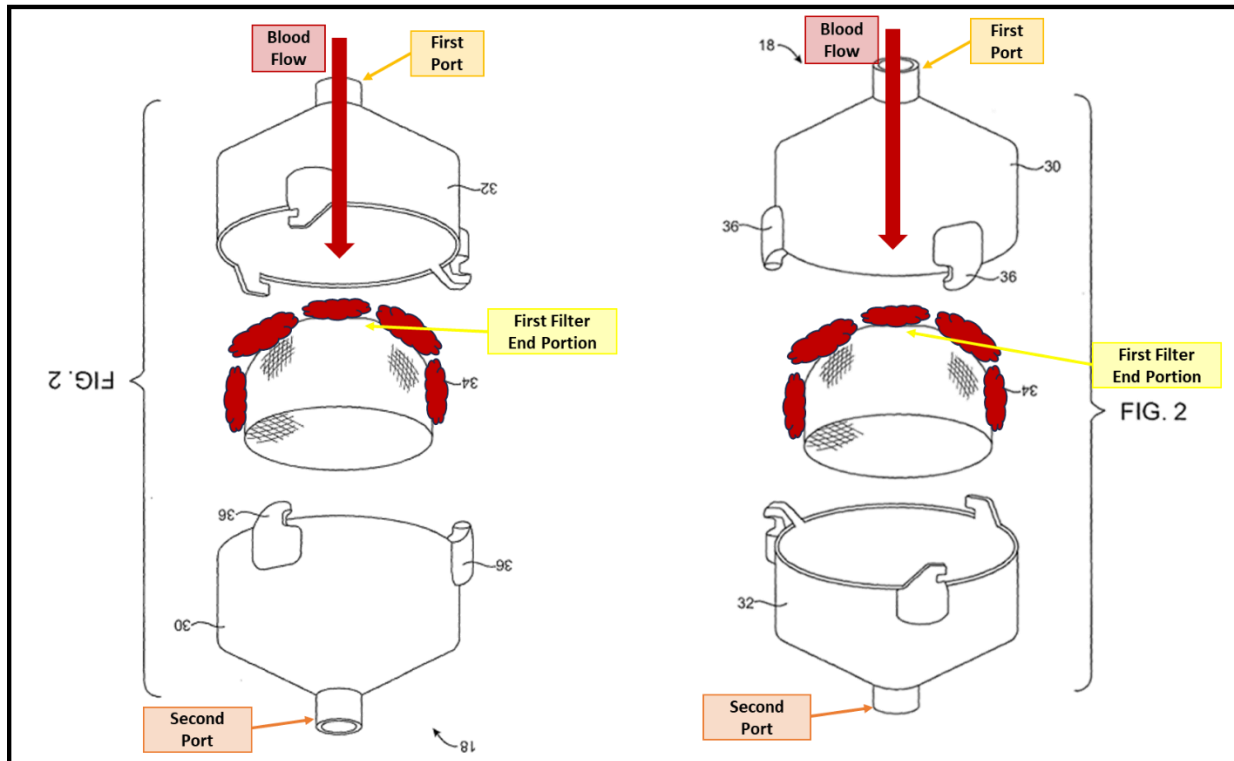
Goff – Orientation 1



Ex. 1005 (Goff) at Fig. 2.

103. In the second orientation, clot material would be drawn against the enclosed end of the cylindrical filter element (first filter end portion) as I've illustrated below:

Goff – Orientation 2



Ex. 1005 (Goff) at Fig. 2 (modified by Petitioner).

104. Indeed, a person of ordinary skill would have understood that clot material would have been drawn against all portions of the filter element facing the inflow port, particularly when a large amount of clot material is removed. This is illustrated in Figure 3 of the Ram article, which shows clinical uses of the AngioVac System filter:



Fig 3. Procedure results, all demonstrating various intravascular material trapped by the inline filter.

Ex. 1030 (Ram) at Fig. 3.

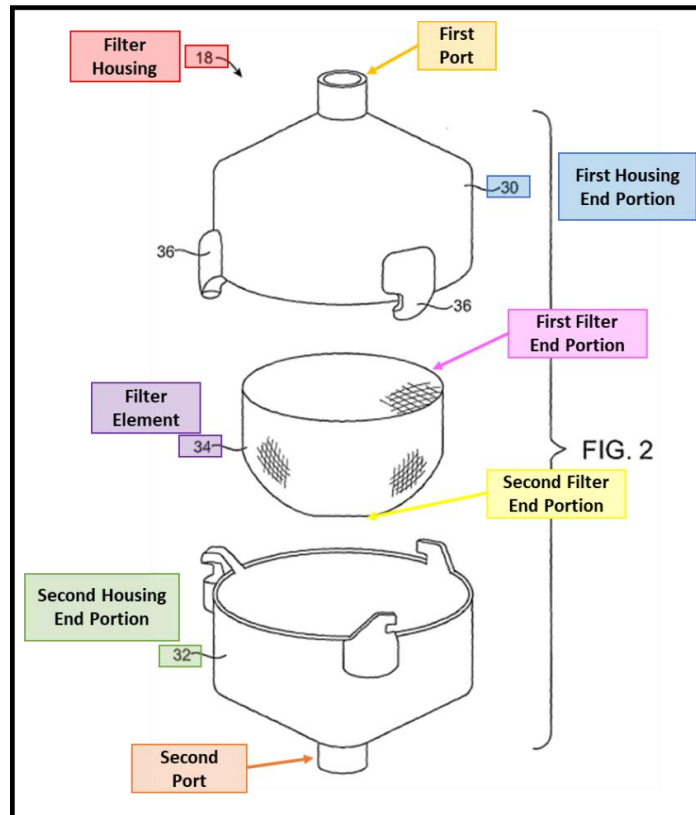
- D. Claim 7 – the first filter end portion is positioned closer to the first housing end portion than the second filter end portion, and wherein the

second filter end portion is positioned closer to the second housing end portion than the first filter end portion

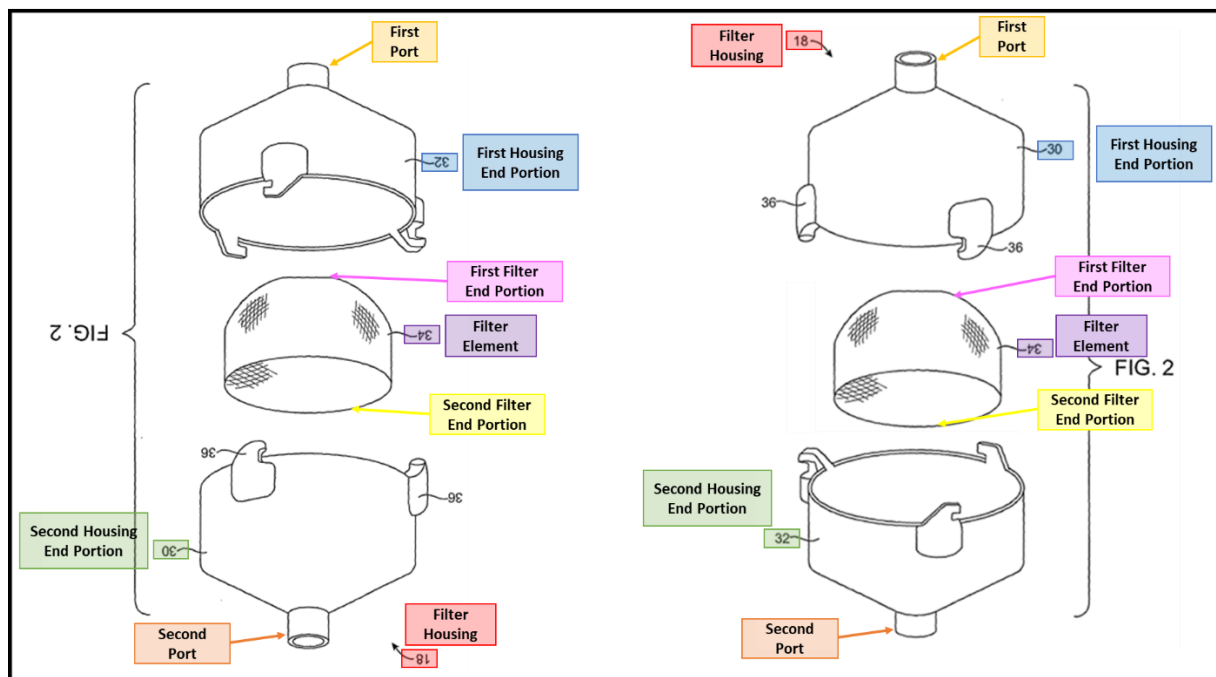
105. Claim 7 recites the “clot collection reservoir of claim 1 wherein the first filter end portion is positioned closer to the first housing end portion than the second filter end portion, and wherein the second filter end portion is positioned closer to the second housing end portion than the first filter end portion.” Goff anticipates Claim 7 or renders it obvious.

106. As I’ve illustrated below, in both of the possible orientations of Goff’s filter that I discussed for Claim 1, the first filter end portion of Goff’s filter is positioned closer to the first housing end portion than the second filter end portion, and the second filter end portion is positioned closer to the second housing end portion than the first housing end portion:

Orientation 1



Orientation 2



Ex. 1005 (Goff) at Fig. 2 (modified by Petitioner).

E. Claim 10

107. Goff anticipates independent Claim 10 or renders it obvious.

1. Preamble – clot treatment system

108. The preamble of Claim 10 recites a “clot treatment system.” If this preamble is limiting, Goff discloses this limitation.

109. Goff states that its invention is directed to “methods ... for separating material in fluid aspirates removed from a hollow body structure.” Ex. 1005 (Goff) at [0007]. Goff also states that its system is “intended for introduction to a blood vessel for introducing a thrombolytic agent in order to disrupt clot,” and that “the solid material aspirated by the catheter will frequently comprise disrupted clot, thrombus, and/ or plaque, which is then discharged through the aspirate line 16 to the aspirate receptacle.” *Id.* at [0024]. Goff’s system is therefore a “clot treatment system” at least because it is designed and intended for disrupting and aspirating blood clots from a patient’s blood vessel.

2. an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient

110. Claim 10 next recites “an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient.” Goff discloses this limitation.

111. Goff states that its aspiration system’s “catheter 12 has a distal end or portion 26 which is introducible into a target hollow body structure in order to withdraw fluid therefrom to produce the aspirate stream.” Ex. 1005 (Goff) at [0024]. Goff further states that “the catheter 12 will be intended for introduction to a blood vessel for introducing a thrombolytic agent in order to disrupt clot.” *Id.* Goff’s catheter 12 is therefore “an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient” as recited in Claim 10.

3. an aspiration source

112. Claim 10 next recites “an aspiration source.” Goff discloses this limitation for the reasons I explained for Claim 1. *Supra* §VI.A.4.

4. clot collection reservoir

113. Claim 10 next recites a “clot collection reservoir” comprising various features. Goff discloses a “clot collection reservoir” for the reasons I explained for Claim 1. *Supra* §VI.A.1.

5. a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion

114. Claim 10 next recites that the clot collection reservoir comprises “a housing defining a sealed chamber and having a first housing end portion and a

second housing end portion opposite the first housing end portion.” Goff discloses this limitation for the reasons I explained for Claim 1. *Supra* §VI.A.2

6. **a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber**

115. Claim 10 next recites that the clot collection reservoir comprises “a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber.” Goff discloses this limitation for the reasons I explained for Claim 1. *Supra* §VI.A.3.

7. **a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber**

116. Claim 10 next recites that the clot collection reservoir comprises “a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber.” Goff discloses this limitation for the reasons I explained for Claim 1. *Supra* §VI.A.4.

8. **a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port**

117. Claim 10 next recites that the clot collection reservoir comprises “a filter positioned within the chamber, wherein the filter has a substantially

cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.” Goff discloses this limitation or renders it obvious for the reasons I explained for Claim 1. *Supra* §VI.A.5.

9. **the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port**

118. Claim 10 next recites: “wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.” Goff discloses this limitation for the reasons I explained for Claim 1. *Supra* §VI.A.6.

10. **the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port**

119. Claim 10 next recites: “wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.” Goff discloses this limitation for the reasons I explained for Claim 1. *Supra* §VI.A.7.

11. the filter is removably positioned within the chamber to provide access to the clot material within the chamber

120. Claim 10 finally recites: “wherein the filter is removably positioned within the chamber to provide access to the clot material within the chamber.” Goff discloses this limitation for the reasons I explained for Claim 1. *Supra* §VI.A.5.

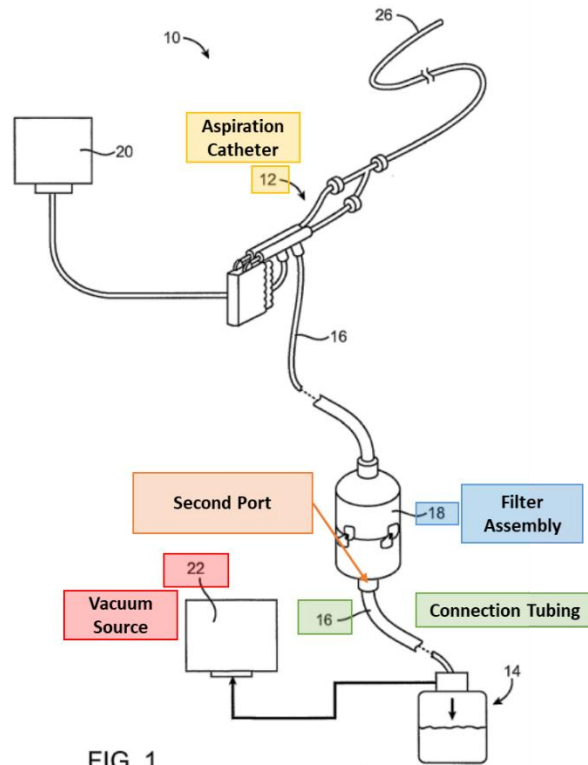
F. Claim 11 – the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region

121. Claim 11 recites the “clot treatment system of claim 10 wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.” Goff anticipates claim 11 or renders it obvious for the reasons I explained for Claims 1 and 10. *Supra* §§VI.A.8; VI.E.

G. Claim 13 – the clot collection reservoir is spaced apart from the aspiration source, and further comprising at least one tube fluidly coupling the second port to the aspiration source

122. Claim 13 recites the “clot treatment system of claim 10 wherein the clot collection reservoir is spaced apart from the aspiration source, and further comprising at least one tube fluidly coupling the second port to the aspiration source.” Goff anticipates Claim 13 or renders it obvious.

123. As shown in Figure 1 below, Goff’s filter housing (i.e., clot collection reservoir) is spaced apart from the aspiration source, and the second port of the filter housing is fluidly coupled to the aspiration source via connection tubing 16:



Ex. 1005 (Goff) at [0022]-[0025], Fig. 1.

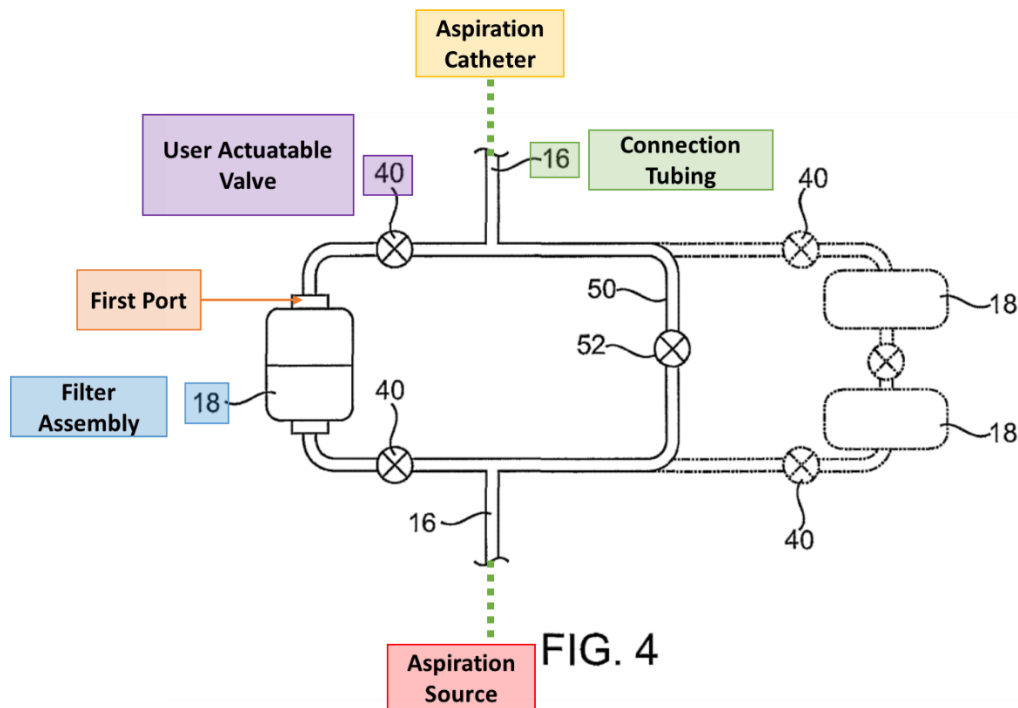
H. Claim 15

124. Claim 15 is an independent claim that recites the same limitations as Claim 10 with two exceptions: (1) Claim 15 does not require that the filter is “removably positioned within the chamber” and (2) Claim 15 recites “a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user actuable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter.” Goff anticipates Claim 15 or renders it obvious.

1. a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user actuatable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter

125. Goff discloses “a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user actuatable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter.”

126. Goff describes an arrangement of its aspiration system shown in Figure 4 below wherein “first filter assembly 18 may be provided and isolated by valves 40 in parallel with an unfiltered flow path 50 having a valve 52 therein “:



Ex. 1005 (Goff) at [0028], Fig. 4. Goff states that in this arrangement, “all flow could be directed through the filter assembly 18 with valve 52 being closed” and that “[s]hould it be desired to gain access to filter 18, the isolation valves 40 could be closed and the flow path valve 52 open.” *Id.* Thus, Goff’s valve 40 may be actuated by a user to move from an open position in which the first port of Goff’s filter is fluidly connected to the aspiration catheter such that “all flow [is] directed through the filter assembly 18” to a closed position in which the first port of the filter assembly is fluidly disconnected to the aspiration catheter. A person of ordinary skill in the art would have recognized that Goff’s valve 40 could be any type of valve known in the art, such as a stopcock or a pinch valve, both of which were commonly used in cardiovascular medical devices prior to 2018. Goff therefore discloses a valve as recited in Claim 15.

2. Remaining Limitations

127. Goff discloses or renders obvious the remaining limitations of Claim 15 for the reasons I explained for Claim 10. *Supra* §VI.E.

VII. GROUNDS 3-4: CLAIMS 1, 4-5, 7, 10-11, 13, 15-17, 19-21 RENDERED OBVIOUS BY GARRISON AND GOFF OR LEE

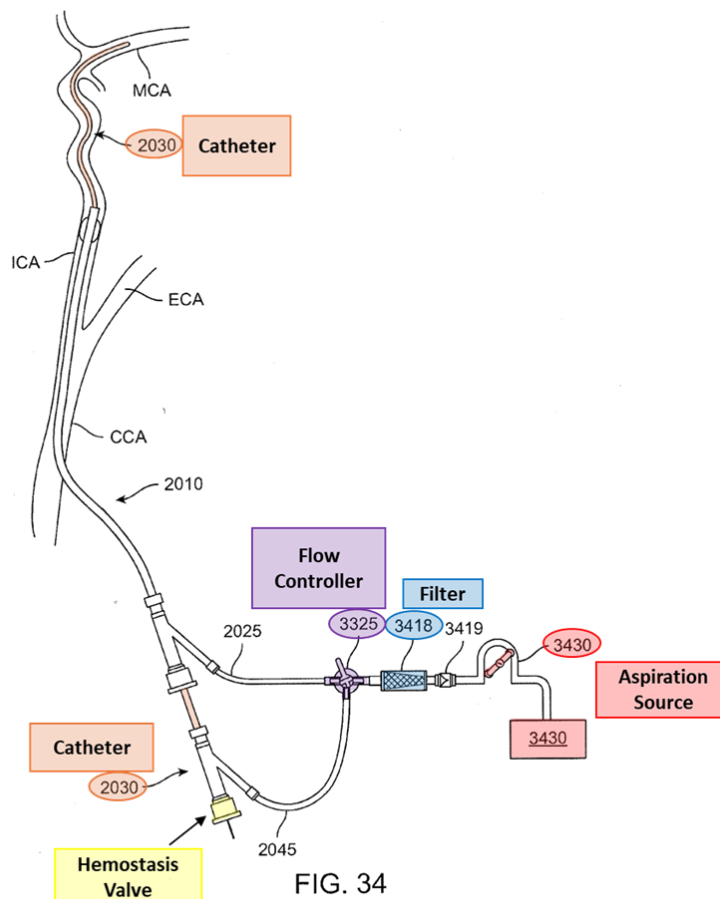
A. Claim 1

128. In my opinion, Claim 1 is obvious in view of Garrison in combination with Goff *or* Lee.

1. Preamble – clot collection reservoir

129. The preamble of Claim 1 recites a “clot collection reservoir.” If this preamble is limiting, Garrison discloses this limitation.

130. Garrison discloses a system “to provide aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” Ex. 1006 (Garrison) at [0007]. Garrison discloses an embodiment, depicted in Figure 34, that includes a filter 3418 [blue] that is fluidly coupled to the flow line 2045 (i.e., connection tubing) between the proximal end of the aspiration catheter 2030 [orange] and the vacuum source 3430 [red]:



Id. at [0131], Fig. 34. A person of ordinary skill would have recognized that the purpose of Garrison’s filter 3418 is to filter aspirated clot material from the aspirated blood by collecting the clot material within the filter while the aspirated blood passed through the filter toward the aspiration source. Garrison’s filter 3418 is therefore a “clot collection reservoir.”

2. **a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion**

131. Claim 1 next recites: “a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.” Garrison combined with Goff or Lee renders this limitation obvious.

a. **Goff**

132. Goff discloses this limitation for the reasons I explained previously for Grounds 1-2. *Supra* §VI.

133. It is my opinion that a person of ordinary skill in the art would have been motivated to substitute Goff’s filter for the filter 3418 in Garrison. Goff’s filter is used for the same purpose as the filter in Garrison – filtering clots from aspirated blood. Ex. 1005 (Goff) at [0001]. Goff’s filter is also positioned between the aspiration catheter and the vacuum source with standard medical tubing, like the filter in Garrison. *Id.* at [0025]. Thus, substituting Goff’s filter for Garrison’s

filter would have merely entailed the substitution of one known element (Goff's filter) for another (Garrison's filter) to yield the predictable result of filtering aspirated blood. In addition, Goff's disclosure that its filter "permit[s] introduction, removal, and replacement of the filter element in the interior of the housing" and provides "a convenient structure or assembly to permit easy removal and observation" of aspirated clot material would have further motivated a person of ordinary skill in the art to use Goff's filter in Garrison's aspiration system. *Id.* at [0005]. A person of ordinary skill in the art would have understood the option to remove the filter would have had advantages for the user. For example, the user could empty the filter before continuing the procedure, which would have been particularly useful when removing large amounts of clot. Or the user could observe the aspirated clot material to better understand the patient's condition by removing it from the filter.

134. The similarities between the filters in Goff and Garrison would have given a person of ordinary skill in the art a reasonable expectation of success that Goff's filter could be incorporated into Garrison's aspiration system. For example, Goff discloses that its "filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff," the same requirement for Garrison's filter (or any aspiration filter). *Id.* at [0011]. In addition, Goff's filter is fluidly coupled between an aspiration catheter and a vacuum source using

conventional connectors and medical tubing, just like the arrangement for Garrison's filter. *Id.* at [0015], [0023]-[0025], Fig. 1; Ex. 1006 (Garrison) at Fig. 34. A person of ordinary skill in the art in January 2018 would have been familiar with these conventional, predictable components (connectors and medical tubing) and would have reasonably expected success in using them to couple Goff's filter to Garrison's flow line 2045.

b. Lee

135. Lee also discloses this limitation.

136. Lee is a U.S. Patent Application Publication that is entitled "Medical Fluid Aspirator." Ex. 1007 (Lee). Lee describes a filter assembly that comprises a "barrel 1" [red] that houses a cylindrical "isolation sleeve 2" and an "inner filter tube 3" (i.e., filter) that includes a plurality of holes for filtering solid particles from blood:

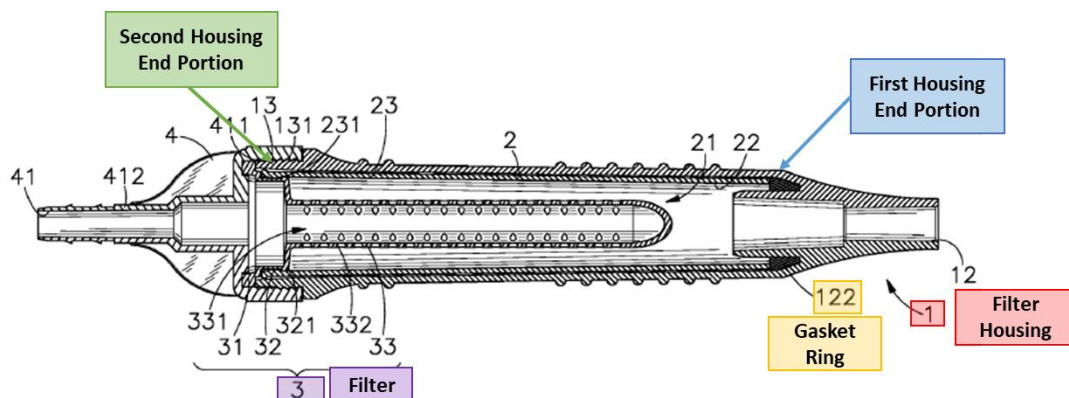


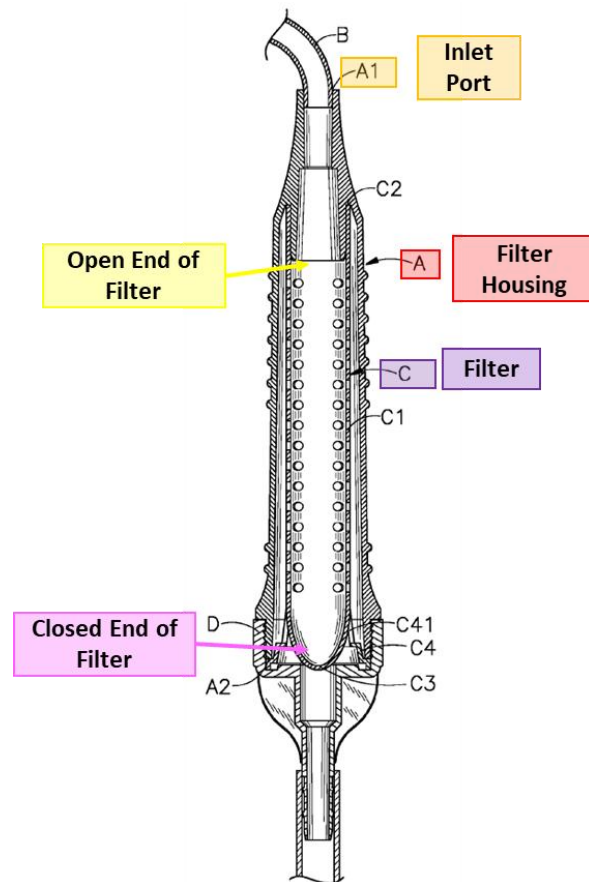
FIG. 3

Id. at [0019]-[0021], Fig. 3. As shown in Figure 3 above, Lee's barrel 1 (i.e., housing) has a first housing end portion [blue] at its distal end and a second housing end portion [green] at its proximal end opposite from the first housing end portion. *Id.* Lee also explains that its housing includes a gasket ring 122, and that the "front end of the isolation sleeve 2 is stopped against the gasket ring 122 so that waste fluid does not leak out of the isolation sleeve." *Id.* at [0027], Fig. 3. Thus, Lee's housing forms a sealed chamber. Indeed, as I discuss below, Lee explains that the sealing of its housing is one of the benefits it provides over prior filter designs. *Id.* at [0027], [0031].

137. It is my opinion that a person of ordinary skill in the art would have been motivated to substitute Lee's filter assembly for the filter 3418 in Garrison for several reasons.

138. First, a person of ordinary skill would have been motivated by would have been motivated by Lee's disclosure that its filter "remove[s] waste solid matters" from aspirated blood, "preventing block of the suction tube 5 and the suction pump by waste solid matters." *Id.* at [0032]. In other words, Lee teaches that its filter performs the same function as the filter in Garrison – removing solid materials from aspirated blood so that the solids do not clog the aspiration pump or other downstream components.

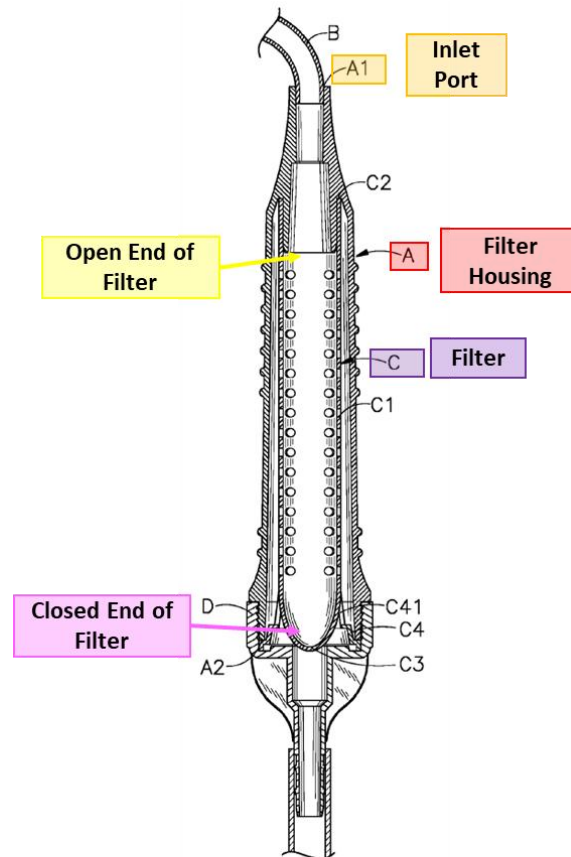
139. Second, a person of ordinary skill would have been motivated by would have been motivated by Lee's disclosure that its design allows for the filter to be removed from the housing so that filtered material may be collected and disposed, and so the filter may be "washed and sterilized for a repeated use." *Id.* at [0027], [0032]. Lee explains that in prior filters designs, which Lee illustrates in Figures 8 and 9, the closed end of the filter faced the outflow port and the open end faced the inflow port:



PRIOR ART
FIG. 8

Id. at [0004], Fig. 8. Lee explains that there were known issues with this filter arrangement. One such drawback was that “waste fluid and waste solid matters may be scattered all over the floor” when the filter is removed from the housing. *Id.* at [0006]. Lee’s design overcomes that drawback by allowing for convenient removal of the inner sleeve and filter tube from the housing, while keeping the filtered solid material within the chamber between the sleeve and the filter. *Id.* at [0027], [0032]. A person of ordinary skill would have recognized that the ability to quickly and easily remove and replace the filter would have benefitted Garrison’s aspiration system because it would allow the operating physician to remove and replace the filter if the canister filled with clot material.

140. Third, a person of ordinary skill would have been motivated by would have been motivated by Lee’s disclosure that its “gasket ring 122 seals the gap between the isolation sleeve 2 and the inside connection tube 111, preventing leakage.” *Id.* at [0031]. Lee explains that another one of the drawbacks with the prior filter designs shown in Figures 8 and 9 was that aspirated blood and solid material could leak through “a gap between the front open end C2 of the inner tube C and the inside extension tube of the barrel A”:



PRIOR ART
FIG. 8

Id. at [0005], Fig. 8. Lee's design overcomes this issue by creating a seal between the inner sleeve 2 and the barrel 1 via the gasket ring, preventing leakage of blood from the filter. *Id.* at [0031]. A person of ordinary skill in the art would have recognized that the leak-proof seal of Lee's design would also benefit Garrison's system.

141. Fourth, a person of ordinary skill would have recognized that Garrison's filter and Lee's filter assembly are both designed and used to filter solid particles from aspirated blood during medical procedures. Ex. 1006 (Garrison) at

[0130]-[0132], Fig. 34; Ex. 1007 (Lee) at [0026]. Moreover, like Garrison's filter, Lee's filter assembly is designed to be positioned between an aspiration source and an aspiration catheter. *Id.* at [0019]-[0023]. Accordingly, a person of ordinary skill would have recognized that substituting Lee's filter assembly for Garrison's filter would have merely entailed the substitution of one known element (Lee's filter) for another (Garrison's filter) to yield the predictable result of filtering aspirated blood. A person of ordinary skill in 2018 would have possessed the skills and ability to make this simple substitution. In addition, although Lee does not expressly disclose aspiration or filtration of blood clots, a person of ordinary skill designing a thrombectomy system would have been motivated to look to filters that were designed and used to filter similarly sized solid particles beyond just blood clots. In my personal experience designing cardiovascular medical devices, I and the engineers that I supervised often drew guidance and inspiration from components that were originally designed or used for non-cardiovascular procedures. This was especially true for common mechanical components such as filters, pumps, valves, and tubing, which often share similar designs across different applications.

142. A person of ordinary skill in the art would have reasonably expected success in substituting Lee's filter assembly for Garrison's filter because both filters are designed to separate solid particles from aspirated fluid during medical procedures, and both filters are designed to be fluidly coupled to an aspiration

catheter at one end and an aspiration source at the other. Ex. 1006 (Garrison) at [0130]-[0132], Fig. 34; Ex. 1007 (Lee) at [0019]-[0023], Figs. 1-5. In addition, Lee discloses that its filter includes a plurality of filter holes 332 that “remove solid matters of diameter greater than the filter holes” from aspirated blood. Ex. 1007 (Lee) at [0022], [0026]. A person of ordinary skill would have reasonably expected that Lee’s filter holes would similarly trap aspirated clot material within the filter housing if appropriately sized. And to the extent it was necessary, a person of skill in 2018 would have possessed the skills and knowledge to optimize the size or position of the holes to filter clot material.

143. That a person of ordinary skill would have possessed those abilities is reflected in both the prior art and the 12-’333 patent. For example, Aklog, a U.S. Patent issued in 2014, discloses a blood clot aspiration system that includes a filter device 14 with a “permeable sheet” that “prevent[s] undesirable material captured from the site of interest from moving downstream. Ex. 1013 (Aklog) at 11:31-35. Aklog states that the permeable sheet “may include a plurality of pores sufficiently sized so as to permit fluid from the site of interest to flow therethrough, while preventing any undesirable material captured from the site of interest from moving downstream.” *Id.* 11:36-45. However, Aklog does not disclose the specific pore sizes of its permeable sheet, reflecting that selecting and optimizing such sizes was within the abilities of a person of skill at the time. As another example, Laub, a

2017 U.S. Patent Publication, also discloses a blood clot aspiration system that includes a filter 300 “configured to trap solid material received through aspiration catheter 200 from the body of the patient during use,” including “thrombi, emboli, tumor tissue, debris or other materials aspirated from the patient’s body.” Ex. 1011 (Laub) at [0040]. Laub states that “[a]ny suitable filtering apparatus known in the art may be used” and that the filter may include “a screen, mesh, membrane, etc., that is configured to allow blood or other fluid to flow through while preventing passage of the solid materials.” *Id.* Like Aklog, Laub does not disclose the specific characteristics of the “screen, mesh, [or] membrane” and instead presumes that a person of ordinary skill would have possessed the knowledge and skills to select and optimize the filter for blood clots. *Id.*

144. The 12-’333 patent also reflects that a person of skill would have possessed this capability. While the 12-’333 patent states that “the filter 321 inhibits clot material from passing into the check valve assembly,” it does not disclose any specifications for the filter, such as pore size or arrangement. Ex. 1001 (12-’333 patent) at 9:35-47. Instead, the 12-’333 patent presumes that a person of ordinary skill in the art would have understood to how make and optimize a filter material capable of capturing aspirated clot material.

3. **a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber**

145. Claim 1 next recites: “a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber.” Garrison combined with Goff or Lee renders this limitation obvious.

a. **Goff**

146. Goff discloses this limitation for the reasons I explained for Grounds 1-2. *Supra* §VI.A.3.

b. **Lee**

147. Lee also discloses this limitation.

148. Lee’s barrel (i.e., housing) includes a front suction hole 12 located proximate to the first housing portion, which is configured to be fluidly connected to suction tip 121 (i.e., aspiration catheter):

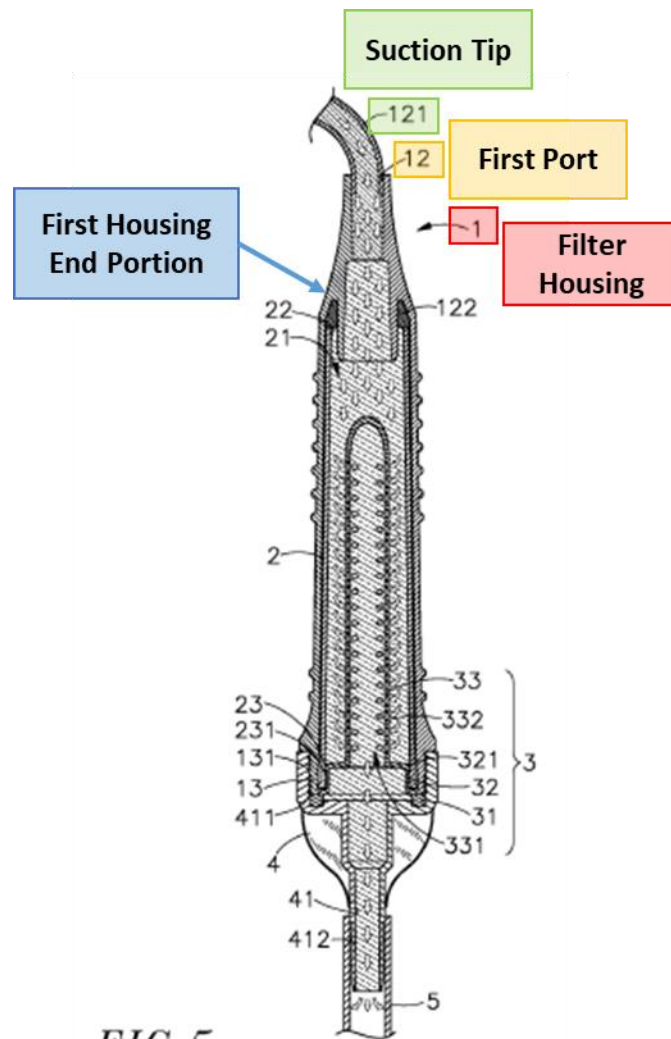


FIG. 5

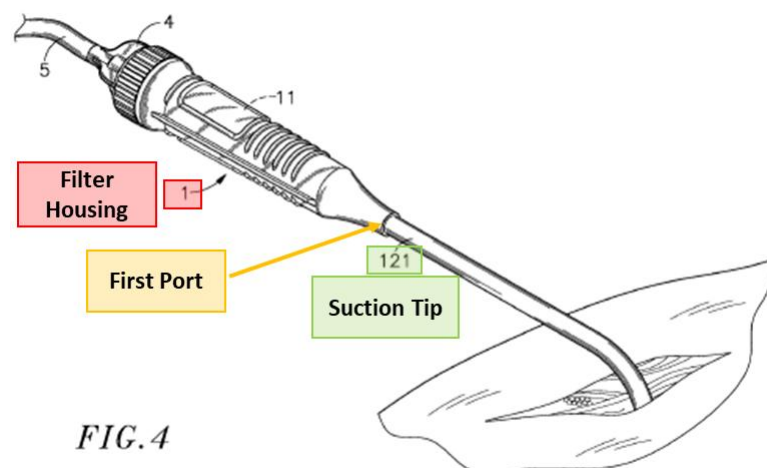


FIG. 4

Ex. 1007 (Lee) at [0019]-[0020], Figs. 4-5. As shown in Figures 4 and 5 above, the front hole provides a first fluid path into the housing. *Id.* Indeed, Lee explains that during use, the suction pump draws fluid and unwanted solid material “into the tapered accommodation chamber 21 of the isolation sleeve 2 through the front suction hole 12.” *Id.* at [0026]. The front hole 12 is therefore a “first port” as recited in Claim 1.

4. **a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber**

149. Claim 1 next recites: “a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber.” Garrison combined with Goff or Lee renders this limitation obvious.

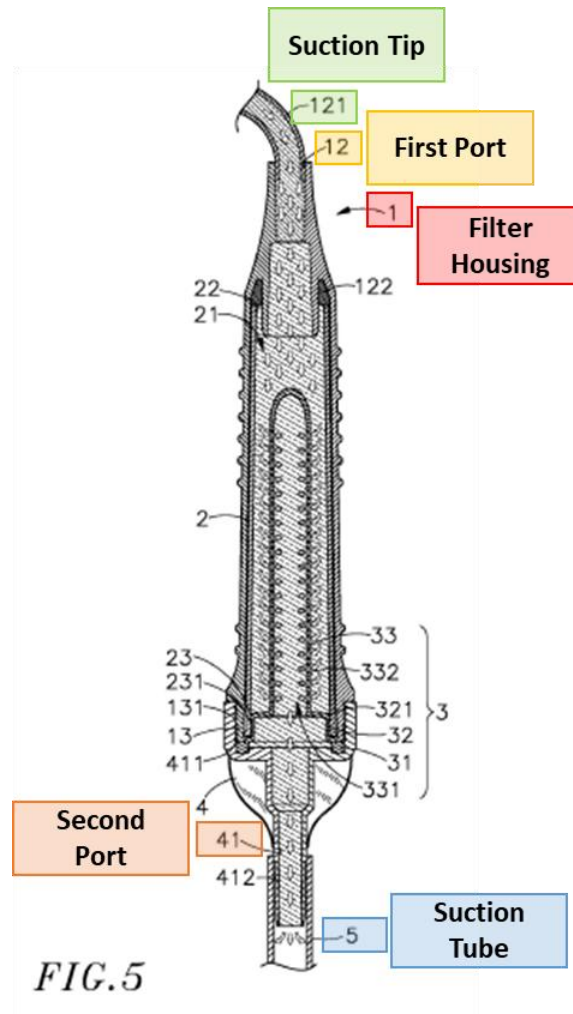
a. **Goff**

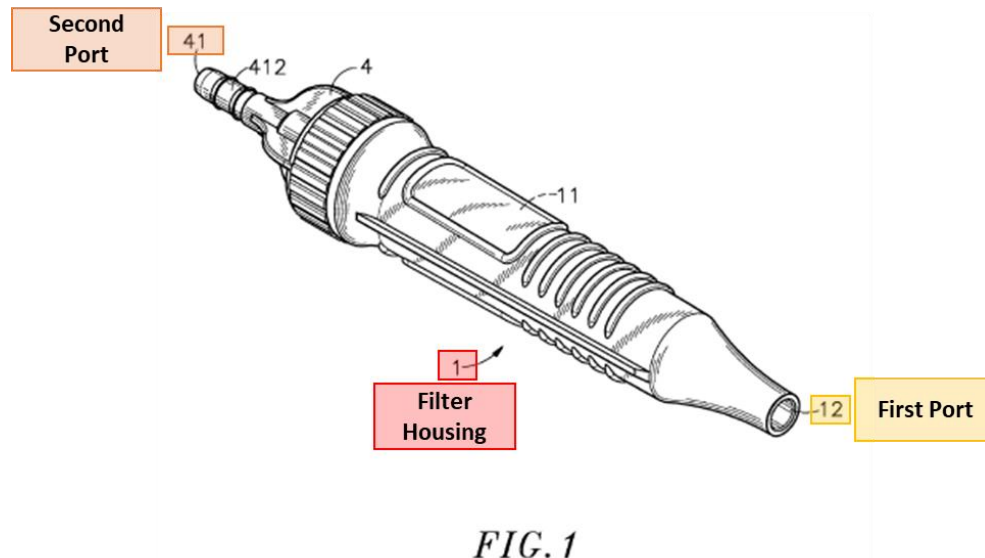
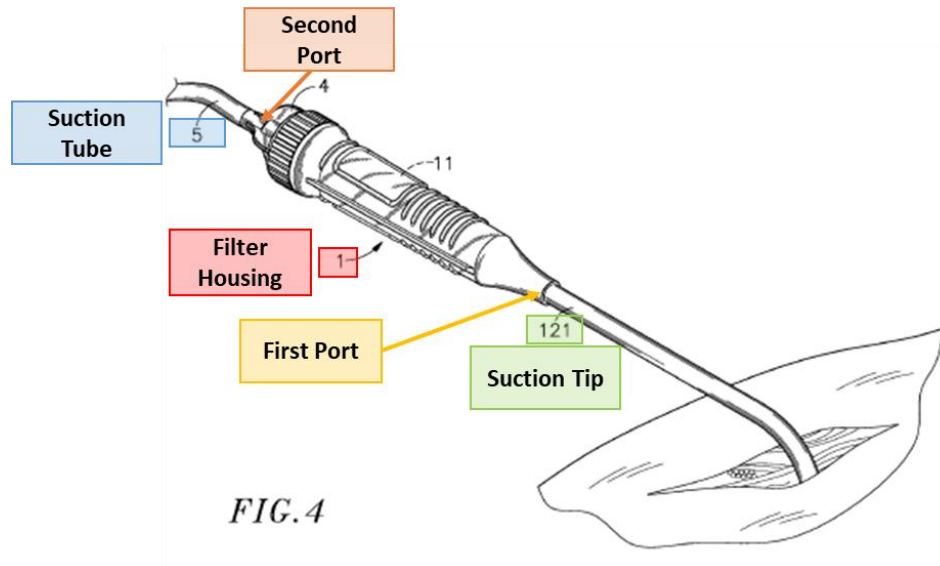
150. Goff discloses this limitation for the reasons I explained for Grounds 1-2. *Supra* §VI.A.4.

b. **Lee**

151. Lee also discloses this limitation.

152. Lee's housing includes a drainage hole 41 that is configured to be fluidly coupled to an aspiration source via suction tubing 5, as shown below:





Ex. 1007 (Lee) at [0019]-[0026], Figs. 1, 4-5. Lee explains that during use, the suction pump draws fluid “into the suction tube 5 through the filter holes 332 and axial passage 331 of the inner filter tube 3 and the drainage hole 41.” *Id.* at [0026]. The drainage hole 41 therefore provides a second fluid path from the housing chamber and is a “second port” as recited in claim 1.

5. **Filter**

153. Claim 1 next recites: “a filter removably positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.” Garrison combined with Goff or Lee renders these limitations obvious.

a. **a filter removably positioned within the chamber**

i. **Goff**

154. Goff discloses this limitation for the reasons I explained for Grounds 1-2. *Supra* §VI.A.5.a.

ii. **Lee**

155. Lee also discloses this limitation.

156. As shown in Figure 3 below, Lee includes a cylindrical filter tube 3 with holes for filtering unwanted material from aspirated blood:

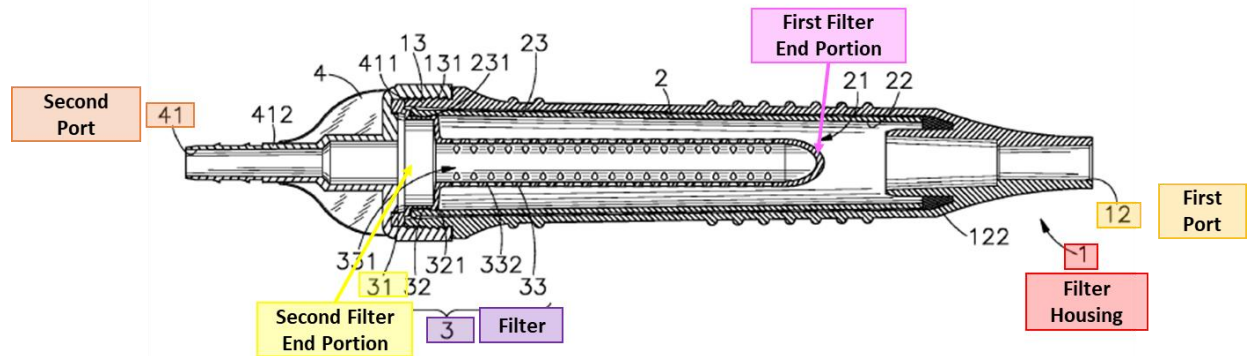


FIG. 3

Ex. 1007 (Lee) at [0019]-[0026], Fig. 3. Lee explains that that its filter 3 and the inner sleeve 2 may be removed from the housing. *Id.* at [0028]. Thus, Lee’s filter tube 3 is a “filter removably positioned within the chamber” as recited in claim 1.

b. the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion

i. Goff

157. Goff discloses this limitation for the reasons I explained for Grounds 1-2. *Supra* §VI.A.5.b.

ii. Lee

158. Lee also discloses this limitation.

159. As shown in Figure 3 below, Lee includes a cylindrical filter tube 3 with holes for filtering unwanted material from aspirated blood:

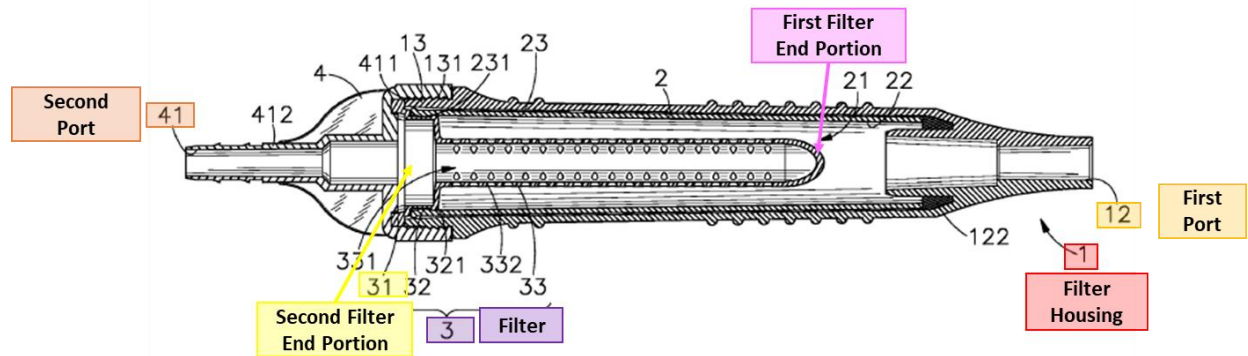


FIG. 3

Ex. 1007 (Lee) at [0019]-[0026], Fig. 3. As shown in Figure 3, Lee's filter extends from a closed end nearest the inflow port (i.e., the first filter end portion) to a base 31 that surrounds the outflow port (i.e., the second filter end portion). *Id.*

- c. the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port

- i. Goff

160. Goff discloses this limitation or renders it obvious for the reasons I explained for Grounds 1-2. *Supra* §VI.A.5.c.

- ii. Lee

161. Lee also discloses this limitation.

162. As I explained above, Lee's filter extends from a closed end nearest the inflow port (i.e., the first filter end portion) to a base 31 that surrounds the outflow port (i.e., the second filter end portion):

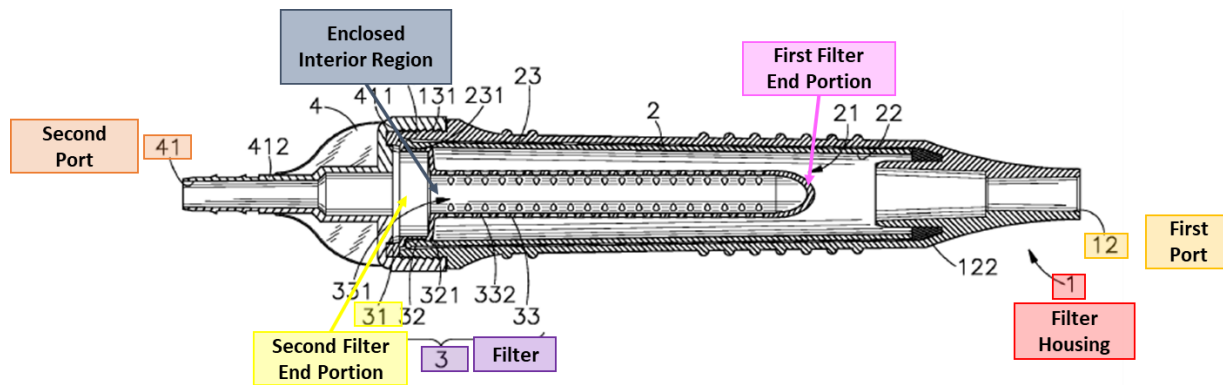


FIG. 3

Ex. 1007 (Lee) at [0019]-[0026], Fig. 3. As shown in Figure 3 above, the filter extends continuously around the closed end of the tube such that the filter encloses an interior region around the outlet port, which Lee refers to as “an axial fluid passage 331.” *Id.*

6. **the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port**

163. Claim 1 next recites: “wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.” Garrison combined with Goff or Lee renders this limitation obvious.

164. The system in Garrison's Figure 34 includes an aspiration source 3430 that "may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like":

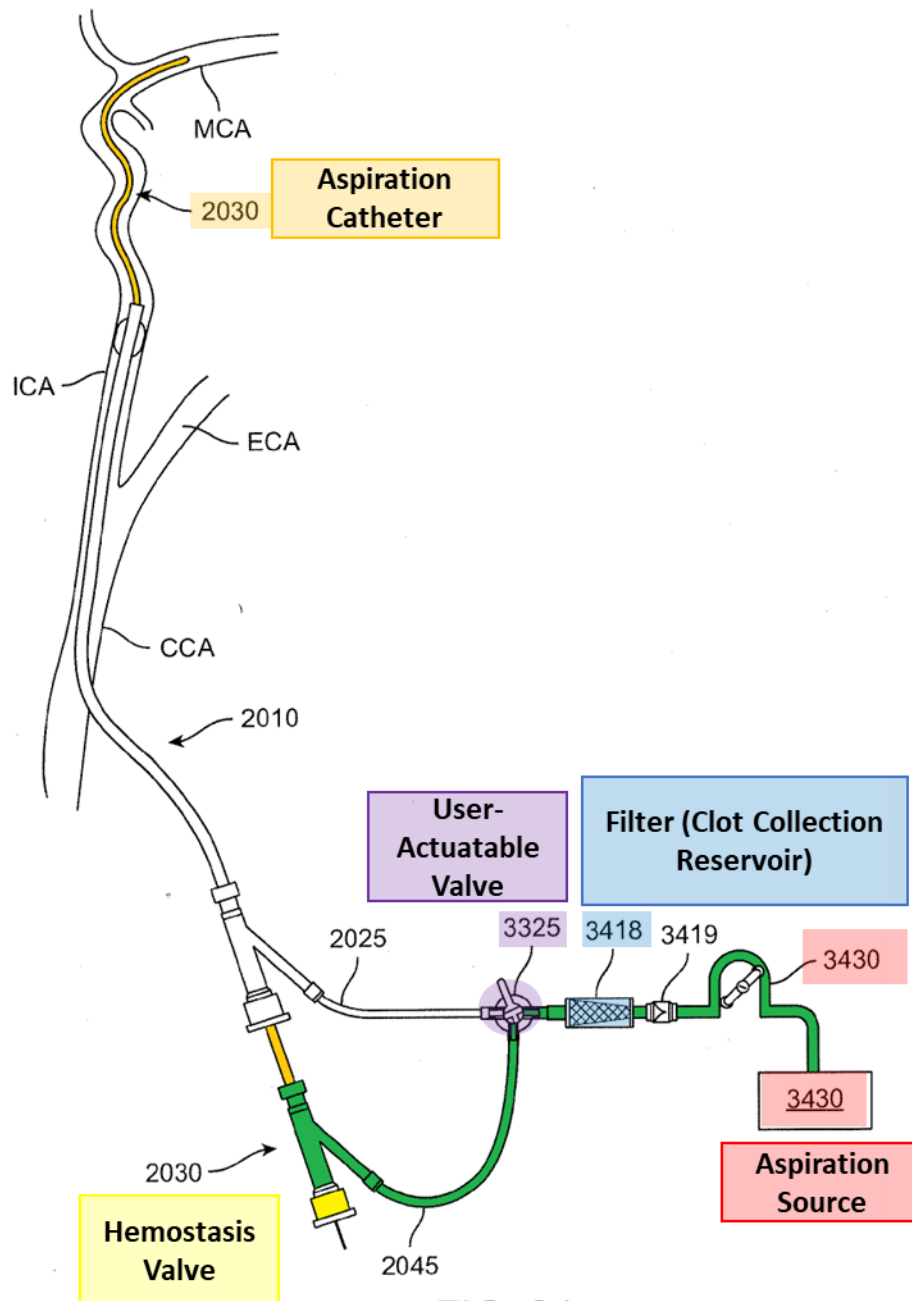


FIG. 34

Ex. 1006 (Garrison) at [0132], [0134], Fig. 34. Garrison's aspiration source creates negative pressure which is then applied to the aspiration catheter via tubing and the

flow line 2045 to remove clot material from the patient's vessels. *Id.* at [0130]-[0134], Fig. 34. Because Garrison's filter is distal from the aspiration source and fluidly connected to the aspiration source along the flow path to the aspiration catheter, Garrison's aspiration source would necessarily generate negative pressure within the filter's chamber. Indeed, a person of ordinary skill would have recognized that the purpose of Garrison's filter 3418 is to filter aspirated clot material from the aspirated blood by collecting the clot material within the filter while the aspirated blood is drawn through the filter toward the aspiration source via the negative pressure being applied by the aspiration source.

165. A person of ordinary skill in the art would have recognized that when Garrison's filter is replaced with Goff's or Lee's filter assembly, the negative pressure generated by Garrison's aspiration source would draw blood into Goff's or Lee's filter via the first port and out of the chamber through the second port in order to separate the aspirated clot material from the patient's blood.

7. **the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port**

166. Claim 1 next recites: "wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port." Garrison combined with Goff or Lee renders this limitation obvious.

a. **Goff**

167. Goff discloses this limitation or renders it obvious for the reasons I explained for Grounds 1-2. *Supra* §VI.A.7.

b. Lee

168. Lee also discloses this limitation or renders it obvious.

169. Lee discloses that its filter includes a plurality of filter holes 332, which “remove solid matters of diameters greater than the filter holes” from aspirated blood during use. Ex. 1007 (Lee) at [0022], [0026]. A person of ordinary skill in the art would have reasonably expected that Lee’s filter holes would similarly inhibit aspirated clot material from passing into the interior region and through the second port when Lee’s filter is used with Garrison’s aspiration system if the holes are appropriately sized. And to the extent it was necessary, a person of skill in 2018 would have possessed the skills and knowledge to optimize the size or positioning of the holes to filter clot material, as reflected in the prior art and the 12-’333 patent, for the reasons I explained previously. *Supra* ¶¶[142]-[144].

8. the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region

170. Claim 1 finally recites: “wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.” Garrison combined with Goff or Lee renders this limitation obvious.

a. Goff

171. Goff discloses this limitation or renders it obvious for the reasons I explained for Grounds 1-2. *Supra* §VI.A.8.

b. Lee

172. Lee renders this limitation obvious.

173. Lee does not expressly describe the material that forms its filter housing and instead presumes that a person of ordinary skill in the art would have been capable of selecting an appropriate material. A person of ordinary skill would have been motivated to use a transparent material to form Lee's housing, such as plastic, to allow the user to visualize the aspirated clot material during procedures.

174. In addition, a person of ordinary skill in the art would have been aware of prior art aspirators such as the Paco-Flow Orthopaedic Suction Set, which is a commercial filter produced by Pacific Hospital Supply Co., which is the company listed as the "assignee" on Lee. Ex. 1040 (PACO Wayback page). The Paco-Flow filter included a transparent housing and had a similar structure to Lee's filter:



Paco-Flow Orthopaedic Suction Set

CLOSE X

Id. The Paco-Flow filter would have further motivated a person of ordinary skill to form Lee’s housing from transparent material, such as plastic, and it would have given them a reasonable expectation of success in doing so.

B. Claim 4 – the first filter end portion is curved

175. Claim 4 recites the “the “clot collection reservoir of claim 1 wherein the first filter end portion is curved.” Garrison combined with Goff or Lee renders this claim obvious.

1. Goff

176. Goff discloses this limitation for the reasons I explained for Grounds 1-2. *Supra* §VI.B.

2. Lee

177. Lee also discloses this limitation.

178. The closed end (i.e., first filter end portion) of Lee's filter is curved, as shown in Figure 3 below:

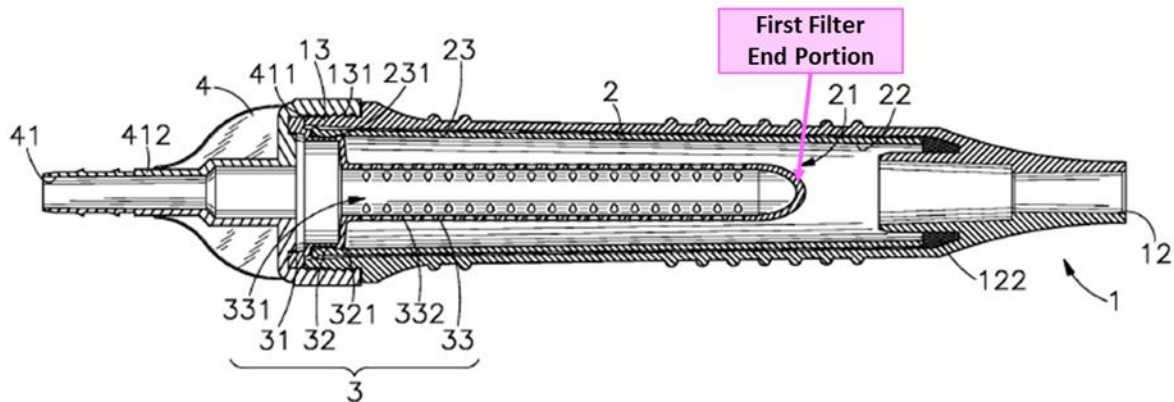


FIG. 3

Ex. 1007 (Lee) at Fig. 3.

C. **Claim 5 – the source of aspiration is configured to generate the negative pressure in the chamber via the second port to draw the clot material against the first filter end portion**

179. Claim 5 recites: the “clot collection reservoir of claim 1 wherein the source of aspiration is configured to generate the negative pressure in the chamber via the second port to draw the clot material against the first filter end portion.”

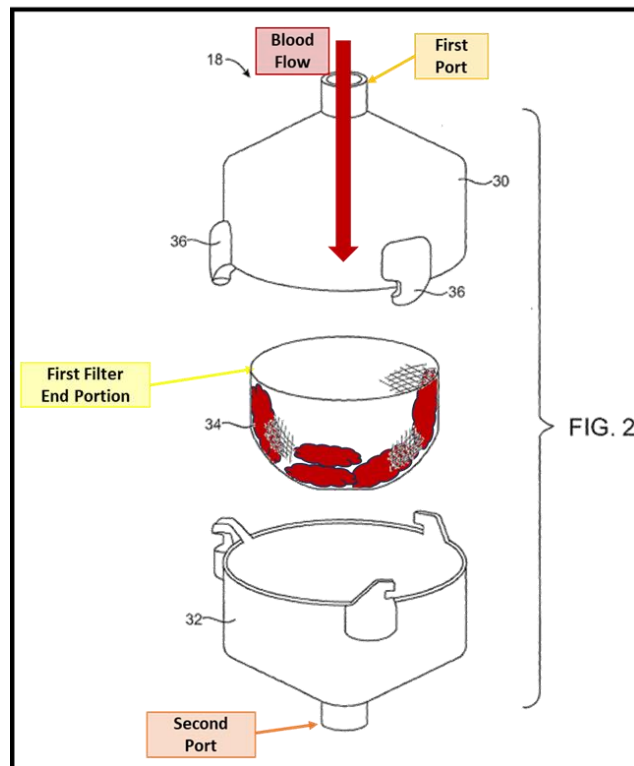
Garrison in combination with Goff or Lee renders this claim obvious.

180. As I explained for claim 1, because Goff's or Lee's filter would be located distal from Garrison's aspiration source along the flow path, the aspiration

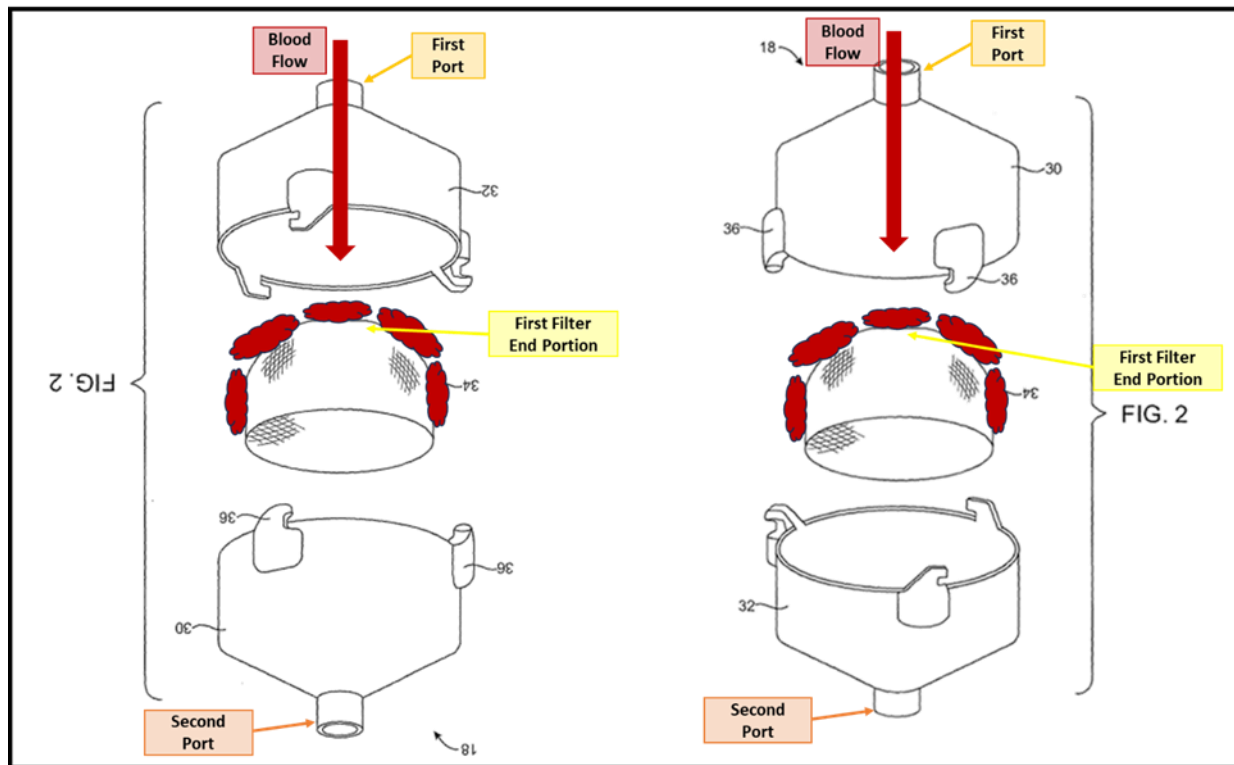
source would generate negative pressure within Goff's or Lee's filter chamber, which would draw aspirated blood and clot material into the filter via the first (i.e., inflow) port. *Supra* §VI.C.

181. As I explained for Grounds 1-2, a person of ordinary skill in the art would have understood that clot material would be drawn against the first filter end portion of Goff's filter in both orientations that I discussed for claim 1, as I've illustrated below:

Goff – Orientation 1

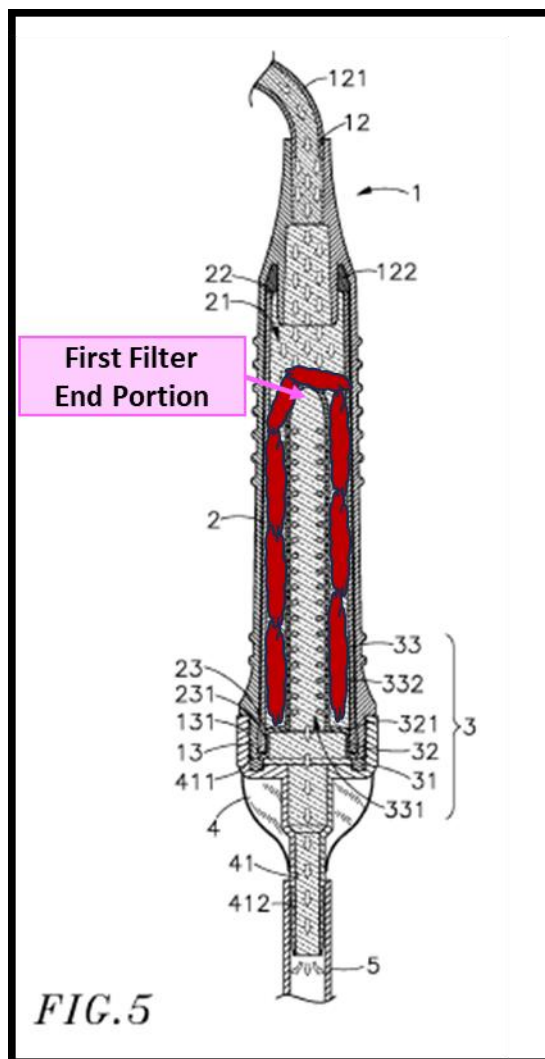


Goff – Orientation 2



Ex. 1005 (Goff) at Fig. 2 (modified by Petitioner).

182. As I've illustrated below, a person of ordinary skill would have also understood that clot material would be drawn against the first filter end portion of Lee's filter as it is drawn into the filter chamber:



Ex. 1007 (Lee) at Fig. 5.

183. Indeed, a person of skill would have understood that clot material would have been drawn against all portions of Goff's and Lee's filter facing the inflow port, particularly when a large amount of clot material is removed. This is illustrated in Figure 3 of the Ram article, which shows the clinical results of the AngioVac System filter:



Fig 3. Procedure results, all demonstrating various intravascular material trapped by the inline filter.

Ex. 1030 (Ram) at Fig. 3.

- D. Claim 7 – the first filter end portion is positioned closer to the first housing end portion than the second filter end portion, and wherein the

second filter end portion is positioned closer to the second housing end portion than the first filter end portion

184. Claim 7 recites the “clot collection reservoir of claim 1 wherein the first filter end portion is positioned closer to the first housing end portion than the second filter end portion, and wherein the second filter end portion is positioned closer to the second housing end portion than the first filter end portion.” Garrison in combination with Goff or Lee renders this claim obvious.

1. Goff

185. Goff discloses this limitation for the reasons I explained for Grounds 1-2. *Supra* §VI.D.

2. Lee

186. Lee also discloses this limitation.

187. As shown in Figure 3 below, Lee’s first filter end portion (the closed end of the filter tube) is closer to the first housing end portion than the second housing end portion, and the second filter end portion (the base 31 of the filter tube) is closer to the second housing end portion than the first housing end portion:

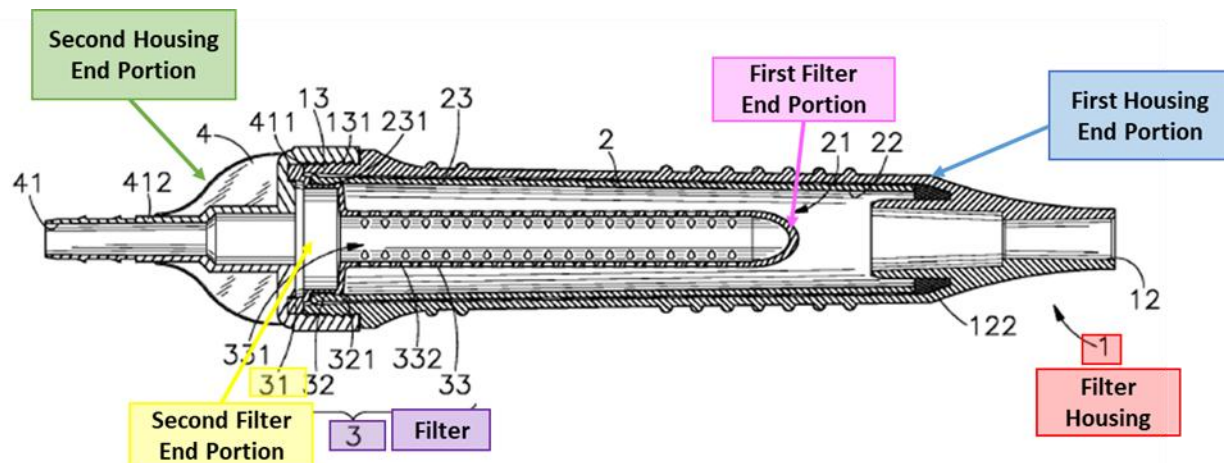


FIG. 3

Ex. 1007 (Lee) at Fig. 3.

E. Claim 10

188. Garrison combined with Goff or Lee renders Claim 10 obvious.

1. Preamble – clot treatment system

189. The preamble of Claim 10 recites a “clot treatment system.” If this preamble is limiting, Garrison discloses this limitation.

190. Garrison discloses a system “to provide aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” Ex. 1006 (Garrison) at [0007]. Garrison discloses an embodiment, depicted in Figure 34, that includes an aspiration catheter 2030 [orange] coupled to a vacuum source [red] via connection tubing [green] (i.e., flow line 2045):

2. **an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient**

191. Claim 10 next recites “an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient.” Garrison discloses this limitation.

192. Garrison’s aspiration system includes an aspiration catheter 2030 that “is placed through the arterial access device 2010 or the guide catheter 2105 and positioned such that the distal tip reaches the treatment site.” Ex. 1006 (Garrison) at [0130]-[0134], [0164], Fig. 34. Garrison’s aspiration catheter is “configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient.” For example, Figure 2 of Garrison illustrates that the distal portion of the aspiration catheter 2030 (orange) is positioned proximate to clot material 10 (pink) within a patient’s blood vessel during the aspiration procedure:

4. **clot collection reservoir**

194. Claim 10 next recites a “clot collection reservoir” comprising various features. Garrison discloses a “clot collection reservoir” for the reasons I explained for Claim 1. *Supra* §VII.A.1.

5. **a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion**

195. Claim 10 next recites that the clot collection reservoir comprises “a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.2.

6. **a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber**

196. Claim 10 next recites that the clot collection reservoir comprises “a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.3.

7. **a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber**

197. Claim 10 next recites that the clot collection reservoir comprises “a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.4.

8. **a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port**

198. Claim 10 next recites that the clot collection reservoir comprises “a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.5.

9. **the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into**

the chamber and (b) draw blood through the filter into the interior region and through the second port

199. Claim 10 next recites: “wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.6.

10. the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port

200. Claim 10 next recites: “wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.7.

11. the filter is removably positioned within the chamber to provide access to the clot material within the chamber

201. Claim 10 finally recites: “wherein the filter is removably positioned within the chamber to provide access to the clot material within the chamber.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.8.

F. **Claim 11 – the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region**

202. Claim 11 recites the “clot treatment system of claim 10 wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.” Garrison combined with Goff or Lee renders this claim obvious for the reasons I explained for Claims 1 and 10. *Supra* §§VII.A.8; VII.E.

G. **Claim 13 – the clot collection reservoir is spaced apart from the aspiration source, and further comprising at least one tube fluidly coupling the second port to the aspiration source**

203. Claim 13 recites the “clot treatment system of claim 10 wherein the clot collection reservoir is spaced apart from the aspiration source, and further comprising at least one tube fluidly coupling the second port to the aspiration source.” Garrison combined with Goff or Lee renders this claim obvious.

204. As illustrated in Figure 34 of Garrison below, Garrison’s clot collection reservoir (filter 3418) is spaced apart from Garrison’s aspiration source 3430, and the clot collection reservoir is fluidly coupled to the aspiration source via tubing:

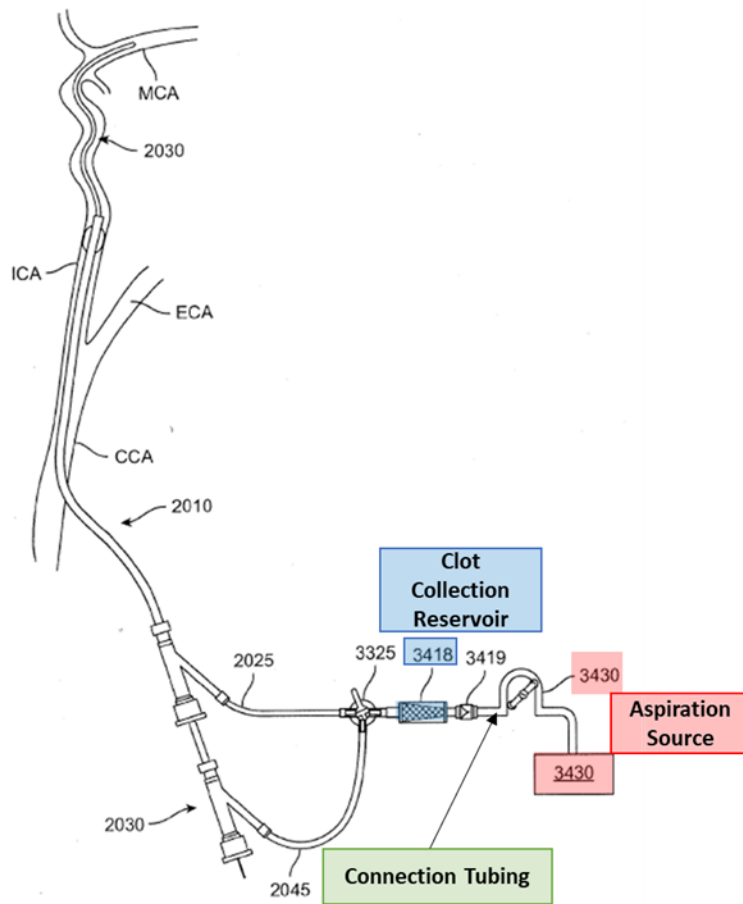


FIG. 34

Ex. 1006 (Garrison) at [0130]-[0132], Fig. 34. A person of ordinary skill would have recognized that when Garrison's filter is replaced with Goff's or Lee's filter assembly, Garrison's tubing would fluidly couple the second port on Goff's or Lee's filter housing to the aspiration source. The filter must be fluidly coupled to the aspiration source for the negative pressure generated by the aspiration source to pass through the filter to the aspiration catheter and ultimately the clot material being removed from the patient.

H. Claim 15

205. Claim 15 is an independent claim that recites the same limitations as Claim 10 with two exceptions: (1) Claim 15 does not require that the filter is “removably positioned within the chamber” and (2) Claim 15 recites “a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user actuatable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter.” Garrison combined with Goff or Lee renders Claim 15 obvious.

1. **a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user actuatable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter**

206. Garrison discloses “a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user actuatable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter.”

207. Garrison’s aspiration system includes a valve 3325 [purple] placed along the fluid path between the filter [blue] (i.e., clot collection reservoir) and the aspiration catheter [orange]:

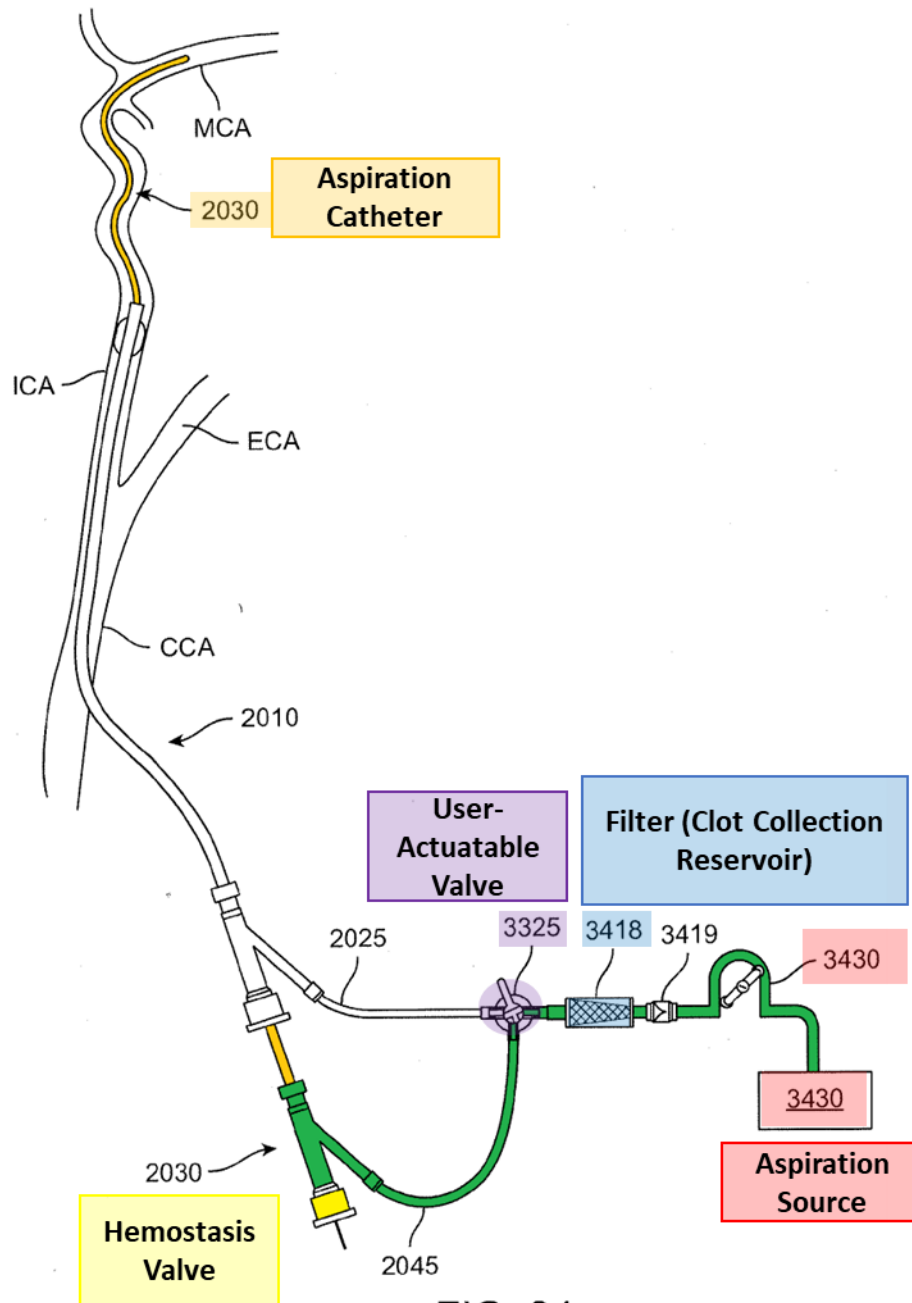


FIG. 34

Ex. 1006 (Garrison) at Fig. 34, [0131]-[0134]. Garrison explains that the “valve 3325 controls which device is connected to the aspiration source 3430” and “enable[s] one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” *Id.* at [0132]. Accordingly,

the valve has an open position in which the first port on the filter is fluidly connected to the aspiration catheter 2030 and a closed position in which the first port is disconnected from the aspiration catheter.

208. Garrison explains that “[t]he valve may be a 3-way or 4-way stopcock.” *Id.* Garrison’s stopcock valve includes a lever that is rotated by the user to change the orientation of the valve and couple or decouple the pressure source from the catheters:

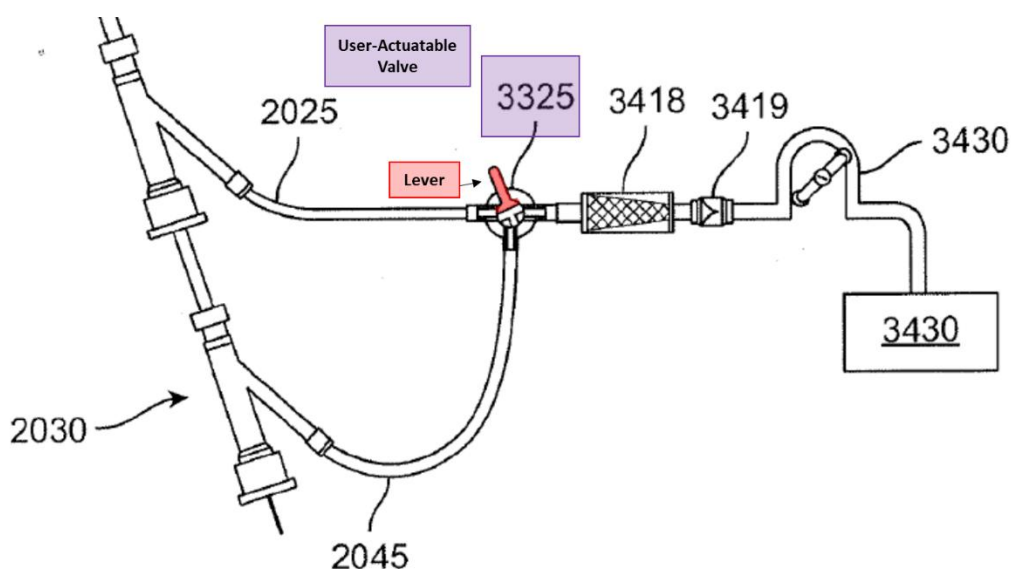


FIG. 34

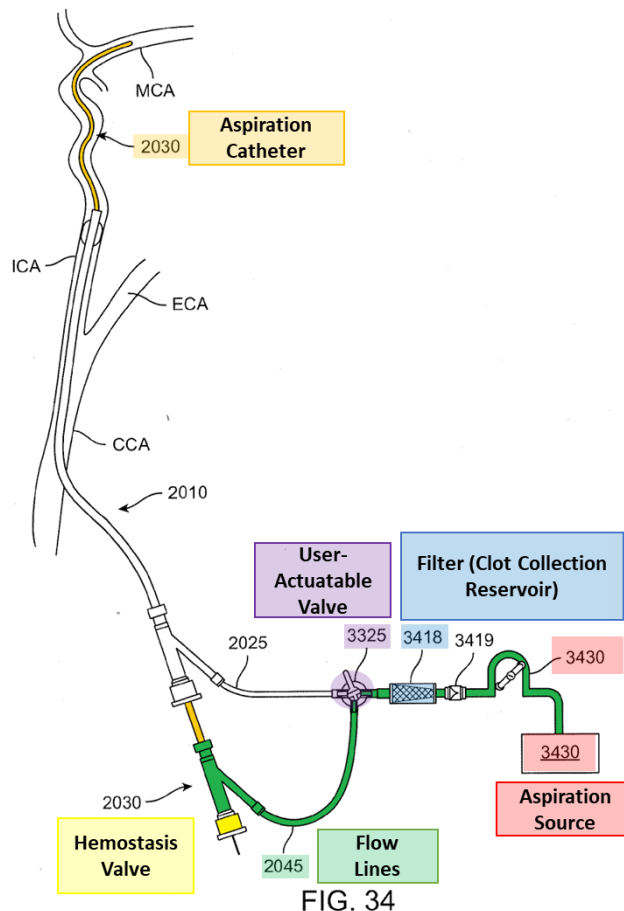
Id. at Fig. 34. Garrison’s stopcock valve is therefore a “user-actuable” valve as recited in Claim 15.

209. Garrison discloses that its flow controller, identified by reference number 3400, “may include one or more control interfaces that a user may actuate to regulate which device is being aspirated,” which is illustrated in Figure 35:

wherein the valve is configured to be moved to the open position to apply the negative pressure to the aspiration catheter

211. Claim 16 recites: the “clot treatment system of claim 15 wherein the aspiration source is configured to generate the negative pressure in the chamber with the valve in the closed position, and wherein the valve is configured to be moved to the open position to apply the negative pressure to the aspiration catheter.” Garrison combined with Goff or Lee renders this claim obvious.

212. As I explained for Claim 15, Garrison discloses a system including a valve 3325 [purple] between the filter [blue] (clot collection reservoir) and the aspiration catheter 2030 [orange]:



Id. at Fig. 34, [0131]-[0134]. As shown above, the filter is positioned between the valve and the aspiration source 3430 [red]. *Id.*

213. Garrison describes that the aspiration source can be a syringe, in addition to other types of aspiration sources such as pumps. *Id.* at [0131]; *see also* [0071], [0129], [0134]. Garrison also describes that its aspiration source is configured to generate negative pressure in the chamber of the filter (clot collection reservoir) when the valve 3325 is in the closed position. Specifically, Garrison describes that “a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user ***while the connection to the flow line is closed*** prior to the thrombectomy step of the procedure.” *Id.* at [0134] (emphasis added). Pulling back the syringe plunger while the connection (i.e., flow controller) is closed would generate negative pressure in every component of the system located between the valve and the aspiration source, including the filter 3418 (clot collection reservoir). *Id.* at [0134], Fig. 34.

214. Garrison also describes that the valve is configured to be moved to the open position to apply the negative pressure to the aspiration catheter. Garrison states that once the aspiration catheter is positioned proximate to the thrombus in the patient’s vasculature, “the user may open the connection to the aspiration syringe” to “enable the maximum level of aspiration in a rapid fashion.” *Id.* A

person of ordinary skill would have recognized that opening the valve in this manner would apply the negative pressure generated by the aspiration source to the aspiration catheter to apply “the maximum level of aspiration in a rapid fashion” and remove the thrombus from the patient. *Id.*

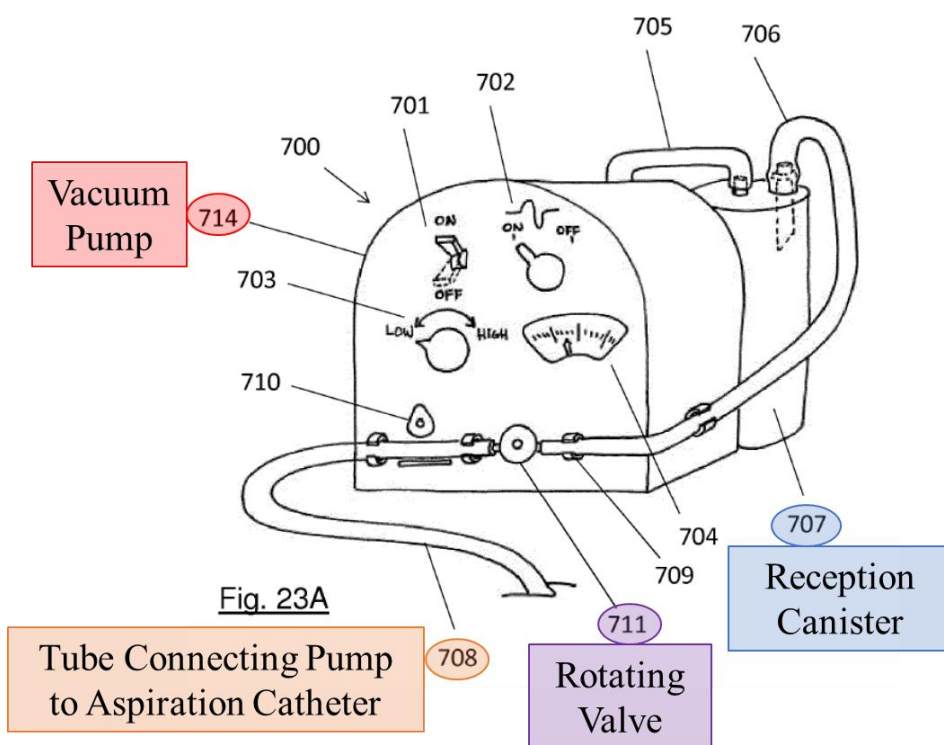
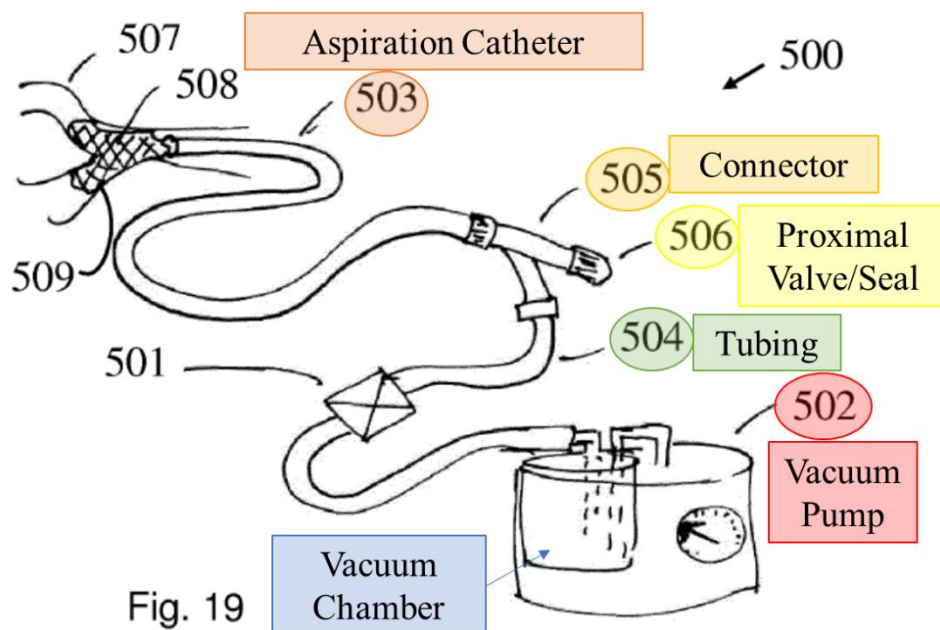
215. I am aware that in prior IPRs, Patent Owner has argued that Garrison’s rapid aspiration method described in paragraph 134 does not apply to the system shown in Figure 34. I disagree with Patent Owner’s interpretation of Garrison. A person of ordinary skill in the art would have understood that Garrison’s rapid aspiration method applies to the system described and shown in Figure 34, which includes all the components necessary to carry out the method – the aspiration catheter, the aspiration source, and the valve/flow controller.

216. I am also aware that in prior IPRs, Patent Owner has argued that the rapid aspiration method described in paragraph 134 requires that the aspiration source is a syringe, and that the aspiration source in Figure 34 of Garrison can only be a peristaltic pump due to the illustration in Figure 34. I disagree with Patent Owner’s arguments, which are inconsistent with Garrison.

217. In the sentence directly preceding Garrison’s description of the rapid aspiration method, Garrison expressly states that its aspiration source may be “an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” *Id.* at [0134]. It would therefore be contrary to Garrison’s

express disclosure to interpret the rapid aspiration method to require a syringe or to interpret Figure 34 as requiring a peristaltic pump. In fact, Garrison only mentions a peristaltic pump once, in paragraph 135, where it states that “peristaltic pumps are known to cause damage to blood cells.” *Id.* at [0135]. Given these descriptions in Garrison, a person of ordinary skill in the art would not have understood that the aspiration source 3430 in Figure 34 is limited to a peristaltic pump.

218. A person of ordinary skill in the art in January 2018 would have been familiar with many types of aspiration pumps that would be suitable for use as the aspiration source in Garrison’s aspiration system. For example, Brady discloses an aspiration pump that is “particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion”:



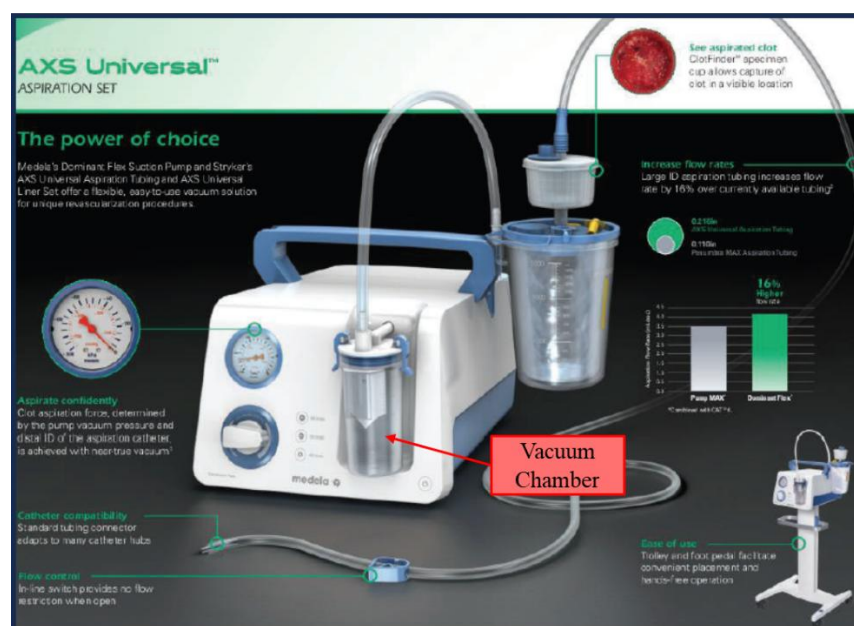
Ex. 1020 (Brady) at 1:13-17, 20:19-29, 21:16-32, Figs. 19, 23A. Brady's pump generates vacuum in a reception canister, which is then applied to an aspiration

catheter via tubing. *Id.* 21:16-32. This design is similar to several commercial aspiration pumps, such as the Penumbra Max and Medela Dominant Flex, that were available prior to 2018 and used to aspirate clot material:

Penumbra Pump



Medela Pump



Ex. 1041 (Penumbra Max Pump); Ex. 1042 (AXS Brochure). A person of ordinary skill in the art would have understood that Garrison's broad disclosure of an "aspiration pump" would encompass these types of prior art aspiration pumps.

219. I am also aware that in prior IPRs, Patent Owner has argued that Garrison's description of generating negative pressure with the aspiration source while the valve is closed describes a different arrangement than the Figure 34 embodiment, and that this allegedly different system does not include a filter. Patent Owner has argued that in Garrison's rapid aspiration method, the aspiration source is attached "directly" to the flow controller, and that there cannot be a filter between the flow controller and the aspiration source as illustrated in Figure 34. I disagree with Patent Owner's argument, which is inconsistent with Garrison's disclosure. Garrison does not state that the syringe is attached "directly" to the flow controller in paragraph 134. *See* Ex. 1006 (Garrison) at [0134]. Nothing in Garrison's disclosure would suggest to a person of ordinary skill in the art that Garrison's rapid aspiration method could not be used with the system shown in Figure 34. To the contrary, Garrison broadly states that "[c]ertain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment" and "various features that are described in the context of a single embodiment can also be implemented in

multiple embodiments separately or in any suitable sub-combination.” *Id.* at [0175]. Thus, even if a person of ordinary skill interpreted Garrison’s rapid aspiration method and Figure 34 to be different embodiments, which they would not, Garrison expressly teaches that the features of its embodiments can be combined.

J. Claim 17

220. Garrison combined with Goff or Lee renders Claim 17 obvious.

1. Preamble – clot treatment system

221. The preamble of Claim 17 recites a “clot treatment system.” If this preamble is limiting, Garrison discloses this limitation for the reasons I explained for Claim 10. *Supra* §VII.E.1.

2. an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient

222. Claim 17 next recites “an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient.” Garrison discloses this limitation for the reasons I explained for Claim 10. *Supra* §VI.E.2.

3. a hemostasis valve coupled to a proximal portion of the aspiration catheter

223. Claim 17 next recites “a hemostasis valve coupled to a proximal portion of the aspiration catheter.” Garrison discloses this limitation.

224. Garrison discloses a catheter 2030 [orange] having a hemostasis valve [yellow] in its proximal hub 2065 (item 2065 not labeled in Figure 34):

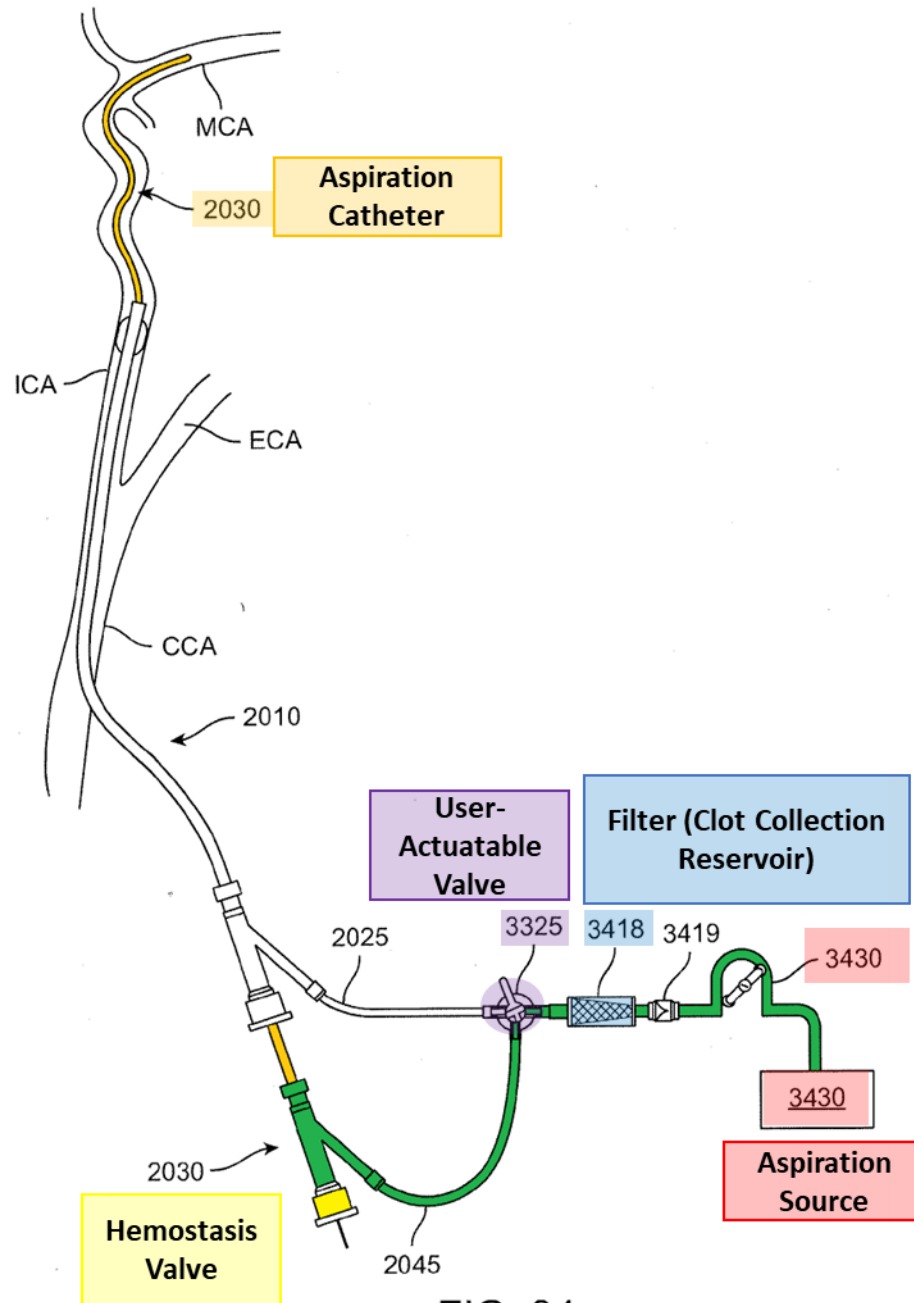


FIG. 34

Ex. 1006 (Garrison) at [0098], Fig. 34. Garrison specifically states that “a separate hemostasis valve may be attached to proximal hub 2065, to allow introduction of

devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” *Id.* Garrison also discloses that “the hemostasis valve may be integral to the catheter proximal adaptor.” *Id.* Garrison further discloses that the hemostasis valve can take many configurations, including “an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)” or “a passive seal hemostasis valve.” *Id.* at [0098].

225. Figure 34 (above) does not expressly label the proximal adaptor and hemostasis valve, but other, related figures do. For example, Figure 3 identifies a “proximal adaptor having a proximal port 2015 *with a hemostasis valve* to allow introduction of devices while preventing or minimizing blood loss during the procedure”:

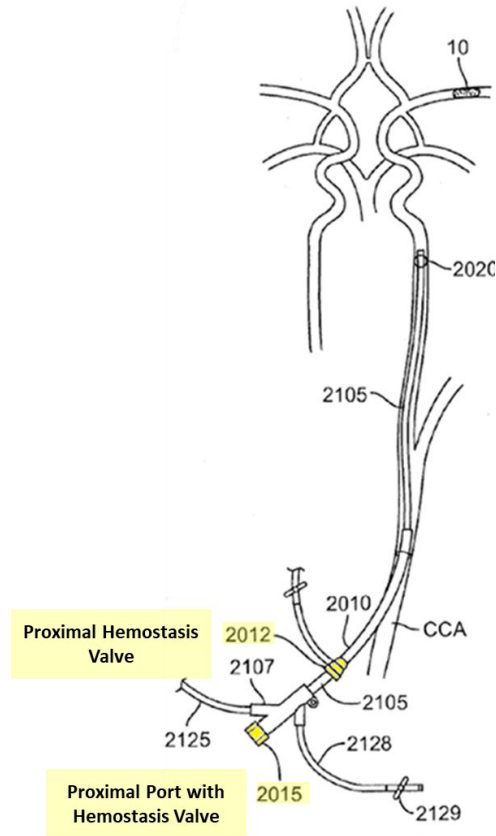
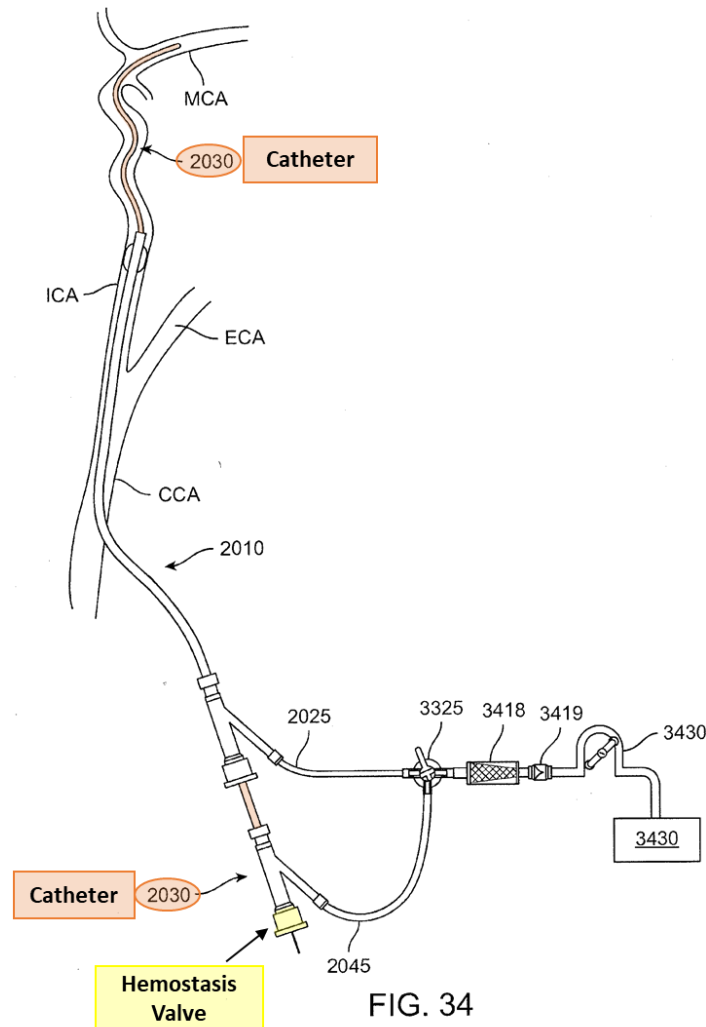


FIG. 3

Id. at [0053] (emphasis added), Fig. 3; *see also id.* at [0050]-[0053], [0059], [0062], Figs. 1-3, 6 (Garrison also explains that the arterial access device also has a hemostasis valve 2012). The location of the hemostasis valves shown in Figure 3 is the customary location for a hemostasis valve on a catheter.

226. A person of ordinary skill in the art would have understood that catheter 2030's hemostasis valve is located at the end of the proximal hub/adaptor as in Figure 3 at least because that is the location where a user would insert other devices through the hub and where sealing would be necessary:



Id. at [0098], Fig. 34. Therefore, a person of ordinary skill in the art would have understood that Garrison’s hemostasis valve is coupled to a proximal portion of the aspiration catheter 2030.

4. **at least one tube fluidly coupling the first port to a portion of the aspiration catheter distal of the hemostasis valve**

227. Claim 17 next recites “at least one tube fluidly coupling the first port to a portion of the aspiration catheter distal of the hemostasis valve.” Garrison discloses this limitation.

FIG. 34

- 138 -

Goff's/Lee's filter housing to the aspiration catheter 2030 at a position distal to the hemostasis valve (i.e., the y-arm connector).

5. an aspiration source

229. Claim 17 next recites “an aspiration source.” Garrison discloses this limitation for the reasons I explained for Claim 1. *Supra* §VII.A.4.

6. clot collection reservoir

230. Claim 17 next recites a “clot collection reservoir” comprising various features. Garrison discloses a “clot collection reservoir” for the reasons I explained for Claim 1. *Supra* §VII.A.1.

7. a housing defining a chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion

231. Claim 17 next recites that the clot collection reservoir comprises “a housing defining a chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.2.

8. a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion

232. Claim 17 next recites that the clot collection reservoir comprises “a first port configured to be fluidly coupled to the aspiration catheter, wherein the

first port is positioned proximate to the first housing end portion.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.3.

9. **a second port configured to be fluidly coupled to the aspiration source**

233. Claim 17 next recites that the clot collection reservoir comprises “a second port configured to be fluidly coupled to the aspiration source.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.4.

10. **a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port**

234. Claim 17 next recites that the clot collection reservoir comprises “a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port.” Garrison in combination with Goff or Lee renders these limitations obvious for the reasons I explained for Claim 1. *Supra* §VII.A.5.

11. **the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into**

the chamber and (b) draw blood through the filter into the interior region and through the second port

235. Claim 17 next recites: “wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.6.

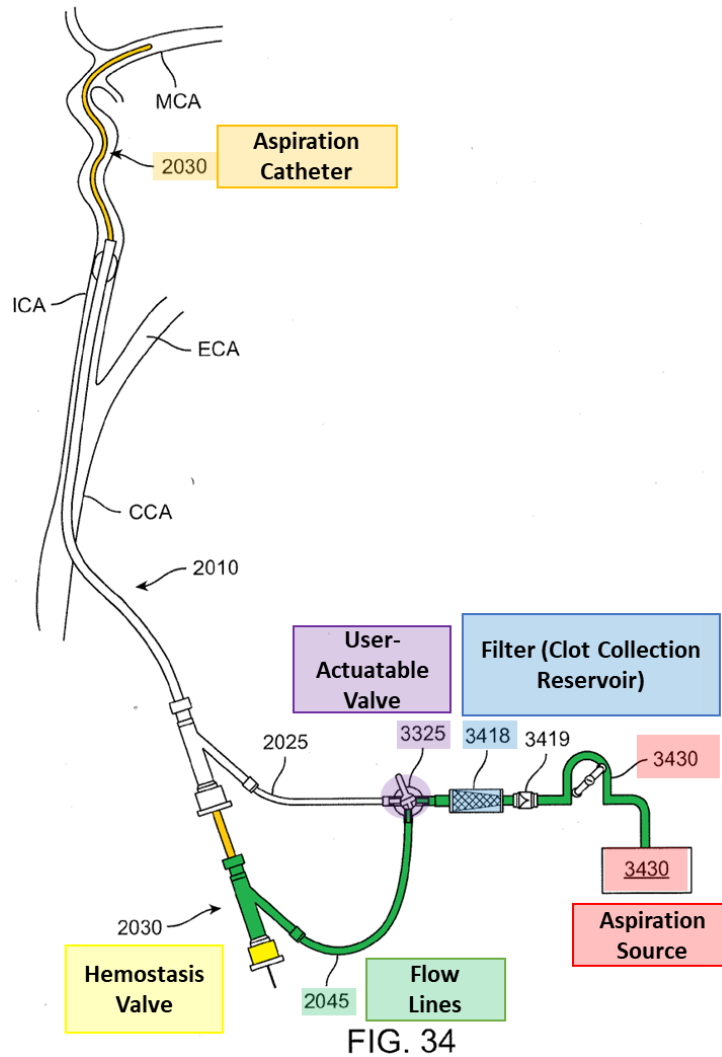
12. the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port

236. Claim 17 finally recites: “wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.” Garrison in combination with Goff or Lee renders this limitation obvious for the reasons I explained for Claim 1. *Supra* §VII.A.7.

K. Claim 19 – the aspiration source is fluidly couplable to the at least one tube

237. Claim 19 recites the “clot treatment system of claim 17 wherein the aspiration source is fluidly couplable to the at least one tube.” Garrison and Goff or Lee renders claim 19 obvious.

238. As shown in Figure 34 below, Garrison aspiration source is fluidly couplable to the tubing that comprises Garrison’s flow line:



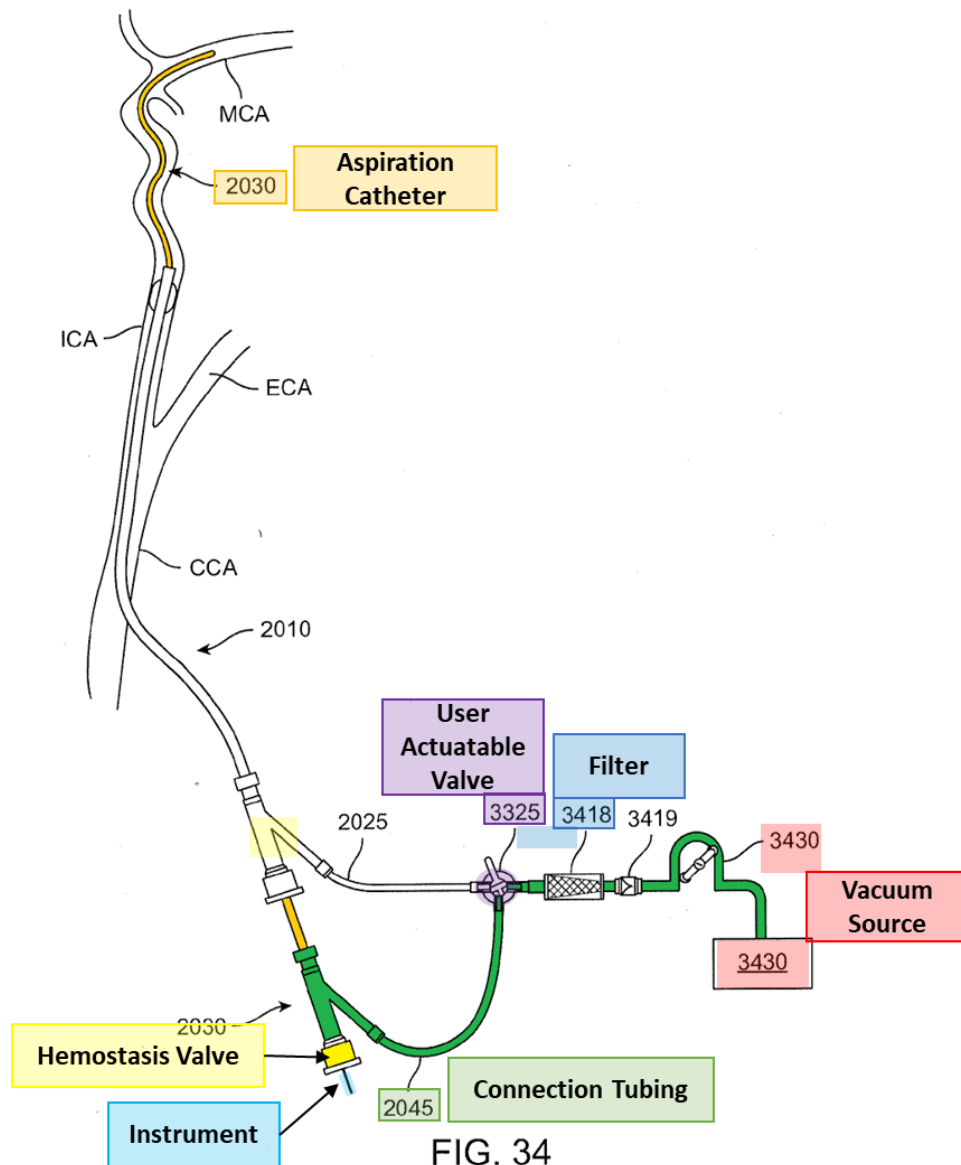
Ex. 1006 (Garrison) at [0130], [0132], Fig. 34.

L. Claim 20 – hemostasis valve is configured to receive an instrument therethrough

239. Claim 20 recites the “clot treatment system of claim 17 wherein the hemostasis valve is configured to receive an instrument therethrough.” Garrison combined with Goff or Lee renders this claim obvious.

240. Garrison states that its hemostasis valve allows “introduction of devices such as a microcatheter, guide wire, or thrombectomy device while

preventing or minimizing blood loss during the procedure.” Ex. 1006 (Garrison) at [0098]. A person of ordinary skill would understand that each of a “microcatheter, guide wire, or thrombectomy device” is an “instrument” as recited in claim 20. In addition, Garrison’s Figure 34 illustrates an instrument inserted through the hemostasis valve:



Id. at Fig. 34.

M. Claim 21 – the hemostasis valve and the aspiration catheter are configured to receive and route an instrument therethrough

241. Claim 21 recites the “clot treatment system of claim 17 wherein the hemostasis valve and the aspiration catheter are configured to receive and route an instrument therethrough.” Garrison and Goff or Lee renders claim 21 obvious.

242. Garrison states that its aspiration catheter 2030 may “provide distal access for additional devices, localized fluid or contrast delivery, or localized aspiration at a location distal of the distal-most end of the arterial access device 2010.” Ex. 1006 (Garrison) at [0054]. Garrison also discloses that its aspiration catheter can be used with “[m]echanical thrombectomy devices [such as] coil-tipped retrievers, stent retrievers, expandable cages, wire or filament loops, graspers, brushes, or the like.” *Id.* at [0144]. Garrison also discloses an embodiment having “a separate thrombus disruption device with an expandable distal segment [that] is inserted into the catheter” and is then used to “break up the clot” material as it is being aspirated into the catheter during the procedure. *Id.* at [0125]. Garrison also explains that “[i]f the thrombus is too large or too strongly embedded into the vasculature such that it is not possible to remove the occlusion via aspiration alone, further steps are taken to remove the occlusion” such as deploying a “thrombectomy device 15 ... through the arterial access device to remove the clot.” *Id.* at [0165]. A person of ordinary skill would understand that

the thrombectomy devices disclosed in Garrison would be an “instrument” as recited in claim 21.

243. Garrison’s hemostasis valve is “configured to receive and route an instrument therethrough” for the reasons I explained previously for Claim 20. *Supra* §VII.L.

VIII. GROUNDS 5-8: CLAIMS 18, 22-25 RENDERED OBVIOUS BY GARRISON AND GOFF OR LEE COMBINED WITH SHAFFER AND HARTLEY OR ELLER

A. Claim 18

244. Claim 18 recites the “clot treatment system of claim 17 wherein the hemostasis valve comprises: a tubular member; a button; and a filament coupled to the button and the tubular member, wherein the button is actuatable to loosen the filament to unseal the hemostasis valve.” Garrison combined with Goff or Lee and further combined with Schaffer and Hartley or Eller renders claim 18 obvious.

1. a tubular member

245. Schaffer discloses a hemostasis valve comprising a “tubular member.”

246. Schaffer discloses an adjustable opening “fluid stasis valve” for use with catheters to prevent the flow of blood through the valve. Ex. 1008 (Schaffer) at [0002], [0046], [0055]. Schaffer’s hemostasis valve includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” *Id.* at [0049], [0051], [0054], [0075]. The seal module 100 defines a lumen 193:

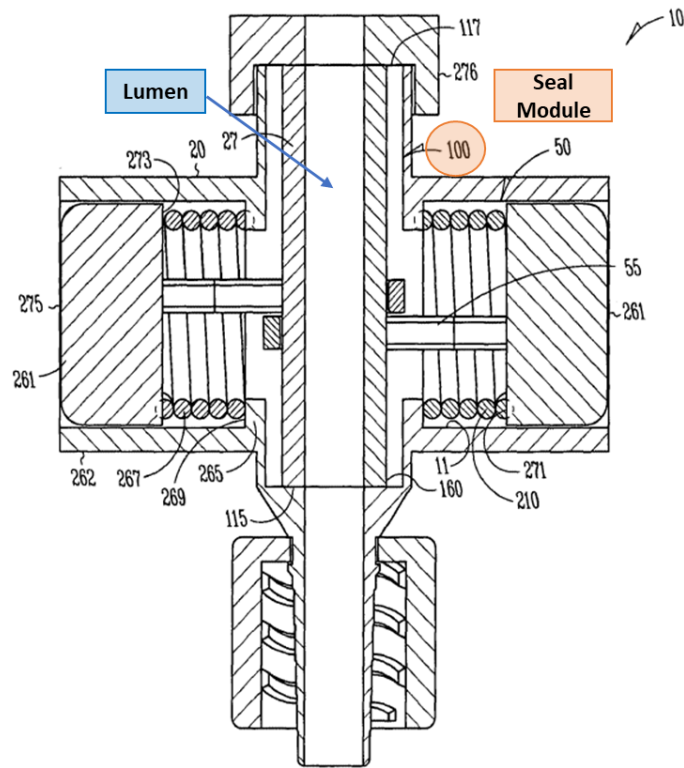


Fig. 34

Id. at [0058], Figs. 12, 34. Schaffer discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber.” *Id.* at [0056]. Thus, Schaffer’s seal module 100 is “a tubular member.”

2. a button

247. Schaffer discloses a hemostasis valve that comprises “a button.”

248. Schaffer discloses an embodiment of its valve depicted in Figures 31-34 that includes two circular actuators 50 that are “movable from a first position to a second position on opposing sides of the housing.” Ex. 1008 (Schaffer) at [0075]-[0076]. The actuators each include an actuator button 261 and a spring 210/267, as illustrated in Figure 32 below:

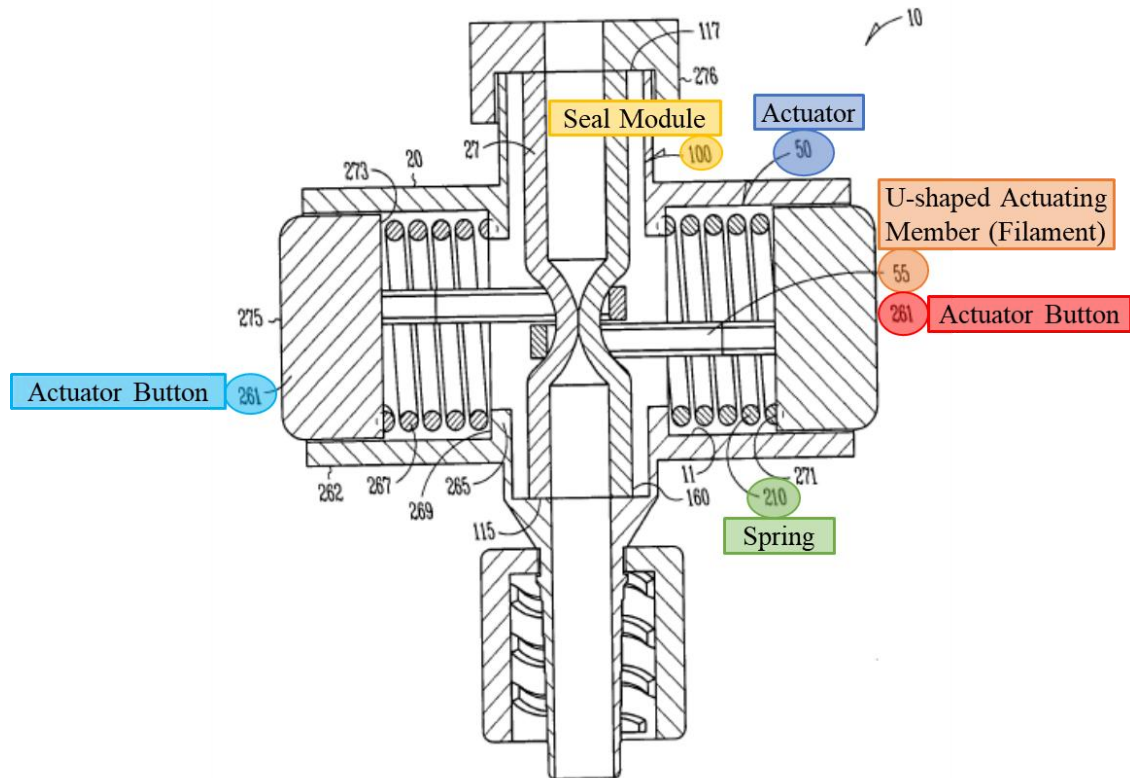


Fig. 32

Id. at [0075]-[0076], Figs. 31-32.

3. **a filament coupled to the button and the tubular member, wherein the button is actuatable to loosen the filament to unseal the hemostasis valve**

249. Schaffer in combination with Hartley or Eller renders obvious a hemostasis valve comprising “a filament coupled to the button and the tubular member, wherein the button is actuatable to loosen the filament to unseal the hemostasis valve.”

250. Schaffer’s valve includes two actuating members, which may be U-shaped, coupled to the actuator buttons:

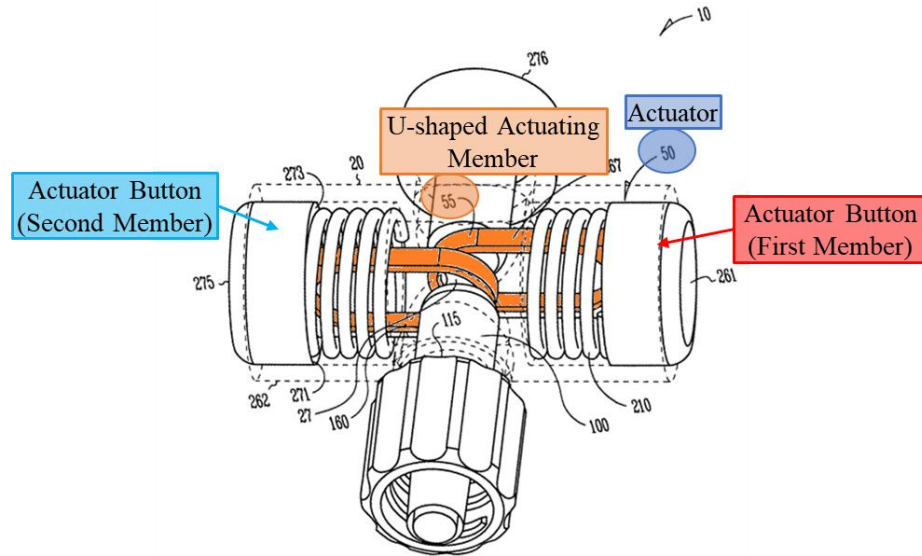
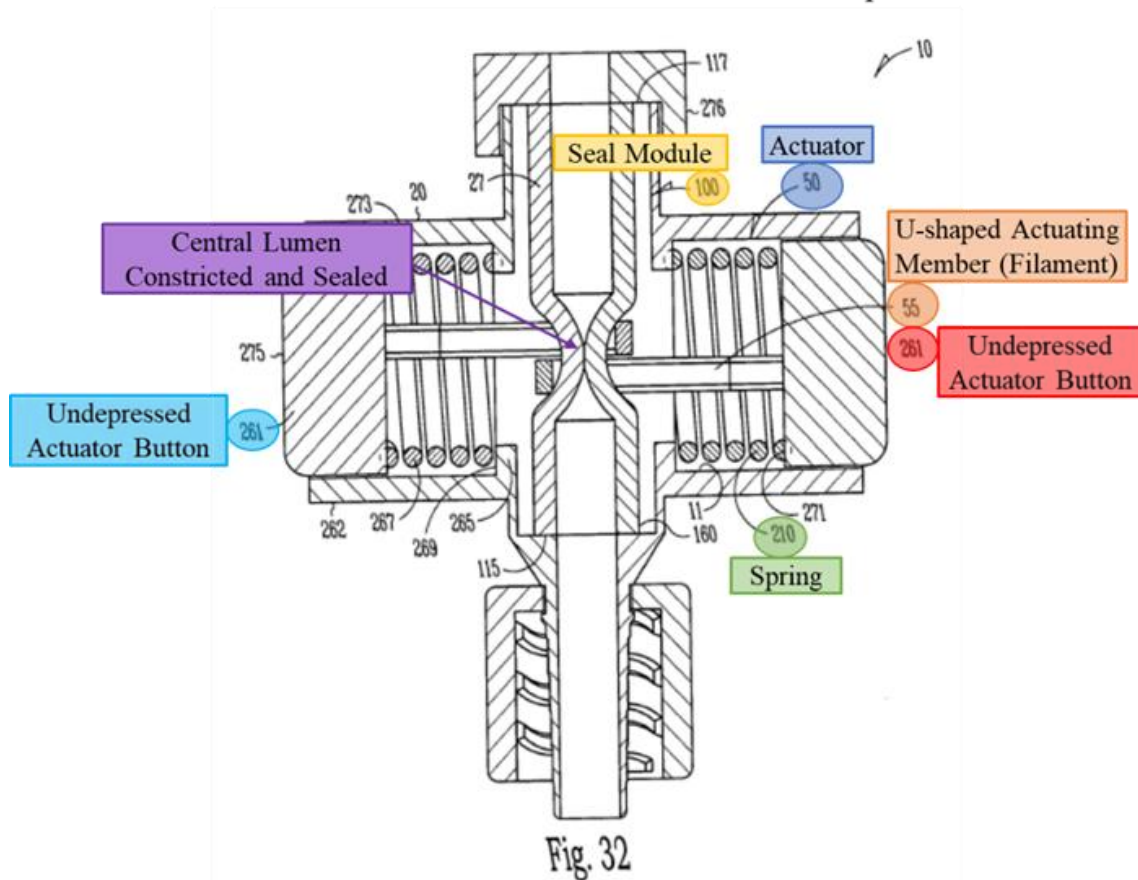


Fig. 31

Ex. 1008 (Schaffer) at [0076], Fig. 31. Schaffer discloses that in a first position, shown in Figure 32 below, the U-shaped actuating members are “at least partially circumferentially [sic] 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)”:

First Position – Actuator Buttons Undepressed

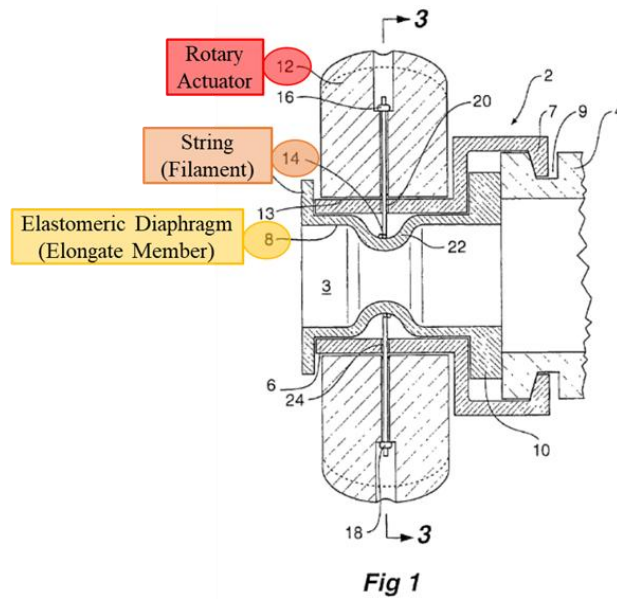


Id., at [0077], Fig. 32. Schaffer then explains that in a second position, the actuator buttons are depressed, which compresses the spring and allows the actuator members to “forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough.” *Id.* The second position is illustrated in Figure 34:

Fig. 34

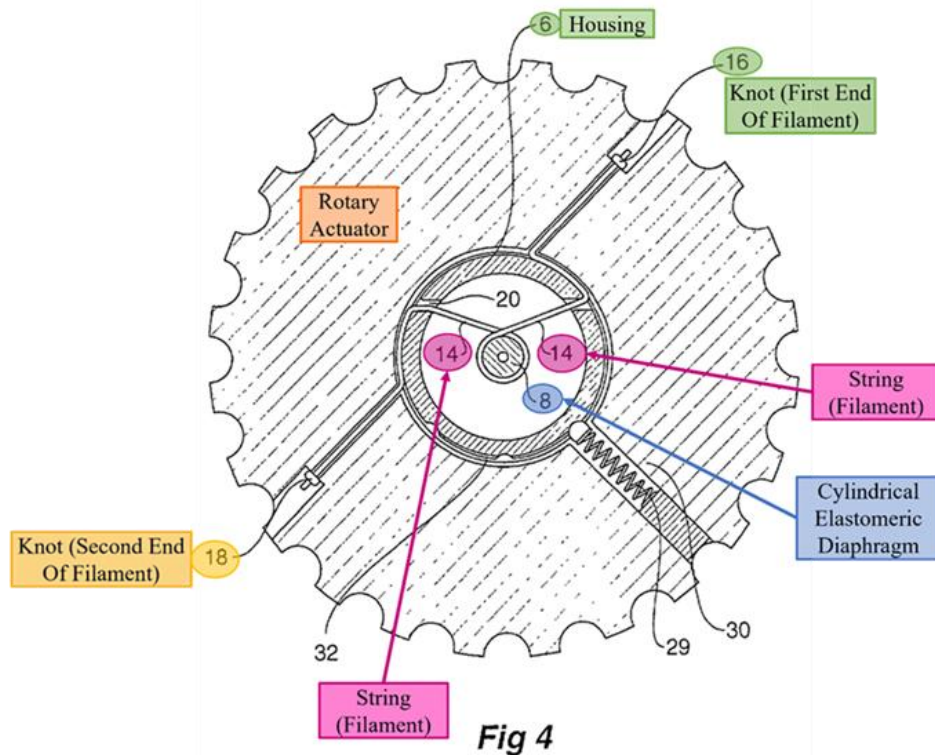
a. Hartley

252. Hartley describes a hemostasis valve having a cylindrical housing that a “cylindrical elastomeric diaphragm,” and a rotary actuator mounted to the housing:



Ex. 1009 (Hartley) at [0031], Fig. 1. Hartley’s valve includes a “string 14 ... mounted into the rotary actuator.” *Id.* Hartley’s string 14 is a “filament” because the string is made of at least one or more threads, lines, or cords.

253. Hartley’s string is secured to the rotary actuator via knots 16 at the ends of the filament and “is wound preferably twice around the cylindrical diaphragm 8”:



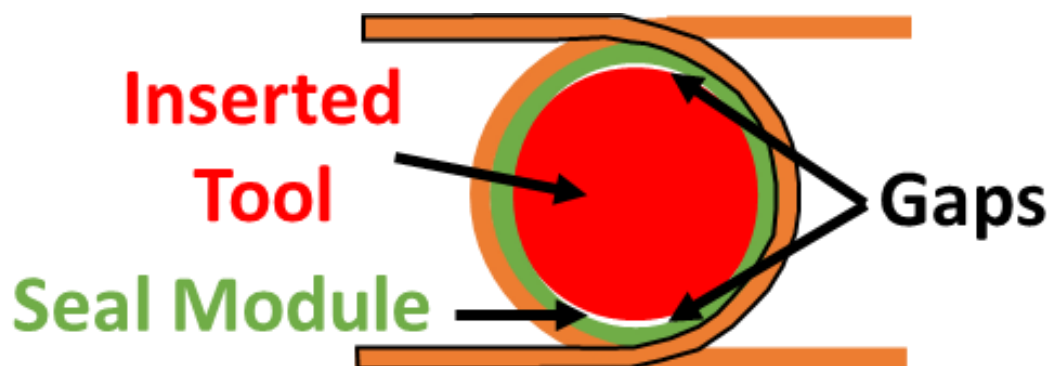
Id. at [0031], Fig. 4.

254. Hartley discloses that “[r]otation 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.” *Id.* at [0031], [0034], Fig. 4. Hartley further discloses the valve “will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” *Id.* at [0037]. Hartley also discloses that rotation of the valve in the opposite direction “will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape.” *Id.* at [0034].

255. A person of ordinary skill in the art would have found it obvious to substitute Hartley’s string for Schaffer’s actuating members in Schaffer’s valve.

The combination of Hartley's string and Schaffer's valve would have merely entailed substitution of one known element, Hartley's string, for another, Schaffer's actuating members, to yield the predictable result of sealing Schaffer's valve.

256. Hartley's disclosure that its string can "close over a range of diameters of devices passed through the valve or can close completely down to be self sealing" would have further motivated a person of ordinary skill in the art to substitute Hartley's string for Shaffer's actuating members. Ex. 1009 (Hartley) at [0037]. A person of ordinary skill in the art would have recognized that Hartley's string may seal more effectively across a wider range of tool diameters and shapes than Schaffer's U-shaped actuating members. Depending on the inserted tool, Schaffer's actuating members may form small gaps between the valve's seal module and the tool's outer surface, as I illustrate below:



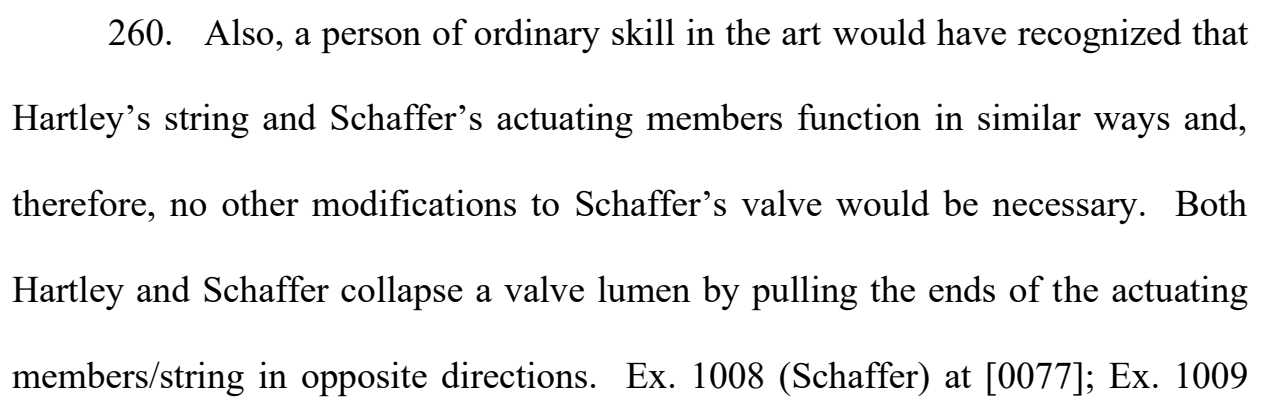
Hartley's string would not suffer from this potential issue because the string more precisely conforms to the tool diameters.

257. A person of ordinary skill in the art had a finite number of materials to select from to constrict a tubular member in a hemostasis valve in January 2018. Hartley and Schaffer disclose two such materials: Hartley's string and Schaffer's actuating members (which can be plastic or metal). A person of ordinary skill in the art would have found it obvious to select from these finite, predictable materials for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them.

258. Likewise, a person of ordinary skill in the art would have had a finite number of filament configurations to select from to constrict a tubular member in a hemostasis valve in January 2018. Hartley discloses a string that runs from one side of the valve to the other and wraps around the tubular member, while Schaffer discloses two u-shaped members that collective wrap around the tubular member. A person of ordinary skill in the art would have found it obvious to select either of these finite, predictable configurations for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them.

259. A person of ordinary skill in the art would have had a reasonable expectation of success in substituting Hartley's string for Schaffer's actuating members. Hartley teaches using simple knots to attach the string to the rotary actuator. Ex. 1009 (Hartley) at [0031]. A person of ordinary skill in the art would have reasonably expected that similar knots would secure Hartley's string to

Demonstrative Illustration Schaffer + Hartley's String



(Hartley) at [0031]. Thus, if Hartley's string were incorporated into Schaffer's valve, as can be seen below would have reasonably expected Schaffer's springs to pull the ends of the string in opposite directions to constrict Schaffer's seal module.

Id.

261. Likewise, a person of ordinary skill in the art would have also reasonably expected that pressing Schaffer's buttons inwardly (i.e., second position) would release the tension on the string, allowing the lumen to open. *See* Ex. 1008 (Schaffer) at [0077]; Ex. 1009 (Hartley) at [0034]. Schaffer's seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." Ex. 1008 (Schaffer) at [0054]. Thus, Schaffer's seal module has the resilience to open when the tension on the string is released. Moreover, if the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, a person of ordinary skill in the art would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. Schaffer discloses various materials for the seal module, including "modified vinyl, silicone, polyurethane or a combination thereof." *Id.* at [0081].

b. Eller

262. Eller also discloses a "filament" as recited in Claim 18.

263. Eller discloses a hemostasis valve that includes “a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22”:

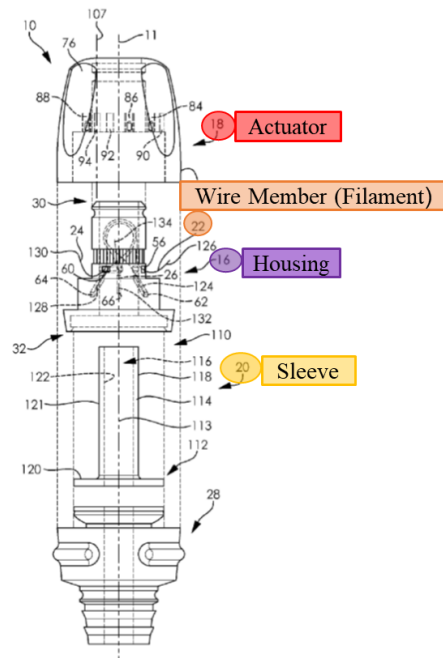


FIG. 2

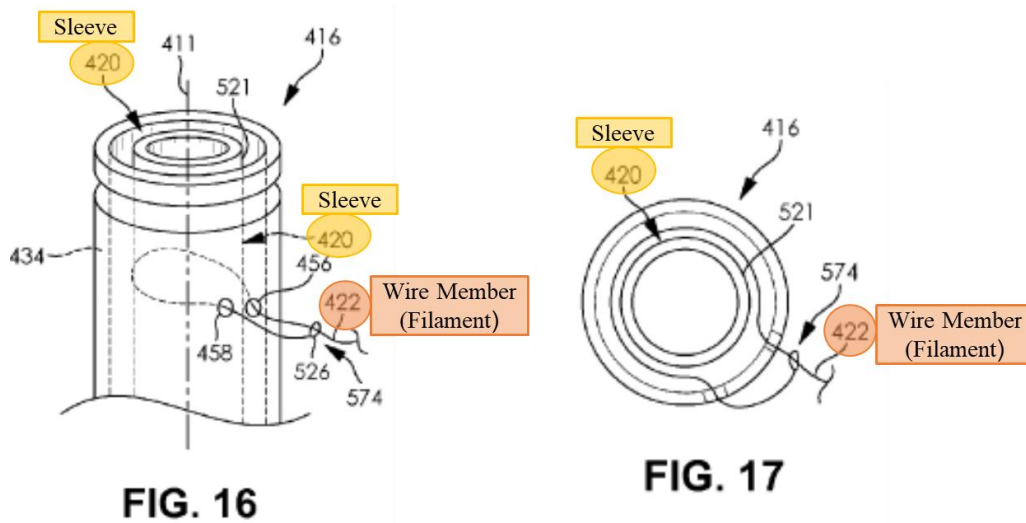


FIG. 16

FIG. 17

Ex. 1010 (Eller) at 5:1-5, Figs. 2,¹ 16-17. Some of Eller's examples, such as Figure 2 above, include three wire members: a first wire member, a second wire member, and a third wire member. *See* Ex. 1010 (Eller) at 5:1-5, Figs. 2, 8-10. However, Eller also discloses that "a selective fluid barrier device can include any suitable number of wire members." *Id.* at 16:7-19.

264. Eller says that its wire member "can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted, or otherwise interconnected to one another" and can comprise, for example, "a suture or a cable." Ex. 1010 (Eller) at 15:61-16:6. The 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." *Id.* at 15:65-16:2. Eller's wire member is therefore a "filament" as claimed in the 12-'333 patent because the wire member is at least one or more threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

265. Eller's first wire member has a first end 124 (first end portion) attached to the housing 16 and a second end 126 attached to the actuator 18. Ex. 1010 (Eller) at 12:52-58. Eller discloses that first wire member extends from its first end attached to the housing 16 and "around a portion of the outer surface 121 of the

¹ Eller's Figure 2 shows an exploded view of the device. Ex. 1010 (Eller) at 2:46-47. An un-exploded view is depicted in Figure 1. *Id.* at Fig. 1.

sleeve 20” to the second end attached to the actuator 18. *Id.* at 12:58-64. Figure 21 below illustrates the arrangement of the wire member around the outer surface of the sleeve:

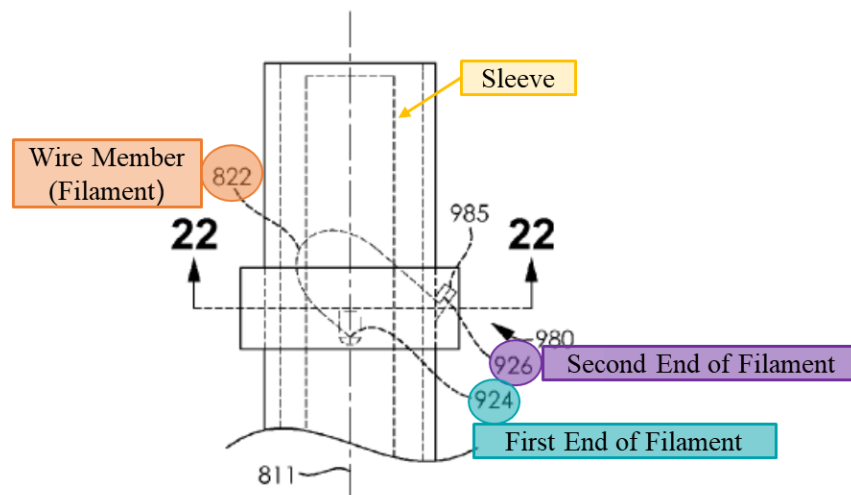
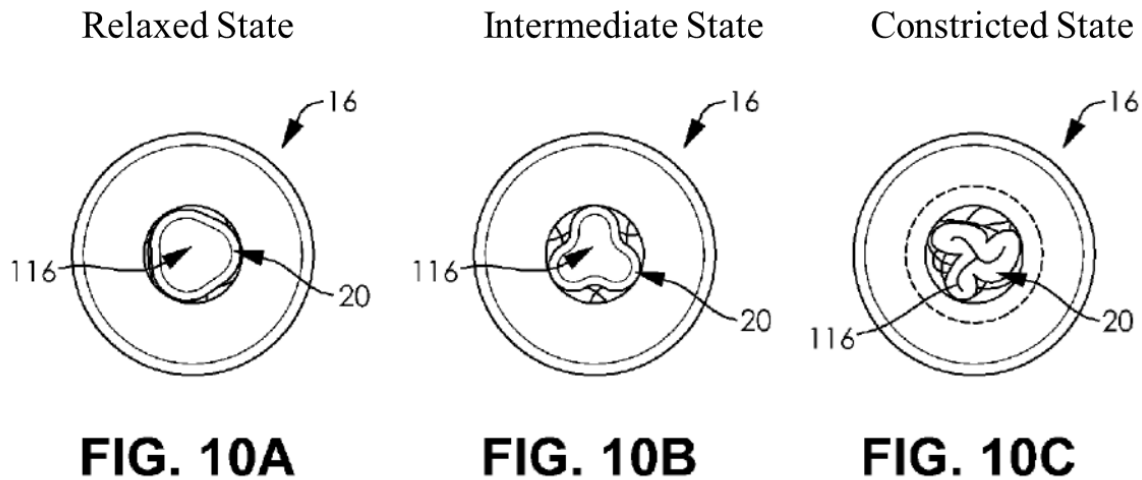


FIG. 21

Id. at 24:50-57, Fig. 21.

266. Eller’s actuator and wire member are “movable between a first configuration and a second configuration.” *Id.* at 15:21-25. Eller explains that in the first configuration, the actuator is rotated so that the wire member is in a relaxed state and fluid is permitted to flow through the sleeve. *Id.* at 15:21-40, 17:38-43. Then, when the actuator is rotated, the valve is moved to the second configuration where the actuator places the wire member in a tensioned state, causing the wire member to constrict the sleeve and prevent fluid from passing therethrough. *Id.* at 15:21-40, 17:62–67. Figures 10A through 10C illustrate the valve transitioning from the first relaxed position (10A) to the second constricted position (10C):



Id. at 15:21-40, Figs. 10A-10C. Eller also discloses that “when one or more medical devices are passed through the passageway 116 defined by the sleeve 20, the material that forms the sleeve 20 contacts a portion of one or more of the medical devices to close the passageway 116 such that fluid is prevented from passing through the passageway 116.” *Id.* at 18:3-8.

267. 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. *Id.* 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.

268. Second, like I explained previously with respect to Hartley's string (the discussion of which I incorporate herein), a person of ordinary skill in the art would have recognized that Eller's wire member may seal more effectively than Schaffer's metallic/plastic U-shaped actuating members when constricting the valve lumen. The compliancy of Eller's wire member would allow it to conform to a wider range of tools of varying diameters and shapes than Schaffer's U-shaped members. A person of ordinary skill in the art would have recognized that if a tool did not fit the size of Schaffer's U-shaped members, small gaps could form between the tool and the valve's lumen. However, a more compliant constricting mechanism, like Eller's wire member, could conform to the size and shape of a wider range of tools. Thus, Schaffer's valve combined with Eller's wire member may accommodate a wider range of tools/devices, which would have been a highly desirable feature to a person of ordinary skill in January 2018.

269. Third, the combination of Eller's wire member and Schaffer's valve would have merely entailed the substitution of one known element (Eller's wire member) 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 issues that would have prevented a person

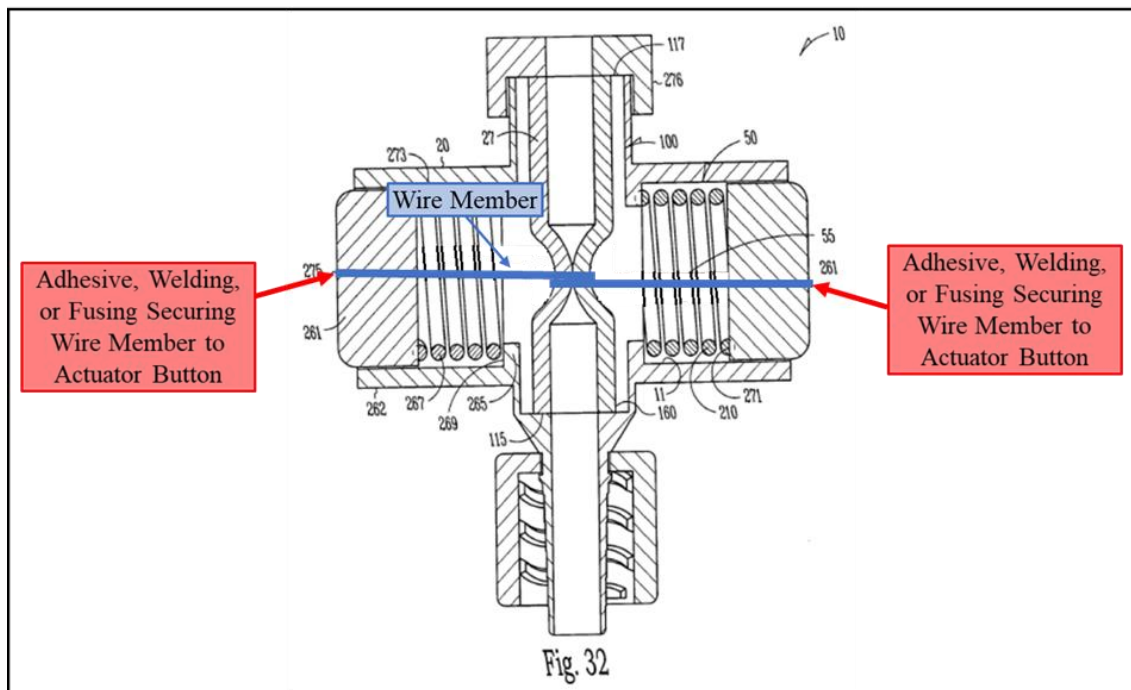
of ordinary skill in the art from combining Eller's wire member with Schaffer's valve. The substitution would have been well within the level of ordinary skill in January 2018.

270. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise "a resilient material in compression within a housing or clamping member." Ex. 1008 (Schaffer) at [0003]. As I explained previously with respect to the Schaffer-Hartley combination, there were a finite number of methods to compress the resilient material in a stasis valve in January 2018. Eller and Schaffer disclose two such methods – Eller's wire member and Schaffer's U-shaped actuating members. A person of ordinary skill in the art in January 2018 would have found it obvious to select either of these finite, predictable options. And as I explain below, they would have had a reasonable expectation of success in implementing them.

271. 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. 1010 (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 common and predictable to a person of ordinary skill in the art in January 2018, and a person of ordinary skill would have reasonably expected success in securing Eller’s wire member to Schaffer’s actuator buttons using one or more of those methods. The demonstrative illustration that I provide below depicts a basic diagram of how this could be achieved. As shown, the first end of the wire member would be secured to the first actuator button, the wire member would loop at least once around the lumen of Schaffer’s valve, and then the second end of the wire member would be secured to the second actuator button on the opposite side of the valve:

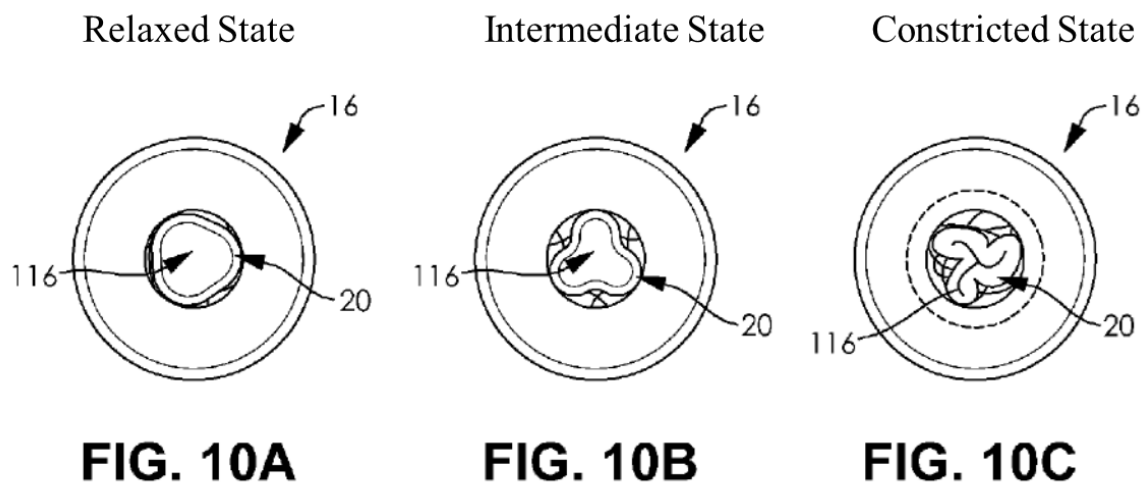
Demonstrative Illustration Schaffer + Eller's Wire Member



272. Second, Eller discloses that its wire member may be used with “any suitable actuator capable of moving the selective fluid barrier valve device between a first configuration and a second configuration” and that “[s]killed artisans will be able to select a suitable actuator to include on a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the number of wire members included in the selective fluid barrier valve device and/or the structural arrangement of the housing.” *Id.* at 8:27–39. Eller discloses that suitable actuators include “rotatable actuators, **linear actuators**, **slidable actuators**, pivotable actuators, levers, and any other actuator considered suitable for a particular embodiment.” *Id.* at 8:39–44 (emphasis added). A person of

ordinary skill in the art would have understood that Schaffer's actuator is an example of a linear and slidable actuator. *See* Ex. 1008 (Schaffer) at [0076]-[0077]. Thus, Eller's disclosure regarding the wide range of actuators suitable for use with its wire member would have reinforced the person of ordinary skill in the art's reasonable expectation that Eller's wire member could be successfully combined with Schaffer's actuator buttons.

273. Third, a person of ordinary skill in the art would have recognized that Eller's wire member and Schaffer's U-shaped actuating members use similar mechanisms to compress and seal the central lumen of the valve. Eller's wire member seals the valve when the actuator is placed in the second position, which creates tension in the wire member and causes the wire member to constrict the sleeve, as illustrated in Figures 10A-10C below:



Constricted State



274. In view of the similarities between Eller and Schaffer's valves, a person of ordinary skill in the art would have expected that Eller's wire member would serve as a reasonable, if not superior, substitute for the U-shaped actuating members. For example, in a first position Schaffer's undepressed actuator buttons

would pull the wire member in opposing directions, placing tension on the wire member. *See* Ex. 1008 (Schaffer) at [0077]; Ex. 1010 (Eller) at 15:21-40, 17:47-18:3. This would cause the wire member to constrict and collapse the lumen of Schaffer's containment structure, sealing the valve. Then, when Schaffer's actuator buttons are depressed and moved to the second position, the compressive forces from the springs would be relaxed, relieving the tension on the wire member, and causing the wire member to loosen around the central lumen so that the lumen least partially opens. *See* Ex. 1008 (Schaffer) at [0077]; Ex. 1010 (Eller) at 15:21-40, 17:47-18:3. Schaffer discloses that the seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." Ex. 1008 (Schaffer) at [0054]. A person of ordinary skill in the art would have therefore expected that Schaffer's lumen would have the resilience to return to open configuration when the actuator buttons are pressed inwardly, and the tension on the wire member is released such that "no compressive force [] is applied" to the lumen." *Id.* Further, as I explained with respect to the Schaffer-Hartley ground, if the spring of Schaffer did not initially exert sufficient force to constrict the valve, a person of ordinary skill in the art would have reasonably expected success in adjusting the spring strength to exert more tension on the filament by, for example, changing the spring material or adjusting the springs coils. *Supra* §VIII.A.3.a.

Likewise, if the resiliency of Schaffer's lumen required adjustment to function with Eller's wire, a person of ordinary skill in the art would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. *Supra* ¶VIII.A.3.b. These similarities between Eller's wire member and Schaffer's U-shaped actuating members would have reinforced a person of ordinary skill in the art's reasonable expectation that Eller's wire member could be successfully implemented in Schaffer's valve.

c. **Schaffer's Seal Module Would Not Dissuade A Person Of Ordinary Skill From Combining Schaffer With Hartley's String or Eller's Wire**

275. I am aware that in related proceedings Patent Owner argues a person of ordinary skill in the art would not have been motivated to modify Schaffer's valve with Hartley's string or Eller's wire because Schaffer would not result in gaps because Schaffer discloses an exemplary embodiment with a "gelatinous" or "sticky" seal module with "selfclosing" properties. Ex. 1043 ('011 IPR, Patent Owner Response) at 46-52. I disagree for several reasons.

276. First, even Schaffer recognizes it may not form a complete seal with the "gelatinous" and "sticky" valves identified by Patent Owner, stating the valves form a "*nearly* fluid/gas tight seal." Ex. 1008 (Schaffer) at [0059] (emphasis added).

277. Second, Schaffer discloses that the “sticky” or “gelatinous” seal module is an optional feature for some embodiments, but it does not state or suggest that it is required for all embodiments, including the embodiment depicted in Figures 31-34. *See id.* at [0059], [0081]. Moreover, the portion of Schaffer that refers to a “sticky” or “gelatinous” substance refers to embodiments of the valve having three portions where one of the portions can optionally be made from a “sticky” or “gelatinous” substance having a specific “shore hardness.” *Id.* at [0059]. 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 clear that the valves in Figures 31-34 do not require three portions stating: “The seal module 100 is formed of one or more seal members, as discussed above.” *Id.* at [0075].

278. Third, 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 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.”).

279. A person of ordinary skill in the art would have understood that small gaps may form with Schaffer’s valve, particularly if the tool inserted through the valve does not match the size or shape of Schaffer’s U-shaped actuating members or if the members do not conform sufficiently to the size or shape of the tool inserted. Each of Schaffer’s U-shaped actuating members is secured to the actuator buttons at two fixed, spaced-apart points:

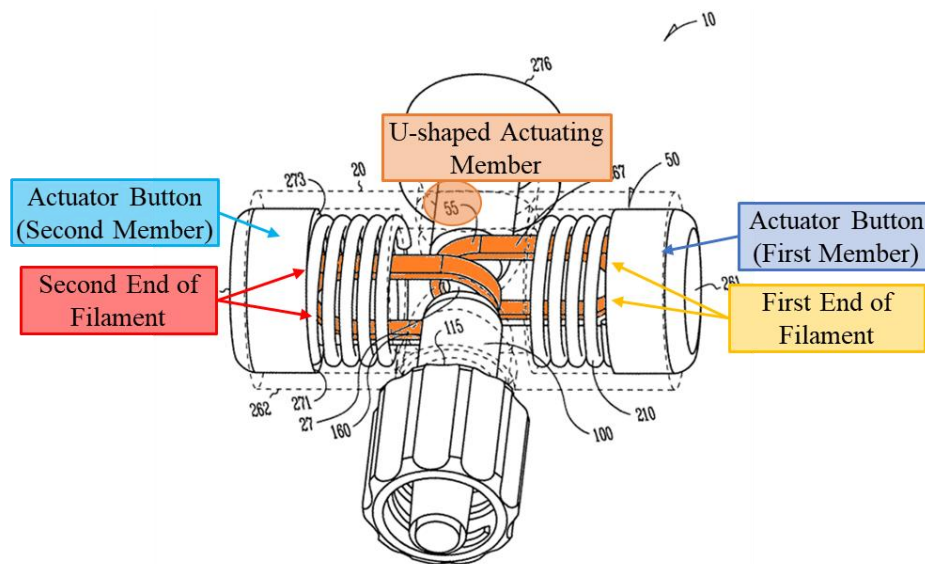
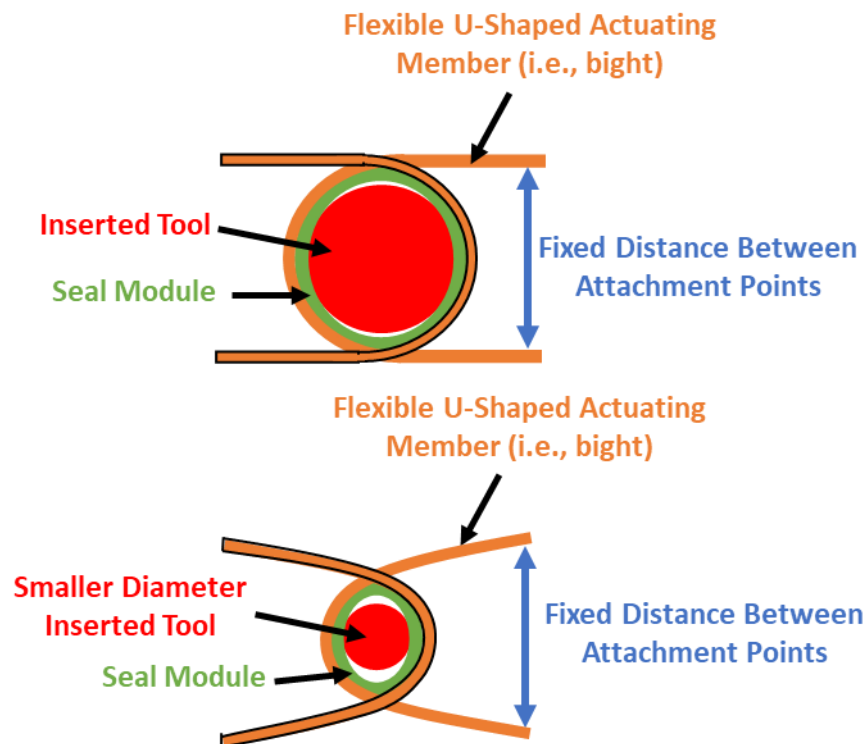
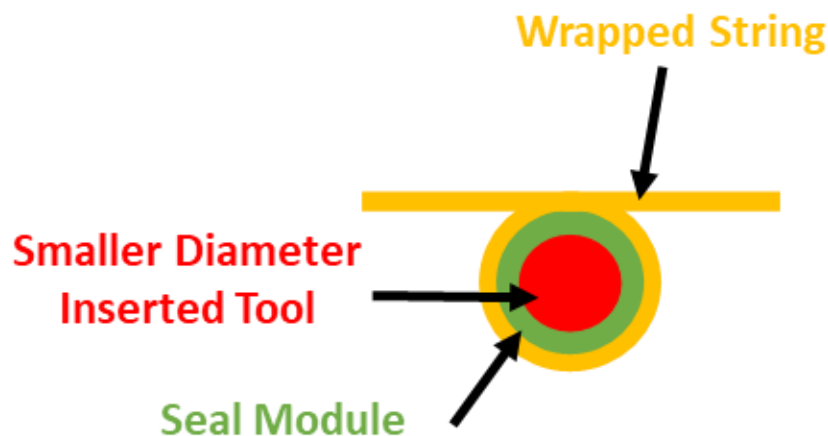


Fig. 31

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:

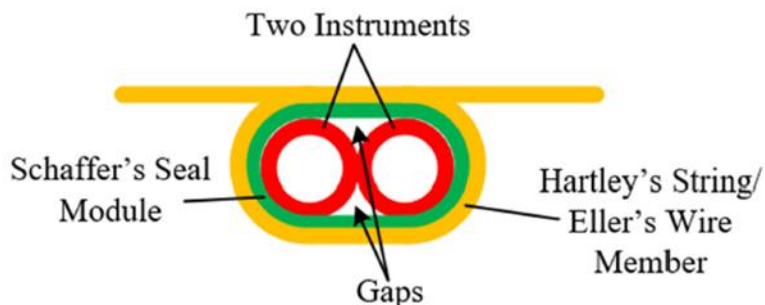


Because Hartley's string or Eller's wire would be wrapped around Schaffer's seal module with each respective end secured to the opposing actuator buttons, the string/wire member would be better able to conform to the varying diameter tools in this situation:



280. I am also aware that in the related IPR proceedings, Patent Owner argues that Schaffer’s valve with Hartley’s string or Eller’s wire would seal “less effectively” when two instruments are inserted through the valve. Ex. 1043 (’011 IPR, Patent Owner Response) at 51. Patent Owner cites to Schaffer’s disclosure of an embodiment with sealing member that is “so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped.” Ex. 1007 (Schaffer) at [0068]. This particular disclosure appears in the section of Schaffer referring to Figures 12-15 (not Figure 30-34), which describes a three-piece valve that closes as a result of “pressure from the antegrade flow 272,” not an actuator. *Id.* at [0068]-[0069]; *see also id.* at [0063] (referencing Figures 12-15). Clearly, this embodiment operates differently than the embodiment in Figures 30-34. *See id.* at [0069] (“While this arrangement may not be as friction-less as the other embodiments using an actuator 50, it may offer the advantages of ‘hands-free’

operation.”). Patent Owner also provides the following illustration as alleged support for its argument:



Ex. 1043 ('011 IPR, 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 was replaced with two U-shaped actuating members. Because of the non-compliant seal depicted in the illustration, the same gaps would exist with U-shaped actuating members. Accordingly, Patent Owner's illustration is not representative of Schaffer's valve and does not demonstrate that Schaffer's valve would work less effectively with a string.

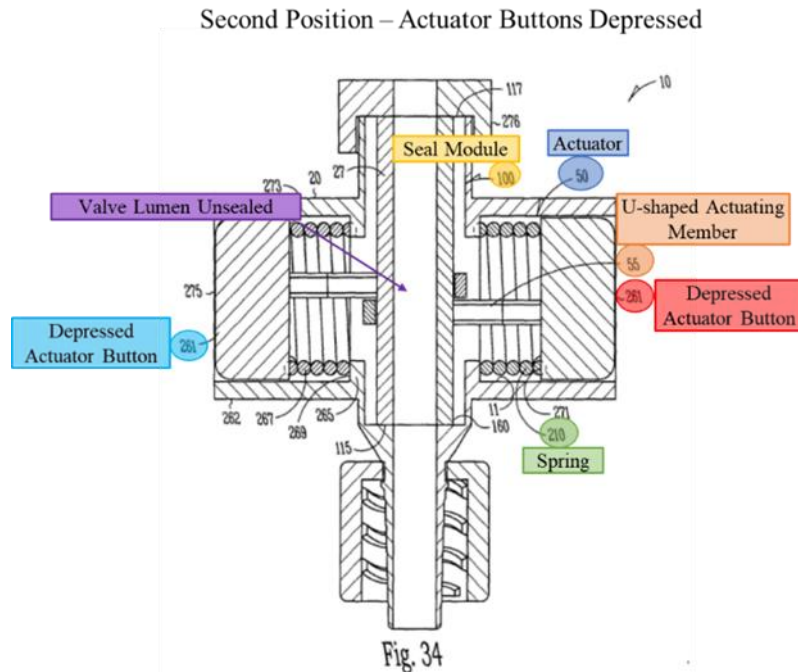
d. **Substituting Schaffer's U-Shaped Actuating Members With Hartley's String Or Eller's Wire Would Not Change Schaffer's Principles Of Operation**

281. I am aware that in the related IPR proceedings, Patent Owner and Dr. Zalesky assert that substituting Schaffer's U-shaped actuating members with

Hartley's string or Eller's wire would "change Schaffer's principles of operation." Patent Owner and Dr. Zalesky provide three rationales for why they believe this to be the case: (1) Hartley's string or Eller's wire would not "forcibly disengage" from Schaffer's seal module, (2) Hartley's string or Eller's wire would prevent "easy assembly" of Schaffer's valve, and (3) Hartley's string or Eller's wire would reduce the durability of Schaffer's valve. *See* Ex. 1043 ('011 IPR, Patent Owner Response) at 52-60; Ex. 1044 ('011 Zalesky Supp. Decl.) at §§VIII.E-F. I disagree with each of these assertions for the reasons I explain below.

i. **Hartley's String And Eller's Wire Would Not Prevent "Forcible Disengagement" From Schaffer's Seal Module**

282. I disagree with Patent Owner's contention that depressing Schaffer's actuator buttons would not allow Hartley's string or Eller's wire 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." Ex. 1008 (Schaffer) at [0077]. The description in Schaffer that the actuating members "forcibly disengage opposing outer walls of the seal module 100" does not mean that the actuating members do not remain in contact with the seal module. As shown in Figure 34, the actuating members are still in contact with the seal module 100 even after being forcibly disengaged:



Ex. 1008 (Schaffer) at Fig. 34. Rather, the term “forcibly disengage” refers to the act of applying force to the buttons to release the tension created by the actuating members on the seal module, which in turn allows the seal module “to retract to an uncollapsed configuration where gases and fluids can pass therethrough.” *Id.* at [0077], Fig. 34. Schaffer’s buttons move inwardly when force is applied, releasing tension on the actuating members (filaments) and allowing the seal module/tubular member to retract to an uncollapsed configuration, the exact same way that the 12-’333 patent’s filament does.

ii. **Hartley’s String And Eller’s Wire Would Not Prevent Assembly Of Schaffer’s Valve**

283. Patent Owner and Dr. Zalesky argue that Hartley’s string or Eller’s wire would “introduce assembly difficulties” to Schaffer’s valve and would prevent

assembly of the valve using the exemplary steps provided in paragraph 83 of Schaffer. I disagree.

284. First, I note that Schaffer does not claim to be easy to manufacture or assemble.

285. Second, Schaffer states that the assembly steps in paragraphs 82-83 are “one option” or “an example.” Ex. 1008 (Schaffer) at [0082]-[0083]. Schaffer does not state or suggest that the exemplary processes described in paragraphs 82-83 are the only way to assemble the valve.

286. Third, as I explained during my deposition in the Litigation, Hartley’s string and Eller’s wire would not have made Schaffer’s valve so much more difficult to manufacture that it would have discouraged a person of ordinary skill in the art from making the combination. A person of ordinary skill in the art would have known of many ways to assemble the valve with the string or wire member. For example, a tapered fixture could be used to introduce the seal module through the looped string/wire member that is already attached to the buttons. Alternatively, the seal module could be positioned in the valve and the string/wire member could be looped around the module, then the springs and buttons inserted before the string/wire member is attached to the buttons. Schaffer’s housing could also be formed from two detachable pieces, which would allow the internal components of the valve to be assembled prior to closing the housing. After the string/wire member

and seal module are assembled, the housing could then be secured through well-known means such as adhesives, screws, or clips.

287. Notably, the 12-'333 patent is silent on how its disclosed hemostasis valves can or should be assembled. The 12-'333 patent therefore presumes that it would have been within the capabilities of a person of ordinary skill in the art to determine how to assemble its valves. Thus, the 12-'333 patent is consistent with my opinion that a person of ordinary skill in the art would have known of many ways to assemble a hemostasis valve with a string or wire like the valve that would result from the combination of Schaffer and Hartley or Eller.

288. Fundamentally, Schaffer's valve uses simple, predictable components and a person of skill would have had ample training and experience to manufacture the valve using Hartley's string or Eller's wire member.

iii. Hartley's String Or Eller's Wire Member Would Not Weaken The Durability Of Schaffer's Valve

289. I disagree with Patent Owner's assertion that substituting Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member would weaken the durability of Schaffer's valve. Hartley and Eller use the string/wire for the same purpose they would be used in Schaffer's valve and neither suggests any issues with durability. In addition, a person of ordinary skill in the art in 2018 would have known of many durable materials that could be used to form a string or wire for use in a medical device, such as polypropylene or other suture material.

Accordingly, to the extent that a person of ordinary skill in the art was concerned about the durability of the valve, they could have simply used one of the known, durable materials to form the string. Durability concerns would not have dissuaded a person of ordinary skill in the art from substituting Schaffer's U-shaped actuating members with Hartley's string or Eller's wire.

290. I also note that the same durability concerns that Patent Owner raises for Hartley's string and Eller's wire member would apply equally to the filaments disclosed in the '931 Application allegedly incorporated by reference into the 12-'333 patent. Therefore, I do not believe that durability provides any basis to distinguish the 12-'333 patent from the prior art.

4. Motivation to Combine Garrison with Schaffer and Hartley or Eller

291. In my opinion, a person of ordinary skill in the art would have been motivated, and found it obvious, to use Schaffer's valve with Hartley's string or Eller's wire member with Garrison's aspiration systems for several reasons.

292. First, Garrison describes combining "an adjustable-opening valve" with its catheters. Ex. 1006 (Garrison) at [0062], [0065], [0098]. Schaffer discloses an adjustable-opening valve and, therefore, a person of ordinary skill in the art would have been motivated to combine, and would have reasonably expected success in combining, Schaffer's valve with Garrison based on Garrison's express suggestion to do so.

293. Second, Schaffer discloses that its hemostasis valve is intended “for use with catheters” and provides “a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” Ex. 1008 (Schaffer) at [0002], [0008]. Schaffer further discloses that a range of instruments can be used within the valve, such as “a catheter, guidewire, needle, or fiber.” *Id.* at [0056], [0074]. Thus, Schaffer’s valve would allow for tools to be inserted through Garrison’s proximal hub/adaptor 2065, as disclosed in Garrison, while preventing blood from leaking through the ports during the procedure.

294. Third, a person of ordinary skill in the art would have recognized that Schaffer’s hemostasis valve could simplify the operation of Garrison’s system. For example, Schaffer’s springs bias the valve to the closed position when no pressure is applied to the buttons, which would eliminate the need for the operator to manually seal or close the valve during a procedure. This feature could make the procedure simpler for the physician and save time during the procedure. A person of ordinary skill in the art would have therefore been motivated to implement Schaffer’s valve in Garrison’s system to achieve this benefit.

295. Fourth, combining Schaffer’s valve with the aspiration catheters Garrison would merely entail the combination of known elements (Schaffer’s valve and the aspiration catheter) according to known methods (attaching the valve to

Garrison's proximal hub/adaptor 2065). This combination would yield the predictable result of preventing or minimizing blood loss and preventing the introduction of air into the catheter. Combining known elements in such a predictable fashion would have been well within the level of ordinary skill in the art in January 2018.

296. Fifth, a person of ordinary skill in the art in January 2018 had a finite number of predictable hemostasis valves to choose from, including Schaffer's valve. A person of ordinary skill in the art would have found it obvious to try any of these hemostasis valves in combination with Garrison's system. Moreover, the known valves, including Schaffer's adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. I cannot see any technical reason that a person of ordinary skill in the art would not have been able to attach Schaffer's valve to the aspiration catheters in Garrison. For this additional reason, a person of ordinary skill in the art would have reasonably expected success in combining any of the known valves with Garrison.

B. Claim 22

297. Claim 22 recites the "clot treatment system of claim 17 wherein the hemostasis valve comprises: a tubular member defining a lumen; a first filament extending in a first loop around the tubular member; a second filament extending in a second loop around the tubular member; and a pair of actuators biased to

circumferentially constrict the first loop and the second loop to elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open.” Garrison combined with Goff or Lee and further combined with Schaffer and Hartley or Eller renders claim 22 obvious.

1. a tubular member defining a lumen

298. Schaffer discloses a hemostasis valve with a “tubular member defining a lumen” for the reasons I explained previously for Claim 18. *Supra* §VIII.A.1.

2. a first filament extending in a first loop around the tubular member [and] a second filament extending in a second loop around the tubular member

299. Schaffer in combination with Hartley or Eller renders obvious “a first filament extending in a first loop around the tubular member [and] a second filament extending in a second loop around the tubular member.”

300. As I discussed above, Schaffer discloses a valve having “two circular actuators 50” on opposite sides of the housing that are “movable from a first position to a second position”:

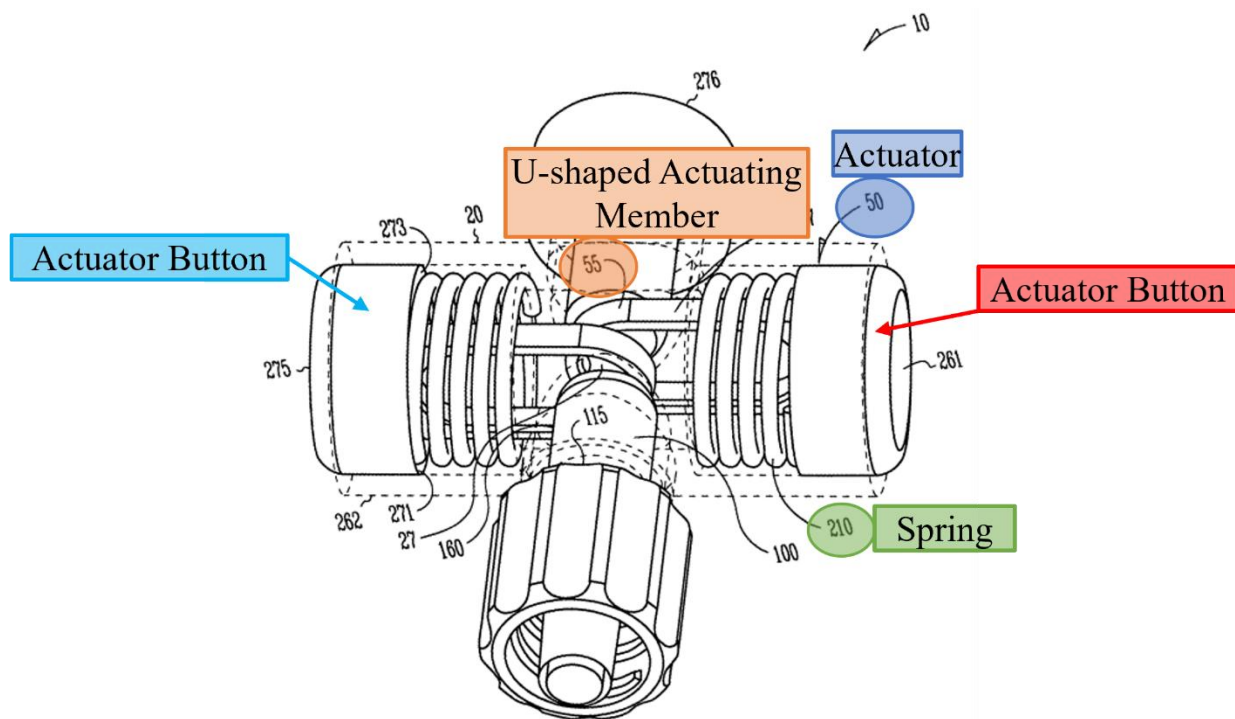
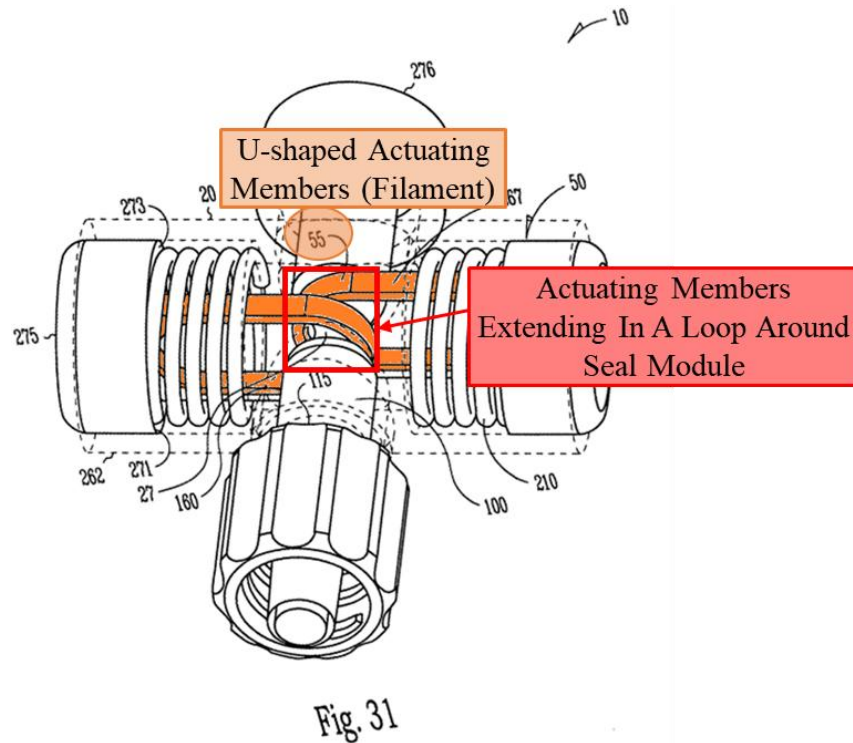


Fig. 31

Ex. 1008 (Schaffer) at [0075]-[0076], Figs. 31-32. Each actuator 50 includes “an actuator button 261” and a “spring 210.” *Id.* Schaffer’s valve also includes two actuating members, which may be U-shaped, coupled to the actuator buttons and forming a loop around the seal module 100 (tubular member):



Id. at [0076], Fig. 31.

301. As shown in Figure 31 of Schaffer above, Schaffer's configuration of its filament differs slightly from the filament configuration recited in Claim 22, which requires that each of the first and second filaments forms a loop around the tubular member. Schaffer's two u-shaped filaments collectively form a loop around the tubular member. However, as I explain below, the filament configuration recited in Claim 22 was not novel in 2018. Both Hartley and Eller disclose hemostasis valves with first and second filaments that form a loop around a collapsible tubular member, and a person of ordinary skill in the art would have been motivated to substitute Hartley's or Eller's filaments for Schaffer's U-shaped

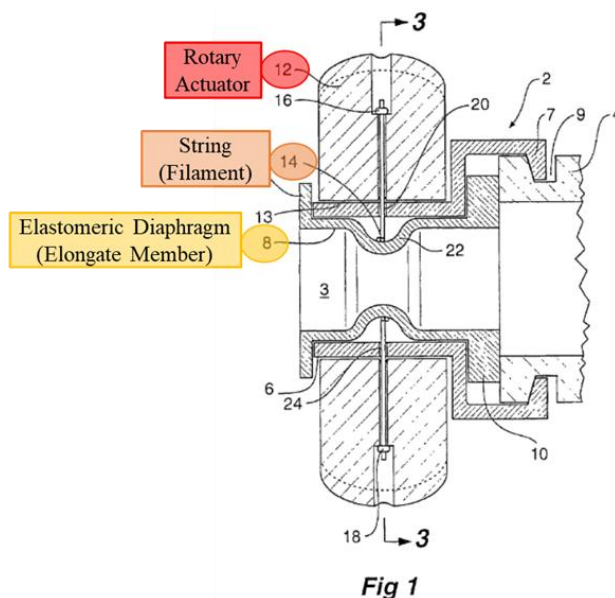
actuating members, and they would have had a reasonable expectation of success in doing so.

a. **Hartley**

302. Schaffer in combination with Hartley renders obvious a “first filament” and a “second filament” as recited in Claim 22 in two ways.

i. **Hartley’s String Includes Two Filaments**

303. *First*, Hartley describes a hemostasis valve having a cylindrical housing that holds a “cylindrical elastomeric diaphragm,” and a rotary actuator mounted to the housing:



Ex. 1009 (Hartley) at [0031], Fig. 1. Hartley’s valve includes a “string 14 ... mounted into the rotary actuator.” *Id.*

304. A person of ordinary skill in the art would have understood that Hartley’s string 14 would be formed from at least two threads twisted together. The

common understand of a string is a “material consisting of threads of cotton, hemp, or other material twisted together to form a thin length.” Ex. 1045; *see also* Ex. 1046. Therefore, Hartley’s string 14 is itself a “filament,” and each thread forming Hartley’s string is a “filament” as described by the ’931 application allegedly incorporated into the 12-’333 patent as well because each thread is at least one or more threads, lines, or cords. Ex. 1019 (’931 application) at [0046] (stating that the filament “can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”). I also note that each of the threads making up Hartley’s string would be a “filament” under the construction that Patent Owner proposed in the prior IPRs, which is “a thin, flexible length of material formed by one or more strands of material.” Accordingly, Hartley’s string 14 includes a “first filament” and a “second filament” as recited in Claim 22 of the 12-’333 patent.

305. Hartley discloses that the string “may be mounted at both of its ends to an actuator arrangement and hence the flexible member can be simultaneously pulled in substantially opposite directions to constrict the valve.” Ex. 1009 (Hartley) at [0010]. As shown in Figure 3 below, Hartley’s string is secured to the rotary actuator at a first end via knot 16 and “then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 ... and then passes through a further aperture 24 in the cylindrical housing before being fixed by knot 18 again in the rotary actuator”:

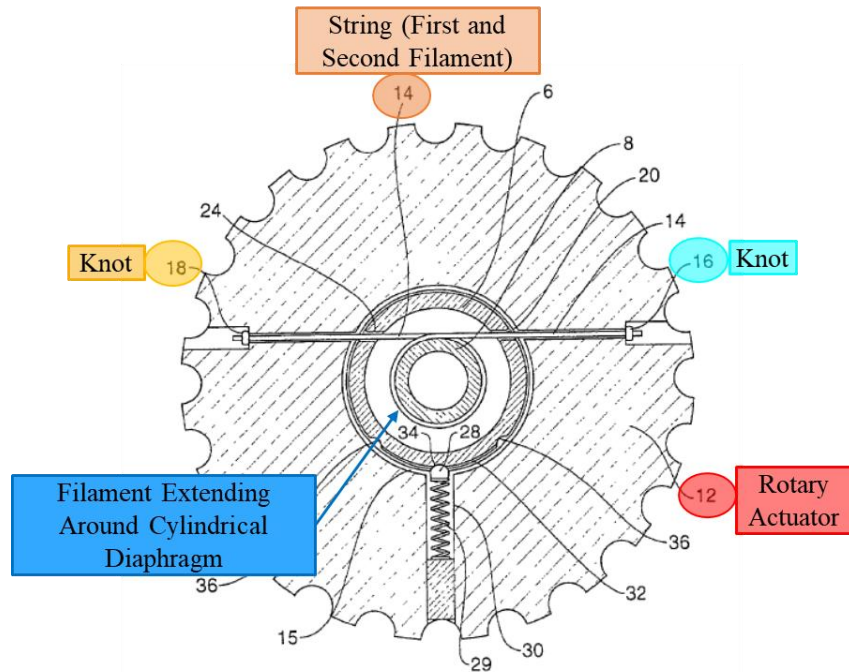


Fig 3

Id. at [0031], Fig. 3. Hartley’s string, and therefore each of the at least two filaments making up the string, is therefore formed into a loop around the “tubular member.”

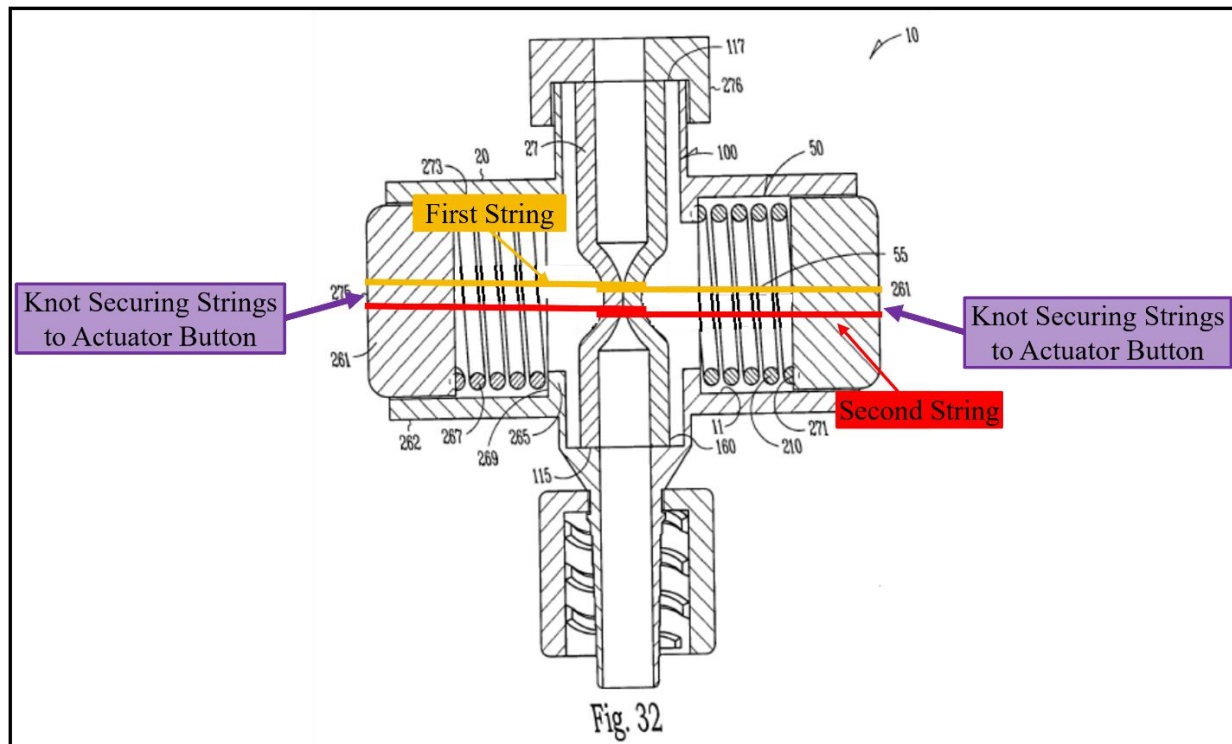
306. A person of ordinary skill in the art would have been motivated to substitute Hartley’s string for Schaffer’s actuating members, and would have reasonably expected success in doing so, for the reasons I explained previously for Claim 18. *Supra* §VIII.A.3. Further, Hartley discloses that winding the string around the central lumen forms an effective seal. Ex. 1009 (Hartley) at [0031], [0037]. Thus, when replacing Schaffer’s actuating members with Hartley’s string, a person of ordinary skill in the art would have been motivated to similarly wind Hartley’s string around Schaffer’s seal module. A person of ordinary skill in the

art would have reasonably expected success in using this configuration because Hartley teaches the configuration forms an effective seal.

ii. **A POSITA Would have been Motivated to Use Two of Hartley's Strings**

307. *Second*, if the Board concludes that Hartley's string does not constitute first and second filaments as recited in Claim 22, a person of ordinary skill in the art would have found it obvious to substitute two of Hartley's strings for Schaffer's two actuator members. Such a substitution can be seen in the figure below:

**Demonstrative Illustration
Schaffer + Hartley's String**



308. A person of ordinary skill in the art would have been motivated to use two of Hartley's strings when replacing Schaffer's u-shaped actuating members

based on Hartley's teachings and to create a more robust and reliable seal. Hartley discloses that its string "is wound preferably twice around the cylindrical diaphragm." Ex. 1009 (Hartley) at [0031]. A person of ordinary skill in the art exchanging Hartley's string for Schaffer's two u-shaped actuating members would have recognized that another way to create two loops (or windings) around the tubular member would have been to use two strings, each forming a single loop, as opposed to a single string wrapped twice around the tubular member. Hartley does not explain why the string would be "preferably" wound twice around the tubular member. However, a person of ordinary skill in the art would have understood that two loops of string would apply constricting force along a greater length of the tubular member, thereby creating a larger sealing area and a more robust seal.

309. A person of ordinary skill in the art would have been motivated to combine Hartley with Schaffer for the reasons I provided in the previous section. A person of ordinary skill in the art would have been motivated to use two separate strings, each wound or looped around the tubular member once, instead of a single string looped twice around the tubular member for several reasons. First, a person of ordinary skill in the art would have recognized that a single string looped twice around the tubular member would create more friction with the outer surface of the tubular member because more of the string is in contact with the surface of the tubular member. Because of the higher friction of the string against the tubular

member, the springs of Schaffer's valve would need to exert more pulling force to constrict the tubular member, and the tubular member would need greater resiliency to overcome the friction of the string and return to its expanded configuration. A person of ordinary skill would have been motivated to use two separate strings to form two separate loops to reduce the friction, which would reduce the force needed to operate the valve, while still accomplishing the same result (a larger sealing area).

310. Second, a person of ordinary skill in the art would have recognized that using two separate strings, each looped once around the tubular member, would allow the manufacturer to optimally space the strings to achieve the maximum sealing area. With only a single string, the loops formed by the string would tend to lie immediately next to each other on the outer surface of the tubular member, particularly after Schaffer's buttons have been depressed once or twice. However, with two strings, the manufacturer can design a small gap between the strings that remains after use to ensure that the sealing area is wider. A person of ordinary skill in the art would have recognized that a wider sealing area may be advantageous because it would create constrictive pressure over a larger area of the tools inserted through the valve.

311. Third, the second string would provide redundancy to the valve that cannot be accomplished with a single string. The second string would help ensure that the valve seals even if one of the strings were to fail to tighten around the

tubular member. This backup would not exist with a single string looped twice around the tubular member. Thus, the second string would add advantages not available with a single-string arrangement.

312. A person of ordinary skill in the art would have reasonably expected success in substituting Schaffer's two actuating members with two of Hartley's strings because Schaffer already discloses attaching two filament ends to each of its actuator buttons. Ex. 1008 (Schaffer) at [0075]-[0077], Figs. 30-34. In Schaffer's valve, both ends of each u-shaped actuating member are attached to the same actuator button on either side of the valve. *Id.* Thus, Schaffer already discloses that two filament ends can be secured to each of the buttons. *Id.* When Schaffer's actuating members are replaced with two of Hartley's strings, one end of each of the strings would be attached to each of the actuator buttons, resulting in two filament ends attached to each button. This is the same arrangement used for Schaffer's u-shaped actuating members, and a person of ordinary skill in the art would have therefore reasonably expected success implementing it for Hartley's strings.

313. In addition, as explained above, Hartley teaches using simple knots to attach the string to Hartley's rotary actuator. Ex. 1009 (Hartley) at [0031]. A person of ordinary skill in the art would have reasonably expected that similar knots would secure Hartley's strings to Schaffer's actuator buttons. For example, each end of

Hartley's strings could be threaded through small holes drilled or otherwise created in Schaffer's buttons and knotted on the other side. This simple modification would have been within a person of ordinary skill in the art's knowledge. Thus, Schaffer combined with Hartley discloses this limitation.

b. Eller

314. Schaffer combined with Eller renders the first/second filament limitations obvious in two ways.

i. Eller's Wire Member Includes Two Filaments

315. *First*, Eller discloses a hemostasis valve that includes "a housing 16, an actuator 18, a sleeve 20, a first wire member 22, a second wire member 24, [and] a third wire member 26":

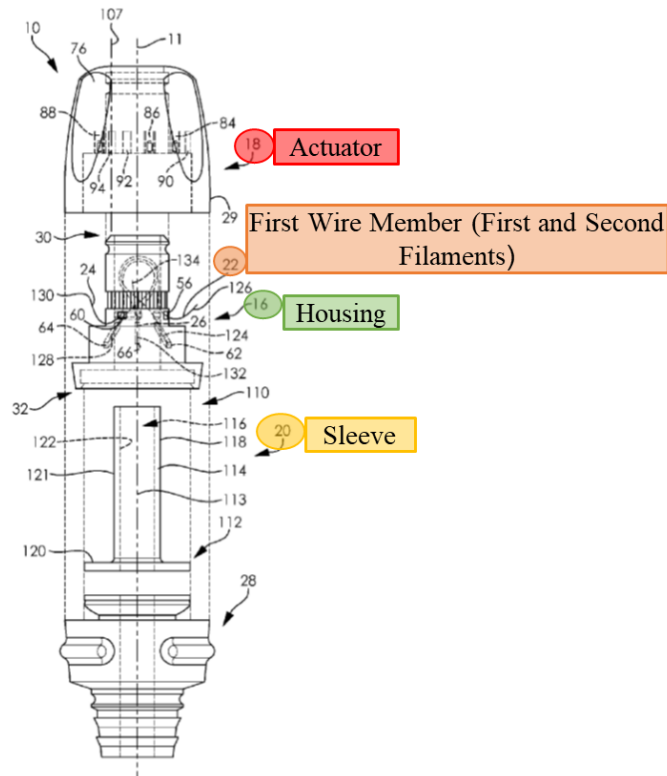


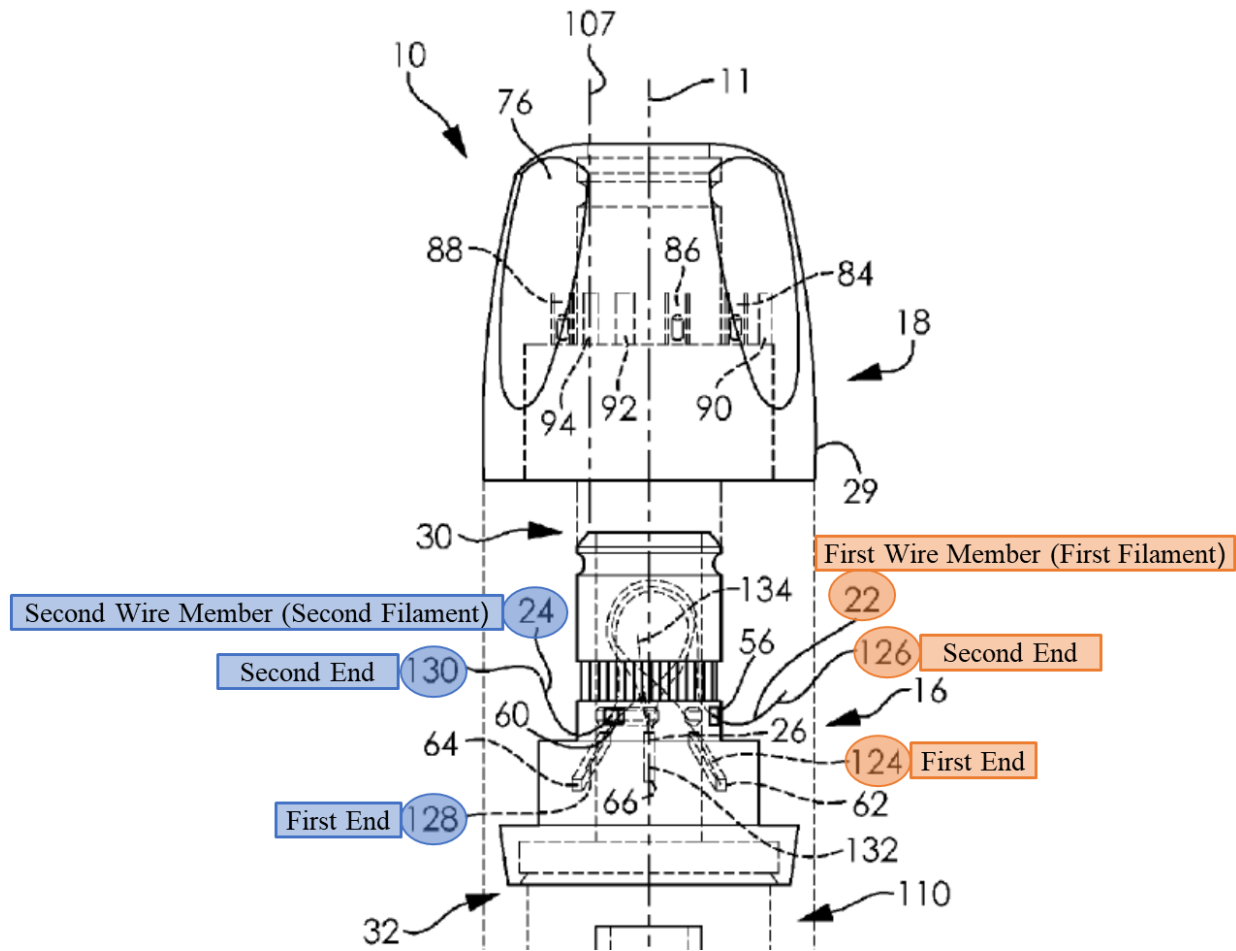
FIG. 2

Ex. 1010 (Eller) at 5:1-5, Fig. 2. Eller explains that its wire member “can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted, or otherwise interconnected to one another” and can comprise, for example, “a suture or a cable.” *Id.* at 15:61-16:6. Eller states that the wire member can be formed from various materials including “metals,” “polymers,” “polyester,” “nylon,” and “flexible materials. *Id.* at 15:41-60. A person of ordinary skill in the art would have therefore understood that each of the twisted “strands and/or fibers” making up Eller’s wire member would be a filament so that Eller’s wire member includes at least a first and second filament as recited in Claim 22 of the 12-’333

patent. Ex. 1019 ('931 application) at [0046] (stating that the filament “can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”).

316. I also note that each of the “strands and/or fibers” making up Eller’s wire member would be a “filament” under the construction that Patent Owner has proposed in prior IPRs, which is “a thin, flexible length of material formed by one or more strands of material.” Eller’s wire member therefore comprises a “first filament” and a flexible “second filament” as recited in Claim 22.

317. In some embodiments, Eller’s wire members each have a first end attached to the housing 16 and a second end attached to the actuator 18. Ex. 1010 (Eller) at 12:52-58. Eller discloses that the first wire member extends from its first end attached to the housing 16 and “around a portion of the outer surface 121 of the sleeve 20” to the second end attached to the actuator 18. *Id.* at 12:58-64. Figure 21 below illustrates the arrangement of the wire member around the outer surface of the sleeve:



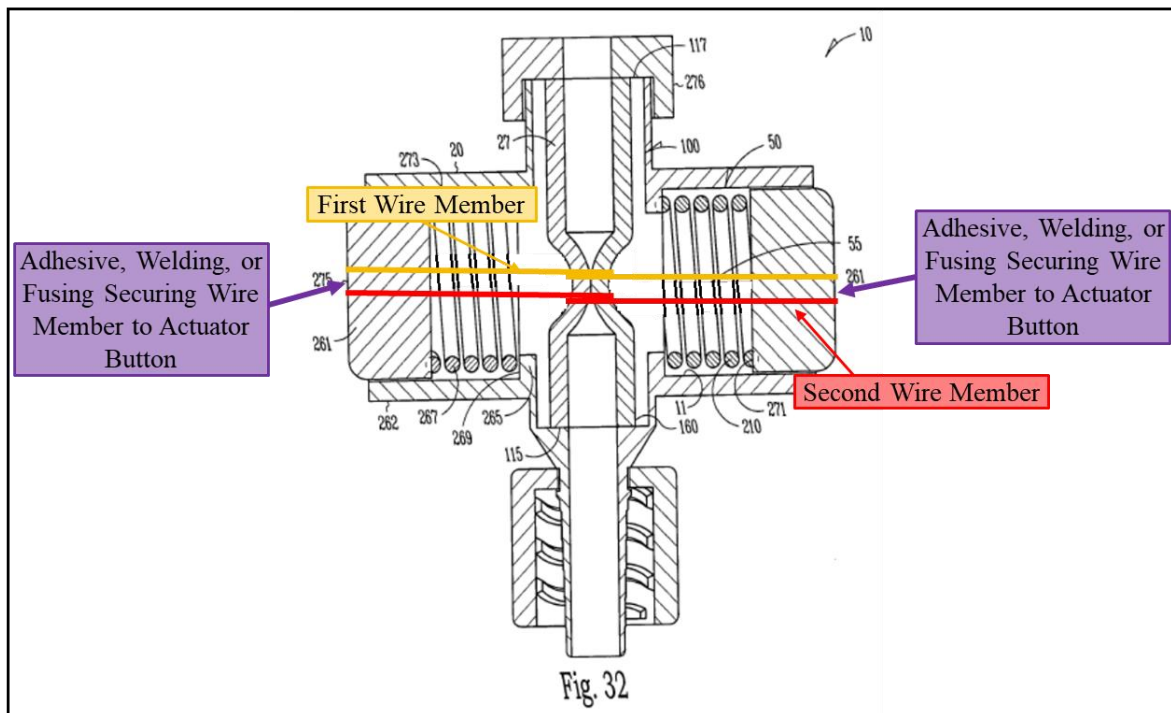
Id. at 24:50-57, Fig. 21. Eller further explains that the “wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.” *Id.* at 22:22-24. When replacing Schaffer’s actuating members with Eller’s wire member, a person of ordinary skill in the art would have been motivated to loop Eller’s wire member(s) at least one full revolution around Schaffer’s seal module to ensure the wires formed a constrictive seal. A person of ordinary skill in the art would have reasonably expected success in doing so because Eller encourages looping the wires one revolution around the sleeve and discloses that such a configuration forms a seal.

318. A person of ordinary skill in the art would have been motivated to substitute Eller's wire member for Schaffer's two actuating members, and would have reasonably expected success in doing so, for the reasons I explained previously for Claim 18. *Supra* §VIII.A.3.

ii. **A POSITA Would have been Motivated to Use Two of Eller's Wire Members**

319. *Second*, if the Board concludes that one of Eller's wire members does not constitute a "first filament" and a "second filament" as recited in Claim 22, a person of ordinary skill in the art would have found it obvious to substitute two of Eller's wire members for Schaffer's two actuator members. Specifically, a person of ordinary skill in the art would have found it obvious to substitute Schaffer's two actuating members with two of Eller's wire members by attaching one end of the first and second wire members to Schaffer's first button, looping the wire members around the seal module, and attaching the second end of the first and second wire members to Schaffer's second button:

Demonstrative Illustration Schaffer + Eller's Wire Member



320. A person of ordinary skill in the art would have been motivated to combine Eller with Schaffer for the reasons I provided in the previous section. *Supra* VIII.A.3. Further, Eller's teachings would have motivated a person of ordinary skill in the art to use two of Eller's wire members with Schaffer's valve. Eller states that its valve "can include any suitable number of wire members," including "one, at least one, *two*, a plurality, three, four, five, or any other number considered suitable for a particular embodiment." Ex. 1010 (Eller) at 16:7-19 (emphasis added). Eller also explains that "[s]killed 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.” *Id.* Eller’s statement is consistent with the skills and knowledge that a person of ordinary skill in the art would have possessed in January 2018. Accordingly, Eller expressly suggests varying the number of wire members (i.e., filaments) in a valve depending on the conditions of its use and confirms a person of ordinary skill in the art would have possessed the skills to make such routine adjustments.

321. In addition, combining two of Eller’s wire members with Schaffer’s valve would have entailed merely substituting one known element (Eller’s two wire members) for another (Schaffer’s two actuating members) to yield the predictable results of constricting and sealing Schaffer’s valve. A person of ordinary skill in the art would have been motivated to use two wire members with Schaffer’s valve to provide a more robust and reliable seal for the same reasons that I explained above with respect to Hartley (e.g., creating a larger sealing area, allow the manufacturer to optimally space the strings, adding redundancy to the system). *Supra* §VIII.A.3.

322. A person of ordinary skill in the art would have reasonably expected success in substituting two of Eller’s wire members for Schaffer’s actuating members for several reasons. First, as I explained above for Hartley, Schaffer already discloses a method of attaching two ends of a filament with each button. Ex. 1008 (Schaffer) at [0075]-[0077], Figs. 30-34. In Schaffer’s valve, both ends

of each u-shaped actuating member are attached to the same actuator button on either side of the valve. *Id.* Thus, Schaffer already discloses that two filament ends can be secured to each of the buttons. *Id.* When Schaffer's actuating members are replaced with two of Eller's wire members, one end of each of the wires would be attached to each of the actuator buttons, resulting in two filament ends attached to each button. This is the same arrangement used for Schaffer's u-shaped actuating members, and a person of ordinary skill in the art would have therefore reasonably expected success implementing it for Eller's wires.

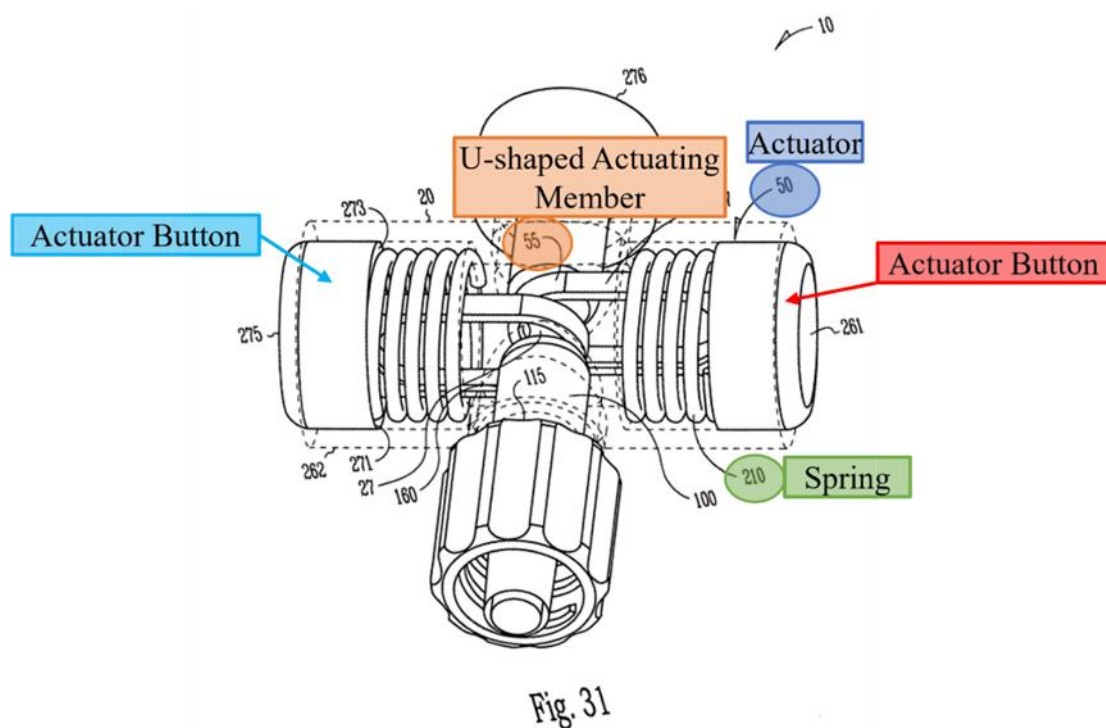
323. Second, as I explained above, Eller discloses that the “[a]ttachment between a wire member and a housing and/or an actuator can be accomplished using any suitable method or technique” and identifies several means for securing its wire members to an actuator. Ex. 1010 (Eller) at 14:37-49. A person of ordinary skill in the art would have reasonably expected success in securing Eller's wire members to Schaffer's actuator buttons using these simple methods.

3. **a pair of actuators biased to circumferentially constrict the first loop and the second loop to elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open**

324. Schaffer combined with Hartley or Eller renders obvious “a pair of actuators biased to circumferentially constrict the first loop and the second loop to

elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open.”

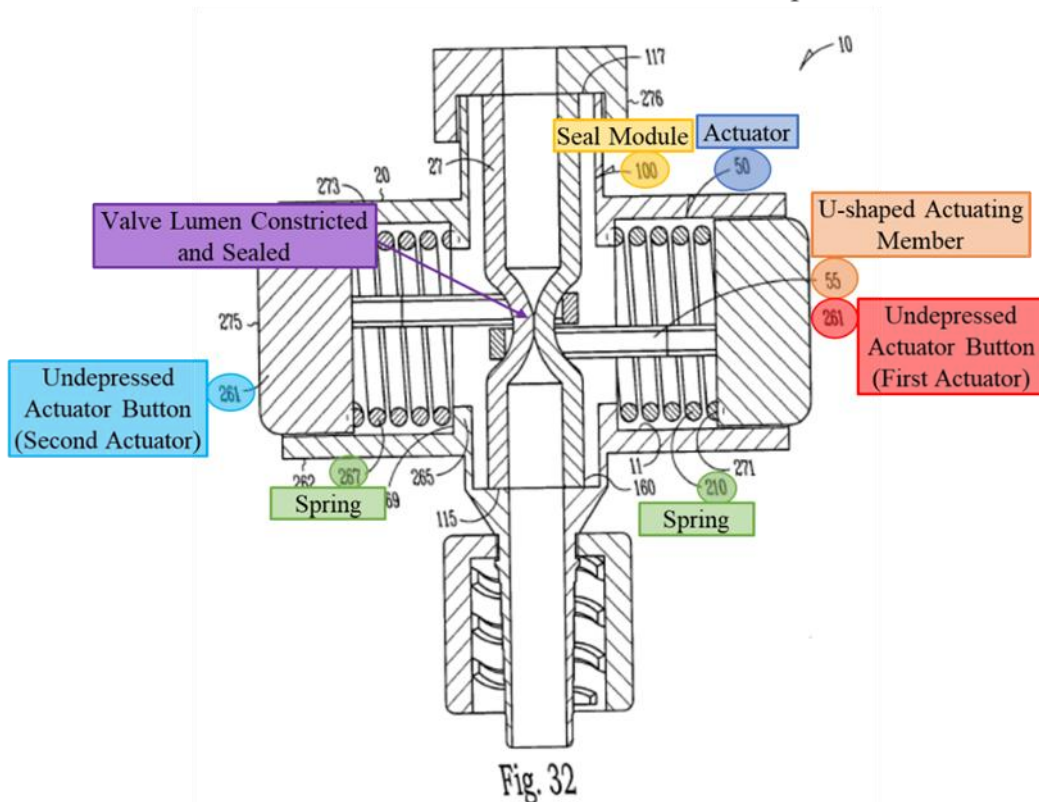
325. As I explained previously, Schaffer’s valve depicted in Figures 30-34, includes two spring-loaded actuators 50 that are “movable from a first position to a second position on opposing sides of the housing.” Ex. 1008 (Schaffer) at [0075]-[0076]. The actuators each include an actuator button 261 and a spring 210/267, as illustrated in Figure 32 below:



Id. at [0075]-[0076], Fig. 31.

326. Schaffer's actuators are movable from a first position in which the seal module is constricted to a second position in which the seal module is at least partially opened. Schaffer discloses that in a first position, the U-shaped actuating members are "at least partially circumferentially [sic] 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)." Ex. 1008 (Schaffer) at [0077]. This position is depicted in Figure 32, which shows that the central lumen constricted and sealed in the first position, when the buttons are undepressed:

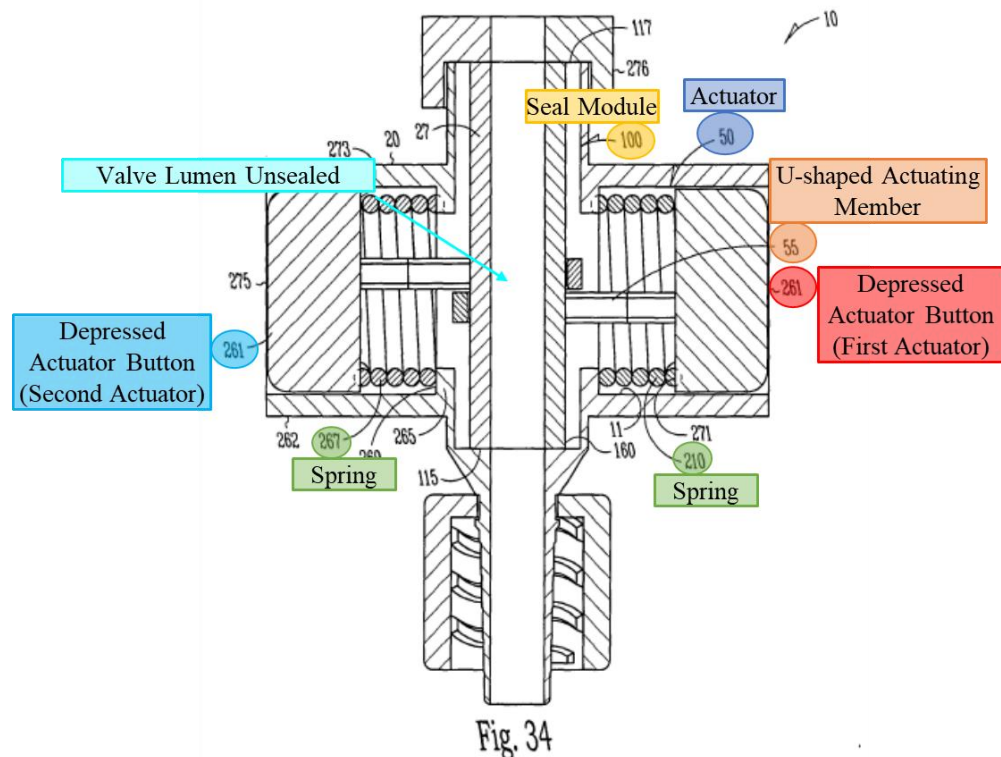
First Position – Actuator Buttons Undepressed



Id. at [0077], Fig. 32. Thus, Schaffer's springs bias the valve toward the first (closed) position when no force is being applied to the actuators.

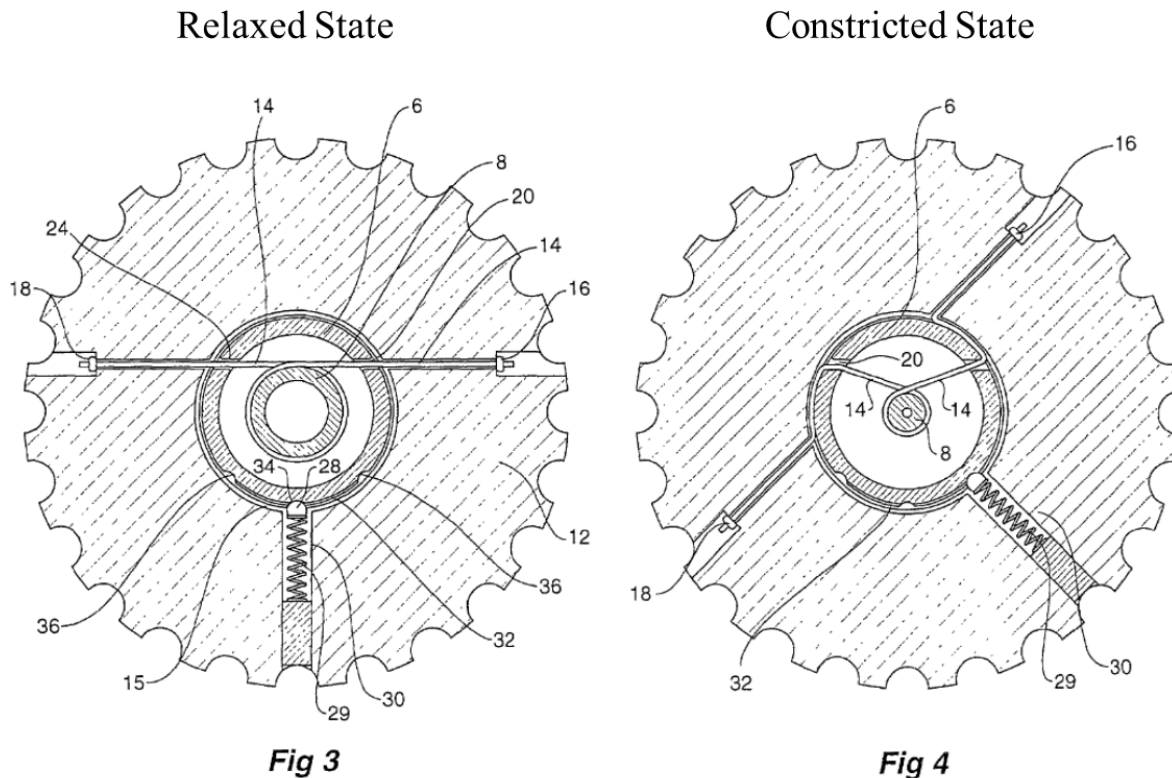
327. Schaffer then explains that in a second position, the actuator buttons are depressed, which compresses the spring and allows the actuator members to “forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough.” *Id.* The second position is illustrated in Figure 34:

Second Position – Actuator Buttons Depressed



Id. at [0077], Fig. 34.

328. Hartley discloses that “[r]otation 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.” Ex. 1009 (Hartley) at [0031], [0034], Fig. 4. In other words, tension placed on Hartley’s string by the actuator reduces the dimension of the loop around the cylindrical diaphragm constrict and seal the valve as shown, for example, in Hartley’s Figures 3 and 4:



Id. at Figs. 3-4. Eller similarly discloses that rotation of its actuator places the wire members under tension, which reduces the dimension of the wire loops around its sleeve and causes the wire members to constrict the sleeve to prevent fluid from passing therethrough. Ex. 1010 (Eller) at 15:21-40, 17:62–67.

329. Given these disclosures in Schaffer, Hartley, and Eller, a person of ordinary skill in the art would have understood that when Schaffer's actuating members are replaced with Hartley's strings or Eller's wire members, Schaffer's springs and actuators would be biased in a first position (i.e., when no force is applied to the buttons) to apply tension to the strings/wire members to decrease the dimensions of the loops formed by the strings/wire members around the seal members to circumferentially constrict and seal the valve. A person of ordinary skill would have further understood that when Schaffer's actuators are depressed to the second position, the tension on the strings/wire members would be relaxed as the buttons are depressed, which would loosen the strings/wire members and allow Schaffer's seal module to expand to an opened configuration.

C. Claim 23 – the actuators each comprise a button

330. Claim 23 recites the “clot treatment system of claim 22 wherein the actuators each comprise a button.” Garrison and Goff or Lee combined with Schaffer and Hartley or Eller renders Claim 23 obvious for the reasons explained for claims 18 and 22.

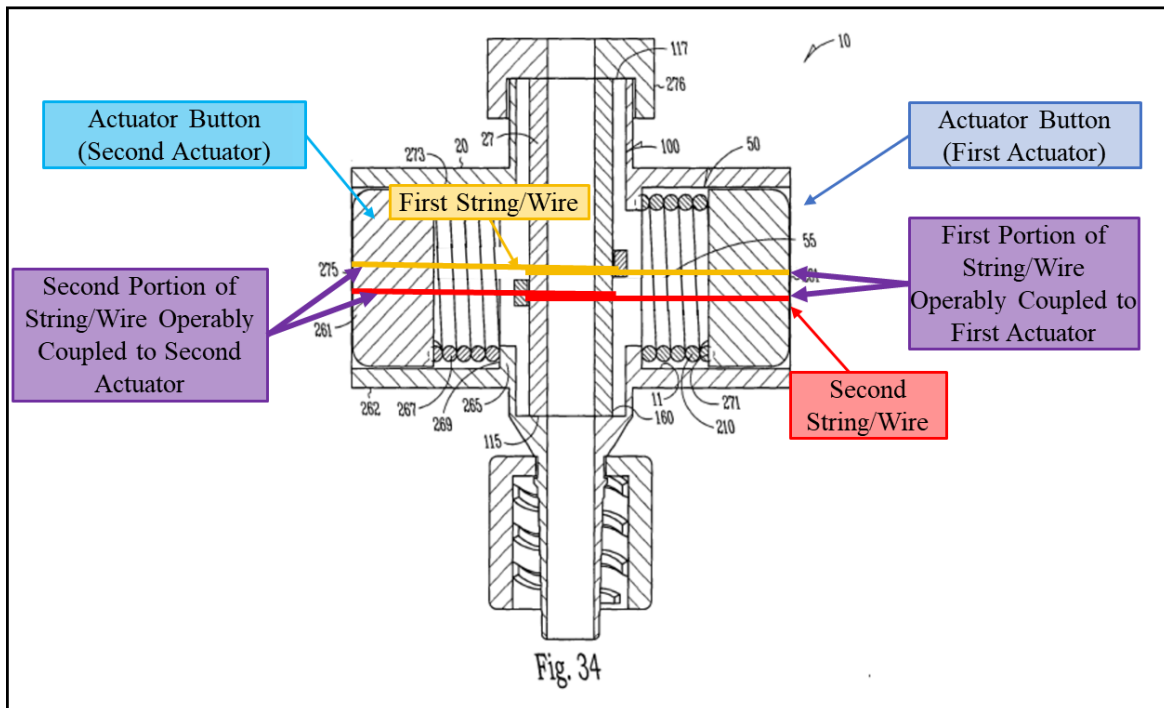
D. Claim 24 – the first filament includes a first portion operably coupled to a first one of the actuators and a second portion operably coupled to a second one of the actuators, and wherein the second filament includes a

first portion operably coupled to the first one of the actuators and a second portion operably coupled to the second one of the actuators

331. Claim 24 recites the “clot treatment system of claim 22 wherein the first filament includes a first portion operably coupled to a first one of the actuators and a second portion operably coupled to a second one of the actuators, and wherein the second filament includes a first portion operably coupled to the first one of the actuators and a second portion operably coupled to the second one of the actuators.” Garrison and Goff or Lee combined with Schaffer and Hartley or Eller renders Claim 24 obvious.

332. As I explained previously for Claim 22, a person of ordinary skill in the art would have been motivated to secure the first end of Hartley’s strings or Eller’s wires to a first one of Schaffer’s buttons using the conventional means taught by Hartley and Eller, including knots, adhesives, welding, or fusing. *Supra* §VIII.B. A person of ordinary skill would have similarly been motivated to secure the second end of Hartley’s strings or Eller’s wires to a second one of Schaffer’s buttons on the opposite side of the tubular member using similar means, as I’ve illustrated below:

Demonstrative Illustration Schaffer + Hartley's String/ Eller's Wire



Supra §VIII.B. Thus, when Schaffer's actuating members were replaced with Hartley's strings or Eller's wires, a first portion of the strings/wires would be attached to and "operably coupled to" the first one of Schaffer's actuators, and a second portion of the strings/wires would be attached to and "operably coupled to" by a second one of Schaffer's actuators.

E. **Claim 25 – the first filament is flexible, and wherein the second filament is flexible**

333. Claim 25 recites the "clot treatment system of claim 22 wherein the first filament is flexible, and wherein the second filament is flexible." Garrison and Goff or Lee combined with Schaffer and Hartley or Eller renders Claim 25 obvious.

334. Hartley describes its string as a “flexible member.” Ex. 1009 (Hartley) at [0017]. Thus, Hartley’s string is “flexible.”

335. Eller states that its wires may be formed from various materials such as “metals,” “polymers,” “polyester,” “[n]ylon,” and “flexible materials.” Ex. 1010 (Eller) at 15:41-65. Thus, Eller’s wires are “flexible.”

**IX. GROUNDS 9-10: CLAIMS 26-28 RENDERED OBVIOUS BY
GARRISON WITH GOFF OR LEE AND LAUB**

A. Claim 26 – the aspiration catheter has a size of at least 16 French

336. Claim 26 recites the “clot treatment system of claim 17 wherein the aspiration catheter has a size of at least 16 French.” Garrison and Goff or Lee combined with Laub renders Claim 26 obvious.

337. Garrison’s disclosure focuses on the “treatment of cerebral occlusions,” and Garrison discloses using catheters ranging from 5-10 French to treat cerebral clots. Ex. 1006 (Garrison) at [0002]. However, a person of ordinary skill in the art in January 2018 would have been motivated to use larger catheters with Garrison’s system, including catheters at least 16 French, to treat other types of clots, such as pulmonary embolisms and deep vein thrombosis, based on Laub.

338. Laub discloses “a system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient’s vasculature.” Ex. 1011 (Laub) at [0005]. Laub discloses that its system may be used “to remove clots from patients suffering from or at risk of pulmonary embolisms.” *Id.* Laub’s

Ex. 1011 (Laub) at [0024], [0039]-[0040], Fig. 1A. Laub discloses that “[i]n some embodiments, aspiration catheter 200 has a French size of at least 16 Fr.” *Id.* at [0028].

Laub's 16 Fr. catheters in Garrison's system to treat pulmonary embolisms because Laub explains that pulmonary embolisms are a harmful type of clot that can block blood flow to the lungs and cause death. Thus, a person of ordinary skill in the art

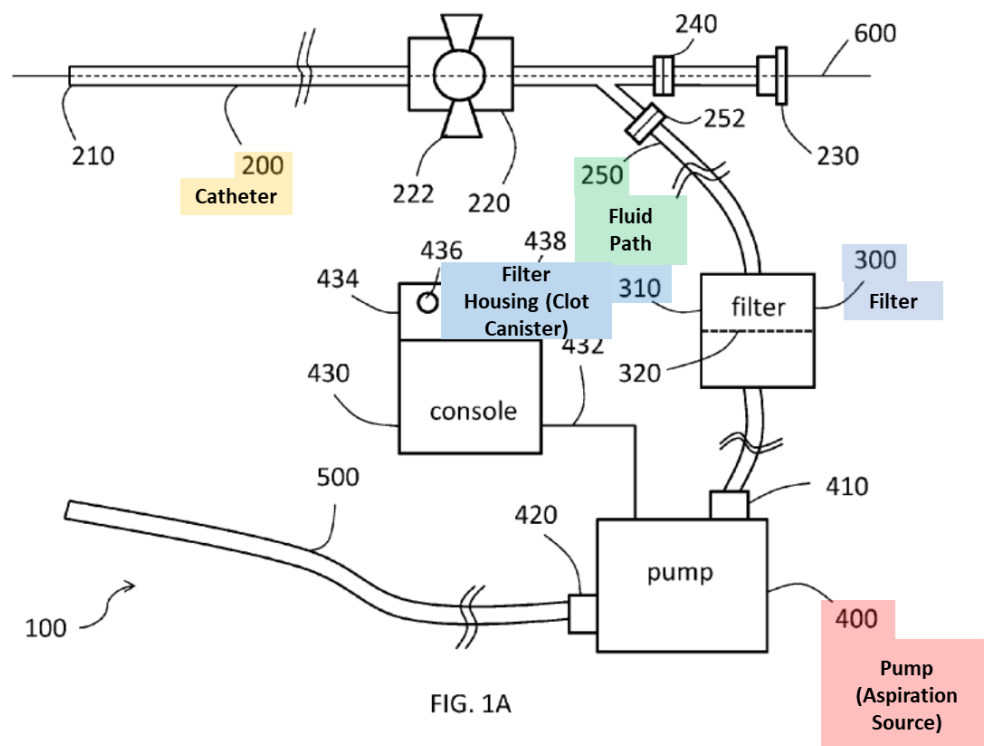


FIG. 1A

would have been motivated to use the existing and proven technology described in Garrison and Laub to treat pulmonary embolisms.

340. A person of ordinary skill in the art would have been further motivated to use Laub's 16 Fr. catheters in Garrison's system to treat pulmonary embolisms because Laub discloses that aspiration (like the aspiration disclosed in Garrison) can effectively remove the pulmonary embolism. Ex. 1011 (Laub) at [0005]. Moreover, the aspiration systems described in Garrison and Laub are similarly configured. As illustrated below, both systems include an aspiration catheter [orange] that is positioned proximate to the clot material prior to aspiration, an aspiration source (e.g., aspiration pump) [red], a filter [blue], and a flow line [green] fluidly coupling the aspiration catheter to the filter and aspiration source:

Garrison

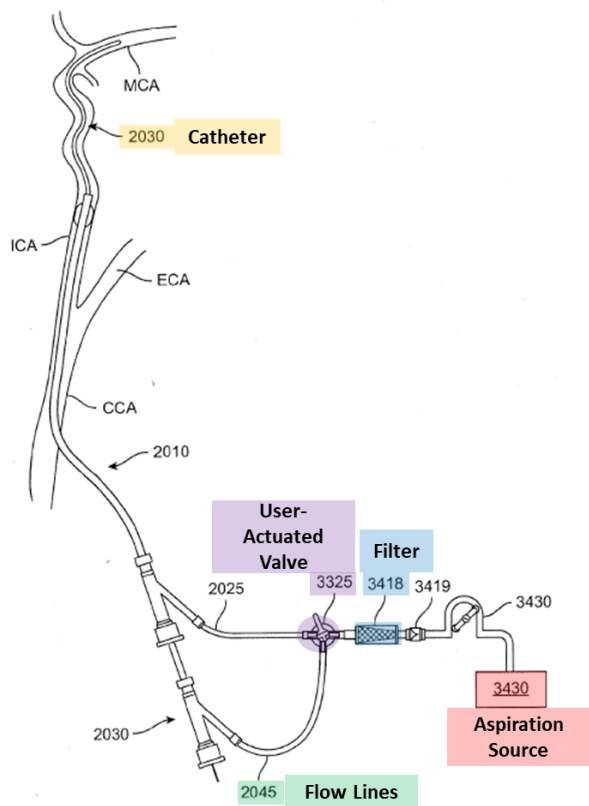


FIG. 34

Laub

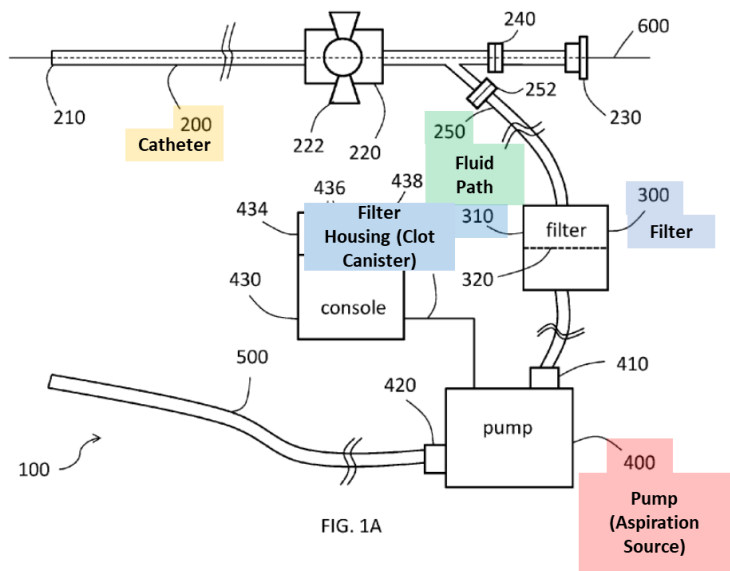


FIG. 1A

Ex. 1006 (Garrison) at [0131]-[0134], Fig. 34; Ex. 1011 (Laub) at [0024], [0039]-[0040], Fig. 1A.) Additionally, the systems are inserted into the patient in the same way (e.g., through an artery or vein). Ex. 1011 (Laub) at [0024] [0026] (describing that the catheter may be inserted into the patient's body via a vein or artery); Ex. 1006 (Garrison) at [0048] ("Disclosed also are methods and devices that optimize clot aspiration through either transfemoral or transcarotid access approaches."). A person of ordinary skill in the art would have reasonably expected success in using Laub's 16 Fr. catheters in Garrison's system to treat the conditions described in Laub, including PE, based on the similar system configurations, insertion locations, and methods of treatment.

341. A person of ordinary skill in the art in January 2018 would have known that some simple modifications to Garrison's system could optimize the system to treat other types of clots, such as pulmonary embolisms, depending on the specific location and size of the clot to be removed, such as increasing the size (i.e., diameter or French size) of the aspiration catheter (and related components), optimizing the flexibility and torque characteristics of the catheter, potentially adjusting the suction force, and adjusting the catheter strength to resist the suction force. Laub reflects that persons of ordinary skill in the art possessed the requisite knowledge to make such adjustments. For example, Laub discloses that its system can use aspiration catheters ranging from at least 5 to at least 20 Fr. and in some embodiments has a

catheter equal to or greater than 10 Fr. “to allow for aspiration of large thrombi and/or other solid materials from the patient.” Ex. 1011 (Laub) at [0028]. Thus, Laub presumes that a person of ordinary skill in the art possessed the requisite knowledge to make these simple modifications, and I agree with Laub’s presumption. In my own time overseeing engineers developing catheter-based medical devices, the engineers routinely optimized catheter size, flexibility, and torque as a standard part of the design process and would adapt catheters and other components for different sized vasculatures, depending on the location and tortuosity of the target vessel. Even Garrison discloses a range of possible sheath and catheter sizes for its system, further demonstrating that the size of the catheter was not novel or unique. Ex. 1006 (Garrison) at [0063] (describing 6 and 8 French size sheaths); [0070] (describing 10 French size sheaths). Simply put, a person of ordinary skill in the art in January 2018 possessed the necessary knowledge to select an appropriate catheter size for a given application and integrate that catheter into an aspiration system.

342. Laub also discloses systems and methods for reintroducing aspirated blood into the patient during procedures and explains that “returning the aspirated blood back to the patient ... allows for aspiration while minimizing the blood loss of the patient. In certain embodiments, reinfusing the patient's blood continuously during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4

L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible. Without returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient. Ex. 1011 (Laub) at [0045]. Garrison also describes the problem of aspirating excessive blood. Ex. 1006 (Garrison) at [0135]. To reduce blood loss, Garrison describes an “aspiration pump device 3250 which is configured not to harm blood cells and which may be configured to return blood to the central venous system in real time during the procedure, so there is no reservoir in which the blood remains static.” *Id.* at [0136]; *see also id.* at [0140], Fig. 38 (describing additional blood return variations). Thus, Garrison already addresses the primary challenge a person of ordinary skill in the art would have encountered in enlarging Garrison’s aspiration catheters. Consequently, it is my opinion that a person of ordinary skill in the art would have had a reasonable expectation of success in enlarging Garrisons’ catheters to 16 Fr. as taught by Laub.

343. As described above, it is my opinion that a person of ordinary skill in the art would have found it obvious to use Laub’s 16 Fr. catheters with Garrison’s aspiration system to remove the clot materials identified in Laub, including pulmonary embolisms, because the adaption would have been the predictable use of prior art elements (Garrison’s system and Laub’s 16 Fr. catheter) according to their established functions (aspiration of clot material). Based on my experience in

the field, I am aware that persons of ordinary skill in the art developing catheter-based medical devices in January 2018 regularly adapted innovations developed for one portion of the vasculature to treat another. For example, the references cited in this declaration illustrate the close relationship between clots and embolisms across the vasculature (e.g., pulmonary embolism, deep vein thrombosis (“DVT”), cerebral embolisms). This relationship is reflected in Laub, which recognizes that a thrombus can migrate to the vessels of the brain, causing stroke, or to the lungs, causing potentially fatal PE. Ex. 1011 (Laub) at [0004]. Consequently, a person of ordinary skill in the art developing treatments for clots in one part of the body would naturally consult innovations for treating clots in other parts of the body.

344. Garrison also specifically suggests combining components with its aspiration systems that come from aspiration systems for treating other parts of the vasculature. For example, Garrison states that “it may be desirable to incorporate features on the arterial access sheath in order to minimize flow resistance through the insertable portion of the access sheath.” Ex. 1006 (Garrison) at [0070]. Garrison incorporates by reference two patents for this purpose: (1) Chang (Ex. 1016), which describes “a method for treating lesions in the *carotid artery* of a mammalian body (*id.*, abstract (emphasis added)), and (2) Criado (Ex. 1017), which describes “[a] system for use in accessing and treating a *carotid artery*” (*id.*, abstract (emphasis added)).

345. Garrison also incorporates by reference several patents describing thrombectomy devices having aspiration catheters to remove thrombus. Ex. 1006 (Garrison) at [0144]. Many of these patents describe the use of aspiration catheters for parts of the vasculature outside of cerebral applications. For example, Garrison incorporates U.S. Patent No. 6,481,439, which describes methods of treating blocked or occluded blood vessels. Ex. 1018 (Lewis) at 3:15-17. While the reference primarily focuses on the treatment of a “catastrophic blockage of a cerebral artery,” the patent states that the “present invention, however, will also be useful for treating acute blockages in other portions of the vasculature as well as for treating chronic occlusions in the cerebral, cardiac, peripheral, mesenteric, and other vasculature.” *Id.* at 3:28-39. Garrison also incorporates U.S. Patent No. 5,938,645, which discloses “a device adapted to break up and extract clots or thrombi which may form within the *coronary artery* comprising an improved percutaneous aspiration thrombectomy catheter system.” Ex. 1014 (Gordon) at 1:17-20 (emphasis added). Thus, Garrison demonstrates that persons of ordinary skill in the art readily borrowed innovations for one part of the vasculature for another.

346. Garrison is not an outlier. Other prior art patents disclose aspiration systems intended for use across all portions of the vasculature. For example, Brady, a PCT patent application published in February 2018, describes “devices intended

for removing acute blockages from blood vessels.” Ex. 1020 (Brady) at 1:5; *see also id.* at 3:32 (“This invention improves the ability of a catheter to aspirate a clot fully.”). Brady states, “The invention is particularly suited to removing clot from *cerebral arteries* in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MY), and from pulmonary arteries in patients suffering from *pulmonary embolism* (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.” *Id.* at 1:13-17 (emphasis added).

B. Claim 27 – the aspiration catheter has a size of at least 20 French

347. Claim 27 recites the “clot treatment system of claim 17 wherein the aspiration catheter has a size of at least 20 French.” Garrison and Goff or Lee combined with Laub renders Claim 27 obvious.

348. Laub states that “[i]n some embodiments, aspiration catheter 200 has a French size of at least 20 Fr.” Ex. 1011 (Laub) at [0028]. A person of ordinary skill in the art would have been motivated to use Laub’s 20 Fr. catheters with Garrison’s system for the same reasons I explained previously for Claim 26. *Supra* §IX.A.

C. **Claim 28 – the aspiration catheter has a size of at least 22 French**

349. Claim 28 recites the “clot treatment system of claim 17 wherein the aspiration catheter has a size of at least 22 French.” Garrison and Goff or Lee combined with Laub renders Claim 28 obvious.

350. Laub states that “[i]n some embodiments, aspiration catheter 200 has a French size of ***at least*** 20 Fr,” which would include catheters that are 22 Fr. Ex. 1011 (Laub) at [0028] (emphasis added). A person of ordinary skill in the art would have been motivated to use Laub’s catheters that are “at least 20 Fr., including 22 Fr. catheters, with Garrison’s system for the same reasons I explained previously for Claim 26. *Supra* §IX.A.

X. **SECONDARY CONSIDERATIONS**

351. I am not aware of any secondary considerations of nonobviousness relating to the claims of the 12-’333 patent.

352. The methods and devices claimed in the 12-’333 patent are not new, and were invented long before January 2018. Therefore, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged inventions or copying of the alleged inventions by other companies. Many aspiration systems were available on the market by January 2018, and many of those

systems included the conventional components recited in the claims of the 12-'333 patent. *See, e.g., supra* §VII.A; ¶¶133-134 (discussing Goff and Garrison).

353. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

XI. CONCLUSION

354. For the foregoing reasons, it is my opinion that of Claims 1, 4-5, 7, 10-11, 13, and 15-28 of the 12-'333 patent are not patentable because they are anticipated by or would have been obvious in view of the prior art discussed above and the knowledge of one of ordinary skill in the art at the time of the alleged claimed inventions.

355. I reserve the right to supplement my opinions in the future to address or respond to any arguments that Patent Owner may raise, as well as new information, including, but not limited to, any claim constructions advanced by Patent Owner or adopted by the Board in the Institution Decision, and respond to any alleged secondary considerations as they become available to me.

356. I declare that the foregoing is true and correct, and further that the foregoing statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on January 16, 2026 in Glen Ellen, CA.

troy thornton

Troy Thornton