

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PENUMBRA, INC.
Petitioner

v.

RAPIDPULSE, INC.
Patent Owner

U.S. Patent No. 11,406,402

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,406,402**

TABLE OF CONTENTS

I.	Mandatory Notices Under 37 C.F.R. §42.8(a)(1).....	1
A.	Real Party-in-Interest under 37 C.F.R. §42.8(b)(1).....	1
B.	Lead and Back-Up Counsel under 37 C.F.R. §42.8(b)(3).....	1
C.	Service Information under 37 C.F.R. §42.8(b)(4)	2
II.	Claim Listing	3
III.	Introduction.....	8
IV.	Requirements Under 37 C.F.R. §42.104	8
A.	Grounds for Standing.....	8
B.	Priority Date	8
C.	Grounds	8
V.	the '402 Patent	9
A.	Background	9
B.	Prosecution History.....	10
VI.	Discretionary Considerations	10
A.	35 U.S.C. §314(a)	10
B.	35 U.S.C. §325(d)	10
VII.	Level of Skill	11
VIII.	Prior Art.....	12
A.	Yang (Ex[1012])	12
B.	Ofek (Ex[1007]).....	12
C.	Mullins (Ex[1008])	13
D.	Rubenstein (Ex[1011]).....	14
E.	Matteo (Ex[1013]).....	14
IX.	Claim Construction.....	15
A.	“limited/limiting... to a positive amount of exit flow”	15

X.	ARGUMENT.....	16
A.	Ground 1: Claims 1-8 and 10-20 Are Rendered Obvious by Yang in View of Mullins and the Knowledge of a POSA.....	16
B.	Ground 2: Claims 4-6 and 9-13 are Obvious Over Yang and Mullins in View of Rubenstein.....	53
C.	Ground 3: Claims 15 and 16 are Rendered Obvious Over Yang in View of Mullins, Matteo, and the Knowledge of a POSA.....	64
D.	Ground 4: Claims 1-8 and 10-20 are Rendered Obvious Over Ofek in view of Mullins and the Knowledge of a POSA.....	67
E.	Ground 5: Claims 5-6 and 18-19 Are Rendered Obvious Over Ofek in View of Mullins, Rubenstein, and the Knowledge of a POSA.....	103
F.	Ground 6: Claim 9 is Rendered Obvious Over Ofek in view of Mullins, Matteo, and the Knowledge of a POSA.....	106
I.	Secondary Considerations	107

EXHIBIT LIST

Exhibit No.¹	Description
1001	U.S. Patent No. 11,406,402 (“the ’402 Patent”)
1002	U.S. Provisional Application No. 62/701,086 (“Deville-Prov1”)
1003	U.S. Provisional Application No. 62/750,011 (“Deville-Prov2”)
1004	Prosecution File History of the ’402 Patent
1005	Expert Declaration of Brian Brown
1006	CV of Brian Brown
1007	U.S. Patent No. 10,322,230 (“Ofek”)
1008	U.S. Patent No. 11,197,977 (“Mullins”)
1009	Prosecution File History of U.S. Patent No. 11,197,977 (“Mullins”)
1009.1	U.S. Provisional Application No. 62/599,560 (“Mullins-Prov1”)
1009.2	U.S. Provisional Application No. 62/599,573 (“Mullins-Prov2”)
1009.3	U.S. Provisional Application No. 62/616,188 (“Mullins-Prov3”)
1010	International Application No. WO 2014/151209 A1 (“Grey”)
1011	U.S. Patent No. 3,955,574 (“Rubenstein”)
1012	U.S. Patent Publication No. 2017/0238953 A1 (“Yang”)
1013	U.S. Patent Publication No. 2012/0138833 A1 (“Matteo”)
1014	Patricia E. Thorpe & Francisco J. Osse, <i>Endovenous Management of Iliocaval Occlusion</i> , in THE VEIN BOOK, 2007 MECHANICAL THROMBECTOMY
1015	Dave Fornell, <i>Catheter-Based Clot Busting Therapies</i> , DIAGNOSTIC AND INTERVENTIONAL CARDIOLOGY (Feb. 4, 2013), https://www.dicardiology.com/article/catheter-based-clot-busting-therapies
1016	International Application No. WO 2018/019829 A1 (“Brady”)
1017	Gilles Rioufol, et al., <i>Large Tube Section Is the Key to Successful Coronary Thrombus Aspiration: Findings of a Standardized Bench Test</i> , 67 CATHETERIZATION &

¹ Citations to patents are made by column and line cite; citations to patent publications are made by paragraph number; citations to other exhibits are made with reference to the Bates-stamped pagination.

Exhibit No. ¹	Description
	CARDIOVASCULAR INTERVENTIONS 254-257 (Dec. 5, 2005), https://onlinelibrary.wiley.com/doi/10.1002/ccd.20471
1018	Michael Haude, <i>Mechanical Thrombectomy Catheter Systems</i> , 2 INTERVENTIONAL CARDIOLOGY 58-60 (2007), https://www.icrjournal.com/articles/thrombectomy-catheter-systems
1019	U.S. Patent No. 3,086,528 (“Eichelman”)
1020	U.S. Patent No. 3,659,605 (“Sielaff”)
1021	U.S. Patent No. 3,042,042 (“Blanck”)
1022	Scott Simon, et al., <i>Exploring the Efficacy of Cyclic vs. Static Aspiration in a Cerebral Thrombectomy Model: An Initial Proof of Concept Study</i> , 6 J. NEUROINTERVENT. SURG. 677 (Dec. 14, 2014)
1023	Expert Declaration of Ian Ross, MD
1024	CV of Ian Ross, MD
1025	U.S. Patent Publication No. 2010/0204672 A1 (“Lockhart”)
1026	U.S. Patent No. 4,634,435 (“Ingraham”)
1027	Stephan A. Munich, et al., <i>Overview of Mechanical Thrombectomy Techniques</i> , 85 NEUROSURGERY S60-S67 (June 14, 2019) https://academic.oup.com/neurosurgery/article/85/suppl_1/S60/5512732
1028	U.S. Patent No. 10,531,883 (“the ’883 Patent”)
1029	Prosecution File History of the ’883 Patent
1030	U.S. Patent No. 10,722,253 (“the ’253 Patent”)
1031	Prosecution File History of the ’253 Patent
1032	Troy D. Long, et al., <i>Novel Aspiration Catheter Design for Acute Stroke Thrombectomy</i> , 11 JOURNAL OF NEUROINTERVENTIONAL SURGERY 2 (July 30, 2018) https://jnis.bmj.com/content/11/2/190
1033	Richard E. Klabunde, <i>Viscosity of Blood</i> , CARDIOVASCULAR PHYSIOLOGY CONCEPTS (revised Dec. 27, 2022) https://cvphysiology.com/hemodynamics/h011
1034	U.S. Patent No. 9,820,761 (“Garrison”)

I. MANDATORY NOTICES UNDER 37 C.F.R. §42.8(a)(1)

A. Real Party-in-Interest under 37 C.F.R. §42.8(b)(1)

Penumbra, Inc. is the Petitioner and the real party-in-interest. No other parties exercised or could have exercised control over this Petition and no other parties funded or directed this Petition.

U.S. Patent No. 11,406,402 (“the ’402 Patent”) is a continuation of U.S. Patent Application No. 16/899,514, currently pending before the USPTO, which is a continuation of U.S. Patent No. 10,722,253 (“the ’253 Patent”), which is a continuation of U.S. Patent No. 10,531,883 (“the ’883 Patent”). The ’883 Patent and the ’253 Patent, were subject to IPR proceedings IPR2021-01466 and IPR2022-00608, respectively, in which all claims were found to be unpatentable for both patents. IPR2021-01466 and IPR2022-00608 are currently pending on appeal before the Federal Circuit in cases CAFC-2024-1130 and CAFC-2024-1131.

B. Lead and Back-Up Counsel under 37 C.F.R. §42.8(b)(3)

Petitioner provides the following designation of counsel.

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C. Service Information under 37 C.F.R. §42.8(b)(4)

A copy of this entire Petition, including all Exhibits and a Power of Attorney, is being served by FEDERAL EXPRESS, costs prepaid, to the address of the attorney or agent of record for Patent Owner at the USPTO for the '402 Patent, and to counsel for Patent Owner in the related cases pending on appeal before the Federal Circuit, CAFC-2024-1130 and CAFC-2024-1131:

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II. CLAIM LISTING

Limitation	Claim Language from '402 Patent
[1-Pre]	An aspiration thrombectomy system, comprising:
[1-A]	an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;
[1-B]	a vacuum source fluidically coupled to the catheter;
[1-C]	a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;
[1-D]	a vent valve fluidically coupled to the proximal portion of the catheter, the vent valve being configured to control a flow of a vent fluid in the catheter lumen; and
[1-E]	a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle
[1-F]	to change a level of vacuum at the distal end of the catheter
[1-G]	and to control fluid flow in and out from the distal end of the catheter.
Limitation	Claim Language from '402 Patent
[2-A]	The system of claim 1, further comprising a vent fluid source, and wherein:
[2-B]	the vent fluid source is configured to provide vent fluid at a pressure greater than atmospheric pressure; and
[2-C]	the controller is configured to cyclically open and close the vacuum valve and the vent valve
[2-D]	to change a level of negative pressure and positive pressure at the distal end of the catheter during each cycle.
Limitation	Claim Language from '402 Patent
[3-A]	The system of claim 2 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve
[3-B]	such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow... before fluid is drawn back into the catheter lumen.

[3-C]	limited to a positive amount of exit flow from approximately 0.001 ml to approximately 1.0 ml
Limitation	Claim Language from '402 Patent
[4-A]	The system of claim 2 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve
[4-B]	such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow... before fluid is drawn back into the catheter lumen.
[4-C]	limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml
Limitation	Claim Language from '402 Patent
[5-A]	The system of claim 1 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle
[5-B]	comprising an off-off state in which the vacuum valve is closed while the vent valve is closed.
Limitation	Claim Language from '402 Patent
[6-A]	The system of claim 1 wherein: the controller is configured to cyclically open and close the vacuum valve and the vent valve in a cycle comprising
[6-B]	(a) a first off-off state in which the vacuum valve is closed while the vent valve is closed, (b) a vacuum-only state following the first off-off state in which the vacuum valve is open while the vent valve is closed, (c) a second off-off state following the vacuum-only state in which the vacuum valve is closed while the vent valve is closed, and (d) a vent-only state following the second off-off state in which the vacuum valve is closed while the vent valve is open; and the cycle is repeated.
Limitation	Claim Language from '402 Patent
[7]	The system of claim 6 wherein the cycle is repeated at a frequency of 2 Hz to 12 Hz.
Limitation	Claim Language from '402 Patent

[8]	The system of claim 1 wherein the vacuum valve and the vent valve are solenoid pinch valves.
Limitation	Claim Language from '402 Patent
[9]	The system of claim 1 wherein the vacuum valve and the vent valve are cammed pinch valves.
Limitation	Claim Language from '402 Patent
[10-A]	The system of claim 1 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve
[10-B]	such that an amount of momentum transfer from the fluid column in the catheter lumen is sufficient to unstick thromboembolic material at the distal end of the catheter.
Limitation	Claim Language from '402 Patent
[11-Pre]	A method for removing thromboembolic material, comprising: aspirating thromboembolic material from a person using the system of claim 1 by—
[11-A]	(a) positioning the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person;
[11-B]	(b) applying a vacuum through the lumen of the catheter such that a vacuum flow draws at least a portion of the thromboembolic material into the catheter lumen; and
[11-C]	(c) controlling the vacuum valve fluidically coupled to the vacuum source and the catheter and the vent valve fluidically coupled to a vent fluid source and the catheter
[11-D]	such that a level of vacuum at the distal end of the catheter changes
[11-E]	and thereby controls flow in and out from the distal end of the catheter.
Limitation	Claim Language from '402 Patent
[12-A]	The method of claim 11 wherein: the vent fluid source is configured to provide the vent fluid at a pressure greater than atmospheric pressure; and
[12-B]	controlling the vacuum valve and the vent valve comprises cyclically opening and closing the vacuum valve and the vent valve

[12-C]	to change a level of negative pressure and positive pressure at the distal end of the catheter during each cycle.
Limitation	Claim Language from '402 Patent
[13-A]	The method of claim 12 wherein controlling the vacuum valve and the vent valve comprises limiting movement of a fluid column in the catheter lumen at the distal end of the catheter to a positive amount of exit flow
[13-B]	limiting... to a positive amount of exit flow within a range of a length of the fluid column that exits the distal end of the catheter.
Limitation	Claim Language from '402 Patent
[14-A]	The method of claim 13 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen... before fluid is drawn back into the catheter lumen.
[14-B]	such that the positive amount of exit flow is approximately 0.5 mm to approximately 30 mm of the fluid column
Limitation	Claim Language from '402 Patent
[15-A]	The method of claim 12 wherein controlling the vacuum valve and the vent valve comprises limiting movement of a fluid column in the catheter lumen at the distal end of the catheter to a positive amount of exit flow
[15-B]	limiting... to a positive amount of exit flow within a range of volume of fluid that exits the distal end of the catheter.
Limitation	Claim Language from '402 Patent
[16-A]	The method of claim 15 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen... before fluid is drawn back into the catheter lumen.
[16-B]	such that the positive amount of exit flow is approximately 0.001 ml to approximately 1.0 ml
Limitation	Claim Language from '402 Patent

[17-A]	The method of claim 15 wherein limiting movement of the fluid column at the distal end of the catheter comprises stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen... before fluid is drawn back into the catheter lumen.
[17-B]	such that the positive amount of exit flow is approximately 0.1 ml to approximately 0.5 ml
Limitation	Claim Language from '402 Patent
[18-A]	The method of claim 11, further comprising cyclically opening and closing the vacuum valve and the vent valve in a repeated cycle
[18-B]	including an off-off state in which the vacuum valve is closed while the vent valve is closed.
Limitation	Claim Language from '402 Patent
[19-A]	The method of claim 11, further comprising: cyclically opening and closing the vacuum valve and the vent valve in a cycle including
[19-B]	(a) a first off-off state in which the vacuum valve is closed while the vent valve is closed, (b) a vacuum-only state following the first off-off state in which the vacuum valve is open while the vent valve is closed, (c) a second off-off state following the vacuum-only state in which the vacuum valve is closed while the vent valve is closed, and (d) a vent-only state following the second off-off state in which the vacuum valve is closed while the vent valve is open; and repeating the cycle.
Limitation	Claim Language from '402 Patent
[20]	The method of claim 19 wherein the cycle is repeated at a frequency of 2 Hz to 12 Hz.

III. INTRODUCTION

Penumbra, Inc. (“Petitioner”) petitions for *inter partes* review of Claims 1-20 (collectively, “Challenged Claims”) of U.S. Patent No. 11,406,402 (“the ’402 Patent”), assigned to RapidPulse, Inc. (“Patent Owner” or “PO”). For the reasons discussed below, the Challenged Claims should be found unpatentable and canceled.

IV. REQUIREMENTS UNDER 37 C.F.R. §42.104

A. Grounds for Standing

Petitioner certifies that the ’402 Patent is eligible for *inter partes* review and that Petitioner is not barred or otherwise estopped.

B. Priority Date

The ’402 Patent was filed on February 11, 2022, and claims priority to two provisional applications, No. 62/701,086 filed on July 20, 2018 (“Deville-Prov1”) and No. 62/750,011 filed on October 24, 2018 (“Deville-Prov2”). Ex[1001], 1-2; *See* also Ex[1002]; Ex[1003]. PO bears the burden of showing entitlement to priority of the provisionals, but the relied-upon art predates those as well.

C. Grounds

Petitioner requests *inter partes* review of Claims 1-20 of the ’402 Patent under the following grounds.

Ground	Claims	Basis for Challenge
1	1-8 and 10-20	§103 – Obvious over Yang in view of Mullins
2	5, 6, 18, and 19	§103 – Obvious over Yang in view of Mullins and Rubenstein
3	9	§103 – Obvious over Yang in view of Mullins and Matteo
4	1-8 and 10-20	§103 – Obvious over Ofek in view of Mullins
5	5, 6, 18, and 19	§103 – Obvious over Ofek in view of Mullins and Rubenstein
6	9	§103 – Obvious over Ofek in view of Mullins and Matteo

V. THE '402 PATENT

A. Background

The '402 Patent is directed to aspiration thrombectomy systems, including catheters becoming clogged with blood clots and risks of distal migration of thrombi. Ex[1001], 1:43-3:22. The purported invention is the use of known vacuum aspiration systems and known catheters with known methods to “change a level of vacuum at the distal end of the catheter” and “control fluid flow in and out from the distal end of the catheter.” Ex[1001], Cl. 1. The '402 Patent admits that “Those of skill in the art know that these situations [of clogged catheters and forward flow] are to be avoided because of the serious potential risks to the patient.” Ex[1001], 2:35-37; Ex[1005], ¶¶49-65, 70-77; Ex[1023], ¶¶13-20.

B. Prosecution History

The '402 Patent had no office actions. Ex[1004]. Earlier applications in the patent family (e.g., U.S. Patent No. 10,531,883; U.S. Patent No. 10,722,253) had notable prosecution history. Prior IPR proceedings involving two of the parent patents to the '402 Patent resulted in invalidation of those claims. *See* IPR2021-01466; IPR2022-00608.

VI. DISCRETIONARY CONSIDERATIONS

A. 35 U.S.C. §314(a)

The factors identified in *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB, Sept. 6, 2017), do not provide a basis for denying institution. To Petitioner's knowledge, there is no prior petition challenging the validity of the '402 Patent, no litigation involving that patent, and no reason why the PTAB could not complete this review within a year of institution.

B. 35 U.S.C. §325(d)

None of the prior art references relied upon herein were substantively raised during prosecution. Yang, Rubinstein, and Matteo were cited in an IDS containing 266 references. However, the Board has declined to exercise its discretion under §325(d) based solely on a reference being cited in an IDS. *See, e.g., Microsoft Corp. v. Parallel Networks*, IPR2015-00486, Paper 10 at 15 (PTAB, 2015); *HTC Corp. v. Motiva Patents, LLC*, IPR2019-01666, Paper 9 at 6-10 (PTAB, 2020).

Additionally, Yang, Rubinstein, and Matteo were never considered in combination with the other references, or each other, as relied upon herein. The Examiner erred in allowing the challenged claims because they are unpatentable for the reasons set forth herein. Accordingly, the Board should not decline institution under 35 U.S.C. §325(d).

VII. LEVEL OF SKILL

A POSA at the relevant time would be either (1) a person with a B.S. in engineering or an equivalent field, with two-four years of academic or industry experience in aspiration embolectomy and thrombectomy or comparable industry experience who would, where appropriate, work or consult with others, including a physician, to develop embolectomy or thrombectomy devices; or (2) an interventional neurosurgeon with at least three years of experience developing and/or using medical devices in embolectomy or thrombectomy procedures, and who would, where appropriate, work or consult with others, including an engineer, to develop such a medical device. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard. Ex[1005], ¶48.

VIII. PRIOR ART

A. Yang (Ex[1012])

U.S. Patent Publication No. 2017/0238953 A1 (“Yang”) was filed on February 27, 2017, and published on August 24, 2017. Ex[1012], pg.1. Yang qualifies as prior art at least because it was published prior to the filing date of the ’402 Patent.

Yang is directed to an “aspiration catheter” Ex[1012], ¶¶[0065]-[0067]. Yang explains that “catheters of the present invention can readily be modified to incorporate additional structures.” Ex[1012], ¶[0063]. In particular, Yang discloses that the “aspiration catheter” can be implemented with an “aspiration [catheter] system configured to apply pulsatile negative pressure through the aspiration catheter.” Ex[1012], ¶¶[0029], [0063].

B. Ofek (Ex[1007])

U.S. Patent No. 10,322,230 (“Ofek”) was issued on June 18, 2019, from U.S. Patent Application No. 15/619,219 filed on June 9, 2017. Ex[1007], pg.1. Ofek qualifies as prior art at least because it issued before the effective filing date of the ’402 Patent and because it has an effective filing date earlier than that of the ’402 Patent.

Ofek is directed to medical devices for catheter assemblies. Ex[1007], Abs. Ofek teaches a system and method which “preserves patency of one or more lumens”

by providing “impulses of positive pressure” which includes “negative pressure” to “aspirate the occlusion.” Ex[1007], Abs.

C. Mullins (Ex[1008])

U.S. Patent No. 11,197,977 (“Mullins”) was filed March 13, 2020, and was issued on December 14, 2021. Ex[1008], pg.1. It is a continuation of International Application No. PCT/EP2018/085064 filed on December 14, 2018, which claims priority to U.S. Provisional Application 62/599,560 (“Mullins-Prov1”), filed December 15, 2017, U.S. Provisional Application 62/599,573 (“Mullins-Prov2”), filed December 15, 2017, and U.S. Provisional Application 62/616,188 (“Mullins-Prov3”), filed January 11, 2018. Ex[1009.1]; Ex[1009.2]; Ex[1009.3]. Mullins qualifies as prior art at least because it claims priority to Mullins-Prov1, Mullins-Prov2, and Mullins-Prov3, each of which were filed prior to the earliest effective filing date of the ’402 patent, and because everything disclosed in Mullins that is relied upon herein is fully supported by the Mullins provisional applications, as evidenced by the corresponding citations to the Mullins provisional below.

Mullins is directed to a catheter and accompanying aspiration system to help insure effective aspiration of a clot of thrombus. Ex[1008], Abs., 3:29-38; Ex[1009.1], ¶¶[0001]-[0023], FIGs.1-7; Ex[1009.2], pg.1-11, FIGs.1-10; Ex[1009.3], pg.1-4. Mullins teaches the aspiration system having a pump, a fluid reservoir, and tubing connected to a catheter, the system being capable of creating

both positive and negative pressure, and being programmed using a controller to cycle through both negative and positive pressures to aid in thrombus removal. Ex[1008], 3:29-4:11, 26:17-27:67, FIGs.46-49; Ex[1009.2], pg.4-9, FIGs.2-8.

D. Rubenstein (Ex[1011])

U.S. Patent No. 3,955,574 (“Rubenstein”) was filed on December 9, 1974, and issued on May 11, 1976. Ex[1011], pg.1. Rubenstein qualifies as prior art at least because it was issued prior to the earliest effective filing date of the ’402 Patent.

Rubenstein is directed to an “improved pumping system for use with catheter suction units.” Ex[1011], Abstract, 1:7-14. Rubenstein discloses applying cyclical reversals of positive and negative pressure to create a “self-cleaning” catheter that can clear clogs at the catheter tip. Ex[1011], 1:10-68.

E. Matteo (Ex[1013])

U.S. Patent Publication No. 2012/0138833 (“Matteo”) was filed on December 2, 2010, and published on June 7, 2012. Ex[1013], pg.1. Matteo qualifies as prior art at least because it was published prior to the earliest effective filing date of the ’402 Patent.

Matteo is directed to a microfluidics system with for use in a variety of chemical, biological, and biomedical applications, including “medical and scientific instrumentation.” Ex[1013], Abstract, ¶¶[0006], [0012], [0029], FIGs.11-12. Matteo

discloses that “[c]am-driven pinch-style microvalves are useful for serving as on/off valve devices for a microfluidic system.” Ex[1013], ¶[0010].

IX. CLAIM CONSTRUCTION

For terms not explicitly construed below, Petitioners interpret them for this proceeding in accordance with their ordinary and customary meaning.²

A. “limited/limiting... to a positive amount of exit flow”

Claims 3-4, 13, and 15 recite “[limited / limiting] to a positive amount of exit flow,” with certain claims specifying threshold exit flow values. Ex[1001], Claims:3-4, 13, 15-17. specify values for the total permitted exit flow.

The ’402 Patent does not define or describe “[limited / limiting] to a positive amount of exit flow.” The specification uses “exit flow” once (*cf.* “forward flow”), and provides no further details on what “limiting” the “exit flow” entails:

When the controller is actuated, a positive amount of exit flow is created without possibility of overshooting. The exiting movement of fluid is limited to a specific volume and/or pressure and is automatically and precisely controlled.

Ex[1001], 4:50-54. Based on this disclosure, the claim language, and the stated purpose of the alleged invention (i.e., prevent “sending thrombi further distally in the vasculature”), a POSA would have understood “limiting” the “positive amount

² Petitioners do not concede that the terms of the challenged claims satisfy 35 U.S.C. §112.

of exit flow” as the threshold value, or range of threshold values, of total positive exit flow that cannot be exceeded. Ex[1005], ¶¶78-82; Ex[1001], 4:50-54, 24:36-25:26.

Accordingly, a POSA would have understood the term to mean the maximum permitted amount of positive exit flow in the distal direction, including no exit flow.

X. ARGUMENT

A. Ground 1: Claims 1-8 and 10-20 Are Rendered Obvious by Yang in View of Mullins and the Knowledge of a POSA

Motivation to Combine

A POSA would have been motivated to combine the teachings of Yang and Mullins. Ex[1005], ¶¶96-103. Both Yang and Mullins address similar problems related to conventional aspiration thrombectomy, and share the common objective of improving the efficiency of removing blood clots. Both teach similar solutions involving using a positive pressure state to provide cyclical changes in pressure to efficiently remove blood clots.

Both Yang and Mullins comment on the limitations and risks associated with traditional methods to treat ischemic strokes. Both discuss clogged catheters and the limitations of static aspiration technologies for controlled clot aspiration. Ex[1005], ¶97; Ex[1012], ¶¶[0008]-[0009], [0014], [0085], [0148], [0166]; Ex[1008], 25:22-26:16, 28:27-37; Ex[1009.2], pg.2-9. Both describe a similar approach of creating a dynamic aspiration force to more effectively clear clots in a blood vessel.

Ex[1005]¶98; Ex[1012], ¶¶[0014], [0067], [0091], [0123]-[0128], [0131], [0135]-[0136], [0168]-[0170]; Ex[1008], 1:53-2:2, 26:43-49, 26:65-27:17. Both utilize an aspiration thrombectomy system to vary fluid flow and pressure to at least partially cyclically relieve the system's vacuum pressure to create an acceleration force on the clot for optimal clot aspiration. Ex[1005], ¶98; Ex[1012], ¶¶[0123]-[0128], [0131], [0135], [0168]-[0170]; Ex[1008], 3:29-38, 3:46-59, 26:31-37; Ex[1009.2], pg.2-10.

Combining the teachings of Yang and Mullins would have been well within the skill of a POSA, because it is nothing more than combining known vacuum aspiration technologies described in these references to perform their intended functions with described benefits and predictable results. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007); Ex[1005], ¶99.

A POSA would have been motivated to implement Mullins's disclosures of forward flow and improvements in unsticking clots to modify Yang's system, which already includes a catheter aspiration system, to provide efficient and effective cyclical aspiration of blood clots. Ex[1005], ¶100; Ex[1012], ¶¶[0131], [0168]-[0170]; Ex[1008], 3:29-4:11, 26:17-28:64. A POSA would recognize Yang could be configured to achieve the benefits, as taught by Mullins, of cyclical pressure changes, including the use of a pressure sensor. Ex[1005], ¶100; Ex[1012], ¶¶[0103],

[0123], [0131], [0168]-[0170]; Ex[1008], 3:29-4:11, 26:17-27:675; Ex[1009.2], 2-10.

A POSA would have had a reasonable expectation of success in combining Yang and Mullins. Because Yang's system is already computer-controlled, it would have been well within a POSA's level of skill to modify the logic of Yang's controller to implement Mullins's teachings, and/or to incorporate well-known mechanical components, if needed, to carry out the functionality described in Mullins. Ex[1005], ¶101. Moreover, Mullins simply modulates pressures contained within the aspiration system, which is consistent with Yang's pressure cycles. Ex. 1005, ¶101.

Furthermore, a POSA would have recognized the benefit to Yang's system of monitoring vacuum pressure levels at the distal tip of the catheter, as taught in Mullins. Ex[1005], ¶102. Ex[1008], 3:29-59, 6:34-36, 26:12-64; Ex[1009.2], pg.2-10.

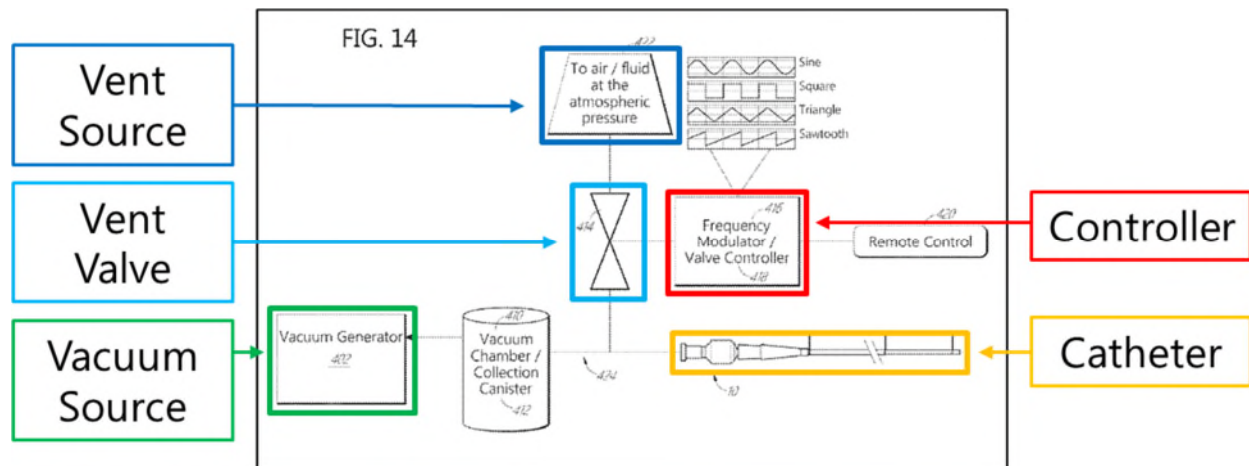
Claim 1

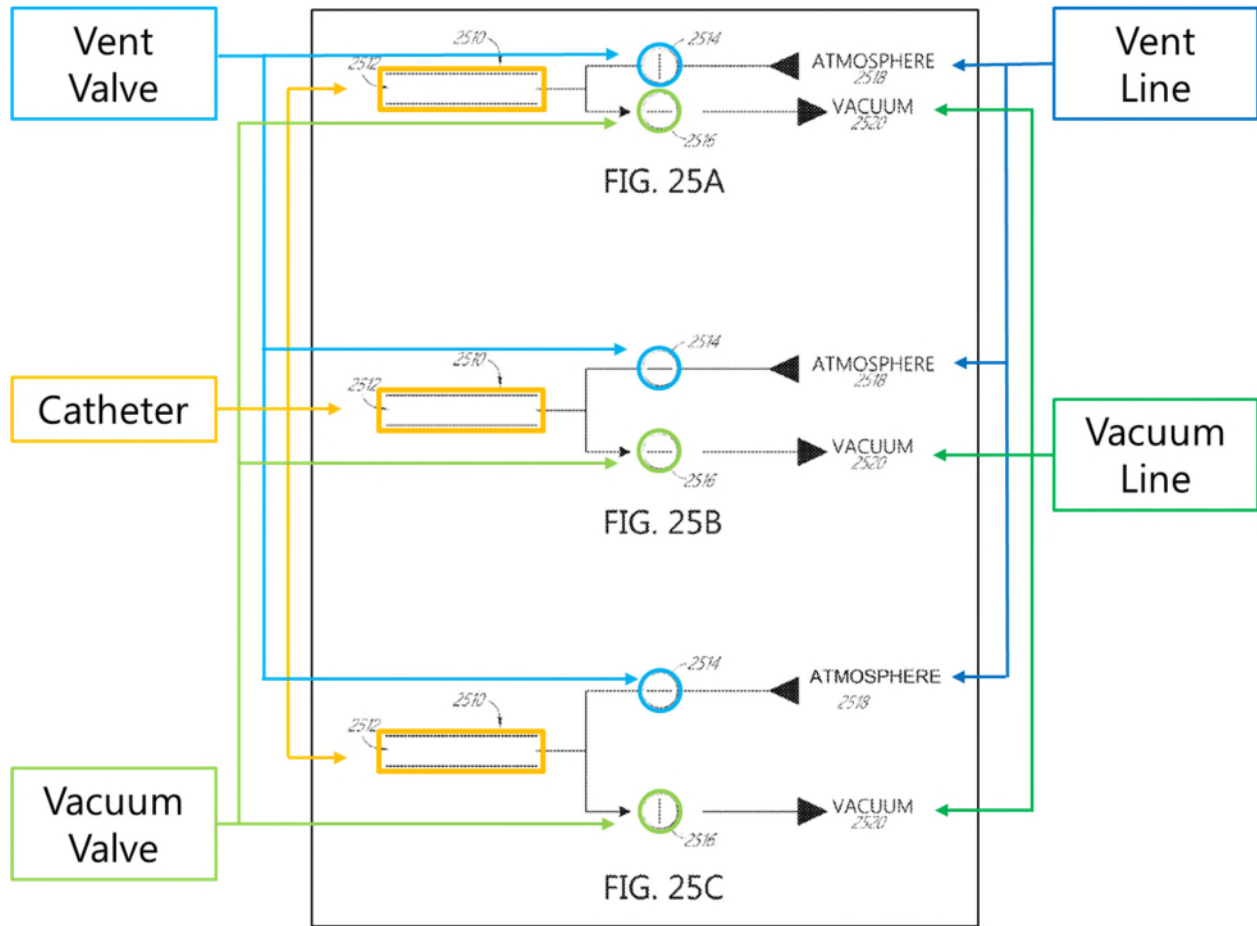
[1-Pre]

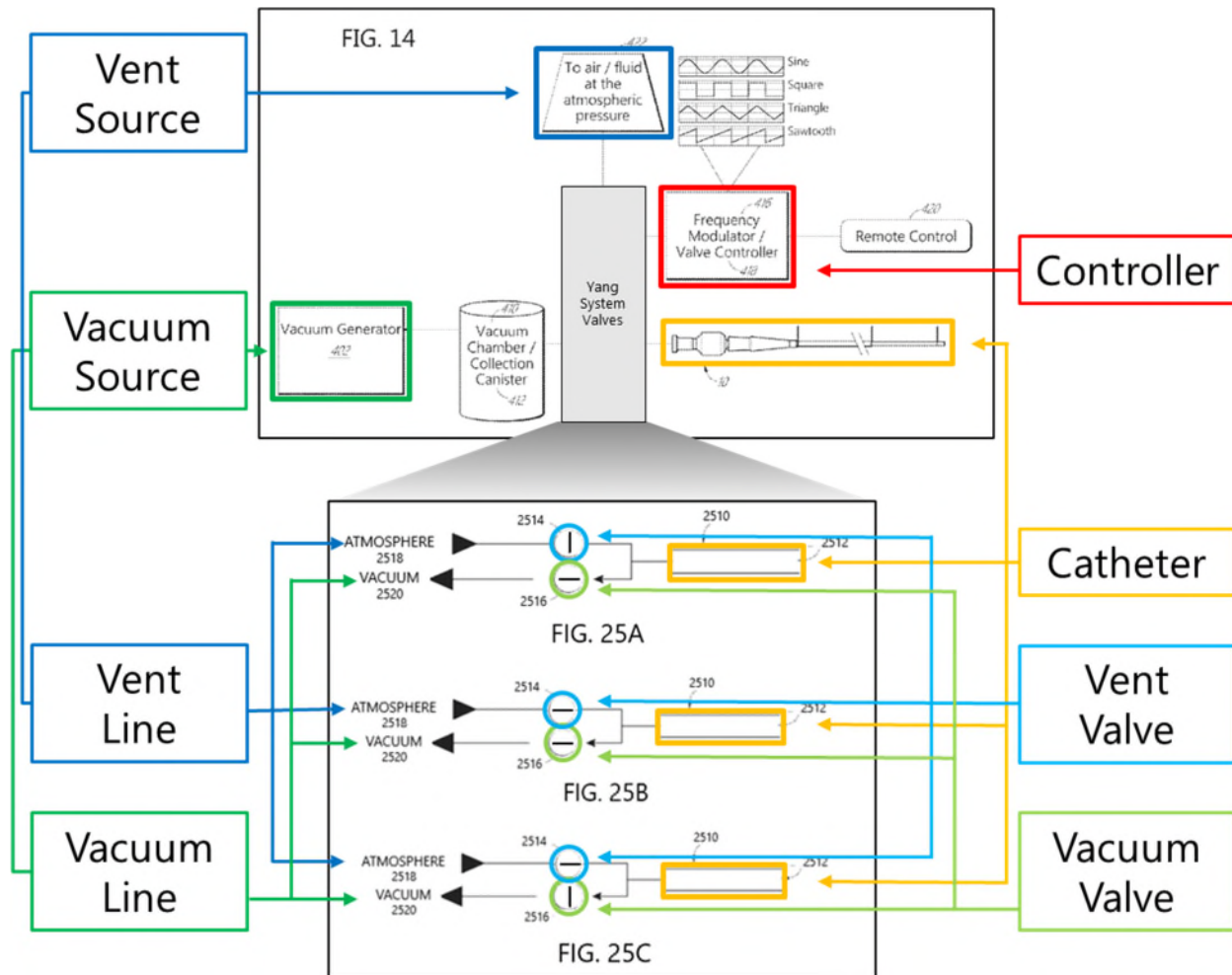
To the extent the preamble is limiting, Yang discloses it. Ex[1005], ¶¶104-106.

Yang discloses an aspiration thrombectomy system. Ex[1012], FIGs.13-18;¶[0237]. As shown below in Figures 14 and 25 (shown separately and also shown

transposed/reoriented/annotated showing the relationship between Figures 14 and 25), Yang teaches aspiration systems which “apply pulsatile negative pressure through the aspiration catheter” and “a pulsed aspiration cycle” to remove “obstructive material from remote vasculature in the brain.” Ex[1012], ¶¶[0028]-[0029], [0040], [0063], [0123].



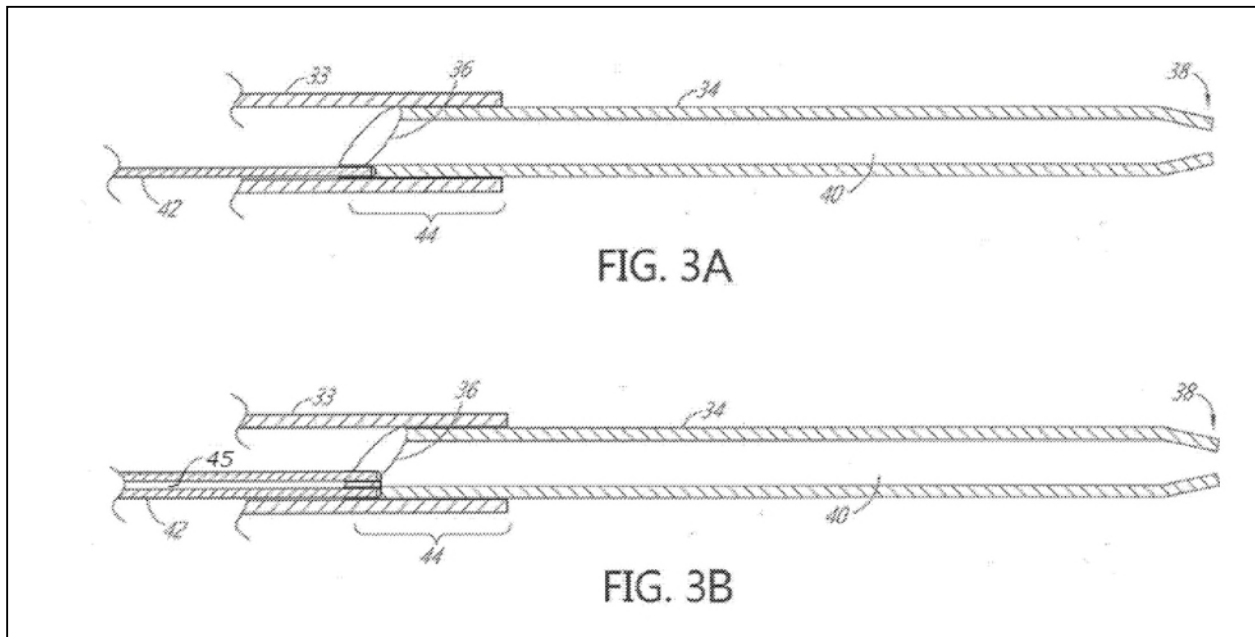
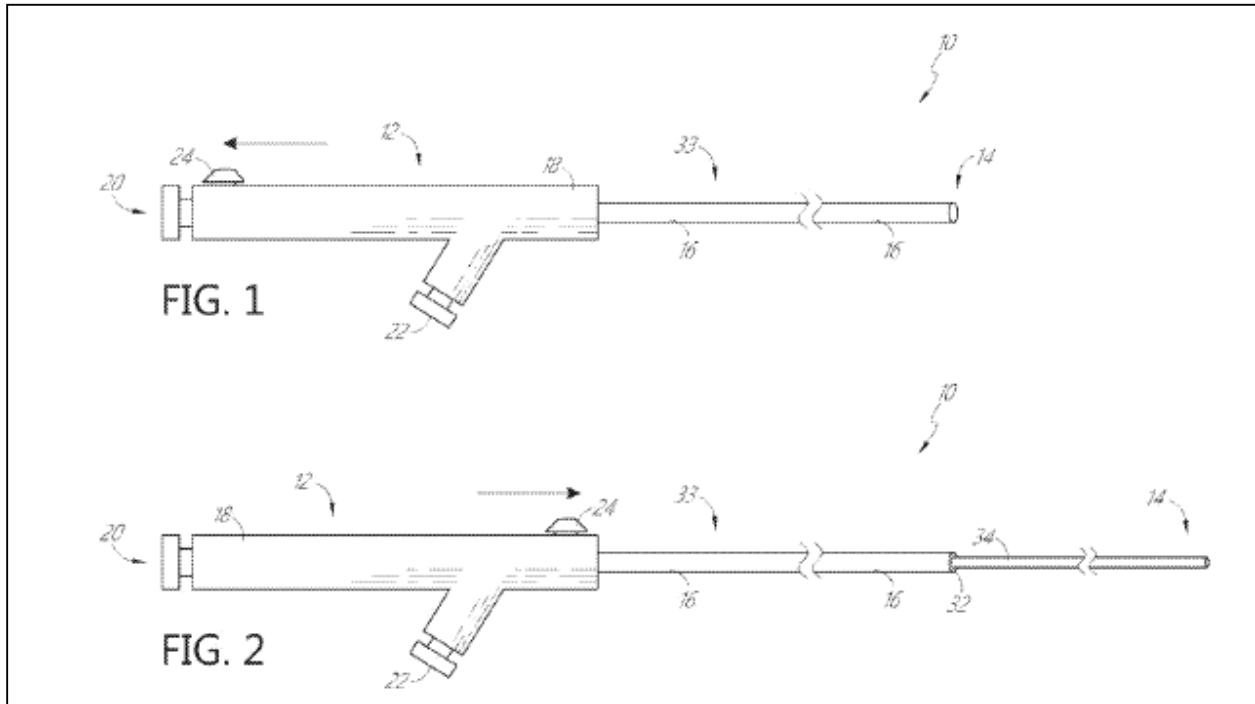




[1-A] (catheter with lumen)

Yang discloses this. Ex[1005], ¶¶107-110.

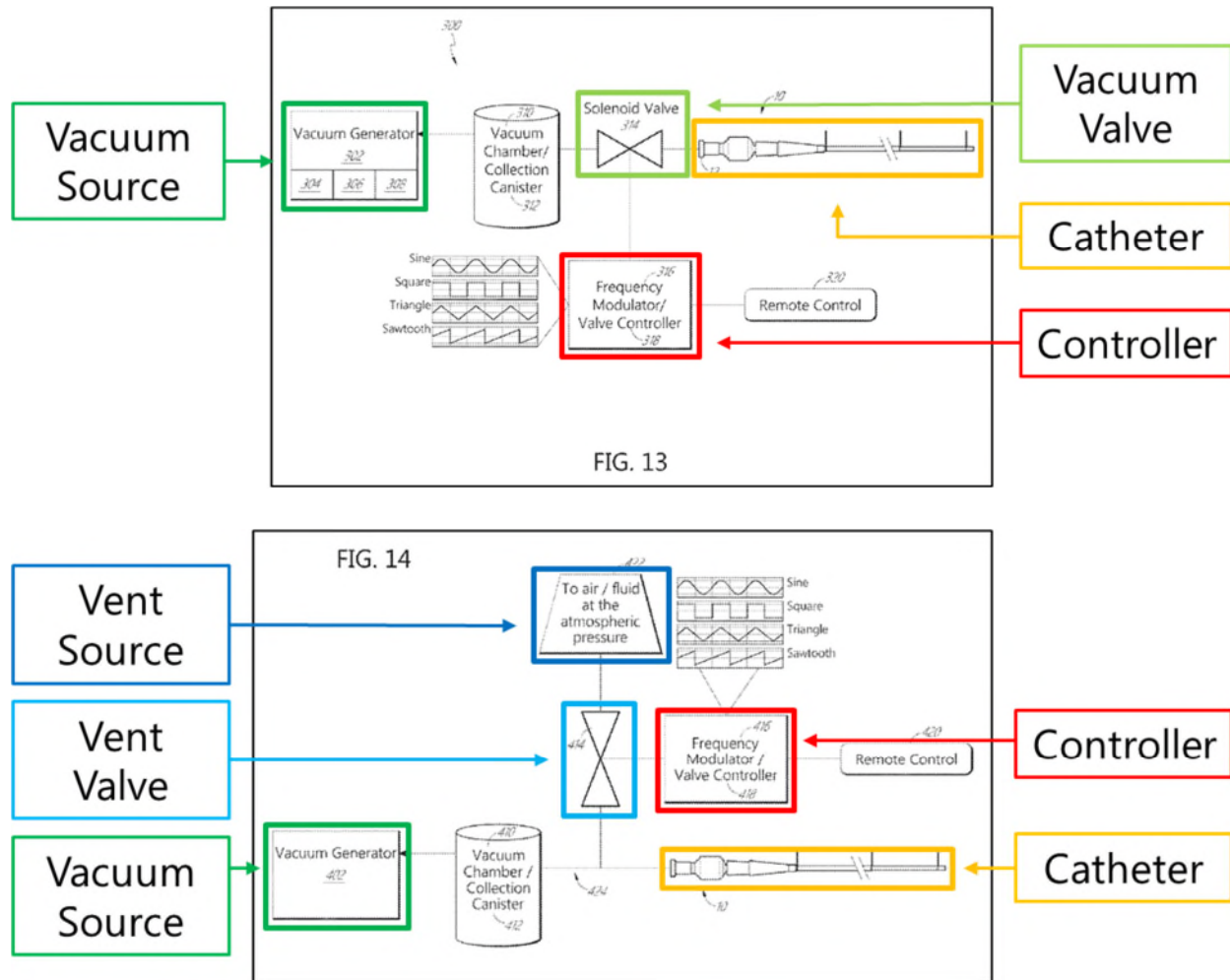
Yang discloses “[a]spiration may be applied via lumen 40.” Ex[1012], Abstract, ¶¶[0063]-[0071], [0101]-[0102], [0108], [0123]-[0128], [0131], [0168]-[0170], [0237]. Yang teaches “[d]istal segment 34 extends between a proximal end 36 and a distal end 38 and defines at least one elongate central lumen 40.” Ex[1012], ¶¶[0065]-[0067], FIGS. 1-4, 13-14, 25. A POSA would have understood this to include a distal and a proximal portion. Ex[1005], ¶110.



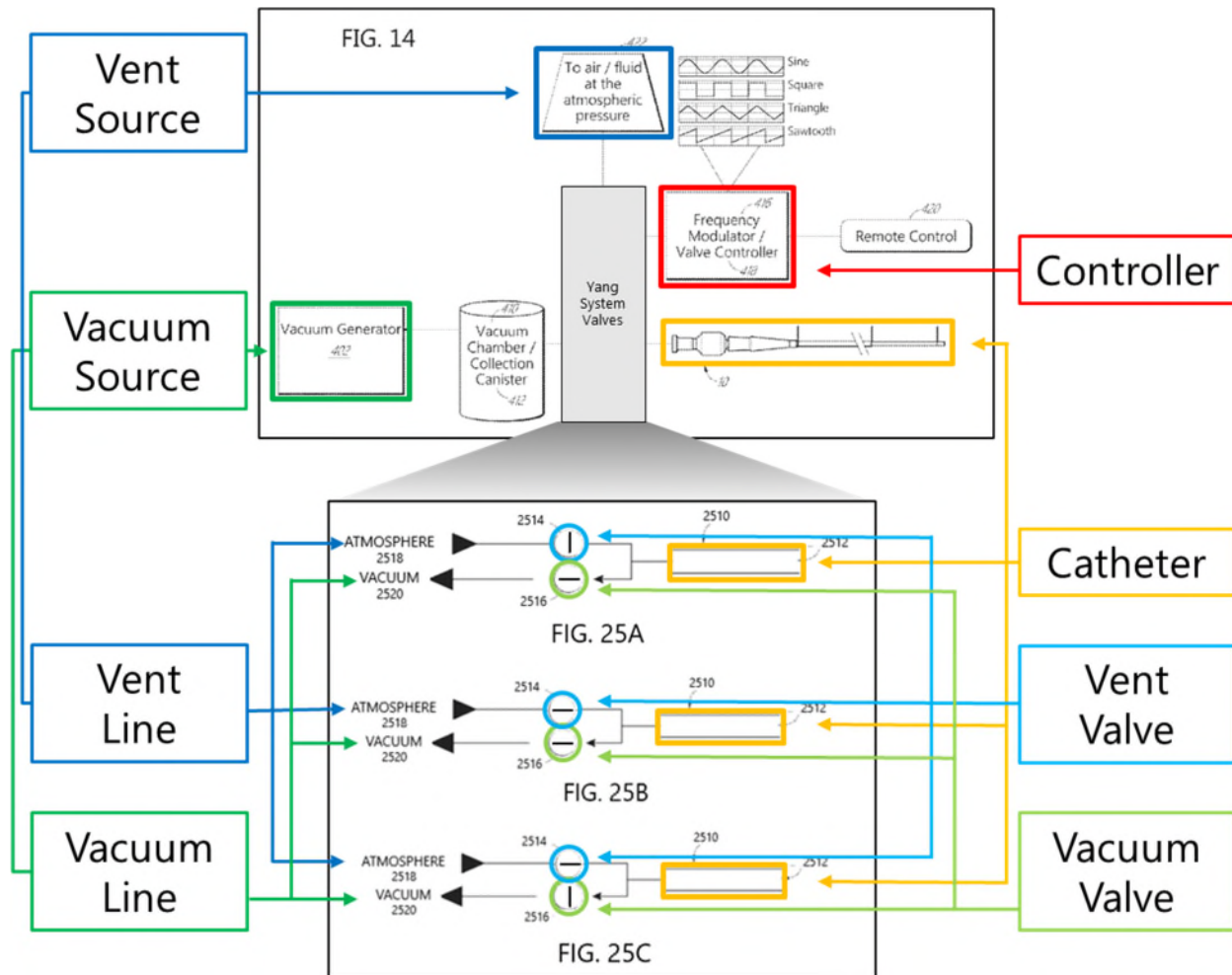
[1-B] (vacuum source)

Yang discloses this. Ex[1005], ¶¶111-115.

Yang discloses a vacuum generator with a vacuum pump that “generates vacuum” and applies “vacuum pressure” to the catheter. Ex[1012], ¶¶[0114], [0123]-[0125], [0131], FIGs.13-14. A POSA would understand this “vacuum generator” to be a vacuum source fluidically coupled to the catheter. Ex[1005], ¶112



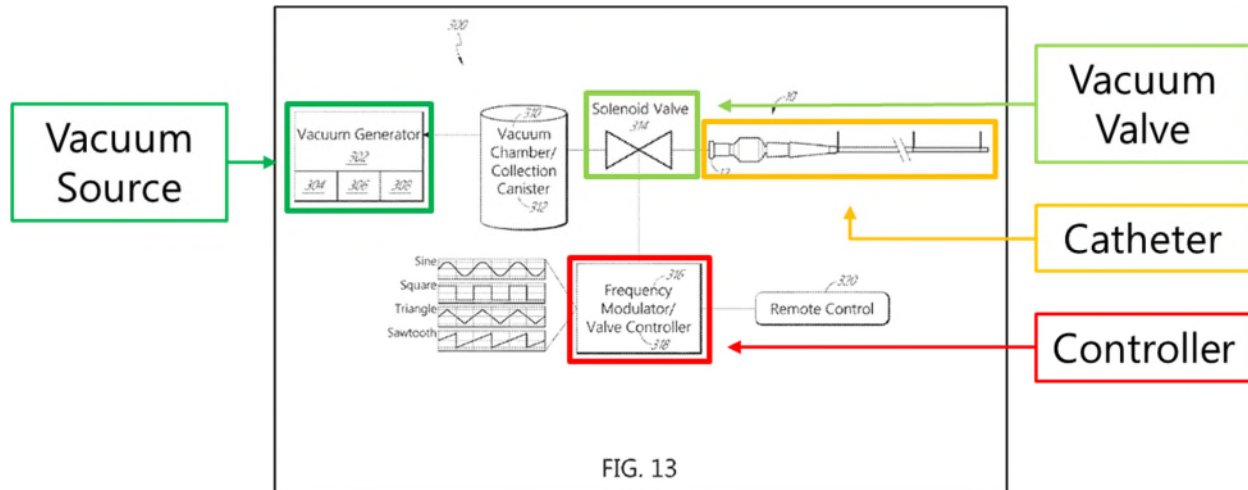
Yang’s FIG. 25 further illustrates how the vacuum source operates with a vacuum to provide vacuum to the catheter. Ex[1012], ¶¶[0168]-[0170], FIGs.14, 25.



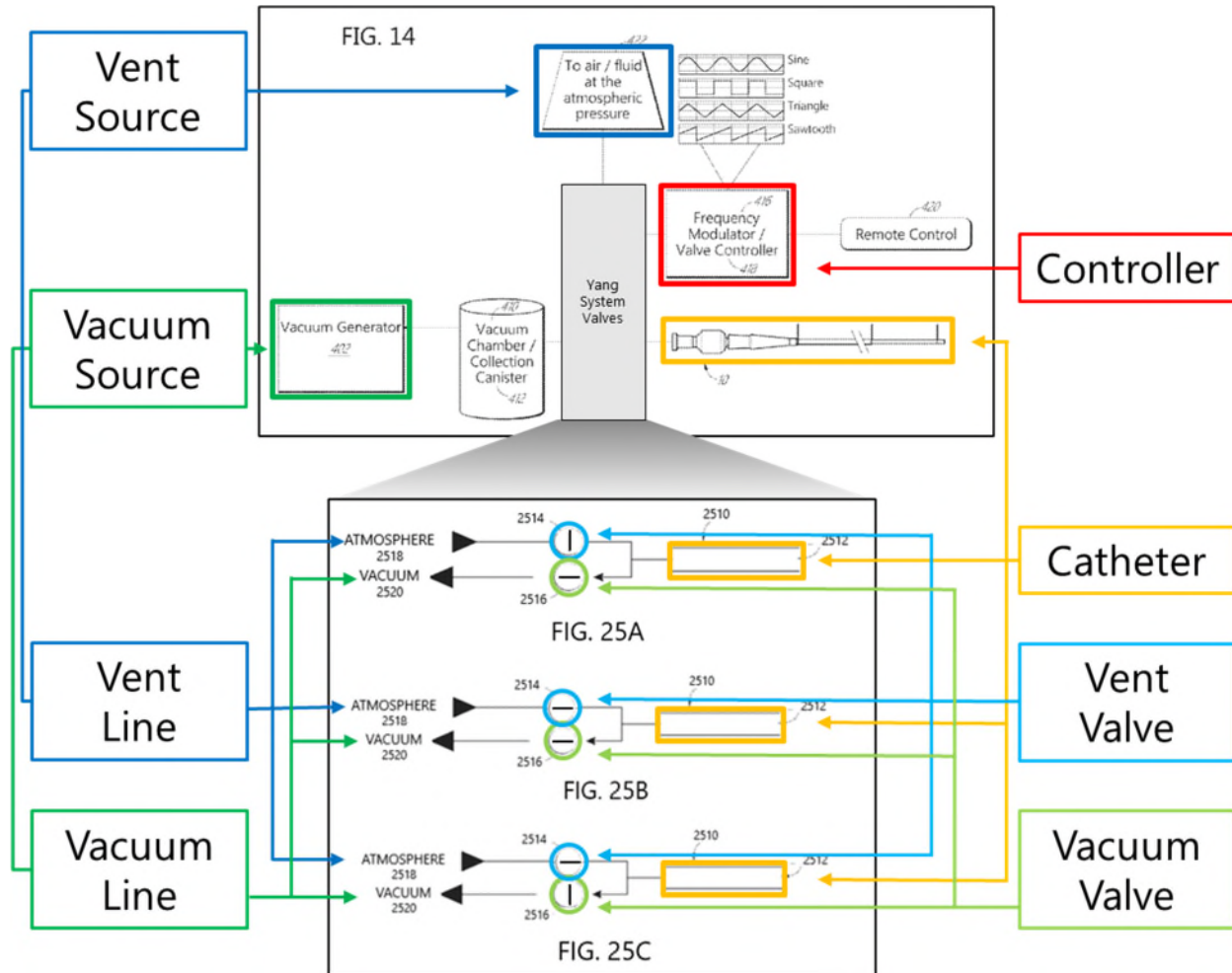
[1-C] (vacuum valve)

Yang discloses this. Ex[1005], ¶¶116-119.

Yang illustrates (e.g., in Fig. 13) a vacuum valve (e.g., “solenoid valve 314”) connected between the vacuum source (e.g., “vacuum generator 302”) and the “proximal end 12” of the catheter. Ex[1012], ¶[0123], FIG.13. A POSA would understand this valve controls vacuum flow at least because it “controls the fluid flow from the catheter 10 to the vacuum chamber 310/collection canister 312.” Ex[1012], ¶¶[0126], [0128]; Ex[1005], ¶117.



Also, Yang describes cycling of vacuum and vent valves. “FIGS. 25A-25C show a logical progression of the vacuum and release cycle as applied to the catheter....The vacuum line 2520 is connected to vacuum...and has a ***vacuum valve*** 2516 configured to open or close the fluid communication between the catheter 2510 and the vacuum.” Ex[1012], ¶¶[0169]-[0170], FIG.25 (“***vacuum valve*** 2516 is open such that the vacuum is applied to the catheter 2510 to aspirate the clot.”).

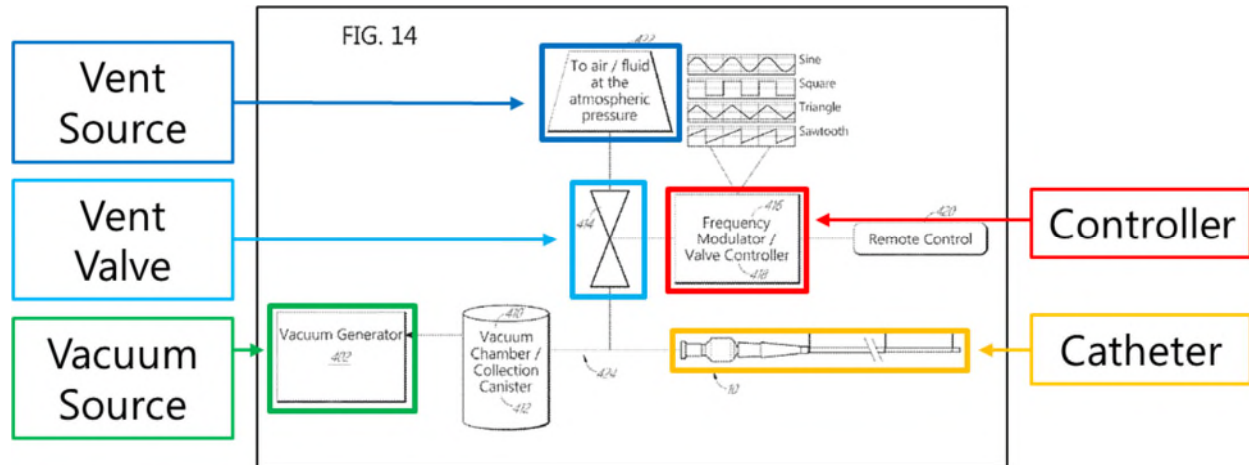


[1-D] (vent valve)

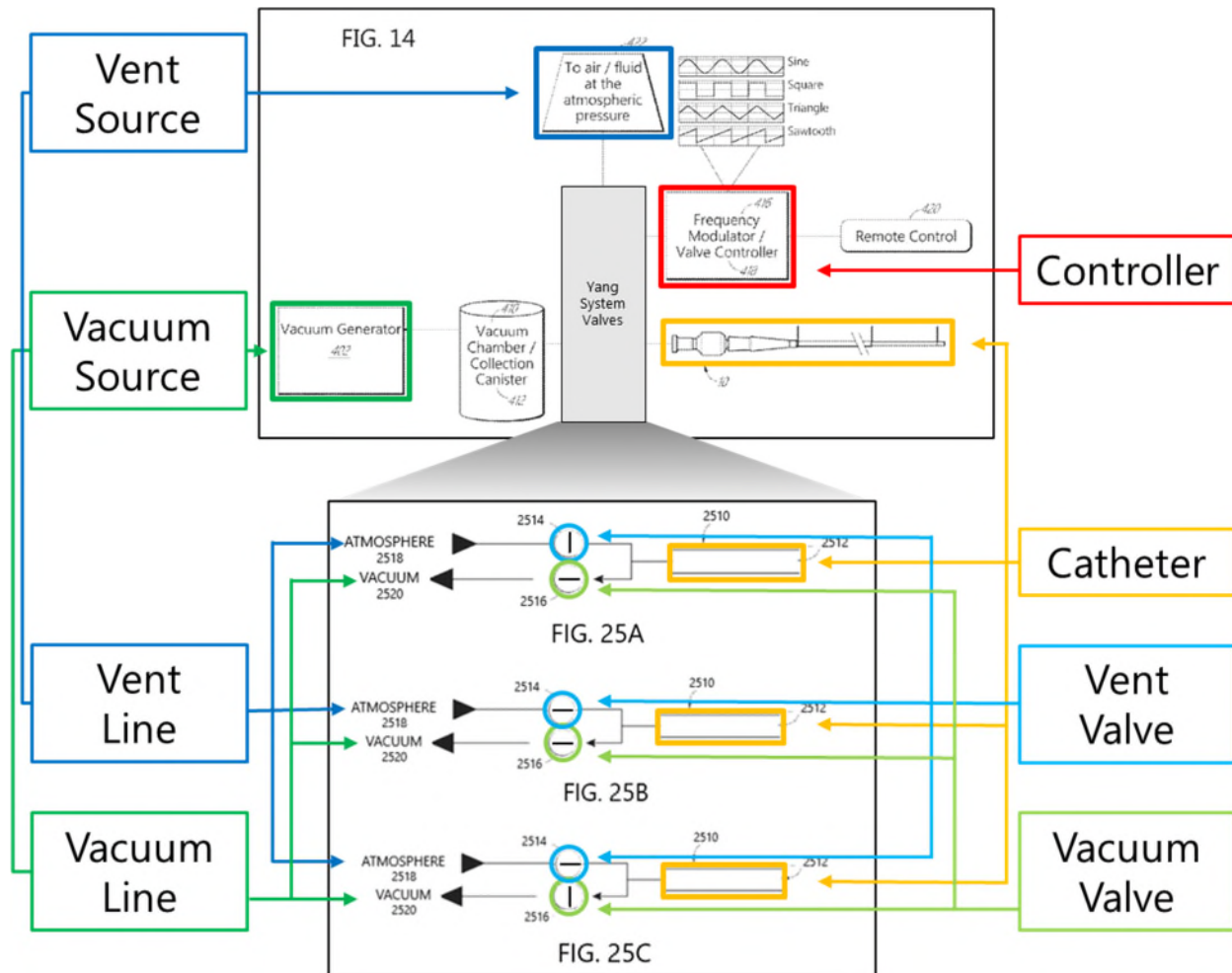
Yang discloses this. Ex[1005], ¶¶120-124.

Yang illustrates (e.g., in Figure 14) a vent valve fluidically coupled to the proximal portion of the catheter. “[T]he solenoid valve 414 ...connects between the air/fluid reservoir 422 ...and the aspiration line 424... When the solenoid valve 414 is open to the air/fluid reservoir 422...the vacuum pressure in the aspiration line 424 decreases to the atmospheric pressure. When the solenoid valve 414 is closed, it

increases the vacuum pressure in the aspiration line 424.” Ex[1012], FIG.14, ¶[0131]. A POSA would understand valve 414 is a vent valve. Ex[1005], ¶121.



Yang illustrates (e.g., in Figure 25) “release valve 2514 [is] configured to open or close the fluid communication between the catheter 2510 and the vacuum.” Ex[1012], ¶¶[0169]-[0170] (“[T]he release valve 2514 is closed, and the vacuum valve 2516 is open such that the vacuum is applied to the catheter 2510 to aspirate the clot. Then...the release valve 2514 is opened”). A POSA would have understood the release valve 2514 is a vent valve as claimed. Ex[1005], ¶122.



A POSA would have understood Yang's "pulsed aspiration" mechanism includes a vent valve configured to control a flow of vent fluid in the catheter lumen.

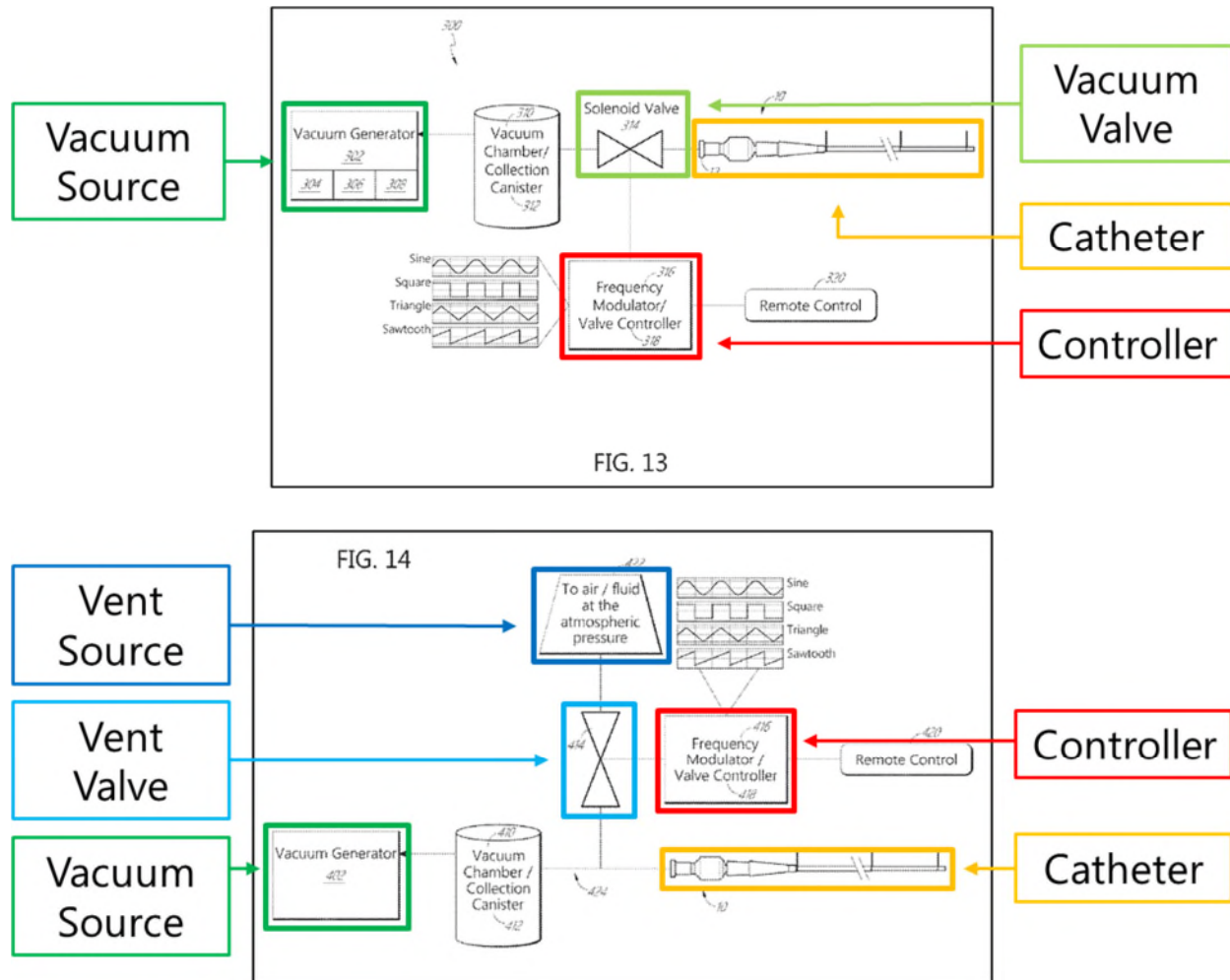
Ex[1012], ¶¶[0102], [0162]-[0170]; Ex[1005], ¶123.

[1-E] (controller)

Yang alone or in view of Mullins discloses or renders this obvious. Ex[1005], ¶¶125-135.

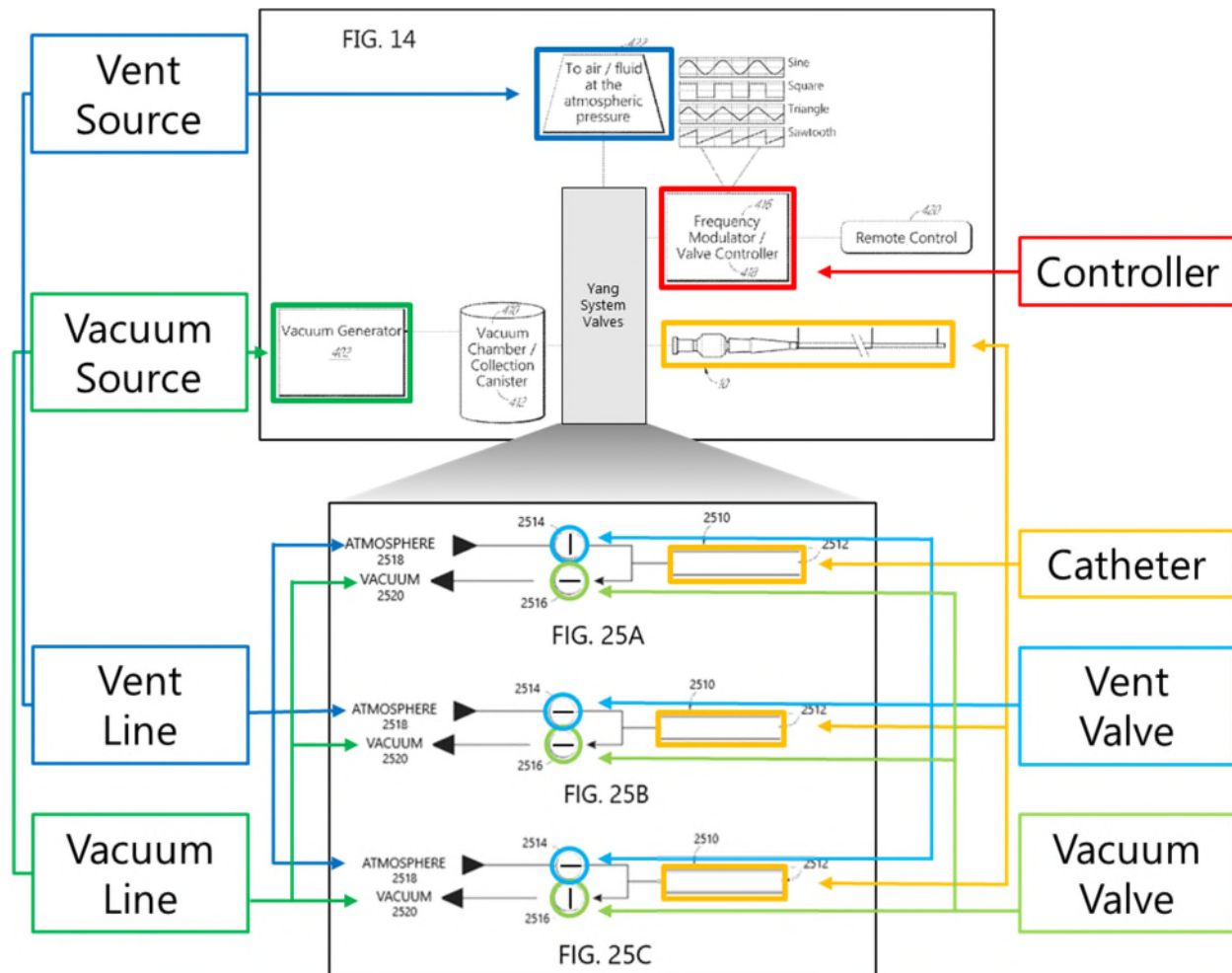
Yang illustrates (e.g., Figures 13-14) a valve controller to control the vacuum and vent valves. “FIG. 13 shows...Valve controller 318 modulates the solenoid

valve 314 on and off.” Ex[1012], ¶¶[0123], [0128], [0131], FIG.13. “[A]spiration system may comprises [sic] a vacuum generator 402...a valve controller 418... this system modulates pressure in the catheter 10 by allowing pressure to vary from vacuum to atmospheric pressure.” Ex[1012], ¶¶[0169], [0131], FIG.14.



Yang further illustrates the controller repeatedly cycling the vacuum and vent valves: “each vacuum and release cycle may be equal to or greater than about 0.1, 0.5, 1,... 9, or 10 seconds.” Ex[1012], ¶[0168], FIGS. 25A-25C. “In the first step ...the release valve 2514 is closed, and the vacuum valve 2516 is open ...Then...the

release valve 2514 is opened while the vacuum valve 2516 stays open...Finally, ...the vacuum valve 2516 is shut off...Then, another cycle ...begins....” Ex[1012], ¶[0170], FIG.25. A POSA would understand this to be opening and closing the valves predetermined cycle. Ex[1005], ¶¶128-129.



Mullins similarly discloses a cycling controller that “varies aspiration pressure according to sensed pressure within the catheter lumen.” Ex[1008], 3:46-59. “The controller may increase a vacuum to ingest more of a clot and reverse at a low limit of pressure defined such that during vacuum, a portion of the clot has been aspirated

but not so much that the clot has become irreversibly clogged” Ex[1008], 4:5-11.

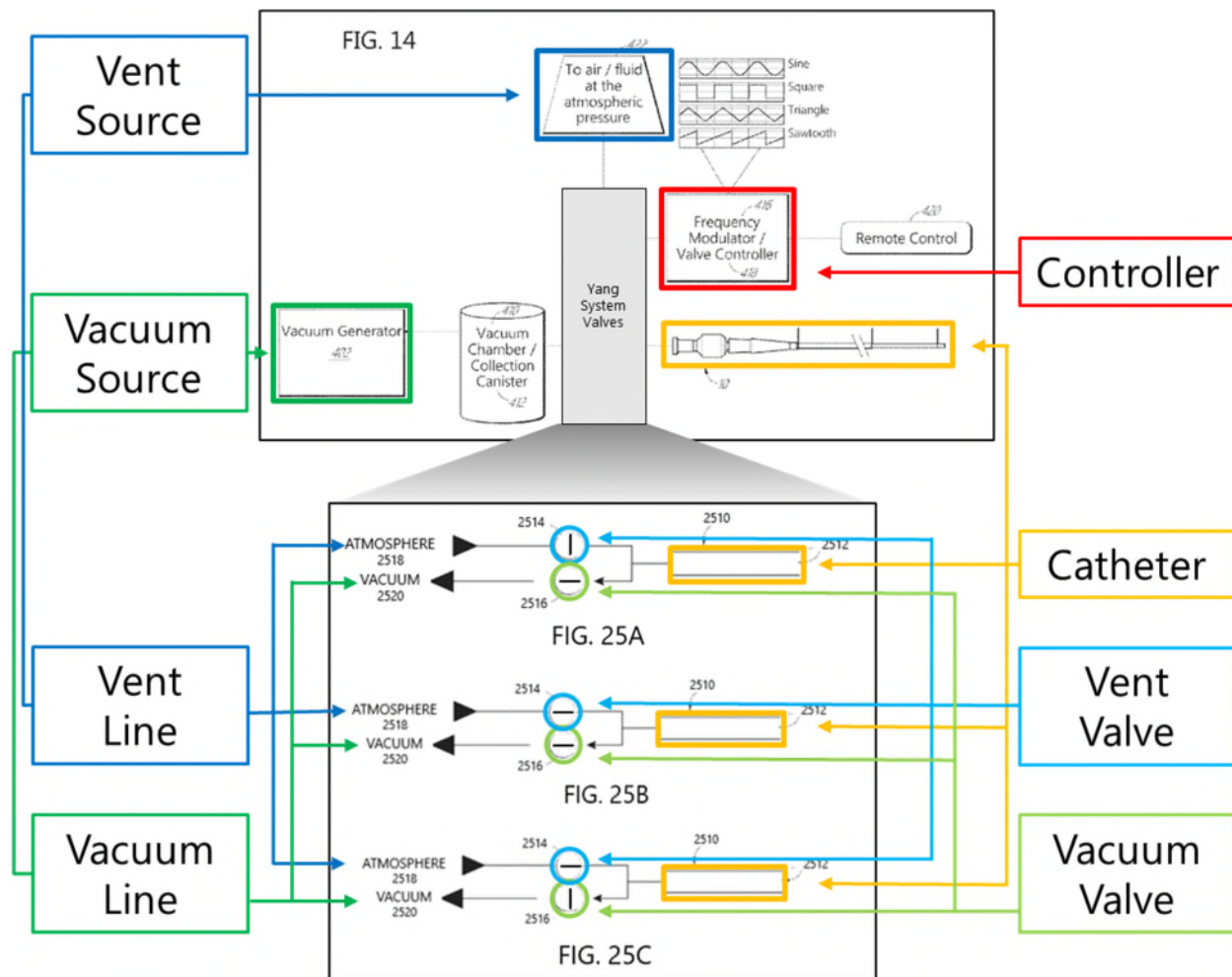
Mullins explains the controller works “*cyclically*” to aspirate the clot. Ex[1008], 3:60-4:4, 27:40-28:10, 28:59-64 (“the applied pressure signal incorporates an oscillation or ‘shake’ signal [involving] application of pulse cycling between two pressure limits”). This involves “positive and negative fluid displacement to alternately infuse and aspirate the catheter” controlled using an “infuse-to-aspirate cycle” ratio. A POSA would recognize Mullins’ “pulse cycling” and “infuse-to-aspirate cycles” are predetermined cycles. Ex[1005], ¶134.

[1-F] (changing vacuum)

Yang alone or in view of Mullins discloses or renders this obvious. Ex[1005], ¶¶136-147.

Yang discloses the controller applying vacuum to the catheter, and changing a level of vacuum at the distal end of the catheter. Ex[1012], ¶¶[0014], [0028]-[0029], [0101]-[0102], [0108], [0135] (“...vacuum applied to lumen 40 may be adjusted to cause the distal tip ...to experience [a] water hammer effect”). A POSA would understand this water hammer effect is created by changes in vacuum pressure, and that causing “the pressure wave [to] propagate[] in the catheter” would change the level of vacuum at the distal end of the catheter. Ex[1005], ¶138.

Yang also explains how the controller operates the valves in steps to affect a level of vacuum at the distal tip to dislodge a clot. Ex[1012], Fig. 25A-C, ¶¶[0168]-[0170]. “an interrupted vacuum can help aspirating a corked clot ...by loosening the clot and reshaping it...after each vacuum and release cycle.” Ex[1012], ¶[0168]. Because the distal end is engaged against the clot during aspiration, the pressure differential and force caused by cyclically opening and closing the vacuum/vent valves would affect the level of vacuum at the distal end. Ex[1005], ¶140.



Mullins similarly teaches “pulse cycling,” of pressure at the distal end of the catheter to ingest a clot. Ex[1008], 26:65-27:31 (“increases in the vacuum ingest more of the clot...the pump will reverse at some Low Limit of pressure... Upon reversal, the catheter will begin to pressurize... As the catheter is pressurized (vacuum is reversed), the load which was applied to ingest the clot will be reduced, thereby unloading the clot...During this loading/unloading the clot is being macerated....”) Ex[1008], 26:23-27:39, 28:59-64 (“The invention utilizes control and/or, variation of the vacuum pressure...at the catheter tip.” A POSA would find it obvious to implement Mullins’s pulse cycling and infuse-to-aspirate cycles to control Yang’s vacuum and vent valves. *See supra* Gr.1, [Motivation]; Ex[1005], ¶¶96-103, 146.

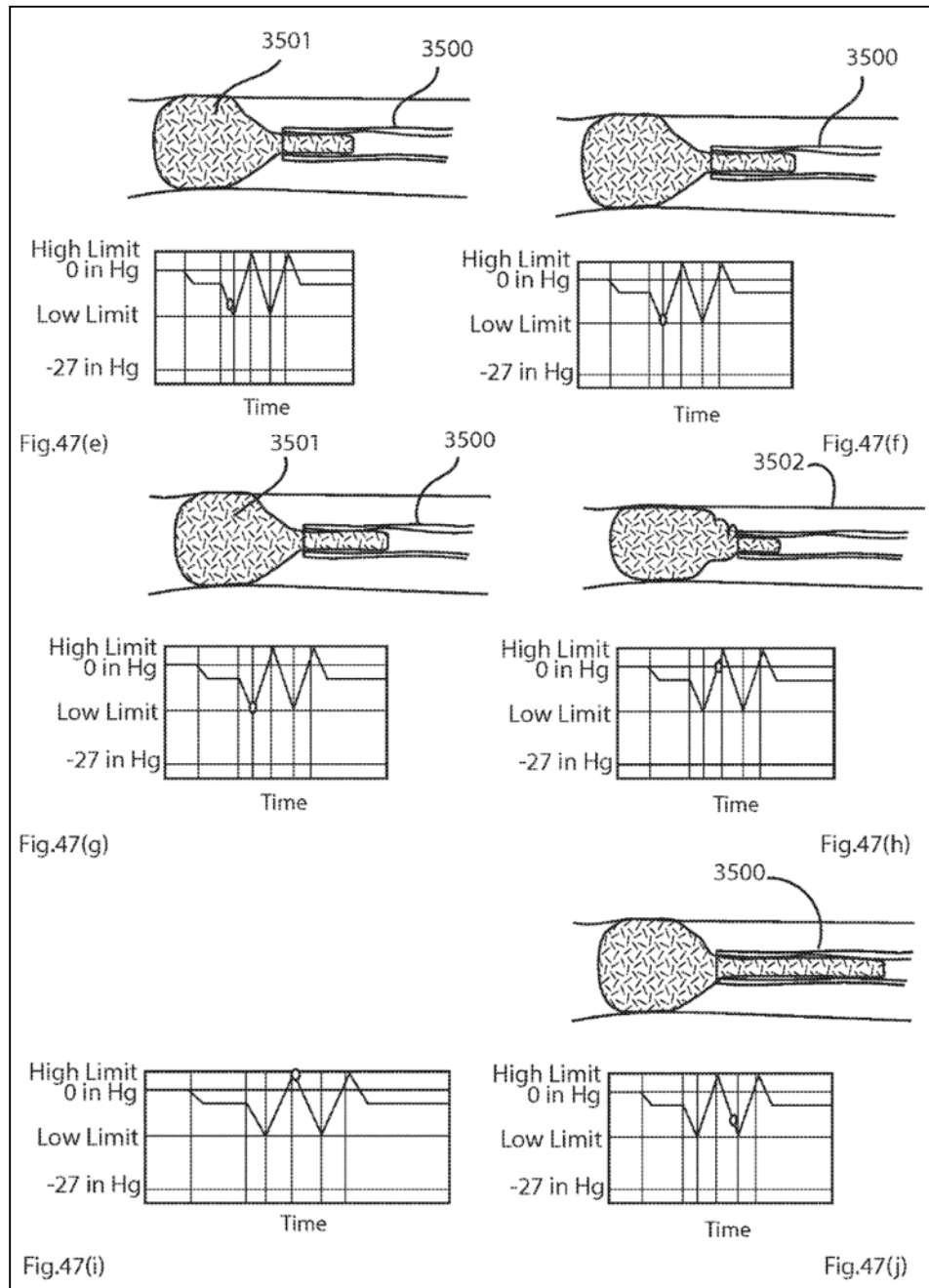
[1-G] (control flow in/ out)

Yang alone or in view of Mullins discloses or renders this obvious. Ex[1005], ¶¶148-158.

Yang discusses controlling fluid flow in and out from the distal end of the catheter. Ex[1012], ¶¶[0108], [0135], [0168]. (“pulsatile vacuum applied to lumen 40 may be adjusted to cause the distal tip 38 of the catheter 10 to experience an axial reciprocation or water hammer effect....”) A POSA would have understood that this reciprocation would cause fluid to move partially in and out at the distal end. Ex[1005], ¶¶149-151.

Mullins further teaches controlling distal fluid flow via measured pressure levels and predetermined cycles. Ex[1008], 3:46-4:11, 26:23-64 (“The invention utilises control and/or, variation of the vacuum pressure and/or, fluid displacement” which “...help achieve... maceration and deformation of the clot...”).

Mullins’s controller uses positive/negative pressure to control flow of clot and fluid in/out at the distal tip. Ex[1008], FIGs. 47(a)-(n). A POSA would understand that the cyclical application of positive/negative pressure to the catheter would control fluid flow in and out from the distal end. Ex[1005], ¶¶153-157.

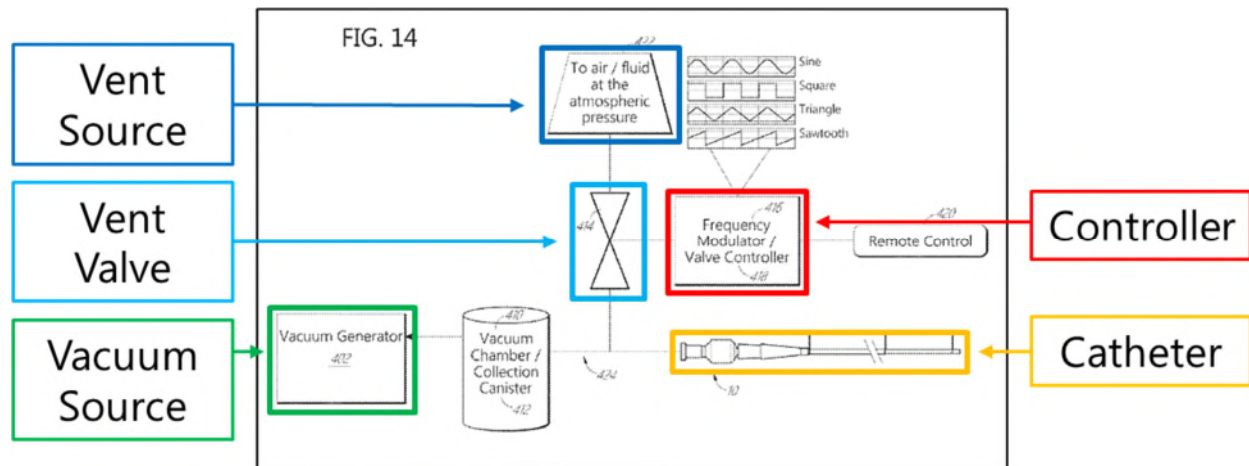


Claim 2

[2-A] (vent fluid source)

Yang discloses this. Ex[1005], ¶¶159-161.

Yang discloses “air/fluid reservoir 422.” Ex[1012], FIG.14, ¶[0131]. A POSA would understand air/fluid reservoir 422 as a vent fluid source that can fluidically communicate vent fluid to the catheter for pulsated aspiration. Ex[1005], ¶160.

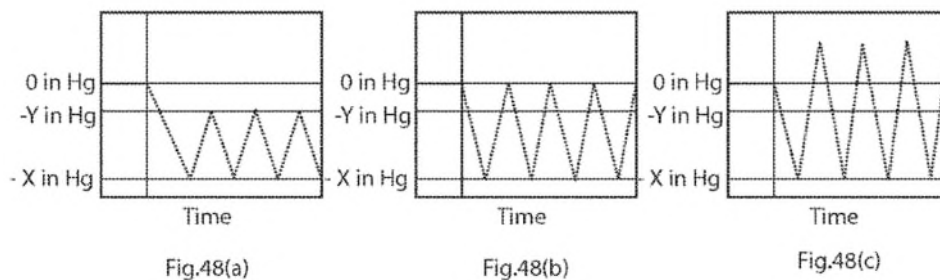


[2-B] (vent fluid pressure)

Yang discloses this limitation. Ex[1005], ¶¶162-171. “The release line 2518 is in communication with atmospheric pressure.” Ex[1012], ¶¶ [0131], [0168]-[0169]. Yang also discloses or suggests the use of varying levels of positive and negative pressure, including “a slight positive pressure.” Ex[1012], ¶¶[0102], [0237] (“alternating negative and positive pressure...”) Also, a POSA would have understood Yang contemplated using various levels of positive pressure, e.g., “atmospheric pressure,” “positive vacuum,” or “slight positive pressure,” and that the pressure levels are adjustable via an “adjustment control”. Ex[1012], ¶¶[0108], [0124]. Ex[1005], ¶166. As such, Yang conveys that positive pressure is a result effective variable that can be optimized to achieve effective aspiration. A POSA

experimenting with positive pressure values would find it obvious to experiment with levels near (i.e., higher/lower) than atmospheric pressure, and would therefore find it obvious for the vent fluid to be greater than atmospheric pressure. Ex[1005], ¶166.

Mullins similarly invites a POSA to treat the positive pressure level as a result effective variable, disclosing varying “High Limit” pressure levels, and noting that “Real numbers” are to be determined “based on experiment” to “improve efficiency”. Ex[1008], 27:18-28:39 (“the High Limit [may be] a positive pressure...”); Figs. 48A-C.



Finally, a POSA would find pressures near atmospheric pressure to be an obvious starting point for experimentation, at least because of Yang’s explicit disclosure of “venting to atmospheric pressure,” thereby rendering “greater than atmospheric pressure” obvious. Ex[1005], ¶170.

[2-C]

See supra §[1-E]. Ex[1005], ¶172.

[2-D]

For the reasons discussed above regarding [1-F], Yang alone or Yang/Mullins discloses or renders obvious this element. *See supra* §[1-F]; Ex[1005], ¶¶173-183.

Yang/Mullins changes the level of vacuum at the distal end of the catheter by changing a level of negative pressure and positive pressure during each cycle. Ex[1012] ¶¶[0014], [0102], [0108], [0237]. Yang's adjustment of pulsatile vacuum intensity represents changing pressure levels, and its disclosure of water hammer at the distal tip means that pressure levels change there. Ex[1005], ¶¶175-176. These distal end pressure changes occur during each of Yang's "pulse/duty/vacuum and release "cycles." Ex[1005], ¶177.

Mullins similarly discloses changing pressures at the distal end during each cycle, and further discloses the pressure limit being any of a negative, 0, or high pressure. Ex[1008], 3:46-4:11, 26:31-27:65; Ex[1005], ¶¶179-180. Mullins also describes an oscillation or "shake" signal cycling between the two pressure limits including "[v]ariations in pressure and/or fluid displacement at the catheter tip." Ex[1008], 27:54-65; 26:23-30. Thus, Yang/Mullins changes changing positive/negative pressure levels at the distal end of the catheter. Ex[1005], ¶¶181-183.

Claim 3

[3-A]

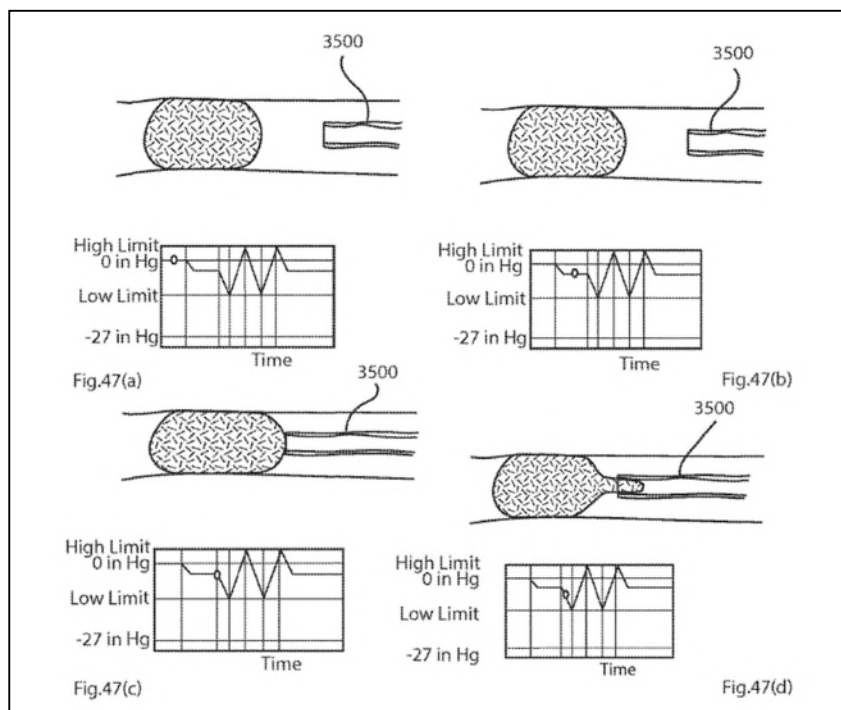
See supra §[1-E]; Ex[1005], ¶184.

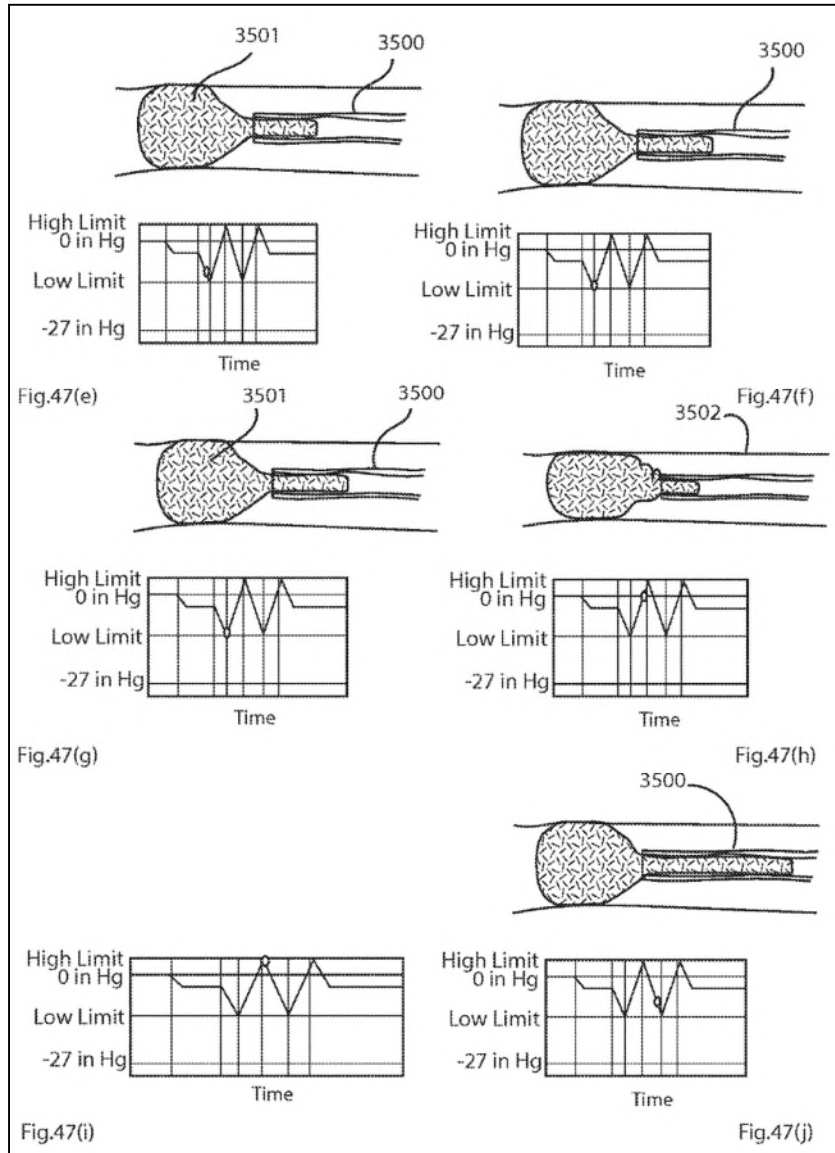
[3-B] (movement limited).

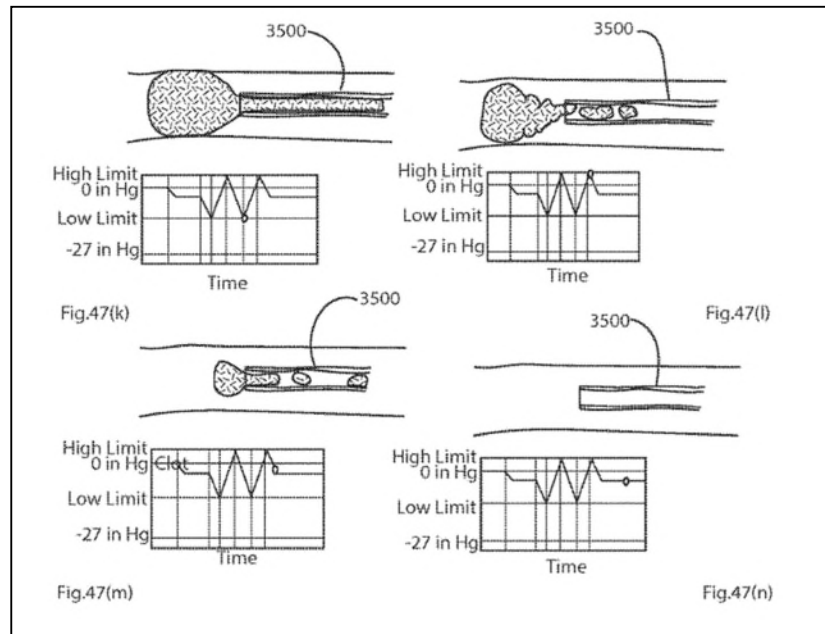
Yang alone or Yang/Mullins discloses or renders this obvious. Ex[1005], ¶¶185-198, *see also* Ex[1023], ¶¶17-20.

Yang teaches controlling pressures and flow to loosen the clot including generating and propagating vibrations and shock waves to the catheter's distal end. Ex[1012], ¶¶[0168], [0135]. *See supra* §[1- F], [1-G]. A POSA would recognize and/or consider it obvious that the positive amount of exit flow at the distal end of the catheter would be limited when performing pulsated/cyclical aspiration, e.g., some small positive exit flow may occur due to the water hammer effect, just before fluid is drawn back into the catheter lumen. Ex[1005], ¶¶186-190.

Further, Yang/Mullins renders this limitation obvious. Mullins discloses controlling distal exit flow using changes in pressure. *See supra* §[1-F], [1-G]. Mullins also illustrates some distal movement of the clot when showing how the controller limits positive exit flow. Ex[1008], FIGs. 47(a)-(n). A POSA would understand that Mullins intentionally controls and limits the positive exit flow to ensure that the clot is not entirely expelled from the catheter, risking patient safety. Ex[1005], ¶¶192-197.







[3-C] (exit flow from approximately 0.001 ml to approximately 1.0 ml)

See supra §[3-B]; Ex[1005], ¶¶199-221.

Although Yang/Mullins doesn't specify a particular value of acceptable exit flow, a POSA would understand approximately 0.001 ml to approximately 1.0 ml to be reasonable values for implementation and/or would perform routine optimization resulting in that range, because a POSA would understand at least some values in that range would not result in an unacceptable risk of distal clot migration. Ex[1005], ¶201.

Moreover, Mullins discloses measured upper and lower pressure limits to control amounts of fluid displacement, and limit distal exit flow. *See supra* [1-F], [1-G]. Mullins further contemplates experimenting with particular values and ranges

in implementing its fluid displacement and aspiration techniques. Ex[1008], 28:59-64.

Further, a POSA would have found it obvious determine values for the extent to which exit flow should be limited, as invited to do by Yang/Mullins. Ex[1005], ¶¶202-207. One such example determination, along with an explanation of methodology, is explained in the declaration of expert Brian Brown, which demonstrates that the claimed exit flow values are within the expected values that a POSA would determine through routine optimization based on the disclosures of Yang and Mullins and known catheter/physiological data. Ex[1005], ¶¶208-220.

Claim 4

[4-A]

See supra §[1-E]; Ex[1005], ¶222.

[4-B]

See supra §[3-B]. Ex[1005], ¶223.

[4-C]

See supra §[3-C]. Ex[1005], ¶224.

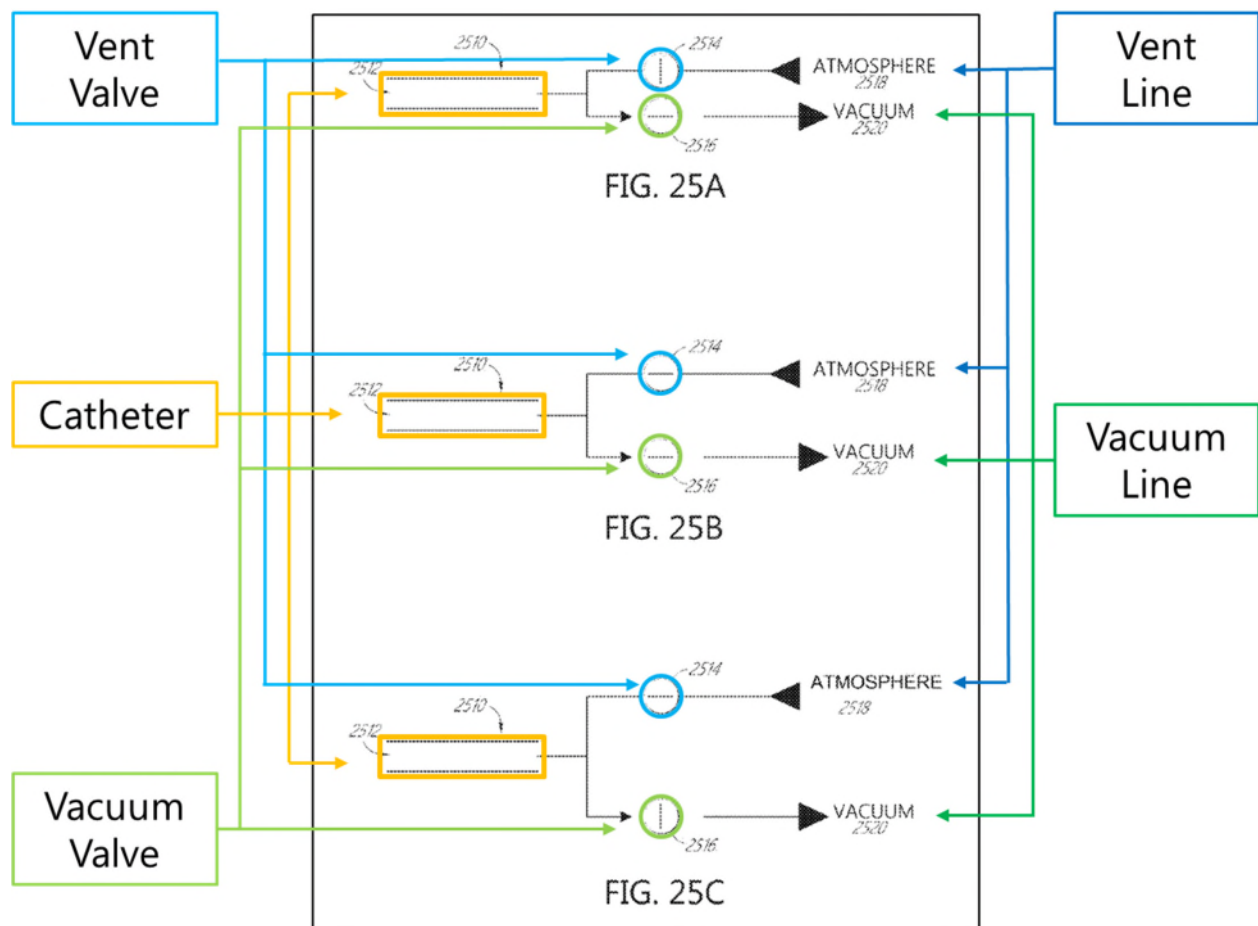
Claim 5

[5-A]

See supra §[1-E]. Ex[1005], ¶225.

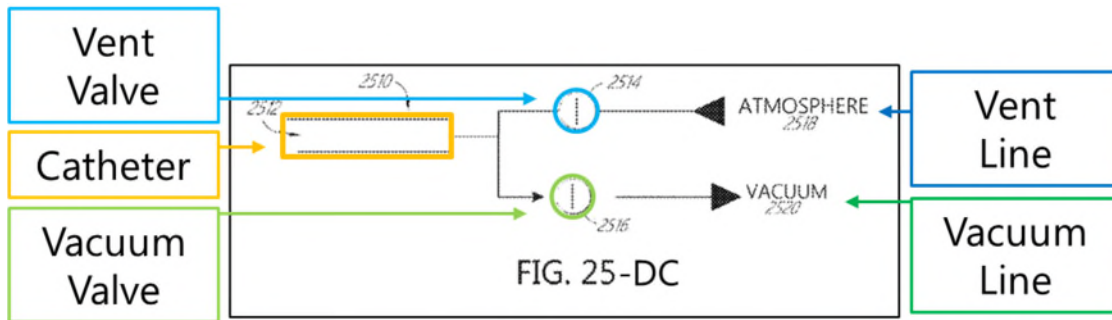
[5-B] (double-closed state)

Yang and Yang/Mullins discloses or renders obvious repeated valve cycles. See *supra* §[1-E] Ex[1005], ¶¶226-236. Yang discloses serial operation of the vacuum and vent valves in different states. Ex[1012], ¶[0170], FIG.25A-25C; Ex[1005], ¶¶228-229.



Yang further explains that another cycle begins after the ‘vent-only state’ of Figure 25C “by closing the release valve 2514 and opening the vacuum valve 2516.” Ex[1012], ¶[0170]. A POSA would understand this is an additional valve state in transitioning from Figure 25C to the Figure 25A state. Ex[1005], ¶230. Yang’s

“closing the release valve 2514,” results in state in which the vent valve is closed while the vacuum valve is still closed (as shown in Figure 25C), i.e., an “off-off state,” as reflected in the modified image below. Ex[1005], ¶230.



A POSA would recognize Yang to have this double-closed state because: (1) it would be consistent with the operation and transition of each other disclosed vacuum state, (2) it is consistent with Yang’s other disclosures, e.g., of various possible levels of vacuum during pulsed aspiration cycles (Ex[1012], ¶¶[0040], [0102], [0169]), (3) a POSA would have understood the sequences of opening and closing the vacuum and vent valves to include periods where both valves are closed for at least short periods of time, e.g., before the start of each new cycle illustrated in Fig. 25, (4) a POSA would have found a double-closed state an obvious manner of implementing the dynamic aspiration sequence disclosed by Yang, e.g., for logical generation of a pulse, including extending the full vacuum force on the clot (Ex[1012], ¶[0168]), (5) there are only a finite number of ways to order the opening and closing of valves, one of which is including a valve state where both valves are

closed, (6) a POSA would find it more typical and reliable to conduct serial operations in medical devices and understand that parallel operations can create unpredictable states, reducing system reliability, and (7) because an off-off state would preclude flow within the catheter, avoiding risk of clot migration. Ex[1005], ¶¶231-235.

Claim 6

[6-A]

See supra §[1-E]. Ex[1005], ¶237.

[6-B]

Yang and Yang/Mullins discloses or renders obvious cyclical valve operations. *See supra* §[1-E]; Ex[1005], ¶239. Furthermore, Yang and the knowledge of a POSA renders obvious an off-off state. *See supra* §[5-B]; Ex[1005], ¶240. Moreover, in implementing Yang/Mullins, a POSA would find it obvious to carry out the following sequence of valve states: (1) double-closed state, (2) vacuum-only state, (3) double-open state, and (4) vent-only state. Ex[1005], ¶¶238-244.

Yang's cycle starts with a double-closed state. *See* §[5-B]. Ex[1012], ¶[0170]; Ex[1005], ¶241. Yang describes a vacuum-only state ("valve 2514 is closed, and the vacuum valve 2516 is open"), followed by a double-open state ("valve 2514 is opened while the vacuum valve 2516 stays open.") Ex[1012], ¶[0170], which a POSA would find obvious to modify to become a double-closed state because, in

progressing to the vent-only state (See Fig. 25C), the vacuum valve would already need to be turned off. Ex[1005], ¶242.

Additionally, a second double-closed instead of a double-open state would be understood to (1) prevent blood loss, and (2) conserve injection fluid from being vacuumed into the canister. Ex[1005], ¶243. Additionally, Yang's stated reasoning for using a double-open state for the third phase is "dropping vacuum applied to the catheter," which a POSA would have recognized could be achieved in a simpler, cheaper, and more efficient manner by using a double-closed state instead, especially given that both Yang and Mullins (including the embodiments discussed herein) are specifically directed to pulsated aspiration. Ex[1005], ¶243. In particular, as discussed above and throughout this ground (e.g., [1-Pre], [1-A]), both Yang and Mullins are explicitly directed to pulsated aspiration thrombectomy systems which implement "pulsed aspiration cycle[s]" that "alternate between applying pulses of higher negative pressure and lower negative pressure." Ex[1012], ¶¶[0014], [0040]; *see also* Ex[1008], 27:54-65 ("the applied pressure signal incorporates... the application of pulse cycling between two pressure limits... [that] provides acute aspiration of the clot"); Ex[1005], ¶243. As Mr. Brown explains, a POSA would recognize and find obvious that a double-closed state is a better solution for pulsated aspiration, whereas a double-open state is a better solution for a different well-known purpose, which is implementing a flushing functionality within an aspiration

system while retaining vacuum in the catheter. *See, e.g.*, Ex[1001], 41:23-31; Ex[1005], ¶243. As Mr. Brown also explains, a POSA would understand that a double-closed state (in contrast to a double-open state) would generate the strongest water hammer effect possible by allowing for abrupt changes in pressure or flow direction. Ex[1005], ¶243.

Claim 7

[7]

Yang discloses various periods for each vacuum and release cycle, including frequencies of 2 Hz and 10 Hz, which a POSA would understand correspond to the claim. Ex[1012], ¶[0168]; Ex[1005], ¶¶245-251.

Moreover, Yang describes a wide variety frequencies for various purposes, and encourages a POSA to tune “frequency, duty cycle, and wave form” to “further enhance the efficiency of aspiration,” which would encourage a POSA to optimize frequencies in implementing the combination to control fluid momentum to minimize risks of exit flow while encouraging clot ingestion. Ex[1005], ¶¶245-251. Ex[1012], ¶¶[0127], [0129]-[0130]. Ex[1023], ¶19.

Claim 8

[8]

Yang describes solenoid valves, which a POSA would understand includes solenoid pinch valves and/or from which implementation using known solenoid

pinch valves would be obvious. Ex[1012], ¶[0126] (“The solenoid valve 314 controls the fluid flow from the catheter 10 to the vacuum chamber 310/collection canister 312.”), [0131] (same for “solenoid valve 414”). Ex[1005], ¶¶252-254.

Claim 10

[10-A]

See supra §[1-E]; Ex[1005], ¶255.

[10-B]

Yang describes loosening and aspirating a clot at the distal end of the catheter. Ex[1012], ¶¶[0108], [0168]. Similarly, Mullins teaches reversing the direction of fluid displacement and allowing some or all of the clot to be pushed to cause the clot to become “free” with respect to the catheter, which a POSA would understand to take place at the distal end (where thrombus engagement occurs). Ex[1008], 27:18-26. Thus Yang/Mullins renders this obvious. Ex[1005], ¶¶256-260.

Claim 11

[11-Pre]

See supra [1-Pre]; Ex[1005], ¶261.

[11-A]

Yang and Mullins describe placing the catheter with the distal end proximate to the material sought to be removed in a vessel. Ex[1012], ¶¶[0101], [0177]; Ex[1008], 3:6-9, 29:26-35; Ex[1005], ¶¶262-266.

[11-B]

Yang discloses using vacuum such that “[a]spiration may be applied via lumen 40”. Ex[1012], ¶¶[0101], [0120]. Mullins describes “the pump applies a vacuum enabling the catheter to ingest some of the clot.”. Ex[1008], 4:5-11, 26:65-66; Ex[1005], ¶¶267-271.

[11-C]

See supra §§[1-B], [1-E], and [2-A]; Ex[1005], ¶¶272-274.

[11-D]

See supra §[1-F]. Ex[1005], ¶275.

[11-E]

See supra §[1-G]; Ex[1005], ¶276.

Claim 12

[12-A]

See supra §[2-B]; Ex[1005], ¶277.

[12-B]

See supra §[1-E]; Ex[1005], ¶278.

[12-C]

See supra §[2-D]; Ex[1005], ¶279.

Claim 13

[13-A]

See supra §[3-B]; Ex[1005], ¶280.

[13-B]

See supra §[3-B]; Ex[1005], ¶¶281-283.

A POSA would also recognize the equivalence between measuring exit flow could be based on length and volume because volume is a function of length and catheter diameter-a known quantity. Ex[1005], ¶282. A POSA would understand the benefit of controlling exiting column length rather than volume: that it would more directly correspond to the distance a coked clot would travel away from the distal end. Ex[1005], ¶282.

Claim 14

[14-A]

See supra §[3-B]; Ex[1005], ¶¶284-289. Yang describes stopping distal flow and reapplying vacuum, resulting in fluid being drawn back into the catheter lumen. Ex[1012], ¶¶[0108], [0168]. Ex[1005], ¶286. Additionally, Mullins's sensor would be used in Yang/Mullins to determine fluid displacement as part of the vacuum application cycle. Ex[1008], 3:35-59, Figs. 47(g)-(h). Ex[1005], ¶¶287-289.

[14-B]

See supra §[13-B]; Ex[1005], ¶¶290-296. A POSA would understand the values of approximately 0.5 mm to approximately 30 mm of fluid column to be a reasonable distance that would not prevent clot migration beyond the catheter

vacuum's zone of influence. Ex[1005], ¶292. *See also supra* §[3-C] (explaining POSA's motivation to optimize exit flow). Ex[1005], ¶¶290-296.

Additionally, a POSA would understand how to convert the exit flow volumes described in Ground 1, [3-C] to respective values of exit flow length. Ex[1005], ¶294. As explained in the declaration of expert Brian Brown, the claimed exit flow values are within the expected values that a POSA would experiment with through routine optimization. Ex[1005], ¶295.

Claim 15

[15-A]

See supra §[3-B]; Ex[1005], ¶297.

[15-B]

See supra §§[3-B]-[3-C]; Ex[1005], ¶298.

Claim 16

[16-A]

See supra §§[3-B], [14-A]; Ex[1005], ¶299.

[16-B]

See supra §[3-C]; Ex[1005], ¶300.

Claim 17

[17-A]

See supra §§[3-B], [14-A]; Ex[1005], ¶301.

[17-B]

See supra §§[3-C], [4-C]; Ex[1005], ¶302.

Claim 18

[18-A]

See supra §§[1-E], [5-A]; Ex[1005], ¶303.

[18-B]

See supra §[5-B]; Ex[1005], ¶304.

Claim 19

[19-A]

See supra §§[1-E], [5-A]; Ex[1005], ¶305.

[19-B]

See supra §[6-B]; Ex[1005], ¶306.

Claim 20

See supra §[7]; Ex[1005], ¶307.

B. Ground 2: Claims 4-6 and 9-13 are Obvious Over Yang and Mullins in View of Rubenstein

Motivation to Combine

A POSA would have been motivated to modify Yang/Mullins' cyclical aspiration thrombectomy system with Rubenstein's teachings of: (1) a pumping system to eliminate clogs within the catheter; (2) applying cyclical reversals of positive and negative pressure in the catheter; and (3) transitioning between a vacuum suction state and a blowing, or positive pressure state when necessary, using

a time-controlled valve. The motivation to combine Yang and Mullins is discussed above. See §Gr.1, [Motivation]; Ex[1005], ¶¶308-311.

A POSA would have been motivated to combine Yang, Mullins, and Rubenstein because (1) all three references address similar problems related to medical aspiration, including clogged catheters and limitations of static aspiration, and (2) all three references teach similar solutions involving using a positive pressure state to temporarily relieve the negative pressure within the system to more efficiently remove clogged from the catheter and/or the patient, e.g., creating a dynamic force using vacuum and vent/pressure sources via controllable valves. Ex[1012] ¶¶[0008]-[0014], [0123]-[0131], [0135]-[0136], [0168]-[0170]; Ex[1008], 1:53-2:2, 3:29-4:11, 24:22-28:64; Ex[1009.2], 2-10; Ex[1011], 1:7-14, 1:64-2:12; Ex[1005], ¶309.

Moreover, it would be obvious to implement the Yang/Mullins system using rotary valves, as in Rubenstein, because those valves were a known implementation, shown to work in similar catheter systems, with predictable function and known benefits. Ex[1005], ¶310. This combination was within the skill of a POSA, and a POSA would expect success because of the predictable operation of Rubenstein's valves in systems like Yang/Mullins. Ex[1005], ¶310.

Claim 5

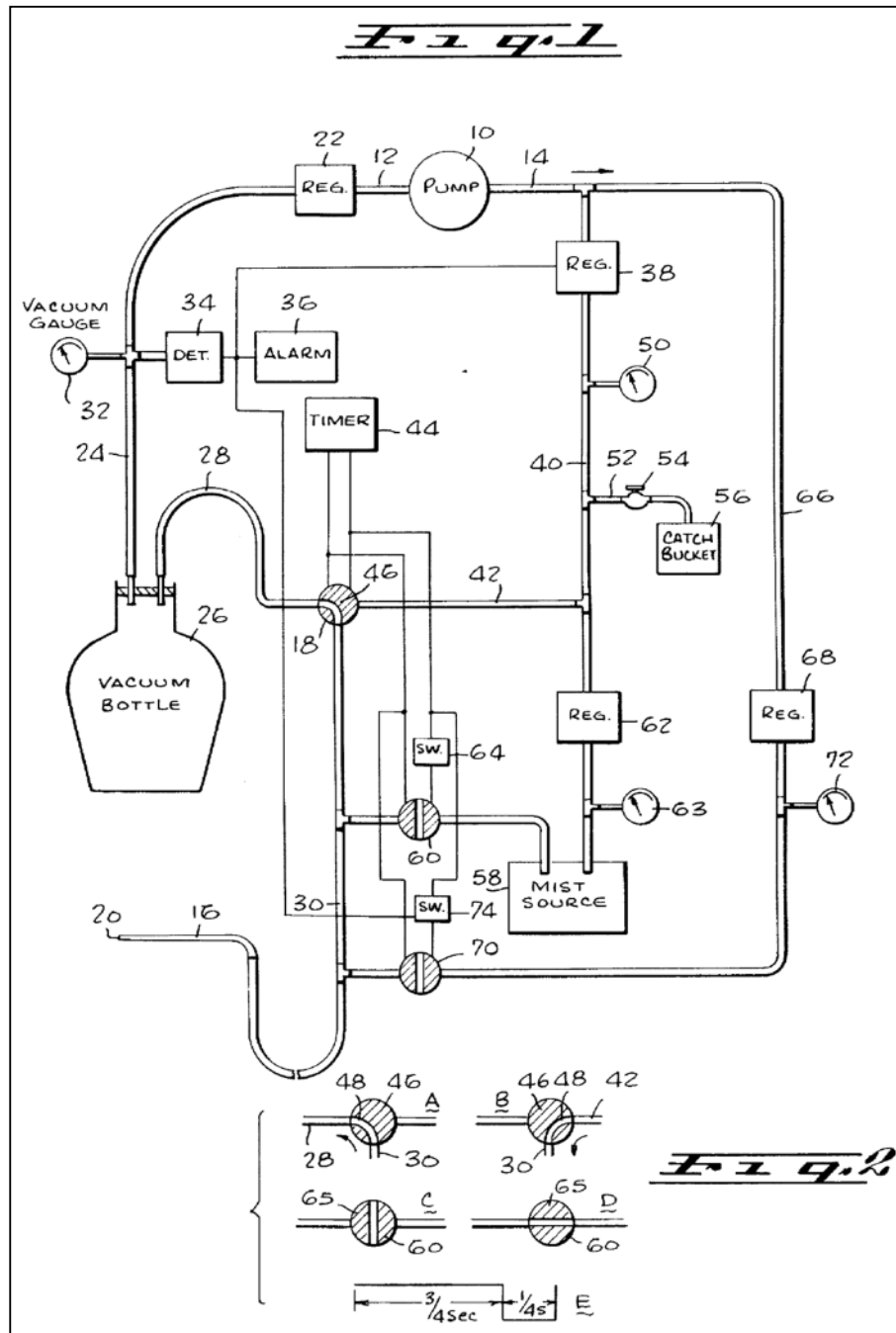
[5-A]

See §Gr.1, [1-E]; Ex[1005], ¶312.

[5-B]

Yang/Mullins discloses or renders obvious cyclical valve operations. See §§Gr.1, [1-E], [5-B]. It is additionally obvious in view of Rubenstein. Ex[1005], ¶¶313-333.

Rubenstein's catheter includes "a pumping system wherein cyclical reversals of pumping pressure are applied to the catheter connected thereto to have negative and positive pressure cyclically alternated" to "have the flow of fluid through a catheter cyclically reversed and thereby self-cleaning." Ex[1011], 1:7-14, 1:64-68; Ex[1005], ¶315.



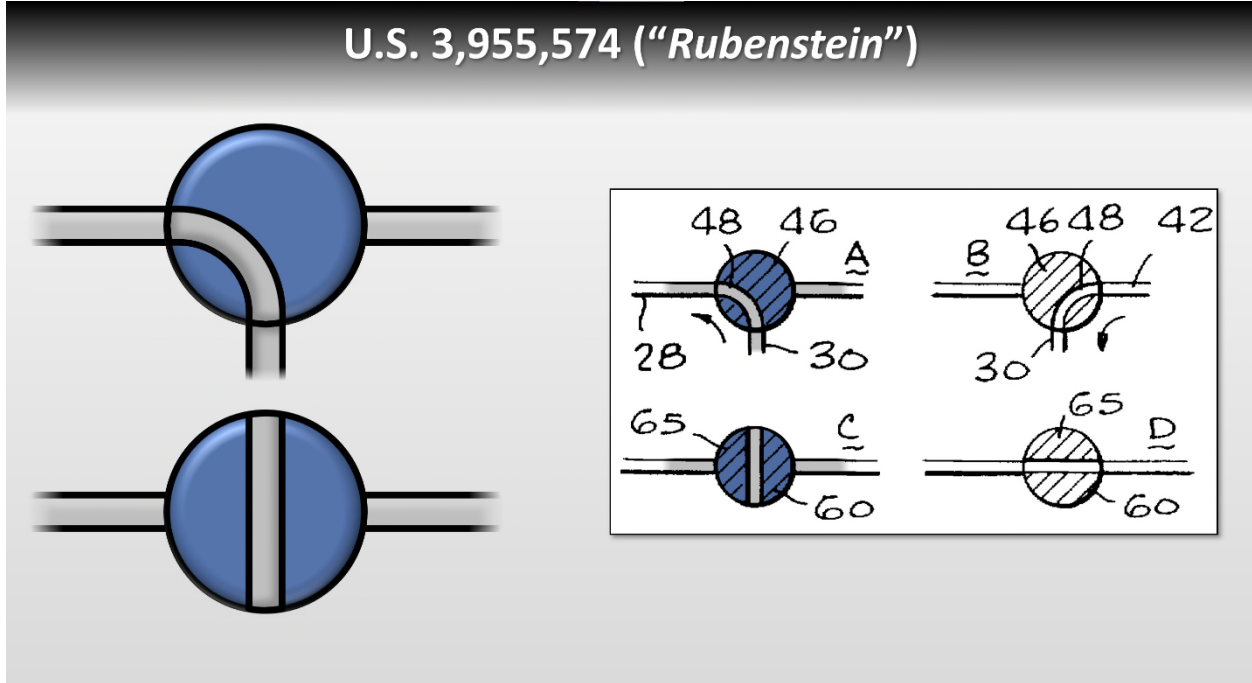
Rubenstein's Figs. 1-2 illustrate a system for ejecting fluid through a catheter and facilitating suction with "a time-controlled valve which is operated at predetermined time intervals to have suction through the catheter interrupted by a predetermined period of positive pressure to cause a reversal of fluid flow

therethrough,” and “[a] source of mist is connected to allow controlled injection of detergent or enzymatic fluid through the catheter.” Ex[1011], 1:51-61, 2:1-8.

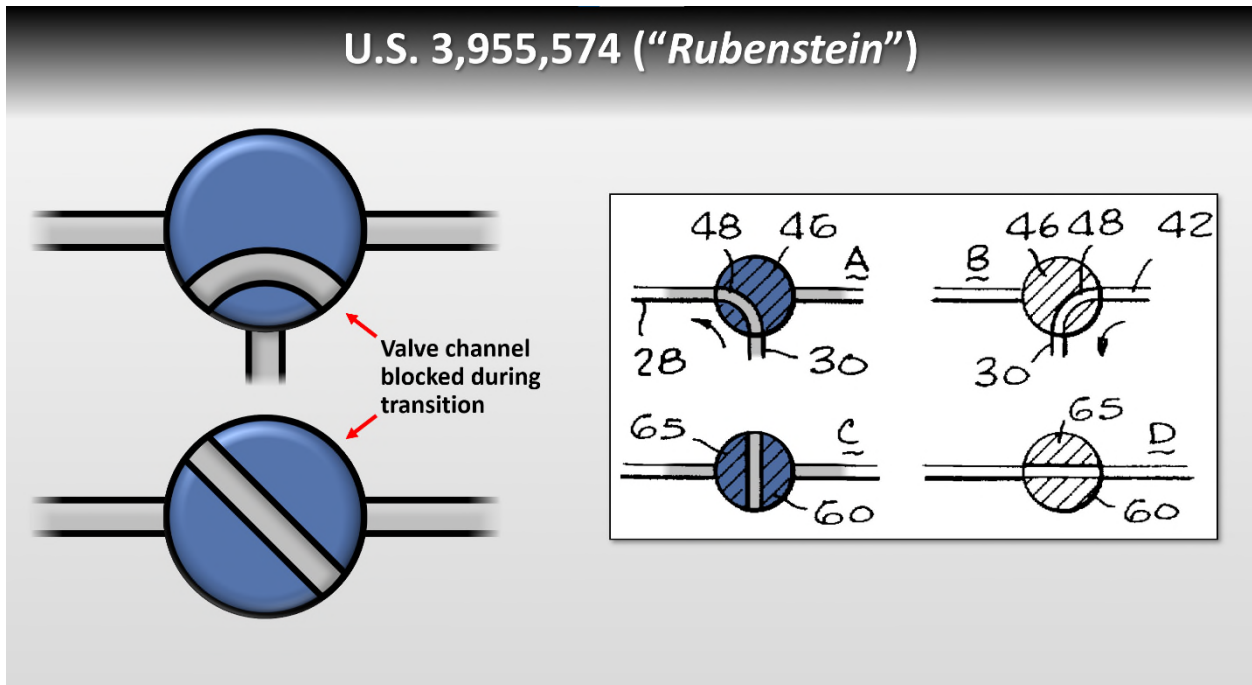
A POSA would find it obvious that Rubenstein discloses a double-closed state at least because Rubenstein discloses a rotary valve 46/18 which may rotate between a first position fluidically connecting the catheter to vacuum, and a second position where the vacuum is disconnected. Ex[1011], 1:10-14, FIGs.1-2. Ex[1005], ¶¶320-327. Similarly, Rubenstein discloses a rotary valve 60 which rotates between a first position where a fluid line is fluidically disconnected from the catheter, to a second position where the fluid line is connected. Ex[1011], FIGs.1-2.

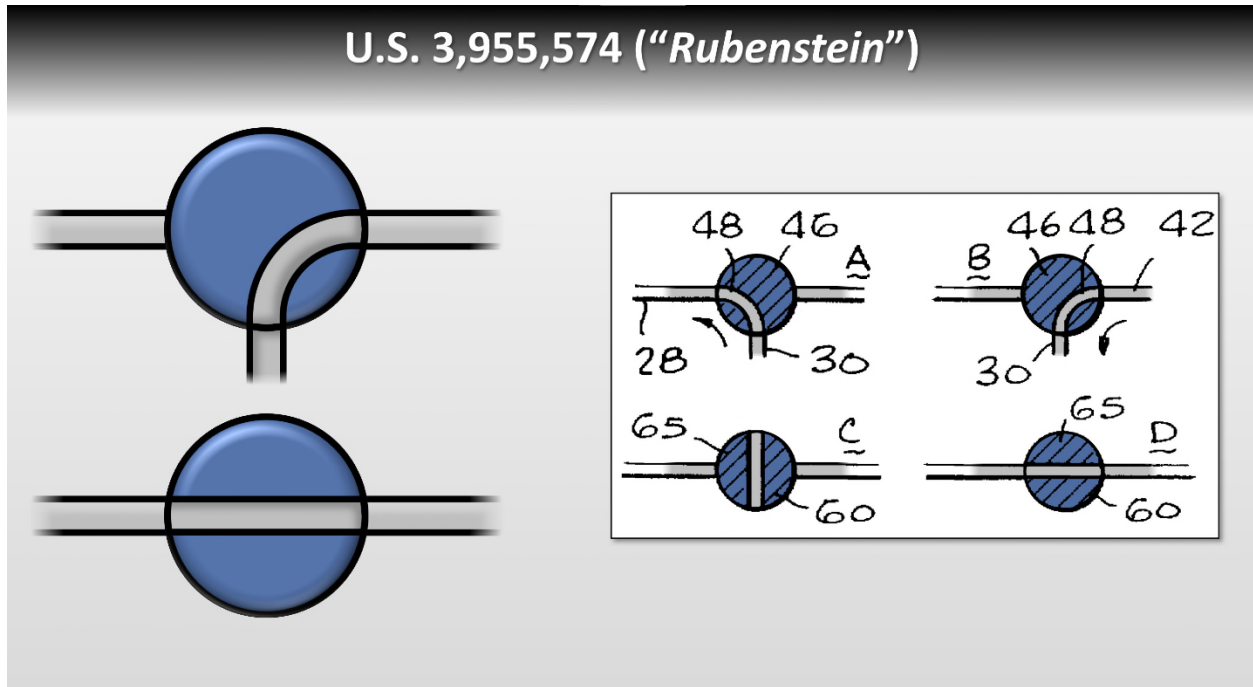
Rubenstein explicitly describes the rotational transition: “valve 18...is **alternately rotated** under the control of the timer 44 to have the channel 48 connect the tubing 30 to either the tubing 28 or the tubing 42... diagram B illustrates the movable plug 46 as **having been rotated** to have the channel 48 positioned to permit fluid flow between the tubing 42 and the tubing 30.” Ex[1011], 3:21-36.

U.S. 3,955,574 ("Rubenstein")



U.S. 3,955,574 ("Rubenstein")



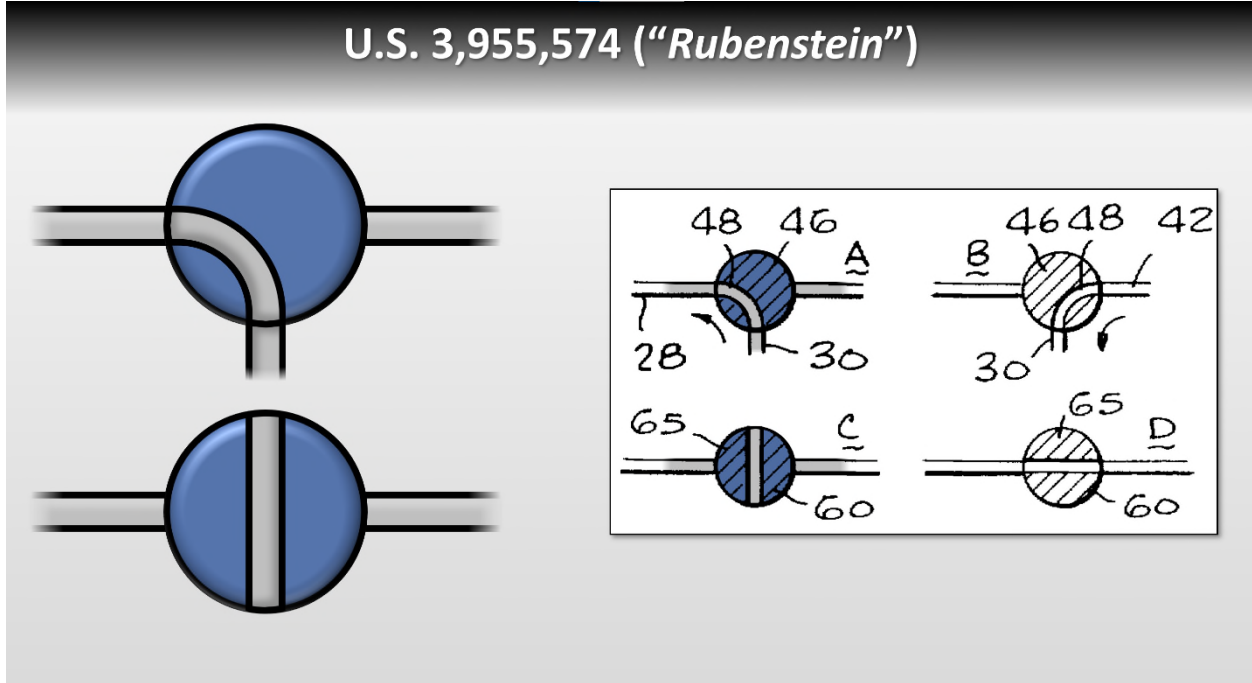


Ex[1005], ¶¶320-327.

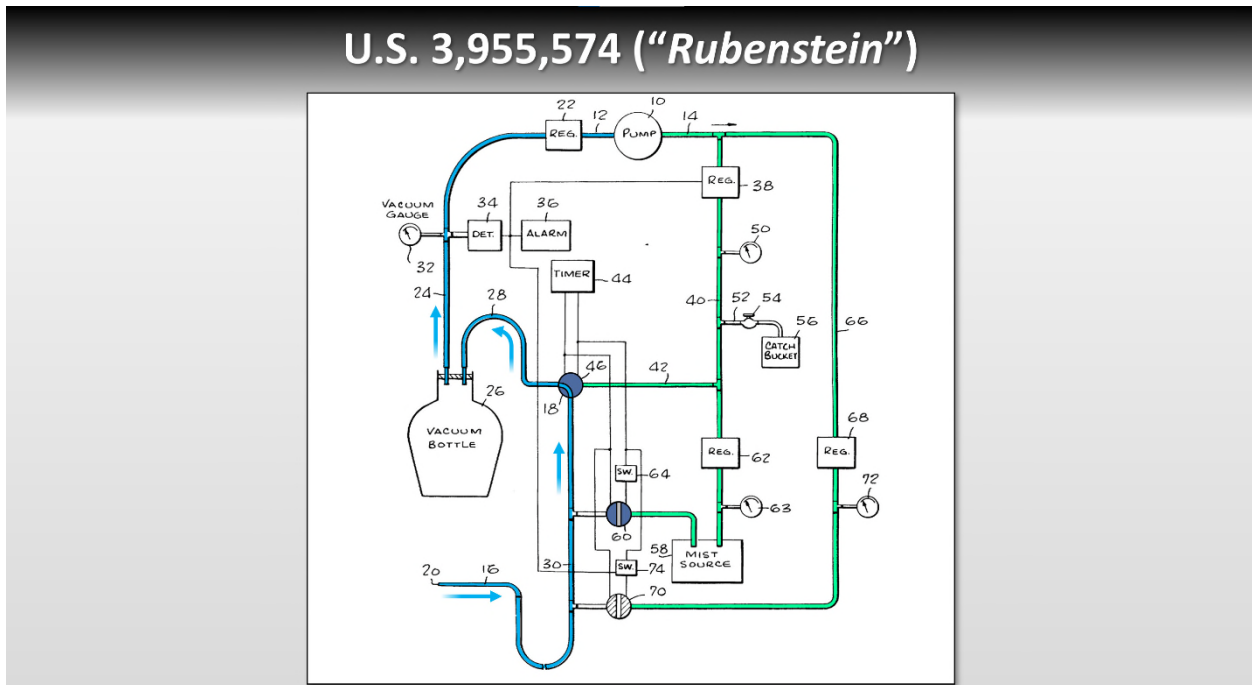
A POSA would find it obvious that Rubenstein's rotary valves **rotate** between their different positions rather than making an instantaneous transition. A rotary valve functions by rotating a connecting channel to different locations to connect/disconnect channels attached to the valve. Ex[1011], 3:21-26; Ex[1005], ¶¶320-327.

Rubenstein's rotary valves are in a double-closed state when they are rotating between the connected positions, as illustrated below. The rotary valves begin in a first position "A" and "C," where the catheter is connected through a connecting channel 48 of valve 46/18 to the vacuum, but disconnected from the fluid line, which is closed off by valve 60:

U.S. 3,955,574 ("Rubenstein")

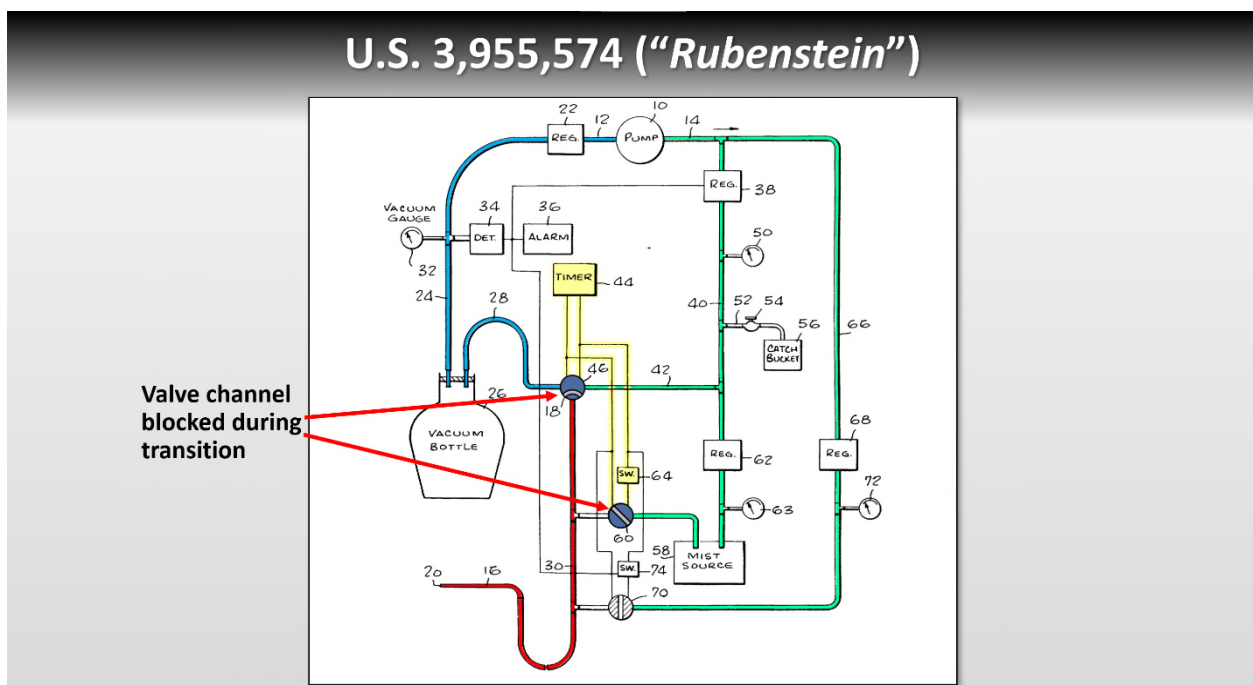
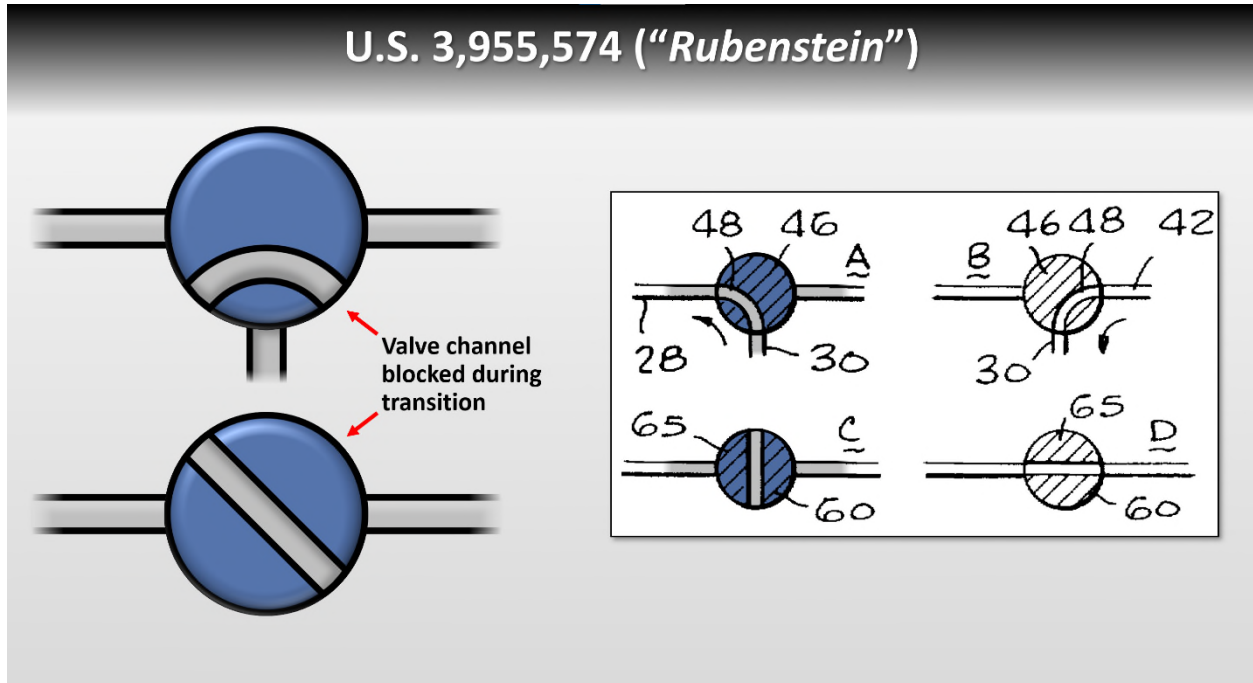


U.S. 3,955,574 ("Rubenstein")

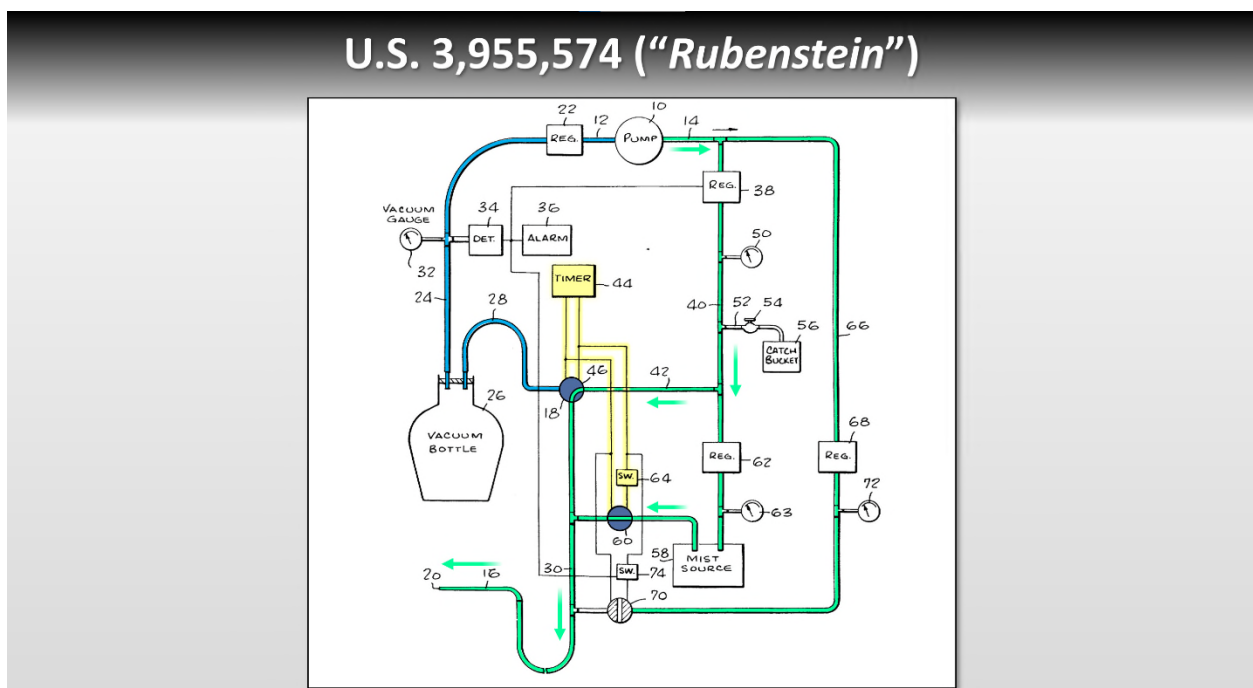
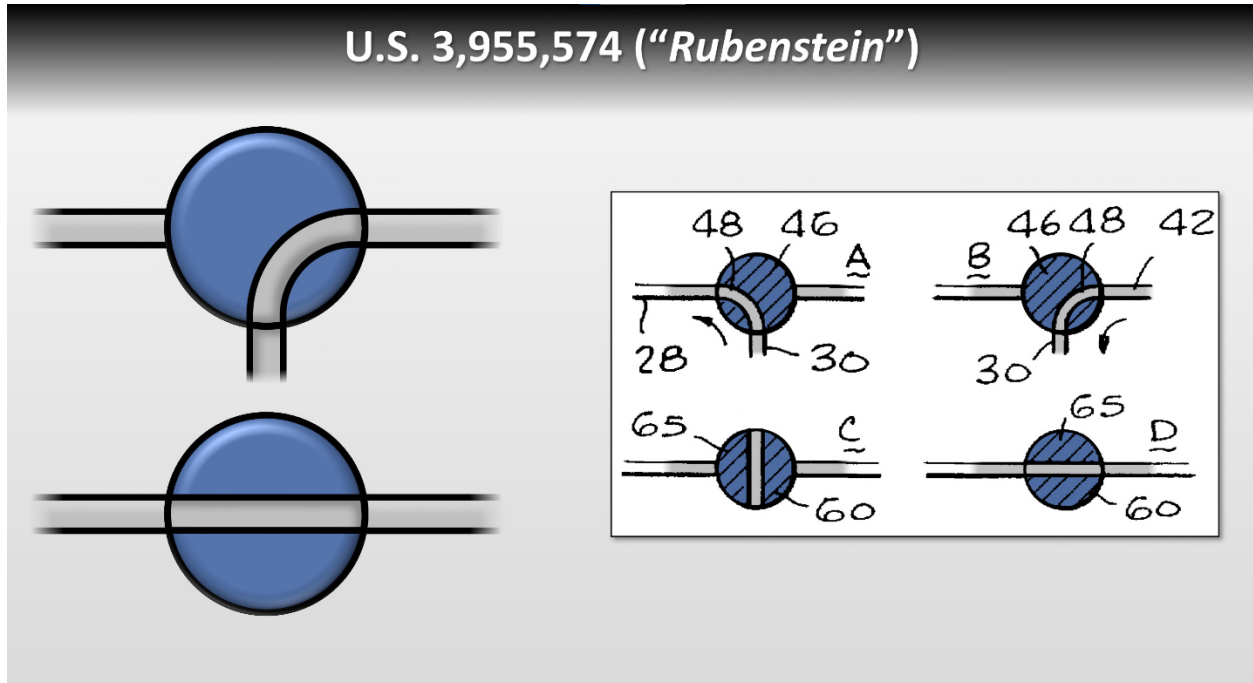


The valves then rotate towards a second position. A POSA would understand that during this transition, the connecting channels are not aligned with either the

vacuum or fluid line, and are therefore in a double-closed state. Ex[1005], ¶¶320-327.



Following the double-closed state transition period, the connecting channels of rotary valves 46/18 and 60 rotate to their second position “B” and “D,” where the catheter is connected to the fluid line and disconnected from the vacuum:



Thus, a POSA would understand that Rubenstein discloses and/or renders obvious a “double-closed state.” Ex[1005], ¶¶320-327.

A POSA would also find it obvious to employ Rubenstein’s time-controlled valve opening and closing in Yang/Mullins because Rubenstein notes that “any cycle and ratio of negative and positive pressure can be used to satisfy a particular need” which would invite a POSA to optimize the valve cycle times for optimal clot aspiration. Ex[1011], 2:64-68, 3:41-50; Ex[1005], ¶¶328-329.

Consistent with Yang’s serial valve states, a POSA would have understood, and it would be logical and obvious, to operate the valves in serial to yield effective pulsing. Rubenstein similarly discloses such serial operations of vacuum and vent valves that a POSA would readily and easily adopt for dynamic aspiration taught by Ex[1012], ¶¶[0102], [0108], [0168]-[0170], FIGs.13, 14, 25(a)-(c); Ex[1008], 3:48-59, 4:5-11, 26:65-27:65, FIGs.46-49; Ex[1011], 1:10-14, 1:64-68. Ex[1005], ¶¶328-329. Alternatively, a POSA could also adopt the valves disclosed in Rubenstein to accomplish the dynamic aspiration taught by Yang and Mullins including an off-off state in which the vacuum valve is closed while the vent valve is closed. Ex[1005], ¶¶328-329.

Claim 6

[6-A]

See §Gr.1, [1-E]; Ex[1005], ¶334.

[6-B]

See §§Gr.1, [5-B], [6-B]; Ex[1005], ¶335. Additionally, in view of the reasons discussed above (See §Gr.2, [5-B]), the combined system would include a double-closed state as taught in Rubenstein. Ex[1005], ¶335.

Claim 18

[18-A]

See §Gr.1, [1-E]; Ex[1005], ¶336.

[18-B]

See §§Gr.1, [5-B]; Gr.2, [5-B]; Ex[1005], ¶337.

Claim 19

[19-A]

See §Gr.1, [1-E]; Ex[1005], ¶338.

[19-B]

See §§Gr.1, [5-B], [6-B]; Gr.2, [6-B]; Ex[1005], ¶339.

C. Ground 3: Claims 15 and 16 are Rendered Obvious Over Yang in View of Mullins, Matteo, and the Knowledge of a POSA

Motivation to Combine

A POSA would have been motivated to modify Yang/Mullins with Matteo's teaching of cam system for valve control. Ex[1005], ¶¶340-344.

Yang, Mullins, and Matteo all (1) address similar problems related to the precise combination of multiple fluids at precise times in scientific and medical

applications, and (2) teach similar solutions involving flow control mechanisms (e.g., valves or pumps) switched between varying states of open and closed positions. Ex[1012], ¶¶[0102], [0108], [0170], FIGs. 13, 14, 25(a)-(c); Ex[1008], 26:31-37, 26:65-27:39; Ex[1013], ¶[0059], FIGs.10A-C; Ex[1005], ¶341.

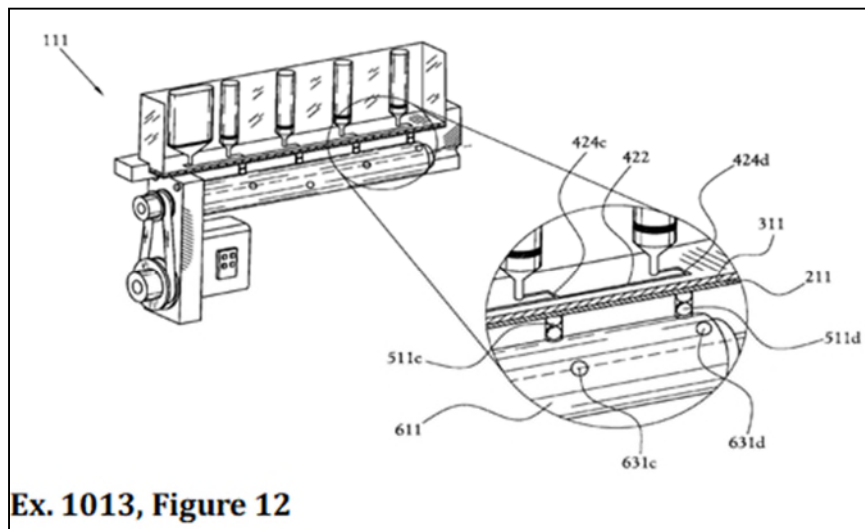
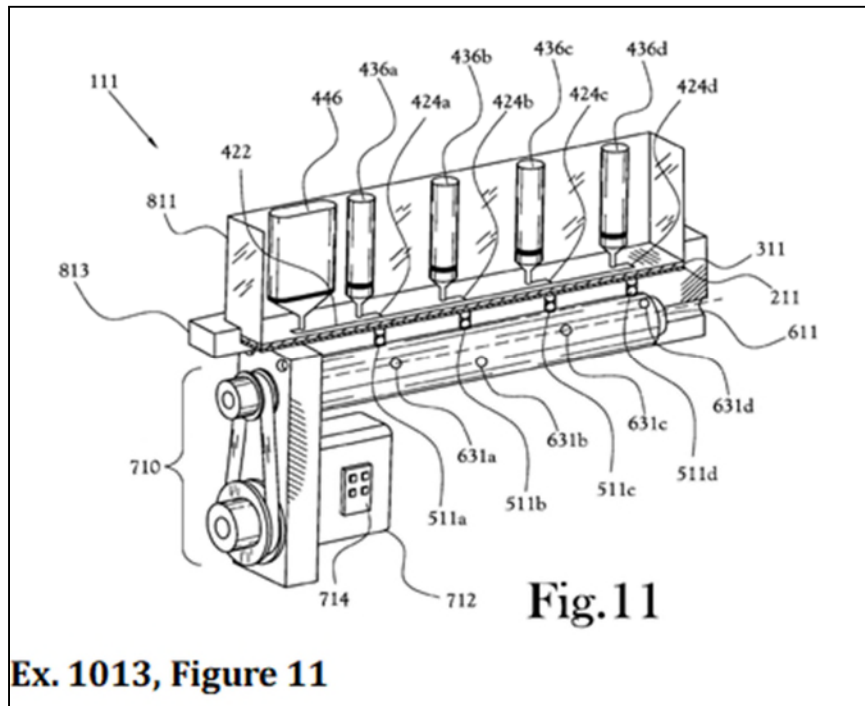
Combining the teachings would have been well within the skill of a POSA, because it entails nothing more than combining known vacuum aspiration technologies described in these references to perform their intended functions with described benefits and predictable results. Ex[1005], ¶342.

Claim 9

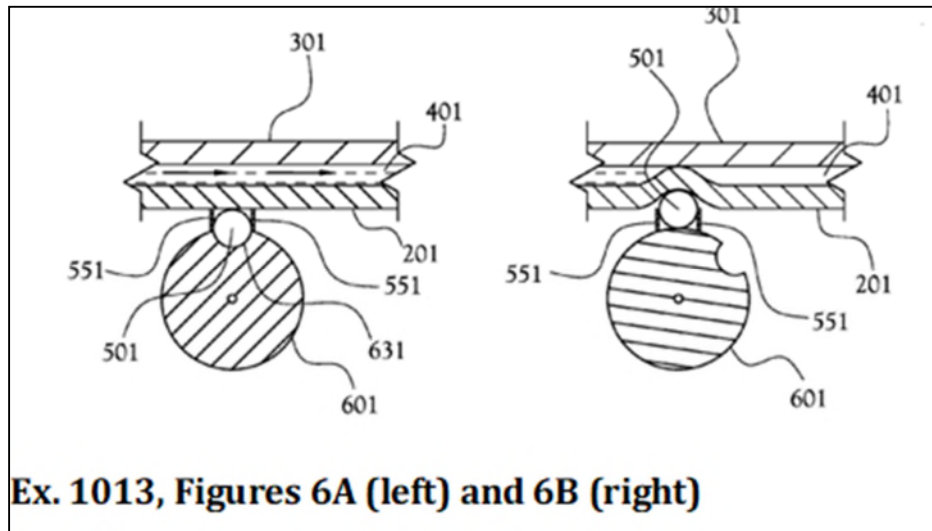
[9]

See §Gr.1, [1-Pre]-[1-G]. It would further be obvious to implement Yang/Mullins's valves with Mateo's cammed pinch valves. Ex[1005], ¶¶346-354.

Matteo discloses a microfluidics system “to control multiple microvalves” for use in biological and biomedical applications. Ex[1013], Abs., ¶¶[0006], [0012]. It discloses “one cylindrical cam controlling several actuator balls and several microvalves” in Figures 11 and 12. Ex[1013], ¶[0029]. Matteo further discloses that “[c]am driven pinch-style microvalves are useful for serving as on/off valve devices for a microfluidic system.” Ex[1013], ¶[0010], *see also* Abs., ¶¶[0009], [0045]-[0047].



Matteo's pinch valves have open and closed states. Ex[1013], Figs. 6A (open), 6B (closed). Matteo further discloses that the "position-control mechanism (PCM) 701 controls the cam 601 by turning the axle 651, thereby turning the cylindrical cam 601." Ex[1013], ¶[0045], FIGs. 3, 11-12.



It would have been obvious for a POSA and required no undue experimentation to implement the Yang/Mullins valves with the cam-driven valves disclosed in Matteo to achieve the desired dynamic aspiration. Ex[1005], ¶¶346-354.

D. Ground 4: Claims 1-8 and 10-20 are Rendered Obvious Over Ofek in view of Mullins and the Knowledge of a POSA

Motivation to Combine

A POSA would have been motivated to combine the teachings of Ofek and Mullins. Ex[1005], ¶¶355-362. Both Ofek and Mullins address similar problems related to aspiration thrombectomy and share the common objective of improving the removal of blood clots using dynamic aspiration catheters. Ex[1007], 2:56-3: 42, 4:21-44, 5:63-6:45, 8:38-49, FIGs.2-3; Ex[1008], 3:29-4:11, 26:17-27:67, FIGs.46-49; Ex[1009.2], pg.3-10, FIGs.3-8.

Combining the teachings of Ofek and Mullins would have been well known within the skill of a POSA, because it is nothing more than combining known and

predictable aspiration technologies to perform their intended functions with described benefits and predictable results. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007); Ex[1005], ¶358.

A POSA would have been motivated to implement Mullins's disclosures of controlling levels of vacuum and fluid flow in and out of the distal end of the catheter to modify Ofek's system, which already includes a catheter aspiration system utilizing positive and negative pressure sources to control vacuum in the catheter, to provide efficient and effective cyclical aspiration of blood clots. Ex[1005], ¶356; Ex[1007], Abs., 1:16-33, 2:38-3:2, 3:43-4:6, 4:45-6:19; Ex[1008], 3:29-4:11, 26:17-28:64. A POSA would recognize Ofek could be configured to achieve the benefits, as taught by Mullins, of cyclical pressure changes to control levels of vacuum and fluid flow at the distal tip of the catheter. Ex[1005], ¶361; Ex[1008], 3:29-4:11, 26:17-27:67, FIGs.46-49; Ex[1009.2], pg.2-10.

A POSA would have had a reasonable expectation of success in combining Ofek and Mullins. Because Ofek's system is already computer-controlled, and already has similar sources of positive and negative pressure to manipulate vacuum within the catheter, it would have been well within a POSA's level of skill to modify the logic of Ofek's controller to implement Mullins's teachings, and/or to incorporate well-known mechanical components, if needed, to carry out the functionality described in Mullins. Ex[1005], ¶360. Moreover, Mullins simply

modulates pressures contained within the aspiration system, which is done in line with preferable pressure cycles as taught by Ofek. Ex[1005], ¶360.

Furthermore, a POSA would have recognized the benefit of controlling the level of vacuum and fluid flow at the distal tip of the catheter, as taught in Mullins, in the context of Ofek's aspiration system. Ex[1005], ¶¶346-354; see Ex[1008], 3:29-4:11, 26:12-28:64; Ex[1009.2], pg.2-10.

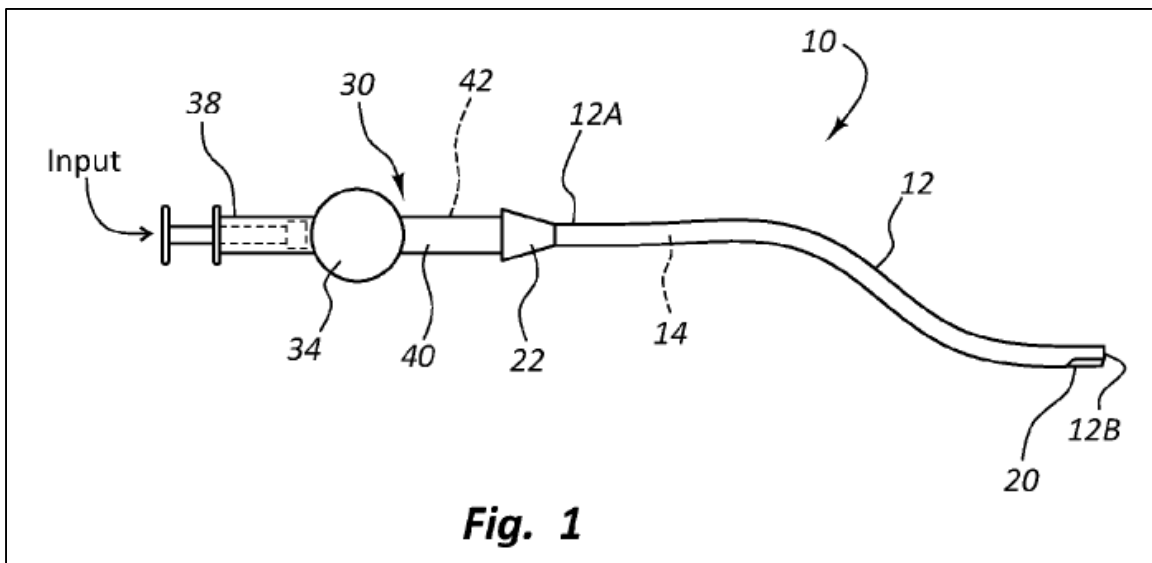
Claim 1

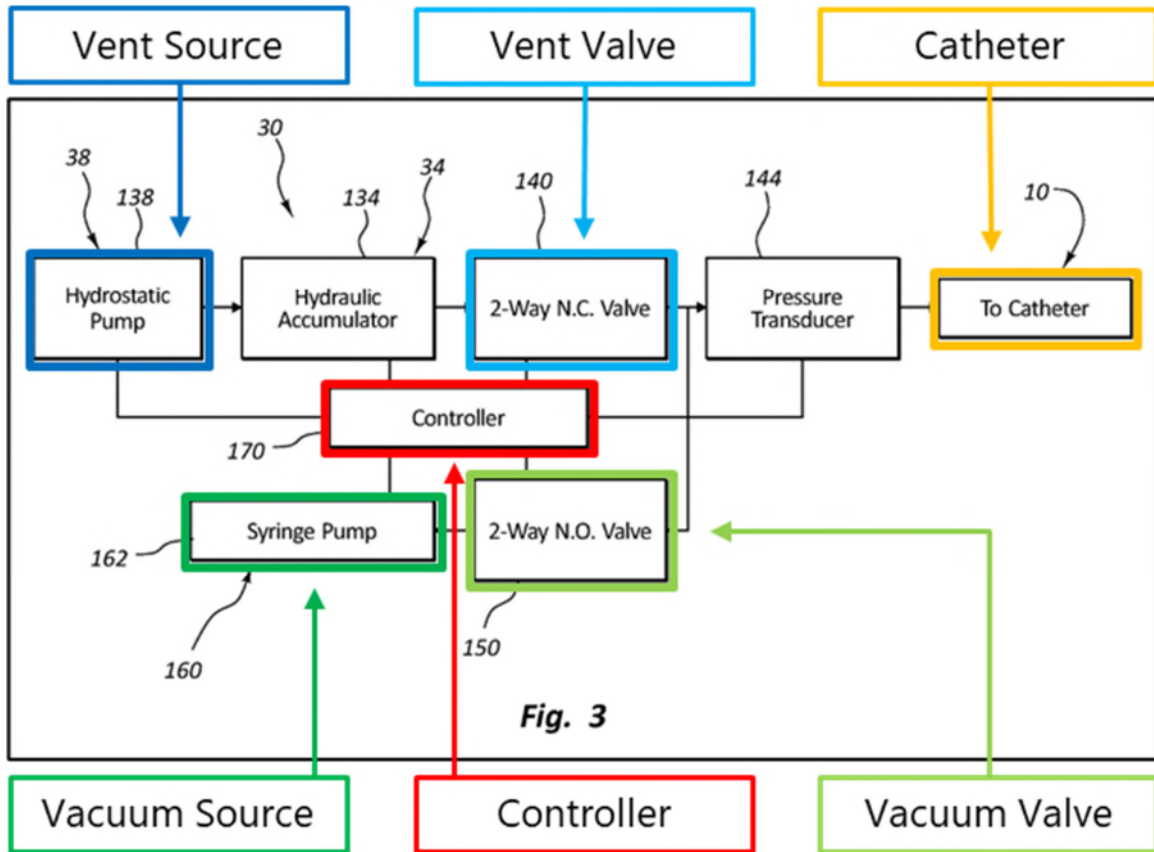
[1-Pre]

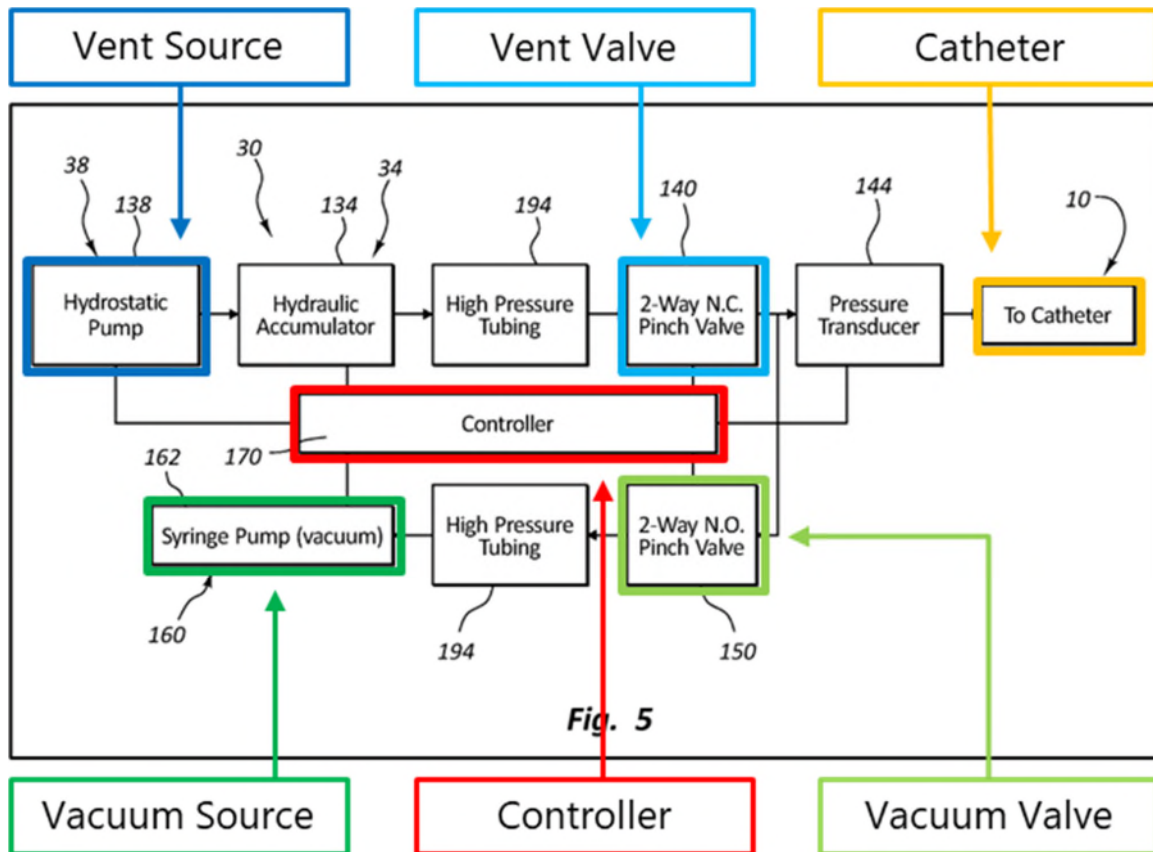
To the extent the preamble is limiting, Ofek/Mullins discloses or renders it obvious. Ex[1005], ¶¶363-371.

Ofek discloses a patency device for catheter assemblies to aspirate and remove occlusions with, for example, "arterial catheters." Ex[1007], 1:16-33, 2:38-55. Ofek explains that the device can be used for both (1) aspirating occlusions (including thrombus) at the distal end of the catheter and (2) to provide patency within the catheter lumen. Ex[1007], 2:56-3:2. Ofek's aspiration techniques use predetermined patterns to alternate periodic impulses (e.g., infusing pressurized fluids) and periods of vacuum (negative pressure). Ex[1007], 6:46-58, 8:38-49. "[G]roups of impulses are separated by rest periods 286 of negative baseline pressure 284 to enable aspiration from the catheter 10 of any occlusions... the number of impulses in each group can vary according to [] a pre-set predetermined pattern, as can the pressure,

frequency, etc.” Ex[1007], 8:38-49. “Such impulses...performed periodically...prevent the formation of thrombus...at the distal end....” Ex[1007], 2:56-3:2. Pressure is controlled to prevent distal migration: “...the high-pressure impulses [] are strong enough to dislodge the occlusion but are not of sufficient duration to push it out the distal end.” Ex[1007], 4:21-44; FIGs.1, 3, 5; Ex[1005], ¶¶364-368.



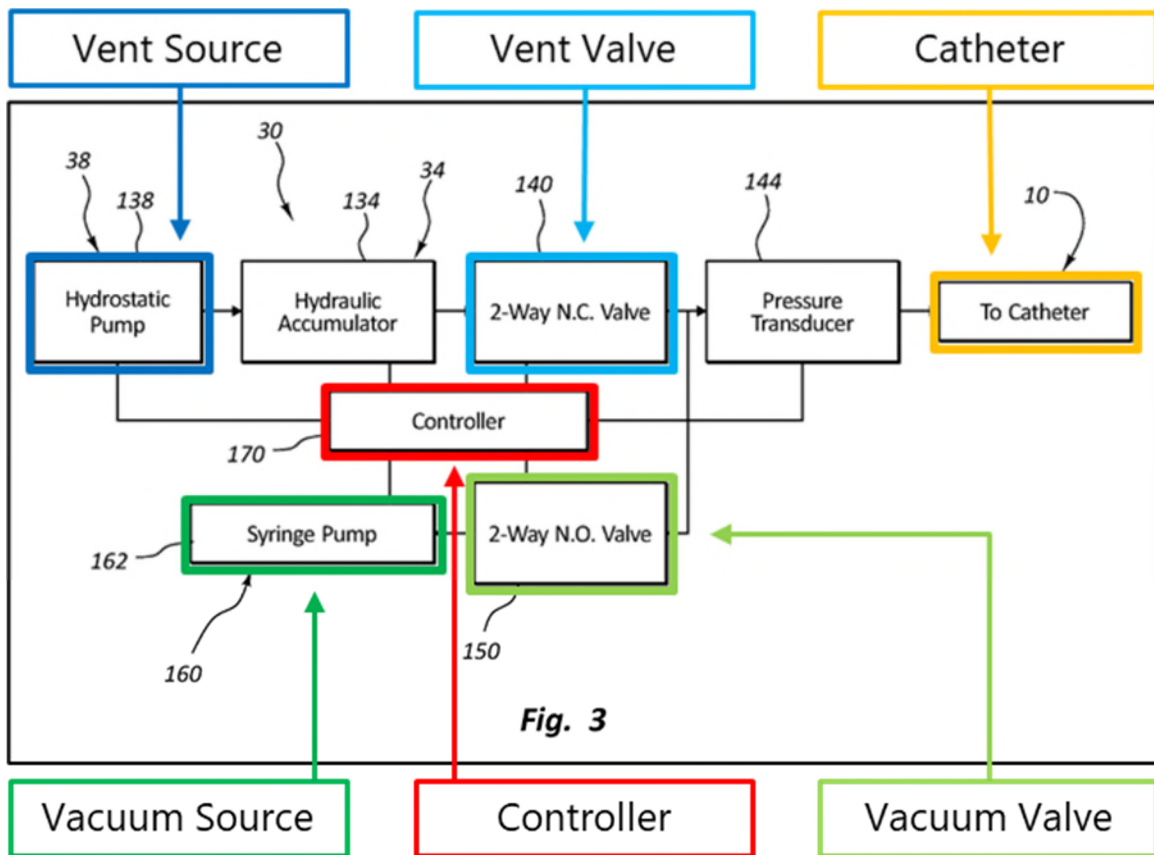
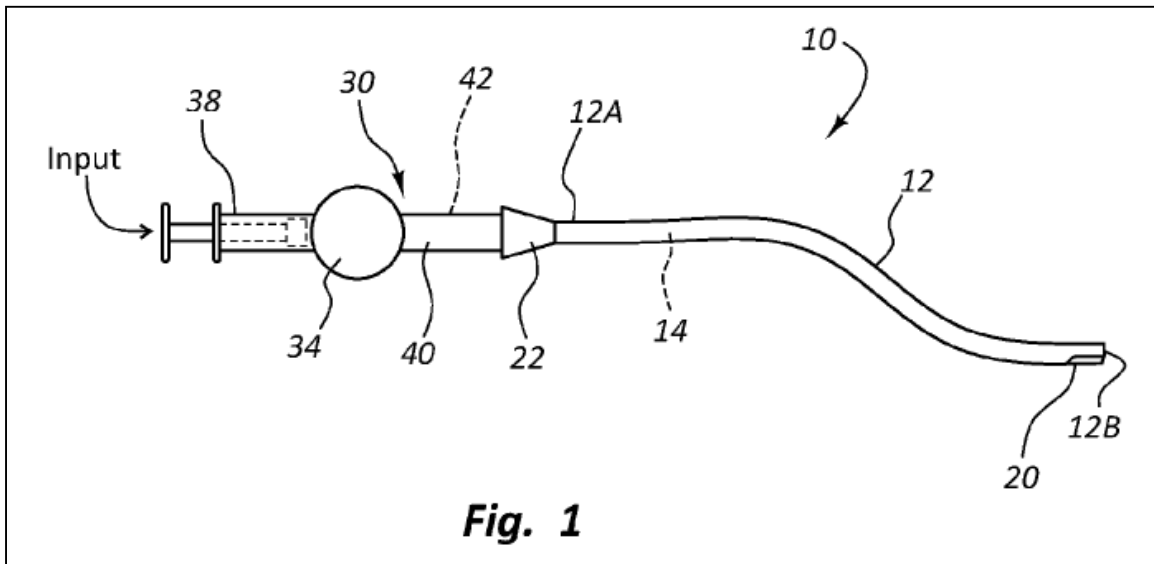


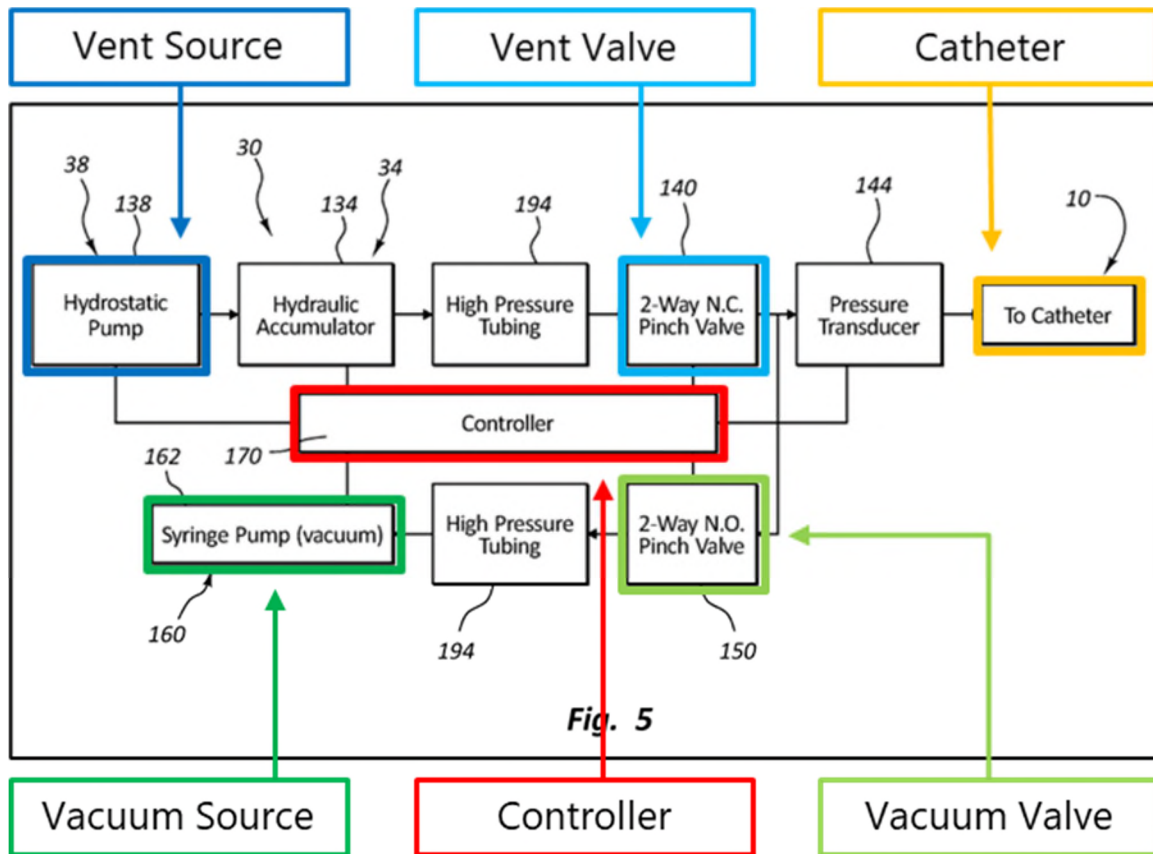


Mullins similarly discloses an aspiration thrombectomy system cyclically applying vacuum or pressure “to improve efficiency of aspiration.” Ex[1008], 3:29-4:11, 25:22, 26:17-28:64. Ex[1005], ¶¶369-371.

[1-A]

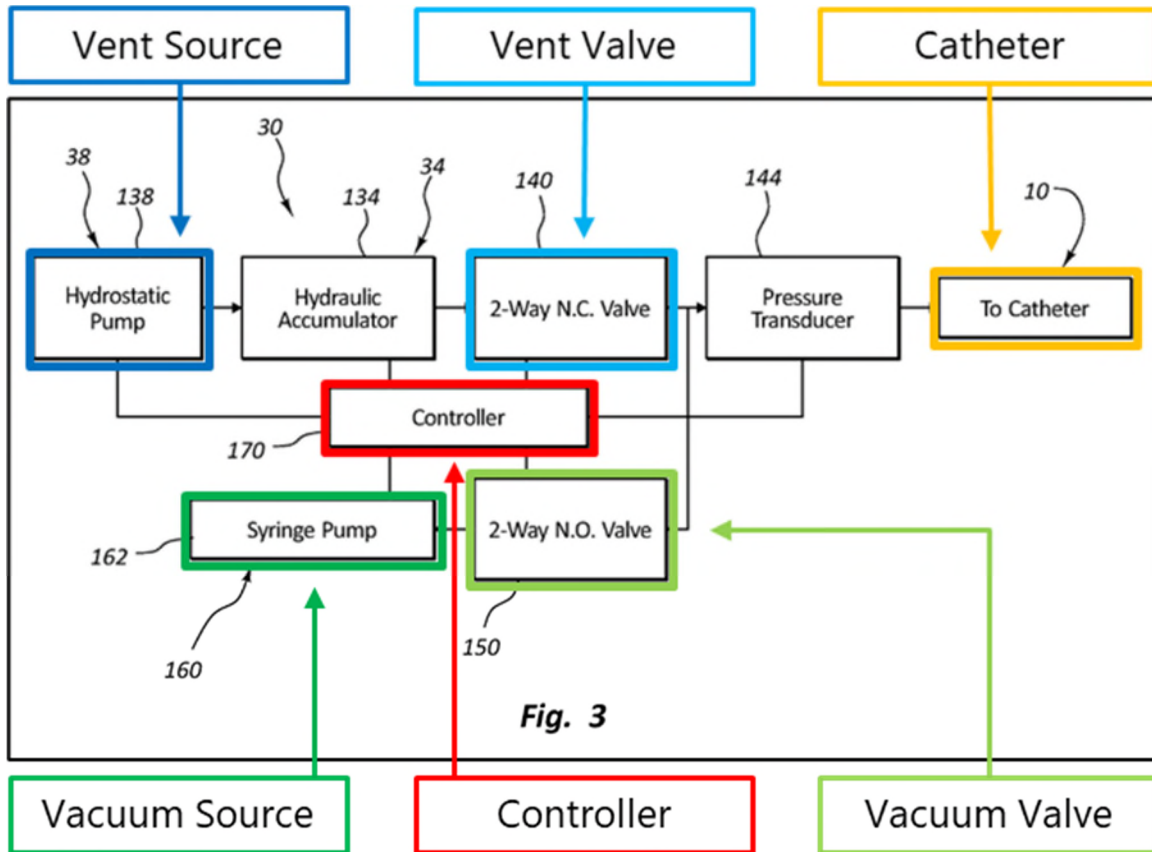
Ofek teaches a catheter (e.g., an “arterial” catheter) which has “a lumen 14 extending between a proximal end 12A and a distal end 12B of the catheter tube,” and is used for aspirating “thrombus [] in the lumen 14, especially at the distal end thereof.” Ex[1007], 2:38-3:2, 8:38-49, FIGs.1, 3, 5. Ex[1005], ¶¶372-378.

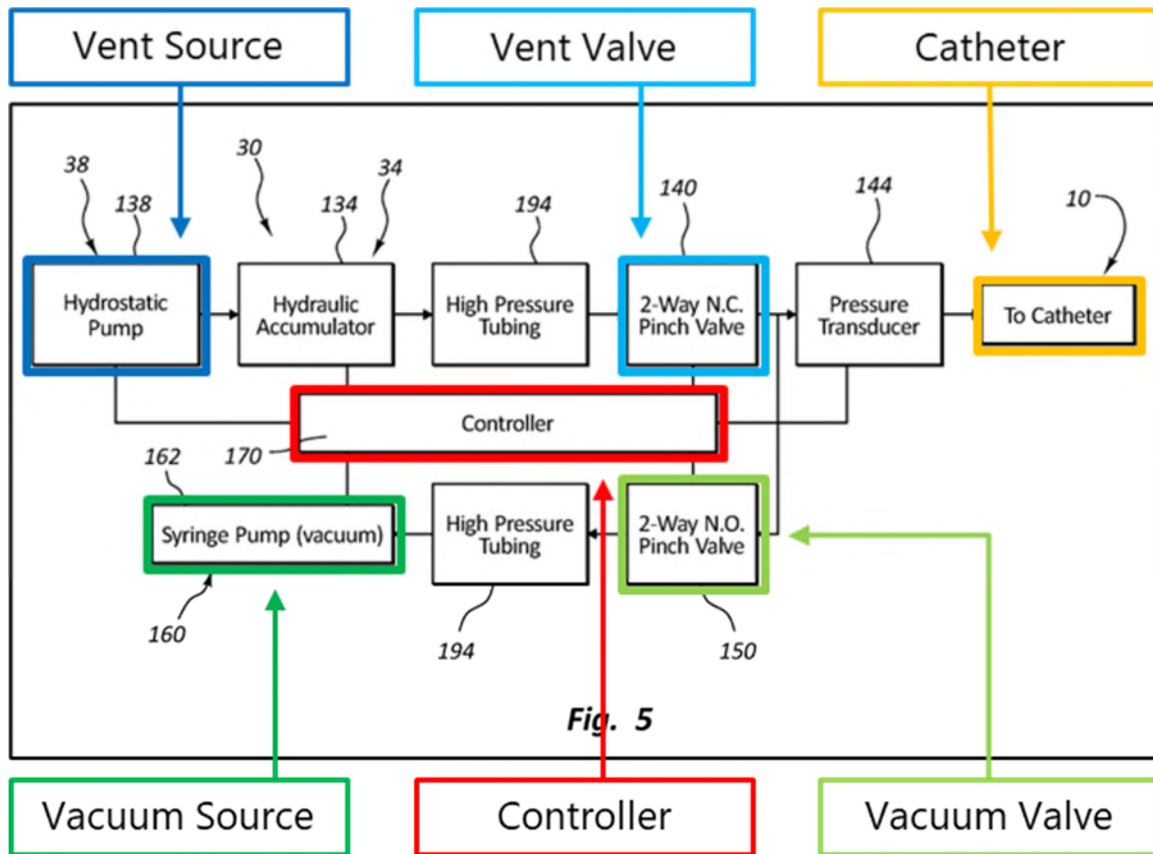




[1-B]

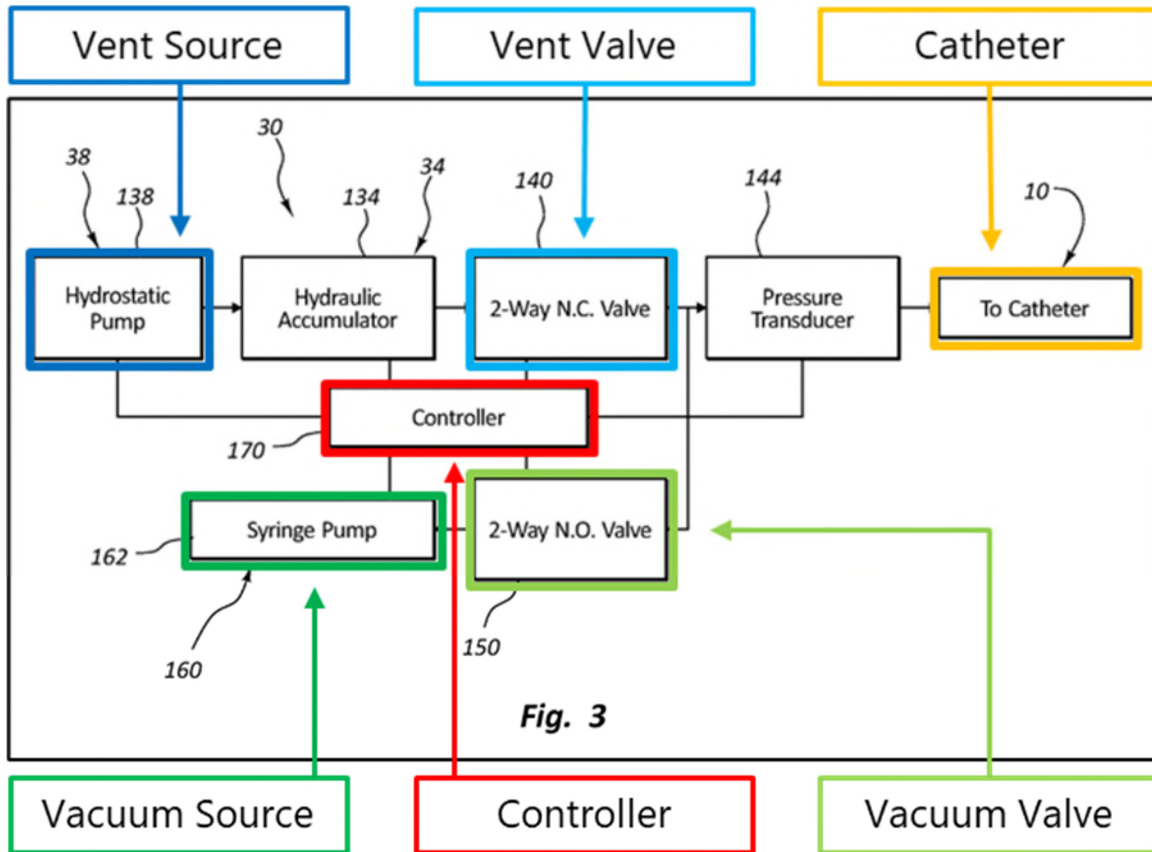
Ofek teaches a vacuum source (e.g. “a vacuum pump”) coupled to the catheter which can “supply negative baseline pressure/negative pressure impulses to fluid in the lumen 14.” Ex[1007], 4:62-5:7, 8:50-67, Claims 4, 5, FIGs. 3, 5; Ex[1005], ¶¶379-381.

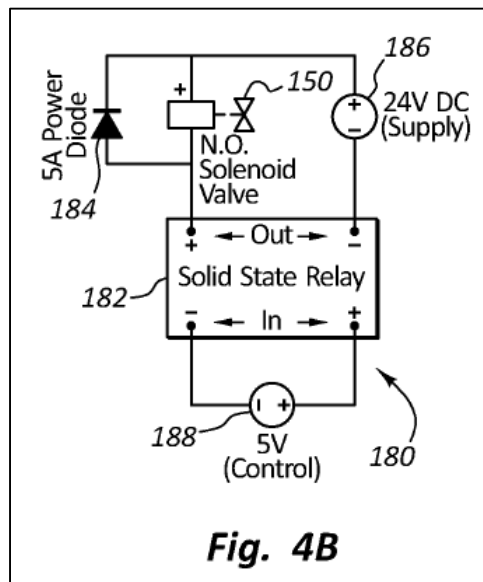
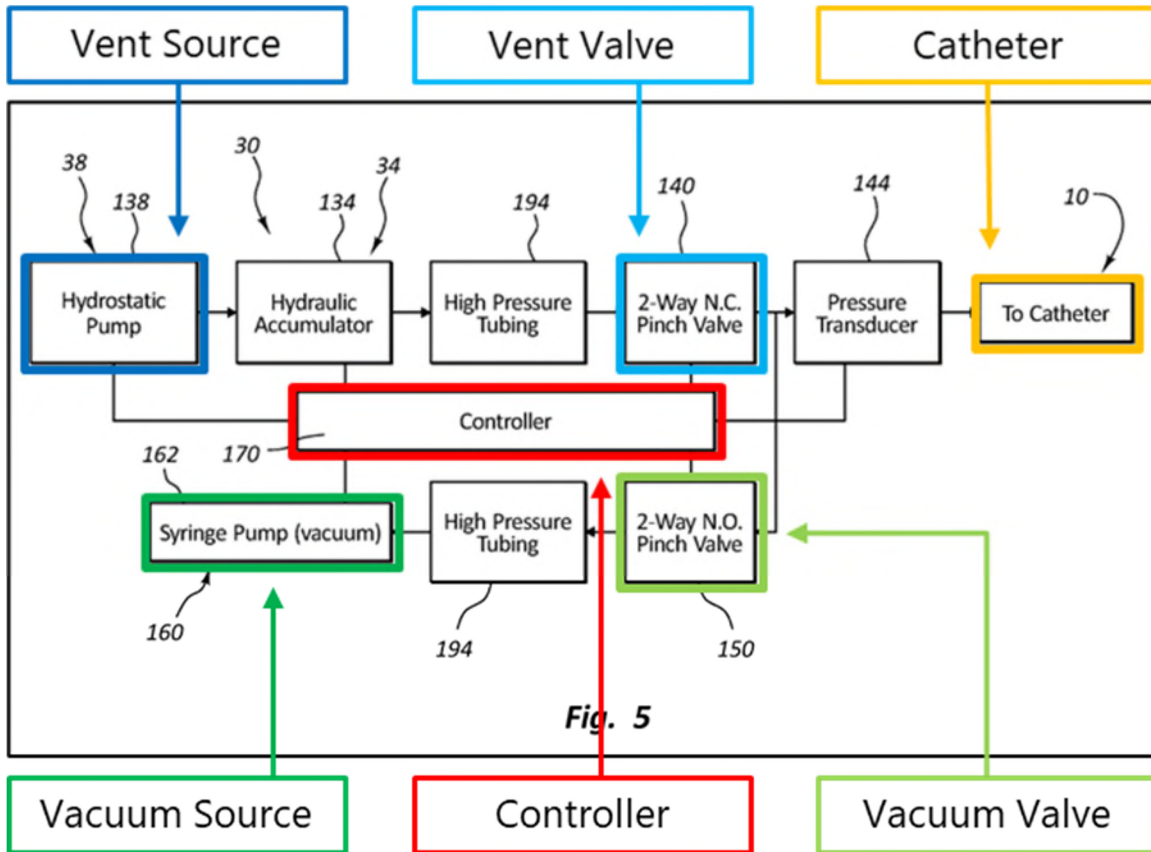




[1-C]

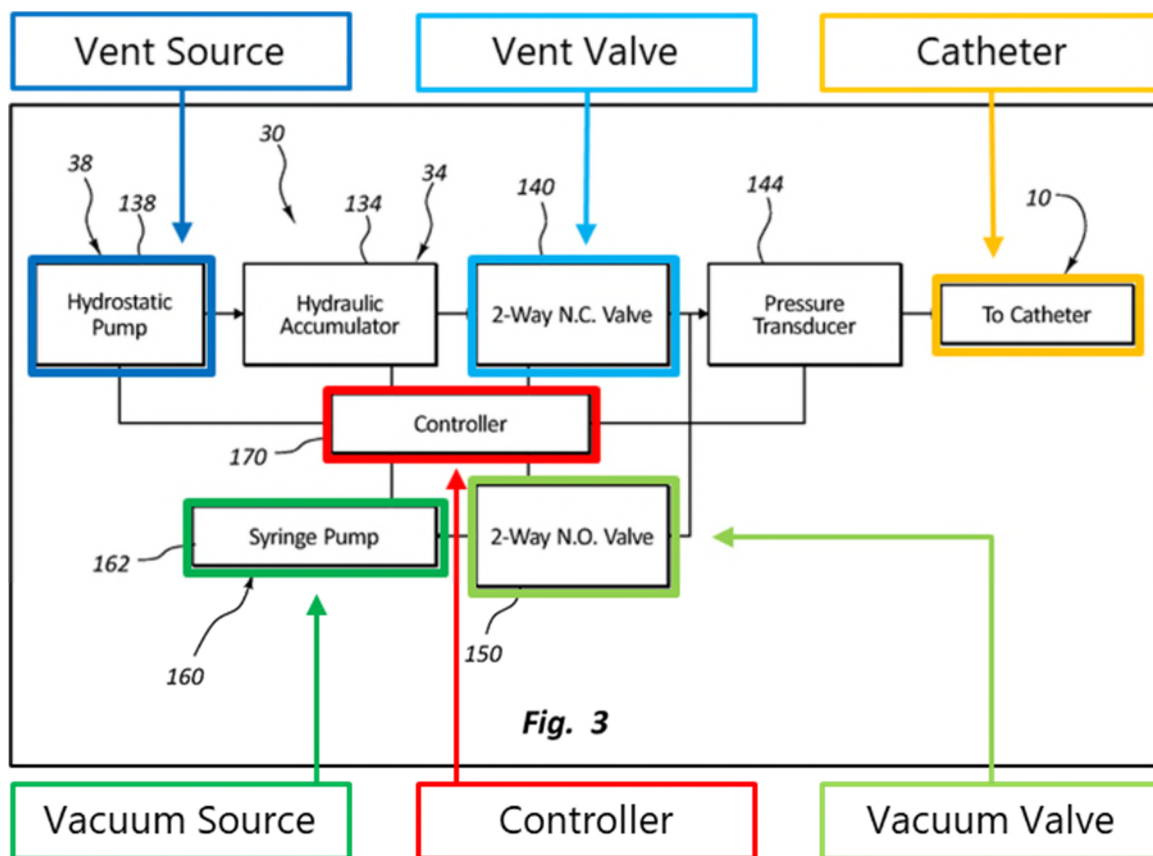
Ofek teaches a vacuum valve (“two-way, normally open (“N.O.”) valve 150”) connected between the “vacuum input portion 160” and the catheter proximal portion via “transducer 144” to control flow in the catheter lumen. Ex[1007], 4:51-67, 5:8-6:8, 7:18-26, FIGs. 3, 4B, 5. This “enable[s] any occlusion dislodged by the impulses to be suctioned proximally out of the lumen, through the N.O. valve to the syringe pump 162.” Ex[1007], 5:63-6:8. Ex[1005], ¶¶382-384.

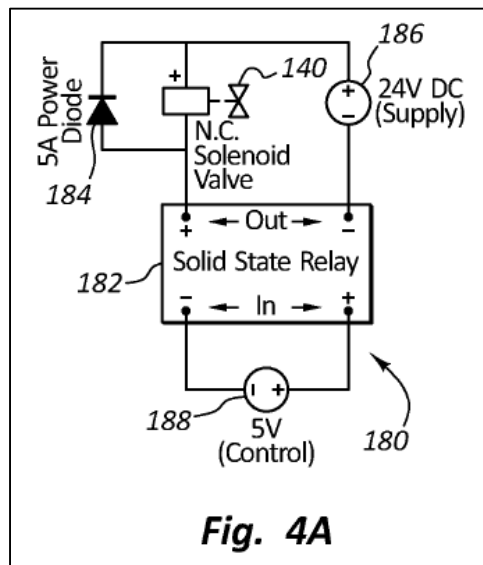
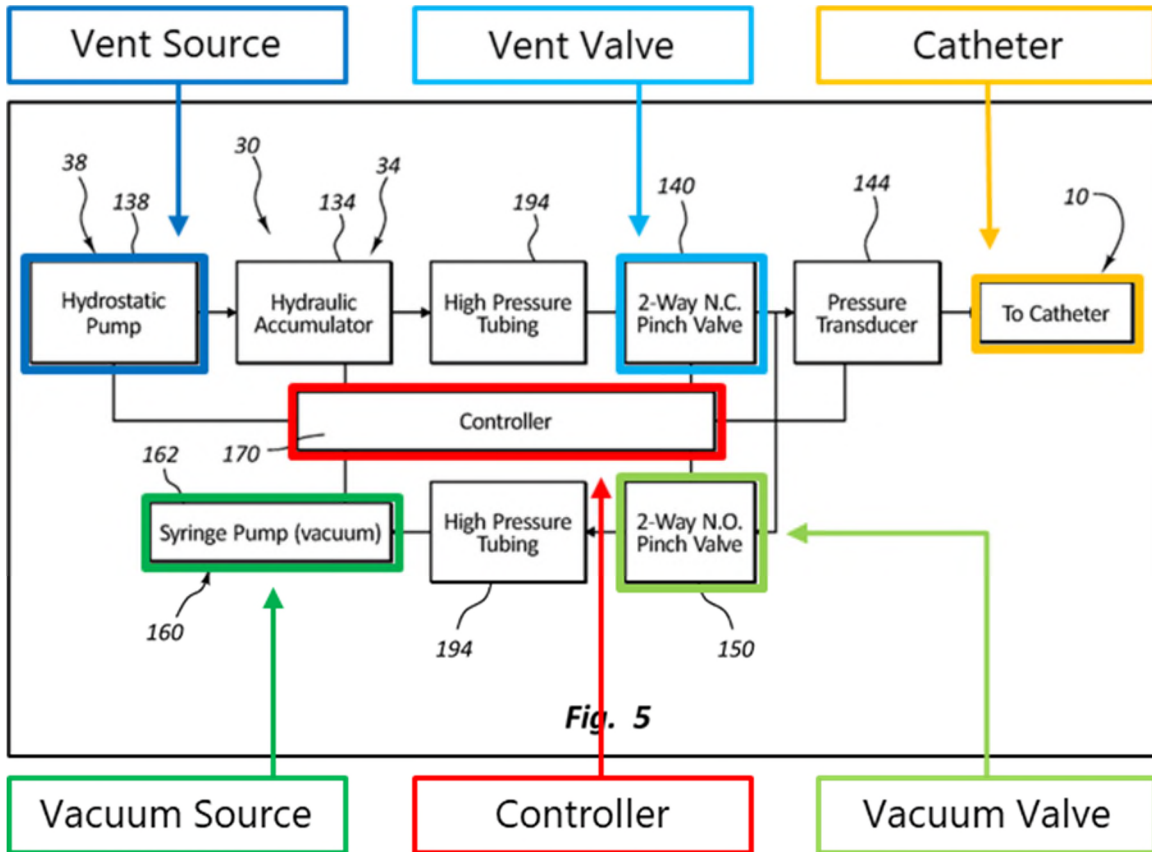




[1-D]

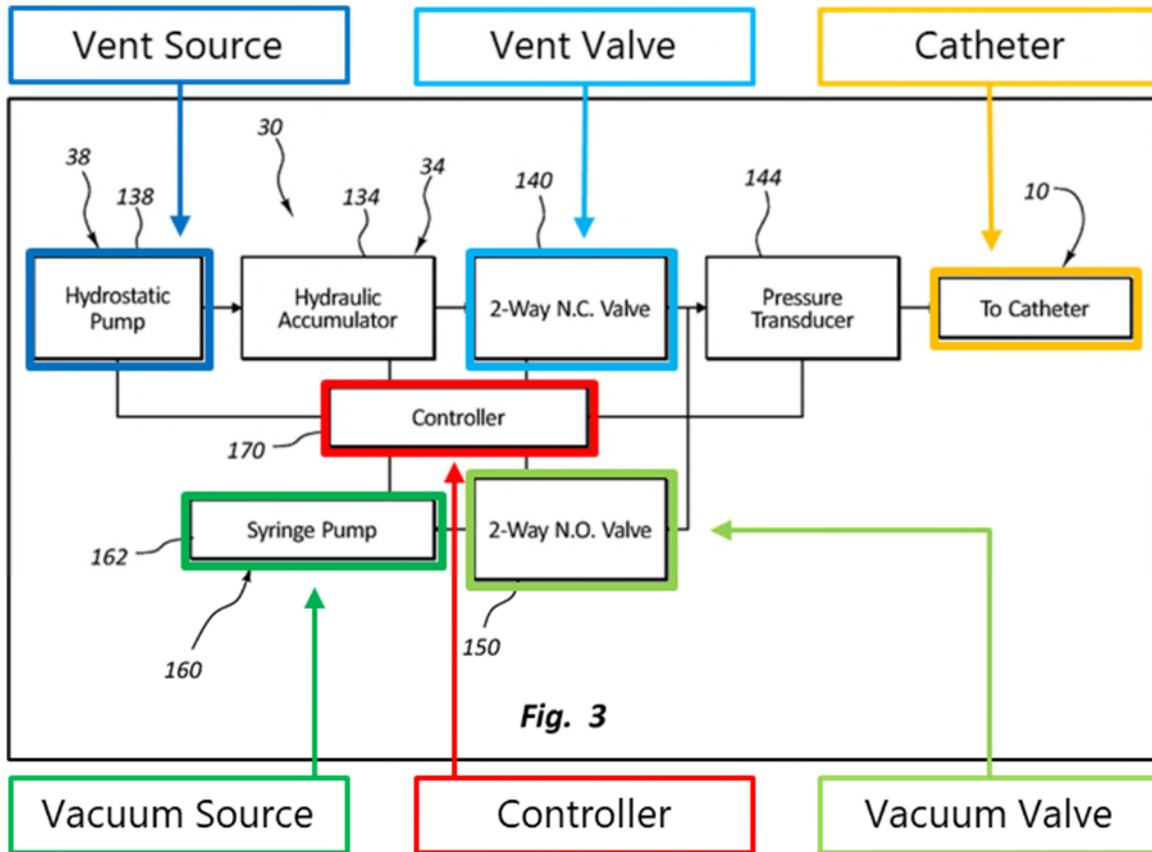
Ofek teaches a “two-way, normally closed (“N.C.”) valve 140” to control vent fluid flow in the catheter. Ex[1007], 4:45-5:62, 7:18-26, FIGs. 3, 4A, 5. The valve is connected to “hydrostatic pump 138 [] serves as the pressure input portion 38.” Ex[1007], 4:45-61. The valve is cyclically actuated to inject pressure pulses “into the lumen 14 of the catheter 10.” Ex[1007], 5:49-62. Ex[1005], ¶¶385-387.

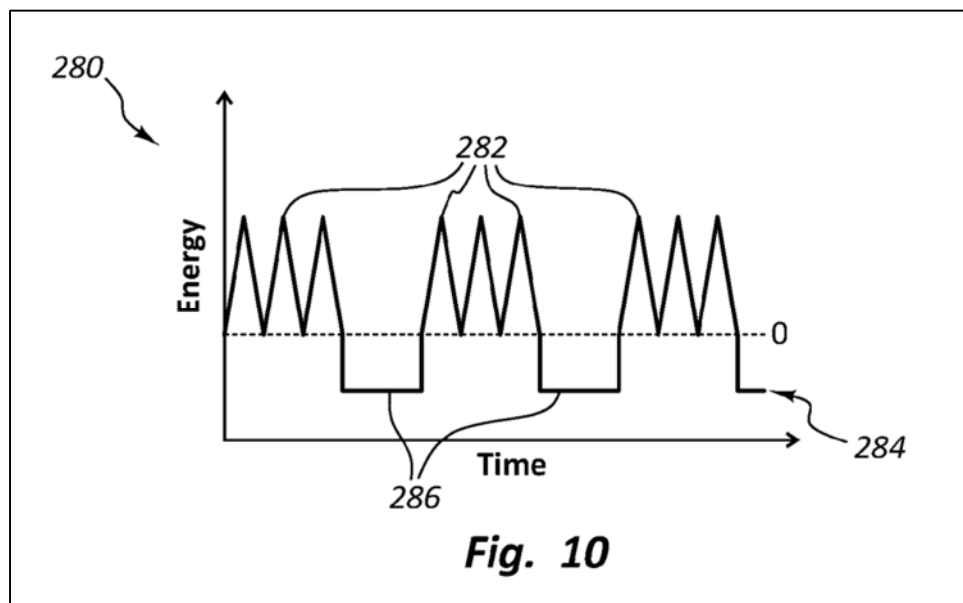
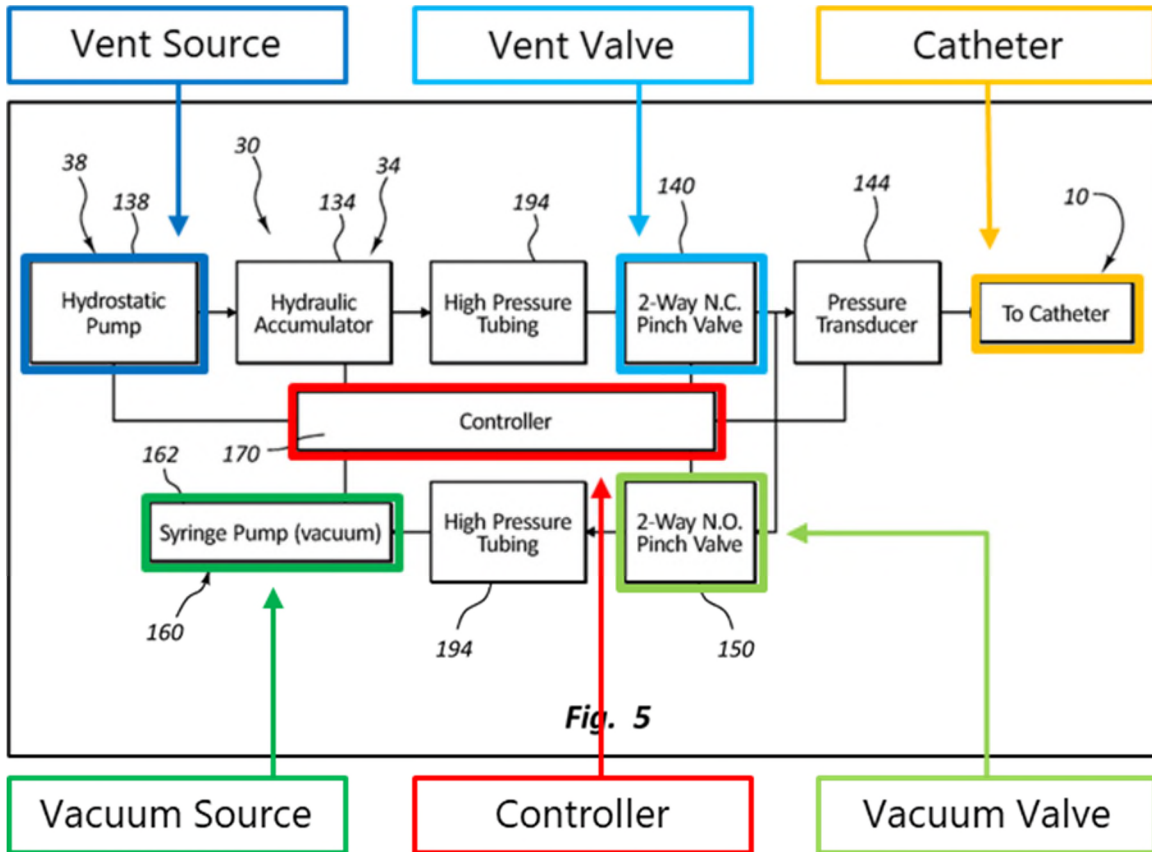




[1-E]

Ofek teaches a “controller 170” to “precisely control the opening/closing of ...valve 140 and ...valve 150 so as to provide the impulses and the negative baseline pressure to the lumen 14 as desired” in a “predetermined pattern”. Ex[1007], 4:62-5:7, 5:34-7:17, 8:23-49, FIGs. 3, 5, 10. “The controller 170 determines the number, frequency, rest periods, etc., of the impulses to be delivered...valve 140 is opened and close [sic] repeatedly at predetermined time intervals to provide a series of fluid impulses.” Ex[1007], 5:49-62. “FIGS. 8-10 depict various operation cycles for the positive pressure impulses... In FIG. 10, a series of groups of impulses is shown... separated by rest periods 286 of negative baseline pressure 284 to enable aspiration from the catheter 10.” Ex[1007], 8:23-49; Ex[1005], ¶¶388-391.





[1-F]

See §Gr.4, [1-Pre]; §Gr.4, [1-E]; Ex[1005], ¶¶392-400. Ofek further discloses the controller changing levels of vacuum in the catheter, including at the distal tip via impulses. Ex[1007], 2:56-3:60, 4:21-44, 5:49-6:8; FIG. 2. “The impulses are propagated distally down the lumen 14, which is fluid-filled....” Ex[1007], 5:49-6:8. “Such impulses, when performed periodically, are configured to prevent the formation of thrombus... in the lumen 14, especially at the distal end.” Ex[1007], 2:56-3:2. “The negative baseline pressure present between impulses... prevent[s] the dislodged occlusion from entering the bloodstream from the distal end 12B of the catheter.” Ex[1007], 3:43-60, 4:21-44.

A POSA would recognize that the positive and negative pressure impulses that change the level of vacuum in the catheter would propagate through the fluid in the catheter, and would thereby also change the level of vacuum at the distal end, which a POSA would also find obvious given Ofek’s stated goal of “prevent[ing] the formation of thrombus... at the distal end.” Ex[1007], 2:66-67; Ex[1005], ¶¶393-397.

As discussed above regarding Mullins in Gr.1, [1-F], Mullins’s techniques when applied to an aspiration catheter system like Ofek’s would also change a level of vacuum at the distal end of the catheter. Ex[1005], ¶¶398-400.

[1-G]

Ex[1005], ¶¶401-409. As discussed above for Gr.4, [1-F], Ofek/Mullins discloses or renders obvious cycling vacuum and vent valves to change a level of vacuum at the distal end of the catheter. Furthermore, Ofek permits control of fluid flow at the distal end. Ex[1007], 2:56-3:2, 3:43-4:44. “The subsequent negative pressure ...prevent[s] escape of the clot from the catheter tube.” Ex[1007], 4:21-44. A POSA would find it obvious that Ofek’s use of impulses and vacuum control over clots at the distal end of the catheter means that it is controlling the flow of material and fluid at the distal end, at least because Ofek utilizes negative pressure in conjunction with the impulses to prevent clots from escaping the distal end and entering the bloodstream. Ex[1005], ¶¶403-404.

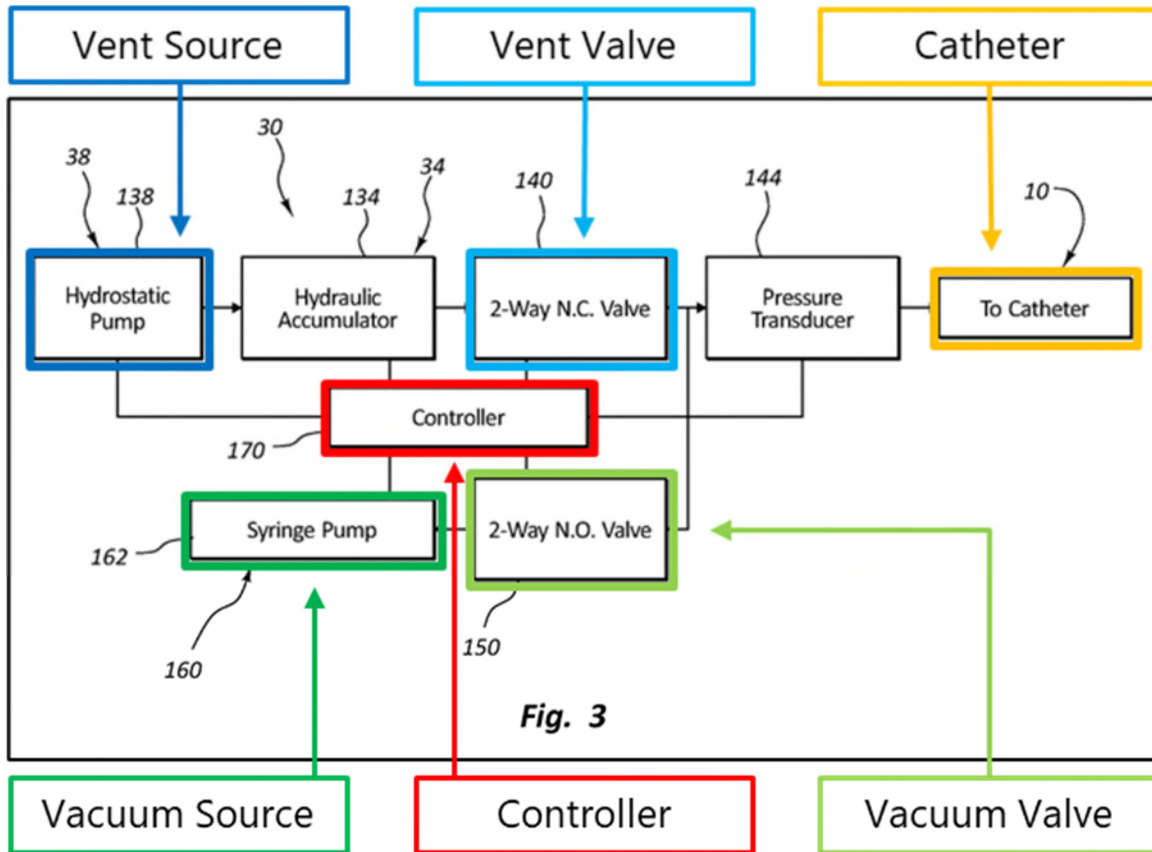
Ofek also teaches that the controller can customize the pressure/vacuum cycles (e.g., number of impulses, level of pressure, frequency, etc.), and discloses specific examples of manipulating the pressure impulses to have substantially high pressure peaks (e.g., “400 psi”). Ex[1007], 3:43-4:20. A POSA would recognize and find obvious, based on Ofek’s customizable characteristics (e.g., number of impulses, level of pressure, frequency, etc.) along with the substantially high 400 psi pressure disclosed, that Ofek’s system may result in controlled flow of fluid and/or clot out from the distal end of the catheter. Ex[1005], ¶¶405-406. In such a case, a POSA would also find it obvious, consistent with the teachings and stated purpose

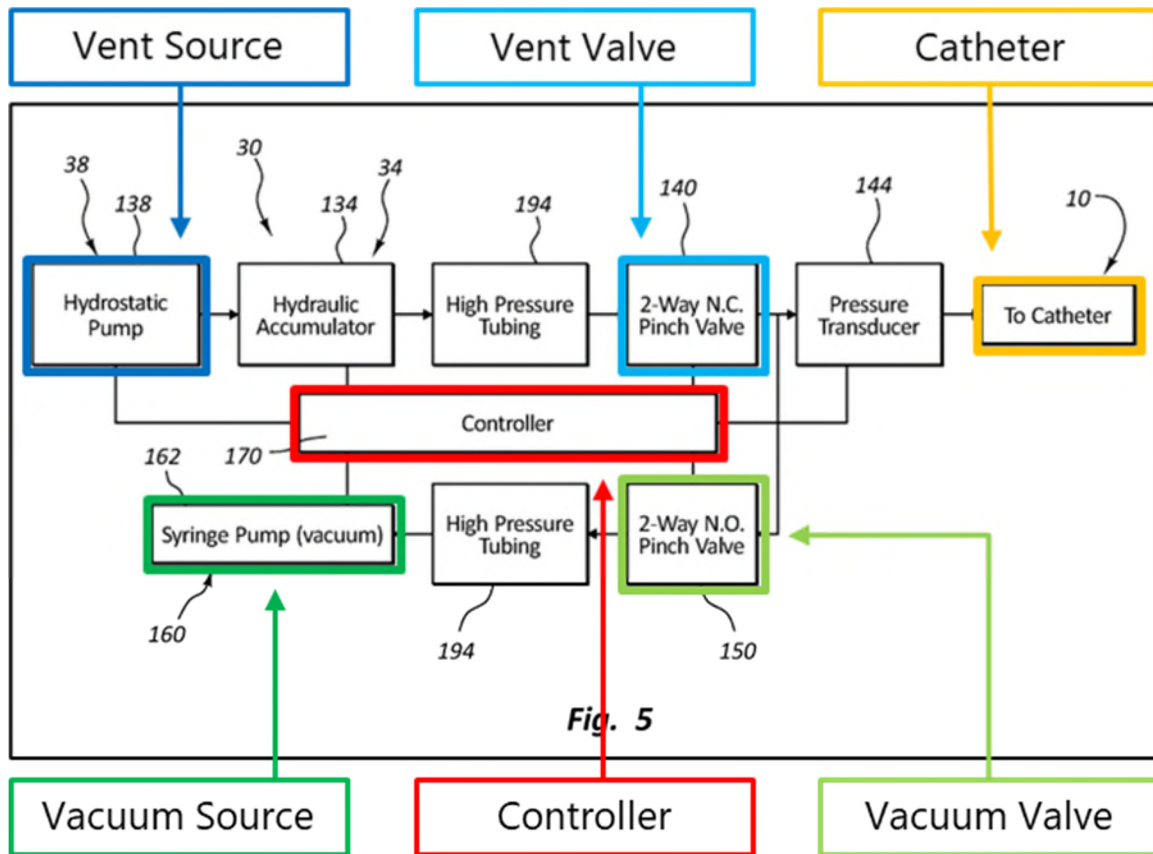
of Ofek, that negative pressure characteristics could similarly be configured in the operation cycles and pressure profiles to prevent the clot from escaping into the bloodstream even if some portion of it had shifted out from the distal end of the catheter due to the positive pressure impulses. Ex[1005], ¶¶405-406. This is further obvious when this approach is implemented in view of Mullins's additional teachings about controlling flow at the distal end of a catheter in aspiration catheter systems, as explained above. See §Gr.1, [1-G]; Ex[1005], ¶¶407-409.

Claim 2

[2-A]

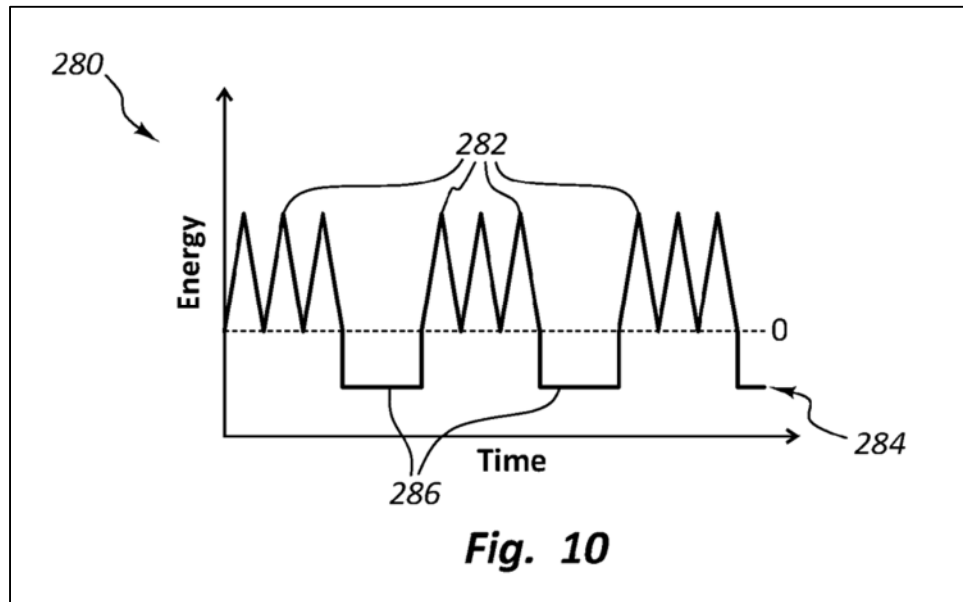
Ofek teaches a vent fluid source (“hydrostatic pump 138 that serves as the pressure input portion 38 for providing hydraulic pressure to fluid contained and maintained at pressure in a hydraulic accumulator (“accumulator”) 134 that serves as the fluid reservoir 34”). Ex[1007], 4:21-61, 5:34-48; Ex[1005], ¶¶410-412.





[2-B]

As discussed (See Gr.4, [1-G]), Ofek's vent source can provide high-pressure impulses with pressure peaks including "400 psi." Ex[1007], 4:7-44, FIG.10. This is larger than atmospheric pressure (e.g., 14.696 psi). Ex[1005], ¶¶413-418.

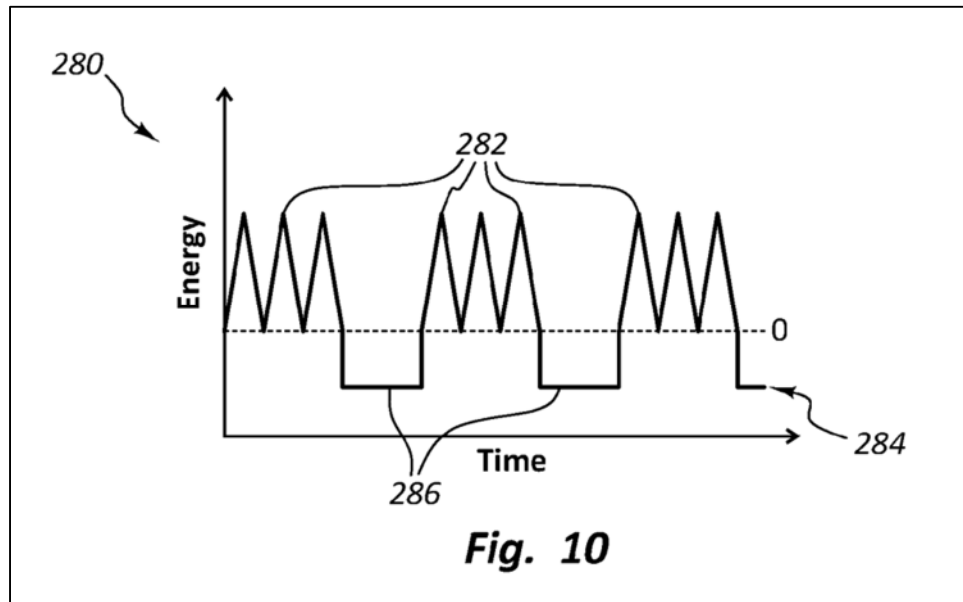


[2-C]

See §Gr.4, [1-E]; Ex[1005], ¶419.

[2-D]

See §Gr.4, [1-F]; Ex[1005], ¶¶420-426. Further, Ofek teaches the controller changing levels of vacuum in the catheter, including at the distal tip. See §Gr.4, [1-E], [1-F]. A POSA would recognize that Ofek changes the level of vacuum at the distal end of the catheter by changing a level of negative pressure and positive pressure at the distal end of the catheter during each cycle. Ex[1005], ¶¶422-423.



This control is further enhanced when combined with Mullins, which, as discussed above involves techniques for cycling positive and negative pressures at the distal end of the catheter in an aspiration system like Ofek's. *See* §Gr.1, [2-D]; Ex[1005], ¶¶424-426.

Claim 3

[3-A]

See §Gr.4, [1-E]; Ex[1005], ¶427.

[3-B]

See §Gr.4, [1-G]; Ex[1005], ¶¶428-435. Moreover, this element is met when Ofek is modified in view of Mullins to implement Mullins' technique of cycling from negative to positive pressure to unload and reload the clot at the distal tip of the catheter within Ofek's system while limiting exit flow. Ex[1005], ¶¶432-435. This would be desirable as it would further improve Ofek's ability to ingest a clot

while minimizing patient risk, and a POSA would be further motivated to do this and expect success for the same reasons discussed above (See §Gr.1, [3-B]) with respect to a Yang's similar aspiration system. Ex[1005], ¶¶432-435.

[3-C]

See §Gr.4, [3-B]; Ex[1005], ¶¶436-442. As also discussed above regarding Mullins in Gr.1, [3-C], a POSA would understand the values of approximately 0.001 ml to approximately 1.0 ml to be reasonable values for implementing a limited amount of exit flow when applying Mullins techniques to an aspiration catheter system, such as Ofek's. Ex[1005], ¶438. A POSA would have found it obvious, in implementing the techniques taught by Mullins, to experiment, using routine optimization, with particular values of measured flow displacement to achieve the desired goal of aspirating the clot while still limiting the likelihood of distal migration of the clot, resulting in the claimed range. See §Gr.1, [3-C]. The reasoning there is equally applicable to Mullins' combination with Ofek.

Regarding cycle frequency, Ofek discloses specific timing constraints for a positive and negative pressure cycle (e.g., 1 Hz to 150 Hz), however, such timing requirements were also accounted for by the analysis and experimentation values demonstrated in the declaration of expert Brian Brown, which establish the claimed exit flow values are within the expected values that a POSA would experiment with

through routine optimization based on the disclosures of Ofek and Mullins and known catheter/physiological data. Ex[1005], ¶¶439-442.

Claim 4

[4-A]

See §Gr.4, [1-E]; Ex[1005], ¶443.

[4-B]

See §Gr.4, [3-B]; Ex[1005], ¶444.

[4-C]

See §Gr.4, [3-C]; Ex[1005], ¶445.

Claim 5

[5-A]

See §Gr.4, [1-E]; Ex[1005], ¶446.

[5-B]

See §Gr.4, [1-E]; Ex[1005], ¶¶447-453. Moreover, Ofek further discloses “During each impulse when the [N. C.] valve 140 is opened, the N.O valve 150 is shut... Between each impulse and after the series of impulses has ended, the N.C. valve 140 closes and the N.O. valve 150 opens.” Ex[1007], 5:63-6:8, Claim:8. A POSA would have found it obvious to execute the transition between the closing and opening of the respective valves in serial. Because of the nature of serial operation, it would be obvious to have a finite delay (e.g., for confirming the state of the valve) between the closing of one valve and the opening of the other, which leads to at least

a brief period where both valves are closed, i.e., a double-closed, or off-off state. Ex[1005], ¶¶448-450. This would lead to more reliable and predictable operation of the system. Ex[1005], ¶¶448-450.

Additionally, Ofek discloses that the vent and vacuum valves “can be combined into a single valve, such as a three-way valve... [which] is operated to alternately provide the impulses of positive pressures as well as the negative baseline pressures/negative impulses.” Ex[1007], 5:26-31; Ex[1005], ¶451.

A POSA would find it obvious, that in this situation, an intermediary “off-off” state would occur when the three-way valve transitions from one state to another state (e.g., from vent to vacuum), because neither of the respective channels would be connected through the three-way valve. Ex[1005], ¶452. For example, when using a rotary three-way valve, an off-off state would occur when the three-way valve rotates between the positions where the connecting channels are aligned to fluid and vacuum channels. A similar example was discussed in Gr.2, [5-B], with regard to the three-way valve 46 in Rubenstein. As was illustrated in the associated visual representations in that ground, the channels of the three-way valve would be disconnected from both the vent and vacuum channels while it is in transition. A POSA would recognize that the same result would occur here if the vent and vacuum valves are combined into a three-way valve. Ex[1005], ¶452.

Claim 6

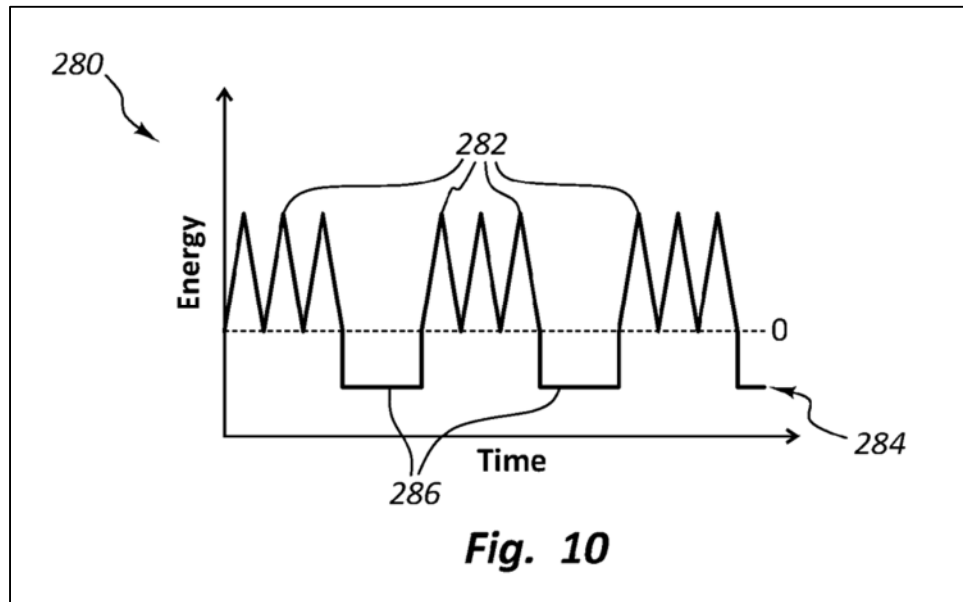
[6-A]

See §Gr.4, [1-E]; Ex[1005], ¶454.

[6-B]

See §Gr.4, [1-E]; Ex[1005], ¶¶455-459. Moreover, Ofek discloses cyclically opening and closing the vacuum valve and the vent valve in a repeated cycle. As also discussed above for Gr.4, [5-B], Ofek/Mullins renders obvious an off-off state in which the vacuum valve is closed while the vent valve is closed.

Additionally, in Ofek Figure 10, the example operation cycle sequence appears as: (1) (time=0) no positive/negative pressure, (2) positive pressure impulses 282, (3) no positive/negative pressure (transition from impulses 282 to vacuum 286), (4) negative pressure 286. A POSA would recognize an obvious implementation of that sequence to be the valve states sequence: (1) off-off state, (2) vent-only states 282, (3) off-off state, (4) vacuum-only state 286. Ex[1005], ¶457. A POSA would also recognize that, given the explicit customization options and invitations in Ofek, the Figure 10 cycle could customize the number of impulses in a given impulse period 282 to just a single positive pressure impulse, thereby resulting in the claimed sequence. Ex[1005], ¶458.



Claim 7

See §Gr.4, [1-E], Ex[1005], ¶¶460-464. See also Gr.4, [6-A], [6-B].

As discussed (Gr.4, [1-G]), Ofek discloses various customizations of operating cycles providing a POSA with configuration flexibility. Ex[1007], 3:30-42, 6:20-45. Ofek discloses suggested cycle frequencies: “impulse frequency, can be set according to a predetermined pattern... and can range ...from about 1 to over about 150 Hz, though other frequency ranges are also possible.” Ex[1007], 6:20-45.

Consistent with the above discussion on routine optimization, a POSA would be motivated to experiment with the claimed range of “2 Hz to 12 Hz,” given that neither Ofek nor Mullins teaches away from the cycle being “repeated at a frequency of 2 Hz to 12 Hz,” and Ofek explicitly invites the reader to customize variables (e.g.,

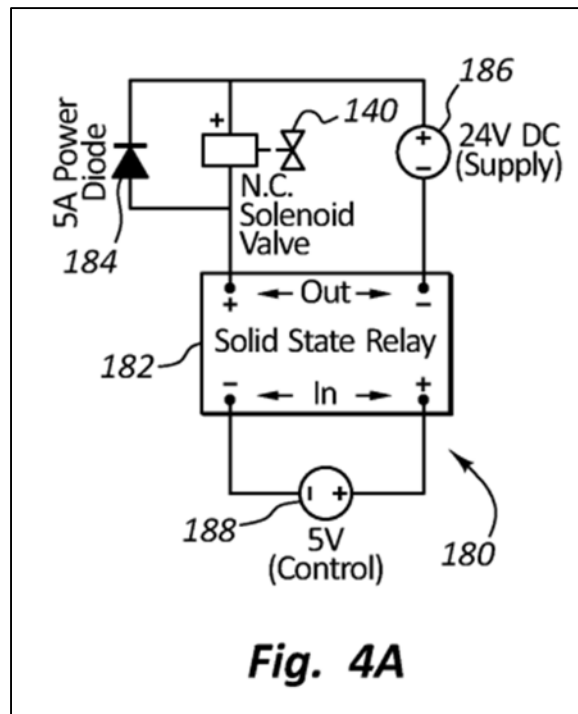
number of impulses, level of pressure, frequency, etc.) in the claimed range.

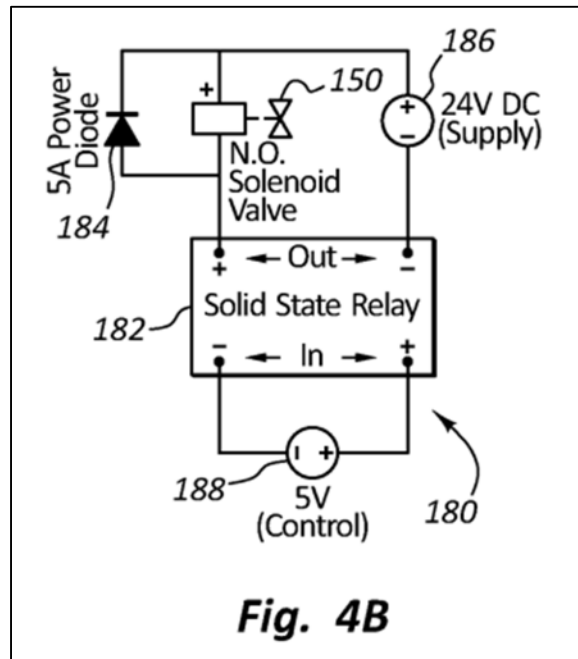
Ex[1007], 3:61-4:20; Ex[1005], ¶463.

Claim 8

Ofek discloses the vacuum and vent valves being solenoid “pinch valves”.

Ex[1007], 7:18-26, FIGs. 4A, 4B. Ex[1005], ¶¶465-468.





Claim 10

[10-A]

See §Gr.4, [1-E]; Ex[1005], ¶469.

[10-B]

See §Gr.4, [1-G], [2-D]; Ex[1005], ¶¶470-476. Further, Ofek discusses using positive/negative pressure to dislodge occlusive material. Ex[1007], 2:64-67, 4:21-44, 6:9-19, 8:16-22. A POSA would also recognize that by using positive/negative pressure to dislodge the thrombus, the direction of flow within the catheter fluid column must change, which in turn requires or results in momentum transfer within the fluid column. Ex[1005], ¶473. Additionally, when applying Mullins techniques, (See §Gr.1, [10-B]), the combined system would reverse the direction of fluid displacement and allowing some or all of the clot to be pushed to cause the clot to

become more “free” with respect to the catheter, and a POSA would understand and find it obvious that causing the clot to become more “free” may take place at the distal end of the catheter, at least because the nature of thrombus removal involves the distal end of the catheter being engaged with the thrombus. Ex[1005], ¶475.

Claim 11

[11-Pre]

See §Gr.4, [1-Pre]; Ex[1005], ¶477.

[11-A]

See §§Gr.4, [Motivation], [1-Pre]; Ex[1005], ¶¶478-482. Ofek discloses an aspiration thrombectomy system, for which a central aspect is positioning the distal end of the catheter next to the thrombus and applying Mullins’s technique to Ofek would entail placing the catheter tip adjacent to the clot. See §Gr.1, [11-A],

[11-B]

See §§Gr.4, [Motivation], [1-Pre]; Ex[1005], ¶¶483-488. Ofek discloses using negative pressure to draw an occlusion into the catheter lumen. “A negative pressure can then be provided to the lumen to aspirate the occlusion and remove it from the catheter assembly.” Ex[1007], Abstract.

Moreover, when applying Mullins’s techniques (See §Gr.1, [11-B]), the system would use vacuum to cause at least a portion of the clot to be aspirated and ingested by the catheter. Ex[1005], ¶487.

[11-C]

See §§Gr.4, [1-B], [1-E], [2-A]; Ex[1005], ¶¶489-491.

Ofek also teaches that the vent valve is fluidically coupled to the vent fluid source. “A two-way, normally closed (“N.C.”) valve 140 is disposed at and operably connected at its fluid inlet to a fluid outlet of the accumulator 134 via a fluid line.” Ex[1007], 4:45-61, FIGs. 3-5.

[11-D]

See §Gr.4, [1-F]; Ex[1005], ¶492.

[11-E]

See §Gr.4, [1-G]; Ex[1005], ¶493.

Claim 12

[12-A]

See §Gr.4, [2-B]; Ex[1005], ¶494.

[12-B]

See §Gr.4, [1-E]; Ex[1005], ¶495.

[12-C]

See §Gr.4, [2-D]; Ex[1005], ¶496.

Claim 13

[13-A]

See §Gr.4, [3-B]; Ex[1005], ¶497.

[13-B]

See §Gr.4, [3-C] (regarding limiting volumes of positive exit flow). A POSA would also recognize the equivalence between measuring exit flow could be based on length and volume because volume is a function of length and catheter diameter-a known quantity. Ex[1005], ¶¶498-500. A POSA would understand the benefit of controlling exiting column length rather than volume: that it would more directly correspond to the distance a coked clot would travel away from the distal end. Ex[1005], ¶499.

Claim 14

[14-A]

See §Gr.4, [3-B]; Ex[1005], ¶¶501-506. Ofek further discloses stopping distal impulses and reapplying vacuum in a predetermined pattern. “In FIG. 10,... groups of impulses are separated by rest periods 286 of negative baseline pressure 284 to enable aspiration from the catheter 10 of any occlusions dislodged by the impulses.” Ex[1007], 5:63-6:8, 8:38-49, FIG.10.

To the extent that Ofek does not explicitly disclose limiting movement of the fluid column at the distal end by stopping a distal flow through the catheter lumen and reapplying the vacuum through the catheter lumen before fluid is drawn back into the catheter lumen, when implemented in view of Mullins teachings, the combination does this. Figures 47(g)-(h) of Mullins illustrate this start and stop of

fluid flow and vacuum within the lumen. Ex[1008], Figs. 47(g)-(h). Moreover, Mullins discloses a sensor used to determine fluid displacement and vary pressure, such as by reapplying vacuum. Ex[1008], 3:35-38. Mullins also explicitly discloses the controller providing vacuum for this task. Ex[1008], 3:56-59. Ex[1005], ¶505.

[14-B]

See §Gr.4, [13-B]; Ex[1005], ¶¶507-513. In limiting the amount of positive exit flow, and having a reasonable expectation that such a level would not result in an unacceptable level of risk of distal migration, a POSA would understand the values of approximately 0.5 mm to approximately 30 mm of fluid column to be reasonable limits on exit flow. Ex[1005], ¶509. Specifically, a POSA would recognize that clot migration of that distance should still be within the zone of influence of the catheter vacuum. Ex[1005], ¶510. Further, as discussed above (§Gr.4, [3-C]) a POSA would have found it obvious to calculate and optimize values for the extent to which exit flow should be limited, as invited to do by Ofek and Mullins. Ex[1005], ¶511.

A POSA would understand how to convert the exit flow volumes described in Gr.1, [3-C] to respective values of exit flow length. As explained in the declaration of expert Brian Brown, the claimed exit flow values are within the expected values that a POSA would experiment with through routine optimization. Ex[1005], ¶¶512-513.

Claim 15

[15-A]

See §Gr.4, [3-B]; Ex[1005], ¶514.

[15-B]

See §Gr.4, [3-B], [3-C]; Ex[1005], ¶515.

Claim 16

[16-A]

See §Gr.4, [3-B], [14-A]; Ex[1005], ¶516.

[16-B]

See §Gr.4, [3-C]; Ex[1005], ¶517.

Claim 17

[17-A]

See §Gr.4, [3-B], [14-A]; Ex[1005], ¶518.

[17-B]

See §Gr.4, [3-C], [4-C]; Ex[1005], ¶519.

Claim 18

[18-A]

See §Gr.4, [1-E]; Ex[1005], ¶520.

[18-B]

See §Gr.4, [5-B]; Ex[1005], ¶521.

Claim 19

[19-A]

See §Gr.4, [1-E]; Ex[1005], ¶522.

[19-B]

See §Gr.4, [6-B]; Ex[1005], ¶523.

Claim 20

See §Gr.4, [7]; Ex[1005], ¶524.

E. Ground 5: Claims 5-6 and 18-19 Are Rendered Obvious Over Ofek in View of Mullins, Rubenstein, and the Knowledge of a POSA

Motivation to Combine

A POSA would have been motivated to modify the combined Ofek/Mullins cyclical aspiration system with Rubenstein's teachings of: (1) a pumping system to eliminate clogs within the catheter; (2) applying cyclical reversals of positive and negative pressure in the catheter; and (3) transitioning between a vacuum suction state and a blowing, or positive pressure state when necessary, using a time-controlled valve. The motivation to combine Ofek and Mullins is discussed above at Ground 4 (Ofek in view of Mullins and the knowledge of a POSA). Ex[1005], ¶¶525-528.

Ofek, Mullins, and Rubenstein all: (1) address similar problems related to conventional methods of medical aspiration procedures, including clogged catheters, and (2) teach similar solutions involving a temporary positive pressure state to

relieve negative pressure and more efficiently remove blood clots from the clogged catheter and ultimately the patient, e.g., creating a dynamic force within the catheter using a combination of vacuum and vent/pressure sources connected to a catheter via controllable valves. Ex[1007], Abstract, 1:16-33, 2:28-37, 4:45-5:7, 7:18-26; Ex[1008], 1:53-2:2, 3:29-4:11, 25:22-28:64; Ex[1011], Abstract, 1:7-2:12; Ex[1005], ¶526.

Combining the teachings of Ofek, Mullins, and Rubenstein would have been well within the skill of a POSA, because it is nothing more than combining known vacuum aspiration technologies described in these references to perform their intended functions with described benefits and predictable results. Ex[1005], ¶527. Moreover, for substantially the same reasons that a POSA would be motivated to implement Yang/Mullins's system using Rubenstein's rotary valves, a POSA would similarly be motivated to implement the similar Ofek/Mullins combination using those valves. See §Gr.2, [Motivation]; Ex[1005], ¶527.

Claim 5

[5-A]

See §Gr.4, [1-E]; Ex[1005], ¶529.

[5-B]

See §Gr.4, [5-B]; Ex[1005], ¶¶530-536.

Additionally, as previously discussed (§Gr.2, [5-B]), Rubenstein discloses an off-off state in which the vacuum valve is closed while the vent valve is closed. Ex[1005], ¶533. Therefore Ofek/Mullins when implemented in view of Rubenstein would render this element obvious. Ex[1005], ¶¶534-536.

Claim 6

[6-A]

See §Gr.4, [1-E]; Ex[1005], ¶537.

[6-B]

See §Gr.4, [6-B]; Ex[1005], ¶538.

Additionally, as discussed above (§Gr.2, [6-B]), Rubenstein discloses the sequence of valve states in [6-B]. Ex[1005], ¶538. Because a POSA would be motivated to include Rubenstein's valve and valve states in the Ofek/Mullins combination for substantially the same reasons that a POSA would have incorporated them into the Yang/Mullins combination, this element is obvious over Ofek/Mullins in view of Rubenstein. Ex[1005], ¶538.

Claim 18

[18-A]

See §Gr.4, [1-E]; Ex[1005], ¶539.

[18-B]

See §Gr.4, [5-B]; Ex[1005], ¶540.

Additionally, for the reasons discussed above for Gr.5, [5-B], this limitation is met by Ofek/Mullins in view of Rubenstein. Ex[1005], ¶540.

Claim 19

[19-A]

See §Gr.4, [1-E]; Ex[1005], ¶541.

[19-B]

See §Gr.4, [6-B]; Ex[1005], ¶542.

Additionally, for the reasons discussed above for Gr.5, [6-B], this limitation is met by Ofek/Mullins in view of Rubenstein. Ex[1005], ¶542.

F. Ground 6: Claim 9 is Rendered Obvious Over Ofek in view of Mullins, Matteo, and the Knowledge of a POSA

Motivation to Combine

A POSA would have been motivated to modify Ofek and Mullins' cyclical aspiration system with Matteo's teaching of cam system for valve control. The motivation to combine Ofek and Mullins is discussed above at Gr.4 (Ofek in view of Mullins and the knowledge of a POSA). Ex[1005], ¶¶543-548.

Ofek, Mullins, and Matteo all (1) address similar problems related to the precise combination of multiple fluids at precise times in scientific and medical applications, and (2) teach similar solutions involving using multiple flow control mechanisms (e.g., valves or pumps) to separate and combine the fluids to achieve desired results, e.g., using a controller to control flow control mechanisms (e.g.,

valves or pumps) that can be switched between varying states of open and closed positions. Ex[1007], 4:21-6:8, 6:20-7:26; Ex[1008], 26:31-27:39; Ex[1013], ¶[0059], FIGs.10A-C.

Combining the teachings of Ofek, Mullins, and Rubenstein would have been well within the skill of a POSA, because it is nothing more than combining known vacuum aspiration technologies described in these references to perform their intended functions with described benefits and predictable results. Ex[1005], ¶546. Thus, for substantially the same reasons as discussed in Gr.3, [9], it would be obvious to implement Ofek/Mullins's valves with Mateo's cammed pinch valves. Ex[1005], ¶¶543-548.

Claim 9

See §Gr.4, [Claim 1]. Additionally, as noted above (§Gr.3, [9]), Matteo discloses the vacuum valve and the vent valve being cammed pinch valves. Thus, when implemented using those valves, Ofek/Mullins in view of Matteo renders this limitation obvious. Ex[1005], ¶¶549-552.

I. SECONDARY CONSIDERATIONS

Petitioner is unaware of evidence of secondary considerations of non-obviousness with nexus to the claimed invention. Ex[1005], ¶17. Even if Patent Owner showed secondary considerations and nexus, such secondary considerations

would be unlikely to overcome the strong case of obviousness presented here.

Leapfrog Enters., Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1162 (Fed. Cir. 2007).

August 5, 2024

Respectfully submitted,

/Eliot D. Williams/

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CERTIFICATE OF SERVICE

The undersigned hereby certifies on this August 5, 2024, a true and correct copy of the foregoing **Petition for *Inter Partes* Review of U.S. Patent No. 11,406,402**, Exhibits 1001-1034, and Power of Attorney were served to the following parties via electronic mail and Federal Express:

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**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME
LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE
REQUIREMENTS**

This Petition complies with the type-volume limitations as mandated in 37 C.F.R. §42.24, totaling less than 14,000 words. Counsel has relied upon the word count feature provided by Microsoft Word.

Respectfully submitted,

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