Penumbra, Inc.,

v.

RapidPulse, Inc.

IPR2024-01261

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

RapidPulse's Oral Argument Demonstratives

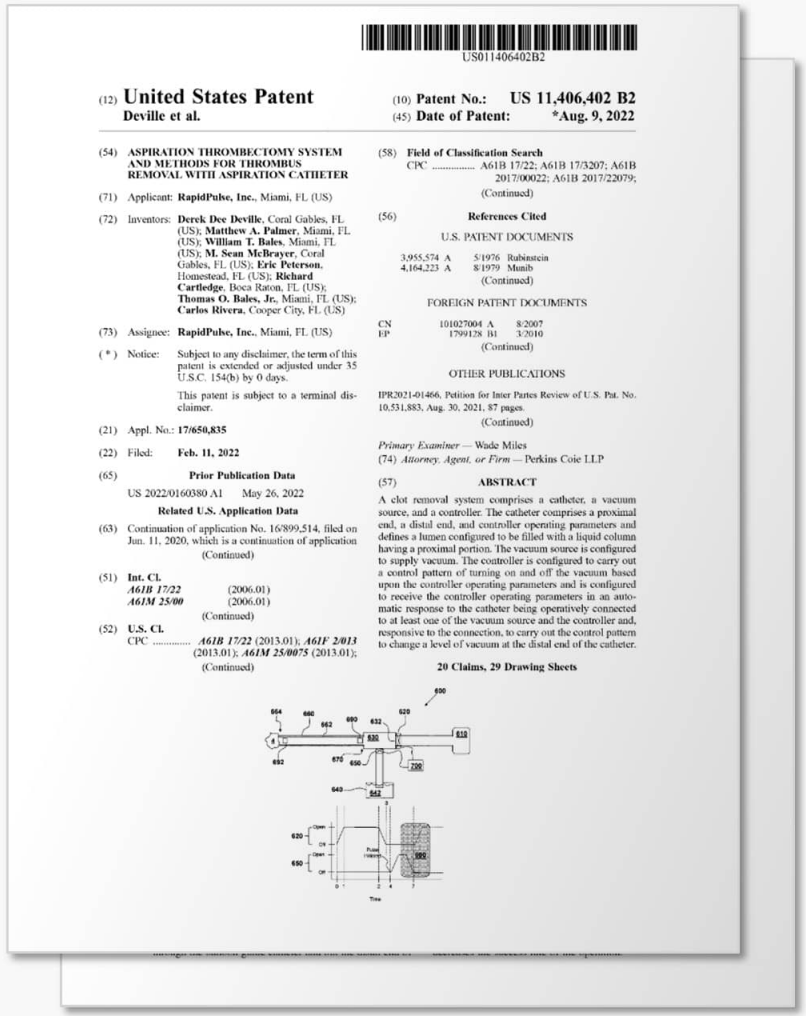
Overview

Overview

Claim(s)	Summary	Slides
Claim 1 ("aspiration thrombectomy system")	Neither Yang/Mullins nor Ofek/Mullins render obvious "a predetermined cycle … to control fluid flow in and out."	Slides 11-15, 23-55.
Claim 11 ("method for … aspirating thromboembolic material from a person using the system of claim 1")	See claim 1, and no reasonable expectation of success for "aspirating thromboembolic material from a person" by "controlling" the valves "in a predetermined cycle" to "thereby control[] fluid flow in and out."	See claim 1, and slides 56-68, and 78-85.
Claims 3-4, 14, and 16-17 ("positive amount of exit flow" within specific ranges)	Claims 3-4: see claim 1. Claims 14 & 16-17: see claim 11. Further, "positive amount of exit flow" within claimed ranges are not obvious results of "routine optimization."	Claims 3-4: see claim 1. Claims 14 & 16-17: see claim 11. See also slides 16-22 and 69-77.

Technology Background

Aspiration Thrombectomy System



US011406402B2

(12) **United States Patent**
Deville et al.

(10) **Patent No.: US 11,406,402 B2**
(45) **Date of Patent: *Aug. 9, 2022**

(54) **ASPIRATION THROMBECTOMY SYSTEM AND METHODS FOR THROMBUS REMOVAL WITH ASPIRATION CATHETER**

(71) Applicant: **RapidPulse, Inc.**, Miami, FL (US)

(72) Inventors: **Derek Dee Deville**, Coral Gables, FL (US); **Matthew A. Palmer**, Miami, FL (US); **William T. Bales**, Miami, FL (US); **M. Sean McBrayer**, Coral Gables, FL (US); **Eric Peterson**, Homestead, FL (US); **Richard Cartledge**, Boca Raton, FL (US); **Thomas O. Bales, Jr.**, Miami, FL (US); **Carlos Rivera**, Cooper City, FL (US)

(73) Assignee: **RapidPulse, Inc.**, Miami, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/650,835**

(22) Filed: **Feb. 11, 2022**

(65) **Prior Publication Data**

US 2022/0160380 A1 May 26, 2022

Related U.S. Application Data

(63) Continuation of application No. 16/899,514, filed on Jun. 11, 2020, which is a continuation of application
(Continued)

(51) **Int. Cl.**
A61B 17/22 (2006.01)
A61M 25/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/22*** (2013.01); ***A61F 2/013*** (2013.01); ***A61M 25/0075*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/22; A61B 17/3207; A61B 2017/00022; A61B 2017/22079;
(Continued)

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(Continued)

Primary Examiner — Wade Miles
(74) *Attorney, Agent, or Firm* — Perkins Coie LLP

(57) **ABSTRACT**

A clot removal system comprises a catheter, a vacuum source, and a controller. The catheter comprises a proximal end, a distal end, and controller operating parameters and defines a lumen configured to be filled with a liquid column having a proximal portion. The vacuum source is configured to supply vacuum. The controller is configured to carry out a control pattern of turning on and off the vacuum based upon the controller operating parameters and is configured to receive the controller operating parameters in an automatic response to the catheter being operatively connected to at least one of the vacuum source and the controller and, responsive to the connection, to carry out the control pattern to change a level of vacuum at the distal end of the catheter.

20 Claims, 29 Drawing Sheets

The present systems, apparatuses, and methods lie in the field of thrombus removal. The present disclosure relates to an aspiration thrombectomy system and methods for thrombus removal with aspiration catheter.

Ex. 1001 ('402 Patent) at 1:37-39

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Vacuum And Vent Valve System

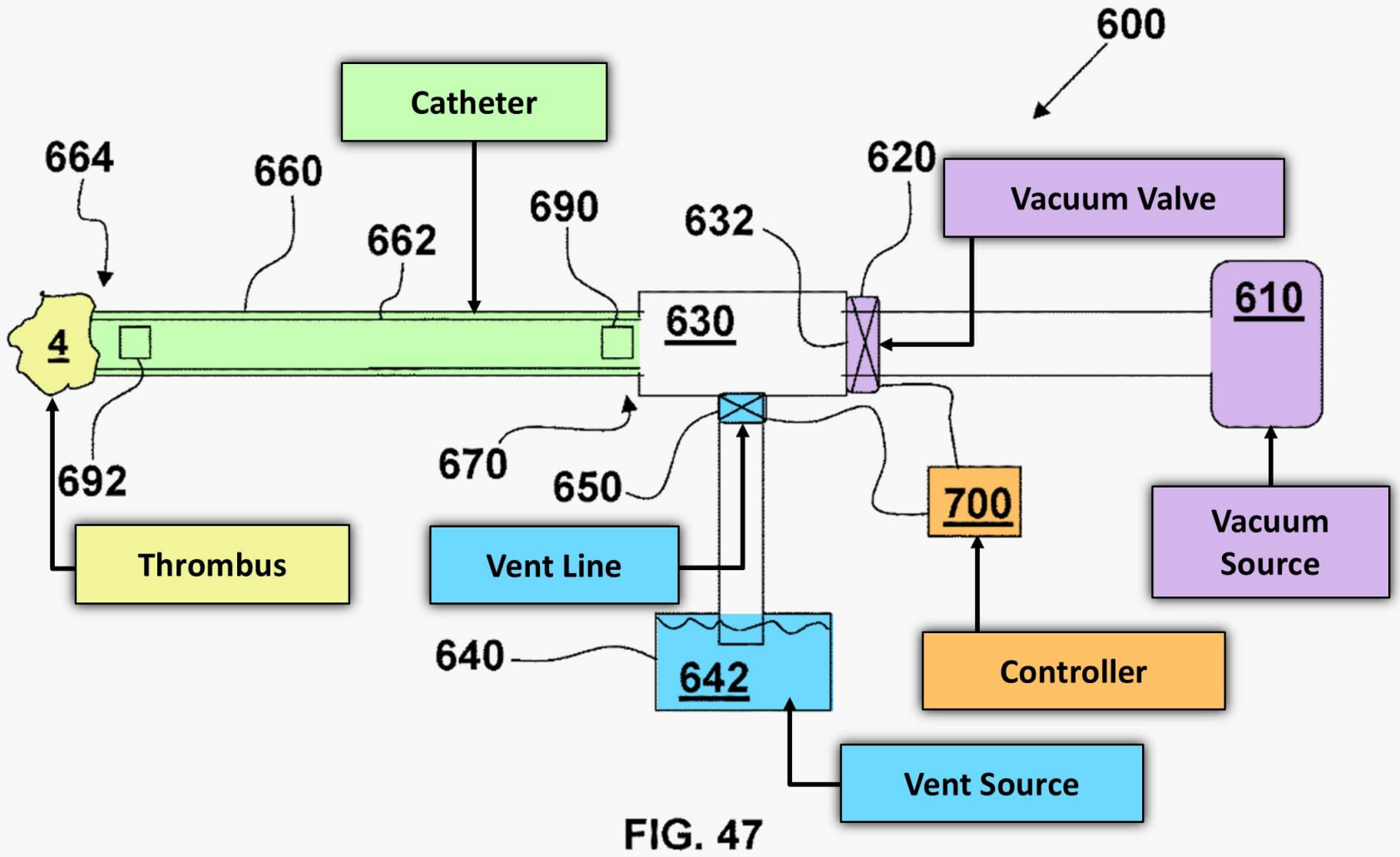


FIG. 47

Ex. 1001 ('402 Patent), Fig. 47

Predetermined Cycle Of Vacuum And Vent Valve Operation

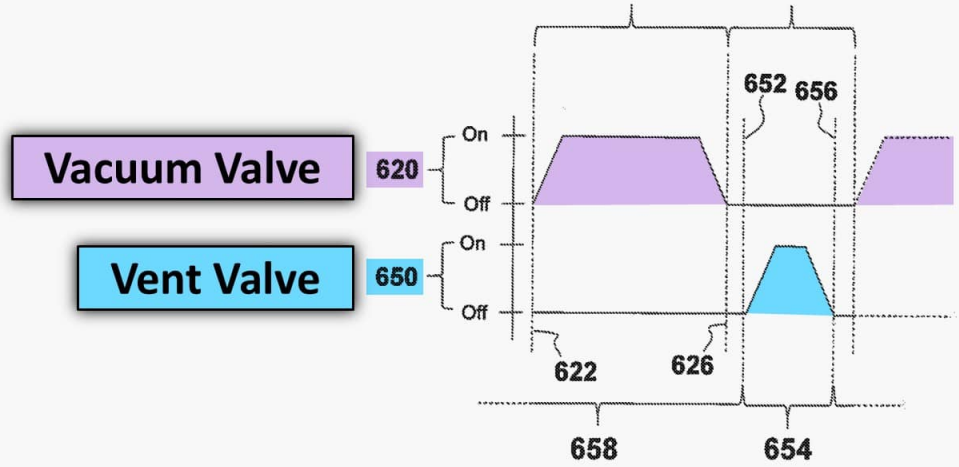
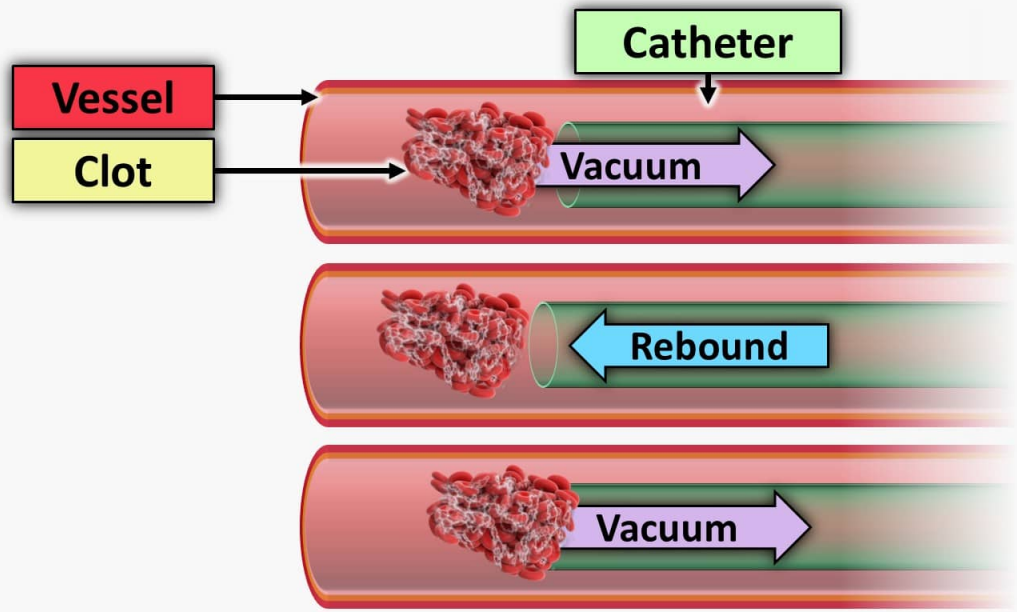


FIG. 52 Ex. 1001 ('402 Patent), Fig. 52

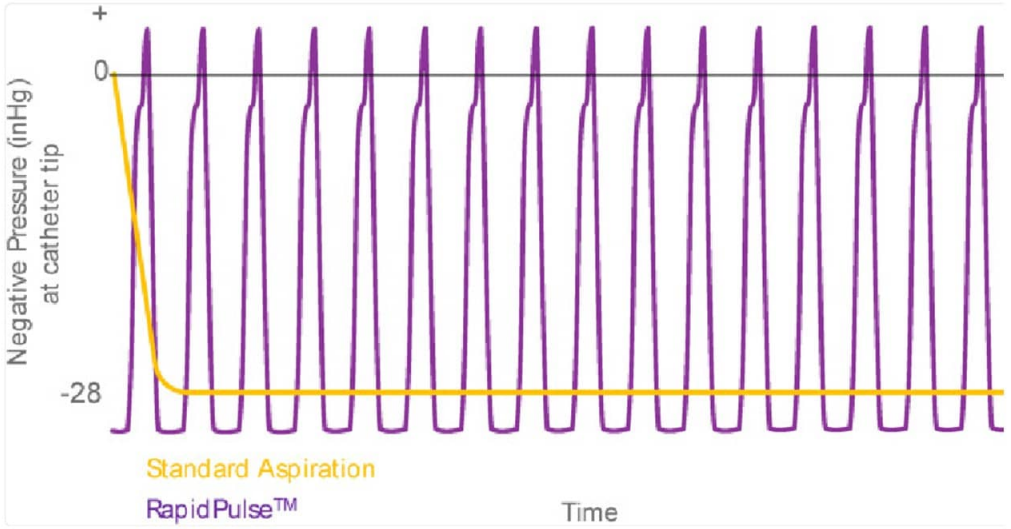


In the ROAR cycle, suction is applied to the clot by rapidly opening a valve, causing a rapid rise in vacuum pressure. The source of suction is then turned off and a vent fluid source is rapidly opened. This relieves the vacuum present in the catheter **660**, which again rapidly changes the pressure applied to the clot. The vent valve **650** is then rapidly closed and the vacuum valve **620** is rapidly opened. This cycle is repeated multiple times per second. For example, the period for repetition is between approximately 2 Hz and approximately 16 Hz, in particular, between approximately 8 Hz and approximately 12 Hz. The rapid drop of pressure across the clot **4** when the vacuum valve **620** is opened causes the clot **4** to accelerate into the lumen **662** of the catheter **660**. The release of vacuum pressure when the vent valve **650** is opened causes the clot **4** to rebound back from the catheter **660**. When the vacuum is applied again, the clot **4** once again accelerates towards the catheter **660**. These accelerations and rebounds cause the distributed mass of the clot **4** to oscillate. The large internal accelerations of the distributed mass from the oscillation creates internal forces in the clot **4** that are high enough to exceed the tensile strength of the clot **4** and cause it to fail.

Ex. 1001 ('402 Patent) at 46:45-66

Predetermined Cycle Of Vacuum And Vent Valve Operation

Bajrami Article



Ex. 2027 (Bajrami Article), Fig. 1

In accordance with another feature, the controller is configured to open and close the vent and vacuum valves in a repeated cycle of the pre-determined pattern and prevent forward flow of the distal portion out from the distal end during each cycle by regulating timing of the vent valve.

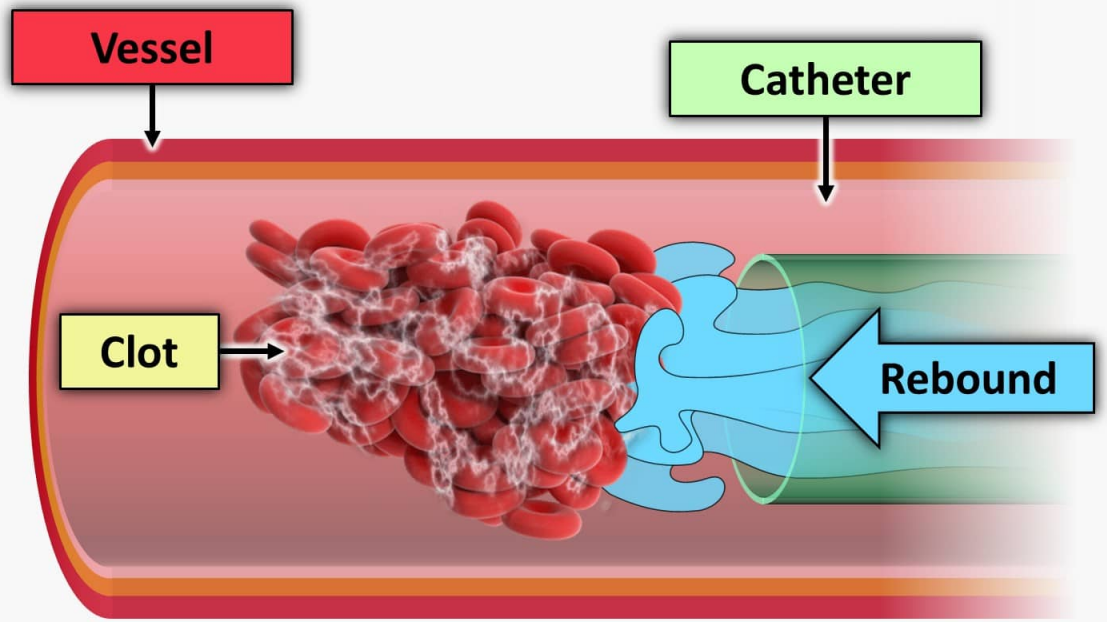
Ex. 1001 ('402 Patent) at 11:1-5

In accordance with an exemplary embodiment, the clot removal system comprises a fixed cycle with plurality of pinch valves and plurality of cams mechanically coupled to the valves so that orientations of the cams cannot be changed.

Ex. 1001 ('402 Patent) at 9:9-14

Paper No. 1 (Petition) at 9; Paper No. 15 (POR) at 70-71;
Paper No. 34 (Sur-reply) at 7-8

Controlled Flow Out



distance 70 in the distal direction. An exemplary volume of the shift distance is approximately 0.001 ml to approximately 1.0 ml, in particular, approximately 0.1 ml to approximately 0.5 ml. An exemplary length of the shift distance **70** is approximately 0.5 mm to approximately 30 mm, in particular, approximately 0.5 mm to approximately 15 mm. To effect such a movement, the compressor-actuator

Ex. 1001 ('402 Patent) at 24:45-51

Claim Construction

Claim 1 Requires Controller Configured To Control Flow Out

1. An aspiration thrombectomy system, comprising:
an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;
a vacuum source fluidically coupled to the catheter;
a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;
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
a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 1

Claim 11 Requires Controlled Flow Out

11. A method for removing thromboembolic material, comprising:

aspirating thromboembolic material from a person using the system of claim **1** by—

(a) positioning the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person;

(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

(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 such that a level of vacuum at the distal end of the catheter changes and thereby controls flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 11

Petitioner Proposed No Construction Of "Flow … Out"

Petition

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"

Paper No. 1 (Petition) at 15

Petitioner Now Reads "Flow … Out" Out Of The Claims

Petitioner's Reply

object on which it operates. *Id.* Thus, a POSA would recognize that to "control" the "flow in and out" means having "control" over flow in and out, including preventing or permitting flow out. *Id.* PO's contention that flow out must always occur is wrong. *Id.*

Paper No. 24 (Reply) at 3-4

1. An aspiration thrombectomy system, comprising:
an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;
a vacuum source fluidically coupled to the catheter;
a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;
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
a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 1

Specification Distinguishes Embodiments With And Without Flow Out

The flow of fluid forward in this exemplary embodiment is intentional, which is in contrast to other exemplary embodiments herein where substantially no forward flow occurs.

Ex. 1001 ('402 Patent) at 36:67-37:2

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dependent Claims Recite Positive (Above Zero) Exit Flow Ranges

3. The system of claim **2** wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow from approximately 0.001 ml to approximately 1.0 ml before fluid is drawn back into the catheter lumen.

4. The system of claim **2** wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

Ex. 1001 ('402 Patent), Claims 3-4

Dependent Claims Recite Positive (Above Zero) Exit Flow Ranges

13. 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 within a range of a length of the fluid column that exits the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 13

15. 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 within a range of volume of fluid that exits the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 15

Petitioner's Construction Contradicts Plain Meaning Of "Positive Amount"

Petitioner's Expert Agrees "Positive" Means "Above Zero"

Brown Sur-reply Deposition

Q. Claims 3 and 4 recite that the movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow, right?

A. Correct.

Q. Do you agree that the ordinary and customary meaning of positive is greater than zero?

A. I do.

Q. Do you agree that positive as it appears in the claims has its ordinary and customary meaning?

A. I do.

Ex. 2044 (Brown Sur-reply Depo.) at 11:8-21 (objections omitted)

Brown POR Deposition

Q. Do you agree that a positive amount of exit flow is an amount of exit flow above zero?

A. As you have stated it, a positive amount of exit flow is something that is above zero, correct.

Ex. 2018 (Brown POR Depo.) at 9:7-11

Petitioner's Construction Contradicts Plain Meaning Of "Positive Amount"

4. The system of claim 2 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

Ex. 1001 ('402 Patent), Claim 4

Brown POR Deposition

Q. Do you agree that a positive amount of exit flow is an amount of exit flow above zero?

A. As you have stated it, a positive amount of exit flow is something that is above zero, correct.

Ex. 2018 (Brown POR Depo.) at 9:7-11

Petitioner's Reply

The same principle applies here—a zero amount of exit flow would satisfy the claimed exit flow limit. Notably, a corked catheter will have zero exit flow, as

Paper No. 24 (Reply) at 4

Paper No. 1 (Petition) at 4; Paper No. 15 (POR) at 22; Paper No. 24 (Reply) at 4; Paper No. 34 (Sur-reply) at 5

Petitioner's Construction Contradicts Plain Meaning Of "Positive Amount"

4. The system of claim 2 wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

Ex. 1001 ('402 Patent), Claim 4

Brown POR Deposition

Q. Do you agree that a positive amount of exit flow is an amount of exit flow above zero?

A. As you have stated it, a positive amount of exit flow is something that is above zero, correct.

Ex. 2018 (Brown POR Depo.) at 9:7-11

Petitioner's R

The same principle applies here—a ount of exit flow would satisfy the claimed exit flow limit. Notably, a heter will have zero exit flow, as

Paper No. 24 (Reply) at 4

Paper No. 1 (Petition) at 15-16; Paper No. 15 (POR) at 22; Paper No. 24 (Reply) at 4

Petitioner's Verb Chart Contradicts The Plain Claim Language

4. The system of claim **2** wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

Ex. 1001 ('402 Patent), Claim 4

Brown Sur-reply Deposition

Q. The lower limit on the amount of exit flows that is recited in each of Claim 3 and 4 is above zero, correct?

A. **The lower limit value in each of claims is above zero.**

Ex. 2044 (Brown Sur-reply Depo.), 12:20-13:3 (objection omitted)

Petitioner's Reply

Distal flow: **Operative claim term**	Distal flow: **Permitted?**	Distal flow: **Capped?**	Distal flow: **Required?**	RapidPulse Patent Family – Distal Flow: **Operative Claim Language**
			* *	*
"**Limit**…"	Yes	Yes	No	RP-4, Cl. 1 = "**limiting** … to a displacement limit of fluid at the distal end"
				RP-6, Cl. 4 = "**limited** to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml"
				RP-8, Cl. 3 = "**limited** to a positive amount of exit flow of less than 20 microliters"

Paper No. 24 (Reply) at 7

Paper No. 24 (Reply) at 6-8; Paper No. 34 (Sur-reply) at 6

Petitioner's Verb Chart Contradicts The Plain Claim Language

4. The system of claim **2** wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

Ex. 1001 ('402 Patent), Claim 4

Brown Sur-reply Deposition

Q. The lower limit on the amount of exit flows that is recited in each of Claim 3 and 4 is above zero, correct?

A. **The lower limit value in each of claims is above zero.**

Ex. 2044 (Brown Sur-reply Depo.), 12:20-13:3 (objection omitted)

Petitioner's Reply

Distal flow: **Operative claim term**	Distal flow: **Permitted?**	Distal flow: **Capped?**	Distal flow: **Required?**	RapidPulse Patent Family – Distal Flow: **Operative Claim Language**
			*	*
"**Limit**…"	Yes	Yes		RP-4, Cl. 1 = "**limiting** … to a displacement limit of fluid at the distal end"
				RP-6, Cl. 4 = "**limited** to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml"
				RP-8, Cl. 3 = "**limited** to a positive amount of exit flow of less than 20 microliters"

Paper No. 24 (Reply) at 7

Paper No. 24 (Reply) at 6-8; Paper No. 34 (Sur-reply) at 6

“A Predetermined Cycle” To “Control Fluid Flow In And Out” (All Claims)

“A Predetermined Cycle” (All Claims)

Claim 1

1. An aspiration thrombectomy system, comprising:
an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;
a vacuum source fluidically coupled to the catheter;
a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;
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
a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 1

Petitioner Reads "Predetermined" Out Of The Claims

Petitioner's Reply

measurement devices" to "time the valves properly"). Thus, a POSA would understand "predetermined" as describing the "cycle" of opening and closing the valves, in an established sequence, with no restriction on sensor usage to making timing adjustments to the cycle. Ex[1035], ¶¶68-70. This is consistent with the plain

Paper No. 24 (Reply) at 15

Petitioner Reads "Predetermined" Out Of The Claims

Petitioner's Reply

measurement devices" to "time the valves properly"). Thus, a POSA would understand "predetermined" as describing the "cycle" of opening and closing the valves, in an established sequence, with no restriction on sensor usage to making timing adjustments to the cycle. Ex[1035], ¶¶68-70. This is consistent with the plain meaning of "cycle," which is a complete sequence of repeating events or states (e.g., "cycle of life"). *Id.*

Paper No. 24 (Reply) at 15

Using "sensor … to mak[e] timing adjustments" ≠ "predetermined"

"Predetermined" Means The Timing Of Valve Operation Is Fixed

In accordance with an exemplary embodiment, the clot removal system comprises a fixed cycle with plurality of pinch valves and plurality of cams mechanically coupled to the valves so that orientations of the cams cannot be changed.

Ex. 1001 ('402 Patent) at 9:9-14

TABLE 1

State	Vacuum	Venting	Cam Angle
Off	0	0	0 to +30
Vac	1	0	+30 to +250
Off	0	0	+250 to +280
Vent	0	1	+280 to 0

Ex. 1001 ('402 Patent) at 37:15-23

"Predetermined" Means The Timing Of Valve Operation Is Fixed

'402 Patent Prosecution History

The following is an examiner's statement of reasons for allowance: the prior art does not teach or suggest, in the context of the claim, a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change the level of vacuum applied to the catheter. Garrison (US 20160220741) discloses a similar device, but the controller disclosed in [0113] changed the cycle of opening and closing the valves based on feedback from sensors and is not a pre-determined pattern.

Ex. 1004 ('402 Patent Prosecution History) at 86

Using "sensor … to mak[e] timing adjustments" ≠ "predetermined"

"Predetermined" Means The Timing Of Valve Operation Is Fixed Beforehand

> [9] As to the term "predetermined plunger performance." again the initial focus is on the word "predetermined." The ordinary meaning of "predetermine" is "to determine beforehand." *Webster's, supra,* at 1786.
>
> ***Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1340 (Fed. Cir. 2003)**

> Similarly, in this case, the difference in timing creates a difference of knowing the winning combination before the game starts or after the game starts. Rainbow Bingo always determines the winning combination after start of the game. Therefore, it cannot be "predetermined." This court upholds the district court's refusal to find infringement by equivalents.
>
> ***Planet Bingo, LLC v. GameTech Int'l, Inc.*, 472 F.3d 1338, 1341-45 (Fed. Cir. 2006)**

> For these reasons, we conclude that the district court properly construed "time interval of predetermined duration" to mean that the duration of the time interval for recording signals into the buffer memory must be fixed prior to operation.
>
> ***Pause Tech. LLC v. TiVo Inc.*, 419 F.3d 1326, 1334-36 (Fed. Cir. 2005)**

Petitioner Reads "Predetermined" Out Of The Claims

That consequence, while not inevitably disqualifying a construction in every patent. is counter to an important principle of interpretation, for patent *810 claims as for statutes: "It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous."

Intel Corp. v. Qualcomm Inc., 21 F.4th 801, 809-10 (Fed. Cir. 2021)

Combinations Lack "A Predetermined Cycle" To "Control Fluid Flow In And Out"

Yang/Mullins Uses Mullins's Variable Cycling Based On Sensor Feedback

Petition

[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.

Paper No. 1 (Petition) at 17-18

Petition

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.

Paper No. 1 (Petition) at 51

Paper No. 1 (Petition) at 17-18, 51; Paper No. 15 (POR) at 26-28; Paper No. 34 (Sur-reply) at 9

Combinations Lack "A Predetermined Cycle" To "Control Fluid Flow In And Out"

Yang/Mullins Uses Mullins's Variable Cycling Based On Sensor Feedback

Petition

[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, 26:17-27:67[illegible], 2-10.

Paper No. 1 (Petition) at 17-18

Brown Petition Declaration

pg. 2-10. Additionally, using the pressure sensor provided by Mullins on Yang's device would help implement the most efficient pressure changes to the catheter to reduce the risk of complications from aspiration thrombectomy, including clogged catheters and excessive forward flow of material out of the distal end of the catheter into the patient's blood stream, as explicitly taught by Mullins.

Ex. 1005 (Brown Petition Decl.) ¶ 100

Paper No. 1 (Petition) at 17-18, 51; Paper No. 15 (POR) at 26-28; Paper No. 34 (Sur-reply) at 9

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Combinations Lack "A Predetermined Cycle" To "Control Fluid Flow In And Out"

Ofek/Mullins Uses Mullins's Variable Cycling Based On Sensor Feedback

Petition

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

Paper No. 1 (Petition) at 101

Brown Petition Declaration

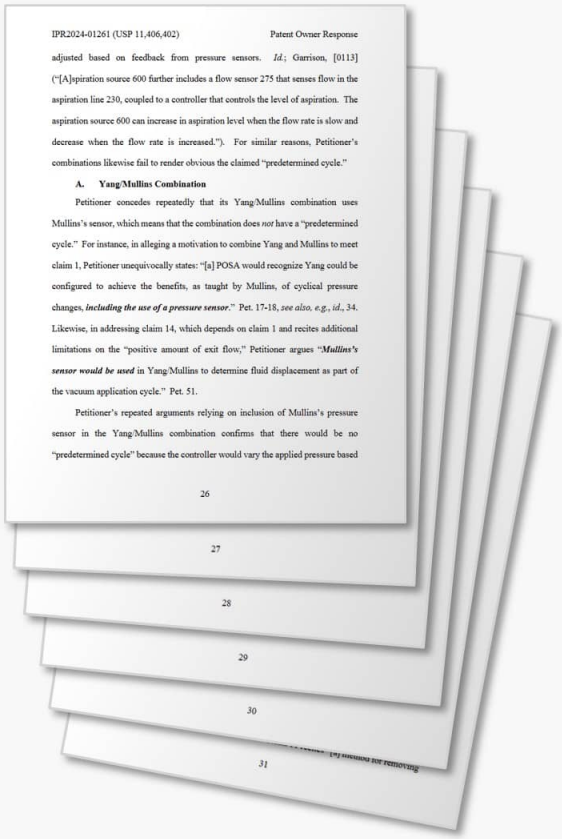
the pressure inside the system. Mullins discloses that a lumen pressure sensor and a controller can be used to monitor the pressure in the system, and builds on the concept of altering vacuum pressure levels by utilizing a pressure sensor. Ex. 1008 (Mullins) at 3:29-59, 6:34-36, 26:31-37; Ex. 1009.2 (Mullins-Prov2) at pg. 2-10. A POSA would have recognized the benefit of controlling the vacuum pressure levels and fluid flow at the distal tip of the catheter, as disclosed in Mullins, in the context of Ofek, which also includes a pressure transducer, and it would have been trivial to implement these within Ofek's aspiration thrombectomy system.

Ex. 1005 (Brown Petition Decl.) ¶ 361

Paper No. 1 (Petition) at 100-101; Paper No. 15 (POR) at 30-31; Paper No. 34 (Sur-reply) at 9

Combinations Lack "A Predetermined Cycle" To "Control Fluid Flow In And Out"

RapidPulse explained that the Petition's combinations rely on including Mullins's pressure sensor



IPR2024-01261 (USP 11,406,402) Patent Owner Response

adjusted based on feedback from pressure sensors. *Id.*; Garrison, [0113] ("[A]spiration source 600 further includes a flow sensor 275 that senses flow in the aspiration line 230, coupled to a controller that controls the level of aspiration. The aspiration source 600 can increase in aspiration level when the flow rate is slow and decrease when the flow rate is increased."). For similar reasons, Petitioner's combinations likewise fail to render obvious the claimed "predetermined cycle."

A. Yang/Mullins Combination

Petitioner concedes repeatedly that its Yang/Mullins combination uses Mullins's sensor, which means that the combination does *not* have a "predetermined cycle." For instance, in alleging a motivation to combine Yang and Mullins to meet claim 1, Petitioner unequivocally states: "[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***." Pet. 17-18, *see also, e.g., id.*, 34. Likewise, in addressing claim 14, which depends on claim 1 and recites additional limitations on the "positive amount of exit flow," Petitioner argues "***Mullins's sensor would be used*** in Yang/Mullins to determine fluid displacement as part of the vacuum application cycle." Pet. 51.

Petitioner's repeated arguments relying on inclusion of Mullins's pressure sensor in the Yang/Mullins combination confirms that there would be no "predetermined cycle" because the controller would vary the applied pressure based

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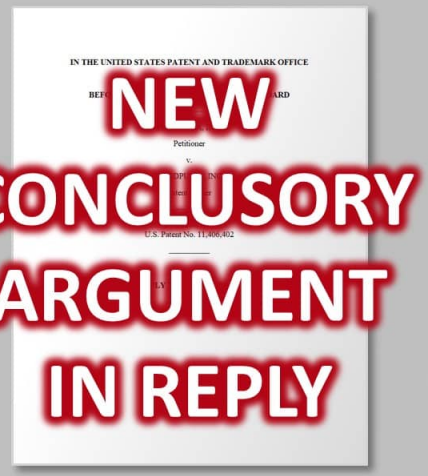
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Paper No. 15 (POR) at 26-31



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Petitioner

v.

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

NEW CONCLUSORY ARGUMENT IN REPLY

Paper No. 24 (Reply)

Petitioner's single sentence rebuttal:

Petitioner's Reply

Ex[1008], 28:59-29:12 (discussing "ratio of the infuse-to-aspirate cycle"). PO also fails to recognize that Mullins' relevance in the prior art combinations is its discussion of distal end flow control, not for its sensors. Ex[1035], ¶83

Paper No. 24 (Reply) at 17

Brown Reply Declaration

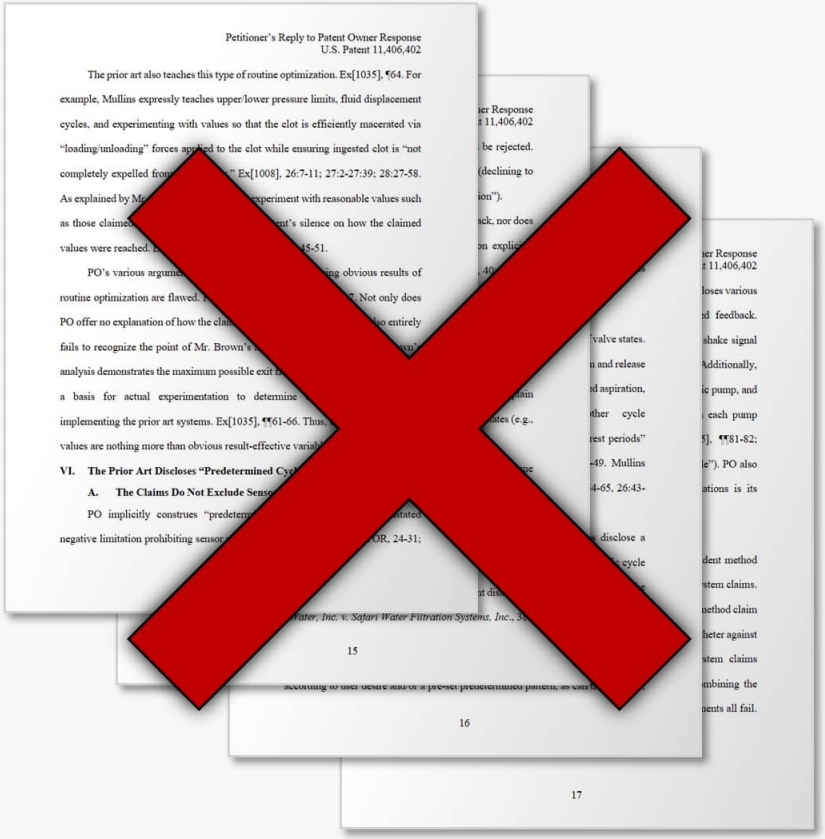
83. It is also worth emphasizing that the relevance of Mullins in the prior art combinations is because of its clarity of discussion of flow at the distal end of the catheter, not because of any feedback loop that may be involved in some subset of Mullins embodiments. As such, and for the reasons discussed above, Patent Owner's

Ex. 1035 (Brown Reply Decl.) ¶ 83

Paper No. 15 (POR) at 26-31; Paper No. 24 (Reply) at 16-17; Paper No. 34 (Sur-reply) at 9

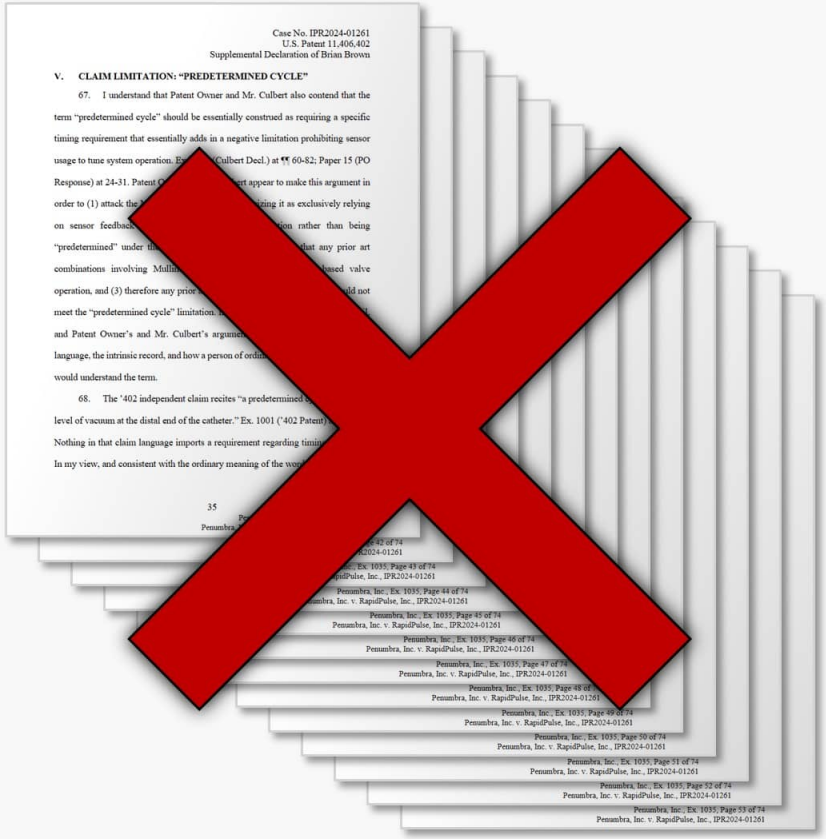
Petitioner Never Explained How Combinations Control Flow Without A Sensor

Petitioner's Reply



Paper No. 24 (Reply) at 14-17

Brown Reply Declaration



Ex. 1035 (Brown Reply Decl.) ¶¶ 67-84

Petitioner Fails To Identify Any Teaching In Mullins Of "A Predetermined Cycle" To "Control Fluid Flow In And Out"

Petitioner's Reply

frequency." Ex[1007], 5:49-62, 6:35-37, 6:61-63, 8:38-49. Mullins discloses various different embodiments which don't require or discuss sensor-based feedback. Ex[1035], ¶¶81-82; *see also, e.g.,* Ex[1008], 26:43-49; 28:1-10 ("the shake signal may be initiated for a predefined number of cycles."); 28:49-52. Additionally,

Paper No. 24 (Reply) at 17

Mullins

In one embodiment, the applied pressure signal incorporates an oscillation or "shake" signal. The shake signal implies the application of pulse cycling between two pressure limits as shown in FIGS. **50**(*a*) and (*b*). The signal

Ex. 1008 (Mullins) at 27:54-57

Petitioner Fails To Identify Any Teaching In Mullins Of "A Predetermined Cycle" To "Control Fluid Flow In And Out"

Petitioner's Reply

frequency." Ex[1007], 5:49-62, 6:35-37, 6:61-63, 8:38-49. Mullins discloses various different embodiments which don't require or discuss sensor-based feedback. Ex[1035], ¶¶81-82; *see also, e.g.,* Ex[1008], 26:43-49; 28:1-10 ("the shake signal may be initiated for a predefined number of cycles."); 28:49-52. Additionally,

Paper No. 24 (Reply) at 17

Culbert POR Declaration

126. First, like the remainder of Mullins and Mr. Brown's proposed combinations with Mullins, and considering Mullins as a whole, this portion of

* * *

upper pressure limits. Ex.1008, 27:66-67. Thus, even if there is some cyclical aspect to Mullins, the cycling is still controlled by the pressure sensor readings, and not "predetermined."

Ex. 2014 (Culbert POR Decl.) ¶ 126

Petitioner Fails To Identify Any Teaching In Mullins Of "A Predetermined Cycle" To "Control Fluid Flow In And Out"

Petitioner's Reply

may be initiated for a predefined number of cycles."); 28:49-52. Additionally, Mullins discloses controlling fluid displacement cycles with a peristaltic pump, and a POSA would recognize that a fixed timing cycle of operation in each pump direction would produce Mullins' predetermined cycles. Ex[1035], ¶¶81-82; Ex[1008], 28:59-29:12 (discussing "ratio of the infuse-to-aspirate cycle"). PO also

Paper No. 24 (Reply) at 17

Culbert POR Declaration

127. Additionally, Mullins contemplates variability of the "ratio of the infuse-to-aspirate cycle" because it states that "the ratio of the infuse-to-aspirate cycle may be ***between*** 0.01 ***and*** 0.99." Ex.1008, 28:59-64 (emphases added). Mullins further contemplates narrowing this range to 0.1 and 0.9, and 0.4 and 0.9. This disclosure suggests that the ratio represents the maximum relative time duration between infuse and aspirate portions, but not that each cycle must follow the same ratio. In other words, the ratio for a first cycle can be 0.05 to 0.95, while the ratio for a later cycle can be 0.10 to 0.90, and the ratio may change throughout a thrombectomy procedure (e.g., based on monitoring and controlling timing, as Dr. Ross stated (Ex.1023 ¶20)); thus, the cycle would not be "predetermined" as required. Mullins only requires that the ratio for any given cycle be no greater than the specified ratio. Thus, there is no "predetermined" cycle, only a variable cycle dependent on pressure sensing.

Ex. 2014 (Culbert POR Decl.) ¶ 127

Petitioner Continues To Rely On Mullins's Sensor-Feedback Approach

Petitioner's Reply

"propagated in a predetermined pattern." Ex[1007], 6:30-7:17, 8:38-49. Mullins discloses "pulse cycling between two pressure limits." Ex[1008], 27:54-65, 26:43-49, FIGs. 46-49.

Paper No. 24 (Reply) at 16

Cycling based on when sensed pressure reaches a limit is a variable—not "predetermined"—cycle

Paper No. 15 (POR) at 25-31; Paper No. 24 (Reply) at 16; Paper No. 34 (Sur-reply) at 9-10

“Control Fluid Flow In And Out” (All Claims)

Claims 1 And 11

1. An aspiration thrombectomy system, comprising:
an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;
a vacuum source fluidically coupled to the catheter;
a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;
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
a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 1

11. A method for removing thromboembolic material, comprising:
aspirating thromboembolic material from a person using the system of claim **1** by—
(a) positioning the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person;
(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
(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 such that a level of vacuum at the distal end of the catheter changes and thereby controls flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 11

Petitioner's Physician Expert Admits POSITAs Avoid Flow Out

Ross Deposition

Q. Okay. How would you, generally, in your work describe flow out of the catheter?

A. It's something that we seek to avoid and generally doesn't happen. That's how I would describe it. It's not really a huge issue because I don't do anything to promote forward flow.

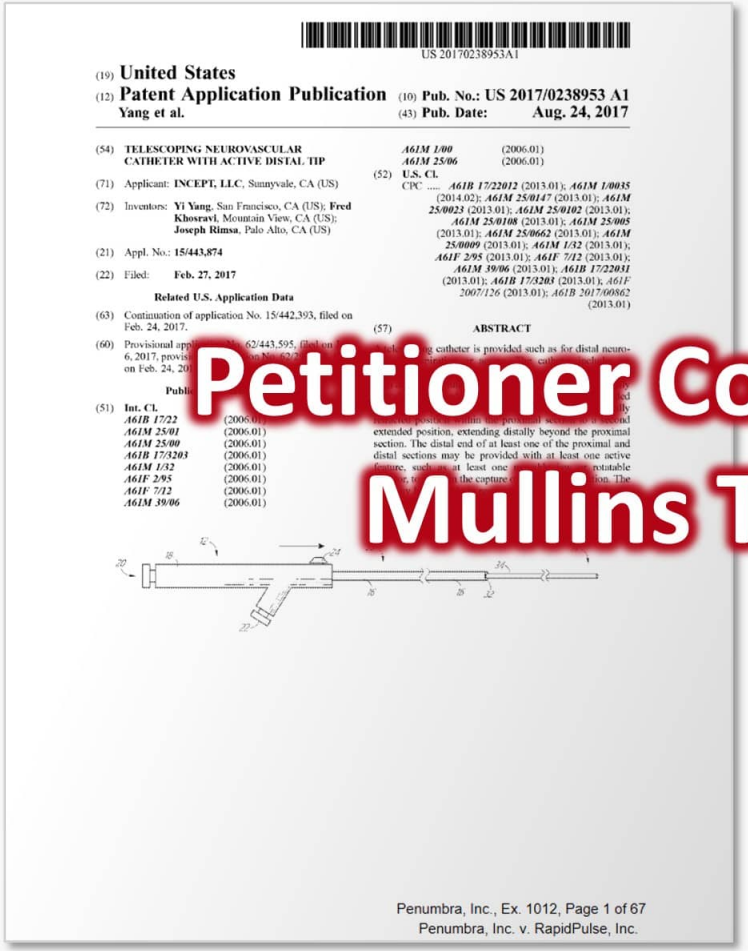
Q. Okay. Does anyone in your field do anything to promote forward flow?

* * *

THE WITNESS: You would have to ask them. Generally speaking, forward flow is something that we -- one seeks to avoid.

Ex. 2006 (Ross Depo.) at 18:24-19:11 (objection omitted)

Combinations Lack "Control Fluid Flow In And Out"



US 20170238953A1

(19) **United States**

(12) **Patent Application Publication**

Yang et al.

(10) **Pub. No.: US 2017/0238953 A1**

(43) **Pub. Date: Aug. 24, 2017**

(54) **TELESCOPING NEUROVASCULAR CATHETER WITH ACTIVE DISTAL TIP**

(71) Applicant: **INCEPT, LLC**, Sunnyvale, CA (US)

(72) Inventors: **Yi Yang**, San Francisco, CA (US); **Fred Khosravi**, Mountain View, CA (US); **Joseph Rimsa**, Palo Alto, CA (US)

(21) Appl. No.: **15/443,874**

(22) Filed: **Feb. 27, 2017**

Related U.S. Application Data

(63) Continuation of application No. 15/442,393, filed on Feb. 24, 2017.

(60) Provisional app... 62/443,595, ... 6, 2017, provis... on Feb. 24, 20...

(51) **Int. Cl.**

A61B 17/22	(2006.01)
A61M 25/01	(2006.01)
A61M 25/00	(2006.01)
A61B 17/3203	(2006.01)
A61M 1/32	(2006.01)
A61F 2/95	(2006.01)
A61F 7/12	(2006.01)
A61M 39/06	(2006.01)
A61M 1/00	(2006.01)
A61M 25/06	(2006.01)

(52) **U.S. Cl.**

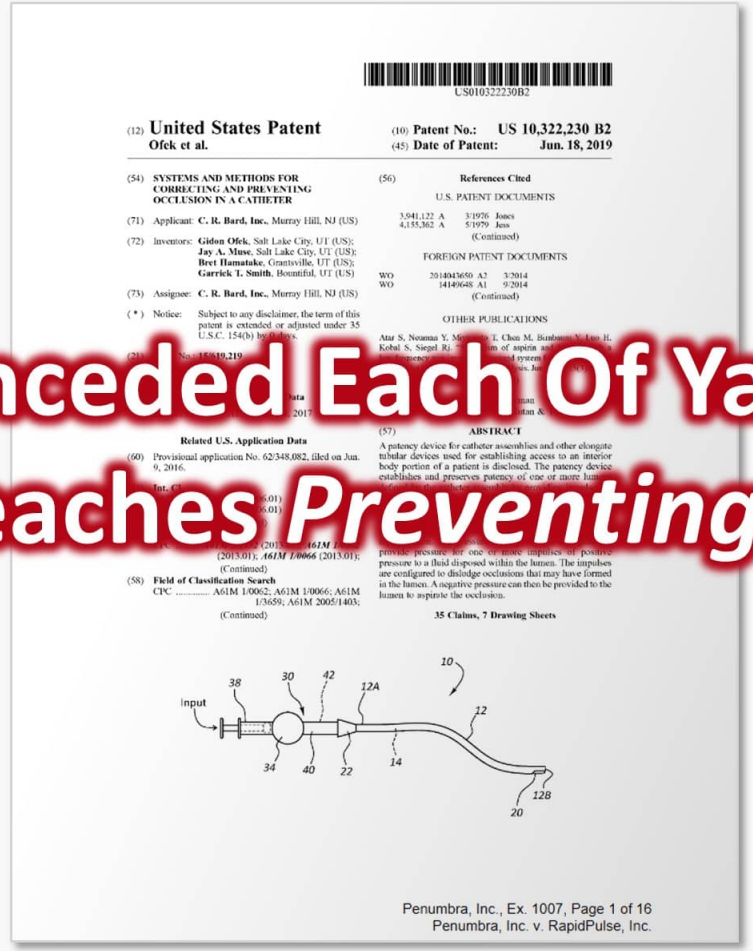
CPC ***A61B 17/22012*** (2013.01); ***A61M 1/0035*** (2014.02); ***A61M 25/0147*** (2013.01); ***A61M 25/0023*** (2013.01); ***A61M 25/0102*** (2013.01); ***A61M 25/0108*** (2013.01); ***A61M 25/005*** (2013.01); ***A61M 25/0662*** (2013.01); ***A61M 25/0009*** (2013.01); ***A61M 1/32*** (2013.01); ***A61F 2/95*** (2013.01); ***A61F 7/12*** (2013.01); ***A61M 39/06*** (2013.01); ***A61B 17/22031*** (2013.01); ***A61B 17/3203*** (2013.01); *A61F 2007/126* (2013.01); *A61B 2017/00862* (2013.01)

(57) **ABSTRACT**

...g catheter is provided such as for distal neuro-... extended position, extending distally beyond the proximal section. The distal end of at least one of the proximal and distal sections may be provided with at least one active feature, such as at least one ... rotatable ... the capture ... ion. The ...

Penumbra, Inc., Ex. 1012, Page 1 of 67
Penumbra, Inc. v. RapidPulse, Inc.

Ex. 1012 (Yang)



US010322230B2

(12) **United States Patent**

Ofek et al.

(10) **Patent No.: US 10,322,230 B2**

(45) **Date of Patent: Jun. 18, 2019**

(54) **SYSTEMS AND METHODS FOR CORRECTING AND PREVENTING OCCLUSION IN A CATHETER**

(71) Applicant: **C. R. Bard, Inc.**, Murray Hill, NJ (US)

(72) Inventors: **Gidon Ofek**, Salt Lake City, UT (US); **Jay A. Muse**, Salt Lake City, UT (US); **Bret Hamatake**, Grantsville, UT (US); **Garrick T. Smith**, Bountiful, UT (US)

(73) Assignee: **C. R. Bard, Inc.**, Murray Hill, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by ... days.

(21) ... No.: 15/419,219

(22) ...

(65) ...

Related U.S. Application Data

(60) Provisional application No. 62/348,082, filed on Jun. 9, 2016.

(51) ...

(52) ...

(58) **Field of Classification Search**

CPC ..... A61M 1/0062; A61M 1/0066; A61M 1/3659; A61M 2005/1403; (Continued)

(56) **References Cited**

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3,941,122 A 3/1976 Jones
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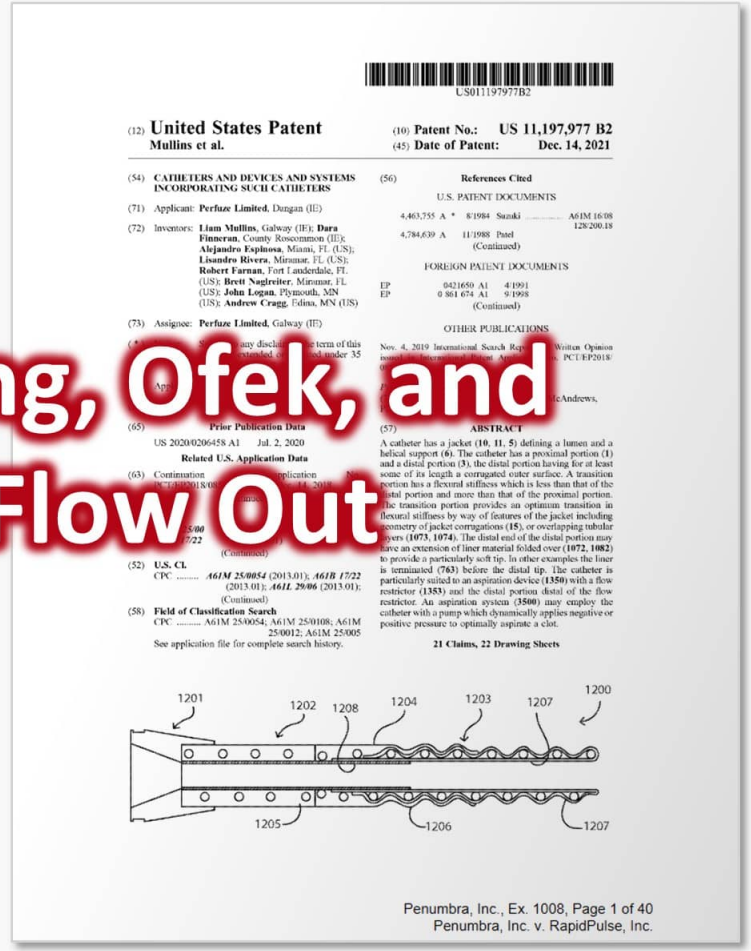
(57) **ABSTRACT**

A patency device for catheter assemblies and other elongate tubular devices used for establishing access to an interior body portion of a patient is disclosed. The patency device establishes and preserves patency of one or more lum... provides pressure for one or more impulses of positive pressure to a fluid disposed within the lumen. The impulses are configured to dislodge occlusions that may have formed in the lumen. A negative pressure can then be provided to the lumen to aspirate the occlusion.

35 Claims, 7 Drawing Sheets

Penumbra, Inc., Ex. 1007, Page 1 of 16
Penumbra, Inc. v. RapidPulse, Inc.

Ex. 1007 (Ofek)



US011197977B2

(12) **United States Patent**

Mullins et al.

(10) **Patent No.: US 11,197,977 B2**

(45) **Date of Patent: Dec. 14, 2021**

(54) **CATHETERS AND DEVICES AND SYSTEMS INCORPORATING SUCH CATHETERS**

(71) Applicant: **Perfuze Limited**, Dungan (IE)

(72) Inventors: **Liam Mullins**, Galway (IE); **Dara Finneran**, County Roscommon (IE); **Alejandro Espinosa**, Miami, FL (US); **Lisandro Rivera**, Miramar, FL (US); **Robert Farnan**, Fort Lauderdale, FL (US); **Brett Naglreiter**, Miramar, FL (US); **John Logan**, Plymouth, MN (US); **Andrew Cragg**, Edina, MN (US)

(73) Assignee: **Perfuze Limited**, Galway (IE)

(*) ... any disclai... the term of this ... under 35 ...

(21) Appl. No.: ...

(22) ...

(65) **Prior Publication Data**

US 2020/0206458 A1 Jul. 2, 2020

Related U.S. Application Data

(63) Continuation ... application ... (Continued)

(52) **U.S. Cl.**

CPC ..... ***A61M 25/0054*** (2013.01); ***A61B 17/22*** (2013.01); ***A61L 29/06*** (2013.01); (Continued)

(58) **Field of Classification Search**

CPC A61M 25/0054; A61M 25/0108; A61M 25/0012; A61M 25/005

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,463,755 A * 8/1984 Suzuki A61M 16/08 128/200.18
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EP 0 861 674 A1 9/1998
(Continued)

OTHER PUBLICATIONS

Nov. 4, 2019 International Search Rep... Written Opinion ... PCT/EP2018/ ... eAndrews, ...

(57) **ABSTRACT**

A catheter has a jacket (**10**, **11**, **5**) defining a lumen and a helical support (**6**). The catheter has a proximal portion (**1**) and a distal portion (**3**), the distal portion having for at least some of its length a corrugated outer surface. A transition portion has a flexural stiffness which is less than that of the distal portion and more than that of the proximal portion. The transition portion provides an optimum transition in flexural stiffness by way of features of the jacket including geometry of jacket corrugations (**15**), or overlapping tubular layers (**1073**, **1074**). The distal end of the distal portion may have an extension of liner material folded over (**1072**, **1082**) to provide a particularly soft tip. In other examples the liner is terminated (**763**) before the distal tip. The catheter is particularly suited to an aspiration device (**1350**) with a flow restrictor (**1353**) and the distal portion distal of the flow restrictor. An aspiration system (**3500**) may employ the catheter with a pump which dynamically applies negative or positive pressure to optimally aspirate a clot.

21 Claims, 22 Drawing Sheets

Penumbra, Inc., Ex. 1008, Page 1 of 40
Penumbra, Inc. v. RapidPulse, Inc.

Ex. 1008 (Mullins)

Petitioner Conceded Each Of Yang, Ofek, and Mullins Teaches *Preventing* Flow Out

Petitioner's Physician Expert Admitted Yang, Ofek, And Mullins Teach Maintaining Sufficient Suction Force To Avoid Flow Out

Ross Declaration

Ex. 1022 ("Simon") at 680. Thus, to reduce the risk of forward flow, the aspiration thrombectomy system and/or persons of skill in the art understood, well before 2019, that the operator of the system should monitor, control, and regulate the timing of the vent and vacuum valves to maintain the levels of suction force, as described in Mullins, Yang, Ofek, and Grey, thereby preserving sufficient levels of pressure contained in the vacuum aspiration system. Ex. 1010 ("Grey") at 7:10-12, 13:7-11;

* * *

Ex. 1012 ("Yang") at ¶¶ [0102], [0178]; Ex. 1022 ("Simon") at 680. By controlling sufficient levels of vacuum in the catheter (i.e., generally keeping the overall pressures exerted on the fluid within the catheter below blood pressure), the risk of creating forward flow of material out of the distal end of the catheter is reduced. One

Ex. 1023 (Ross Decl.) ¶ 20 (citation omitted)

Petitioner's Expert Admitted Yang Lacks Flow Out, Or Control Of It

Brown '253 Patent IPR Deposition

Q. Okay. And so does Yang disclose control of flow out from the distal end of the catheter?

* * *

A. That's an unknown.

Q. And why is it unknown?

* * *

Q. So can you tell me why that is an unknown?

A. Because he does not describe the flow out and whether his system controls flow out.

Ex. 2016 ('253 Brown Depo.) at 93:13-25

Petitioner Admitted A POSITA Would Know Yang Avoids Flow Out

EPO Opposition

Documents O1-O3 are relevant at least to the novelty of the opposed patent:

O1	EP 4 461 253 A2 ("Teigen"), published 13 November 2024 (prior art under Art. 54(3) EPC)
O2	US 2017/0238953 A1 ("Yang"), published 24 August 2017 (prior art under Art. 54(2) EPC)
O2a	Corrections applied to specification of O2
O3	WO 2017/214573 A1 ("Ofek"), published 14 December 2017 (prior art under Art. 54(2) EPC)

Ex. 2035 (EPO Opp.) at 2

EPO Opposition

Second, the skilled reader would appreciate that the teaching of O2 is that forward flow is prevented.

Ex. 2035 (EPO Opp.) at 53

Petitioner Admitted A POSITA Would Know Yang Avoids Flow Out

EPO Opposition

Documents O1-O3 are relevant at least to the novelty of the opposed patent:

O1	EP 4 461 253 A2 ("Teigen"), published 13 November 2024 (prior art under Art. 54(3) EPC)
O2	US 2017/0238953 A1 ("Yang"), published 24 August 2017 (prior art under Art. 54(2) EPC)
O2a	Corrections applied to specification of O2
O3	WO 2017/214573 A1 ("Ofek"), published 14 December 2017 (prior art under Art. 54(2) EPC)

Ex. 2035 (EPO Opp.) at 2

EPO Opposition

O2 would therefore naturally result in forward flow being prevented, by a similar process as the opposed patent itself describes.

Ex. 2035 (EPO Opp.) at 53

Operating an arrangement as described by document O2 would naturally result in the prevention of forward flow, as required by feature **1[i]**.

Ex. 2035 (EPO Opp.) at 52

Petitioner Admitted Ofek Operates To Avoid Flow Out

EPO Opposition

Documents O1-O3 are relevant at least to the novelty of the opposed patent:

O1	EP 4 461 253 A2 ("Teigen"), published 13 November 2024 (prior art under Art. 54(3) EPC)
O2	US 2017/0238953 A1 ("Yang"), published 24 August 2017 (prior art under Art. 54(2) EPC)
O2a	Corrections applied to specification of O2
O3	WO 2017/214573 A1 ("Ofek"), published 14 December 2017 (prior art under Art. 54(2) EPC)

Ex. 2035 (EPO Opp.) at 53

EPO Opposition

The system of O3 is therefore operated so as to prevent forward flow of fluid out of the distal end of the catheter, as recited by claim 1.

Ex. 2035 (EPO Opp.) at 64

As the dislodged occlusion is required to not enter the bloodstream, it is clear that the device is operated so as to prevent forward flow of liquid from the catheter.

Ex. 2035 (EPO Opp.) at 63

Petitioner's Obviousness Arguments Are Legally Wrong

Petitioner's Reply

As discussed above and explained by Mr. Brown, Yang and Ofek each disclose embodiments that could be understood or obvious as controlling flow distal flow out, especially in combination with Mullins. Ex[1035], ¶¶45-46; Pet., 33, 85-86. For similar reasons, a POSA would also recognize that both references disclose

Paper No. 24 (Reply) at 11

These disclosures, however, do not provide any reason why a skilled artisan would use 3D coordinates instead of angular directions in a system. See *Belden Inc. v. Berk-Tek LLC,* 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the combinations or modifications *887 of prior art to arrive at the claimed invention."). The mere fact that these possible arrangements existed in the prior art does not provide a reason that a skilled artisan would have substituted the one-camera angular direction system in Keitler and Bridges with the two-camera 3D coordinate system disclosed in Briggs. There was no argument in the petition regarding why a skilled artisan would make this substitution—other than that the two different coordinate systems were "known to be used." J.A. 194-96, 214-16.

Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc., 97 F.4th 882, 886-88 (Fed. Cir. 2024)

Petitioner Admitted Mullins Teaches Avoiding Flow Out

EPO Opposition

O10 WO 2019/115809 A1 ("Mullins"), published 20 June 2019 (prior art under Art. 54(2) EPC)

Ex. 2035 (EPO Opp.) at 53

EPO Opposition

Mullins is particularly relevant for the consideration of inventive step of features **1[h]** and **1[i]**, as it explicitly teaches changing a vacuum level at the distal end of a catheter to prevent clogging, and preventing forward flow to reduce the risk of distal embolization. The skilled person would therefore contemplate the teaching

Ex. 2035 (EPO Opp.) at 114

The skilled person would therefore be motivated to operate a clot removal system with no forward flow, and by applying varying pressure, in the manner described by O10, in order to avoid worse patient outcomes and to improve aspiration of clots.

Ex. 2035 (EPO Opp.) at 116

Petitioner's Admissions Show A POSITA Would Understand Yang, Ofek, And Mullins Prevent Flow Out

> In addition, Petitioner's representations to the EPO are relevant to determine how an ordinarily skilled artisan would understand Kinde. *See Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n*, 109 F.3d 726, 733 (Fed. Cir. 1997) (stating that "representations made to foreign patent offices are relevant to determine whether a person skilled in the art would consider butanone or other ketones to be interchangeable with acetone')
>
> *Guardant Health, Inc. v. Univ. of Wash.*, IPR2022-00450, Paper 13 at 11 (P.T.A.B. Aug. 1, 2022)

Paper No. 19 (Motion to Submit Supp. Info.) at 2-4;
Paper No. 34 (Sur-reply) at 10-11

Petitioner's Expert Admitted Mullins Would Motivate A POSITA To Create A System *Without* Flow Out, Consistent With A POSITA's Common Knowledge

Brown Sur-reply Deposition

Q. Do you agree that the person skilled in the field would be motivated to operate a clot removal system with no forward flow in the manner described in Mullins?

* * *

A. I believe a person skilled in the art would be motivated to use the teachings of Mullins to create a system that has no forward flow.

Ex. 2044 (Brown Sur-reply Depo.) at 35:8-16

EPO Opposition

Given their common general knowledge relating to distal embolization and the teachings of the various prior art documents cited herein, it would be obvious to the skilled person that when modifying various parameters to optimise the system, for example in view of a particular catheter that is connected to the device, it should be ensured that forward flow is prevented.

Ex. 2035 (EPO Opp.) at 129

Petitioner Hid Its Admissions From Its Expert

Brown Sur-reply Deposition

Q. You, Mr. Brown, testified that you reviewed the claims of the European opposition patent as part of your review of the European opposition; is that fair?

A. That is fair.

Q. Is that all you reviewed of the European opposition?

A. It is.

Q. Why is that all you reviewed of the European opposition?

A. I was not asked to review any more of it.

Ex. 2044 (Brown Sur-reply Depo.) at 84:5-17

Brown Sur-reply Deposition

Q. And you state in Paragraph 35, starting at the second sentence, "I also understand that patent owner appears to intend to argue that petitioner's positions in the European opposition against RP-EP1 allegedly contradicts its arguments here. I disagree that any such contradiction exists." That's what you wrote, right?

A. That is what I wrote.

Q. And all you reviewed of the European opposition to come to that conclusion were the claims for the European patent, right?

A. That is correct.

Ex. 2044 (Brown Sur-reply Depo.) at 84:22-85:14

Petitioner's Expert Endorses Taking Contradictory Positions, But Those Contradictory Positions Cannot Support Obviousness

Brown Sur-reply Deposition

Q. Sure. Would you agree that parties taking contradictory positions about the teachings of a prior art reference would bear on that party's credibility?

* * *

A. I believe that it is acceptable to take contradictory positions, that doesn't necessarily mean that the tactics are disingenuous.

Ex. 2044 (Brown Sur-reply Depo.) at 42:16-43:2

Because the Board rested its finding of a reason to combine on Mr. Hutton's contradictory testimony and that testimony was central to Petitioner's analysis that an ordinarily skilled artisan would have had a reason to combine the disclosures of Szrek and Llach, the Board's finding of unpatentability on the Szrek-based grounds is vacated. *See Finesse Wireless LLC v. AT&T Mobility LLC*, No. 2024-1039, 2025 WL 2713518, at *4 (Fed. Cir. Sept. 24, 2025) ("When the party with the burden of proof, . . . rests its case on an expert's self-contradictory testimony, we may conclude the evidence is insufficient to satisfy that standard.") (citing *Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1349 (Fed. Cir. 2008)).

Interactive Commc'ns Int'l, Inc. v. Blackhawk Network Inc., IPR2024-00465, Paper 40 at 3 (Dir. Oct. 9, 2025)

Claim 11

Claim 11

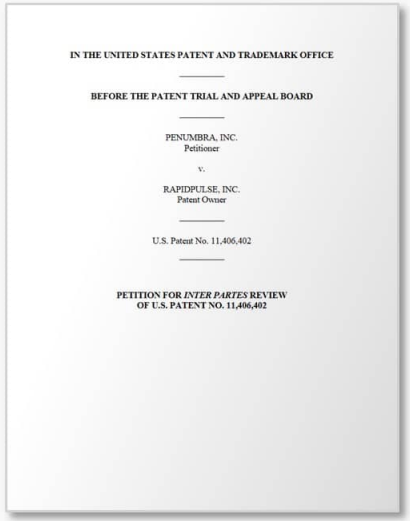
1. An aspiration thrombectomy system, comprising:
an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;
a vacuum source fluidically coupled to the catheter;
a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;
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
a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 1

11. A method for removing thromboembolic material, comprising:
aspirating thromboembolic material from a person using the system of claim **1** by—
(a) positioning the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person;
(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
(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 such that a level of vacuum at the distal end of the catheter changes and thereby controls flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 11

Petitioner Did Not Show A Reasonable Expectation Of Success



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

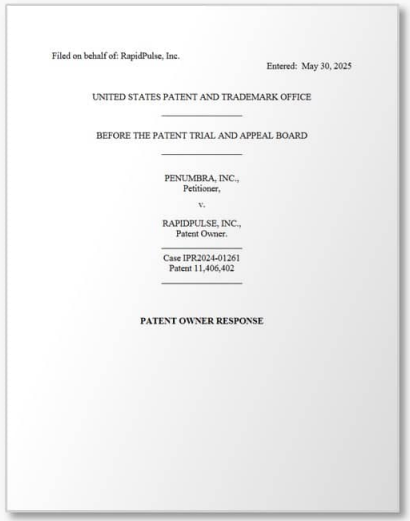
PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,406,402

Petition relied on Mullins's sensor for a reasonable expectation of success

Paper No. 1 (Petition) at 17-18, 68, 101; Ex. 1005 (Brown Petition Decl.) ¶¶ 100, 361

Petition did not include "routine optimization" theory for claim 1 or 11

Paper No. 1 (Petition) at 16-35, 49-50, 67-86, 98-99



Filed on behalf of: RapidPulse, Inc.

Entered: May 30, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PENUMBRA, INC.,
Petitioner,

v.

RAPIDPULSE, INC.,
Patent Owner.

Case IPR2024-01261
Patent 11,406,402

PATENT OWNER RESPONSE

Petitioner failed to show any reasonable expectation of success in achieving clot aspiration using controlled fluid flow in and out in a predetermined cycle

Paper No. 15 (POR) at 33-45; Ex. 2014 (Culbert POR Decl.) ¶¶ 88-105

Petition Relied On Mullins's Variable Cycling Based On Sensor Feedback To Assert A Reasonable Expectation Of Success

Brown Petition Declaration

101. Mullins' methods to change a level of vacuum at the distal end of the catheter are similar to, if not the same as, the pulsatile application of vacuum oscillating between various pressures described by Yang. A POSA would have had a reasonable expectation of success in implementing this combination, because any modification, if necessary, would simply add additional control logic from Mullins' system for modulating the pressures contained within the aspiration system, in accordance with the preferable pressure cycles as taught in Yang. Because Yang's system is already computer-controlled via various disclosed algorithms to be selected by the system implementer, it would have been well within the level of skill in the art to modify the logic of Yang's controller to implement Mullins's teachings, if necessary, or incorporate known mechanical components, if needed.

Ex. 1005 (Brown Petition Decl.) ¶ 101

Mullins's "control logic … for modulating the pressures" provides a variable—not "predetermined"—cycle

Petitioner's New "Routine Optimization" Handwaving Is Improper

> We conclude that the Board did not abuse its discretion in holding HPC to its word and disregarding its new theory first raised in reply.
>
> *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330-31 (Fed. Cir. 2019)

Petitioner's New "Routine Optimization" Argument Fails

Petitioner argues

Petitioner's Reply

success. Ex[1035], ¶95. As Grey explains, "deliberate variations in the suction force/pressure" can be used to "control" and achieve an intended and predictable influence in aspirating a clot. *Id*; Ex[1010], 6:13-25. Adjusting the prior art's valve

Paper No. 24 (Reply) at 20

BUT

'253 Patent Final Written Decision

Ex. 1010, 7:10–12. To minimize this risk, Grey teaches that "the magnitude of the baseline pressure is preferably maintained above zero (i.e., a vacuum is maintained)" and that "[p]roviding a non-zero suction force in the catheter at all times reduces the risk of occlusive material breaking free of a clot and traveling distally in the vessel." *Id.* at 13:7–11. Both parties and their

Ex. 2011 ('253 FWD) at 34-35

Paper No. 24 (Reply) at 20; Paper No. 34 (Sur-reply) at 16

Petitioner's Physician Expert Admitted The Prior Art Teaches Regulating Valve Timing So There Is Sufficient Suction Force To Avoid Flow Out

Ross Declaration

Ex. 1022 ("Simon") at 680. Thus, to reduce the risk of forward flow, the aspiration thrombectomy system and/or persons of skill in the art understood, well before 2019, that the operator of the system should monitor, control, and regulate the timing of the vent and vacuum valves to maintain the levels of suction force, as described in Mullins, Yang, Ofek, and Grey, thereby preserving sufficient levels of pressure contained in the vacuum aspiration system. Ex. 1010 ("Grey") at 7:10-12, 13:7-11;

* * *

Ex. 1012 ("Yang") at ¶¶ [0102], [0178]; Ex. 1022 ("Simon") at 680. By controlling sufficient levels of vacuum in the catheter (i.e., generally keeping the overall pressures exerted on the fluid within the catheter below blood pressure), the risk of creating forward flow of material out of the distal end of the catheter is reduced. One

Ex. 1023 (Ross Decl.) ¶ 20 (citation omitted)

Petitioner Did Not Confront Clot Variability

Patent Owner Response

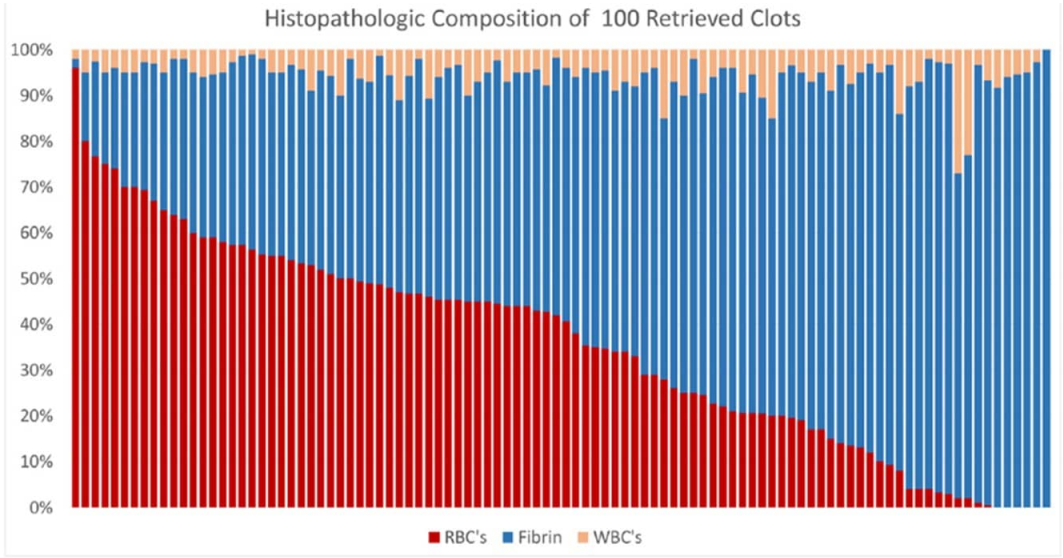


FIGURE 5.
Histopathologic clot composition
Composition distribution of Red Blood Cells (RBC) Fibrin and White Blood Cells (WBC) in 100 clots retrieved from cerebral ischemic stroke patients. (Courtesy of M. Mirza MD, Neuravi/Cerenovus, Galway, Ireland)

Paper No. 15 (POR) at 38-39

Brouwer Paper

confronted with previously unknown hurdles in our endovascular procedures. One of the most important obstacles is the fact that clots tend to differ in consistency and removability.

* * *

On one hand we can face a clot that comes out with simple proximal aspiration or thrombectomy but in a next case we may be faced with a clot that is too resilient to be removed by any of the devices we have at hand. The next case examples show the high variability and, so far, unpredictable nature of the clots in the stroke cases we face on a daily basis.

Ex. 2021 (Brouwer) at 1-2

Petitioner's Handwaving Is Classic Hindsight

Brown Reply Declaration

98. Here, the claimed invention merely involves parameter selection and adjustment within known systems like those disclosed in the prior art, and optimizing such variables is within the skill of the art, and a POSA would reasonably expect success.

99. Patent Owner's and Mr. Culbert's speculation about supposed obstacles does not overcome the disclosures in Yang, Ofek, and Mullins, which provide clear guidance and parameters that POSAs would have recognized as subject to routine optimization.

Ex. 1035 (Brown Reply Decl.) ¶¶ 98-99

Petitioner's Handwaving Is Classic Hindsight

> In cases like *InTouch*, *ActiveVideo*, and *DSS*, we rejected obviousness determinations based on conclusory and unsupported expert testimony. We repeatedly expressed concerns that crediting such testimony risks allowing the challenger to use the challenged patent as a roadmap to reconstruct the claimed invention using disparate elements from the prior art—i.e., the impermissible *ex post* reasoning and hindsight bias that *KSR* warned against. *See Van Os*, 844 F.3d at 1361 (citing *KSR*, 550 U.S. at 418, 421, 127 S.Ct. 1727). Those same concerns apply here.
>
> *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1361 (Fed. Cir. 2019)

Ofek Does Not Disclose Positioning Next To A Clot In A Blood Vessel

11. A method for removing thromboembolic material, comprising:

aspirating thromboembolic material from a person using the system of claim **1** by—

(a) positioning the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person;

(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

(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 such that a level of vacuum at the distal end of the catheter changes and thereby controls flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 11

Ofek Is A Patency Device, Not A Thrombectomy Device

Institution Decision

Ofek, titled "Systems and Methods for Correcting and Preventing Occlusion in a Catheter," is directed to "a patency device for catheter assemblies and other elongate tubular devices used for establishing access to an interior body portion of a patient," wherein "[t]he patency device establishes and[/or] preserves patency of one or more lumens defined by the catheter assembly by providing impulses of positive pressure to fluid disposed in the lumen of the catheter assembly." Ex. 1007, code (54), 1:17–23.

Paper No. 7 (Institution Decision) at 27

Ofek

FIG. **1** further shows details regarding a patency device **30** configured to operably connect on a temporary basis with the catheter **10** and provide patency to the catheter tube lumen **14**, according to one embodiment. Generally, the patency device **30** includes a fluid reservoir **34** that is configured, together with a pressure input portion **38**, to provide one or more relatively short-duration impulses, also referred to herein as positive pressure impulses, of high-pressure fluid to the lumen **14** of the catheter tube **12**. Such impulses, when performed periodically, are configured to prevent the formation of thrombus or other occlusion in the lumen **14**, especially at the distal end thereof. These short-duration, high pressure impulses can also be used to clear the lumen after occlusions have formed therein.

Ex. 1007 (Ofek) at 2:56-3:2

Ofek Does Not Disclose Positioning Next To A Clot In A Blood Vessel, And The Petition Never Argued To Modify Ofek To Do So

WRONG

Petition

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],

Paper No. 1 (Petition) at 98

NOT LEGAL STANDARD

Petitioner's Reply

Ex[1035], ¶¶87-92; Pet. 67-72. A POSA would recognize that Ofek's use of arterial catheters for aspirating a thrombus at the distal end of the catheter means that Ofek's disclosed embodiments were well-suited for thrombectomy procedures. Ex[1035], ¶¶87-92. PO's dissatisfaction with Ofek not using magic words is of no moment. Ex[1035], ¶¶87-92.

Paper No. 24 (Reply) at 18

Paper No. 1 (Petition) at 98; Paper No. 24 (Reply) at 18; Paper No. 34 (Sur-reply) at 18-19

Amount Of Exit Flow Claims: Claims 3-4, 14, And 16-17

Claims 3 And 4

3. The system of claim **2** wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow from approximately 0.001 ml to approximately 1.0 ml before fluid is drawn back into the catheter lumen.

4. The system of claim **2** wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve such that movement of the fluid column at the distal end of the catheter is limited to a positive amount of exit flow of approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

Ex. 1001 ('402 Patent), Claims 3-4

Claims 14, 16, And 17

14. 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 such that the positive amount of exit flow is approximately 0.5 mm to approximately 30 mm of the fluid column before fluid is drawn back into the catheter lumen.

* * *

16. 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 such that the positive amount of exit flow is approximately 0.001 ml to approximately 1.0 ml before fluid is drawn back into the catheter lumen.

17. 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 such that the positive amount of exit flow is approximately 0.1 ml to approximately 0.5 ml before fluid is drawn back into the catheter lumen.

Ex. 1001 ('402 Patent), Claims 14, 16-17

No Disclosure Of Any Exit Flow Amount In Any Reference

Undisputed that Yang, Ofek, and Mullins do *not* disclose *any* specific amount of exit flow

Petitioner Fails To Meet Obviousness Standard

Petitioner's Reply

As discussed above and explained by Mr. Brown, Yang and Ofek each disclose embodiments that could be understood or obvious as controlling flow distal flow out, especially in combination with Mullins. Ex[1035], ¶¶45-46; Pet., 33, 85-86. For similar reasons, a POSA would also recognize that both references disclose

Paper No. 24 (Reply) at 11

Petitioner's Reply

For Yang, a POSA would recognize that some positive exit flow would occur when applying pulsated/cyclical aspiration to a clot at the distal end, and that the disclosed water hammer effect suggests that some distal flow out may occur. Ex[1012], ¶¶[0108], [0135], [0168]; Ex[1035], ¶¶53. For Ofek, a POSA would

Paper No. 24 (Reply) at 11

Ex[1012], ¶¶[0108], [0135], [0168]; Ex[1035], ¶¶53. For Ofek, a POSA would understand that the high-pressure impulses (e.g., 400 psi) would incur distal end pressure impulses that could cause some amount of distal flow out. Ex[1007], 2:56-3:2, 3:43-44; Ex[1035], ¶¶54.

Paper No. 24 (Reply) at 12

Petitioner Fails To Meet Obviousness Standard

> The mere fact that these possible arrangements existed in the prior art does not provide a reason that a skilled artisan would have substituted the one-camera angular direction system in Keitler and Bridges with the two-camera 3D coordinate system disclosed in Briggs. There was no argument in the petition regarding why a skilled artisan would make this substitution—other than that the two different coordinate systems were "known to be used." J.A. 194—96, 214—16.
>
> *Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 886-88 (Fed. Cir. 2024)

Petitioner's Incorrect Theories Contradict Intrinsic Record

Brown Reply Declaration

reasons. First, a POSA would understand that the "fluid column" within the catheter lumen includes both blood and thrombus because both are drawn into the distal end of the catheter by the vacuum source that is fluidically coupled to the catheter. Second, the out flow of the "fluid column" from the catheter lumen contains both the blood and thrombus that were drawn into the catheter. Third, a POSA would understand that thrombus is formed of blood at different stages of coagulation, therefore the flow of thrombus includes the flow of blood.

Ex. 1035 (Brown Reply Decl.) ¶ 60

BUT

10. The system of claim **1** wherein the controller is configured to cyclically open and close the vacuum valve and the vent valve 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.

Ex. 1001 ('402 Patent), Claim 10

distally to the shift distance **70**. This imparts a controlled reversal of flow to the fluid column within the vacuum channel **3** that slightly translates the thrombus to a prescribed shift distance **70** distally relative to the distal opening of the vacuum channel **3**. During a third and final phase,

Ex. 1001 ('402 Patent) at 26:19-23

eter's tip. For the thrombus to accelerate, both it and the fluid column within the catheter system must attain a velocity.

Ex. 1001 ('402 Patent) at 27:3-4

Petitioner's Hindsight-Driven "Routine Optimization" Argument Fails

Petitioner's Reply

V. The Exit Flow Values Are Obvious By Routine Optimization

The claimed exit flow values are also obvious. Ex[1035], ¶¶61-66. Parameters like the claimed exit flow values are result-effective variables that are obvious results of routine optimization. *See Pfizer v. Sanofi Pasteur*, 94 F.4th 1341, 1348 (Fed. Cir. 2024) (routine optimization of result-effective variables is "normally obvious"); *see also In re Applied Materials, Inc.*, 692 F.3d 1289, 1297 (Fed. Cir. 2012) (finding optimization of range of parameters obvious). The '402 exit flow values are merely intended results of adjusting valve timing and pressure limits to break clot while minimizing problematic distal migration—a basic engineering optimization. Ex[1035], ¶¶61-66.

Paper No. 24 (Reply) at 13

Instead, the only way to arrive at the hypothetical ring is by using the '581 patent as a roadmap to piece together various elements of PCT '015. That represents an improper reliance on hindsight.

Merck Sharp & Dohme B.V. v. Warner Chilcott Co., LLC, 711 F. App'x 633, 637 (Fed. Cir. 2017)

Petitioner's Expert's Inaccurate Calculations Cannot Sustain Obviousness

Mr. Brown Does Not Account For Critical Aspects Of Aspiration Thrombectomy Systems

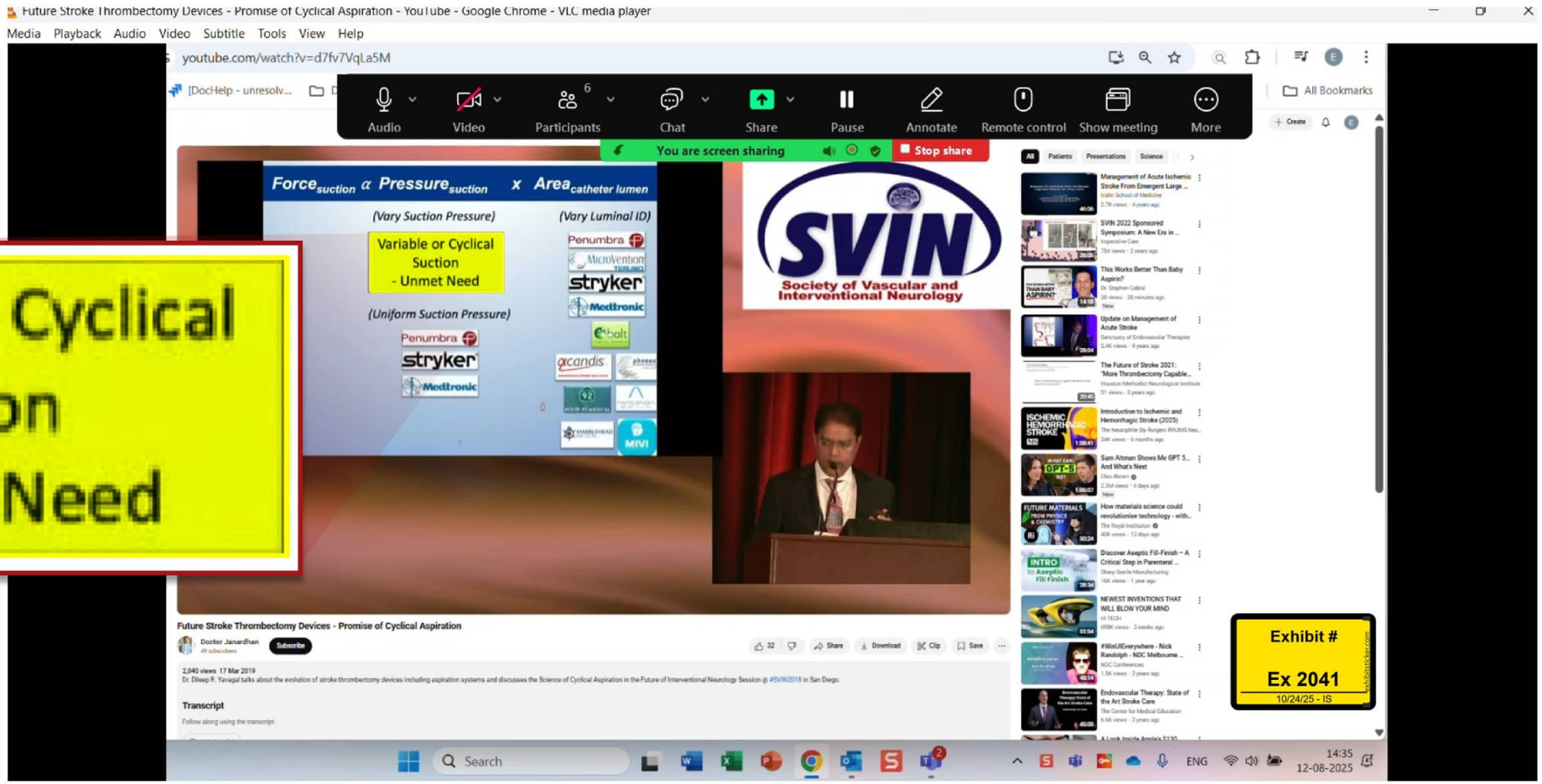
1	Not always free flow of blood through the catheter	IGNORED
2	Pressure level in infusion and aspiration are different	IGNORED
3	No instantaneous reversal of flow	IGNORED
4	Potential energy from compliant catheter	IGNORED
5	Water hammer effect	IGNORED

Objective Indicia

Petitioner's Evidence Shows Long-Felt Unmet Need

Mar. 2019 Society of Vascular Interventional Neurology Conference Presentation

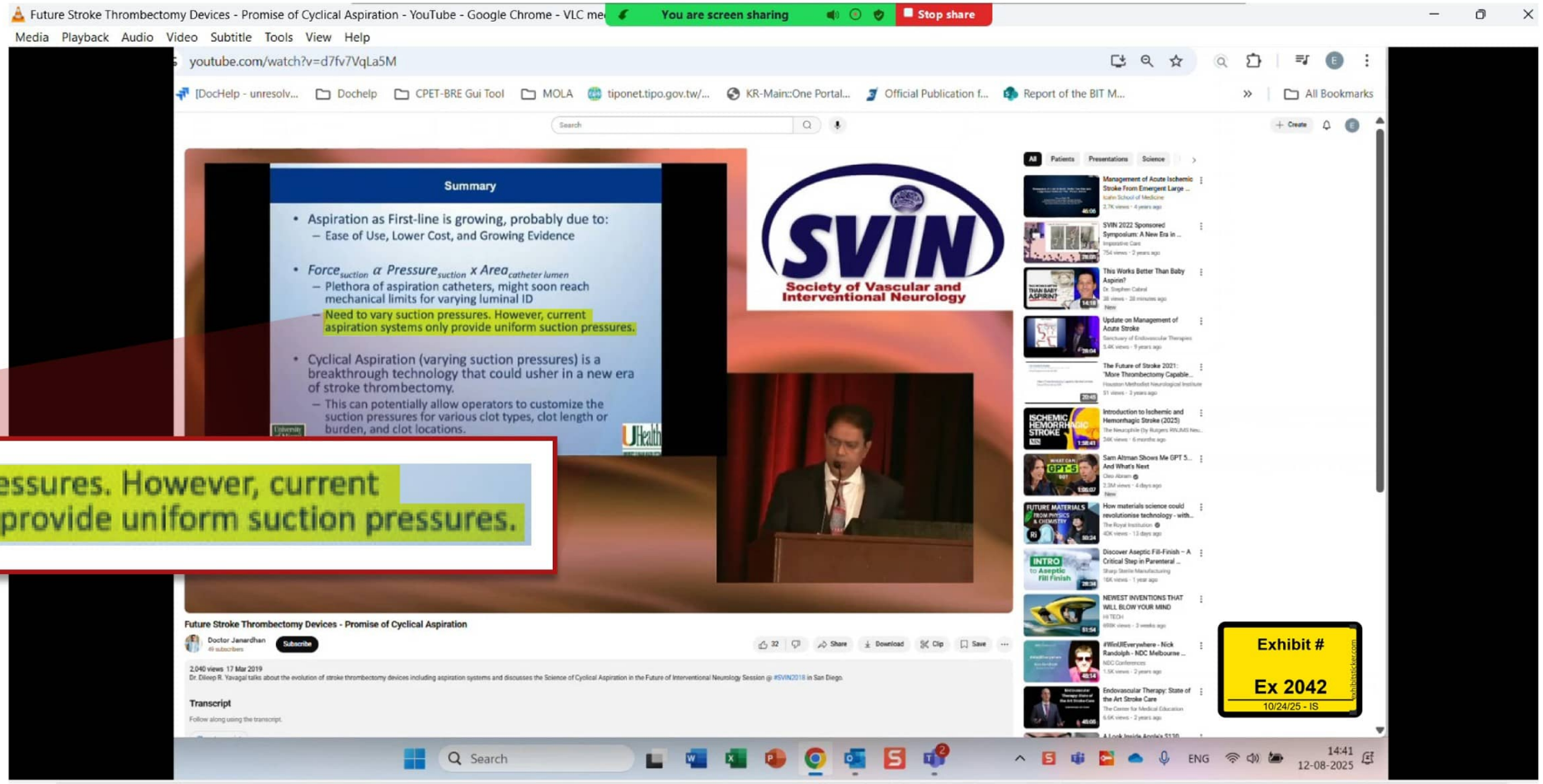
Variable or Cyclical Suction
- Unmet Need



Ex. 2041 (Screenshot of Petitioner's Video)

Petitioner's Evidence Shows Long-Felt Unmet Need

Mar. 2019 Society of Vascular Interventional Neurology Conference Presentation



Need to vary suction pressures. However, current aspiration systems only provide uniform suction pressures.

Ex. 2042 (Screenshot of Petitioner's Video)

Peer Reviewed Literature Confirms That The Claimed Invention Satisfied The Long-Felt Unmet Need

Gal Article

Results A total of 29 patients were included (table 1). The rate of FPE (mTICI ≥2c after one-pass) was significantly higher in the RapidPulse-cohort than in the historical cohort (69% [20/29] vs. 28%; p<0.0001). Minor transient vasospasm

Ex. 2026 (Gal Article) at 2

Peer Reviewed Literature Confirms That The Claimed Invention Satisfied The Long-Felt Unmet Need

Bajrami Article

ASPECTS score was 9 (IQR: 8–10). The rate of mTICI ≥ 2c after first pass was 53.9% in ITT population (60.0% in per-protocol population) versus 38.5% in the corresponding control population. Functional independence (mRS 0-2) at 90 days was achieved in 61.1% (22/36) in the RapidPulse™ arm and 52.8% (19/36) in the control arm. In the RapidPulse™ arm, no sICH within 24 h and no device-related morbidity or mortality occurred.

Ex. 2027 (Bajrami Article) at 2

Peer Reviewed Literature Confirms That The Claimed Invention Satisfied The Long-Felt Unmet Need

Nogueira Article

Effect (FPE), defined as mTICI ≥2c after one reperfusion attempt. Following the final device pass, all 19 subjects (100%) achieved mTICI 2b or greater therapy and 89.5% (17/19) achieved mTICI ≥ 2c without rescue treatment.

Ex. 2028 (Nogueira Article) at 1

Strong Nexus To Claimed Invention

Bajrami Article

Study device

The RapidPulse™ Aspiration System is a novel thrombectomy system that is designed to remove thrombus from the neurovasculature by precisely pulsing aspiration. The feasibility version of the System consists of a Valve Box, which is a controllable valve system that intermittently cycles the vacuum pressure provided from a commercially available thrombectomy pump between fully off and fully on multiple times per second (Figure 1). The Valve Box is powered electrically (standard 120–220 V; AC power is transformed to 12 V DC) to alternately open and close the vacuum line and a saline-filled vent line. For this study, the system was used in conjunction with the commercially available Medtronic React 71 thrombectomy catheter and thrombectomy pump. The system is setup and operated by trained hospital staff; operation requires one operator within the sterile field to perform the thrombectomy while setup and operation of the non-sterile components are completed by an operator outside the sterile field. The diagram in Figure 2 depicts the configuration of the device and its integration into the angiosuite.

Ex. 2027 (Bajrami Article) at 3

Strong Nexus To Claimed Invention

Bajrami Article

Study device

The RapidPulse™ Aspiration System is a novel thrombectomy system that is designed to remove thrombus from the neurovasculature by precisely pulsing aspiration. The feasibility version of the System consists of a Valve Box, which is a controllable valve system that intermittently cycles the vacuum pressure provided from a commercially available thrombectomy pump between fully off and fully on multiple times per second (Figure 1). The Valve Box is powered electrically (standard 120–220 V; AC power is transformed to 12 V DC) to alternately open and close the vacuum line and a saline-filled vent line. For this study, the system was used in conjunction with the commercially available Medtronic React 71 thrombectomy catheter and thrombectomy pump. The system is setup and operated by trained hospital staff; operation requires one operator within the sterile field to perform the thrombectomy while setup and operation of the non-sterile components are completed by an operator outside the sterile field. The diagram in Figure 2 depicts the configuration of the device and its integration into the angiosuite.

Ex. 2027 (Bajrami Article) at 3

11. A method for removing thromboembolic material, comprising:

aspirating thromboembolic material from a person using the system of claim **1** by—

(a) positioning the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person;

(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

(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 such that a level of vacuum at the distal end of the catheter changes and thereby controls flow in and out from the distal end of the catheter.

Ex. 1001 ('402 Patent), Claim 11

Appendix

Off-Off State Claims: Claims 5-7 And 18-20

Claims 5-7

5. 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 comprising an off-off state in which the vacuum valve is closed while the vent valve is closed.

6. 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 (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.

7. The system of claim **6** wherein the cycle is repeated at a frequency of 2 Hz to 12 Hz.

Ex. 1001 ('402 Patent), Claims 5-7

Claims 18-20

18. The method of claim **11**, further comprising cyclically opening and closing the vacuum valve and the vent valve in a repeated cycle including an off-off state in which the vacuum valve is closed while the vent valve is closed.

19. The method of claim **11**, further comprising:

cyclically opening and closing the vacuum valve and the vent valve in a cycle including (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.

20. The method of claim **19** wherein the cycle is repeated at a frequency of 2 Hz to 12 Hz.

Ex. 1001 ('402 Patent), Claims 18-20

Timing Of Off-Off State Is Tuned For Practical Considerations

The goal of the tuning process is at least two-fold: prevent the pressure waves generated during ROAR operation from causing forward flow and optimize the ROAR effect. The length of the fluid column is critical to the tuning of the system. The pressure wave moves rapidly within the fluid column. The time for the wave to reach the distal tip of the catheter is a function of this speed and the length of the fluid column. The speed is a function of the density of the fluid in the column and the bulk modulus of the catheter and extension. The bulk modulus refers to the compliance of the system: both the radial and the longitudinal flexibility of the catheter and the extension tube. The density of the fluid column is not as significant a variable as the bulk modulus unless it changes greatly, such as is the case if the fluid column has gaseous (air) bubbles in it. It is thus, important,

Ex. 1001 ('402 Patent) at 48:37-51

shorter. Each of these values are optimized by the dynamics/resonance/compliance/length of the particular catheter **660** and extension set.

Ex. 1001 ('402 Patent) at 50:49-51

greater flow burping. During ROAR operation, the first double-off time is about 10 ms; therefore, this is significantly less than the flow burping threshold, which means that substantially all forward flow is quelled. The Vnton duration **654** is determined by a maximum time that occurs before a corked clot **4** is dropped from forward flow. A ratio between the Vnton duration **654** and the second double-off time is a compromise for the longest Vnton time **654** and a minimum of the first double-off time. In this embodiment, opening only the vent valve is referred to as the "vent-only" state. Finally, with respect to the second double-off time, the vent valve **650** is off (fully closed) before the vacuum valve **620** is opened and vacuum recommences.

Ex. 1001 ('402 Patent) at 50:11-23

Culbert POR Declaration

130. A POSA would understand that the off-off state claimed in the '402 patent is a deliberate and purposeful state to make use of pressure waves within the catheter such as the wave created by the water hammer effect, not an incidental state occurring from momentary overlap of valve operation. The '402 patent teaches the off-off state to be deliberately set for practical considerations. For

Ex. 2014 (Culbert POR Decl.) ¶ 130

Off-Off State

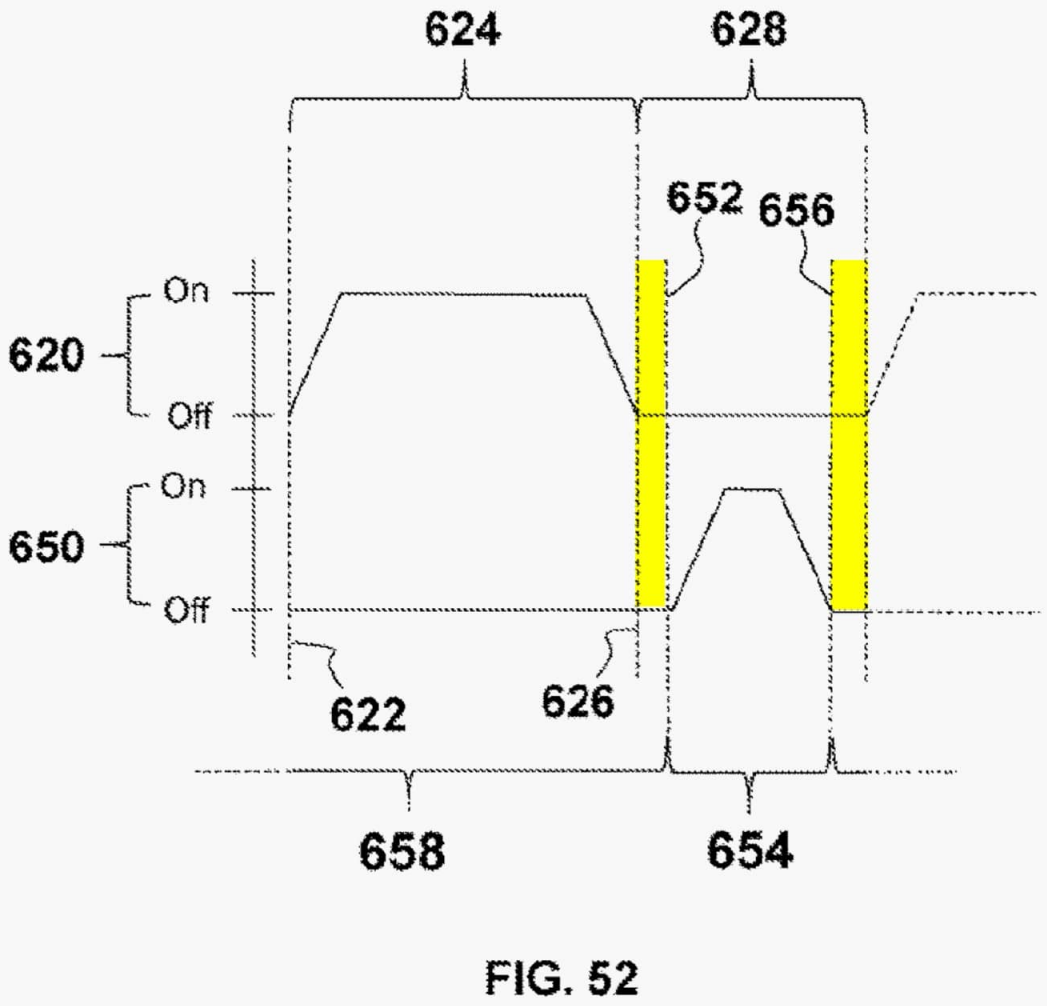


FIG. 52

Ex. 1001 ('402 Patent), Fig. 52

Tuning is accomplished by selecting appropriate times for the vacuum cycle and the vent cycle. In this regard, the vacuum cycle includes Vacon time **622**, Vacon duration **624**, Vacoff time **626**, and Vacoff duration **628** and the vent cycle includes Vnton time **652**, Vnton duration **654**, Vntoff time **656**, and Vntoff duration **658**. Accordingly, tuning is explained with reference to FIG. **52**. A cycle time is the

Ex. 1001 ('402 Patent) at 49:49-55

Yang/Mullins Does Not Disclose Off-Off State

Petition

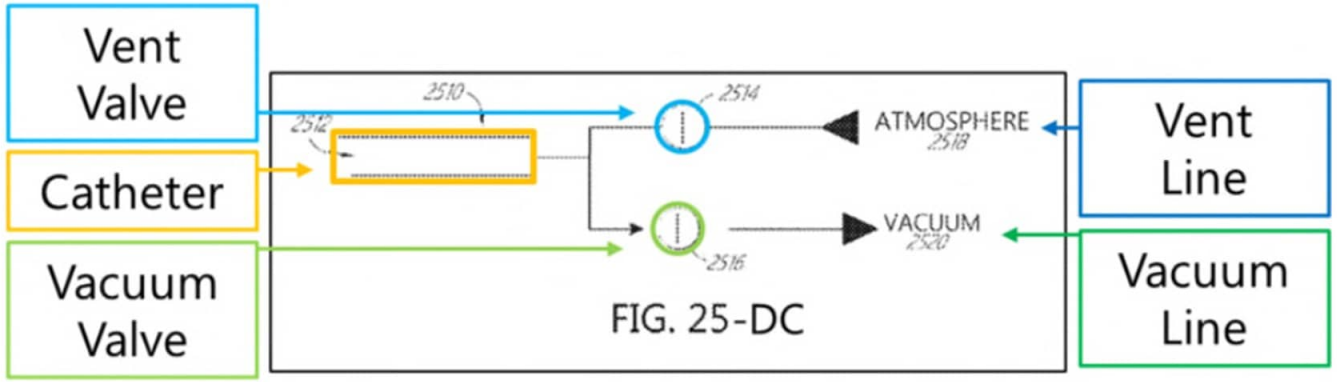


FIG. 25-DC

Paper No. 1 (Petition) at 45

BUT

Yang

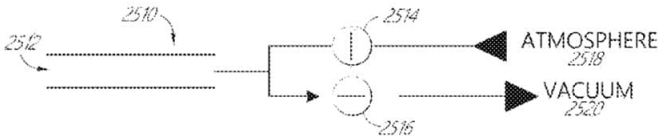


FIG. 25A

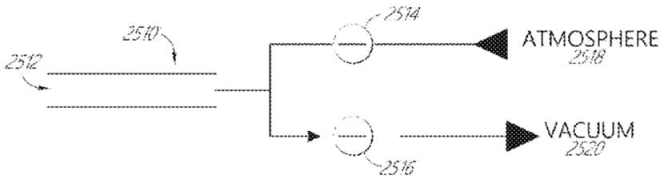


FIG. 25B

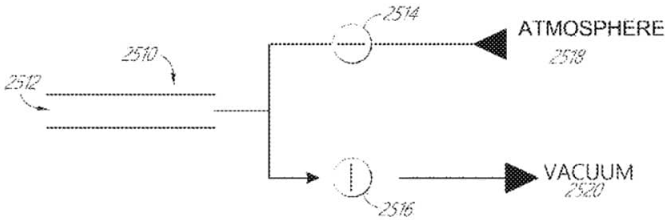


FIG. 25C

Ex. 1012 (Yang), Fig. 25

Yang/Mullins Does Not Disclose Off-Off State

Petitioner's Reply

B. Yang/Mullins Discloses the "Off-Off State"

The Petition shows that Yang discloses and renders obvious a double-closed state for multiple reasons. Pet., 44-46; Ex[1012], ¶¶[0040], [0102], [0168], [0169]. Yang discloses ***serial*** operation of vacuum and vent valves and repeated valve cycles. Pet., 44; Ex[1012], ¶[0170], FIGs. 25A-25C; Ex[1035], ¶104; Ex[1005], ¶¶226-236, 228-229. Thus, PO's argument that Yang does not disclose serial operation is simply false. *See* POR, 59-60 ("instead of operating the valves in serial as Petitioner suggests, a POSA would only find it obvious to operate both valves simultaneously"); Ex[2014], ¶¶135-39. As such, a POSA would understand that there is an additional valve state depicting the transition from Figure 25C to 25A where the vent valve is closed before the vacuum valve is opened. Pet., 44-46; Ex[1012], Figs. 2A-25C; Ex[1035], ¶105.

Moreover, a POSA would consider it obvious to implement the transition with a state where the vent valve is closed before opening the vacuum valve for the reasons mentioned above. Ex[1035], ¶105. Thus, Yang discloses or at least renders obvious the off-off state. Pet., 44-46; Ex[1035], ¶¶103-105.

Paper No. 24 (Reply) at 21-22

Petitioner abandoned argument for a second off-off state

Ofek/Mullins Does Not Disclose Off-Off State

Ofek

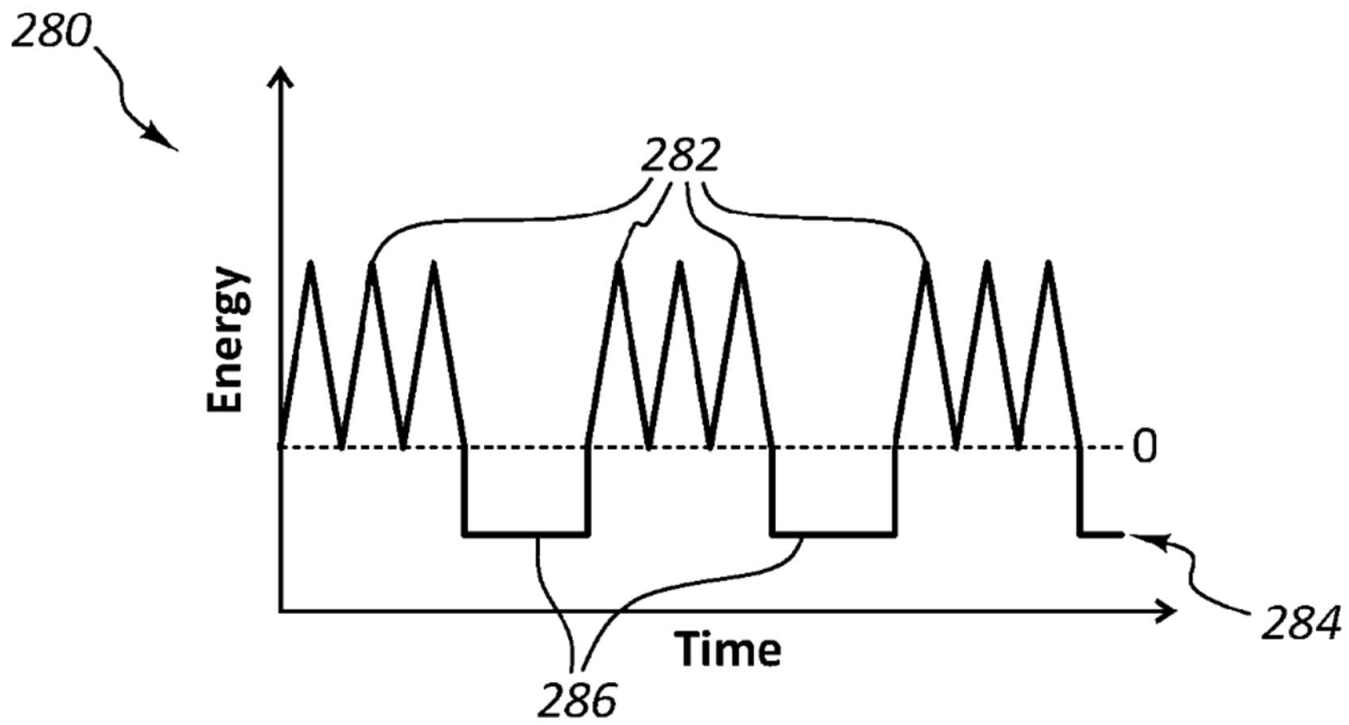


Fig. 10

Ex. 1007 (Ofek), Fig. 10

Rubenstein Does Not Disclose Off-Off State

Rubenstein

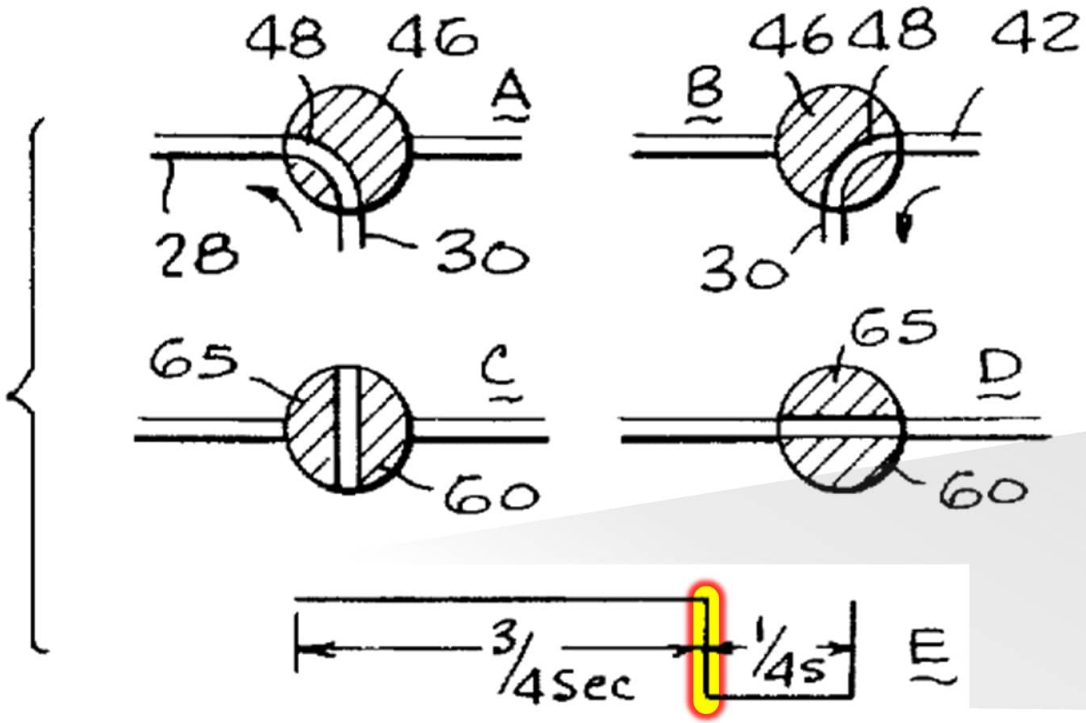
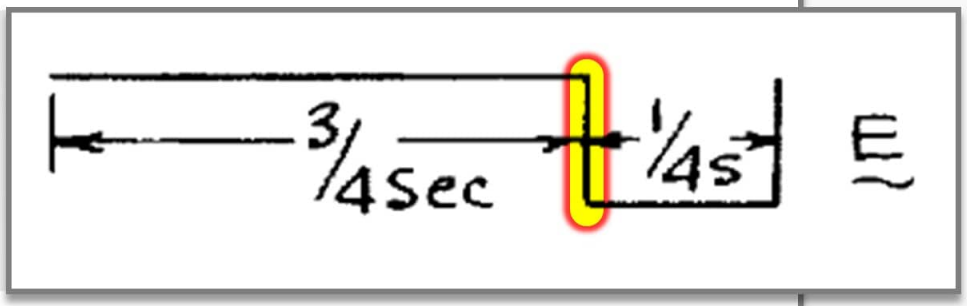


Fig. 2



Ex. 1011 (Rubenstein), Fig. 2

Rubenstein Does Not Disclose Off-Off State

’253 Patent Institution Decision

4. Analysis

On the current record, we agree with Patent Owner that Rubenstein does not appear to disclose a double-closed state.[15] We credit the testimony

Ex. 2023 (’253 Patent Institution Decision) at 45

Rubenstein Does Not Disclose Off-Off State

Memorandum

This Memorandum applies when patent claims being challenged before the Board in an America Invents Act (AIA) trial proceeding, or substantially similar patent claims, have already been adjudicated, post-issuance, before the Office, in district court, or at the U.S. International Trade Commission (ITC). In such instances, if the Board reaches an initial or final decision on a finding of fact or conclusion of law that is different than the prior finding or conclusion of the Office, district court, or the ITC, the Board shall explain in the institution or final written decision why a different outcome is warranted. A more detailed explanation is required from the Board

Memorandum, PTAB Consideration of Prior Findings of Fact and Conclusions of Law (USPTO Sept. 16, 2025)

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 5th day of December 2025, a true and correct copy of the foregoing **Patent Owner's Demonstratives** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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