# Petitioner Penumbra, Inc.'s Oral Argument for PTAB Hearing

***Penumbra, Inc. v. RapidPulse, Inc., Case IPR2024-01261***

**December 10, 2025**

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DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

BAKER BOTTS

# INTRODUCTION

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# Introduction: Patent at Issue – ‘402 Patent

## U.S. Patent No. 11,406,402 [Ex. 1001]

(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)

(56) **References Cited**

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3,955,574 A 5/1976 Rubinstein
4,164,223 A 8/1979 Munib
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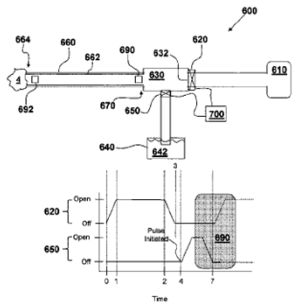
IPR2021-01466, Petition for Inter Partes Review of U.S. Pat. No. 10,531,883, Aug. 30, 2021, 87 pages.
(Continued)

*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**




Ex. [1001] (‘402 Patent) (Cover)

## Example claim - 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) at Claim 1

# ‘402 Patent - Overview

The ‘402 Patent describes “an aspiration thrombectomy system and methods for thrombus removal with aspiration catheter.”

Ex. [1001] (‘402 Patent) at 1:37-39

The “clot removal system” includes “a catheter,” “a controllable vacuum valve,” “a vacuum source,” “a controllable vent valve,” “a vent fluid source,” “a manifold connected to the catheter, to the vacuum valve, and to the vent valve,” and “a controller connected to the vacuum valve and the vent valve.”

Ex. [1001] (‘402 Patent) at 5:23-37

The controller is “configured to cyclically open and close the vacuum valve and the vent valve to change a level of vacuum at the distal end and prevent forward flow.”

Ex. [1001] (‘402 Patent) at 5:43-46

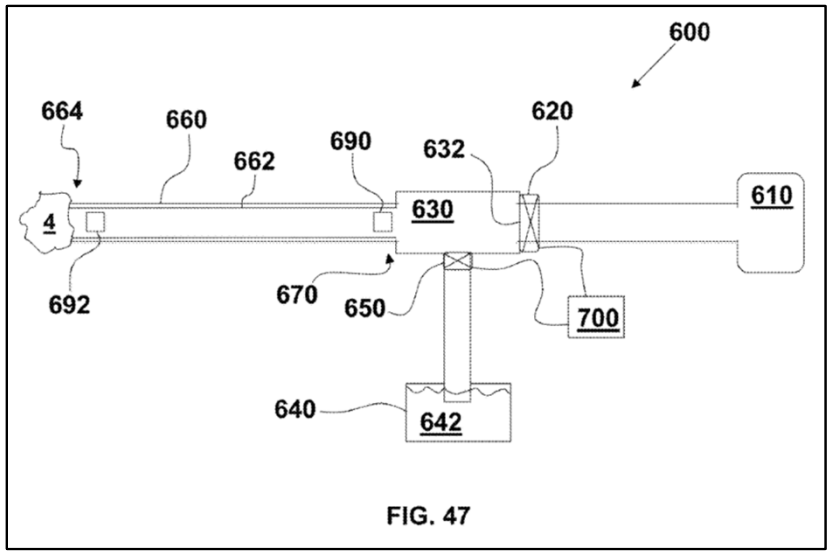



FIG. 47

Ex. [1001] (‘402 Patent) at Fig. 47

# Petitioner's Instituted Grounds

| Grounds | Claims | Statue | Prior art |
|---|---|---|---|
| 1 | Claims 1-8 and 10-20 | § 103(a) | *Yang* and *Mullins* |
| 2 | Claims 5, 6, 18, and 19 | § 103(a) | *Yang, Mullins*, and *Rubenstein* |
| 3 | Claim 9 | § 103(a) | *Yang, Mullins*, and *Matteo* |
| 4 | Claims 1-8 and 10-20 | § 103(a) | *Ofek* and *Mullins* |
| 5 | Claims 5, 6, 18, and 19 | § 103(a) | *Ofek, Mullins*, and *Rubenstein* |
| 6 | Claim 9 | § 103(a) | *Ofek, Mullins*, and *Matteo* |

# Introduction: Overview of Asserted References

## Yang (U.S. Patent Pub. No. 2017/0238953) [Ex. 1012]

"The catheter 10 generally comprises an elongate tubular body 16 extending between a proximal end 12 and a distal functional end 14."

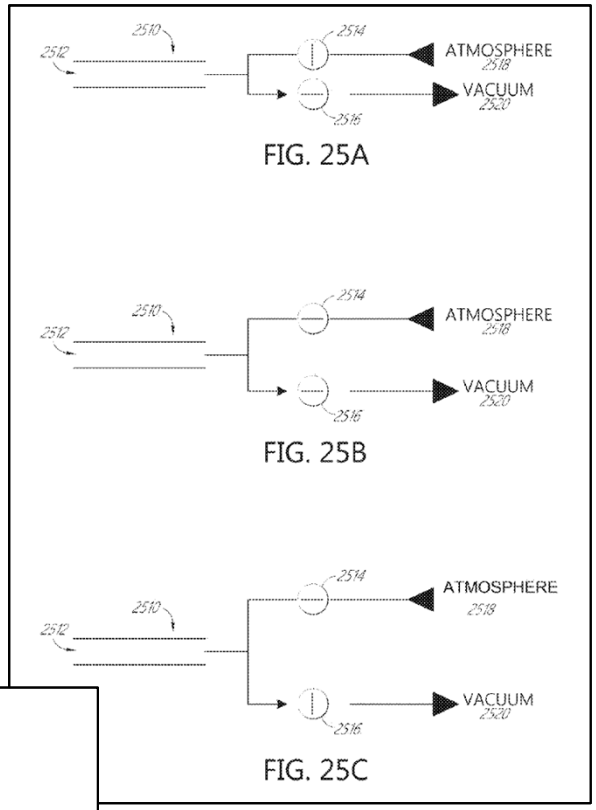
Ex. [1012] (Yang) at [0065]

"catheters of the present invention can be readily modified to incorporate additional structures."

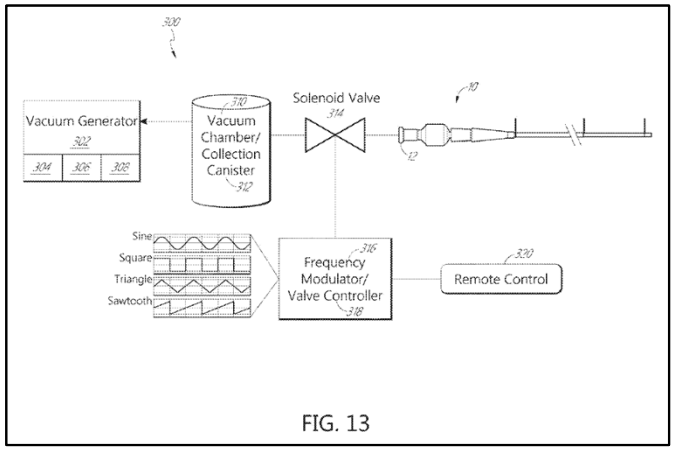
Ex. [1012] (Yang) at [0063]

"an [] aspiration system configured to apply pulsatile negative pressure through the aspiration catheter."

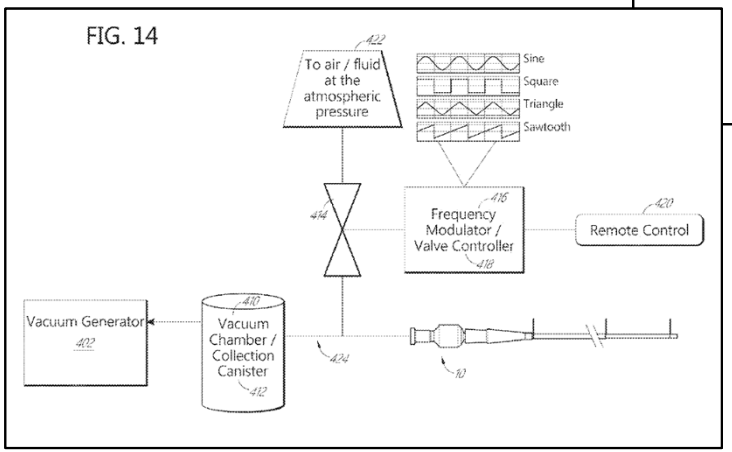
Ex. [1012] (Yang) at [0029]




Ex. [1012] (Yang) at Fig. 25




Ex. [1012] (Yang) at Fig. 13




Ex. [1012] (Yang) at Fig. 14

Paper 1 (Pet.) at 12, 16-37
Ex. [1005] (Brown Decl.) at ¶¶ 84-86, 96-158
Ex. [1012] (Yang)

# Introduction: Overview of Asserted References

## Ofek (U.S. Patent No. 10,322,230) [Ex. 1007]

"The patency device establishes and 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…. A negative pressure can then be provided to the lumen to aspirate the occlusion."

Ex. [1007] (Ofek) at Abstract

"the high-pressure fluid impulses impinge on an occlusion (such as a clot or fibrin sheath) or other obstruction that has formed in the lumen 14, typically at or proximate the distal end 12B of the catheter tube 12."

Ex. [1007] (Ofek) at 4:21-44

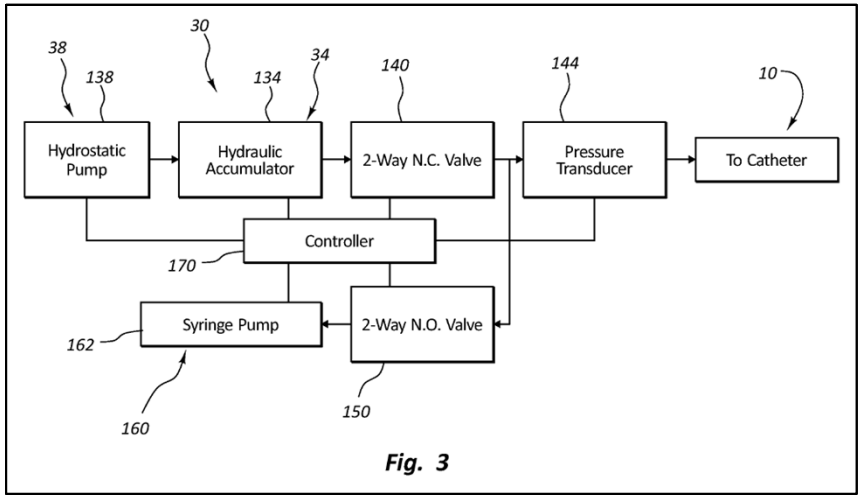


Fig. 3

Ex. [1007] (Ofek) at Fig. 3

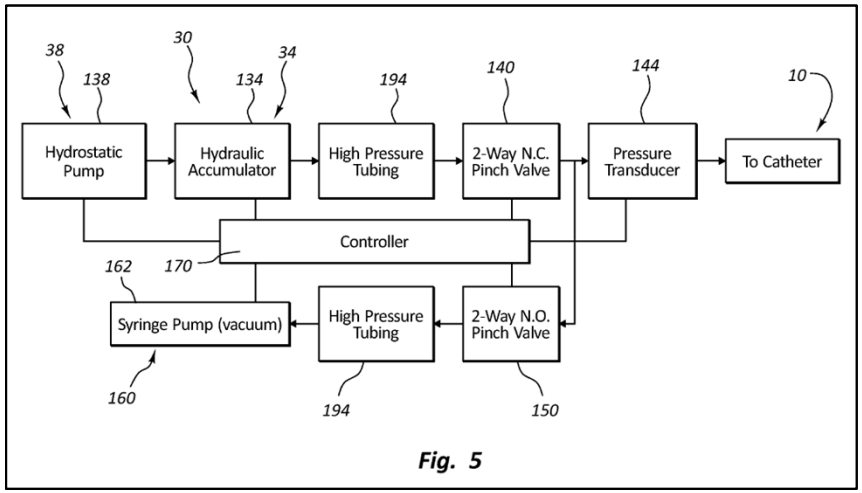


Fig. 5

Ex. [1007] (Ofek) at Fig. 5

Paper 1 (Pet.) at 12-13

Ex. [1005] (Brown Decl.) at ¶¶ 87-89, 355-409

Ex. [1007] (Ofek)

# Introduction: Overview of Asserted References

## Mullins (U.S. Patent No. 11,197,977) [Ex. 1008]

"an aspiration system comprising a catheter…, a pump linked with the catheter proximal portion, and a controller arranged to vary aspiration pressure during aspiration of a clot."

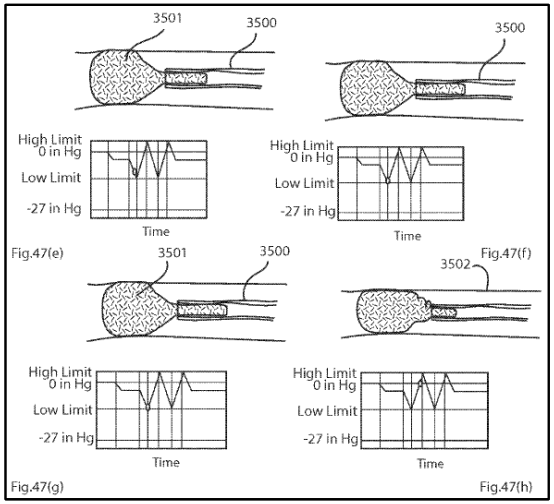
Ex. [1008] (Mullins) at 3:29-32

"The controller may have defined upper and lower limits of pressure or displacement to decide whether to apply a vacuum or pressurize, and/or it may cause the catheter to cyclically ingest and if required expel, at least some of a clot."

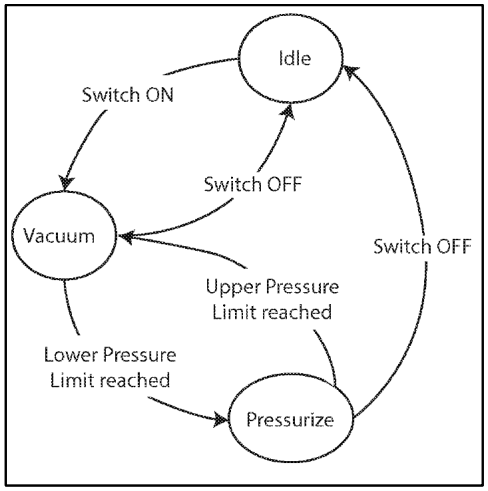
Ex. [1008] (Mullins) at 3:60-63

"As the catheter is pressurized (vacuum is reversed), the load which was applied to ingest the clot will be reduced, thereby unloading the clot, and even allowing some or all of the clot to be pushed distally towards the catheter tip FIG. 47(h). During this loading/unloading the clot is being macerated and accordingly becomes more 'free' within the catheter."

Ex. [1008] (Mullins) at 27:21-26




Ex. [1008] (Mullins) at Fig. 47




Ex. [1008] (Mullins) at Fig. 49

Paper 1 (Pet.) at 13-14

Ex. [1005] (Brown Decl.) at ¶¶ 90-91, 96-103, 125-221

Ex. [1008] (Mullins)

# Introduction: Overview of Asserted References

## Rubenstein (U.S. Patent No. 3,955,574 ) [Ex. 1011]

"An improved pumping system" "used with catheters for drawing fluids and other viscous materials from a body, such as may be required during certain medical procedures."

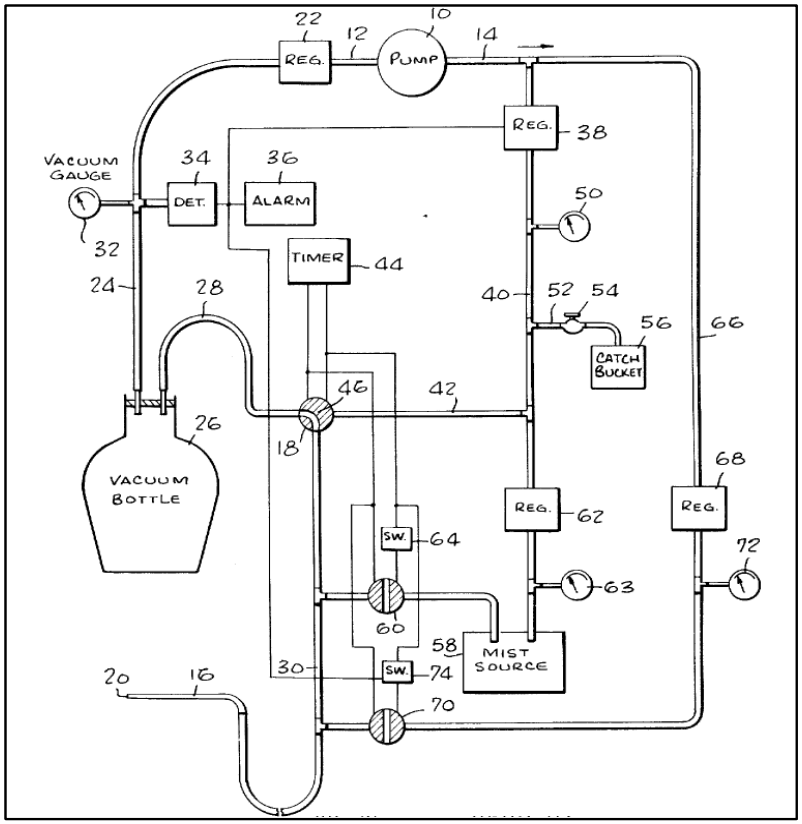
Ex. [1011] (Rubenstein) at Abstract, 1:7-10

"specifically, the present invention concerns a pumping system wherein cyclical reversals of pumping pressure are applied to the catheter connected thereto to have negative and positive pressure cyclically alternated."

Ex. [1011] (Rubenstein) at 1:10-14

"the subject pumping system includes 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."

Ex. [1011] (Rubenstein) at 2:1-5




Ex. [1011] (Rubenstein) at Fig. 1

Paper 1 (Pet.) at 14, 53-64

Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339

Ex. [1011] (Rubenstein)

# Introduction: Overview of Asserted References

## Matteo (U.S. Patent Pub. No. 2012/0138833) [Ex. 1013]

"Disclosed are microvalves and micropumps for use with a microfluidic system."

Ex. [1013] (Matteo) at Abstract, [0008]

"Cam-driven pinch-style microvalves are useful for serving as on/off valve devices for a microfluidic system."

Ex. [1013] (Matteo) at [0010]

"a cam-driven actuator activates a microvalve by pressing on the elastomeric layer, deforming the elastomeric layer so that it meets a second layer at a location within the channel, thereby either partially or completely obstructing the flow of liquid through the channel at that location, i.e. 'pinching' the channel."

Ex. [1013] (Matteo) at Abstract

"when the microvalve 101 is in the open state," as shown in Fig. 6A, "fluid flows through the channel 401."

Ex. [1013] (Matteo) at [0047]

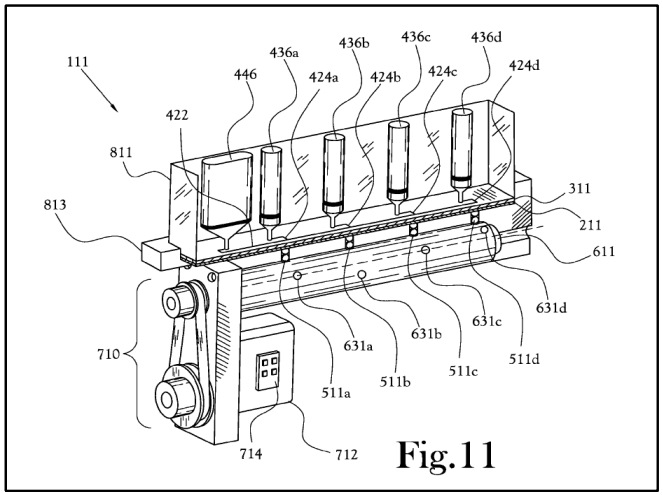
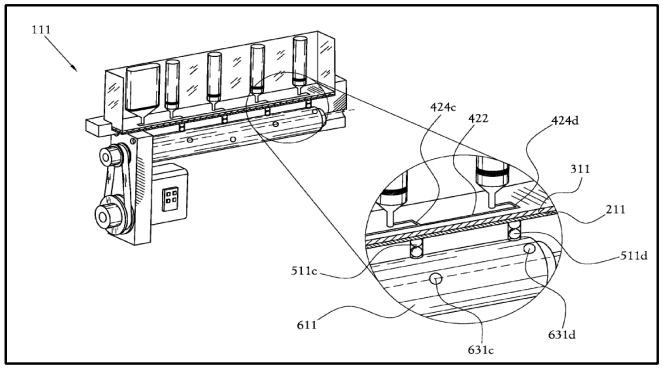


Fig. 11

Ex. [1013] (Matteo) at Fig. 11




Ex. [1013] (Matteo) at Fig. 12

Paper 1 (Pet.) at 14-15, 64-67

Ex. [1005] (Brown Decl.) at ¶¶ 94-95, 340-354

Ex. [1013] (Matteo)

# Contested Issues

| Contested Limitation / Issue | Claims (Dependencies excluded) |
|---|---|
| "control fluid flow in and out" | 1, 11 |
| "limited to a positive amount of exit flow" | 3, 4, 13-17 |
| Limit values for "positive amount of exit flow" | 3-4, 14, 16-17 |
| "predetermined cycle" | 1 |
| "positioning the distal end of the catheter" | 11 |
| "off-off state" | 5-7, 18-20 |
| Secondary considerations | N/A |

Paper 15 (PO Response)
Paper 24 (Pet. Reply)
Ex. [1001] ('402 Patent)
Ex. [1035] (Brown Supp. Decl.)

# Uncontested Claim Limitations

| Uncontested Limitation | Claims (Dependencies included) |
|---|---|
| aspiration thrombectomy system/method | 1-20 |
| aspiration catheter | 1-20 |
| vacuum source / vacuum valve | 1-20 |
| vent valve | 1-20 |
| controller | 1-20 |
| cyclically open/close the vacuum/vent valves | 1-20 |
| change level of vacuum at distal end | 1-20 |
| vent fluid greater than atmospheric pressure | 2-4, 12-17 |
| vacuum-only state; vent-only state | 6-7, 19 |
| cycle frequency | 7, 20 |
| pinch valves | 8-9 |
| momentum transfer / unstick material | 10 |

Paper 15 (PO Response)
Paper 24 (Pet. Reply)
Ex. [1001] ('402 Patent)
Ex. [1035] (Brown Supp. Decl.)

# GROUND 1 & 4

*YANG-MULLINS*
*OFEK-MULLINS*

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## CLAIM CONSTRUCTION

Claims 1, 11 – "Control"
Claims 3, 4, 13-17 – "Limiting"

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# Claim Construction – "Control"

| Claim Term | '402 Patent Claims |
|---|---|
| "control fluid flow in and out from the distal end" | Claims 1, 11 |

## '402 Patent, Claim 1

1. An aspiration thrombectomy system, comprising:

* * *

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.***

## '402 Patent, Claim 11

11. A method for removing thromboembolic material, comprising:
aspirating thromboembolic material from a person using the system of claim 1 by—

* * *

(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 Construction – "Limiting"

| Claim Term | '402 Patent Claims |
|---|---|
| "limited to a positive amount of exit flow" | Claims 3, 4, and 13-17 |

## '402 Patent, Claim 3

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.

## '402 Patent, Claim 13

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.

*Also applicable to Claims 4, 14-17*

Ex. [1001] ('402 Patent)

# Claim Construction – "Control"

| Claim Term | '402 Patent Claims |
|---|---|
| "control fluid flow in and out from the distal end" | Claims 1, 11 |

| Petitioner's Construction | Patent Owner's Construction |
|---|---|
| Ordinary and customary meaning<br><br>Contemporaneous POSA understanding of ordinary and customary meaning: "having an influence or effect that is intended and/or predictable"<br>Ex. [1010] (Grey) at 6:13-25 | "a controller configured… to ~~control~~ cause fluid flow in and out from the distal end of the catheter." |

**Key Issue:**

- Patent Owner ignores/rewrites the operative claim terms

Paper 15 (PO Response) at 23-24
Paper 24 (Pet. Reply) at 1-4
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 10-24

# Claim Construction – "Limiting"

| Claim Term | '402 Patent Claims |
|---|---|
| "limited to a positive amount of exit flow" | Claims 3, 4, and 13-17 |

| Petitioner's Construction | Patent Owner's Construction |
|---|---|
| the maximum permitted amount of positive exit flow in the distal direction, including no exit flow | "wherein… movement of the fluid column at the distal end of the catheter ~~is limited to~~ causes a positive amount of exit flow." |

**Key Issue:**

- Patent Owner ignores/rewrites the operative claim terms

Paper 1 (Petition) at 15-16
Paper 15 (PO Response) at 22-23
Paper 24 (Pet. Reply) at 1-2, 4-5
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 10-13, 25-30

# Claim Construction – "Control" & "Limiting"

**PO ignores the operative claim terms (verbs) and focuses only on the objects**

"Patent Owner and Mr. Culbert isolate 'flow out' or 'positive exit flow' as though the claims require that such flow must exist, while disregarding the fact that the claims actually recite an action regarding those objects — namely, 'controlling' or 'limiting.'"

Ex. [1035] (Brown Supp. Decl.) at ¶ 10

"By its plain language, 'a positive amount' is greater than zero—not 'no exit flow,' as Petitioner proposes. *Id.*; Ex.2020 (New Oxford American Dictionary) ('positive' means '(of a quantity) greater than zero.'); Culbert POR-Decl. ¶42. Petitioner provides no basis to depart from the plain meaning of the word 'positive.'"

Paper 15 (PO Response) at 22

"Petitioner has not proposed a construction of 'flow … out from the distal end,' and Patent Owner agrees that it needs no construction. By its plain language, 'flow… out from the distal end' is the opposite of 'flow in.'"

Paper 15 (PO Response) at 23

"By ignoring the operative verbs, Patent Owner converts the broad functional claim language chosen by the applicant into an exemplary outcome."

Ex. [1035] (Brown Supp. Decl.) at ¶ 13

Paper 15 (PO Response) at 22-23

Paper 24 (Pet. Reply) at 1-2

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 10-17, 25-30

# Claim Construction – "Control" & "Limiting"

**The claims require action taken by the controller which operates on flow, not that any particular flow must actually occur**

"Q. Would in your view a system that has zero exit flow meet the claim limitation positive amount of exit flow?

A. The claim term a positive amount of exit flow is not what's being claimed. What's being claimed is a limit – it's limited to a positive amount of exit flow."

Ex. [2018] (Brown Depo.) at 13:16-14:2

"Q. Do you agree that an aspiration thrombectomy system in order to satisfy Claim 1 needs to have a controller configured to open and close the valves such that it produces pressure that controls flow out of the distal end of the catheter?

A. It must have a controller that is opening and closing valves that change the level of vacuum in order to control flow in and out of the distal end of the catheter. So it's making decisions on whether it wants to have flow in or whether it wants to have flow out."

Ex. [2018] (Brown Depo.) at 17:1-14

Paper 24 (Pet. Reply) at 1-2
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 10-13
Ex. [2018] (Brown Depo.) at 8:12-17:14

# Claim Construction – "Control" & "Limiting"

## '402 specification confirms that exit flow is not required

"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] ('402 Patent) at 4:50-54

"In accordance with an exemplary embodiment, the controller is configured to modulate the vacuum valve and the vent valve in a cycle that, responsive to vacuum being applied to the catheter, the compliance of the catheter causes a reduction in volume such that, when the vacuum is closed and the vent is open, the compliance acts as a spring and the lumen ingests vent fluid in a distal direction and, before a momentum induced by the ingested fluid reaches the distal end of the catheter, the controller modulates the valves to reverse a direction and quell movement of the fluid of the fluid and prevent the fluid from exiting the distal end of the catheter.'"

Ex. [1001] ('402 Patent) at 8:53-64

Paper 24 (Pet. Reply) at 2-3
Ex. [1001] ('402 Patent) at 4:50-54
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 6-9

# Claim Construction – "Control" & "Limiting"

## '402 specification confirms that exit flow is not required

"In each case, no forward flow means that substantially no liquid exits the distal end 664 in the distal direction… The timing of these valves is significant so that the controller 700 can change a level of vacuum at the distal end 664 and prevent the distal portion of the liquid column in the lumen 662 from exiting the distal end 664—substantially no forward flow."

Ex. [1001] ('402 Patent) at 42:40-62

"Movement of the thrombus 4 in a distal direction before or after it has been captured and corked at the distal end 664 of the catheter 660 is to be avoided."

Ex. [1001] ('402 Patent) at 44:37-40

"Through experimentation, net flow of liquid at the distal end 664 remains positive in the proximal direction—in other words, while operating with the ROAR effect in the corked or un-corked state, liquid either moves through the distal end 664 towards the vacuum source (when un-corked) or does not flow at all (when corked). In both circumstances, substantially no liquid exits the distal tip 610."

Ex. [1001] ('402 Patent) at 44:62-45:2

Paper 24 (Pet. Reply) at 2-3
Ex. [1001] ('402 Patent) at 42:40-62, 44:37-45:2
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 6-9

# Claim Construction – "Control" & "Limiting"

## '402 specification confirms that exit flow is not required

"The '402 specification mentions 'exit flow' only once (*cf*. 'forward flow') and never suggests that exit flow greater than 0 is always required…. To the contrary, the specification explicitly discusses several examples that 'prevent the fluid from exiting the distal end' and where 'substantially no liquid exits the distal end.'"

Paper 24 (Pet. Reply) at 2-3

"In the context of the '402 Patent specification (including the excerpt above), the claim language, the intended purpose of the alleged invention, and the inherent and well-known risks of distal clot migration, a POSA would have understood that the patentee intended to characterize the 'limiting' of 'positive amount of exit flow' as the threshold value, or range of threshold values, for which the amount of exit flow could not be permitted to exceed. The '402 Patent specification clearly limits the exit flow 'when the controller is actuated, a positive amount of exit flow is created without possibility of overshooting' i.e., overshooting a limited volume and/or pressure."

Ex. [1035] (Brown Supp. Decl.) at ¶ 8

Paper 24 (Pet. Reply) at 2-3
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 6-9

# Claim Construction – "Control"

## The ordinary meaning of "control" is clear and would be obvious to a POSA

"a POSA would understand the ordinary and customary meaning of the operative term 'control' as requiring exactly what the word conveys, i.e., to have a desired effect on the object on which it operates. As such, a POSA would understand 'control' in the claim phrase as being satisfied by "controlling" any distal end flow out, including by preventing or permitting exit flow, and should not require that outflow actually occur.'"

Ex. [1035] (Brown Supp. Decl.) at ¶ 15

"Furthermore, terms such as 'control' and 'controlling' do not necessarily imply absolute control, but rather indicate having an influence or effect that is intended and/or predictable."

Ex. [1010] (Grey) at 6:13-14

"as a basic commonplace example, the presence of the word 'control' in a 'flood control' device does not indicate that a flood must occur. Thus, prevention of outflow is itself a form of control."

Ex. [1035] (Brown Supp. Decl.) at ¶ 16

Paper 24 (Pet. Reply) at 3-4
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 14-17
Ex. [1010] (Grey) at 6:13-25

# Claim Construction – "Limiting"

**Petitioner's proposed construction for "Limiting" clarifies that a POSA would understand it as meaning having or setting a "limit"**

"Petitioner's proposed construction resolves any ambiguity: "the maximum permitted amount of positive exit flow in the distal direction, including no exit flow." This construction is consistent with the claim language, the specification, and a POSA's understanding of 'limit' as a boundary or cap."

Ex. [1035] (Brown Supp. Decl.) at ¶ 26

"Given that the operative word in the claim phrase is "limiting," a basic example demonstrating the deficiency in Patent Owner's and Mr. Culbert's argument is the universally understood concept of "limiting" automotive speed, for example, within a city to approximately 30 mph to approximately 55 mph. In this example, for the same logical reasons as the claim language here, a speed of 0 mph up to the specified limited (maximum) speed would both be within the legal speed limit. The same principle applies to this claim term — an amount of exit flow of zero milliliters up to the specified limited (maximum) milliliters (e.g., 0.1 ml) would both be within the claimed exit flow limit."

Ex. [1035] (Brown Supp. Decl.) at ¶ 27

Paper 24 (Pet. Reply) at 4-5
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 26-27

# Claim Construction – "Limiting"

## '402 specification is consistent with zero exit flow satisfying "limiting"

"Further, a POSA would recognize that a catheter will have a range of zero exit flow when the catheter is corked, to a maximum value when there is free flow during the relevant valve operation cycle. This is further clear from the disclosure of the '402 Patent, which clearly states that when uncorked, the ROAR effect has substantially no exit flow (i.e., a very small amount), and when corked, the exit flow is zero.'"

Ex. [1035] (Brown Supp. Decl.) at ¶ 28

"The controller 700 is timed to control the vacuum and vent valves 620, 650 to create the ROAR effect even when the distal end 664 is open to vasculature and, therefore, any distally directed pressure pulse in the aspiration thrombectomy system 600 is quelled so that substantially no forward flow occurs… in other words, while operating with the ROAR effect in the corked or un-corked state, liquid either moves through the distal end 664 towards the vacuum source (when un-corked) or does not flow at all (when corked). In both circumstances, substantially no liquid exits the distal tip 610."

Ex. [1001] ('402 Patent) at 44:46-45:2

Paper 24 (Pet. Reply) at 4-5
Ex. [1001] ('402 Patent) at 44:46-45:2
Ex. [1035] (Brown Supp. Decl.) at ¶ 28

# Claim Construction – "Limiting"

**PO's expert's inability to opine on what satisfies "limiting" confirms the need for a clarifying and coherent construction**

"Mr. Culbert: (1) admitted to not knowing or having an opinion on what actual minimum value of distal flow would satisfy the claims, (2) asserted that some unknown rounding convention would be needed to evaluate exit flow amounts below the claimed values, and (3) could not articulate what "non-zero" numerically means, despite being the crux of PO's apparent construction."

Paper 24 (Pet. Reply) at 5

Q. "…so are you saying that there are values below 0.1 milliliters that would still satisfy Claim 4?"
A. "Without going back and reading everything, I have not given an opinion what approximately 0.1 milliliters is in this context of this patent."

*****

Q. "what is the smallest… amount of exit flow that would satisfy this claim, in your view?"
A. "Again, I haven't analyzed that."

*****

Q. "And, in your view, is there some positive amount that is so minuscule that it would effectively be zero exit flow?"
A. "I haven't given an opinion of that. I'm… the opinion I gave was that 'a positive' means not zero."

Ex. [1036] (Culbert Depo.) at 57:6-60:2

Paper 24 (Pet. Reply) at 5
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 14-16
Ex. [1036] (Culbert Depo.) at 57:6-60:2

# Claim Construction – "Control"

## Previous IPR is consistent with "control" including zero exit flow

"In IPR2022-00608 ("IPR#2"), Petitioner challenged US10,722,253 ("Deville'253"), which the Board found unpatentable…. Petitioner's grounds mapped the Teigen'673 claim language ("control flow in and out from the distal end") against the Deville'253 claim language ("substantially prevent forward flow of liquid at a distal end")."

Paper 24 (Pet. Reply) at 5-6

| Claim 1 Patent | "A controller configured to… |
|---|---|
| Ex. [1030] ('253 Patent) | …substantially prevent forward flow of liquid at a distal end" |
| Ex. [1037] (Teigen'683) | …control flow in and out from the distal end" |
| Ex. [1001] ('402 Patent) | …control fluid flow in and out from the distal end |

"Patent Owner therefore cannot credibly argue here that the same controller language in the '402 patent must now effectively be construed as requiring the exact opposite meaning, i.e., mandating that it now can ONLY be satisfied by actively causing distal end flow out. In my opinion, taking such diametrically opposed positions for the same exact claim language relevant to multiple proceedings challenging patents in the same patent family between the same parties is not a defensible position.'"

Ex. [1035] (Brown Supp. Decl.) at ¶ 22

Paper 24 (Pet. Reply) at 5-6
Ex. [1001] ('402 Patent) at Claim 1
Ex. [1030] ('253 Patent) at Claim 1
Ex. [1037] (Teigen'683) at Claim 1
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 18-24

# Claim Construction – "Control" & "Limiting"

## '402 family clarifies the meaning of the operative claim terms

| Distal flow: Operative claim term | Distal flow: Permitted? | Distal flow: Capped? | Distal flow: Required? | RapidPulse Patent Family – Distal Flow: Operative Claim Language |
|---|---|---|---|---|
| "Prevent…" | No | --- | --- | RP-1, Cl. 1 = "**prevent** forward flow" |
| | | | | RP-1, Cl. 18 = "**prevent** forward flow" |
| | | | | RP-2, Cl. 1 = "**substantially prevent** forward flow" |
| | | | | RP-2, Cl. 21 = "**substantially prevent** forward flow" |
| | | | | RP-EP1, Cl. 1 = "**prevent** forward flow" |
| | | | | RP-EP1, Cl. 12 = "**prevent** forward flow" |
| "Control…" | Yes | No | No | RP-6, Cl. 1 = "**control** fluid flow in and out from the distal end" |
| | | | | RP-6, Cl. 11 = "**controls** flow in and out from the distal end" |
| | | | | RP-11, Cl. 1 = "**control** fluid flow in and out from the distal end" |
| "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" |
| "Cause…" "Occur…" | Yes | Yes | Yes | RP-5, Cl. 1 = "**causing** a reverse flow… such that a positive amount of exit flow occurs at the distal end" |
| | | | | RP-9, Cl. 2 = "such that an exit flow **occurs** at the distal end" |
| | | | | RP-16, Cl. 1 = "**cause** an exit volume of fluid to flow out of the distal end" |

"Through the selection of different verbs, the drafter claimed separate states of distal flow, rather than treating each verb as an interchangeable synonym. When distal flow was to be permitted, PO chose the expansive 'control' term. When distal flow was required, PO chose narrower language ('cause,' 'occur,' etc.)."

Paper 24 (Pet. Reply) at 8

Paper 24 (Pet. Reply) at 7-8
Ex. [1038] ('402 Family Excerpts)
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 31-34

# Prior Art – Mullins – "Control" & "Limiting"

## Mullins – "control" and "limiting" expressly disclosed under a POSA's understanding or under PO's improper constructions

"The controller may have defined upper and lower limits of pressure or displacement to decide whether to apply a vacuum or pressurize, and/or it may cause the catheter to cyclically ingest and if required expel, at least some of a clot, whereby there is deformation of the clot to improve efficiency of aspiration and prevent clogging of the catheter."

Ex. [1008] (Mullins) at 3:46-65

"In one embodiment, shown schematically in the form of a state diagram in FIG. 46, the pump uses defined upper and lower limits to decide whether to apply a vacuum or pressurize. These limits enable the catheter to cyclically ingest and if required expel, at least some of the clot. This deformation of the clot improves the efficiency of the aspiration, and prevents clogging of the catheter."

Ex. [1008] (Mullins) at 26:43-49

"For this reason, the pump will reverse at some Low Limit of pressure, FIG. 47 (g)…. The direction of fluid displacement of the pump is now reversed. Upon reversal, the catheter will begin to pressurize, thereby increasing the pressure measured, FIG. 47 (g). As the catheter is pressurized (vacuum is reversed), the load which was applied to ingest the clot will be reduced, thereby unloading the clot, and even allowing some or all of the clot to be pushed distally towards the catheter tip FIG. 47(h). **During this loading/unloading the clot is being macerated and accordingly becomes more 'free' within the catheter**."

Ex. [1008] (Mullins) at 27:2-26

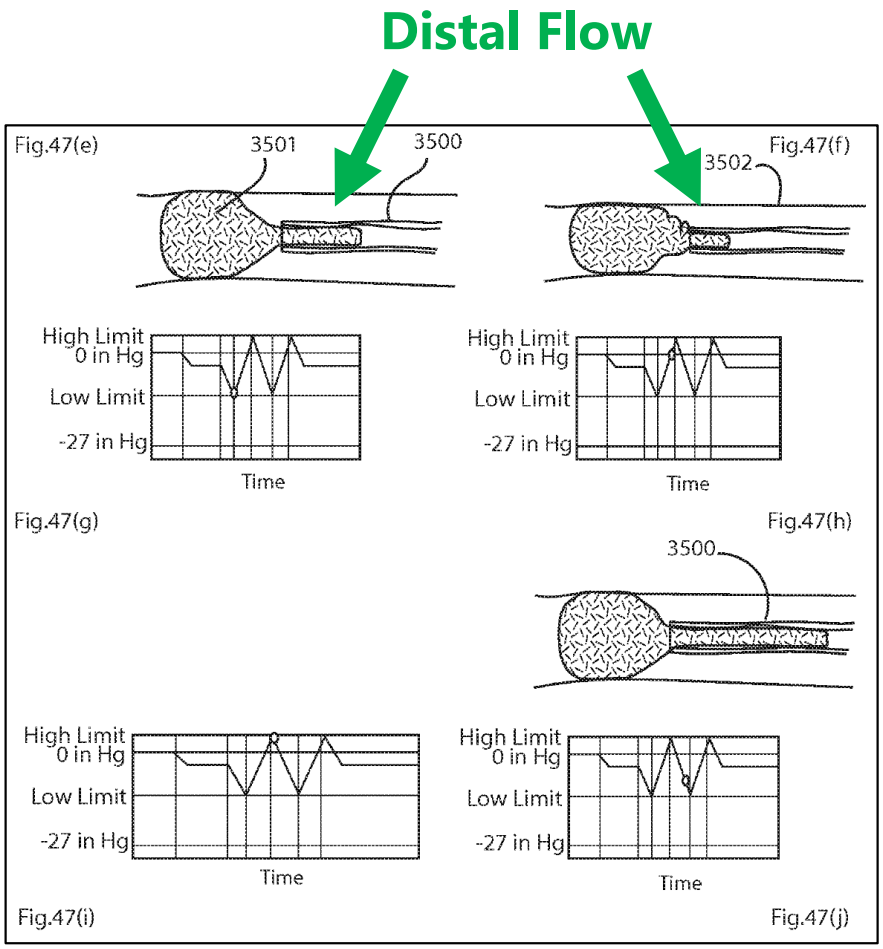
Paper 24 (Pet. Reply) at 10-13

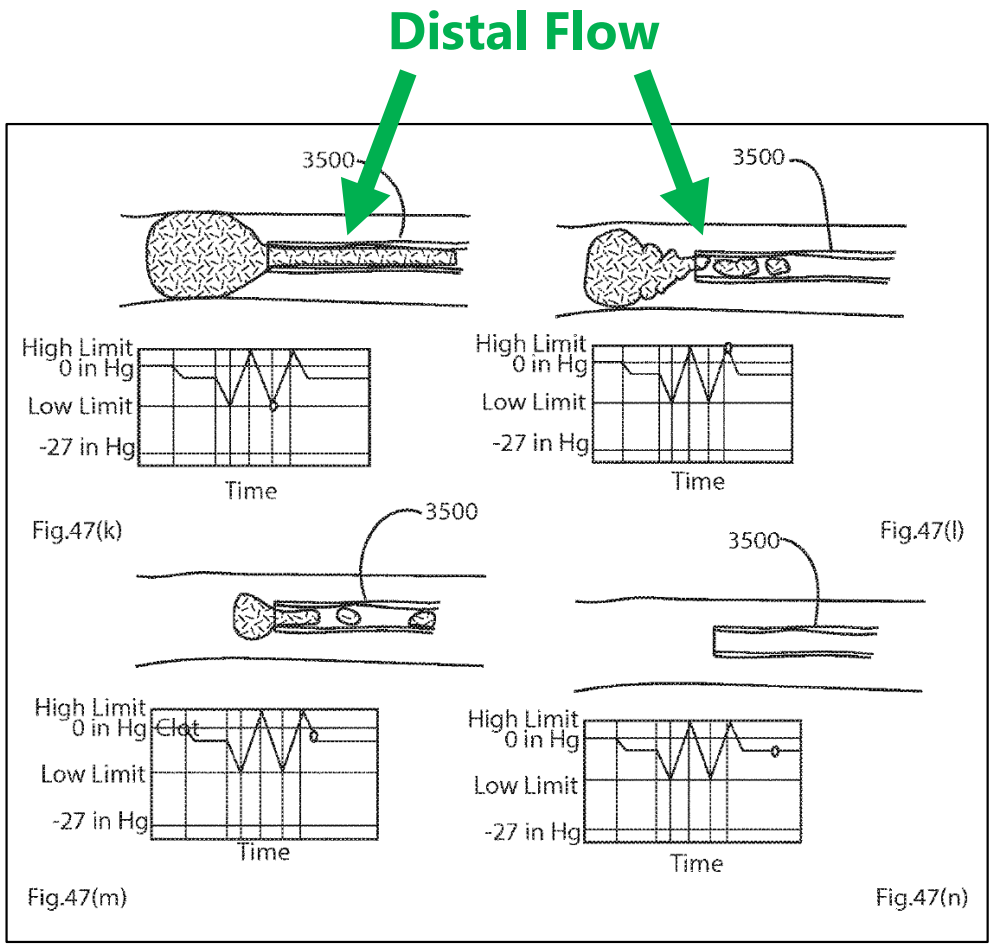
Ex. [1008] (Mullins)

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 47, 55-57

# Prior Art – Mullins – "Control" & "Limiting"

**Mullins – "control" and "limiting" expressly disclosed under a POSA's understanding or under PO's improper constructions**




Paper 24 (Pet. Reply) at 10-13
Ex. [1008] (Mullins) at FIG. 47
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 47, 55-57

# Prior Art – Mullins – "Control" & "Limiting"

## Mullins – "control" and "limiting" expressly disclosed under a POSA's understanding or under PO's improper constructions

"Mullins defines specific numerical limits for its infuse-to-aspirate cycles that a POSA would understand as being directly translatable to specific limits for the amount of positive exit flow."

Ex. [1035] (Brown Supp. Decl.) at ¶ 56

"In another embodiment, the pump may use positive and negative fluid displacement to alternately infuse and aspirate the catheter. In one embodiment, the ratio of the infuse-to-aspirate cycle may be between 0.01 and 0.99. Preferably the ratio will between 0.1 and 0.9, or more preferably between 0.4 and 0.9."

Ex. [1008] (Mullins) at 28:59-64

"This describes exactly what 'limiting' means: the controller sets a ceiling on the aspiration phase of the cycle to avoid clogging, and, even under Mr. Culbert's improper construction, Mullins conversely sets a limit on the infusion phase of the cycle to avoid excess distal end flow out."

Ex. [1035] (Brown Supp. Decl.) at ¶ 56

"Thus, a POSA would recognize that the prior art, including Mullins, provides clear disclosure of 'limiting' distal flow out as appropriately construed, but also clearly discloses, in some, but not all, of Mullins' embodiments, an amount of distal flow out that would satisfy some minimum permitted limit of distal flow outwards under Mr. Culbert's improper construction."

Ex. [1035] (Brown Supp. Decl.) at ¶ 57

Paper 24 (Pet. Reply) at 10-13

Ex. [1008] (Mullins)

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 47, 55-57

# Prior Art – Mullins – "Control" & "Limiting"

## Mullins – PO's expert's new positions fail

"PO's expert's new positions regarding Mullins fail. Ex[1035], ¶¶58-60. PO's expert argues that (1) Mullins' distal flow out in FIG. 47(g)-(h) doesn't satisfy the exit flow claims because clot flowing out is not fluid, and (2) Mullins' distal flow out in FIG. 47(k)-47(l) doesn't satisfy the exit flow claims because the fluid between the fragments is only either flowing back in or not at all. Ex[1036], 70:23-73:18; Ex[1035], ¶¶58-60."

Paper 24 (Pet. Reply) at 12-13

Q. "With regard to the earlier Mullins figures in 47E through F and G, you're agreeing that clot flows back out of the distal end, but disagreeing that clot qualifies as fluid in the claims, correct?"
A. "Correct."

Ex. [1036] (Culbert Depo.) at 72:7-16

"These new positions are not only implausible and/or dubious, but are also unsupported by any evidence or justification, and are deeply flawed for multiple 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 Supp. Decl.) at ¶ 60

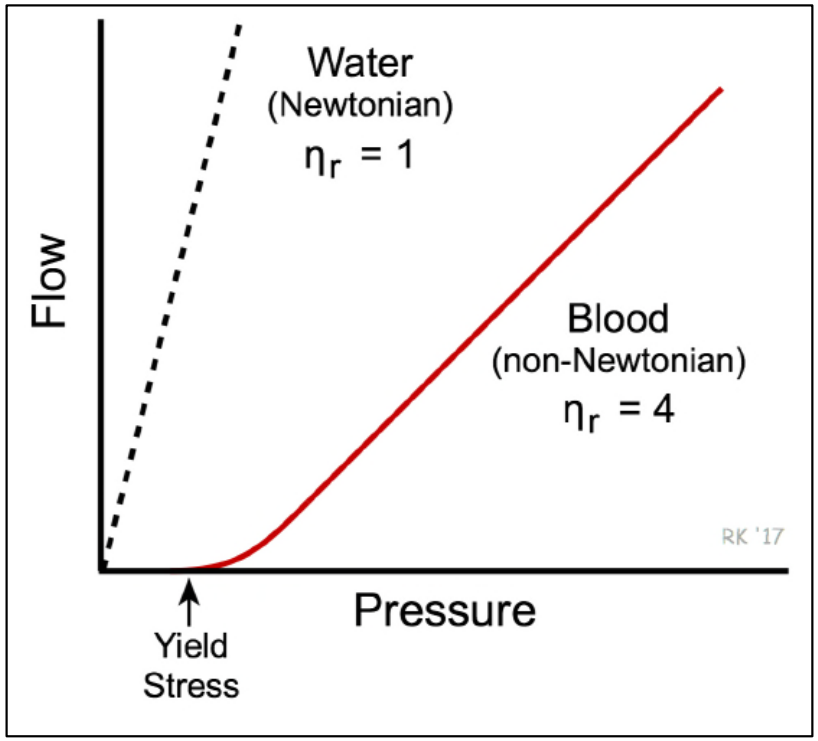
Paper 24 (Pet. Reply) at 12-13
Ex. [1036] (Culbert Depo.) at 70:23-73:18
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 58-60

# Context – "Control" & "Limiting"

## Clotting blood results in increased viscosity

"**Viscosity is an intrinsic property of fluid** related to the internal friction of adjacent fluid layers sliding past one another …Unlike water, **blood is non-Newtonian because its viscosity increases at low flow velocities**… Low flow states permit increased molecular interactions to occur between red cells and between plasma proteins and red cells. This can cause red cells to stick together… which increases the blood viscosity… **If clotting mechanisms are stimulated…[t]his leads to entrapment of red cells and clot formation, which dramatically increases blood viscosity**"

Ex. [1033] (Klabunde) at 1




Ex. [1033] (Klabunde) at Fig. 1

Paper 24 (Pet. Reply) at 13
Ex. [1005] (Brown Decl.) at ¶ 211
Ex. [1033] (Klabunde)

# Prior Art – Yang – "Control" & "Limiting"

## Yang – "control" and "limiting" disclosed and/or obvious under a POSA's understanding or under PO's improper constructions

"The intensity of intermittent or 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, which can further facilitate both transluminal navigation as well as dislodging or breaking up the obstruction."

Ex. [1012] (Yang) at [0108]

"In addition or as an alternative to the water hammer construction discussed above, axial mechanical vibration or shock waves may be propagated to or generated at the distal end of the catheter."

Ex. [1012] (Yang) at [0135]

"Referring to FIGS. 25A-25C, experiments showed that an interrupted vacuum can help aspirating a corked clot stuck at the distal end 2512 of the catheter 2510 by loosening the clot and reshaping it to fit into the catheter 2510 after each vacuum and release cycle. Merely stopping the vacuum is not sufficient to loosen the clot. Completely releasing (venting to atmospheric pressure) the vacuum and allowing the clot to relax before reapplying a vacuum is found to aspirate the corked clot most efficiently."

Ex. [1012] (Yang) at [0168]

Paper 24 (Pet. Reply) at 10-13
Ex. [1005] (Brown Decl.) at ¶¶ 148-151, 185-190
Ex. [1012] (Yang)
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 45, 53

# Prior Art – Yang – "Control" & "Limiting"

## Yang – "control" and "limiting" also obvious under a POSA's understanding or under PO's improper constructions

"For example, Yang discloses aspiration and venting cycles that regulate suction at the catheter tip. Yang teaches various means of controlling fluid flow in and out from the distal end of the catheter: 'The intensity of intermittent or 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, which can further facilitate both transluminal navigation as well as dislodging or breaking up the obstruction.' Yang also describes generating 'vibrations or shock waves… at the distal end of the catheter.' Yang further teaches applying alternating negative and positive pressure in vacuum and release cycles to manipulate the shape and position of the clot and fluid engaged at the distal tip of the catheter. This is operative 'control' of fluid flow in and out in Yang under the proper ordinary meaning of the claims, as well as suction cycles and vent cycles in some embodiments that could be understood or obvious as controlling flow in and out under Mr. Culbert's improper construction."

Ex. [1035] (Brown Supp. Decl.) at ¶ 45 (internal citations omitted); Ex. [1012] (Yang) at [0108], [0135], [0168]

"For example, in Yang, a POSA would understand that at least some positive amount of exit flow would occur at the distal end of the catheter when implementing and utilizing pulsated/cyclical aspiration on a clot engaged at the distal end of the catheter. A POSA would also understand that Yang's disclosure of a water hammer effect at the distal end of the catheter suggests that at least a portion of the fluid may flow out from the distal end."

Ex. [1035] (Brown Supp. Decl.) at ¶ 53 (internal citations omitted)

Paper 24 (Pet. Reply) at 10-13
Ex. [1005] (Brown Decl.) at ¶¶ 148-151, 185-190
Ex. [1012] (Yang) at [0108], [0135], [0168]
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 45, 53

# Prior Art – Ofek – "Control" & "Limiting"

## Ofek – "control" and "limiting" disclosed and/or obvious under a POSA's understanding or under PO's improper constructions

"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

"FIG. 2 depicts a graph of a pressure profile 80 (including fluid pressure vs. time)… device 30 provides short-duration, relatively high-pressure impulses through the fluid present in the catheter tube lumen 14 interspersed by relatively longer rest periods 84 of negative baseline pressure provided to the catheter tube lumen. The negative baseline pressure present between impulses enables any occlusion dislodged by the impulses to be sucked proximally up the catheter tube lumen 14 and removed therefrom, thus preventing the dislodged occlusion from entering the bloodstream from the distal end 12B of the catheter tube 12… Note that the rest periods in other embodiments can include a reduction to a neutral pressure or lower (but still positive) pressure or to varying pressures over time as may be desired."

Ex. [1007] (Ofek) at 3:43-60

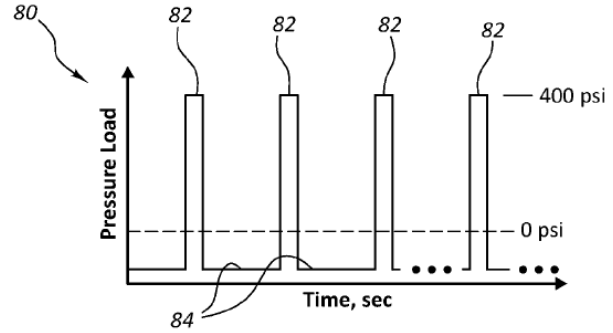



*Fig. 2*

Ex. [1007] (Ofek) at Fig. 2

Paper 24 (Pet. Reply) at 11-13
Ex. [1007] (Ofek)
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 24

# Prior Art – Ofek – "Control" & "Limiting"

## Ofek – "control" and "limiting" also obvious under a POSA's understanding or under PO's improper constructions

"As another example, Ofek teaches changing the level of vacuum at the distal end in order to control fluid flow at the distal end: "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." Ofek also discloses how the operation cycles and pressure profiles can be customized by the controller in various different ways (e.g., number of impulses, level of pressure, frequency, etc.) to control the pressure in the lumen, and further includes examples of the pressure impulses being high-pressure impulses that can be configured to have substantially high pressure peaks. This is also operative "control" of fluid flow in and out in Ofek under the proper ordinary meaning of the claims, including controlling vacuum and high-pressure impulses in some embodiments that could be understood or obvious as controlling flow in and out under Mr. Culbert's improper construction.'"

Ex. [1035] (Brown Supp. Decl.) at ¶ 46 (internal citations omitted); Ex. [1007] (Ofek) at 2:56-3:2, 3:43-60, 4:21-44

"Similarly, in Ofek, a POSA would recognize that pressure levels as high as the disclosed 400 psi, (depending on the number, duration, and frequency, which Ofek explicitly describes as being configurable to the desired application) would place sufficient amounts of positive pressure on the fluid in the catheter to not only incur distal pressure impulses in the fluid within the catheter, but could also cause at least some amount of controlled flow of fluid and occlusive material out from the distal end of the catheter."

Ex. [1035] (Brown Supp. Decl.) at ¶ 54 (internal citations omitted)

Paper 24 (Pet. Reply) at 10-13
Ex. [1007] (Ofek) at 2:56-3:2, 3:43-60, 4:21-44
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 46, 54
Ex. [1005] (Brown Decl.) at ¶¶ 401-406, 428-431

# GROUND 1 & 4

*YANG-MULLINS*
*OFEK-MULLINS*

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## Claims 3, 4, 14, 16, 17 – Exit Flow Limit Values

BAKER BOTTS

# Exit Flow Limit Values

| Claim Term | '402 Patent Claims |
|---|---|
| "limited to a positive amount of exit flow of [$Max_{Low}$] to [$Max_{High}$]" | Claims 3-4, 14, 16-17 |

## '402 Patent, Claim 3

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.

## '402 Patent, Claim 4

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.

*Also applicable to Claims 14, 16-17*

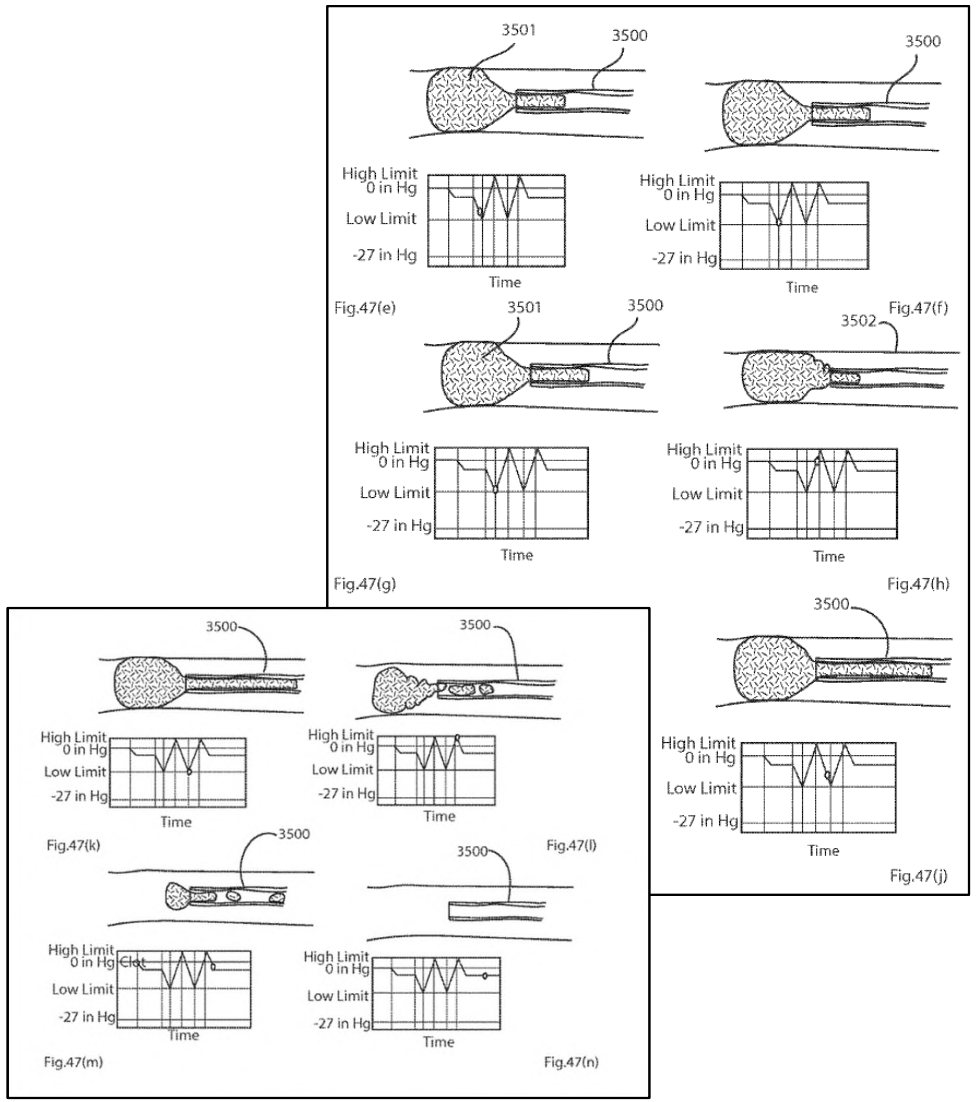
Ex. [1001] ('402 Patent)

# Exit Flow Limit Values

## The claimed exit flow limit values are obvious

"The direction of fluid displacement of the pump is now reversed. Upon reversal, the catheter will begin to pressurize, thereby increasing the pressure measured, FIG. 47 (g). As the catheter is pressurized (vacuum is reversed), the load which was applied to ingest the clot will be reduced, thereby unloading the clot, and even allowing some or all of the clot to be pushed distally towards the catheter tip FIG. 47(h). During this loading/unloading the clot is being macerated and accordingly becomes more 'free' within the catheter. The pressure is further increased until a High Limit is reached. In one embodiment this High Limit is defined such that the ingested clot may not be completely expelled from the catheter. Additional cycling of the clot between the Low Limit and high limit (FIG. 47 (i) to (j)) further macerates the clot enabling a greater amount of the clot to be ingested for the same Low Limit of vacuum (FIG. 47 (m)), with eventual complete ingestion of the clot, FIG. 47 (n)."

Ex. [1008] (Mullins) at 27:18-35




Paper 24 (Pet. Reply) at 13-14

Ex. [1008] (Mullins) at 27:18-35, FIG. 47

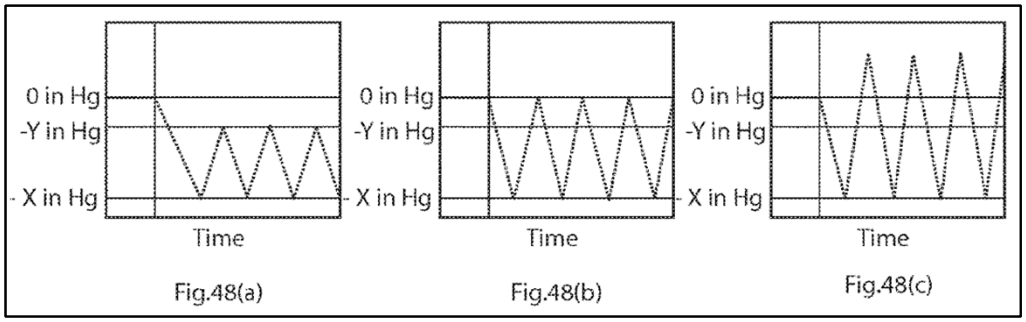
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 61-66

# Exit Flow Limit Values

## The claimed exit flow limit values are obvious

"In one embodiment the High Limit is a negative pressure. In another embodiment, the high limit may be 0 mmHg. In yet another preferred embodiment, the High Limit is a positive pressure (FIG. 48 (a) to (c)."

Ex. [1008] (Mullins) at 27:36-39




"A range of Lower Pressure and Higher-Pressure limit values may improve efficiency of clot transport compared to static aspiration technology."

Ex. [1008] (Mullins) at 28:27-29

"Similarly, the upper pressure may be defined based on a sudden change in the pressure during the pressurize cycle. In one embodiment this may be defined in order to identify a condition where the catheter is de-clogged."

Ex. [1008] (Mullins) at 28:45-48

Paper 24 (Pet. Reply) at 13-14
Ex. [1008] (Mullins) at 27:36-28:48, FIG. 48
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 61-66

# Exit Flow Limit Values

## The claimed exit flow limit values are obvious by routine optimization

"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)."

Paper 24 (Pet. Reply) at 13

"Moreover, the prior art expressly contemplates exactly this type of routine experimentation and optimization. For example, Mullins explicitly discloses upper and lower limits, fluid displacement cycles, and notes that specific numbers would be provided "based on experiment." Ex. 1008 (Mullins) at 28:27-37. That is an express acknowledgment that a POSA would determine suitable maximum volumes through ordinary testing.'"

Ex. [1035] (Brown Supp. Decl.) at ¶ 64

"As I have explained, a POSA would begin by experimenting with reasonable starting values and adjusting as necessary. Ex. 1005 (Brown Decl.) at ¶¶ 205. My calculations demonstrate an example of how a POSA might approach such optimization."

Ex. [1035] (Brown Supp. Decl.) at ¶ 65

Paper 1 (Pet.) at 42-43, 91-92
Paper 24 (Pet. Reply) at 13-14
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 61-66
Ex. [1005] (Brown Decl.) at ¶¶ 199-221, 436-442

# Exit Flow Limit Values

## PO's arguments against the claimed exit flow limit values fail

"Mr. Culbert, by contrast, provided no explanation of how or why the claimed volumes were selected, and Patent Owner's own specification does not disclose any methodology for deriving them. Ex. 1001 ('402 Patent) at 24:45-51."

Ex. [1035] (Brown Supp. Decl.) at ¶ 65

"Not only does PO offer no explanation of how the claimed volumes were selected, but also entirely fails to recognize the point of Mr. Brown's analysis. Ex[1035], ¶66."

Paper 24 (Pet. Reply) at 14

"As explained in my previous declaration, as well as in this declaration with regard to routine optimization and expectation of success, it would have been obvious to a POSA to simply experiment and optimize the valve timing to determine appropriate parameters to operate the disclosed prior art systems. Moreover, a POSA would readily recognize that my example calculations clearly demonstrate the maximum possible exit flow, which is a plainly obvious and reasonable starting point for a POSA's actual experimentation and routine optimization to determine any particular parameters for the prior art systems. The example calculations demonstrate that catheters of the prior art, when combined with the cycles disclosed in Mullins, can be limited to the maximum amount of exit flow of the fluid column at the distal end of the catheter as claimed by the '402 Patent."

Ex. [1035] (Brown Supp. Decl.) at ¶ 66

Paper 1 (Pet.) at 42-43, 91-92
Paper 24 (Pet. Reply) at 13-14
Ex. [1001] ('402 Patent) at 24:45-51
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 61-66
Ex. [1005] (Brown Decl.) at ¶¶ 199-221, 436-442

# GROUND 1 & 4

*YANG-MULLINS*
*OFEK-MULLINS*

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## Claims 1, 11 – “Predetermined Cycle”

BAKER BOTTS

# "Predetermined Cycle"

| Claim Term | '402 Patent Claims |
|---|---|
| "predetermined cycle" | Claim 1 |

## '402 Patent, Claim 1

1. An aspiration thrombectomy system, comprising:

* * *

a controller configured

to open and close the vacuum valve and the vent valve in a predetermined cycle…

Ex. [1001] ('402 Patent)

# Claim Construction – "Predetermined Cycle"

| Claim Term | '402 Patent Claims |
|---|---|
| "predetermined cycle" | Claim 1 |

| Petitioner's Construction | Patent Owner's Construction |
|---|---|
| No construction necessary<br><br>Ordinary and customary meaning is clear: "***open and close the vacuum valve and the vent valve*** **in a predetermined cycle**" | Includes negative limitation prohibiting sensor usage to tune system operation |

**Key Issue:**

- Patent Owner creates and imports a negative claim limitation

Paper 15 (PO Response) at 24-31
Paper 24 (Pet. Reply) at 14-17
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 67-84

# "Predetermined Cycle"

## PO's position against "predetermined cycle" relies on a framework combining multiple flawed arguments

"PO implicitly construes 'predetermined cycle,' to include an unstated negative limitation prohibiting sensor usage to tune system operation. POR, 24-31; Ex[2014], ¶¶60-82. This construction is legally erroneous and should be rejected. *See Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1060 (Fed. Cir. 2009) (declining to add negative limitation where "there is no basis in the patent specification")."

Paper 24 (Pet. Reply) at 14-15

"Patent Owner and Mr. Culbert appear to make this argument in order to

(1) attack the Mullins reference by characterizing it as exclusively relying on sensor feedback to dynamically alter valve operation rather than being 'predetermined' under their apparent construction,

(2) argue that any prior art combinations involving Mullins must include dynamic feedback-based valve operation, and

(3) therefore, any prior art combinations including Mullins could not meet the 'predetermined cycle' limitation.

In my opinion, each of these points fail, and Patent Owner's and Mr. Culbert's argument is inconsistent with the claim language, the intrinsic record, and how a person of ordinary skill in the art ("POSA") would understand the term."

Ex. [1035] (Brown Supp. Decl.) at ¶ 67

Paper 15 (PO Response) at 24-31
Paper 24 (Pet. Reply) at 14-17
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 67-84

# "Predetermined Cycle"

## Nothing in the claims excludes using sensors

"Nothing in that claim language imports a requirement regarding timing or sensors. In my view, and consistent with the ordinary meaning of the words, a POSA would understand 'predetermined cycle' to simply mean a 'predetermined cycle' of valve states for opening and closing the vacuum valve and vent valve. The claim language plainly states exactly what is 'predetermined,' which is that the controller opens and closes the valves in sequences that have been predetermined in advance. That is, a defined cycle that repeats in a known way."

Ex. [1035] (Brown Supp. Decl.) at ¶ 68

"To the contrary, the specification explicitly includes sensors similar to those in the prior art. Ex[1001], 32:55-33:7, 40:66-41:5, 44:9-29 (discussing controller use of data from 'sensors' including "pressure measurement devices" to "time the valves properly")."

Paper 24 (Pet. Reply) at 15

"a POSA would understand a cycle as simply including a complete sequence of events that repeat (e.g., as in 'the cycle of life'). Thus, so long as the system opens and closes the valves in a 'predetermined cycle,' as required by the claims, this could be satisfied by any embodiment that completes and repeats that predetermined sequence, both in situations involving fixed timing as well as situations involving sensor-based feedback."

Ex. [1035] (Brown Supp. Decl.) at ¶ 70

Paper 24 (Pet. Reply) at 14-17
Ex. [1001] ('402 Patent) at 32:55-33:7, 40:66-41:5, 44:9-29
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 68-72

# "Predetermined Cycle"

## PO's arguments based on Garrison and an Examiner's statement fail

"PO's reliance on an Examiner statement—that the '402 Claims overcame Garrison because of Garrison's sensor use—is misplaced as it is not a disclaimer and is technically incorrect. Not only was Applicant itself silent on Garrison, it expressly refused to agree with the Examiner's statement. Ex[1004], 29. *See, e.g., Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005) (refusing to create rule or presumption that applicant's silence to examiner's unilateral statement disavowed claim scope); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1124 (Fed. Cir. 2004) ("It is well settled [] that it is the applicant, not the examiner, who must give up or disclaim subject matter…"). Further, the examiner failed to recognize that Garrison disclosed embodiments where the cycle timing was controlled only by the user, not sensor feedback. Ex[2015], ¶[0114]."

Paper 24 (Pet. Reply) at 15-16

"the '402 Patent clearly discloses embodiments that in some cases rely on, and in other cases don't rely on, sensor-based feedback. *See, e.g.*, Ex. 1001 ('402 Patent) at 32:55-33:7, 40:50-41:5, 44:9-29. In the very same manner, both Mullins, as well as the Garrison reference that Patent Owner and Mr. Culbert place great focus on, each disclose some embodiments that involve sensor-based feedback, and other embodiments that don't. *See, e.g.*, Ex. 1008 (Mullins) at 26:43-49, 27:54-28:10, 28:49-29:12; Ex. 2015 (Garrison) at ¶¶ [0113]-[0114]. Again, Patent Owner and Mr. Culbert cannot hold the prior art to a different standard than they would for their own disclosure."

Ex. [1035] (Brown Supp. Decl.) at ¶ 72

Paper 15 (PO Response) at 6-7
Paper 24 (Pet. Reply) at 14-16
Ex. [1001] ('402 Patent) at 32:55-33:7, 40:50-41:5, 44:9-29
Ex. [1008] (Mullins) at 26:43-49, 27:54-28:10, 28:49-29:12
Ex. [2015] (Garrison) at ¶¶ [0113]-[0114]
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 72-73, fn.4

# "Predetermined Cycle"

## Yang – "predetermined cycle" is disclosed under a POSA's understanding or under PO's improper construction

"FIGS. 25A–25C show a logical progression of the vacuum and release cycle… 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 from FIG. 25A to FIG. 25C begins by closing the release valve 2514 and opening the vacuum valve 2516."

Ex. [1012] (Yang) at [0169]-[0170]

"The components may be manipulated individually or in a synchronized manner using predetermined operating parameters (e.g., for synchronized aspiration, injection, and rotation)."

Ex. [1012] (Yang) at [0176]

"The period of each vacuum and release cycle may be equal to… 0.1, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 seconds)."

Ex. [1012] (Yang) at [0127]

Paper 24 (Pet. Reply) at 16-17
Ex. [1012] (Yang) at [0127], [0169]-[0170], [0176]
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 75, 79

# "Predetermined Cycle"

## Ofek – "predetermined cycle" is disclosed under a POSA's understanding or under PO's improper construction

"frequency of the impulses, or impulse frequency, can be set according to a predetermined pattern."

Ex. [1007] (Ofek) at 6:30-31

"in one embodiment… the catheter assembly 10 comprises… propagating a plurality of impulses of positive pressure through the fluid disposed in the lumen, noting that the impulses are propagated in a predetermined pattern."

Ex. [1007] (Ofek) at 7:11-17

"note that the number of impulses in each group can vary according to user desire and/or a pre-set predetermined pattern."

Ex. [1007] (Ofek) at 8:38-49

"The N.C. valve 140 is opened and close repeatedly at predetermined time intervals."

Ex. [1007] (Ofek) at 5:49-62

"Note further that in one embodiment that the controller 170 can enable customization of the characteristics of the impulses, rest periods, baseline pressure, etc. by the user."

Ex. [1007] (Ofek) at 6:61-63

Paper 24 (Pet. Reply) at 16-17
Ex. [1007] (Ofek) at 5:49-7:17, 8:38-49
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 76, 80

# "Predetermined Cycle"

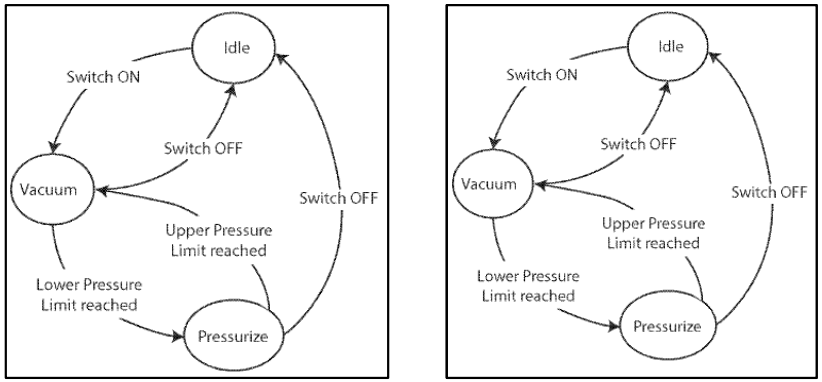
## Mullins – "predetermined cycle" is disclosed under a POSA's understanding or under PO's improper construction

"In one embodiment, shown schematically in the form of a state diagram in FIG. 46, the pump uses defined upper and lower limits to decide whether to apply a vacuum or pressurize. These limits enable the catheter to cyclically ingest and if required expel, at least some of the clot. This deformation of the clot improves the efficiency of the aspiration, and prevents clogging of the catheter."

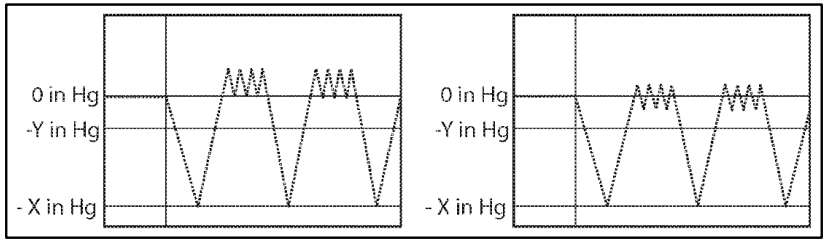
Ex. [1008] (Mullins) at 26:43-49, FIG. 46

"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 provides acute aspiration of the clot in order to cause deformation and, or, fragmentation of the clot to improve transport through the catheter. Another aspect is the incorporation of rate based cycling of a negative and positive pressure signal. Oscillating frequencies can be defined that may cause the elastic modulus of a clot to be exceeded, thereby, fragmenting the clot in the catheter and promoting easier transport. The addition of this oscillation is shown in the form of the state diagram in FIG. 49. In one embodiment the shake signal may be initiated for a predefined number of cycles."

Ex. [1008] (Mullins) at 27:54-28:2, FIG. 49




Ex. [1008] (Mullins) at Fig. 46, 49




Ex. [1008] (Mullins) at Fig. 50

Paper 24 (Pet. Reply) at 16-17

Ex. [1008] (Mullins) at 26:43-49, 27:54-28:2, FIGs. 46, 49, 50

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 77, 81-82

# "Predetermined Cycle"

## Mullins – "predetermined cycle" is disclosed even under PO's improper construction

"Further, despite Patent Owner's and Mr. Culbert's insistence that Mullins and any combination involving Mullins must unquestionably incorporate sensor-based feedback, a POSA would recognize that Mullins discloses numerous embodiments, only some of which involve sensor-based feedback, and others that have no mention or relevance to any sensor-based feedback. For example, Mullins explains that its oscillating aspiration cycles may be driven by predefined/specified parameters."

Ex. [1035] (Brown Supp. Decl.) at ¶ 81

"the pump uses defined upper and lower limits to decide whether to apply a vacuum or pressurize. These limits enable the catheter to cyclically ingest and if required expel, at least some of the clot."

Ex. [1008] (Mullins) at 26:43-49

"It should be appreciated that the upper and lower limits may be defined by a combination of rate of change in pressure, or specific pressure value, or a combination of both."

Ex. [1008] (Mullins) at 28:49-52

Paper 24 (Pet. Reply) at 16-17
Ex. [1008] (Mullins) at 26:43-49, 27:54-67, FIGs. 46, 49
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 77, 81-82

# "Predetermined Cycle"

## Mullins – "predetermined cycle" is disclosed even under PO's improper construction

"As another example, Mullins provides a range of predetermined fluid displacement cycles, and that those cycles may be controlled by the pump using positive and negative fluid displacement, and also that the pump may be a positive displacement pump (i.e., fixed amount of displacement per revolution, such as a peristaltic pump mechanism)… In that case, a POSA would recognize that a fixed timing cycle of operation in each pump direction would produce the predetermined cycles of Mullins."

Ex. [1035] (Brown Supp. Decl.) at ¶ 81

"In one configuration, the pump incorporates a peristaltic pump mechanism. This ensures that there is no blood contact with the pump parts."

Ex. [1008] (Mullins) at 29:4-12

"In another embodiment, the pump may use positive and negative fluid displacement to alternately infuse and aspirate the catheter. In one embodiment, the ratio of the infuse-to-aspirate cycle may be between 0.01 and 0.99. Preferably the ratio will between 0.1 and 0.9, or more preferably between 0.4 and 0.9."

Ex. [1008] (Mullins) at 28:59-64

Paper 24 (Pet. Reply) at 16-17
Ex. [1008] (Mullins) at 26:43-49, 27:54-67, FIGs. 46, 49
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 77, 81-82

# "Predetermined Cycle"

## Mullins – Each argument in PO's "predetermined cycle" framework fails

"Patent Owner's and Mr. Culbert's attempts to (1) impute some critical level of importance to Mullins' optional feedback loop and (2) force that optional feedback loop into every prior art combination, fail for multiple reasons.

**First**, it relies on an improper importation of a timing requirement into the 'predetermined cycle' claim limitation.

**Second**, it fundamentally misunderstands the relevance of Mullins's disclosure to the prior art combinations for its extensive discussion of flow at the distal end (including forward flow, regardless of whether it's actually required), rather than any allegedly required feedback loop.

**Third**, it fails to recognize that all of the prior art references disclose predetermined cycles of opening and closing valves under the ordinary meaning of the claim language.

**Fourth**, even if a timing requirement were to be improperly read into the claims, Patent Owner and Mr. Culbert still fail to recognize that all of the prior art references disclose predetermined cycles with specific timings, including Mullins, which, as discussed, specifically includes embodiments that don't require any feedback loop."

Ex. [1035] (Brown Supp. Decl.) at ¶ 83

Paper 24 (Pet. Reply) at 16-17
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 67-83

# GROUND 1 & 4

*YANG-MULLINS*
*OFEK-MULLINS*

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## Claims 11-20 – Method Claim Arguments

BAKER BOTTS

# "Positioning"

| Claim Term | '402 Patent Claims |
|---|---|
| "positioning" | Claim 11 |

## '402 Patent, Claim 11

1. A method for removing thromboembolic material, comprising:

* * *

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

Ex. [1001] ('402 Patent)

# "Positioning"

## PO's repackaged use case argument against Ofek still fails

"PO's argument that Ofek doesn't sufficiently disclose "positioning the distal end of the catheter" in method claim 11 (POR, 46-48) fails for substantially the same reasons as the previous iteration (*cf POPR*, 54-59). Ex[2014], ¶¶106-108; Ex[1035], ¶¶87-92; *see also* ID, 33-37. PO's argument is essentially that Ofek doesn't discuss thrombectomy procedures using PO's preferred terminology."

Paper 24 (Pet. Reply) at 18

"Ofek explains that the catheter can be used for aspirating a thrombus at the distal end… Although Ofek may not specifically use the term 'aspiration catheter'… it does describe catheters that… include arterial catheters."

Paper 7 (Inst. Dec.) at 33

"It would be obvious to a POSA (or just through common sense), that if Ofek is capable of engaging with and ingesting occlusive matter such that it could clog the aspiration catheter, then it would also be capable of and/or obvious to position the end of the aspiration catheter in a location proximate to that same occlusive matter it is ingesting."

Ex. [1035] (Brown Supp. Decl.) at ¶ 89

Paper 7 (Inst. Dec.) at 33
Paper 15 (PO Response) at 31-48
Paper 24 (Pet. Reply) at 17-20
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 85-100

# "Positioning"

## A POSA would find it obvious to combine Ofek and Mullins

"Ofek affirmatively demonstrates functionality and operability consistent with the reasons stated for combining with Mullins."

Ex. [1035] (Brown Supp. Decl.) at ¶ 89

"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

"A POSA would find it obvious to implement Mullins' disclosures of forward flow and improvements in unsticking clots to modify Ofek's system, which includes a catheter aspiration system that is ready for improvement by Mullins's techniques for efficient and effective cyclical aspiration of blood clots. A POSA would find it obvious to implement Mullins' disclosures of forward flow and improvements in unsticking clots to modify Ofek's system, which includes a catheter aspiration system that is ready for improvement by Mullins's techniques for efficient and effective cyclical aspiration of blood clots."

Ex. [1005] (Brown Decl.) at ¶ 359 (citations omitted)

Paper 24 (Pet. Reply) at 18-19
Ex. [1005] (Brown Decl.) at ¶¶ 355-362
Ex. [1007] (Ofek)
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 87-92

# "Positioning"

## PO does not dispute that Ofek-Mullins discloses a thrombectomy system

"PO's arguments are also flawed as they attack the references individually rather than the combination in the Invalidity Ground."

Paper 24 (Pet. Reply) at 19

"Indeed, the only arguments that Patent Owner and Mr. Culbert appear to maintain for Claim 1 are the controller arguments discussed above (i.e., (1) distal end-flow limitations and (2) sensor-based feedback loop), none of which are specific to Ofek or its use case…. In which case…, since all that Patent Owner and Mr. Culbert contest for Claim 1 now are the controller limitation arguments, then there's no argument that Ofek-Mullins discloses an aspiration thrombectomy system ***generally***. Thus, Patent Owner's and Mr. Culbert's argument now is essentially that the mere presence of the word "positioning" saves the dependent method claims from the Ofek-Mullins combination… It simply does not stand to reason that a functional aspiration thrombectomy system performing aspiration thrombectomy with an aspiration catheter according to Claim 1 would not be capable of positioning the aspiration catheter against the clot it is aspirating."

Ex. [1035] (Brown Supp. Decl.) at ¶ 91

Paper 24 (Pet. Reply) at 18-19

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 87-92

# Expectation of Success

| Claim Terms At-Issue | '402 Patent Claims |
|---|---|
| Result-oriented claim terminology | Claim 11 |

## '402 Patent, Claim 11

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.

***[in a predetermined cycle]*** (not recited in Claim 11)

Ex. [1001] ('402 Patent)

# Expectation of Success

## Results-oriented claim language does not save PO's method claims

"PO also now relies on Claim 11's outcome-oriented claim language to re-argue their controller limitations arguments under the premise of 'expectation of success.' POR, 31-46; Ex[2014], ¶¶88-105. These arguments fail for all of the same reasons explained for the "control," "limited to," "predetermined cycle," and "exit flow" limitations."

Paper 24 (Pet. Reply) at 19

"First… these versions of the prior Claim 1 arguments fail for the same reasons discussed above for the respective system claims. As explained, the apparent constructions by Patent Owner and Mr. Culbert of all of those claim terms are equally inapplicable and improper to the corresponding claim terms in the dependent method claims, and also because the prior art references disclose both the proper plain meaning as well as the incorrect constructions advanced by Patent Owner and Mr. Culbert…

Second, each reference affirmatively demonstrates operability consistent with Petitioner's combinations, and the state of the art… confirms that a POSA would have every reason to expect success…

Third… In contrast to the '402 Patent's lack of guidance, it is my opinion that the extensive disclosures in Yang, Ofek, and Mullins would have given a POSA a reasonable expectation of success in implementing the prior art combinations"

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 94-96

Paper 24 (Pet. Reply) at 19-21
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 93-100

# Expectation of Success

## A reasonable expectation of success does not demand certainty

"Finally, the Federal Circuit has repeatedly explained that the 'reasonable expectation of success' inquiry does not demand certainty. *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1352 (Fed. Cir. 2024) ("[a]n expectation of success need only be reasonable, not absolute.") (emphasis in original); *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009). Moreover, the Federal Circuit has established that "a finding of reasonable expectation of success can be implicit." *Elekta Ltd. v. Zap Surgical Sys., Inc.*, 81 F.4th 1368, 1376, 1377 (Fed. Cir. 2023)."

Paper 24 (Pet. Reply) at 19

"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."

Ex. [1035] (Brown Supp. Decl.) at ¶ 98

"…the law is clear: optimizing such variables is within the skill of the art, and POSAs would reasonably expect success therein. *Application of Boesch* 617 F.2d 272, 276 (CCPA 1980) ("discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art."); *ImmunoGen, Inc. v. Stewart*, 130 F.4th 1328, 1334 (Fed. Cir. 2025)."

Paper 24 (Pet. Reply) at 19

Paper 24 (Pet. Reply) at 19-21

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 93-100

# Expectation of Success

## A reasonable expectation of success does not demand certainty

"Furthermore, terms such as 'control' and 'controlling' do not necessarily imply absolute control, but rather indicate having an influence or effect that is intended and/or predictable. The term 'dynamic' does not preclude temporary or brief plateaus or temporary intervals of constant pressure. Rather, over the course of an aspiration procedure (e.g. thrombectomy), the aspiration profile includes a plurality of deliberate variations in the suction force/pressure (this sometimes being referred to as a dynamic suction force). These variations may be repetitive, cyclic, rhythmic, stochastic, or otherwise. A combination of these variation types may also be used together. The terms 'dynamic aspiration' and 'dynamic suction' may be used interchangeably with the term 'impact aspiration'. It is noted that 'constant pressure', particularly as used in describing the prior art, may include incidental perturbations such as caused by adjustments in the position of a catheter tip relative a thrombus. Such incidental perturbations to an aspiration profile or suction force do not alone provide sufficient basis for characterization of an aspiration profile as 'dynamic'."

Ex. [1010] (Grey) at 6:13-25

Paper 24 (Pet. Reply) at 19-21
Ex. [1010] (Grey) at 6:13-25
Ex. [1035] (Brown Supp. Decl.) at ¶ 95

# GROUNDS 1-2 & 4-5

Claims 5-7, 18-20 – “off-off state”

BAKER BOTTS

# "Off-Off State"

| Claim Term | '402 Patent Claims |
|---|---|
| "off-off state" | Claims 5-7 and 18-20 |

## '402 Patent, Claim 5

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.

## '402 Patent, Claim 18

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.

Ex. [1001] ('402 Patent)

# "Off-Off State"

"Contrary to what patent Owner argues, nowhere in the claims does it require the off-off state be "a purposeful state" or that the off-off state is "not a mere incidental, momentary overlap as valves transition." See Ex. 1001 ('402 Patent) at Claims 5-7, 18-20; Paper 15 (PO Response) at 57; Ex. 2014 (Culbert Decl.) at ¶ 130."

Ex. [1035] (Brown Supp. Decl.) at ¶ 101

Q. "So in these claims, the off/off state has to... satisfy this predetermined cycle of states, but does not itself have a specific time requirement; correct?"
A. "In the claims themselves, no. To achieve that, obviously, in the spec, it discloses best practices on how to make this work."
Q. "Sure."
A. "But that precise amount is not listed in the claims, no."

Ex. [1036] (Culbert Depo.) at 47:24-48:6

"It is my opinion that Patent Owner and Mr. Culbert are attempting to include limitations that are not required by the claims of the '402 Patent, and that the "off-off state" limitations in the '402 Patent do not require the "off-off state" to be purposeful or persist for a certain amount of time."

Ex. [1035] (Brown Supp. Decl.) at ¶ 102

Paper 24 (Pet. Reply) at 21
Ex. [1036] (Culbert Depo.) at 47:24-48:6
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 101-102

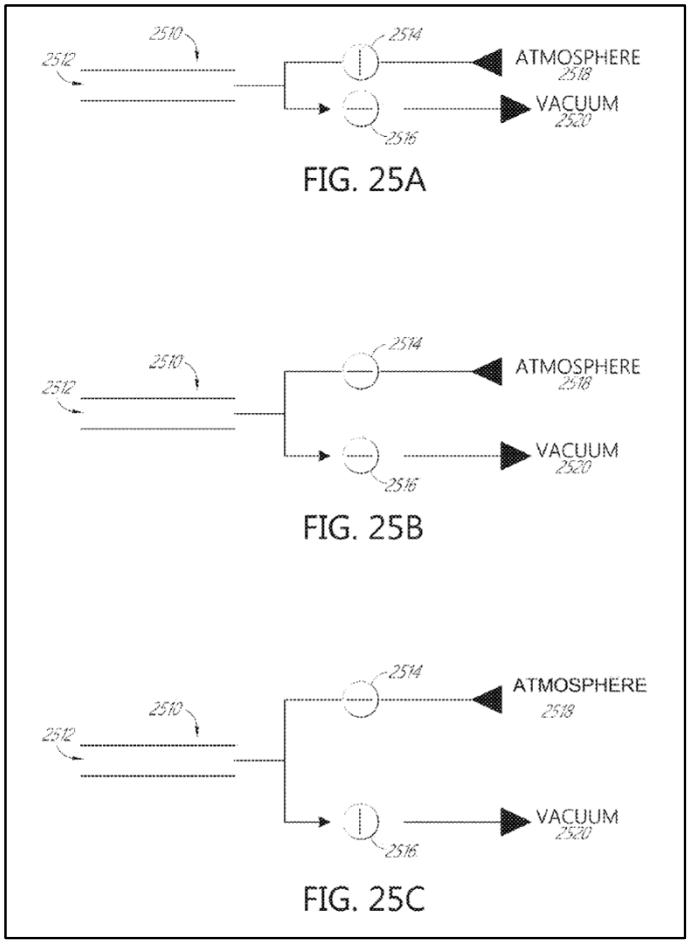
# GROUND 1

*YANG-MULLINS*

Claims 5-7, 18-20 – “off-off state”

BAKER BOTTS

# Yang – "Off-Off State"




Ex. [1012] (Yang) at Fig. 25

"In the first step as shown in FIG. 25A, the 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, as shown in FIG. 25B, the release valve 2514 is opened while the vacuum valve 2516 stays open. Because the release line 2518 and the vacuum line 2520 are in fluid communication, either directly or via at least a portion of the catheter 2510, the vacuum is applied mainly through the release line 2518, dropping vacuum applied to the catheter. Finally, as shown in FIG. 25C, the vacuum valve 2516 is shut off, allowing the vacuum to be completely released and the clot to relax. Then, another cycle from FIG. 25A to FIG. 25C begins by closing the release valve 2514 and opening the vacuum valve 2516."

Ex. [1012] (Yang) at [0170]

Paper 1 (Pet.) at 44-46
Ex. [1005] (Brown Decl.) at ¶¶ 226-236
Ex. [1012] (Yang) at [0170], FIG. 25

# Yang – "Off-Off State"

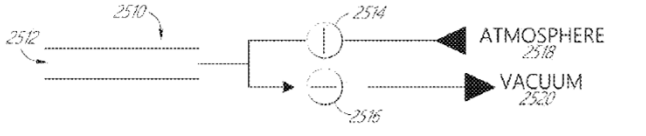


FIG. 25A

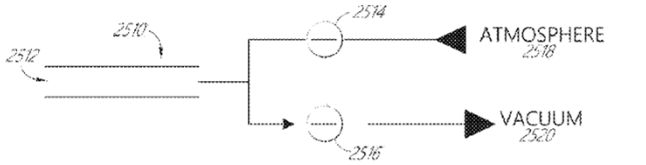


FIG. 25B

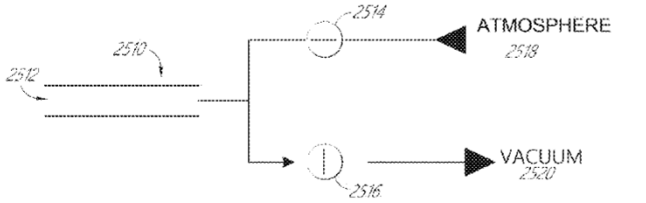


FIG. 25C

Ex. [1012] (Yang) at Fig. 25

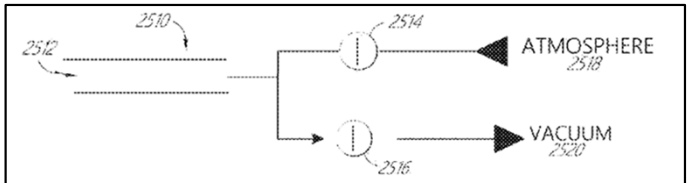


FIG. 25-DC

"Although not illustrated in Figure 25, Yang specifically explains that after the 'vent-only state' of Figure 25C, "another cycle from FIG. 25A to FIG. 25C begins by closing the release valve 2514 and opening the vacuum valve 2516." Ex. 1012 (Yang) at ¶ [0170]. A POSA would understand, in the context of Figures 25A-25C and the other valve states disclosed in [0170], that Yang is describing an additional valve state that enables Yang to transition from the vent-only state in Figure 25C to the vacuum-only state in Figure 25A. This disclosure in Yang teaches that the transition state is achieved from Figure 25C by "closing the release valve 2514," which a POSA would understand results in a state in the aspiration cycle where the vent valve is closed while the vacuum valve is still closed (as it was in the vent-only state of Figure 25C). Thus, this transition state disclosed by Yang is a 'double-closed state' (or 'off-off state') where the vent valve is closed and the vacuum valve is closed. A modified illustration of Yang's double-closed state consistent with the other valve states shown in Figures 25A-C is shown below ('FIG. 25-DC'). Yang then completes the loop and begins another cycle by "opening the vacuum valve 2516," thereby resulting in the vacuum-only state of Figure 25A. Ex. 1012 (Yang) at ¶ [0170]"

Ex. [1005] (Brown Decl.) at ¶ 230

Paper 1 (Pet.) at 44-46
Ex. [1005] (Brown Decl.) at ¶¶ 226-236
Ex. [1012] (Yang) at FIG. 25

# Yang – "Off-Off State"

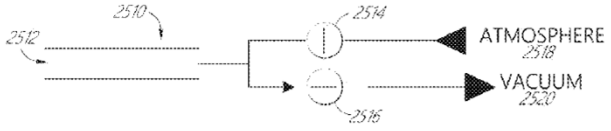


FIG. 25A

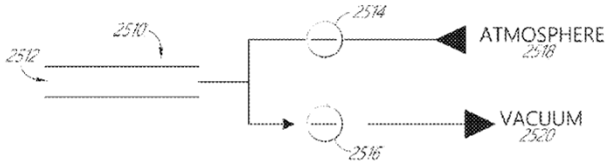


FIG. 25B

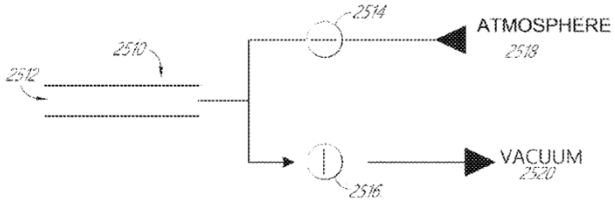


FIG. 25C

Ex. [1012] (Yang) at Fig. 25

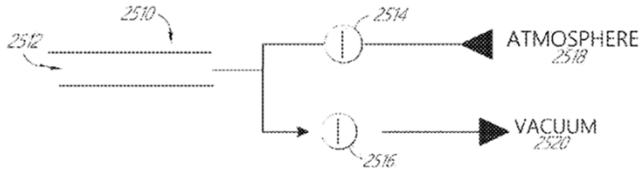


FIG. 25-DC

"A POSA would recognize that Yang would transition from the vent-only state to the vacuum-only state via a double-closed state at least in part because it would be consistent with the operation and transition of each of the other disclosed vacuum states, in which each successive state is reached by serially opening or closing one of the valves while maintaining the other valve in the same open/closed state as it was in the previous state."

Ex. [1005] (Brown Decl.) at ¶ 231

"Closing the vent valve first before reopening the vacuum would be the logical approach to efficiently generate a pulse, allowing the full force of the vacuum to be exerted on the clot. Closing the vent valve first cuts off the positive pressure source and then opening the vacuum valve then allows the full force of the vacuum to be exerted on the clot. In this way, after the vent valve has been closed and the vacuum valve opened, the applied vacuum would not be minimized by the positive pressure of an open vent valve, thereby efficiently building up a full negative pulse."

Ex. [1005] (Brown Decl.) at ¶ 233

Paper 1 (Pet.) at 44-46
Ex. [1005] (Brown Decl.) at ¶¶ 226-236
Ex. [1012] (Yang) at FIG. 25

# Yang – "Off-Off State"

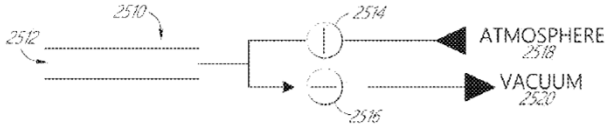


FIG. 25A

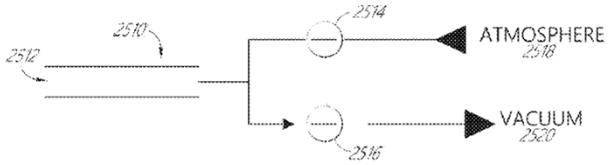


FIG. 25B

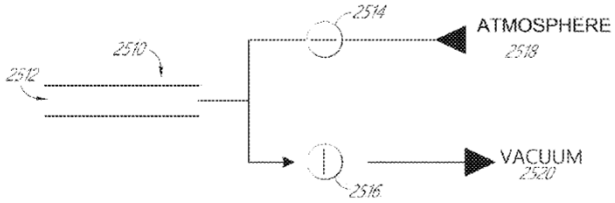


FIG. 25C

Ex. [1012] (Yang) at Fig. 25

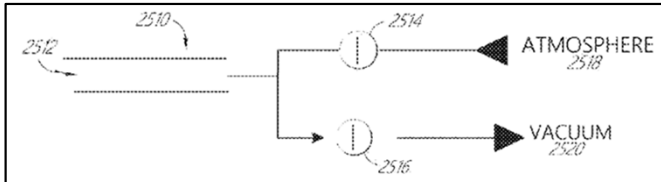


FIG. 25-DC

"…a POSA would have further found it obvious to implement a double-closed state in Yang because there are only a finite number of ways to order the opening and closing of valves, and one such way is by including a phase where both valves are closed. Given that there is a limited number of combinations and states in which two valves can individually be opened or closed, in implementing and optimizing the system of Yang, a POSA would find it obvious to experiment with each such combination. In particular, a POSA would be motivated to experiment with a double-closed state because if both valves are closed, there would not be any resulting flow within the catheter, and therefore would not risk any distal clot migration."

Ex. [1005] (Brown Decl.) at ¶ 234

"…a POSA would have also found it obvious to implement a double-closed state in Yang because it is far more typical, predictable, and reliable to conduct serial operations in medical devices… A POSA would also understand that parallel operations tend to compound operation errors of the parallel steps, reducing system reliability."

Ex. [1005] (Brown Decl.) at ¶ 235

Paper 1 (Pet.) at 44-46
Ex. [1005] (Brown Decl.) at ¶¶ 226-236
Ex. [1012] (Yang) at FIG. 25

# Yang – "Off-Off State"

"As discussed previously, a POSA would understand Yang discloses and renders obvious a double-closed or "off-off" state for multiple reasons. For example,

**(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 (Yang) at ¶¶ [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 (off-off) 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 (Yang) at ¶ [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. [1035] (Brown Supp. Decl.) at ¶ 103

Paper 24 (Pet. Reply) at 45-46

Ex. [1035] (Brown Supp. Decl.) at ¶ 103

# GROUND 4

*OFEK-MULLINS*

Claims 5-7, 18-20 – “off-off state”

BAKER BOTTS

# Ofek – "Off-Off State"

"In another embodiment, the functionality of the N. C. valve 140 and the N. O. valve 150 can be combined into a single valve, such as a three-way valve, with the fluid lines being arranged so as to provide such an embodiment. In such a single valve embodiment, the single three-way valve is operated to alternately provide the impulses of positive pressures as well as the negative baseline pressures/negative impulses."

Ex. [1007] (Ofek) at 5:26-31

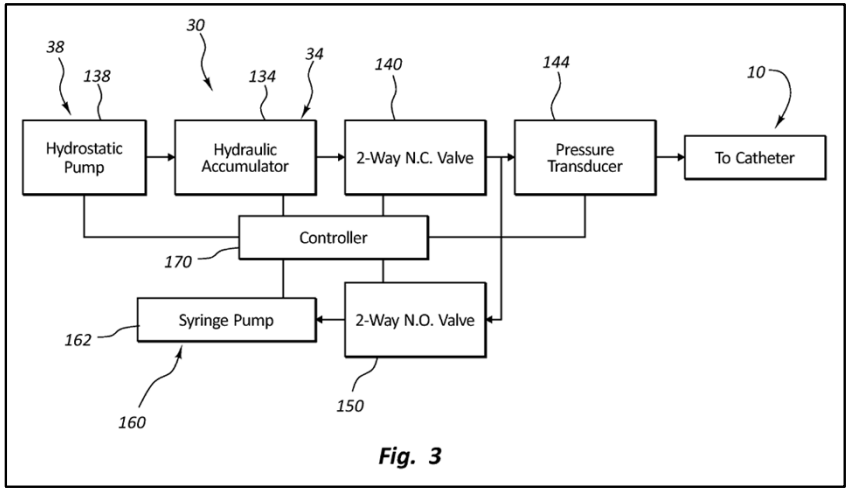



Fig. 3

Ex. [1007] (Ofek) at Fig. 3

"Between each impulse and after the series of impulses has ended, the N.C. valve 140 closes and the N.O. valve 150 opens" and "wherein the normally open valve is configured to provide the temporary negative pressure to the fluid disposed in the at least one lumen, the normally open valve configured to close upon opening of the normally closed valve, the normally closed valve configured to provide the at least one impulse to the fluid disposed in the at least one lumen."

Ex. [1007] (Ofek) at 5:63-6:8, Claim 8

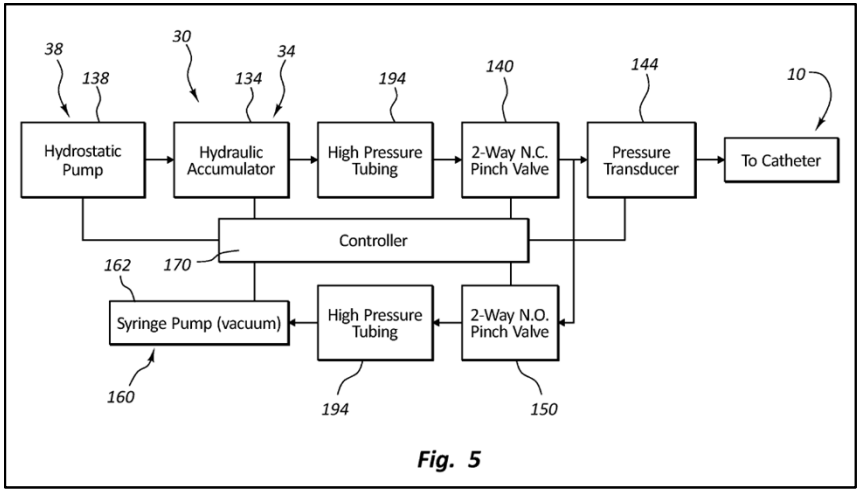



Fig. 5

Ex. [1007] (Ofek) at Fig. 5

Paper 1 (Pet.) at 92-93
Ex. [1007] (Ofek) at 5:26-6:8
Ex. [1005] (Brown Decl.) at ¶¶ 447-453

# Ofek – "Off-Off State"

"A POSA would have found it obvious to execute the transition between the negative and positive pressure serially to generate the positive pulse. 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 the vacuum valve and the opening of the vent valve, which leads to at least a brief period where both valves are closed, i.e., a double-closed, or off-off state. This would lead to more reliable and predictable operation of the system. Similarly, [this] would be a logical and obvious method of efficiently generating a negative pulse. Thus, it would be obvious for a second double-closed state to occur in the course of generating a negative pulse during an aspiration cycle."

Ex. [1005] (Brown Decl.) at ¶ 450

"In a situation where a three-way valve comprises both the vent valve and the vacuum valve… a POSA would find it obvious that while the three-way valve is transitioning from one state to another state (e.g., from a vent state to a vacuum state), there would be an intermediary 'off-off' state during the transition because neither of the respective channels would be connected through the three-way valve… if the three-way valve were a rotary three-way valve, it would result in an off-off state when the three-way valve is rotating between the positions where the connecting channels are aligned to fluid and vacuum channels…"

Ex. [1005] (Brown Decl.) at ¶ 452

Paper 1 (Pet.) at 92-93

Ex. [1005] (Brown Decl.) at ¶¶ 447-453

# Yang – "Off-Off State"

"Ofek discloses serial valve operation including a moment where both valves are shut before the N.C. valve is opened to prevent fluid from entering the vacuum, thus satisfying the off-off state."

Ex. [1035] (Brown Supp. Decl.) at ¶ 106

"…a POSA would find it obvious to execute the transition between the closing and opening of the respective valves in serial so that there is a finite delay between closing of one valve and the opening of another, which leads at least to a brief period where both valves are closed. A POSA would understand that having at least a brief moment where both valves are closed provides the system the opportunity to confirm the state of each valve and to prevent instances where the vacuum is applied while the vent valve is open."

Ex. [1035] (Brown Supp. Decl.) at ¶ 107

"…Ofek does not specify which types of three-way valves may be used… a POSA would find it obvious to use a rotary-type three-way valve… because a rotary three-way valve is readily available, is mechanically simple, and is durable."

Ex. [1035] (Brown Supp. Decl.) at ¶ 108

"…when using a rotary three-way valve, an off-off state necessarily occurs when the three-way valve rotates between the positions where the connecting channels are aligned to fluid and vacuum channels…"

Ex. [1035] (Brown Supp. Decl.) at ¶ 109

Paper 24 (Pet. Reply) at 22-24

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 106-109

# GROUNDS 2 & 5

*YANG-MULLINS-RUBENSTEIN*
*OFEK-MULLINS-RUBENSTEIN*

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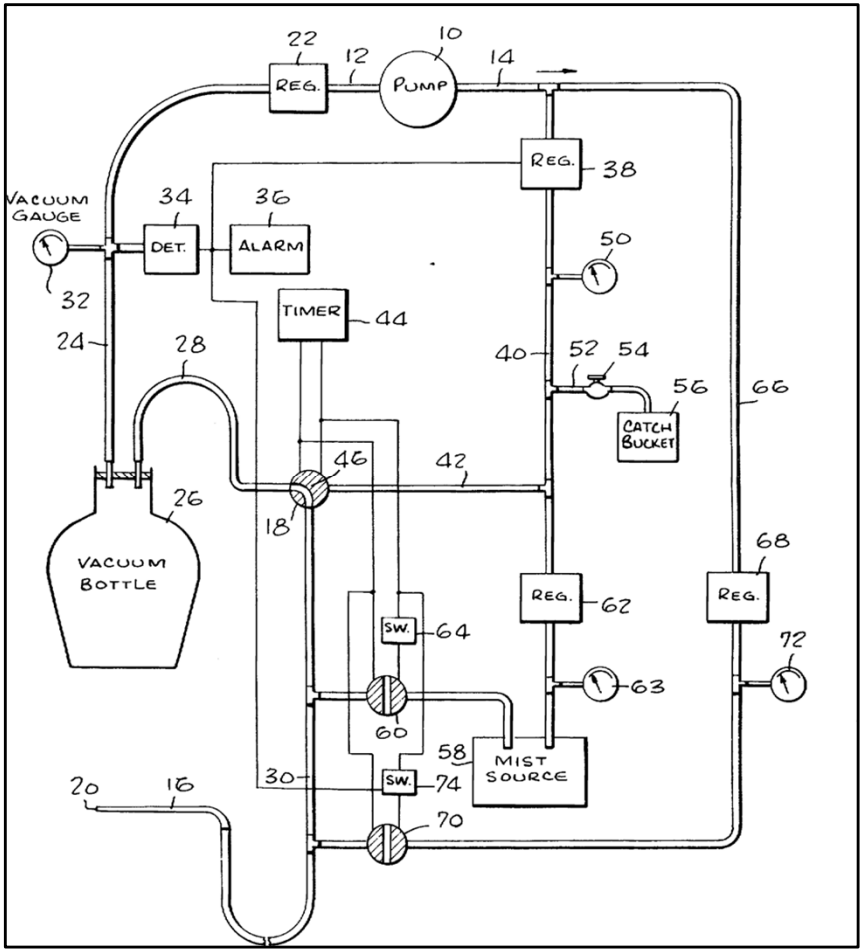
Claims 5-7, 18-20 – “off-off state”

BAKER BOTTS

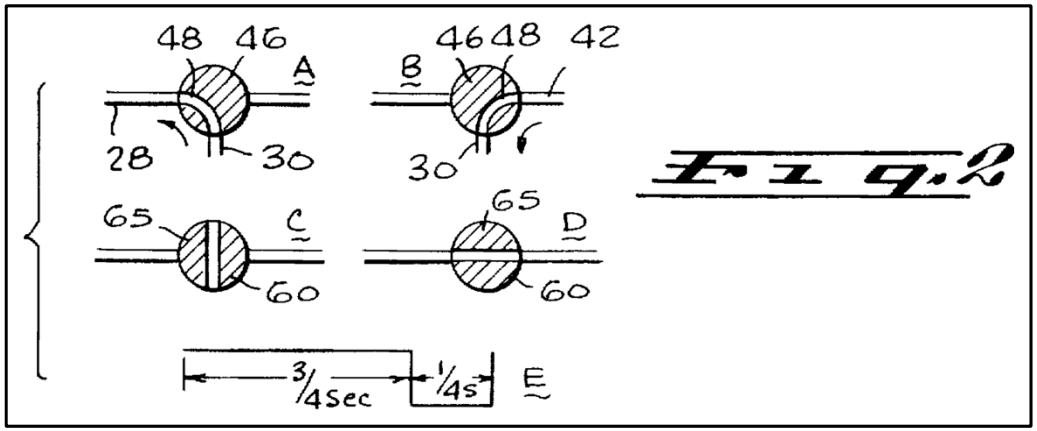
# Grounds 2 & 5 – Rubenstein

"the present invention concerns a pumping system wherein cyclical reversals of pumping pressure are applied to the catheter connected thereto to have negative and positive pressure cyclically alternated."

Ex. [1011] (Rubenstein) at 1:11-14




Ex. [1011] (Rubenstein) at Fig. 1




Ex. [1011] (Rubenstein) at Fig. 2

Paper 1 (Pet.) at 53-64, 103-106
Paper 24 (Pet. Reply) at 24-25
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113
Ex. [1011] (Rubenstein)

# Rubenstein – "Off-Off State"

"the subject pumping system includes 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 the fluid flow therethrough. A source of mist is connected to allow controlled injection of… fluid through the catheter."

Ex. [1011] (Rubenstein) at 2:1-8

"The negative pressure when applied to a catheter 16 via a valve 18 causes suction of fluids and other viscous materials situated at or in close proximity to a tip 20 of the catheter 16."

Ex. [1011] (Rubenstein) at 2:28-31

"Positive pressure provided at the outlet port 14 of the pump 10 may be provided to the catheter 16 via a pressure regulator 38, tubing 40 and 42, the valve 18, and the tubing 30, whenever the valve 18 is positioned to connect the tubing 42 to the tubing 30. Position control or switching of the valve 18 may be readily accomplished by use of a timer 44 having any conventional design."

Ex. [1011] (Rubenstein) at 2:56-63

Paper 1 (Pet.) at 53-64, 103-106
Paper 24 (Pet. Reply) at 24-25
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113
Ex. [1011] (Rubenstein)

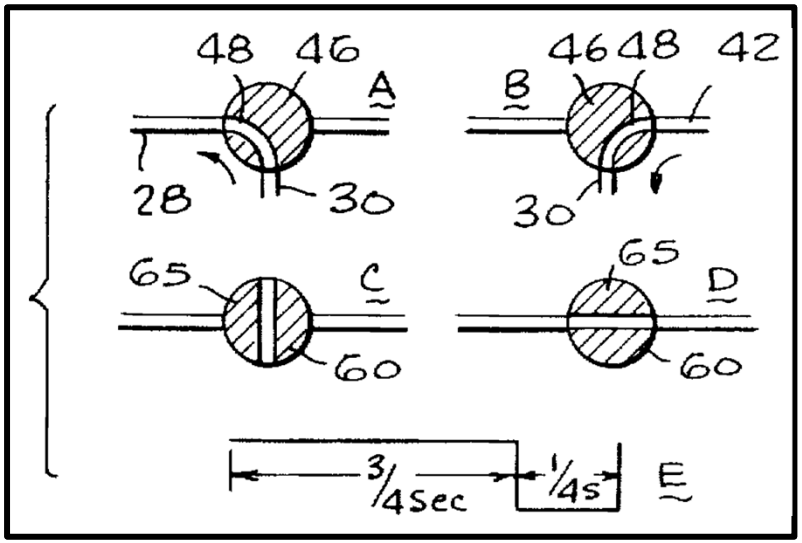
# Rubenstein – "Off-Off State"

"The valve 18 simply may involve a movable plug 46 having a connecting channel 48 and which 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 which would be connected to the standard parts of the valve 18. Referring to FIG. 2, diagram A illustrates the movable plug 46 of the valve 18 as being positioned to have the channel 48 permit fluid flow between the tubing 28 and the tubing 30 such that negative pressure is applied through the tubing 30 to the catheter 16. By comparison, 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 such that positive pressure is applied to the catheter 16 connected to the hose 30."

Ex. [1011] (Rubenstein) at 3:26-36

"Referring to FIG. 2, diagram C illustrates a movable plug 65 as being positioned to prohibit fluid flow through the valve 60. By comparison, diagram D illustrates the movable plug 65 as being positioned to allow fluid flow through the valve 60."

Ex. [1011] (Rubenstein) at 4:17-23




Ex. [1011] (Rubenstein) at Fig. 2

Paper 1 (Pet.) at 53-64, 103-106
Paper 24 (Pet. Reply) at 24-25
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113
Ex. [1011] (Rubenstein)

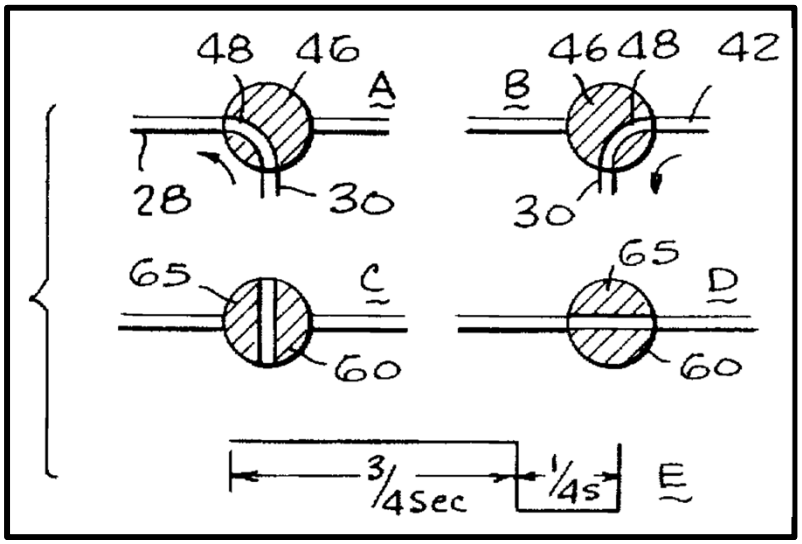
# Rubenstein – "Off-Off State"

"Referring once again to FIG. 1, the valve 60 is connected to be controlled by the timer 44 when electrically connected thereto via a switch 64. Accordingly, the valve 60 is operated, when actuated, in synchronization with the valve 46 such that the mist source 58 is connected to the tubing 30 via the valve 60 only during blowing periods when positive pressure is being provided to the catheter 16."

Ex. [1011] (Rubenstein) at 4:24-31

"Any time periods can be employed for the periods of suction and blowing as well as for the total cycle by adjustment of the timer 44… It has been found that suction periods of three-fourths of a second interrupted by blowing periods of one-fourth of a second as illustrated by waveform E of FIG. 2, is highly effective to have net suction accomplished by the suction unit using a vacuum of approximately twenty inches of mercury and a positive pressure of five pounds per square inch. However, any cycle and ratio of negative to positive pressure can be used to satisfy a particular need."

Ex. [1011] (Rubenstein) at 3:42-50




Ex. [1011] (Rubenstein) at Fig. 2

Paper 1 (Pet.) at 53-64, 103-106
Paper 24 (Pet. Reply) at 24-25
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113
Ex. [1011] (Rubenstein)

# Rubenstein – "Off-Off State"

"A POSA would find it obvious that Rubenstein's **rotary valves** must actually **rotate** between their different positions, and that it would be impossible for rotary valves to make an instantaneous transition that does not include any delay time, otherwise it would be contrary to basic physics and common sense. It is well-known, and explained in Rubenstein, that a rotary valve functions by rotating a connecting channel to different locations in order to connect and/or disconnect channels attached to the valve. Ex. 1011 (Rubenstein) at 3:21-26. Given the finite distance between the different positions, it requires a finite time period for the valve to rotate between different positions, which therefore, by definition, not instantaneous."

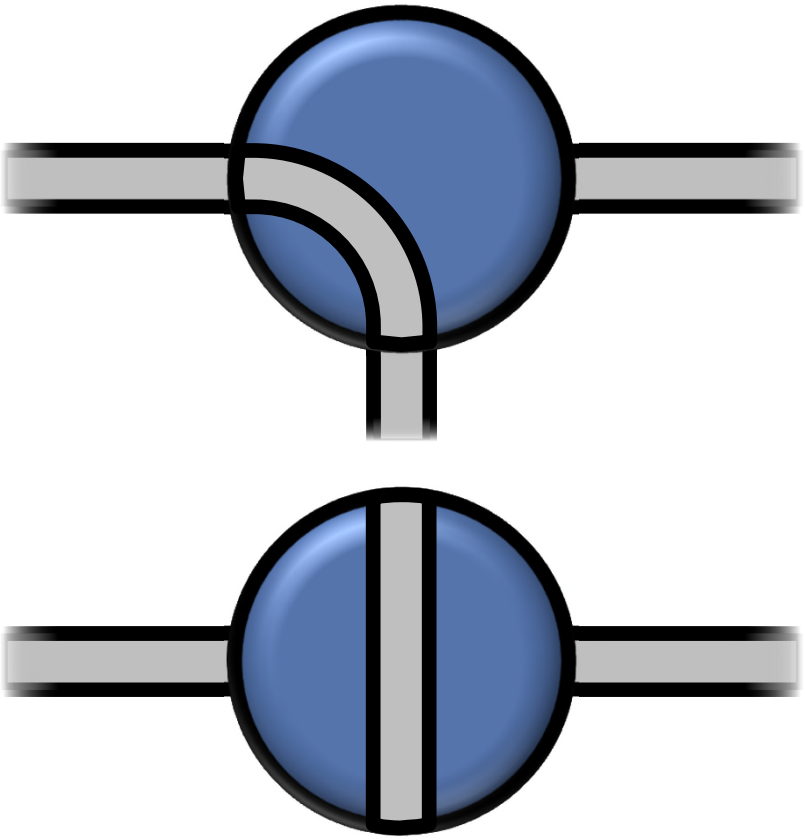
Ex. [1035] (Brown Supp. Decl.) at ¶ 323

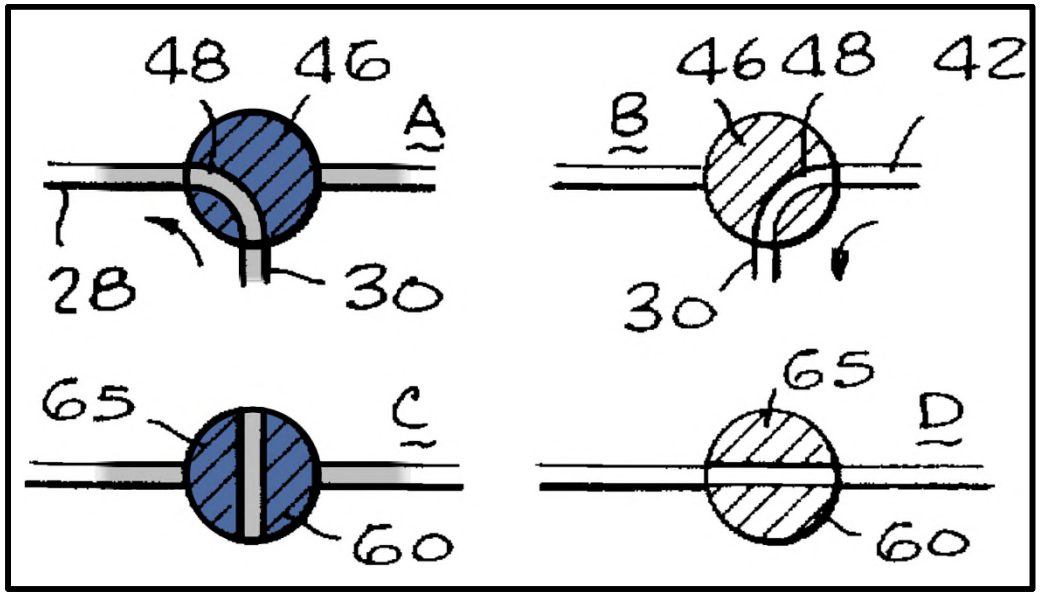
"Further, a POSA would find it obvious to modify the system in Yang to adopt the valves disclosed in Rubenstein, which would result in a double-closed state during serial or parallel operation of the incorporated valves. A POSA would also find it obvious to employ Rubenstein's time-controlled valve opening and closing 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 positive and negative pressure system in Rubenstein to achieve optimal clot aspiration within the Yang system."

Ex. [1035] (Brown Supp. Decl.) at ¶ 328

Paper 1 (Pet.) at 53-64, 103-106
Paper 24 (Pet. Reply) at 24-25
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113
Ex. [1011] (Rubenstein)

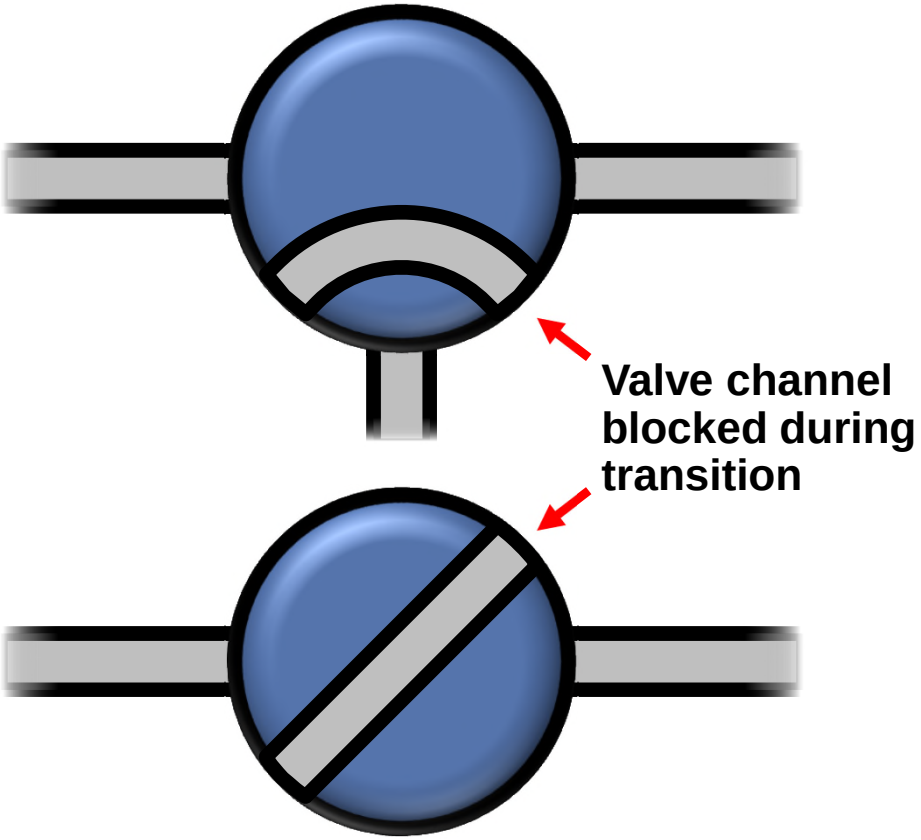
# U.S. 3,955,574 (“*Rubenstein*”)

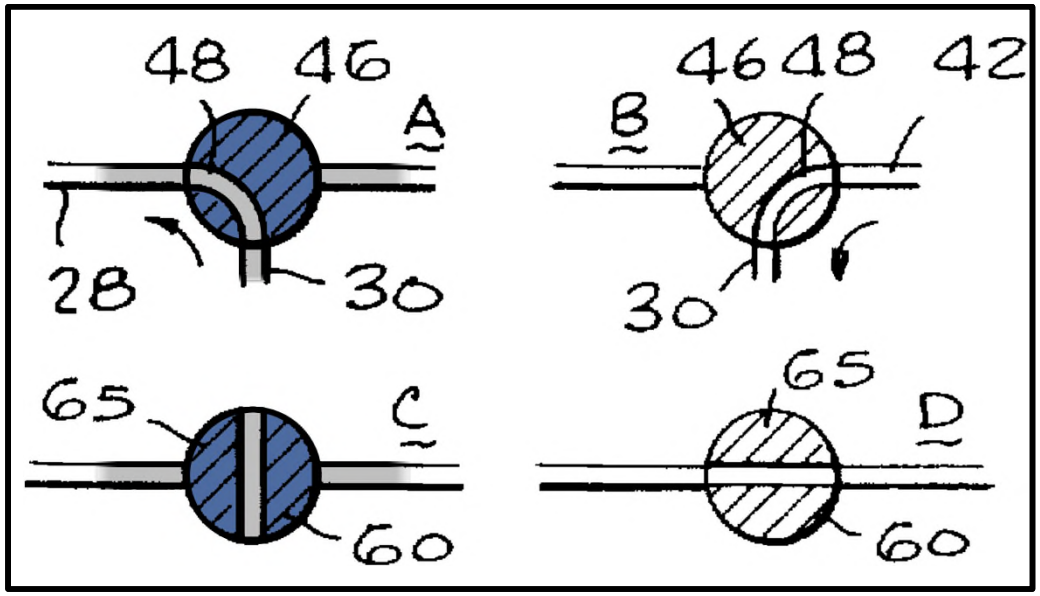





Paper 1 (Pet.) at 53-64, 103-106
Paper 24 (Pet. Reply) at 24-25
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113
Ex. [1011] (Rubenstein) at Fig. 2 (Annotated)

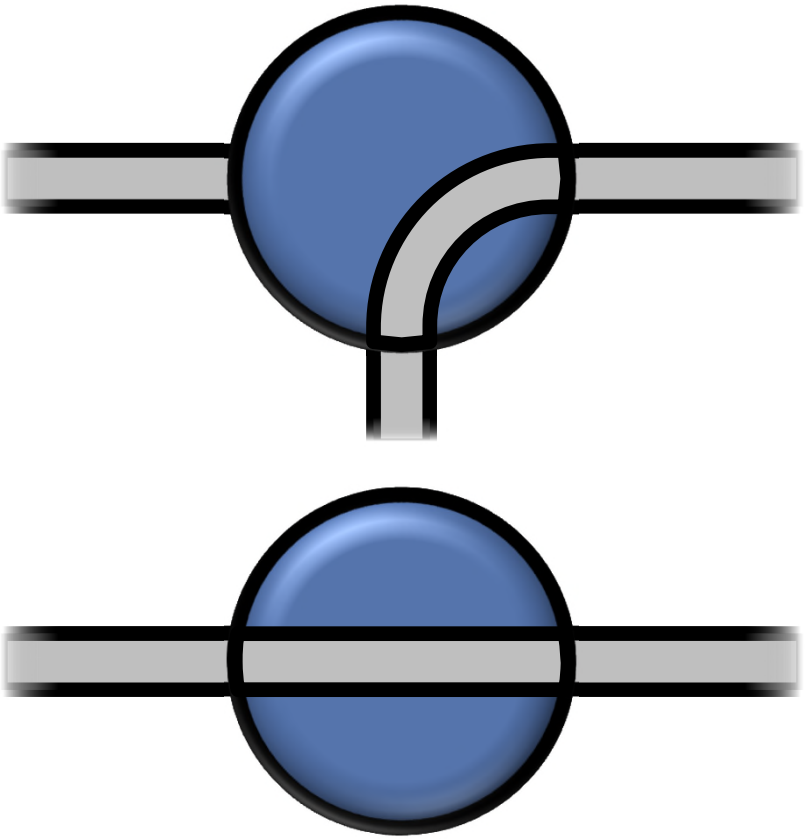
# U.S. 3,955,574 (“*Rubenstein*”)

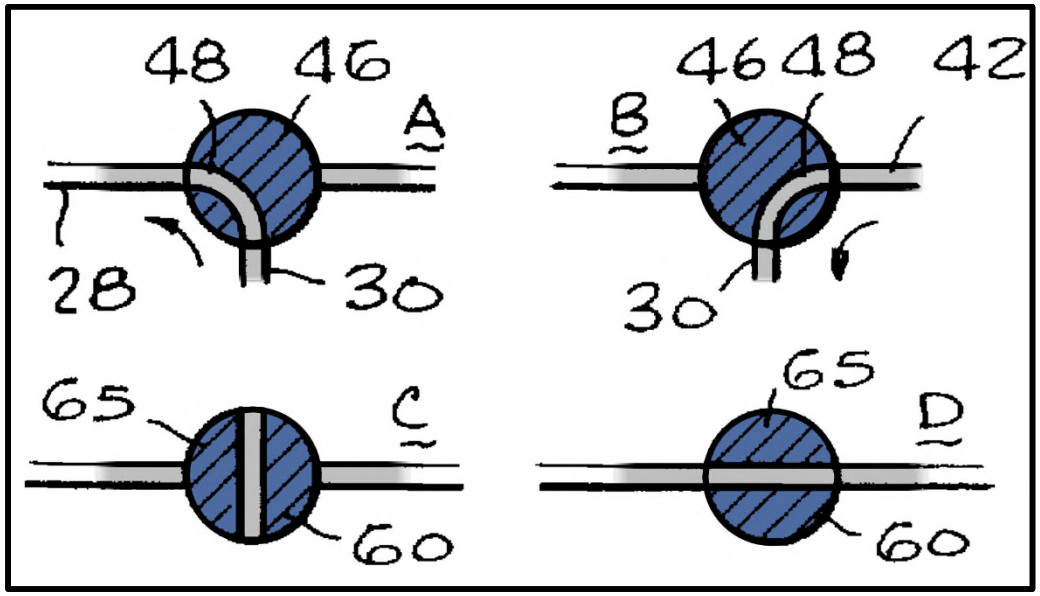



Paper 1 (Pet.) at 53-64, 103-106
Paper 24 (Pet. Reply) at 24-25
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113
Ex. [1011] (Rubenstein) at Fig. 2 (Annotated)

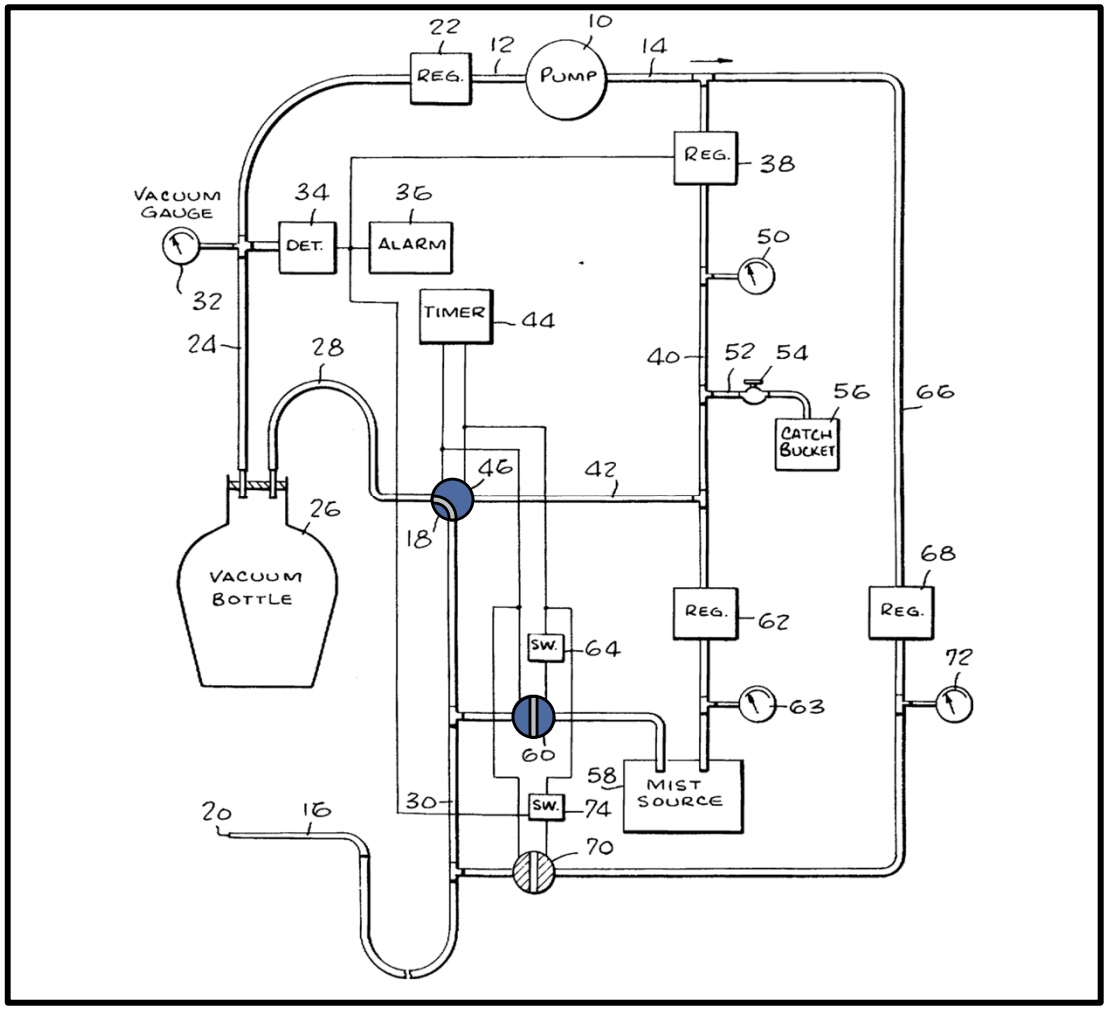
# U.S. 3,955,574 (“*Rubenstein*”)






Paper 1 (Pet.) at 53-64, 103-106
Paper 24 (Pet. Reply) at 24-25
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113
Ex. [1011] (Rubenstein) at Fig. 2 (Annotated)

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




Paper 1 (Pet.) at 53-64, 103-106

Paper 24 (Pet. Reply) at 24-25

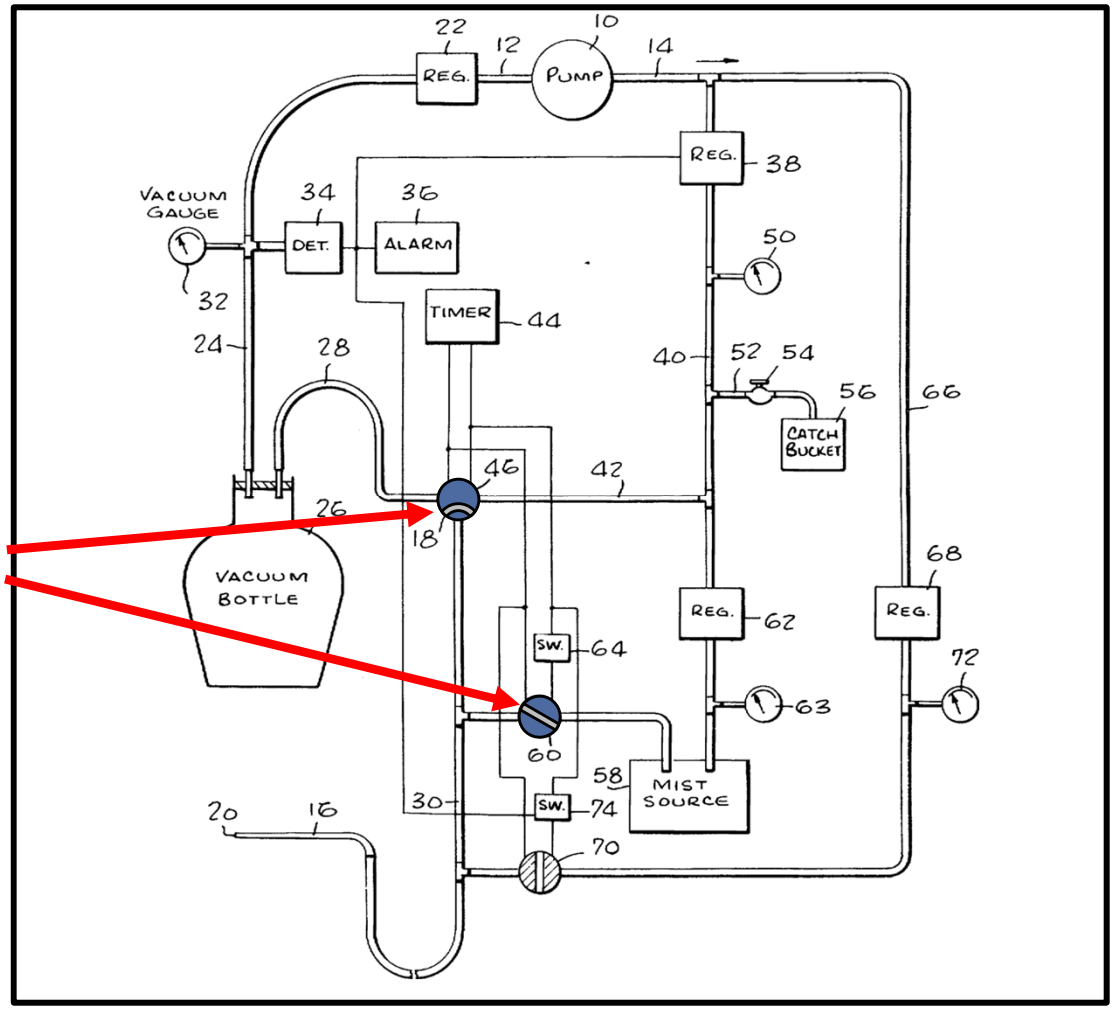
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113

Ex. [1011] (Rubenstein) at Fig. 1 (Annotated)

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

**Valve channel blocked during transition**




Paper 1 (Pet.) at 53-64, 103-106

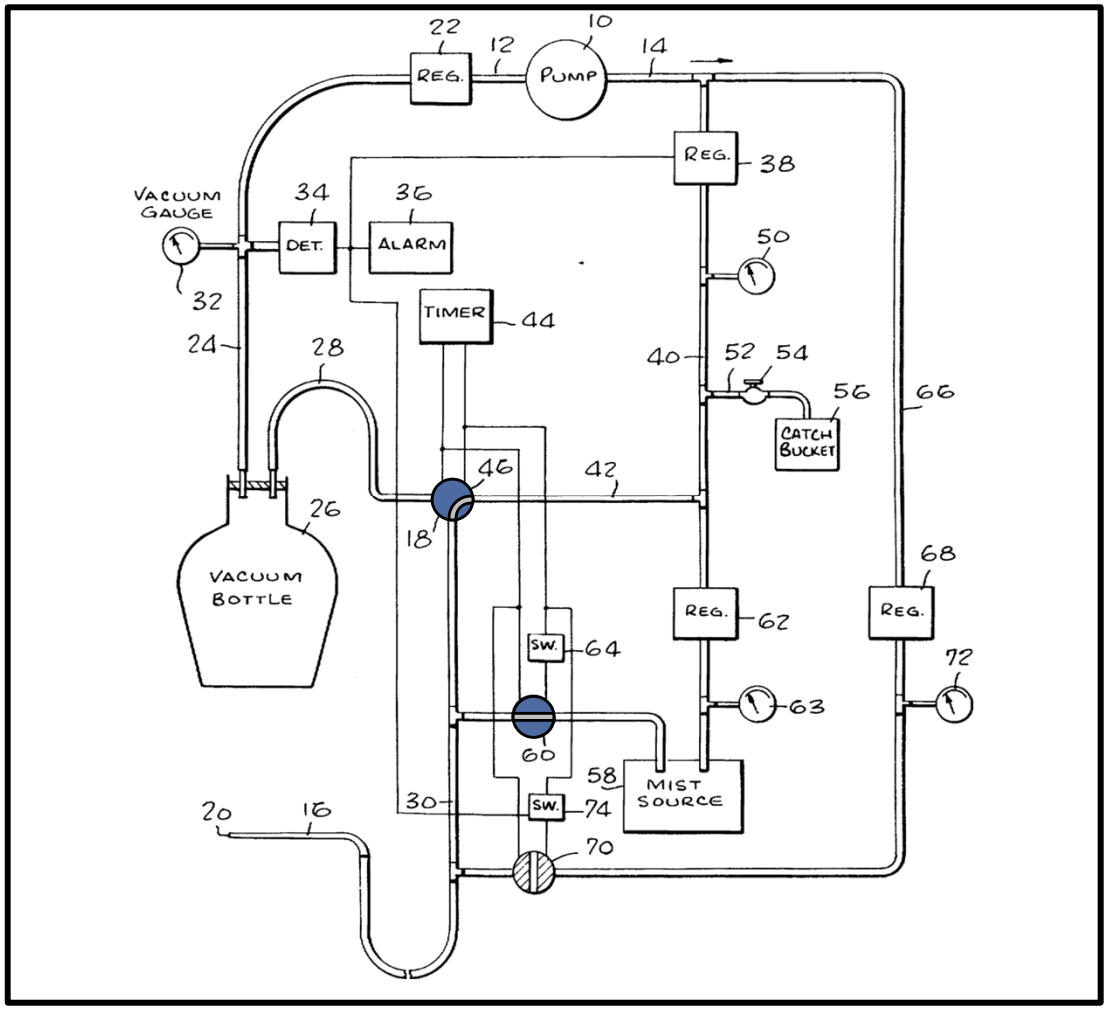
Paper 24 (Pet. Reply) at 24-25

Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113

Ex. [1011] (Rubenstein) at Fig. 1 (Annotated)

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




Paper 1 (Pet.) at 53-64, 103-106

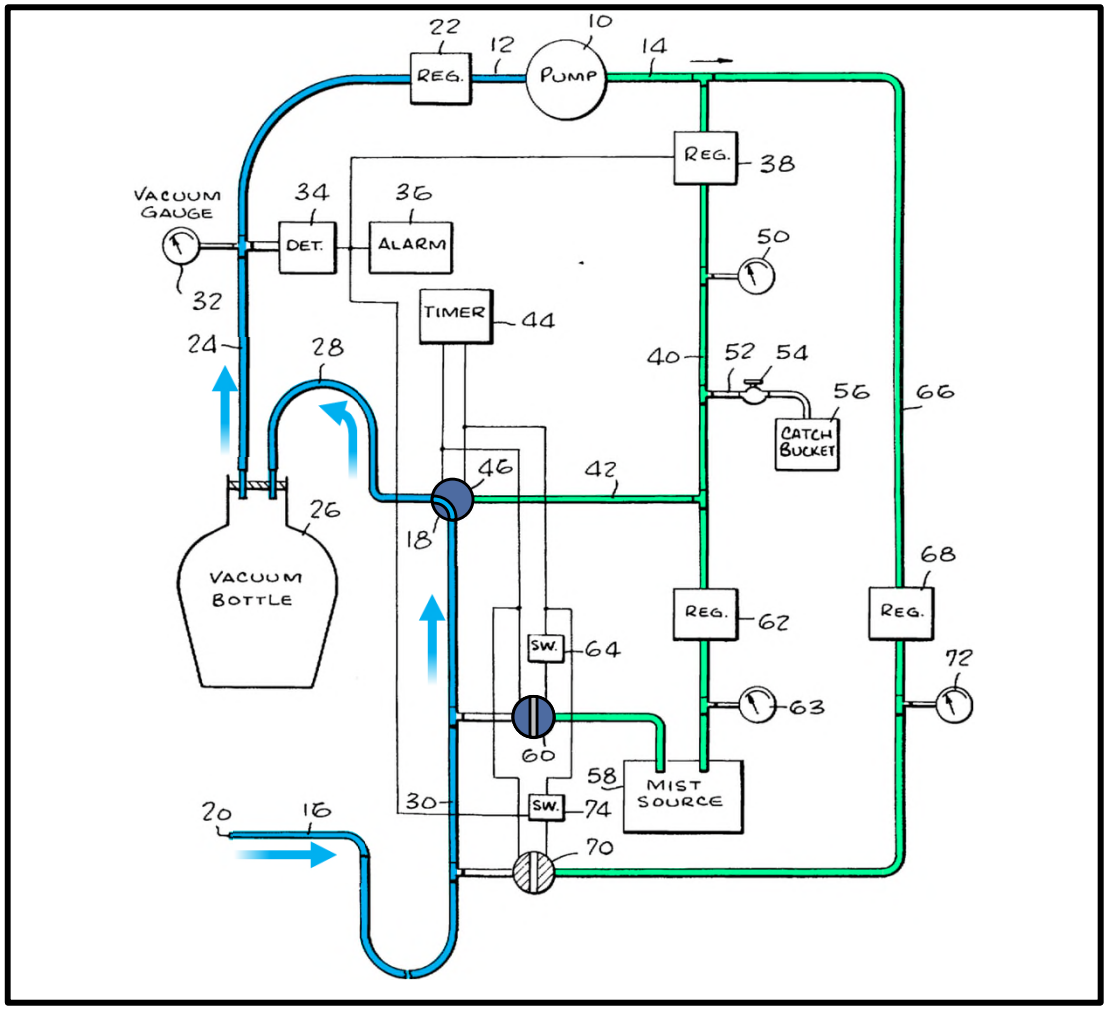
Paper 24 (Pet. Reply) at 24-25

Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113

Ex. [1011] (Rubenstein) at Fig. 1 (Annotated)

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




Paper 1 (Pet.) at 53-64, 103-106

Paper 24 (Pet. Reply) at 24-25

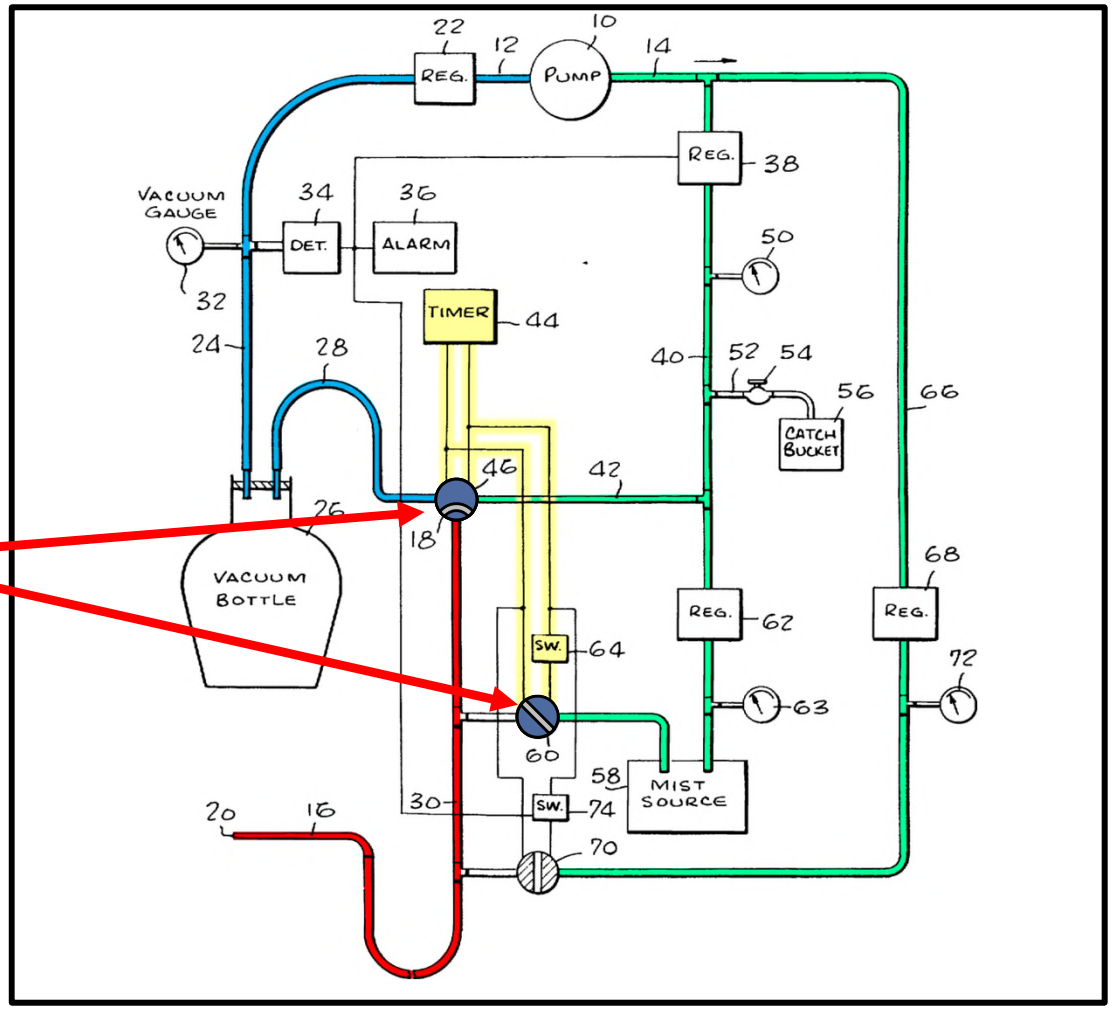
Ex. [1005] (Brown Decl.) at ¶¶ 92-93, 308-339, 525-542

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 110-113

Ex. [1011] (Rubenstein) at Fig. 1 (Annotated)

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

**Valve channel blocked during transition**

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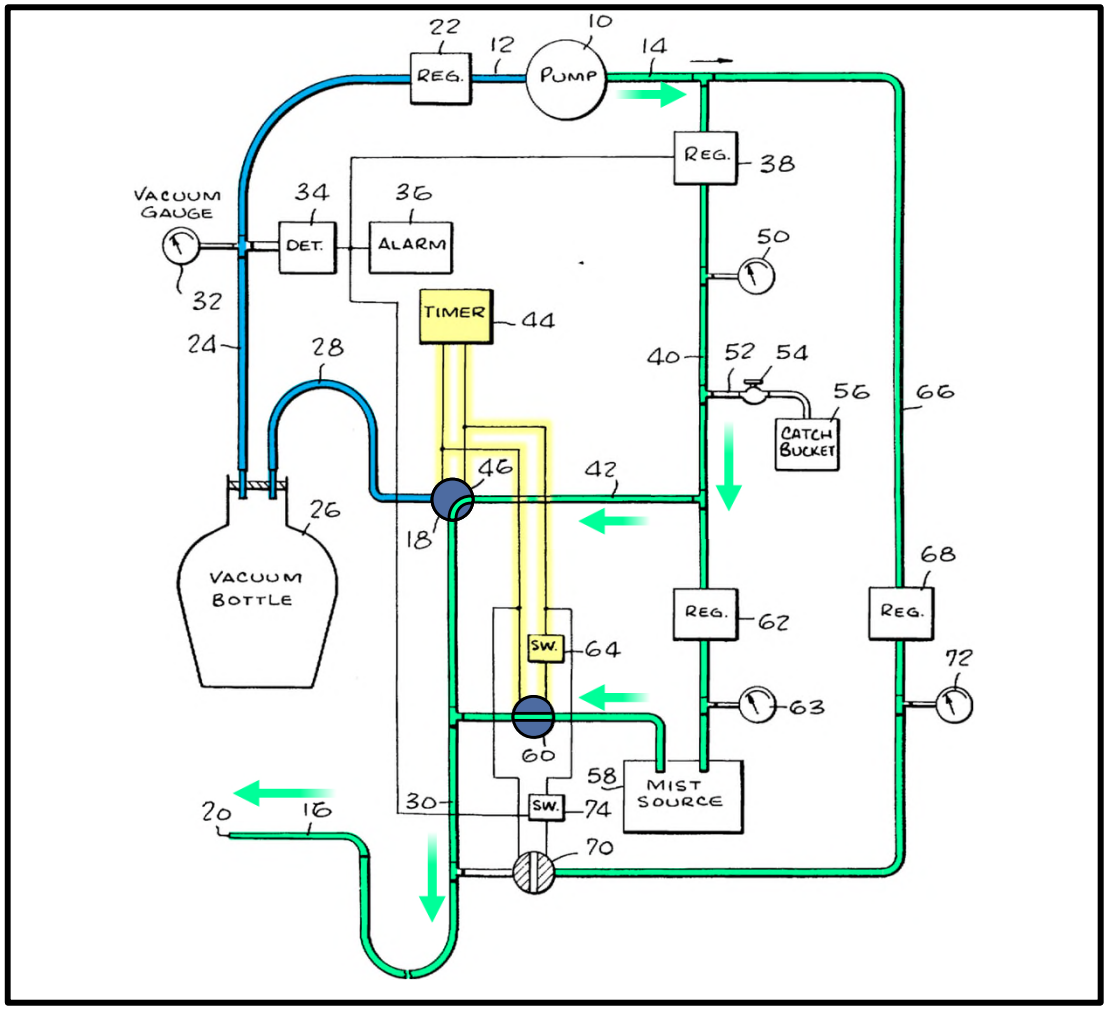


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Ex. [1011] (Rubenstein) at Fig. 1 (Annotated)

# SECONDARY CONSIDERATIONS

Objective Indicia Factors

Nexus to Specific Product

BAKER BOTTS

# Secondary Considerations

## PO fails to address or establish objective indicia of non-obviousness

Objective considerations of non-obviousness:

(1) **[PO fails to show]** a long-felt but unmet need in the prior art that was satisfied by the invention of the patent;
(2) **[Not addressed by PO]** failure of others where the invention succeeds;
(3) **[Not addressed by PO]** commercial success or lack of commercial success of processes covered by the patent;
(4) **[Not addressed by PO]** unexpected results achieved by the invention;
(5) **[Not addressed by PO]** praise of the invention by others skilled in the art;
(6) **[Not addressed by PO]** taking of licenses under the patent by others; and
(7) **[Not addressed by PO]** deliberate copying of the invention.

"PO relies solely on long-felt need, but fails to show how the claimed invention satisfied that purported need… As noted above and in the Petition, the prior art already taught the claimed techniques. The remaining factors weigh against a finding of non-obviousness."

Paper 24 (Pet. Reply) at 25

Paper 24 (Pet. Reply) at 25-26
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 114-121

# Secondary Considerations

## PO fails to address or establish objective indicia of non-obviousness

"In my opinion, Patent Owner failed to show any relationship between the purported need and the claimed invention. For instance, Patent Owner has not shown how the claimed invention within the '402 Patent satisfied a long but unmet need in the prior art. While Patent Owner may have demonstrated a need for an improved catheter system at the time of the '402 Patent, it provides nearly no explanation or evidence supporting how the purported invention of the '402 Patent actually improves clot aspiration."

Ex. [1035] (Brown Supp. Decl.) at ¶ 116

"As for the remaining factors considered regarding objective considerations of non-obviousness, it is my opinion that they would weigh against a finding of non-obviousness. To my knowledge, RapidPulse does not provide a commercial product that embodies the purported invention of the '402 Patent… commercialized products from competing companies such as Penumbra have had far greater commercial success with actual commercialized products than any potential products from RapidPulse that have never been made publicly available, even to this day, much less at any point closer to the relevant time of the challenged patent."

Ex. [1035] (Brown Supp. Decl.) at ¶ 117

Paper 24 (Pet. Reply) at 25-26

Ex. [1035] (Brown Supp. Decl.) at ¶¶ 114-118

# Secondary Considerations

## PO fails to demonstrate a nexus to the claimed invention

"To rely on the presumption of nexus PO must show that the "objective evidence is tied to a specific product" that embodies and is coextensive with the claimed invention. *See WBIB, LLC v, Kohler Co*, 829 F.3d 1317, 1329 (Fed. Cir. 2016)."

Paper 24 (Pet. Reply) at 25-26

"In my opinion, Patent Owner has not demonstrated a nexus between the unmet needs at the time of the '402 Patent for an improved thrombectomy device and the purported invention of the '402 Patent. It is my opinion that had Patent Owner's claimed invention had in fact met an unmet need in the industry, one would expect Patent Owner RapidPulse to have a commercially available and successful product. Further, Patent Owner fails to provide any actual evidence that the purported invention of the '402 Patent is responsible for any purported improvement in aspiration beyond stating that the use of a "predetermined cycle that produces positive pressure at the distal end" must be the "driving factor in improved FPE [(first pass effect)]." Paper 15 (PO Response) at 71."

Ex. [1035] (Brown Supp. Decl.) at ¶ 120

Paper 24 (Pet. Reply) at 25-26
Ex. [1035] (Brown Supp. Decl.) at ¶¶ 119-121

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