

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PENUMBRA, INC.
Petitioner

v.

RAPIDPULSE, INC.
Patent Owner

IPR2024-01261
U.S. Patent No. 11,406,402

**SUPPLEMENTAL DECLARATION OF BRIAN BROWN
FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,406,402**

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LIST OF EXHIBITS

1001	U.S. Patent No. 11,406,402 (“the ’402 Patent”)
1002	U.S. Provisional Application No. 62/701,086 (“Deville-Prov1”)
1003	U.S. Provisional Application No. 62/750,011 (“Deville-Prov2”)
1004	Prosecution File History of the ’402 Patent
1005	Expert Declaration of Brian Brown
1006	CV of Brian Brown
1007	U.S. Patent No. 10,322,230 (“Ofek”)
1008	U.S. Patent No. 11,197,977 (“Mullins”)
1009	Prosecution File History of U.S. Patent No. 11,197,977 (“Mullins”)
1009.1	U.S. Provisional Application No. 62/599,560 (“Mullins-Prov1”)
1009.2	U.S. Provisional Application No. 62/599,573 (“Mullins-Prov2”)
1009.3	U.S. Provisional Application No. 62/616,188 (“Mullins-Prov3”)
1010	International Application No. WO 2014/151209 A1 (“Grey”)
1011	U.S. Patent No. 3,955,574 (“Rubenstein”)
1012	U.S. Patent Publication No. 2017/0238953 A1 (“Yang”)
1013	U.S. Patent Publication No. 2012/0138833 A1 (“Matteo”)
1014	Patricia E. Thorpe & Francisco J. Osse, <i>Endovenous Management of Iliocaval Occlusion</i> , in THE VEIN BOOK, 2007 MECHANICAL THROMBECTOMY
1015	Dave Fornell, <i>Catheter-Based Clot Busting Therapies</i> , DIAGNOSTIC AND INTERVENTIONAL CARDIOLOGY (Feb. 4, 2013),

	https://www.dicardiology.com/article/catheter-based-clot-busting-therapies
1016	International Application No. WO 2018/019829 A1 (“Brady”)
1017	Gilles Rioufol, et al., <i>Large Tube Section Is the Key to Successful Coronary Thrombus Aspiration: Findings of a Standardized Bench Test</i> , 67 CATHETERIZATION & CARDIOVASCULAR INTERVENTIONS 254-257 (Dec. 5, 2005), https://onlinelibrary.wiley.com/doi/10.1002/ccd.20471
1018	Michael Haude, <i>Mechanical Thrombectomy Catheter Systems</i> , 2 INTERVENTIONAL CARDIOLOGY 58-60 (2007), https://www.icrjournal.com/articles/thrombectomy-catheter-systems
1019	U.S. Patent No. 3,086,528 (“Eichelman”)
1020	U.S. Patent No. 3,659,605 (“Sielaff”)
1021	U.S. Patent No. 3,042,042 (“Blanck”)
1022	Scott Simon, et al., <i>Exploring the Efficacy of Cyclic vs. Static Aspiration in a Cerebral Thrombectomy Model: An Initial Proof of Concept Study</i> , 6 J. NEUROINTERVENT. SURG. 677 (Dec. 14, 2014)
1023	Expert Declaration of Ian Ross, MD
1024	CV of Ian Ross, MD
1025	U.S. Patent Publication No. 2010/0204672 A1 (“Lockhart”)
1026	U.S. Patent No. 4,634,435 (“Ingraham”)
1027	Stephan A. Munich, et al., <i>Overview of Mechanical Thrombectomy Techniques</i> , 85 NEUROSURGERY S60-S67 (June 14, 2019) https://academic.oup.com/neurosurgery/article/85/suppl_1/S60/5512732
1028	U.S. Patent No. 10,531,883 (“the ’883 Patent”)

1029	Prosecution File History of the '883 Patent
1030	U.S. Patent No. 10,722,253 (“the '253 Patent”)
1031	Prosecution File History of the '253 Patent
1032	Troy D. Long, et al., <i>Novel Aspiration Catheter Design for Acute Stroke Thrombectomy</i> , 11 JOURNAL OF NEUROINTERVENTIONAL SURGERY 2 (July 30, 2018) https://jnls.bmj.com/content/11/2/190
1033	Richard E. Klabunde, <i>Viscosity of Blood</i> , CARDIOVASCULAR PHYSIOLOGY CONCEPTS (revised Dec. 27, 2022) https://cvphysiology.com/hemodynamics/h011
1034	U.S. Patent No. 9,820,761 (“Garrison”)
1035	[NEW] Supplemental Expert Declaration of Brian Brown
1036	[NEW] IPR2024-01261, Deposition Transcript of Brad Culbert Conducted August 3, 2025
1037	[NEW] U.S. Patent No. 11,197,683 (“Teigen’683”)
1038	[NEW] Compiled Claims for '402 Patent Family for All Issued Patents and Allowed Patent Applications

LIST OF APPENDICES

A.	Biographical Data and Reference Mapping for '402 Patent Family
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I. INTRODUCTION

I, Brian Brown, declare as follows:

1. My name is Brian Brown. I am an engineering consultant in the area of medical device design, development, manufacturing and intellectual property. I have prepared this declaration as an expert witness retained by Penumbra, Inc.

2. I have considered information from various sources in forming my opinions. I have reviewed and considered each of the exhibits listed above in the Table of Exhibits and papers filed in this proceeding in forming my opinions.

3. I have previously submitted a declaration, Ex. 1005 (Brown Decl.), in connection with Penumbra's Petition on August 5, 2024. I incorporate all of the information from my Original Declaration into this Supplemental Declaration, relating to Petitioner's Reply to Patent Owner's Response. I stand by all of my prior testimony in my Original Declaration. I submit this Supplemental Declaration to address the new arguments advanced in Patent Owner's submissions and the supporting declarations of Mr. Culbert.

4. Based on my review of the cited materials, the record evidence, and my technical knowledge and experience, I conclude that Patent Owner's arguments rest on a series of unfounded assumptions, technical mischaracterizations, and flawed reasoning. In particular, the record demonstrates that Mr. Culbert makes a number

of inaccurate technical assessments, misreads prior art references in ways that are inconsistent with their actual disclosures, makes admissions and concessions that directly undermine his conclusions, and fails to understand the analysis and reasoning articulated by Petitioner and agreed with by the Board in its Institution Decision. These deficiencies confirm that Patent Owner's arguments fail and that the claims of the '402 Patent are rendered obvious in view of the prior art.

II. CLAIM CONSTRUCTION

5. Despite Patent Owner's and Mr. Culbert's assertions that they purportedly just apply "plain and ordinary meaning" to all '402 claim terms, as I explain in detail below, many of their arguments effectively attempt to construe various claim terms as having a particular construction that is inconsistent with the actual ordinary and customary meaning of the claim language as would be understood by a POSA. Relatedly, for certain claim phrases, Patent Owner and Mr. Culbert instead attempt to simply eliminate portions of the claim language entirely. I address all of their apparent constructions and attempted omissions below subsequent to the reproduced discussion of my proposed construction.

A. Proposed Construction for Claim Term: "limited to a positive amount of exit flow" / "limiting... to a positive amount of exit flow"

6. Reproduced here is my previous discussion of the proposed construction for "limited to a positive amount of exit flow" and "limiting to a

positive amount of exit flow.” This construction and explanation is supported by, and consistent with, all of my subsequent discussion regarding Patent Owner’s and Mr. Culbert’s attempted constructions and omissions of the various claim terms.

7. The phrases “limited to a positive amount of exit flow” or “limiting to a positive amount of exit flow” appears in Claims 3, 4, 13, and 15. Claims 3, 4, 13, 16, and 17 additionally recite particular values for the maximum amount of exit flow permitted by the claims.

8. The plain language of this claim limitation appears ambiguous. The specification of the ’402 Patent only uses the term “exit flow” a single time (in contrast to “forward flow”), but does not describe, with particularity, what exactly “limiting” the amounts of “exit flow” entails:

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

Ex. 1001 (’402 Patent) at 4:50-54. 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. 1001 ('402 Patent) at 4:50-54, 24:36-25:26.

9. Accordingly, a POSA would have understood the term “[limited / limiting] to a positive amount of exit flow” to mean the maximum permitted amount of positive exit flow in the distal direction and would include no exit flow.

III. CLAIM LIMITATIONS: “CONTROL FLUID FLOW IN AND OUT” & “LIMITED TO A POSITIVE AMOUNT OF EXIT FLOW”

A. Patent Owner And Mr. Culbert Ignore The Operative Claim Limitations In “Control Fluid Flow In And Out” & “Limiting To A Positive Amount Of Exit Flow”

10. Patent Owner’s and Mr. Culbert’s apparent claim construction strategy is based on a fundamental mischaracterization. In both its briefing and through the testimony of Mr. Culbert, Patent Owner and Mr. Culbert ignore the operative language (i.e., verbs) in the claim limitations, and instead focus myopically on just the object (i.e., nouns) without any regard to the actual full claim limitation. That is, 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.”

11. Independent Claim 1 requires “controlling fluid flow in and out from the distal end.” Ex. 1001 (’402 Patent) at Claim 1, *see also* Dependent Claim 11 (“controls flow in and out from the distal end”). Dependent Claims 3, 4, 13, and 15 require “[limited / limiting] to a positive amount of exit flow.” Ex. 1001 (’402 Patent) at Claims 3, 4, 13, 15.

12. For the dependent claims, as discussed above, my position is that the claim phrase should be construed and understood as meaning “limiting to the maximum permitted amount of positive exit flow in the distal direction, including no exit flow.” Patent Owner and Mr. Culbert have not articulated a complete construction, but instead narrow in on the fragment “positive exit flow,” asserting that its plain meaning must be “a quantity greater than zero.” Paper 15 (PO Response) at 22; Ex. 2014 (Culbert Decl.) at ¶¶41-42. For the independent claim phrase, Patent Owner and Mr. Culbert again avoid a complete construction, but insists that because the phrase “flow out” is included, actual distal flow must be required. Paper 15 (PO Response) at 23-24; Ex. 2014 (Culbert Decl.) at ¶¶43.

13. These are misrepresentations of the claim limitations. The operative claim language is “limiting to” and “controlling...flow,” not simply “exit flow” in the abstract. By ignoring the operative verbs, Patent Owner converts the broad functional claim language chosen by the applicant into an exemplary outcome. That

is improper. As I have explained, and as a POSA would understand, the claim language is directed to the **action taken** by the controller — whether setting a maximum limit or controlling the flow — and not as a guarantee that distal flow must occur in every instance. *See, e.g.*, Ex. 2018 (Brown Depo) at 8:12-17:14; Ex. 1005 (Brown Decl.) at ¶¶ 80-82, 148-158, 185-198, 401-409, 428-435.

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.

B. A POSA Would Understand The Operative Meaning Of “Control” Of Fluid Flow

14. Patent Owner's position that “control fluid flow in and out” requires affirmative distal flow is incorrect. The plain language requires only that the

“controller... control fluid flow in and out.” A POSA would readily understand that to “control flow out” can be achieved by preventing flow out.

15. It is my opinion that 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.

16. Contemporaneous technical references confirm that this would be a POSA’s understanding. Grey explains that terms such as “control” and “controlling” do not necessarily imply causing an event to occur, but rather mean “having an influence or effect that is intended and/or predictable.” Ex. 1010 (Grey) at 6:13-25. Similarly, 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.

17. By contrast, Patent Owner’s position effectively rewrites the claim as though it required “a controller configured... to ~~control~~ cause fluid flow in and out from the distal end of the catheter.” That is not what the claims say, and I understand that rewriting the claims in this manner is improper.

C. Related Proceedings Confirm The Operative Meaning Of “Control” Of Fluid Flow

18. The context of a related proceeding also confirms this understanding. In IPR2022-00608 (“IPR #2”), Petitioner challenged the grandparent patent in the same patent family as the ’402 Patent, U.S. 10,722,253 (“RP-2” or “Deville’253”), in which the Board ultimately found all claims unpatentable. Ex. 2011 (’253 FWD) at 1, 66. In IPR #2, Petitioner’s invalidity grounds for the independent claims of Deville’253 were U.S. 11,197,683 (“Teigen’673” – a patent owned by Petitioner, submitted in this proceeding as Ex. 1037) in view of International Application WO 2014/151209 (“Grey”). Ex. 2011 (’253 FWD) at 6-7; Ex. 2008 (’253 Brown Decl.) at ¶¶ 112-152. Specifically, throughout the invalidity grounds for the independent claims of Deville’253, Petitioner expressly relied on the claim language of its own independent claims in its Teigen’673 Patent to demonstrate that the corresponding independent claim limitation in Deville’253 were unpatentable. *See, e.g.*, Ex. 2008 (’253 Brown Decl.) at ¶¶ 113, 116, 120, 125, 129, 135, 147. For example, in my analysis demonstrating the obviousness for each of the controller limitations (1[F] and 1[G]) of Deville’253, my declaration in IPR #2 (submitted by Patent Owner in this proceeding as Exhibit 2008) begins as follows:

(vii) 1[F] a controller configured to carry out a pre-determined pattern of opening and closing the vent and vacuum valves to change a level of vacuum at the distal end and,

135. Teigen discloses a controller configured to carry out a pre-determined pattern of opening and closing the vent and vacuum valves to change a level of vacuum at the distal end. ***Ex. 1007 at Claim 1 (“a controller configured to open and close the vacuum and vent valves in a predetermined cycle to change a level of vacuum at the distal end of the aspiration catheter”) ...***

Ex. 2008 (’253 Brown Decl.) at ¶ 135 (emphasis added).

(viii) 1[G] while changing the level of vacuum at the distal end, to substantially prevent forward flow of liquid at a distal end of the liquid column.

146. Teigen and the combination of Teigen in view of Grey and the knowledge of a POSA renders this claim limitation obvious.

147. Teigen discloses ***“a controller configured to... change a level of vacuum at the distal end of the aspiration catheter and control flow in and out from the distal end of the catheter.” Ex. 1007 at Claim 1***

Ex. 2008 (’253 Brown Decl.) at ¶¶ 146-147 (emphasis added).

19. Ultimately, in its Final Written Decision (submitted by Patent Owner in this proceeding as Exhibit 2011), the Board agreed with Petitioner’s arguments and found the independent claim of Deville’253 as rendered obvious by Teigen’673 in view of Grey.

Petitioner further describes how Teigen, in view of the knowledge of a person of ordinary skill, discloses “a controller configured to carry out a pre-determined pattern of opening and closing the vent and vacuum valves to change a level of vacuum at the distal end” (limitation [1f]). See Pet. 34–38 (citing Ex. 1005 ¶¶ 135–45; Ex. 1007, 11:3–27, 12:25–41, 14:63–18:25, 19:52–20:43 claim 1; Ex. 1008 ¶¶ 57, 61–67; Ex. 1009 ¶¶ 15, 59, 63–69, 77).

Petitioner also shows how Teigen in view of Grey teaches “while changing the level of vacuum at the distal end, to substantially prevent forward flow of liquid at a distal end of the liquid column” (limitation [1g]). Pet. 38–40.

Ex. 2011 (’253 FWD) at 33-34.

20. Turning back to the ’402 Patent, first looking at its relative timing, Teigen’683 issued on December 14, 2021, and then the ’402 patent was filed just under two months later, on February 11, 2022. Ex. 1001 (’402 Patent) at 1; Ex. 2008 (’253 Brown Decl.) at ¶ 86. Next looking at the claim language, the controller claim language of the ’402 independent claim essentially copies the same claim language as in Petitioner’s Teigen’683 patent:

a controller configured to open and close the vacuum and vent valves in a predetermined cycle to change a level of vacuum at the distal end of the aspiration catheter and control flow in and out from the distal end of the catheter.

Ex. 1037 (Teigen’683) at Claim 1.

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.

21. As noted in the above discussion of IPR #2, Petitioner’s invalidity grounds expressly relied upon its own Teigen’673 controller claim language to demonstrate the obviousness of the Deville’253 controller limitations, including the

Deville’253 controller limitation of “prevent forward flow.” Ex. 2008 (’253 Brown Decl.) at ¶¶ 135, 147. In my opinion, the invalidity findings in IPR #2 are directly relevant here because the disclosures of Teigen’683 and Grey, including the express reliance by Petitioner on Teigen’683’s own control language, were found to render obvious “prevent forward flow.”¹

22. 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.

23. Put differently, as a corollary to the table and discussion further below regarding the differences between operative claim language for distal flow, it is my opinion that if the table were expanded in view of IPR #2, it would logically include additional column(s) indicating which of those claim terms either (1) **requires** the ***prevention*** of distal flow (including Deville’253, Claim 1: “prevent forward flow”),

¹ I also understand that Patent Owner did not appeal any invalidity determinations in IPR #2 related to the independent claims of Deville’253.

or (2) at least **permits** the ***prevention*** of distal flow (including Teigen’683, Claim 1: “control flow in and out”), because, as discussed above, given that the “control” claim language was relied upon by Petitioner to find the “prevent” claim language obvious in view of Teigen’683-Grey, then “control flow in and out” must at least overlap and allow for “preventing forward flow,” and at minimum, could not be understood as never allowing for “preventing forward flow.” Thus, the apparent construction by Patent Owner and Mr. Culbert that “control” fluid flow in and out must always require distal flow out, and can never just prevent distal flow out, cannot be correct.

24. In sum, for all of the reasons discussed above, the operative meaning of “control” is simply its ordinary and customary meaning, and therefore just requires controlling the fluid flow, which can include controlling the fluid flow by preventing distal flow out.

D. A POSA Would Agree With The Operative Construction Of “Limiting” Of Exit Flow

25. The same logic applies to the “limiting” claim terms. Patent Owner again isolates “positive exit flow” and asserts that because the claim recites the object of the phrase, “a positive amount of exit flow,” that actual exit flow must always occur. But the operative limitation is “limiting... to a positive amount of exit flow.”

26. 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.

27. 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.

28. 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. 1001 (’402 Patent) at 44:46-45:2 (“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.”). Therefore Claims 3-4, 14, and 16-17 that each require specific amounts of exit flow can only be “limits,” because when cycling, the exit flow will be zero when corked.

29. Additionally, the deficiency of the apparent construction proposed by Patent Owner and Mr. Culbert for these claims — that some minimum amount of exit flow is required — is made further evident by Mr. Culbert’s testimony during deposition, where he (1) admitted that he does not know or have an opinion on what actual minimum value of distal flow is required to satisfy the claims, (2) stated that there must be some unknown or unknowable rounding convention used to evaluate whether the claims are satisfied, and (3) could not articulate what “non-zero” numerically even means, despite that being the basis of his apparent construction.

Q. So to satisfy Claim 4, if the exit -- if the positive amount of exit flow were, let’s say, .05 milliliters, is it your opinion that that would not satisfy Claim 4?

...

A. I haven't looked through the spec to deal with rounding convention, how do you round -- for rounding. Because your significant figures are 0.1. Now you're adding a significant figure, which changes the context.

Q. Okay. Let's go with 0.04. How about that?

A. Same thing. You're adding significant figures. So you're actually going into a more graduated scale than what the patent states.

Q. So is there -- 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. Okay. If you haven't given an opinion on that, then how would you evaluate or give an opinion on the particular amount of positive -- or the particular positive amount of exit flow that would actually satisfy this claim or any other exit flow claim?

A. So it's above zero, so you have some flow. And it -- I don't believe I saw anywhere that I had to give an opinion that this item or whatever we're -- give an opinion that this is .01. So it has to be approximately .1 -- in a range of .1 to .5, which are both positive numbers above zero.

Q. Okay. And what is the smallest amount of positive -- 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.

Q. And what does "not zero" mean in the context of rounding that you mentioned earlier?

A. Again, everybody can -- handles rounding slightly differently. There's many factors involved, and I haven't analyzed it in detail.

Q. Okay. But how would you handle it?

A. It depends. I don't know, and I haven't given an opinion. I'm not prepared right now to give an opinion.

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

30. Finally, Patent Owner's approach effectively rewrites the claim to require exit flow, transforming the limitation into "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~~ causes a positive amount of exit flow." That is not what the claims say, and I understand that rewriting the claims in this manner is improper.

E. Patent Owner's Claim Language Consistently Demonstrates The Operative Meaning Of Its Various Distal Flow Claim Limitations

31. Additionally, Patent Owner's '402 patent family demonstrates the consistent use of different claim language for distal end flow across the entire patent

family. Those claims fall into distinct operative categories with respect to distal flow: (1) flow is prevented; (2) flow is permitted; (3) flow is permitted but capped; or (4) flow is required. The Applicant carefully drafted its claims to reflect these different operative meanings. The '402 claims that Patent Owner and Mr. Culbert present arguments for fall under categories (2) (“control”) and (3) (“limited”). The arguments made by Patent Owner and Mr. Culbert improperly attempt to move all of those claims into category (4).

32. The following table² of examples throughout the issued/allowed patents in this patent family demonstrates this consistency:

² The different '402 Patent family members identified in this table are referenced as “RP-#” for simplicity and convenience, and the number for each member corresponds to the order of the family member’s filing date relative to the other family members (according to public records). Appendix A included with my declaration provides additional bio data and mapping for the '402 Patent Family. Exhibit 1038 is a compilation of excerpts from the public records for the '402 Patent family that compiles (for convenience to the Board and parties) the issued/allowed claims for all members of the family, along with other relevant identifying information (e.g., patent cover pages; Notices of Allowance).

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”

33. I am informed that when patentees use different words, there is a presumption that the patentee intended a different scope, and that this presumption applies across related patents. I have also been informed that this presumption applies across related patents. Patent Owner should not be permitted to redefine the meaning of the chosen claim terms in one member of the family simply to avoid prior art, when it has consistently used the same terms across the portfolio with a clear operative effect. Moreover, these other family members show that the

Applicant knew how to recite the requirement of positive exit flow when that was its intent.

34. Put differently, by selecting different verbs, the Applicant clearly claimed separate states of distal flow, and those different verbs should not be conflated to be interchangeable synonyms. For example, when the Applicant chose the expansive “control” term, they chose to permit distal flow. However, when distal flow was to be required, the Applicant chose narrow language such as “cause” or “occur.”

F. The EP Opposition Is Consistent With The Operative Meanings In All Prior And Current Proceedings

35. I understand that Patent Owner filed a motion in this proceeding to submit an EP Opposition filed against an EP patent, EP 3,823,686 B1 (“RP-EP1”), which is also in the ’402 Patent family. I also understand that Patent Owner appears to intend to argue that Petitioner’s positions in the European opposition against RP-EP1 allegedly contradict its arguments here. Paper 19 (PO Mot.) at 2-4. I disagree that any such contradiction exists. I have reviewed the operative controller claim language in the independent claim of RP-EP1, which recites “the controller (560) configured to cyclically open and close the vacuum valve (420) and the vent valve (440) to: change a level of vacuum at the distal end; and prevent forward flow of the distal portion out from the distal end during each cycle.” Ex. 1038 (RP Family

Claims) at RP-EP1, Claim 1. I recognize that this is the same claim language as the U.S. counterpart, U.S. 10,531,883 (“RP-1” or “Deville’883”), which the Board found invalid in IPR2021-01466 (“IPR #1”).

36. As an initial matter, Patent Owner and Mr. Culbert have themselves taken the express position that “prevent forward flow” limitations are “inapplicable” and “do not apply here” in this proceeding for the ’402 patent. Ex. 2014 (Culbert Decl.) at ¶ 43; Paper 15 (PO Response) at 23. Putting aside the question of whether that position has merit or not, the new position that Patent Owner appears to be planning to take, i.e., the opposite of their prior position, would be clearly contradictory.³

37. Additionally, the ’402 controller claim language is “control fluid flow in and out from the distal end of the catheter.” Ex. 1001 (’402 Patent) at Claim 1. As explained at various points above, to “control” flow simply requires the ordinary and customary meaning of “control” of the flow, which a POSA would understand as permitting, but not requiring, affirmative distal end flow. As also discussed above,

³ I also note that, even assuming for the sake of argument that various positions taken by Patent Owner and Mr. Culbert were true (e.g., required non-zero exit flow, specific minimum value for exit flow, etc.), the presumed arguments by Patent Owner regarding any purported contradictions in the EP Opposition would still fail given that “prevent forward flow” was construed as being within 6 microliters, and multiple ’402 dependent claims, which each depend on the “control” limitation in Claim 1, recite exit flow values well below 6 microliters.

in view of IPR #2, “control flow in and out” also does not preclude, and instead at least allows for “preventing forward flow.”

38. Yet Patent Owner’s motion and position regarding the EP opposition presumably attempts to now conflate the limitations and create an alleged contradiction where none exists. Paper 19 (PO Mot.) at 2-4. Not only is this a non-issue in view of Patent Owner’s and Mr. Culbert’s own unambiguous disclaimers as to the claim language of “prevent forward flow” and “control fluid flow” being unequivocally not the same, as discussed above, but also in view of the distinctions between Patent Owner’s chosen claim language across the patent family of the ’402 Patent, as discussed in the section above, as well as the relevance of the “control” and “prevent” controller claim language in IPR #2, as also discussed above.

39. This tactic is also disingenuous in view of the prior art references themselves. The prior art references at issue in this proceeding (which I’ve been informed are also relied upon in the EP Opposition) are not limited to a single embodiment. As I have explained, the prior art references disclose implementations that can either prevent forward flow or permit a small amount of exit flow. Ex. 1005 (Brown Decl.) at ¶¶ 153-157. For example, Mullins expressly describes embodiments where forward flow is prevented, alongside others where limited flow is permitted. Ex. 1008 (Mullins) at 26:43-27:57, Fig. 46-50.

40. Patent Owner’s attempt to reframe these distinctions as contradictions, by disregarding the fact that the prior art discloses multiple embodiments that can either prevent forward flow or permit distal flow out, is especially misplaced because Patent Owner’s own disclosures expressly describe certain embodiments that require forward flow and others that expressly prevent forward flow. In fact, Patent Owner must recognize this fact given that it takes advantage of those different embodiments by claiming, in certain family members, claims that “prevent” distal flow out, while in other family members, actually require distal flow out (e.g., “cause” or “occur”). *See, e.g.*, Ex. 1038 at RP1, Claim 1; RP5, Claim 1; RP14, Claim 1. Patent Owner cannot hold Petitioner and the prior art references to an artificial standard it does not follow itself.

G. The Prior Art Discloses “Control” Fluid Flow In And Out

41. Patent Owner and Mr. Culbert’s arguments rest on the incorrect premise that the cited prior art does not disclose “control” of distal fluid flow because it does not require actual distal outflow. That premise is incorrect under both the claim language and the prior art.

42. As discussed above, a POSA would understand the operative claim term “control” as not requiring affirmative action to cause flow, but rather encompassing the ability to influence or prevent it. A perfect example of how a

POSA would understand this term is as discussed in the Grey reference (Ex. 1010), which clearly articulates that a POSA would understand that “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 9:13-25. A POSA would thus understand “control” to include preventing distal flow entirely.

43. For all of the reasons discussed in my initial declaration and in this declaration (including all of the above discussion), the prior art discloses the independent claim limitation of “**control** fluid flow in and out.”

44. Furthermore, to the extent that this independent claim limitation were to be improperly interpreted under the apparent proposed construction by Patent Owner and Mr. Culbert as having required distal end flow outwards, this is also disclosed or rendered obvious by the prior art. This is the case for all of the reasons discussed here and in my initial declaration (see Ex. 1005 at ¶¶ 148-158, 185-198, 401-409, 428-435).

45. 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.” Ex. 1012 (Yang) at ¶ [0108]. Yang also describes generating “vibrations or shock waves... at the distal end of the catheter.” Ex. 1012 (Yang) at ¶ [0135]. 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. Ex. 1012 (Yang) at ¶ [0168]. 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.

46. 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.” Ex. 1007 (Ofek) at 2:56-3:2, 3:43-60, 4:21-44. 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. Ex. 1007 (Ofek) at 3:43-4:20. 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.

47. As another example, Mullins discloses controlling fluid at the distal end of a catheter. Ex. 1008 (Mullins) at 3:46-65 (“We also describe methods of use of an aspiration system.... 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.” Mullins additionally illustrates how the controller uses positive and negative pressure to control the flow of clot and fluid in and out at the distal tip of the catheter. Ex. 1008 (Mullins) at 26:43-49 (“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.”), 27:2-24 (“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”). This is also operative “control” of fluid flow in and out in Mullins under the proper ordinary meaning of the claims, including controlling, in some, but not all, of Mullins’ embodiments, cyclical ingesting and expelling of some amount of clot, which would be understood as controlling flow in and out under Mr. Culbert’s improper construction.

48. Therefore, it is my opinion that each of these references, either individually or in combination, disclose the independent claim limitation of “**control** fluid flow in and out.”

H. The Prior Art Discloses “Limiting” The Amount Of Exit Flow

49. The dependent claims recite “limiting...to a positive amount of exit flow.” Properly construed, this limitation sets a maximum permitted limit of distal flow out, including zero. Yang, Ofek, and Mullins each disclose this limitation.

50. For all of the reasons discussed in my initial declaration and in this declaration (including all of the above discussion), the prior art discloses the dependent claim limitation of “**limiting to** a positive amount of exit flow.”

51. Furthermore, to the extent that these dependent claim limitations were to be improperly interpreted under the apparent proposed construction by Patent Owner and Mr. Culbert, as not just capping the maximum permitted limit of distal flow out, but as also requiring some minimum permitted limit of distal flow outwards, this is also disclosed or rendered obvious by the prior art. This is the case for all of the reasons discussed here and in my initial declaration (*see* Ex. 1005 (Brown Decl.) at ¶¶ 185-198, 428-435).

52. As further discussed in the preceding section and in my previous declaration, both Yang and Ofek include certain disclosure in some embodiments that could be understood or obvious as controlling flow distal flow out. This is particularly true with regard to being obvious in view of a combination with Mullins. Ex. 1005 (Brown Decl.) at ¶¶ 185-198, 428-435.

53. 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. Ex. 1005 (Brown Decl.) at ¶¶ 190. 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. 1005 (Brown Decl.) at ¶¶ 190.

54. 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. 1005 (Brown Decl.) at ¶¶ 431.

55. As an even more pertinent example, Mullins provides clear disclosure of "limiting." Mullins' controller is expressly configured to operate between upper and lower pressure limits to limit distal fluid displacement. For example, Mullins teaches that "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.

56. As another example, 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: “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 be 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.

57. Furthermore, to the extent that a required minimum amount of distal flow out were to be imported into this claim language, Mullins not only expressly describes such non-zero amount of distal flow out, but Mullins also provides clear visual disclosure of a positive amount of distal flow out in the figures (along with corresponding specification discussion), for example, as shown in FIG. 47, and specifically in the transition between FIG. 47(g) to 47(h) and the transition from FIG. 47(k) to 47(l). Ex. 1008 (Mullins) at 26:65-27:35, FIG. 47. 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.

58. As an additional point to address, I understand that in his deposition, Mr. Culbert is now apparently taking various new positions, particularly with regard to Mullins. Ex. 1036 (Culbert Depo) at 70:23-73:18. First, Mr. Culbert takes the position, as it relates to Mullins (with regard to the distal end flow visually shown in the transition from FIG. 47(g) to 47(h)), that any ’402 claim limitation involving distal flow out (to the extent it were to be required) would also not be satisfied if it is purely clot that is moving out from the distal end of the catheter, and that instead, it must actually involve blood or some other non-specified fluid that must also exit out from the distal end of the catheter.

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.

59. I further understand that Mr. Culbert also took the position during his deposition that in the clear disclosure of fragmented substance moving out of the

distal end in Mullins (with regard to the distal end flow visually shown in the transition from FIG. 47(k) to 47(l)), that such distal flow out would also fail to satisfy any '402 claim limitation involving distal flow out (again, to the extent it were to be required) because only the fragmented flow would be flowing out distally while any fluid between the fragments would only be flowing in the proximal direction from the blood vessel, or not at all.

Q. With regard to the earlier Mullins figures in 47G through 47I, you're agreeing that clot moves back out of the distal end; correct?

A. It moves towards it. It's hard to -- and some clot does appear to move out of it. Obviously, 47I, based on this figure, is unknown.

Q. Okay. But at least from 47G to 47H, some amount of clot moves through the distal end of the catheter; correct?

A. Correct.

Ex. 1036 (Culbert Depo) at 73:8-18.

Q. So if I understand correctly, you're saying that while -- for example, in 47L, when that pressure is at the high limit, that the clot and the clot pieces would be flowing out through the distal end. But am I understanding correctly that you're saying, at the same time the blood would be flowing inwards or not at all through the distal end, that there would not be blood flowing out?

A. ... So as you apply the positive pressure, you've got the positive pressure pushing on the clot, but you also have elastic forces trying to retract it back out. ... And so if the blood pressure there is greater than the high limit, then there will be no fluid flow coming out.

Ex. 1036 (Culbert Depo) at 70:23-72:1.

60. 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.

IV. CLAIM LIMITATION: “A POSITIVE AMOUNT OF EXIT FLOW FROM APPROXIMATELY [0.001 / 0.1] ML TO APPROXIMATELY [1.0 / 0.5] ML”

A. The Claimed Values Of Positive Exit Flow Are Merely Result-Effective Variables That Would Be Obvious From Routine Optimization

61. Patent Owner’s and Mr. Culbert’s apparent fallback argument for the exit flow claims is that the numerical ranges of claimed outflow values confer patentability. They do not. I understand that under current law, routine optimization of result-effective variables is obvious. Thus, regardless of how the exit flow claims

are construed or interpreted, the specific values recited in the claims are obvious because they are simply result-effective variables in relation to routine optimization.

62. I understand that it is proper to consider whether a parameter would have been recognized as result-effective, and that routine optimization of such parameters is normally obvious.

63. It is my opinion that the parameters at issue in the present case are exactly the type of parameters that a POSA would perform routine optimization on. The only “innovation” in the “exit flow” claims is adjusting valve timing to vary aspiration volumes — a basic engineering optimization step used when designing almost any physical system. Furthermore, the claimed “positive exit flow” volumes are routine optimization of valve timing and pressure limits in aspiration systems.

64. 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.

65. 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. 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.

66. Instead, Mr. Culbert merely focuses on critiquing the example values of exit flow that are calculated/hypothesized in my previous declaration. Ex. 2014 (Culbert Decl.) at ¶¶ 112-127. But Mr. Culbert misses the point of those example calculations. 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. 1005 (Brown Decl.) at ¶¶ 199-221, 281-283, 290-296, 436-442, 498-500, 507-513.

V. CLAIM LIMITATION: “PREDETERMINED CYCLE”

67. I understand that Patent Owner and Mr. Culbert also contend that the term “predetermined cycle” should be essentially construed as requiring a specific timing requirement that essentially adds in a negative limitation prohibiting sensor usage to tune system operation. Ex. 2014 (Culbert Decl.) at ¶¶ 60-82; Paper 15 (PO Response) at 24-31. 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.

68. The ’402 independent claim recites “a predetermined cycle to change a level of vacuum at the distal end of the catheter.” Ex. 1001 (’402 Patent) at Claim 1. 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.

69. As an initial point, Patent Owner and Mr. Culbert state that they are only applying the plain meaning of the claim terms. However, as just discussed, that plain meaning does not include any limitation regarding timing, sensors, or feedback. Reading in a requirement for precise timing or duration of each valve state would be inconsistent with the claim language and contrary to how a POSA would interpret the term. Yet, that is exactly what Patent Owner and Mr. Culbert are attempting to do by importing a rigid timing requirement or negative limitation prohibiting sensors adds words that are not present in the claim.

70. Further, a POSA would recognize that a “predetermined cycle” does not mandate a fixed duration for each event of the cycle. Instead, 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.

71. Further yet, the dependent claims of the '402 Patent also confirm that “predetermined cycle” simply requires that the “cycle” pertains to the opening and closing valve states that must be predetermined. For example, Claim 5 of the '402 Patent recites “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.” Ex. 1001 ('402 Patent) at Claim 5 . In the claim language of Claim 5, the “cycle” is expressly tied to what is being “repeated,” and specifically that the relevant part of what is being “repeated” in the “cycle” is the “off-off **state**,” which makes it further evident to a POSA that the claimed “cycle” in the '402 Patent plainly regards the opening and closing states of the valves.

72. This is also consistent with the disclosure of the '402 Patent in relation to the prior art, given that 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 (discussing controller use of data from “sensors” including “pressure measurement devices” to “time the valves properly”). 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.

73. The prosecution history also does not support Patent Owner's position. Patent Owner and Mr. Culbert place heavy reliance on a statement by the Examiner that the claims were allowable over the Garrison reference because Garrison "changed the cycle of opening and closing the valves based on feedback from sensors and is not a pre-determined pattern." Ex. 2014 (Culbert Decl.) at ¶¶ 39, 63-64; Ex. 1004 ('402 Patent History) at 86; Paper 15 (PO Response) at 6-7, 25-26. However, in response, the Applicant expressly declined to agree with the Examiner's reasons for allowance.⁴ Ex. 1004 ('402 History) at 29 ("Although Applicant agrees

⁴ I also agree with the Applicant's refusal to concede that the Examiner's characterizations of the terms of the claims and the prior art were correct. To the extent that the Examiner actually intended to allow the claims based on any (mistaken) perception of the claims as requiring a static timing requirement and precluding sensor-based feedback, and that the claims were allowable over Garrison because Garrison ¶ [0130] allegedly required sensor-based feedback, any such statements cannot be given any weight, at least because the very next paragraph of Garrison explicitly discloses an embodiment with static timing and no feedback. Ex. 2015 (Garrison) at ¶ [0114] ("In yet another aspiration source implementation, the aspiration source 600 provides a cyclic level of aspiration

with the Examiner's conclusion that these claims are allowable, Applicant notes that the claims may be allowable for reasons other than those identified by the Examiner and does not concede that the Examiner's characterizations of the terms of the claims and the prior art are correct."). I've also been informed that unilateral Examiner statements in a notice of allowance are not binding and do not control claim scope, and that it is the applicant, not the examiner, who must give up or disclaim subject matter. Thus, Patent Owner's and Mr. Culbert's reliance on the prosecution history is misplaced.

74. Further, each of the prior art references discloses a "predetermined cycle" of opening and closing their valves.

75. For example, Yang discloses predetermined cycles of opening and closing its valves. Ex. 1012 (Yang) at ¶¶ [0169]-[0170] ("FIGS. 25A–25C show a logical progression of the vacuum and release cycle as applied to the catheter 2510. ... 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

force, for example, an aspiration force that cycles between a high level of vacuum to a lower level of vacuum ***at a set frequency***"). Thus, consistent with the Applicant's disclaimer, I agree that any such statements by the Examiner would not be viewed as credible by a POSA, and should not be given any weight by the Board.

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.”); ¶ [0176] (“The components may be manipulated individually or in a synchronized manner using predetermined operating parameters (e.g., for synchronized aspiration, injection, and rotation).”).

76. Ofek similarly discloses predetermined patterns of opening and closing its valves. Ex. 1007 (Ofek) at 6:30-31 (“frequency of the impulses, or impulse frequency, can be set according to a predetermined pattern.”); 7:11-17 (“In light of the above, it is appreciated that in one embodiment, a method for providing patency to at the lumen(s) 14 the catheter assembly 10 comprises disposing a fluid in the lumen of the catheter tube 12 of the catheter; and 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.”); 8:38-49 (“In FIG. 10, a series of groups of impulses is shown, wherein groups of impulses are separated by rest

periods 286 of negative baseline pressure 284 to enable aspiration from the catheter 10 of any occlusions dislodged by the impulses, as discussed further above. In these and the other examples herein, note that the number of impulses in each group can vary according to user desire and/or a pre-set predetermined pattern...”).

77. Mullins similarly teaches repeated valve cycling in a predetermined sequence. Ex. 1008 (Mullins) at 27:54-65 (“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”); 26:43-49, FIG. 46 (“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.”); 27:54-67, FIG. 49 (“In one embodiment, the applied pressure signal incorporates an oscillation or “shake” signal... The addition of this oscillation is shown in the form of the state diagram in FIG. 49.”).

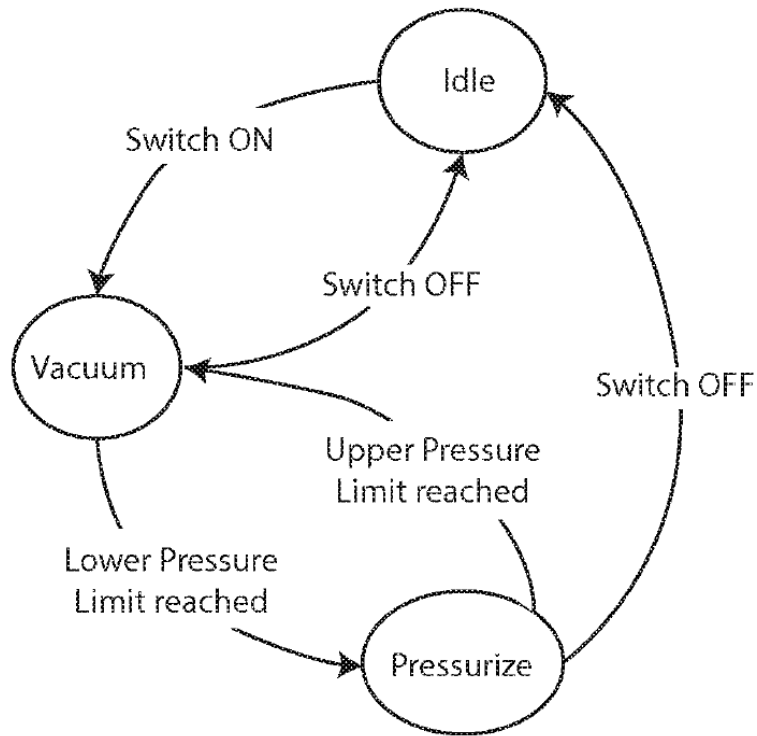


Fig.46

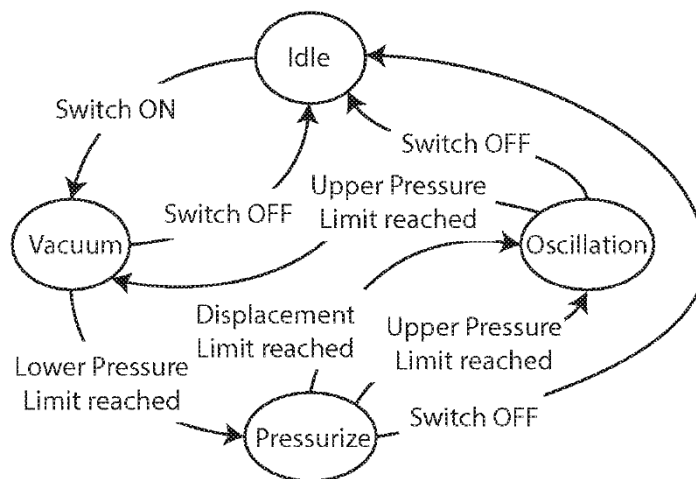


Fig.49

78. Moreover, even assuming for the sake of argument that “predetermined cycle” required Patent Owner’s and Mr. Culbert’s improper timing requirement, the prior art references also teach that possibility.

79. Yang expressly discloses specific timing intervals. Ex. 1012 (Yang) at ¶ [0168] (“Referring to FIGS. 25A-25C, experiments showed that an interrupted vacuum can help aspirating a corked clot... [with] each vacuum and release cycle. ... The period of each vacuum and release cycle may be equal to or greater than about 0.1, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 seconds.”); ¶ [0127] (“Pulsatile vacuum pressure aspirator 300 may comprise frequency modulator 316 for control of the solenoid valve 314. The frequency modulator 316 generates different electrical wave frequencies and forms, which are translated into the movement of the solenoid valve 314 by the valve controller 318. The wave forms generated from the frequency modulator 316 comprise sinusoidal, square, and sawtooth waves. The wave forms generated from the frequency modulator 316 typically have frequencies less than about 500 Hz, in some modes of operation less than about 20 Hz or less than about 5 Hz. The wave forms have duty cycles ranging from 0%, in which the solenoid valve 314 is fully shut, to 100%, in which the solenoid valve 314 is fully open.”)

80. Ofek similarly discloses predetermined timing. Ex. 1007 (Ofek) at 5:49-62 (“The controller 170 determines the number, frequency, rest periods, etc., of the impulses to be delivered by the patency device 30 to the catheter tube lumen(s) 14. The N.C. valve 140 is opened and close repeatedly at predetermined time intervals”); 6:61-63 (“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.”); 6:35-37 (“In one embodiment, the impulse frequency is set to match the resonant frequency of the catheter 10 itself, thus enabling improved propagation of the impulses distally through the lumen 14.”); 8:38-49 (“In FIG. 10, a series of groups of impulses is shown, wherein groups of impulses are separated by rest periods 286 of negative baseline pressure 284 to enable aspiration from the catheter 10 of any occlusions dislodged by the impulses, as discussed further above. In these and the other examples herein, note that the number of impulses in each group can vary according to user desire and/or a pre-set predetermined pattern, as can the pressure, frequency, etc. Note that frequency use of the patency device 30 can vary from continuously, hourly, daily, weekly, occasionally, etc., depending on whether the intended use is prophylactic or corrective, the amount of occlusion present, etc.”).

81. 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. *See, e.g.*, Ex. 1008 (Mullins) at 26:43-49 ("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."); 28:1-10 ("In one embodiment the shake signal may be initiated for a predefined number of cycles."); 28:49-52 ("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.").

82. 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). Ex. 1008 (Mullins) at 29:4-12 ("In one configuration,

the pump incorporates a peristaltic pump mechanism. This ensures that there is no blood contact with the pump parts.”). 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. 1008 (Mullins) at 28:59-64 (“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 be between 0.1 and 0.9, or more preferably between 0.4 and 0.9.”).

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

84. For all of these reasons, I disagree with Patent Owner's and Mr. Culbert's arguments regarding "predetermined cycle," including their attempt to redefine it as requiring a specific timing limitation, as well as all of the other arguments discussed above that are premised on their apparent construction. Thus, it is my opinion that the prior art references satisfy this claim limitation.

VI. CLAIMS: DEPENDENT METHOD CLAIMS 11-20

85. Following the Institution Decision, Patent Owner and Mr. Culbert appear to have introduced various new backup arguments that specifically seek to save the dependent method claims 11-20 from also being found obvious, presumably to address the system claims being obvious in view of the prior art. Ex. 2014 (Culbert Decl.) at ¶¶ 83-127; Paper 15 (PO Response) at 31-48.

86. As a preliminary point, Mr. Culbert’s roughly 15-page section (Ex. 2014 (Culbert Decl.) at ¶¶ 83-108) addressing the new method claim arguments jumps around between various disjointed points that intermingle, confuse, and/or conflate multiple purported issues, including, for example, (1) assertions that the prior art is apparently incapable of “positioning” a catheter against the clot to be aspirated/ingested, (2) arguments against the ability to combine prior art references, (3) the “preliminary cycle” issues discussed above in relation to Claim 1, (4) the “controlling” flow issues also discussed above in relation to Claim 1, (5) the “limiting to” positive amounts of exit flow already discussed above in relation to Claims 3 and 4, and (6) the “predetermined cycle” issues discussed above in relation to Claim 1. With that said, I disagree with all of Mr. Culbert’s method claim arguments, to the extent that they can be understood, for at least the reasons discussed above and below.

A. Patent Owner’s and Mr. Culbert’s Reframed Use Case Argument Against Ofek Still Fails

87. Patent Owner and Mr. Culbert appear to have reframed their use case arguments against the Ofek reference (*see* Ex. 2001 (Orig. Culbert Decl.) at ¶¶ 97-116) to now be premised on the dependent method claim term “positioning the distal end of the catheter at least proximate to thromboembolic material” in dependent method claim 11. Ex. 2014 (Culbert Decl.) at ¶¶ 106-108; Paper 15 (PO Response)

at 46-48. This argument fails for at least the same reasons that I describe for combining Ofek and Mullins in my previous declaration and for the reasons that the Board articulated in its Institution Decision, as well as the reasons discussed below. Ex. 1005 (Brown Decl.) at ¶¶ 355-362; Paper 7 (Inst. Dec.) at 33-37.

88. First, Mr. Culbert begins by asserting that “Petitioner and Mr. Brown contend that ‘***a central aspect***’ **of Ofek is** ‘positioning the distal end of the catheter next to the thrombus.’” Ex. 2014 (Culbert Decl.) at ¶ 107 (emphasis added). However, that (seemingly intentionally) misrepresents my actual testimony, which reads: “A POSA would know that ***a central aspect of performing a thrombectomy procedure is*** positioning the distal end of the catheter next to the thrombus. A POSA would know that navigating the distal portion of the thrombectomy device to the clot in the vasculature is equivalent to positioning the distal end of the catheter proximate to the thrombus.” Ex. 1005 (Orig. Brown Decl.) at ¶ 479 (emphasis added). I then continued by stating “To the extent that Ofek does not explicitly disclose positioning the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person, the combination of Ofek and Mullins renders it obvious. For the reasons discussed above (in greater detail) regarding Mullins in Ground 1, Claim [11-A], Mullins discloses positioning the catheter tip adjacent to the clot.” Ex.

1005 (Brown Decl.) at ¶¶ 480-481. Thus, Mr. Culbert’s attempted mischaracterization of “a central aspect” in my testimony fails.

89. Second, Mr. Culbert’s argument that Ofek couldn’t ever be positioned against a clot because “Ofek does not teach removing clots outside of the catheter lumen, because it only teaches removing thrombi that have formed within the catheter” is nonsensical. Ex. 2014 (Culbert Decl.) at ¶ 107. 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.

90. Third, Ofek affirmatively demonstrates functionality and operability consistent with the reasons stated for combining with Mullins in my previous declaration. For example, Ofek teaches that its patency device “provide[s] one or more relatively short-duration impulses...of high pressure fluid to the lumen of the catheter tube,” and that such impulses can “dislodge occlusions that may have formed.” Ex. 1007 (Ofek) at 4:21-44, 11:30-40. This is direct evidence that Ofek’s system can alternate between positive and negative pressures to successfully ingest clots and prevent clogging. The need to ingest and prevent clogging of thrombectomy catheters occurs when clot is drawn into the distal end of the catheter

and corks the lumen. The corked thrombus is within the lumen as taught by Ofek. Moreover, as I've discussed, and as the Board recognized, Ofek discloses using arterial catheters, explains that the catheter can be used for aspirating a thrombus at the distal end of the catheter, customizes pressure/vacuum cycles, and manipulates pressure impulses to ingest clots. Paper 7 (Inst. Dec.) at 33-34; Ex. 1007 (Ofek) at 2:38-3:2, 3:43-4:20, 8:38-49; Ex. 1005 (Orig. Brown Decl.) at ¶¶ 355-378, 401-409. In any case, beyond all of the reasons discussed above why the "positioning" argument by Patent Owner and Mr. Culbert fails for Ofek, positioning the catheter against the clot is clearly disclosed in Mullins FIGs. 47(c)-(f), as already explained above. *See, e.g.*, Ex. 1008 (Mullins) at FIG. 47.

91. Lastly, Patent Owner and Mr. Culbert appear to have generally abandoned their former use case arguments against Ofek for Claim 1 and the other system claims. 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. Ex. 2014 (Culbert Decl.) at ¶¶ 79-82; Paper 15 (PO Response) at 30-31. In which case, if there's no longer any use case-based argument being advanced for Claim 1 against combining Ofek and Mullins, and 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, despite not contesting that the combination discloses nearly everything in the aspiration thrombectomy system in Claim 1, including the claimed aspiration catheter and all of the claimed components, and which is already capable of performing aspiration thrombectomy (regardless of cycle timing or exit flow). 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.

92. Thus, for all of these reasons, I disagree with the new "positioning" argument by Patent Owner and Mr. Culbert.

B. Patent Owner's and Mr. Culbert's "Expectation of Success" Arguments Fail To Save The Dependent Method Claims

93. Patent Owner and Mr. Culbert also argue that a person of ordinary skill in the art ("POSA") would have lacked a "reasonable expectation of success" in combining Yang, Ofek, and Mullins. Ex. 2014 (Culbert Decl.) at ¶¶ 88-105; Paper 15 (PO Response) at 31-46. Specifically, Patent Owner and Mr. Culbert appear to rely on the more result-oriented claim language in Claim 11 to rehash versions of

their Claim 1 arguments, for both predetermined cycle and distal end flow, in the context of reasonable expectation of success.

94. First, both of 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.

95. Second, each reference affirmatively demonstrates operability consistent with Petitioner's combinations, and the state of the art at or before the time of the '402 Patent confirms that a POSA would have every reason to expect success. Aspiration thrombectomy techniques and valve-based flow regulation were well-known. Grey, for example, explains that "deliberate variations in the suction force/pressure" can be used to "control" and achieve an intended and predictable influence in aspirating a clot. Ex. 1010 (Grey) at 6:13-25. Adjusting valve timing and pressure to regulate distal flow in the prior art combinations is exactly the type of predictable engineering solution POSAs would have expected to work based on prior success in the prior art. Moreover, as discussed previously, the '402

independent claim recites the same controller claim language as was relied upon by Petitioner in IPR #2 from Teigen'683, and as also discussed above, Teigen'683 shares essentially the same relevant dates as the '402 Patent, which further demonstrates that the state of the art would indicate that a POSA would have a reasonable expectation of success.

96. Third, the brevity of Patent Owner's own disclosure in the '402 Patent undercuts some of the "expectation of success" arguments being made now by Patent Owner and Mr. Culbert. For example, the '402 patent specification recites particular end results of particular embodiments, such as, for example, "exemplary volumes" of outflow, but gives little or no explanation of how to achieve them. Ex. 1001 ('402 Patent) at 24:45-51. 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 with regard to the '402 Patent claims. Patent Owner cannot require more of the prior art than its own disclosure, and yet the prior art does teach more.

97. Finally, I understand that the "reasonable expectation of success" inquiry only requires a reasonable expectation and does not demand certainty. I also understand that it is enough if a POSA, in view of the prior art and ordinary skill, would expect the combination to work as intended, and that absolute predictability

is not required. Moreover, I understand that a finding of reasonable expectation of success can be implicit.

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

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

100. In sum, a POSA would have had a reasonable expectation of success in implementing and/or combining Yang-Mullins and Ofek-Mullins with regard to the '402 Patent claims. Thus, it is my opinion that the "expectation of success" arguments by Patent Owner and Mr. Culbert fail to save the dependent method claims from being rendered obvious.

VII. CLAIM LIMITATION: “OFF-OFF STATE IN WHICH THE VACUUM VALVE IS CLOSED WHILE THE VENT VALVE IS CLOSED”

A. Patent Owner Improperly Imputes Limitations Into the Claim Language

101. Claims 5-7 and 18-20 disclose an “off-off state” where the vacuum and vent valves are closed. 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. Further, Mr. Culbert testified that nowhere do the claims require that the “off-off state” persist for a certain amount of time.

Q. Got it. 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.

102. 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.

B. The Yang/Mullins Combination Discloses the “Off-Off State”

103. 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. 1005 (Brown Decl.) at ¶¶ 231-235; Paper 1 (Petition) at 45-46.

104. Furthermore, as discussed, Yang discloses **serial** operation of vacuum and vent valves and repeated valve cycles. See Ex. 1012 at ¶ [0170], FIGs. 25A-25C; Ex. 1005 (Brown Decl.) at ¶¶ 226-236, 228-229; Paper 1 (Petition) at 44. Therefore, Patent Owner's argument that Yang does not disclose serial operation of vacuum and vent valves is simply false. See Paper 15 (PO Response) at 59-60 ("instead of operating the valves in serial as Petitioner suggests, a POSA would only find it obvious to operate both valves simultaneously"); Ex. 2014 (Culbert Decl.) at ¶¶ 135-39.

105. As such, since Yang discloses serial valve operation and repeated valve cycles, it is my opinion that a POSA would understand that there would necessarily be an additional valve state depicting the transition from Figure 25C to 25A where the vent valve is closed before the vacuum valve is opened. Ex. 1012 (Yang) at FIGs. 2A-25C. Moreover, a POSA would consider it obvious to implement the transition with a state where the vent valve is closed before opening the vacuum valve for the reasons mentioned above. Thus, it is my opinion that Yang discloses and renders obvious the off-off state. Ex. 1005 (Brown Decl.) at ¶¶ 226-244.

C. The Ofek/Mullins Combination Discloses the “Off-Off State”

106. In my opinion, Ofek discloses serial valve operation. For example, Ofek discloses that “the normally open valve configured to close **upon** opening of the normally closed valve,” further indicating serial valve operation. Ex. 1007 (Ofek) at Cl. 8 (emphasis added). Ofek further discloses that “[d]uring each impulse when the [N.C.] valve 140 is opened, the N.O. valve 150 is shut so as to prevent impulse fluid from entering the N.O. valve and diverting to the syringe pump 162 instead of entering the catheter tube lumen 14 as desired.” Ex. 1007 (Ofek) at 5:55-59. As such, 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.

107. To the extent that Ofek does not explicitly disclose serial valve operation, as mentioned, 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. 1005 (Brown Decl.) at ¶¶ 448-450; Paper 1 (Petition) at 92-93.

108. Ofek additionally discloses the vacuum and vent valves can be combined into a single valve, such as a three-way valve. Ex. 1007 (Ofek) at 5:26-31; Ex. 1005 (Brown Decl.) at ¶ 451. However, while Ofek discloses the use of a three-way valve, it is my understanding that Ofek does not specify which types of three-way valves may be used. While multiple types of three-way valves exist, a POSA would find it obvious to use a rotary-type three-way valve. A POSA would find it obvious to use a rotary three-way valve because a rotary three-way valve is readily available, is mechanically simple, and is durable.

109. As discussed, 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, for example, as discussed regarding the three-way valve depicted in Rubenstein. *See* Ex. 1005 (Brown Decl.) at ¶ 452; Paper 1 (Petition) at 93. As such, it is my opinion that a POSA would understand that Ofek's disclosure of using a three-way valve would satisfy the off-off state. Ex. 1005 (Brown Decl.) at ¶¶ 447-459.

D. Rubenstein Discloses the “Off-Off State”

110. As discussed, above, the Yang/Mullins and Ofek/Mullins combinations discussed the off-off state. Additionally, Rubenstein also discloses the off-off state. Ex. 1005 (Brown Decl.) at ¶¶ 308-339.

111. As mentioned, Rubenstein discloses a rotary valve 46/18 which may rotate between a first position fluidically connecting the catheter to vacuum, and a second position where the vacuum is disconnected. Ex. 1011 (Rubenstein) at 1:10-14, FIGs. 1-2; Paper 1 (Petition) at 57; Ex. 1005 (Brown Decl. 1) at ¶¶ 320-327. Similarly, Rubenstein discloses a rotary valve 60 which rotates between a first position where a fluid line is fluidically disconnected from the catheter, to a second position where the fluid line is connected. Ex. 1011 (Rubenstein) at FIGs. 1-2; Paper 1 (Petition) at 57. Rubenstein itself explains that a rotary valve functions by rotating a connecting channel to different locations to connect and/or disconnect fluid channels. Ex. 1011 (Rubenstein) at 3:21-26. A POSA would understand that rotary valves necessarily have finite distance between the different positions within the valve, it requires a finite time period for the valve to rotate between each position. As such, Patent Owner’s suggestion that Rubenstein’s valves can instantaneously cycle between positions is simply incorrect. See Paper 15 (PO Response) at 63-65.

112. As discussed, Rubenstein discloses a first position where the catheter is connected through a connecting channel 48 of valve 46/18 to the vacuum, but disconnected from the fluid line, which is closed off by valve 60. *See* Ex. 1011 (Rubenstein) at Fig. 2. Then, the valves rotate to a second position, where the catheter is disconnected from the vacuum line by the 46/18 valve and connected to the fluid line by the 60 valve. *Id.* Since the valves in Rubenstein necessarily rotate between positions as discussed above, a POSA would understand that during the transition from the first positions to the second positions, there is moment where the connecting channels are not aligned with either the vacuum (via the 46/18 valve) or the fluid line (via the 60 valve), and therefore exist in a double closed or off-off state. Patent Owner's argument that the instance in Rubenstein where neither the vacuum or fluid line is connected does not meet the off-off state because it is a "momentary transition" simply incorrect. As discussed above, it is my and Mr. Culbert's understanding that the claims of the '402 Patent do not require the off-off state to persist for a certain amount of time. Ex. 1036 (Culbert Depo) at 47:24-48:6.

113. As such, Rubenstein discloses the off-off state. Ex. 1005 (Brown Decl.) at ¶¶ 308-339.

VIII. SECONDARY CONSIDERATIONS

A. Patent Owner Fails to Show How Objective Considerations of Non-Obviousness Demonstrate the Claimed Invention is Patentable

114. I am informed that there are multiple factors to consider when addressing objective considerations of non-obviousness. The factors include (1) a long-felt but unmet need in the prior art that was satisfied by the invention of the patent; (2) failure of others where the invention succeeds; (3) commercial success or lack of commercial success of processes covered by the patent; (4) unexpected results achieved by the invention; (5) praise of the invention by others skilled in the art; (6) taking of licenses under the patent by others; and (7) deliberate copying of the invention.

115. Patent Owner, at best, provides arguments for a single factor, (1) that a long-felt but unmet need in the prior art was satisfied by the invention of the patent in support of its objective considerations of non-obviousness, and did not address any other factors. *See* Paper 15 (PO Response) at 67-69; Ex. 2014 (Culbert Decl.) at ¶¶ 158-161.

116. 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. See Paper 15 (PO Response) at 67-71; Ex. 2014 (Culbert Decl.) at ¶¶ 158-162.

117. 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, nor am I aware of any licenses issued by RapidPulse for the '402 Patent. Also, I understand that 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.

118. Due to Patent Owner's failure to show a long felt but unmet need in the prior art that was satisfied by the invention of the patent, or address any other factors of non-obviousness, it is thus my opinion that the objective evidence does not support a finding of non-obviousness for the '402 Patent.

B. Patent Owner Fails to Demonstrate a Nexus to the Claimed Invention

119. I understand that there must be a relationship or nexus between any such objective considerations and the claimed invention. I am informed that there is a presumption of nexus for objective considerations when the Patent Owner shows that the identified objective evidence is tied to a specific product that embodies and is coextensive with the claimed invention. In my opinion, the presumption does not apply here because as previously mentioned, RapidPulse does not offer a commercial product that embodies the purported invention claimed by the '402 Patent.

120. 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.

121. Thus, it is my opinion that Patent Owner failed to show a nexus between any objective considerations of non-obviousness and the claimed invention.

XIV. RESERVATION OF RIGHTS

122. My opinions are based upon the information that I have considered to date. As discussed above, I am unaware of any evidence of objective indicia with respect to the '402 Patent that would render any of the challenged claims non-obvious. I reserve the right, however, to supplement my opinions in the future to respond to any arguments raised by the owner of the '402 Patent and to consider new information that becomes available to me.

IX. DECLARATION

123. I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true. I further understand that willful false statements and the like are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code. I declare under penalty of perjury that the foregoing is true and correct.



Executed on September 19, 2025.

Brian Brown

Appendix A

<u>Ref. No.</u>	<u>Filing Date</u>	<u>Issue/Allowed Date</u>	<u>'402 Family Member</u>
RP-1	Filed: 2019-07-18	Issued: 2020-01-14	US 10,531,883
RP-2	Filed: 2019-11-12	Issued: 2020-07-28	US 10,722,253
RP-3	Filed: 2020-06-11	Issued: 2024-08-13	US 12,059,161
RP-4	Filed: 2022-01-26	Issued: 2024-03-05	US 11,918,240
RP-5	Filed: 2022-01-26	Issued: 2023-01-10	US 11,547,426
RP-6	Filed: 2022-02-11	Issued: 2022-08-09	US 11,406,402
RP-7	Filed: 2022-12-02	Allowed: 2025-06-09	US 18/061,094
RP-8	Filed: 2022-12-02	Issued: 2024-09-10	US 12,082,830
RP-9	Filed: 2023-06-30	Issued: 2024-06-11	US 12,004,757
RP-10	Filed: 2023-06-30	Allowed: 2025-07-02	US 18/346,008
RP-11	Filed: 2023-06-30	Allowed: 2025-07-28	US 18/346,027
RP-12	Filed: 2023-06-30	Issued: 2025-01-07	US 12,185,959
RP-13	Filed: 2024-08-12	N/A	US 18/801,022
RP-14	Filed: 2024-11-13	Allowed: 2025-08-14	US 18/946,479
RP-15	Filed: 2024-11-13	Allowed: 2025-08-29	US 18/946,722
RP-16	Filed: 2024-11-13	Allowed: 2025-08-26	US 18/946,766
RP-EP1	Filed: 2019-07-19	Issued: 2024-10-30	EP 3,823,686