

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

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

Petitioner’s Reply to Patent Owner Response
U.S. Patent 11,406,402

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EXHIBIT LIST

Exhibit No. ¹	Description
1001	U.S. Patent No. 11,406,402 (“the ’402 Patent”)
1002	U.S. Provisional Application No. 62/701,086 (“Deville-Prov1”)
1003	U.S. Provisional Application No. 62/750,011 (“Deville-Prov2”)
1004	Prosecution File History of the ’402 Patent
1005	Expert Declaration of Brian Brown
1006	CV of Brian Brown
1007	U.S. Patent No. 10,322,230 (“Ofek”)
1008	U.S. Patent No. 11,197,977 (“Mullins”)
1009	Prosecution File History of U.S. Patent No. 11,197,977 (“Mullins”)
1009.1	U.S. Provisional Application No. 62/599,560 (“Mullins-Prov1”)
1009.2	U.S. Provisional Application No. 62/599,573 (“Mullins-Prov2”)
1009.3	U.S. Provisional Application No. 62/616,188 (“Mullins-Prov3”)
1010	International Application No. WO 2014/151209 A1 (“Grey”)
1011	U.S. Patent No. 3,955,574 (“Rubenstein”)
1012	U.S. Patent Publication No. 2017/0238953 A1 (“Yang”)
1013	U.S. Patent Publication No. 2012/0138833 A1 (“Matteo”)
1014	Patricia E. Thorpe & Francisco J. Osse, <i>Endovenous Management of Iliocaval Occlusion</i> , in THE VEIN BOOK, 2007 MECHANICAL THROMBECTOMY
1015	Dave Fornell, <i>Catheter-Based Clot Busting Therapies</i> , DIAGNOSTIC AND INTERVENTIONAL CARDIOLOGY (Feb. 4, 2013), https://www.dicardiology.com/article/catheter-based-clot-busting-therapies
1016	International Application No. WO 2018/019829 A1 (“Brady”)
1017	Gilles Rioufol, et al., <i>Large Tube Section Is the Key to Successful Coronary Thrombus Aspiration: Findings of a Standardized Bench Test</i> , 67 CATHETERIZATION & CARDIOVASCULAR INTERVENTIONS 254-257 (Dec. 5, 2005), https://onlinelibrary.wiley.com/doi/10.1002/ccd.20471

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

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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., Exploring the Efficacy of Cyclic vs. Static Aspiration in a Cerebral Thrombectomy Model: An Initial Proof of Concept Study, 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://jniss.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

I. Introduction

The Challenged Claims are obvious variants of the techniques disclosed in Yang, Ofek, and Mullins, reciting the same types of systems operated in the same way (changing vacuum levels and controlling fluid flow at the distal end of the catheter). Pet., 15-107; Ex[1035], ¶¶1-121.

II. Claim Construction of “Control Fluid Flow In And Out” & “Limited To A Positive Amount Of Exit Flow”

While Patent Owner (PO) asserts that it is not proposing constructions for the '402 claims (POR, 22-24), its arguments are based on implicit constructions that are erroneous and attempt to rewrite some claim terms entirely. Ex[1035], ¶5.

A. PO Ignores The Operative Claim Terms

For the “limited to a positive amount of exit flow” limitation, PO argues that “‘a positive amount’ is greater than zero—*not* ‘no exit flow’.” POR, 22 (original emphasis). For the “control fluid flow in and out limitation” limitation, PO has a similar argument. POR, 23-24. In both cases, PO’s argument ignores the full claim language, resulting in a flawed understanding of the language’s meaning. Ex[1035], ¶¶10-14.

PO wholly ignores the operative claim terms (verbs) and narrowly focuses only on the objects, thereby ignoring the actual question at issue. *Id.* Specifically, PO’s arguments isolate “flow out” and “positive exit flow” to contend that their mere existence dictates that positive distal flow must occur. POR, 22-24; Ex[2014], ¶¶40-

43. Yet PO's arguments fail to consider or even mention the actual action ("control" or "limiting"), which action is imparted to the flow (i.e., the object of the action). Ex[1035], ¶¶10-14.

A POSA would recognize that the operative claim language is the action of "limiting...to" or "controlling...flow," not the object of the operation (e.g., "flow"). Ex[1035], ¶¶10-14. PO's disregard of the operative verbs improperly converts the applicant's chosen broad functional claim language into a particular exemplary outcome. *Id.* The claim limitations require **action taken** by the controller (i.e., controlling or limiting), which action operates on flow. The claim does not recite that any particular flow must actually occur. As explained by Mr. Brown: "The claim term a positive amount of exit flow is not what's being claimed. What's being claimed is a limit...." Ex[2018], 13:16-14:2; Ex[1035], ¶¶10-14.

B. The Meaning Of "Control" and "Limiting" Do Not Require Exit Flow As the Specification Confirms

As the Petition and Mr. Brown explain, a POSA would understand that the '402 claims include no exit flow, at least because that is the ordinary meaning of the terms "control" and "limiting," and the specification does not provide different guidance. Ex[1035], ¶¶6-9; Pet., 15-16. The '402 specification mentions "exit flow" only once (*cf.* "forward flow") and never suggests that exit flow greater than 0 is always required. Ex[1035], ¶¶6-9; Pet., 15-16; Ex[1001], 4:50-54 ("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.”). To the contrary, the specification explicitly discusses several examples that “prevent the fluid from exiting the distal end” and where “substantially no liquid exits the distal end.” Ex[1001], 8:53-64; 42:40-42, 42:58-62, 44:62-45:2. This is consistent with the alleged invention’s intended purpose and the known risks of distal migration, such that “limited to a positive amount of exit flow” would be understood as a threshold “limit” of allowable exit flow. Ex[1035], ¶¶6-9; Pet., 15-16; Ex[1001], 3:10-22; 4:50-54, 24:36-25:26, 44:37-40. Thus, “[limited/limiting] to a positive amount of exit flow” means limiting to a maximum permitted exit flow, including no exit flow. For the same reasons, the independent claim’s recitation of “control[s] flow” does not require flow to actually exit the catheter.

1. “Control”

PO’s position that “control fluid flow in and out” requires affirmative distal flow is flawed. Ex[1035], ¶¶14-17. A POSA would understand that the ordinary and customary meaning of the operative term “control” is to have a desired effect on the object on which it operates. *Id.* Thus, a POSA would recognize that to “control” the “flow in and out” means having “control” over flow in and out, including preventing

or permitting flow out. *Id.* PO's contention that flow out must always occur is wrong. *Id.*

A POSA's understanding of "control" is also confirmed by the contemporaneous prior art. For example, Grey explains that "control" just means having an influence or effect that is intended and/or predictable. Ex[1010], 6:13-25; Ex[1035], ¶¶14-17. Just as a "flood control" device does not imply a flood must occur, a POSA would understand preventing exit flow to be "control" within the scope of the claims. Ex[1035], ¶¶14-17.

Moreover, PO's argument would erroneously rewrite the claim to recite: "a controller configured...to ~~control~~ cause fluid flow in and out from the distal end of the catheter." Ex[1035], ¶¶14-17. Construction is not an invitation to rewrite claims.

2. "Limited/Limiting"

The operative claim term is "limited" or "limiting," which a POSA would understand based on its ordinary and customary meaning as simply having or setting a limit such as a boundary or cap. Ex[1035], ¶¶25-30. A commonplace example of "limiting" is limiting automotive speeds (e.g., 30 mph). Limiting a car's speed would not preclude a car from being at a stop (i.e., 0 mph) on a street with that speed limit. The same principle applies here—a zero amount of exit flow would satisfy the claimed exit flow limit. Notably, a corked catheter will have zero exit flow, as confirmed by the '402 Patent. Ex[1001], 44:46-45:2 (stating that when uncorked, the

ROAR effect has substantially no exit flow, and when corked, has zero exit flow); Ex[1035], ¶¶25-30. Thus, “limiting” to specific amounts of exit flow must include no exit flow.

PO's expert's testimony to the contrary is not credible as his cross-examination revealed. Particularly, Mr. Culbert: (1) admitted to not knowing or having an opinion on what actual minimum value of distal flow would satisfy the claims, (2) asserted that some unknown rounding convention would be needed to evaluate exit flow amounts below the claimed values, and (3) could not articulate what “non-zero” numerically means, despite being the crux of PO's apparent construction. Ex[1036], 57:6-60:2; Ex[1035], ¶¶25-30.

C. Related Proceedings Confirm The Meaning Of “Control”

Related proceedings confirm the operative meaning of “control.” *See also* Ex[1035], ¶¶18-24. In IPR2022-00608 (“IPR#2”), Petitioner challenged US10,722,253 (“Deville’253”), which the Board found unpatentable. Ex[2011], 1. Petitioner's IPR#2 invalidity grounds combined Petitioner's patent US11,197,683 (“Teigen’673”) with WO2014/151209 (“Grey”). Ex[2011], 6-7; Ex[2008], ¶¶112-152. Petitioner's grounds expressly relied on claim language of Claim 1 in Teigen’673 for the corresponding claim elements of Claim 1 in Deville’253. *See, e.g.,* Ex[2008], ¶¶135, 147. Importantly, Petitioner's grounds mapped the Teigen’673 claim language (“control flow in and out from the distal end”) against

the Deville'253 claim language ("substantially prevent forward flow of liquid at a distal end"). *Id.* (emphasis added).

Here, Claim 1 of the '402 Patent (filed two months after Teigen'683 issued) essentially copies the Teigen'683 claim language at issue in IPR#2. *See* Ex[1001], Claim 1. Thus, the same claim language at issue in the '402 Patent here (control flow in and out) was relied on to disclose claim language encompassing the prevention of forward flow.² Thus, "controlling" flow in and out must encompass "preventing" forward flow, or at minimum, allow for the prevention of forward flow. As such, PO's argument—that "control" flow in and out cannot be satisfied by preventing flow out—is wrong. Ex[1035], ¶¶18-24.

D. Patent Owner's Own Claim Language Shows Its Construction Is Wrong

The File Histories of patents related to the '402 demonstrates that when the PO wanted to restrict claims to require positive exit flow, it did so. In particular, PO has four 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 claims at issue here are in categories (2) and (3). PO's arguments attempt to modify the chosen language such that they become a category (4) case. The Board should not accept PO's invitation to err.

² PO did not appeal any issues regarding Claim 1 in IPR#2.

The following table of examples throughout the issued/allowed patents in this patent family demonstrates the language PO has chosen to describe the various claim categories. Ex[1035], 31-34, *see also*, Ex[1035], Appx. A; Ex[1038].

<u>Distal flow:</u> Operative claim term	<u>Distal flow:</u> Permitted?	<u>Distal flow:</u> Capped?	<u>Distal flow:</u> Required?	<u>RapidPulse Patent Family – Distal Flow:</u> 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”

When patentees use different words, there is a presumption the patentee intended a different scope. *Kara Tech Inc. v. Stamps.com, Inc.*, 582 F.3d 1341, 1347 (Fed. Cir. 2009) (“when the inventor wanted to restrict the claims to require the use of a key, he did so...This further indicates the claims at issue...do not require the

use of a key...”). This presumption applies across related patents. *Clare v. Chrysler Group LLC*, 819 F.3d 1323, 1330 (Fed. Cir. 2016); *Samsung Elecs. Co., Ltd. v. Elm 3DS Innovations, L.L.C.*, 925 F.3d 1373, 1379 (Fed. Cir. 2019); *see also, Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (applying the prosecution history of one patent to a related, subsequently issued patent); *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1383 (Fed. Cir. 2003) (“each of a plurality of fields” does not have the same meaning as family member’s term, “each field”).

Through the selection of different verbs, the drafter claimed separate states of distal flow, rather than treating each verb as an interchangeable synonym. When distal flow was to be permitted, PO chose the expansive “control” term. When distal flow was required, PO chose narrower language (“cause,” “occur,” etc.). Ex[1035], 31-34. Thus, the Board should not alter these claims to require exit flow.

E. The EP Opposition Is Not Inconsistent With Petitioner’s Position

PO apparently seeks to argue that Petitioner’s position here is inconsistent with statements made in a European Opposition (“Opposition”) filed against PO’s European Patent EP3,823,686 (“RP-EP1”). Paper 19, PO Motion, 2-4; *see also* Ex[1035], ¶¶35-40. PO is incorrect. In RP-EP1, the Claim 1 language a controller “configured to... prevent forward flow of the distal portion out from the distal end during each cycle.” Ex[1038], 203. This is identical to its counterpart, US10,531,883 (“RP-1”), which the Board found invalid in IPR2021-01466 (“IPR#1”). Notably, PO

itself has taken position that “prevent forward flow” limitations are “inapplicable” and “do not apply here.” POR, 23; Ex[2014], ¶43. Thus, it is PO's arguments that are inconsistent, not Petitioner's. Regardless, as established above, the meaning of “control” of “flow in and out,” allows for distal flow out, but does not require it. Ex[1035], ¶¶14-17, 35-40.

Moreover, as the Board correctly determined in IPR#1, the language “prevent forward flow” does not require no exit flow, and can encompass up to 6 microliters of exit flow. Ex[2011], 13-16. Thus, even if PO's construction were adopted here, a prior art embodiment with minimal exit flow can map both to a claim that requires no “forward flow” and one that requires some “exit flow.” Indeed, multiple '402 dependent claims (which depend from Claim 1's “control” limitation) recite exit flow values below 6 microliters (*i.e.* those claims encompass the no forward flow condition).

Finally, the prior art involved here and in the Opposition includes disclosures of both preventing and permitting some exit flow, in various different embodiments. Ex[1035], ¶¶35-60; *see also, e.g.*, Ex[1008], 26:43-27:57, Fig. 46-50 (disclosing certain embodiments preventing flow out, and other embodiments permitting some flow out). There is nothing inconsistent about mapping different embodiments of the prior art to different claim language in the different jurisdictions.

III. The Prior Art Discloses The “Control” Limitation

PO's argument that the prior art doesn't satisfy the “control” limitation fails under both the correct interpretation and PO's improper construction. Ex[1035], ¶¶41-48.

Yang teaches adjusting intermittent or pulsatile vacuum to cause axial reciprocation or water hammer effect at the distal tip of the catheter, and 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], ¶¶[0108], [0135], [0168]; Ex[1035], ¶¶41-48; Pet., 33. A POSA would recognize Yang's alternating positive/negative pressure and water hammer at the distal tip as controlling flow in and out, even under PO's improper construction. Ex[1035], 45.

Ofek teaches configuring customizable cycles, pressure profiles, and pressure impulses to prevent clots from forming at the distal end of the lumen, including applying high-pressure impulses to the clot. Ex[1007], 2:56-3:2, 3:43-44; Pet., 85-86. A POSA would recognize Ofek's use of vacuum and high-pressure impulses on clots at the distal end as controlling flow in and out, even under PO's improper construction. Ex[1035], 46.

Mullins discloses controlling fluid at the distal end of a catheter, defining upper and lower pressure limits, causing the catheter to cyclically ingest and optionally expel clot. Ex[1008], 3:46-65. Mullins expressly discloses and illustrates

using positive and negative pressure to control the flow of clot and fluid in and out at the distal tip of the catheter. Ex[1008], 26:43-27:24, FIG. 47; Pet., 34-34. Thus, Mullins clearly discloses controlling flow in and out, at least in FIG. 47(g)-(h) and 47(k)-47(l), even under PO's improper construction. Ex[1035], 47.

Thus, the prior art discloses operative "control" of fluid flow in and out, and also teaches affirmative distal flow out even under PO's improper construction. Ex[1035], ¶¶41-48; Pet., 33-34, 85-86.

IV. The Prior Art Discloses The "Limiting" Limitation

PO's position that the prior art doesn't satisfy the "limiting" limitation also fails under both the correct interpretation and PO's improper construction. Ex[1035], ¶¶49-60.

As discussed above and explained by Mr. Brown, Yang and Ofek each disclose embodiments that could be understood or obvious as controlling flow distal flow out, especially in combination with Mullins. Ex[1035], ¶¶45-46; Pet., 33, 85-86. For similar reasons, a POSA would also recognize that both references disclose or would render obvious distal outflow and limiting said outflow, particularly in combination with Mullins. Ex[1035], ¶¶52-54.

For Yang, a POSA would recognize that some positive exit flow would occur when applying pulsated/cyclical aspiration to a clot at the distal end, and that the disclosed water hammer effect suggests that some distal flow out may occur.

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

As also discussed, Mullins expressly discloses “control and/or variation of...*fluid displacement...at the catheter tip*,” and configuring upper and lower pressure limits to limit such distal fluid displacement. Ex[1035], ¶¶55-57; Ex[1008], 26:23-49. Mullins specifies numerical limits for its infuse-to-aspirate cycles that a POSA would understand as corresponding to specific limits of positive exit flow. Ex[1035], ¶¶55-57; Ex[1008], 28:59-64. A POSA would understand this as satisfying “limiting” exit flow, at least because Mullins sets a ceiling on the aspiration phase of the cycle to avoid clogging, and also sets a limit on the infusion phase to avoid excess distal flow out. Ex[1035], ¶¶55-57. Mullins further provides clear visual disclosure of a positive distal flow out in FIG. 47(g)-(h) and 47(k)-47(l). Ex[1008], 26:65-27:35, FIG. 47.

PO's expert's new positions regarding Mullins fail. Ex[1035], ¶¶58-60. PO's expert argues that (1) Mullins' distal flow out in FIG. 47(g)-(h) doesn't satisfy the exit flow claims because clot flowing out is not fluid, and (2) Mullins' distal flow out in FIG. 47(k)-47(l) doesn't satisfy the exit flow claims because the fluid between

the fragments is only either flowing back in or not at all. Ex[1036], 70:23-73:18; Ex[1035], ¶¶58-60.

These new positions are supported only by the expert's *ipse dixit*, and lack corroborating evidence or cogent reasoning. As a POSA would understand, (1) the “fluid column” includes both blood and thrombus because both are being drawn into the distal end, and thus the outflow of the “fluid column” would also contain both the blood and “macerated” thrombus that were drawn into the catheter, and (2) thrombus is formed of blood at different stages of coagulation, and therefore, the flow of thrombus would include the flow of blood (i.e., fluid). Ex[1035], ¶60; Ex[1008] 27:18-26; Ex[1033] (discussing fluidic properties of clotting blood).

V. The Exit Flow Values Are Obvious By Routine Optimization

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

The prior art also teaches this type of routine optimization. Ex[1035], ¶64. For example, Mullins expressly teaches upper/lower pressure limits, fluid displacement cycles, and experimenting with values so that the clot is efficiently macerated via “loading/unloading” forces applied to the clot while ensuring ingested clot is “not completely expelled from the catheter.” Ex[1008], 26:7-11; 27:2-27:39; 28:27-58. As explained by Mr. Brown, a POSA would experiment with reasonable values such as those claimed, particularly given the '402 Patent's silence on how the claimed values were reached. Ex[1035], ¶¶61-66; Ex[1001], 24:45-51.

PO's various arguments against the claimed values being obvious results of routine optimization are flawed. POR, 48-56; Ex[2014], ¶¶109-127. Not only does PO offer no explanation of how the claimed volumes were selected, but also entirely fails to recognize the point of Mr. Brown's analysis. Ex[1035], ¶66. Mr. Brown's analysis demonstrates the maximum possible exit flow, which a POSA would use as a basis for actual experimentation to determine optimum parameters for implementing the prior art systems. Ex[1035], ¶¶61-66. Thus, the claimed exit flow values are nothing more than obvious result-effective variables.

VI. The Prior Art Discloses “Predetermined Cycle”

A. The Claims Do Not Exclude Sensor Use

PO implicitly construes “predetermined cycle,” to include an unstated negative limitation prohibiting sensor usage to tune system operation. POR, 24-31;

Ex[2014], ¶¶60-82. This construction is legally erroneous and should be rejected. *See Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1060 (Fed. Cir. 2009) (declining to add negative limitation where “there is no basis in the patent specification”).

Nothing in Claim 1's controller language excludes sensors/feedback, nor does the specification exclude their use. To the contrary, the specification explicitly includes sensors similar to those in the prior art. Ex[1001], 32:55-33:7, 40:66-41:5, 44:9-29 (discussing controller use of data from “sensors” including “pressure measurement devices” to “time the valves properly”). Thus, a POSA would understand “predetermined” as describing the “cycle” of opening and closing the valves, in an established sequence, with no restriction on sensor usage to making timing adjustments to the cycle. Ex[1035], ¶¶68-70. This is consistent with the plain meaning of “cycle,” which is a complete sequence of repeating events or states (e.g., “cycle of life”). *Id.*

PO's reliance on an Examiner statement—that the '402 Claims overcame Garrison because of Garrison's sensor use—is misplaced as it is not a disclaimer and is technically incorrect. Not only was Applicant itself silent on Garrison, it expressly refused to agree with the Examiner's statement. Ex[1004], 29. *See, e.g., Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005) (refusing to create rule or presumption that applicant's silence to examiner's unilateral statement disavowed claim scope); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381

F.3d 1111, 1124 (Fed. Cir. 2004) (“It is well settled [] that it is the applicant, not the examiner, who must give up or disclaim subject matter...”). Further, the examiner failed to recognize that Garrison disclosed embodiments where the cycle timing was controlled only by the user, not sensor feedback. Ex[2015], ¶[0114].

B. The Grounds All Have Predetermined Cycles

All of the prior art references disclose a “predetermined cycle” of valve states. Ex[1035], ¶¶74-82. Yang discloses “a logical progression of the vacuum and release cycle” “using predetermined operating parameters (e.g., for synchronized aspiration, injection, and rotation).” Ex[1012], ¶¶[0169]-[0170] (“another cycle from...begins...”), ¶[0176]. Ofek discloses “impulses...separated by rest periods” “propagated in a predetermined pattern.” Ex[1007], 6:30-7:17, 8:38-49. Mullins discloses “pulse cycling between two pressure limits.” Ex[1008], 27:54-65, 26:43-49, FIGs. 46-49.

Even under PO's flawed construction, the prior art references disclose a “predetermined cycle.” Ex[1035], ¶¶78-82. Yang expressly discloses specific cycle times. Ex[1012], ¶[0168] (“The period of each vacuum and release cycle may be equal to... 0.1, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 seconds.”); ¶[0127]. Ofek teaches that its controller “determines the number, frequency, rest periods, etc., of the impulses to be delivered” and “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.” Ex[1007], 5:49-62, 6:35-37, 6:61-63, 8:38-49. Mullins discloses various different embodiments which don't require or discuss sensor-based feedback. Ex[1035], ¶¶81-82; *see also, e.g.*, Ex[1008], 26:43-49; 28:1-10 (“the shake signal may be initiated for a predefined number of cycles.”); 28:49-52. Additionally, Mullins discloses controlling fluid displacement cycles with a peristaltic pump, and a POSA would recognize that a fixed timing cycle of operation in each pump direction would produce Mullins' predetermined cycles. Ex[1035], ¶¶81-82; Ex[1008], 28:59-29:12 (discussing “ratio of the infuse-to-aspirate cycle”). PO also fails to recognize that Mullins' relevance in the prior art combinations is its discussion of distal end flow control, not for its sensors. Ex[1035], ¶83

VII. PO's Method Claim Arguments Fail

PO's various new post-institution arguments fail to save dependent method claims 11-20, which are just as obvious in view of the prior art as the system claims. Ex[1035], ¶¶85-86; Ex[2014], ¶¶83-127; POR, 31-48. PO's disjointed method claim positions reduce to: (1) arguing that the prior art doesn't “position” a catheter against a clot, and (2) rehashing various arguments made against the system claims (regarding “preliminary cycle,” “controlling” flow, “limiting to,” combining the prior art, etc.) under the guise of “expectation of success.” These arguments all fail.

A. “Positioning”

PO's argument that Ofek doesn't sufficiently disclose “positioning the distal end of the catheter” in method claim 11 (POR, 46-48) fails for substantially the same reasons as the previous iteration (*cf* POPR, 54-59). Ex[2014], ¶¶106-108; Ex[1035], ¶¶87-92; *see also* ID, 33-37. PO's argument is essentially that Ofek doesn't discuss thrombectomy procedures using PO's preferred terminology. That is irrelevant. As Mr. Brown and the Petition explained, and as the Board agreed, Ofek discloses using arterial catheters for aspirating a thrombus at the distal end of the catheter. ID, 33; Ex[1035], ¶¶87-92; Pet. 67-72. A POSA would recognize that Ofek's use of arterial catheters for aspirating a thrombus at the distal end of the catheter means that Ofek's disclosed embodiments were well-suited for thrombectomy procedures. Ex[1035], ¶¶87-92. PO's dissatisfaction with Ofek not using magic words is of no moment. Ex[1035], ¶¶87-92.

A POSA would also understand that Ofek's “short-duration impulses...of high pressure fluid to the lumen of the catheter” that can “dislodge occlusions” demonstrates that Ofek's system is well-suited to ingest clots and prevent clogging. Ex[1035], ¶90; Ex[1007], 4:21-44, 11:30-40. A POSA would recognize that the need to ingest and prevent clogging occurs when clot is drawn into the distal end and corks the catheter lumen. Ex[1035], ¶90.

PO's arguments are also flawed as they attack the references individually rather than the combination in the Invalidity Ground. As explained by Mr. Brown and the Petition, a POSA would be motivated to combine Ofek and Mullins "to provide efficient and effective cyclical aspiration of blood clots" thereby "carrying out the functionality described in Mullins." Pet. 68; Ex[1035], ¶90. PO does not dispute that Mullins' disclosed functionality includes performing thrombectomy via a catheter engaged with a thrombus, thus meeting the "positioning" limitation. POR, 47.

B. "Expectation of Success"

PO also now relies on Claim 11's outcome-oriented claim language to re-argue their controller limitations arguments under the premise of "expectation of success." POR, 31-46; Ex[2014], ¶¶88-105.

These arguments fail for all of the same reasons explained for the "control," "limited to," "predetermined cycle," and "exit flow" limitations. Ex[1035], ¶¶93-100; *supra* §§II-VI. PO's implicit constructions are just as improper for the method claims, and nothing in the method claims takes the prior art's disclosures outside of the claim scope, even under PO's improper constructions. Ex[1035], ¶¶93-100; *supra* §§II-VI.

Additionally, the state of the art confirms that aspiration thrombectomy and valve-based flow regulation were well-known such that a POSA would expect

success. Ex[1035], ¶95. As Grey explains, “deliberate variations in the suction force/pressure” can be used to “control” and achieve an intended and predictable influence in aspirating a clot. *Id*; Ex[1010], 6:13-25. Adjusting the prior art’s valve timing and pressure to regulate distal flow is a predictable technical solution POSAs would have expected to work based on prior success in the prior art. Ex[1035], ¶¶95-98. Moreover, the prior art includes at least as much detail regarding valve timing as the ’402 Patent. Ex[1035], ¶¶96; *see also supra* §VI.

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

Where, as here, the claimed invention merely involves parameter selection and adjustment within known systems like those disclosed in the prior art, the law is clear: optimizing such variables is within the skill of the art, and POSAs would reasonably expect success therein. *Application of Boesch* 617 F.2d 272, 276 (CCPA 1980) (“discovery of an optimum value of a result effective variable in a known

process is ordinarily within the skill of the art.”); *ImmunoGen, Inc. v. Stewart*, 130 F.4th 1328, 1334 (Fed. Cir. 2025).

PO's unfounded speculation about supposed obstacles cannot overcome the disclosures in the prior art, which provide clear guidance and parameters that POSAs would have recognized as subject to routine optimization. Ex[1035], ¶¶93-100. PO's "expectation of success" arguments fail.

VIII. The Prior Art Discloses the “Off-Off State”

A. PO Improperly Adds Claim Limitations

Claims 5-7 and 18-20 disclose an “off-off state” where the vacuum and vent valves are closed. Contrary to what PO argues, the claims do not 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], Claims 5-7, 18-20; POR, 57; Ex[2014], ¶130. Mr. Culbert admitted on cross-examination that the claims nowhere state that the “off-off state” must persist for a certain amount of time. Ex[1036], 47:24-48:6. PO's attempt to add new claim limitations should be rejected. Ex[1035], ¶¶101-113.

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

The Petition shows that Yang discloses and renders obvious a double-closed state for multiple reasons. Pet., 44-46; Ex[1012], ¶¶[0040], [0102], [0168], [0169]. Yang discloses *serial* operation of vacuum and vent valves and repeated valve

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

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

C. Ofek/Mullins Discloses the "Off-Off State"

Ofek discloses serial valve operation. Ex[1035], ¶106-109; Ex[1007], Claim 8 ("the normally open valve configured to close **upon** opening of the normally closed valve") (emphasis added), 5:55-59 ("During 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."). As such, Ofek discloses serial valve operation which includes a moment where both valves are shut before the N.C. valve is opened to

prevent fluid from entering the vacuum, thus satisfying the off-off state. Ex[1035], ¶106.

To the extent that Ofek does not explicitly disclose serial valve operation, 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. Ex[1035], ¶107. A POSA would understand that having at least a brief moment where both valves are closed is obvious as it 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. Pet. at 92-93; Ex[1005], ¶¶448-450; Ex[1035], ¶107.

Ofek additionally discloses the vacuum and vent valves can be combined into a single three-way valve. Ex[1007], 5:26-31; Ex[1005], ¶451. A POSA would find it obvious to use a rotary-type three-way valve because a rotary three-way valve is readily available, is mechanically simple, is durable, and is one of a finite number of ways to implement the disclosed valve. Ex[1035], ¶108. As depicted in Rubenstein, 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. See Pet., 93; Ex[1005], ¶452; Ex[1035], ¶109.

As such, a POSA would understand that Ofek's disclosure of using a three-way valve would satisfy the off-off state. Ex[1035], ¶¶106-109.

D. Rubenstein Discloses the "Off-Off State"

Rubenstein also discloses the off-off state as it discloses a rotary valve 46/18 which rotates between a first position fluidically connecting the catheter to vacuum, and a second vacuum-disconnected position as well as rotary valve 60 rotating between a first position disconnecting a fluid line from the catheter, to a second (connected) position. Ex[1011], 1:10-14, 3:21-26, FIGs. 1-2; Pet. at 55-63; Ex[1035], ¶¶110-113; Ex[1005], ¶¶320-327. A POSA would understand that rotary valves have finite distance between the different positions, taking a finite time period to rotate between positions. Ex[1035], ¶111. PO's argument that Rubenstein's valves can instantaneously cycle positions is meritless. See POR, 63-65; Ex[1035], ¶¶110-113.

A POSA would thus understand that during the transition from the first positions to the second positions, there is a 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. Ex[1035], ¶112.

As noted, the claims of the '402 Patent do not require the off-off state to persist for a certain amount of time, thus PO's argument that Rubenstein does not disclose

the off-off state because it is a “momentary transition” is not commensurate with the claims. Ex[1035], ¶112; Ex[1036], 47:24-48:6.

IX. Secondary Considerations

PO relies solely on long-felt need, but fails to show how the claimed invention satisfied that purported need. *See* POR, 67-71; Ex[2014], ¶¶158-161; Ex[1035], ¶¶114-118. As noted above and in the Petition, the prior art already taught the claimed techniques. The remaining factors weigh against a finding of non-obviousness. Ex[1035], ¶114-118. RapidPulse does not provide a commercial product that embodies the purported invention of the '402 Patent, nor any licenses. Commercialized products from competing companies such as Penumbra have had far greater commercial success. Ex[1035], ¶117.

A. PO Fails to Show Nexus

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

PO has not demonstrated a nexus between any objective considerations and the purported invention of the '402 Patent. Had PO's claimed invention in fact met

an unmet need in the industry, one would expect PO to have a commercially available and successful product. Further, PO fails to show that the purported invention of the '402 Patent is responsible for any purported improvement in aspiration. Ex[1035], ¶120; POR, 71. As noted in the Petition and herein, the prior art already discloses all of the claimed techniques. Thus, there was no “unmet” need, and the secondary indicia do not outweigh the evidence of obviousness. Ex[1035], ¶¶114-121.

September 19, 2025

Respectfully submitted,

/Eliot D. Williams/
Eliot D. Williams (Reg. No. 50,822)

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

1. This Reply complies with the type-volume limitation of 5,600 words, excluding the parts exempted by 37 C.F.R. § 42.24(c).

2. This Petition complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word 2016 in 14-point Times New Roman.

Respectfully submitted,

BAKER BOTTS L.L.P.

/Eliot D. Williams/

Eliot D. Williams (Reg. No. 50,822)
Lead Attorney for Petitioner

Date: September 19, 2025

BAKER BOTTS L.L.P.
700 K St.
Washington, D.C. 20001
Tel: (202) 639-7700
Eliot.Williams@BakerBotts.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies on this September 19, 2025, that true and correct copies of the foregoing **Petitioner's Reply to Patent Owner's Response** was served to Patent Owner via electronic mail to:

Charles H. Sanders	(charles.sanders@lw.com)
B. Thomas Watson	(thomas.watson@lw.com)
Raghav Bajaj	(raghav.bajaj@lw.com)

Latham & Watkins LLP

BAKER BOTTS L.L.P.

/Eliot D. Williams/
Eliot D. Williams (Reg. No. 50,822)
Lead Attorney for Petitioner

Date: September 19, 2025

BAKER BOTTS L.L.P.
700 K St.
Washington, D.C. 20001
Tel: (202) 639-7700
Eliot.Williams@BakerBotts.com