

Filed on behalf of: RapidPulse, Inc.

Entered: November 6, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PENUMBRA, INC.,
Petitioner,

v.

RAPIDPULSE, INC.,
Patent Owner.

Case IPR2024-01261
Patent 11,406,402

PATENT OWNER'S SUR-REPLY

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EXHIBIT LIST

Exhibit	Description
2001	Declaration of Brad Culbert in Support of Patent Owner's Preliminary Response (Nov. 22, 2024) ("Culbert Decl.")
2002	<i>Curriculum Vitae</i> of Brad Culbert
2003	Declaration of Brian Brown in Support of Petition for Inter Partes Review of U.S. Patent No. 10,531,883, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2021-01466, Ex. 1005 (P.T.A.B. Aug. 30, 2021) ("883 Brown Decl.")
2004	Declaration of Ian Ross, MD in Support of Petition for Inter Partes Review of U.S. Patent No. 10,531,883, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2021-01466, Ex. 1023 (P.T.A.B. Aug. 30, 2021) ("883 Ross Decl.")
2005	Supplemental Declaration of Brian Brown for Inter Partes Review of U.S. Patent No. 10,531,883, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2021-01466, Ex. 1030 (P.T.A.B. Oct. 3, 2022) ("883 Brown Suppl. Decl.")
2006	Transcript of the Remote Videoconference Deposition of Ian Beaudoin Ross, MD, taken June 24, 2022, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2021-01466, Ex. 2016 (P.T.A.B. July 11, 2022) ("883 Ross Dep. Tr.")
2007	Judgment: Final Written Decision, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2021-01466, Paper 34 (P.T.A.B. Mar. 10, 2023) ("883 FWD")
2008	Declaration of Brian Brown in Support of Petition for Inter Partes Review of U.S. Patent No. 10,722,253, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2022-00608, Ex. 1005 (P.T.A.B. Feb. 15, 2022) ("253 Brown Decl.")

Exhibit	Description
2009	Declaration of Ian Ross, MD in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 10,722,253, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2022-00608, Ex. 1023 (P.T.A.B. Feb. 15, 2022) (“‘253 Ross Decl.”)
2010	Transcript of the Remote Videoconference Deposition of Brian Brown, Vol. 2, taken May 22, 2023, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2022-00608, Ex. 2018 (P.T.A.B. May 26, 2023) (“‘253 Brown Dep. Tr.”)
2011	Judgment: Final Written Decision, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2022-00608, Paper 34 (P.T.A.B. Sept. 6, 2023) (“‘253 FWD”)
2012	Sudheer Gorla et al., <i>The Role of Interventional Cardiology in the Management of Thrombotic Conditions in the Pediatric Population</i> in CARDIOVASCULAR THROMBUS: FROM PATHOLOGY & CLINICAL PRESENTATIONS TO IMAGING, PHARMACOTHERAPY & INTERVENTIONS 565–575 (2018)
2013	<i>Patency</i> , MERRIAM-WEBSTER DICTIONARY, https://www.merriam-webster.com/dictionary/patency (last visited Nov. 22, 2024)
2014	Declaration of Brad Culbert in Support of Patent Owner's Response (May 30, 2025) (“Culbert POR-Decl.”)
2015	U.S. Patent Application Publication No. US 2016/0220741 A1 (“Garrison”)
2016	Transcript of the Remote Videoconference Deposition of Brian Brown (Vol. 1), taken December 9, 2022, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , IPR2022-00608, Ex. 2016 (P.T.A.B. Jan. 6, 2023) (“IPR2022-00608, Ex. 2016”)
2017	Transcript of the Remote Videoconference Deposition of Ian Ross, MD, No. IPR2024-01261, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , taken May 16, 2025 (“Ross Dep.”)

Exhibit	Description
2018	Transcript of the Remote Videoconference Deposition of Brian J. Brown, No. IPR2024-01261, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , taken May 9, 2025 (“Brown Dep.”)
2019	Errata and signed Acknowledgment from Transcript of the Remote Videoconference Deposition of Brian J. Brown, No. IPR2024-01261, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , taken May 9, 2025
2020	NEW OXFORD AMERICAN DICTIONARY (3rd ed. 2010) (excerpt)
2021	Patrick A. Brouwer, MD et al., <i>Clot Pathophysiology: Why is It Clinically Important?</i> , 28 NEUROIMAGING CLINICAL N. AM. 611-623 (2018) (“Brouwer 2018”)
2022	Decision Granting Institution of <i>Inter Partes</i> Review, No. IPR2021-01466, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , dated March 14, 2022
2023	Decision Granting Institution of <i>Inter Partes</i> Review, No. IPR2022-00608, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , dated September 9, 2022
2024	Transcript of the Remote Videoconference Deposition of Brian Brown, taken June 15, 2022 <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , No. IPR2021-1466, Ex. 2013 (P.T.A.B. July 11, 2022) (“IPR2021-01466, Ex. 2013”)
2025	Osama O. Zaidat, MD et al., <i>First Pass Effect – A New Measure for Stroke Thrombectomy Devices</i> , 49 STROKE 660-666 (2018) (“First Pass Effect”)
2026	Gyula Gal et al., <i>Improved LVO First-Pass Effect With Precise Cyclic Aspiration: Early Experience with the RapidPulse™ System</i> , 14 (Suppl.) J. NEUROINTERVENTIONAL SURGERY A40-A41 (2022)

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2027	Arsida Bajrami et al., <i>RapidPulse™ Cyclic Aspiration System for Acute Ischemic Stroke Due to Large Vessel Occlusions</i> , 22 INTERVENTIONAL NEURORADIOLOGY (2024)
2028	Raul Nogueira, MD et al., <i>Data Presented at SVIN 2024</i> , RapidPulse™ (2024)
2029	RESERVED
2030	RESERVED
2031	<i>Duplex Fuel Selectors</i> , ANDAIR PRODUCTS, https://www.andair.co.uk/category/duplex-fuel-selectors/ (last visited May 28, 2025)
2032	<i>Solenoid Valves</i> , CANNON WATER TECHNOLOGY INC., https://cannonwater.com/pipe-valves-and-fittings/solenoid-valves/?srsltid=AfmBOoqfhXocs7qr7O-snnaGmL5GabfvVdzYEE8shLCAPXabAn6YSf (last visited May 28, 2025)
2033	Brian Booth, <i>V-Port Ball Valves vs. Globe</i> , VALVE WORLD AMERICAS (2018)
2034	Declaration of Charles H. Sanders In Response to Petitioner's Objections to Evidence [<i>served, not filed</i>]
2035	European Opposition filed July 29, 2025 against EP 3823686 (excerpts)
2036	Declaration of Qiushi (William) Yao in Support of Patent Owner's Unopposed Motion for <i>Pro Hac Vice</i> Admission Under 37 C.F.R. § 42.10(c) (Sept. 25, 2025)
2037	International Patent Publication No. WO 2017/214573 A1 (Exhibit 2037 entered during the Deposition of Brian Brown taken October 24, 2025)
2038	International Patent Publication No. WO 2019/115809 A1 (Exhibit 2038 entered during the Deposition of Brian Brown taken October 24, 2025)

Exhibit	Description
2039	Video: Dileep R. Yavagal, <i>Future of Stroke Thrombectomy Devices: The Promise of Cyclical Aspiration</i> , Future of Interventional Neurology Session, Soc'y of Vascular Interventional Neurology 2018 Annual Meeting, San Diego, Cal. (Nov. 16, 2018), https://www.youtube.com/watch?v=d7fv7VqLa5M (Exhibit 2039 entered during the Deposition of Brian Brown taken October 24, 2025)
2040	Video Cover Screenshot: Dileep R. Yavagal, <i>Future of Stroke Thrombectomy Devices: The Promise of Cyclical Aspiration</i> , Future of Interventional Neurology Session, Soc'y of Vascular Interventional Neurology 2018 Annual Meeting, San Diego, Cal. (Nov. 16, 2018), https://www.youtube.com/watch?v=d7fv7VqLa5M (Exhibit 2040 entered during the Deposition of Brian Brown taken October 24, 2025)
2041	Video Screenshot @ 4:49 (Ex.2039 pt. 3 @ 00:55): Dileep R. Yavagal, <i>Future of Stroke Thrombectomy Devices: The Promise of Cyclical Aspiration</i> , Future of Interventional Neurology Session, Soc'y of Vascular Interventional Neurology 2018 Annual Meeting, San Diego, Cal. (Nov. 16, 2018), https://www.youtube.com/watch?v=d7fv7VqLa5M (Exhibit 2041 entered during the Deposition of Brian Brown taken October 24, 2025)
2042	Video Screenshot @ 10:28 (Ex.2039 pt. 6 @ 00:42): Dileep R. Yavagal, <i>Future of Stroke Thrombectomy Devices: The Promise of Cyclical Aspiration</i> , Future of Interventional Neurology Session, Soc'y of Vascular Interventional Neurology 2018 Annual Meeting, San Diego, Cal. (Nov. 16, 2018), https://www.youtube.com/watch?v=d7fv7VqLa5M (Exhibit 2042 entered during the Deposition of Brian Brown taken October 24, 2025)

Exhibit	Description
2043	Video Transcription of Exhibit 2039: Dileep R. Yavagal, <i>Future of Stroke Thrombectomy Devices: The Promise of Cyclical Aspiration</i> , Future of Interventional Neurology Session, Soc'y of Vascular Interventional Neurology 2018 Annual Meeting, San Diego, Cal. (Nov. 16, 2018), https://www.youtube.com/watch?v=d7fv7VqLa5M
2044	Transcript of the Remote Videoconference Deposition of Brian J. Brown, No. IPR2024-01261, <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , taken October 24, 2025

I. Introduction

The patentability of the '402 Patent claims should be confirmed. Petitioner's Reply ("Reply," Paper 24) shows that its arguments hinge on rewriting the claims' plain language and strained interpretations of references and motivations that contradict Petitioner's and its expert's admissions.

First, Petitioner's combinations do not render obvious claim 1's "predetermined cycle" to "control fluid flow in and out from the distal end of the catheter." Petitioner improperly reads "predetermined" out of the claim because its combinations, which use Mullins's variable cycling based on sensor feedback, lack a "predetermined cycle." Petitioner also erroneously reads "control fluid flow ... out" out of the claim because, as Petitioner has now admitted, its references teach **preventing** flow out of the catheter's distal end.

Second, Petitioner fails to show obviousness of dependent claim 11's method of aspirating clots from a person. After RapidPulse's Patent Owner Response ("POR," Paper 15) showed that the Petition's reliance on Mullins's sensor cannot lead to a reasonable expectation of success in achieving the claimed method, Petitioner now shifts to a new "routine optimization" argument. Even if Petitioner could raise a new argument now (and it cannot), optimization based on teachings to **prevent** flow out cannot lead to optimizing flow out—let alone control of it to aspirate clots from a person.

Third, Petitioner's hindsight-biased arguments for dependent claims 3-4, 14, and 16-17, requiring specific positive amounts of exit flow, cannot support obviousness. Petitioner's references, all of which **prevent** exit flow, undisputedly fail to teach any amount of acceptable exit flow. Petitioner fails to rebut the POR's presentation of technical reasons why its expert's calculations are meaningless, and Petitioner's generic invocation of optimization cannot support obviousness of the claimed exit flow quantities.

Finally, Petitioner's claim that there was no long-felt unmet need directly contradicts evidence Petitioner submitted to a different tribunal, and Petitioner does not dispute that peer-reviewed literature shows improvement achieved using the claimed invention.

RapidPulse respectfully requests a final written decision affirming all claims' patentability.

II. Claim Construction

Petitioner proposed construing "limit[ed/ing ...] to a positive amount of exit flow" in dependent claims 3-4, 13, and 15 in its Petition (at 15-16)—and now proposes construing "control[s] fluid flow in and out" in independent claims 1 and dependent claim 11—to include zero exit flow, i.e., no flow out from the distal end of the catheter. Petitioner's proposals contradict the plain meaning of "positive amount" and read "flow ... out" out of the claims.

A. Claims 1 and 11

Claim 1 recites a system having “a controller configured to ... control fluid flow *in and out* from the distal end of the catheter.”¹ By its plain language, the claim requires a controller configured to control flow both in and out from the distal end. Claim 11 recites a method of using this system for “controlling the vacuum valve ... and the vent valve ... such that a level of vacuum at the distal end of the catheter changes and thereby controls flow *in and out* from the distal end of the catheter.” Thus, claim 11 requires flow in and out, controlled, in operating the system. These claims cannot be met by a system that operates by “preventing ... [exit] flow,” as Petitioner contends (Reply 3-4), because such systems are not configured to “control fluid flow ... *out* from the distal end,” as claim 1 requires, and “prevent[.]” rather than “control” actual “flow ... *out* from the distal end,” as claim 11 requires.

None of Petitioner's arguments justify reading “flow ... out” out of the claims. Petitioner improperly focuses on the verb “control” (Reply 2-4), disregarding the target of that control—“flow in and out.” *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1347 (Fed. Cir. 2008) (“this court does not interpret claim terms in a vacuum, devoid of the context of the claim as a whole”). Petitioner's misinterpretation leads

¹ All emphases added, and internal quotation marks and citations omitted, unless otherwise noted.

to the absurd result that, as Petitioner's expert Mr. Brown admits, the claims can be met with "no flow in or out." Ex.2044, 16:2-10.

Petitioner's argument that the specification "never suggests that exit flow greater than 0 is always required" likewise does not support its rewrite of the claims.

Reply 2. Petitioner concedes that the specification teaches "a positive amount of exit flow is created" and that this "exiting movement of fluid ... is automatically and precisely controlled." *Id.* 2-3 (quoting Ex.1001, 4:50-54). Mr. Brown agrees that "[t]he '402 Patent does teach having forward flow out of the distal end sometimes." Ex.2044, 7:1-7. The specification expressly distinguishes embodiments with such "intentional" flow out from those "where substantially no forward flow occurs." Ex.1001, 36:67-37:2. While claims in earlier IPRs were directed to embodiments that "prevent" flow out (Ex.2022, 6; Ex.2023, 6), the '402 Patent's claims here are directed to those embodiments that **have** "flow ... out" (Ex.1001, cls. 1, 11). Petitioner improperly conflates them.

Petitioner's extrinsic evidence—Grey's use of "control" and the term "flood control" (Reply 4)—just shows that, depending on context and the subject/target of the "control," its meaning can vary. The subject of the control here includes "flow ... **out**," and extrinsic uses of "control" cannot override this claim language. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995) ("Extrinsic evidence is to be used for the court's understanding of the patent, not for

the purpose of varying or contradicting the terms of the claims.”), *aff'd*, 517 U.S. 370 (1996). Nor are Petitioner's arguments about its own patent in an earlier IPR (Reply 5-6) relevant here, particularly since the Board never endorsed Petitioner's odd view of its own claims. Ex.2011, 34-35 (relying on Teigen's “disclosures,” not its claims, in finding it obvious “to substantially prevent forward flow”).

B. Claims 3-4, 13, and 15

Dependent claims 3-4 recite that the claimed flow out of the distal end is “limited to a positive amount of exit flow” within specific ranges. Claims 13 and 15 recite “limiting movement of a fluid column ... to a positive amount of exit flow.” By their plain language, these claims limit an amount of exit flow that is greater than zero. Mr. Brown agrees that, “in the claims,” “positive” has “its ordinary and customary meaning” of “greater than zero.” Ex.2044, 11:8-21; *see also* Ex.2018, 8:6-9:11 (“a positive amount of exit flow is something that is above zero”). Petitioner's argument that “a zero amount of exit flow would satisfy the claimed exit flow limit” is wrong. Reply 4. It contradicts both the express claim language and its expert's admissions.

Nothing supports Petitioner's rewrite of the claims. Petitioner notes that “a corked catheter will have zero exit flow,” but corking is precisely the issue that “intentional,” controlled exit flow addresses. Ex.1001, 36:34-37:3. Petitioner's analogy to a vehicle speed limit fails too—the issue is not the meaning of “limit” in

isolation, but rather the meaning of limiting “to a positive amount of exit flow,” where the claims include a lower limit.

Petitioner's verb chart only reinforces that its proposed constructions are erroneous. Petitioner and Mr. Brown contend that claims using the verb “limit” do not require distal flow, citing language in claim 4 that *expressly contradicts* their contention by requiring “approximately 0.1 ml to approximately 0.5 ml” of exit flow.

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

Reply 7 (excerpted; annotated); Ex.2044, 21:20-22:17. Even Mr. Brown had to concede that “the lower limit value” on the amount of exit flow “in each of claims” 3 and 4 “is above zero.” Ex.2044, 12:20-13:3.

III. Petitioner Fails To Show Its Combinations Render Obvious “A Predetermined Cycle” To “Control Fluid Flow In And Out” (All Claims)

Petitioner reads the word “predetermined” out of the claim term “predetermined cycle” in claim 1 and now seeks to deviate from the combinations proposed in its Petition, which relied on Mullins's variable cycle based on sensor feedback. Both arguments fail.

A. Petitioner Reads “Predetermined” Out Of The Claims

Petitioner reads “predetermined” out of “predetermined cycle” in contending “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 [*sic*] timing adjustments to the cycle.” Reply 15. Any cycle has “an established sequence”; indeed, Petitioner admits that a “cycle” “is a complete sequence of repeating events or states.” *Id.* Petitioner improperly renders “predetermined” meaningless. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 801, 809-10 (Fed. Cir. 2021) (“It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.”), *aff’d sub nom. Qualcomm Inc. v. Intel Corp.*, 2025 WL 289503 (Fed. Cir. Jan. 24, 2025).

The term “predetermined” establishes that the timing of the sequence of valve operations in the cycle is determined beforehand, i.e., fixed, rather than varying based on feedback after operation begins. *Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1340 (Fed. Cir. 2003) (“ordinary meaning of ‘predetermine’ is ‘to determine beforehand’”); *Planet Bingo, LLC v. GameTech Int’l, Inc.*, 472 F.3d 1338, 1341-45 (Fed. Cir. 2006) (a determination made after the start “cannot be ‘predetermined’”); *Pause Tech. LLC v. TiVo Inc.*, 419 F.3d 1326, 1334-36 (Fed. Cir. 2005) (interpreting “predetermined” as “fixed prior to operation”). The specification uses the term consistent with this plain meaning,

referring to “a fixed cycle” and “predetermined” timing of valve operation. Ex.1001, 9:9-14, 11:1-5, 58:34-38. The prosecution history shows that the Examiner applied this plain meaning in allowing the claims over Garrison, stating that “chang[ing] the cycle of opening and closing the valves based on feedback from sensors” did not teach or suggest the claimed “predetermined cycle.” Ex.1004, 86.

Petitioner's contrary arguments fail. RapidPulse does not “add [a] negative limitation”; RapidPulse gives meaning to all claim terms, including “predetermined.” Reply 15. While the specification discusses a sensor, that does not aid Petitioner. That sensor is used to “trigger” the predetermined cycle and regardless, as discussed above, disclosure of different embodiments is no basis to rewrite the claim language to encompass them all. Ex.1001, 32:55-66; *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) (“Our precedent is replete with examples of subject matter that is included in the specification, but is not claimed.”). Petitioner's argument about the prosecution history is misplaced too because RapidPulse's position does not turn on “disclaimer” or whether the Examiner understood Garrison correctly. Reply 15. The point is that “the prosecution history ... supports interpreting the claims according to the common usage of the word” “predetermined” because the “[E]xaminer understood it in its ordinary sense.” *Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1289 (Fed. Cir. 2021).

B. Petitioner's Combinations Lack "A Predetermined Cycle" To "Control Fluid Flow In And Out"

RapidPulse explained in its POR (26-31) that the Petition's combinations rely on including Mullins's pressure sensor, and Petitioner does not seriously dispute this—its sole rebuttal states, in a single conclusory sentence, without citation to the Petition, that Petitioner did not rely on Mullins "for its sensors." Reply 17. As detailed in the POR, Petitioner is wrong, and regardless, Petitioner cannot pick and choose only so much of Mullins as supports its position, disregarding that Mullins's system is based on sensor feedback. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) (error to "consider[] ... references in less than their entireties, i.e., in disregarding disclosures in [them] ... that diverge from and teach away from the invention"). Moreover, even in Reply, Petitioner fails to explain how its combinations would control the alleged flow *without* using Mullins's sensor feedback approach. Reply 14-17; Ex.1035 ¶¶67-84.

Petitioner contends that Yang and Ofek disclose predetermined cycles but, even if true, that does not help Petitioner because (1) Petitioner relied on Mullins's sensor-feedback approach in its combinations, and (2) as discussed below, Yang and Ofek indisputably do not control fluid flow in and out. Focusing on Mullins, Petitioner admits, "Mullins discloses 'pulse cycling between two pressure limits.'" Reply 16. This cycling, based on when the sensed pressure reaches a limit, is not a "predetermined cycle." POR 25-31.

Petitioner does not identify **any** teaching in Mullins of “a predetermined cycle” to “control fluid flow in and out.” Petitioner cites Mullins’s “shake signal ... initiated for a predefined number of cycles” (Reply 17 (quoting Ex.1008, 28:1-10)), but the experts agree Mullins’s “shake” signal still involves “application of pulse cycling between two pressure limits” (*id.*, 27:54-57; Ex.2014 ¶126; Ex.1035 ¶77), and Mullins does not disclose using it to “control fluid flow in and out.” In addition, Mullins’s disclosure of a “predefined number of cycles” (Ex.1008, 28:1-10) does not help Petitioner because the claim requires the cycle itself to be “predetermined”—a “predetermined number” of cycles, where cycles vary based on sensor feedback, does not satisfy the claim. Petitioner also relies on Mullins’s “infuse-to-aspirate cycle” ratios, such as “between 0.01 and 0.99.” Reply 17 (quoting Ex.1008, 28:59-29:12). But this is not disclosure of “fixed timing” (Reply 17), but rather of boundaries for Mullins’s sensor feedback-based approach. Ex.2014 ¶127 (“the ratio represents the maximum relative time duration between infuse and aspirate portions, but not that each cycle must follow the same ratio”).

C. Petitioner’s Proposed Combinations Do Not “Control Fluid Flow In And Out”

Rejecting Petitioner’s erroneous proposal that “control fluid flow in and out” is met by “preventing” flow out (Reply 3-4, 6), neither Yang/Mullins nor Ofek/Mullins “control fluid flow in and out.” Petitioner’s contrary arguments are not credible and are not supported by substantial evidence.

Petitioner persists in erroneously arguing that Yang teaches “controlling flow in and out,” even though RapidPulse pointed out (POR 24) that Yang lacks disclosure of flow out from the distal end of the catheter (let alone control of it), and Mr. Brown already admitted “[*Yang*] **does not describe ... flow out and whether [Yang’s] system controls flow out.**” Ex.2016, 93:13-25. Mr. Culbert agrees. Ex.2014 ¶¶46, 61. Petitioner also has now conceded, in its European Opposition, that “the skilled reader would appreciate that the teaching of O2 [Yang] is that forward flow is **prevented.**” Ex.2035, 53 (“O2 [Yang] would therefore naturally result in forward flow being prevented”), 52 (“Operating an arrangement as described by document O2 [Yang] would naturally result in the **prevention** of forward flow”), 2 (identifying O2 as Yang); Ex.2044, 46:1-5. Petitioner’s “representations to the EPO are relevant to determine how an ordinarily skilled artisan would understand” Yang. *Guardant Health, Inc. v. Univ. of Wash.*, IPR2022-00450, Paper 13 at 11 (P.T.A.B. Aug. 1, 2022) (citing *inter alia Tanabe Seiyaku Co. v. ITC*, 109 F.3d 726, 733 (Fed. Cir. 1997) (“representations made to foreign patent offices are relevant” to a POSA’s understanding)).

Petitioner also incorrectly argues that Ofek teaches “controlling flow in and out,” despite admitting in its European Opposition that the opposite is true: “The system of O3 [Ofek] is therefore operated so as **to prevent forward flow of fluid out** of the distal end of the catheter.” Ex.2035, 64; *see also id.*, 63 (“As the dislodged

occlusion is required to not enter the bloodstream, it is clear that [Ofek's] device is operated so as *to prevent forward flow* of liquid from the catheter.”) (original underscoring), 79; Ex.2044, 46:6-50:1; *Guardant Health*, IPR2022-00450, Paper 13 at 11; *Tanabe Seiyaku*, 109 F.3d at 733.

Petitioner's argument that “Yang and Ofek each disclose embodiments that *could* be understood or obvious as controlling ... distal flow out” fails not only because Petitioner admits that is not how a POSA would understand them, but also because obviousness requires that a POSA “would” understand them that way—not just that a POSA “could” do so. Reply 11; *see also* Ex.1035 ¶¶45-46 (testifying about what “*could* be understood or [sic] obvious”); *Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 886-88 (Fed. Cir. 2024) (reversing Board's obviousness determination because evidence only showed an arrangement was “possible,” not that a POSA “would have” implemented it).

Combining Yang or Ofek with Mullins fails to provide the missing control of fluid flow in and out. Petitioner concedes that “Mullins ... explicitly teaches ... **preventing forward flow** to reduce the risk of distal embolization.” Ex.2035, 114. Petitioner and Mr. Brown also admit that a POSA “would be motivated to use the teachings of Mullins to create a system that has **no forward flow**”—not to control flow in and out. Ex.2044, 35:8-16; *see also* Ex.2035, 116 (“The skilled person would therefore be motivated to operate a clot removal system with **no forward flow**, ...

in the manner described by O10 [Mullins]"); Ex.2044, 50:2-52:7. Indeed, Petitioner admits that the "common general knowledge ... teachings of the" prior art would motivate a POSA to "ensure[] that **forward flow is prevented.**" Ex.2035, 129, 135; *see also id.*, 131, 135 ("[t]he skilled person would therefore seek to preserve an overall negative pressure in the catheter").

Petitioner's arguments here, which are contradicted by its own and its expert's admissions about references' teachings and a POSA's motivations, cannot support obviousness. *Interactive Commc 'ns Int'l, Inc. v. Blackhawk Network Inc.*, IPR2024-00465, Paper 40 at 3 (Dir. Oct. 9, 2025) (reversing Board's obviousness finding "[b]ecause the Board rested its finding of a reason to combine on [expert]'s contradictory testimony") (citing *Finesse Wireless LLC v. AT&T Mobility LLC*, 2025 WL 2713518, at *4 (Fed. Cir. Sept. 24, 2025) ("When the party with the burden of proof, ... rests its case on an expert's self-contradictory testimony, we may conclude the evidence is insufficient to satisfy that standard.")).

Despite having ample opportunity to address the European opposition in its Reply and being on notice of the contradictory statements RapidPulse had identified (Paper 19), Petitioner declined to address them (Reply 8-9) or even have Mr. Brown review them. Remarkably, Mr. Brown declared that he "disagree[s] that any such contradiction exists" (Ex.1035 ¶35), even though "all [he] reviewed ... were the claims for the European patent," and nothing else. Ex.2044, 84:5-85:14. He "was

not asked to review any more of” the European Opposition—for good reason. *Id.*, 84:14-17. Petitioner did not want him to review the statements contradicting his testimony here. And Mr. Brown believes that it is perfectly “acceptable” for Petitioner to take contradictory positions about what the prior art teaches before this Board and the EPO:

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

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

Id., 42:16-43:2.

The Board can decide how Petitioner's and Mr. Brown's contradictory positions bear on their credibility; regardless, those contradictory positions cannot sustain Petitioner's burden to prove that its combinations render control of fluid flow in and out obvious. *Interactive Commc'ns*, IPR2024-00465, Paper 40 at 3; *Finesse Wireless*, 2025 WL 2713518, at *4.

IV. Petitioner's Combinations Fail To Render Obvious Dependent Claim 11 (Claims 11-20)

Claim 11 requires using the system of claim 1 in a method of “aspirating thromboembolic material from a person ... by ... positioning the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person” and controlling the vacuum and vent valves in “a predetermined cycle” (per

claim 1), “thereby control[ling] flow in and out from the distal end of the catheter.”

As discussed above, Petitioner failed to show any of its combinations teach or suggest having, let alone controlling, “flow in and out from the distal end of the catheter” in operation. Beyond this failure, neither proposed combination renders the claimed method obvious for additional reasons.

A. A POSA Would Not Have A Reasonable Expectation Of Success In “Aspirating Thromboembolic Material From A Person” By “Control[ling] Fluid Flow In And Out” “In A Predetermined Cycle”

To argue a reasonable expectation of success for its combinations, Petitioner relied on Mullins’s sensor feedback approach in the Petition. Pet.17-18, 68, 101; Ex.1005 ¶¶100, 361. The Board recognized Petitioner’s use of Mullins’s sensor. ID 13-14. After RapidPulse explained that Petitioner failed to show a reasonable expectation of success in achieving clot aspiration using controlled fluid flow in and out in a predetermined cycle (POR 33-45; Ex.2014 ¶¶88-105), Petitioner now changes course, handwaving at “routine optimization.” Reply 19-21; Ex.1035 ¶¶93-100. Petitioner’s new argument is procedurally improper and fails on the merits.

Petitioner never relied on any “routine optimization” theory for claim 1 or claim 11 in the Petition. Pet.16-35, 49-50, 67-86, 98-99. The Board should “hold[] [Petitioner] to its word and disregard[] its new theory first raised in reply.” *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330-31 (Fed. Cir. 2019) (affirming Board’s decision to do so).

Regardless, Petitioner's new "routine optimization" argument cannot support obviousness because Petitioner does not present reasons why such optimization would have led to the claimed invention. *In re Stepan Co.*, 868 F.3d 1342, 1346 (Fed. Cir. 2017) ("Absent some additional reasoning, the Board's finding that a skilled artisan would have arrived at the claimed invention through routine optimization is insufficient to support a conclusion of obviousness."). Petitioner relies on Grey for its generic assertions about routine optimization. Reply 19-20. But as the Board already found, Grey discloses "[p]roviding a 'non-zero suction force ... at all times,'" *preventing* flow out of the distal end. Ex.2011, 34-35 (quoting Ex.1010, 13:7-11); Ex.2010, 125:6-18 (no flow out when there is a non-zero suction force). Because Grey avoids flow out, it provides no basis to optimize flow out.

Petitioner's conclusory assertion that "valve timing and pressure to regulate distal flow is a predictable technical solution" (Reply 20) is unsupported by any rationale to have flow out—let alone recognition of the physical phenomena that must be controlled. Contrary to Petitioner's argument that "the prior art includes at least as much detail regarding valve timing as the '402 Patent" (*id.*), the '402 Patent provides detailed explanations of valve timing and addresses the relevant physical phenomena. *See, e.g.*, Ex.1001, 8:36-64 (control of water hammer effect), 36:25-37:2 (addressing distal flow due to the "spring-like force" in a clogged catheter),

40:7-16 (effect of catheter compliance), Tables 1-5 (exemplary valve timing). And contrary to Petitioner's argument that "the claimed invention merely involves parameter selection and adjustment" (Reply 20), Petitioner has failed to identify *any* parameters used to create distal flow in the prior art—there is nothing to select from or adjust.

Petitioner's setting the claimed invention as the goal and handwaving at optimization to achieve it is classic hindsight. *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1361 (Fed. Cir. 2019) (reversing the Board, explaining that "crediting" "conclusory and unsupported expert testimony" "risks allowing the challenger to use the challenged patent as a roadmap to reconstruct the claimed invention," which is "the impermissible *ex post* reasoning and hindsight bias that *KSR* warned against"). Neither Petitioner nor its expert addresses the ample evidence, including peer-reviewed literature and Petitioner's own expert testimony that RapidPulse provided to show that a POSA would not have a reasonable expectation of success. POR 36-45. Unable to respond, they falsely label this evidence "unfounded speculation" and invoke unsupported "clear guidance" in the prior art, which highlights their hindsight-based approach. Reply 19-21; Ex.1035 ¶¶93-100.

Petitioner failed to show the required reasonable expectation of success. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378-79 (Fed. Cir.

2015) (petitioner bears the burden); *Juniper Networks, Inc. v. Correct Transmission, LLC*, IPR2021-00682, Paper 26 at 23 (P.T.A.B. Oct. 3, 2022) (petitioner failed to meet its expectation of success burden), *aff'd*, 2024 WL 3517862, at *5 (Fed. Cir. July 24, 2024) (Board is entitled to weigh witness credibility in evaluating arguments). *Elektro Ltd. v. Zap Surgical Systems, Inc.*, does not save Petitioner: the Federal Circuit held that the *Board's* findings on reasonable expectation of success may be implicit—not that *petitioners* are excused from showing it. 81 F.4th 1368, 1377 (Fed. Cir. 2023).

B. Ofek/Mullins Does Not Render Obvious Positioning As Claimed

Petitioner relied on “applying Mullins’s technique to Ofek,” incorrectly contending that “Ofek discloses an aspiration thrombectomy system” (Pet.98), when it actually discloses a “patency device” (Ex.1007, 1:16-23). Petitioner provides no basis to find that Ofek teaches “*positioning* the distal end of the catheter at least proximate to thromboembolic material in a blood vessel of the person.” Ex.1001, cl. 11. As the POR explained (46-47), Ofek is a device for keeping a catheter lumen free of obstructions by preventing them from forming therein or removing them after they have formed therein—not for deliberately introducing obstructions in a blood vessel into the lumen. Ex.1007, 1:16-23 (quoted at ID 27), 2:56-3:2.

Because the Petition’s argument that “Ofek discloses an aspiration thrombectomy system” (Pet.98) was wrong, Petitioner now shifts to an obviousness

theory for this limitation (Reply 18-19). But Petitioner failed to articulate any such obviousness theory in its Petition, and cannot raise this new theory now. *Henny Penny*, 938 F.3d at 1330-31.

Regardless, Petitioner fails to show it would have been obvious to modify Ofek to remove clots in blood vessels. Petitioner asserts that Ofek's device is "well-suited for thrombectomy procedures" and "well-suited to ingest clots" (Reply 18), but whether Ofek "could" be, or is "well-suited" to be used for that purpose falls short of showing why a POSA would have been motivated to use it for that purpose, which is Petitioner's burden to show for obviousness. *Virtek*, 97 F.4th at 886-88. Indeed, Petitioner provides no explanation of a motivation to modify Ofek, or to use Mullins's aspiration thrombectomy system in Petitioner's combination with Ofek, because that was not Petitioner's argument. Pet.98.

V. Petitioner Fails To Demonstrate The Proposed Combinations Render Obvious The "Amount Of Exit Flow" Claims—Claims 3-4, 14, And 16-17

Claims 3-4, 14, and 16-17 require specific "positive amount of exit flow" limited to specific ranges "before fluid is drawn back into the catheter lumen" by applying vacuum. Petitioner fails to show these claims are rendered obvious.

Petitioner contends "The Prior Art Discloses The 'Limiting' Limitation," (Reply 11), but it is unclear which claims Petitioner addresses. Claims 3-4, 14, and 16-17 require more than just a limit on the "positive amount of exit flow"—they

recite specific ranges for that exit flow. Petitioner addresses those specific ranges in a separate section arguing that they “are obvious results of routine optimization.”

Id. 13-14. Petitioner's arguments fail for three reasons.

First, Petitioner argues obviousness based on what “could” be understood from the references and what “may occur.” Reply 11 (“Yang and Ofek each disclose embodiments that **could** be understood or [*sic*] obvious as controlling flow distal flow [*sic*] out”; “distal flow out may occur”), 12 (“For Ofek, a POSA would understand that the high-pressure impulses ... **could** cause some amount of distal flow out.”). But obviousness requires showing what a POSA “would” have understood and been motivated to do, not merely what a POSA “could” understand. *Virtek*, 97 F.4th at 886-88. And as discussed (*supra* §III.C.), Petitioner conceded that Yang, Ofek, and Mullins all teach preventing flow out, so a POSA would not have understood them to teach having flow out. It is also simply untrue that “a POSA would recognize that some positive exit flow would occur when applying pulsated/cyclical aspiration” (Reply 11), because as Grey teaches, and the Board recognized, net negative pressure can be maintained “at all times” in cyclic aspiration. Ex.2011, 34-35 (quoting Ex.1010, 13:7-11).

Second, Petitioner incorrectly contends “the ‘fluid column’ within the catheter lumen includes both blood and thrombus” to fault Mr. Culbert for testifying that, when only clot is being pushed distally (as Mullins's Figure 47 shows), there

may be no fluid flow out. Ex.1035 ¶¶58-60; Reply 12-13. Petitioner's argument that the fluid column includes the thrombus contradicts the '402 Patent, which expressly differentiates them. Ex.1001, cl. 10 ("the **fluid column** ... is sufficient to unstick **thromboembolic material**"), 26:19-23, 27:3-4 ("For the **thrombus** to accelerate, both **it** and **the fluid column** within the catheter system must attain a velocity."), 27:21-23, 27:36-45, 40:19-24, 46:8-13. Petitioner cannot redefine the fluid column, contrary to the intrinsic record, to include the thrombus to support obviousness.

Third, Petitioner's "routine optimization" argument fails. As discussed (*supra* §III.C.), Petitioner fails to identify any reference disclosing controlled flow out of the distal end to be optimized. Petitioner fails to show why a POSA would be motivated to have flow out or address the physical phenomena that would need to be addressed in seeking to optimize it. POR 48-56. Petitioner cannot disguise its hindsight-driven approach by invoking "routine optimization." *Merck Sharp & Dohme B.V. v. Warner Chilcott Co., LLC*, 711 F. App'x 633, 637 (Fed. Cir. 2017) ("[T]he only way to arrive at the hypothetical [combination] is by using the [patent-at-issue] as a roadmap to piece together various elements of [the prior art reference]. That represents an improper reliance on hindsight."); *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 162 (Fed. Cir. 2021) (rejecting Board's obviousness finding relying on hindsight reasoning).

Contrary to Petitioner's assertions, Mullins does not teach "routine optimization" of flow out from the distal end, and the '402 Patent is not silent "on how the claimed values were reached." Rather than teach optimizing flow out, Mullins teaches avoiding it, as Petitioner and Mr. Brown admit. Ex.2035, 114 (Petitioner: "Mullins ... explicitly teaches ... **preventing forward flow** to reduce the risk of distal embolization"); Ex.2044, 35:8-16 (Mr. Brown: a POSA "would be motivated to use the teachings of Mullins to create a system that has **no forward flow**"). Petitioner thus fails to provide any evidence-based reasoning required to support its "routine optimization" argument. *Stegan*, 868 F.3d at 1346. And unlike Mullins, the '402 Patent not only expressly teaches the claimed amounts of positive exit flow but also the phenomena that must be addressed to optimize them. *E.g.*, Ex.1001, 8:36-64 (control of water hammer effect), 24:45-51 (specific amounts of exit flow), 36:25-37:2 (addressing distal flow due to the "spring-like force" in a clogged catheter), 40:7-16 (effect of catheter compliance).

Petitioner does not dispute that, as RapidPulse showed (POR 50-56), Mr. Brown's calculations reflect a complete failure to account for multiple critical aspects of aspiration thrombectomy systems. While the Petition asserted that these calculations "demonstrate that the claimed exit flow values are within the expected values that a POSA would determine" (Pet.43), Petitioner now retreats to asserting that these calculations "demonstrate[] the maximum possible exit flow" and

represent only a starting point “for actual experimentation” (Reply 14). Even Mr. Brown now calls his calculations a “starting point” that he only asserts show that the “maximum amount of exit flow” “*can be* limited.” Ex.1035 ¶66. Thus, neither Petitioner nor Mr. Brown even contend that Mr. Brown’s calculations show that it would have been obvious to optimize exit flow to achieve the claimed ranges. There is no dispute that the amount of exit flow “can be limited” (*id.*), but that does not support that the specific claimed amounts of exit flow would have been obvious. Indeed, Mr. Brown’s flawed calculations reinforce that Petitioner’s arguments are hindsight-driven. *Merck*, 711 F. App’x at 637; *Univ. of Strathclyde*, 17 F.4th at 162.

VI. Petitioner Fails To Show The Combinations Render Obvious The “Off-Off State” Claims (Claims 5-7 And 18-20)

Claims 5 and 18 recite an “off-off state,” where both vacuum and vent valves are closed, while claims 6-7 and 19-20 recite two such states in each cycle. The specification explains that the timing of the off-off state is tuned for practical considerations, e.g., the catheter’s length and compliance, and thus is a “state” of the cycle—not an incidental, momentary overlap of the valves. Ex.1001, 37:3-38:54 (Tables 1-2, 4-5), 48:37-51, 50:11-23, 50:49-51; Ex.2014 ¶130.

Yang/Mullins lacks an off-off state. Petitioner hypothesizes “an additional valve state” between Yang’s Figures 25C to 25A (Reply 22), but it does not exist. Petitioner also appears to have abandoned any argument that a second off-off state

is present in Yang/Mullins. *See id.* 21-22 (referring only to a singular “the off-off state”).

For Ofek/Mullins, Ofek teaches operating the valves simultaneously, as in its Figure 10, so Ofek does not suggest an off-off state. POR 61-63; Ex.2014 ¶¶143. Ofek also requires no “finite delay,” nor does it contemplate any three-way valve that would necessarily introduce an off-off state. Ex.2014 ¶¶144-145.

Similarly, Petitioner's manufacture of a transition period of Rubenstein's valve 18/46 also fails to render obvious the off-off state; Rubenstein's waveform E in Figure 2 shows no delay during valve transitions. POR 65. The Board was previously “skeptical” about Petitioner's Rubenstein arguments, finding that Rubenstein did not appear to disclose “a double-closed state.” Ex.2023, 45. Petitioner still has not explained “why a different outcome is warranted” now. Memorandum, PTAB Consideration of Prior Findings of Fact and Conclusions of Law (USPTO Sept. 16, 2025), https://www.uspto.gov/sites/default/files/documents/Memo_re_prior_findings_of_fact_and_conclusions_of_law_9_16_25.pdf.

VII. Objective Indicia Of Non-Obviousness

As the POR established, the claimed invention resolved a long-felt unmet need for improving the first-pass success rate of thrombus removal (the First Pass Effect (FPE)). POR 67-71 (citing Exs.2026-2028). Petitioner's assertion that “there was no ‘unmet’ need” (Reply 26) is *refuted by Petitioner's own evidence* submitted

with its European Opposition, identifying “Variable or Cyclical Suction” as an “Unmet Need” in November 2018, near the priority date of the ’402 Patent. Exs.2040-2042.

In arguing against nexus, Petitioner attacks a strawman, arguing RapidPulse does not have “a commercially available and successful product.” Reply 25-26. But RapidPulse does not rely on commercial success; its product is in clinical trials. Petitioner has no response to the evidence RapidPulse actually offered—Mr. Culbert’s explanation, based on peer-reviewed literature, that the inventions of claims 3-7, 11, 14, and 16-20 addressed an unmet need for improved FPE. Ex.2014 ¶¶157-162.

VIII. Conclusion

The patentability of the ’402 Patent claims should be confirmed.

Respectfully submitted,

Dated: November 6, 2025

By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner
RapidPulse, Inc.*

CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that this Patent Owner's Sur-Reply complies with the word count limitation of 37 C.F.R. § 42.24(c)(1) because the Patent Owner's Sur-Reply contains 5,597 words using Microsoft Word's counting feature, excluding the cover page, signature block, and the parts of the Patent Owner's Sur-Reply exempted by 37 C.F.R. § 42.24(c).

By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner
RapidPulse, Inc.*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 6th day of November 2025, a true and correct copy of the foregoing **Patent Owner's Sur-Reply and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

Eliot D. Williams (Reg. No. 50,822)
Baker Botts L.L.P.
700 K St
Washington, D.C. 20001
Tel: 202.639.7700
Eliot.Williams@BakerBotts.com
DLPenumbralIPR@bakerbotts.com

Jeremy J. Taylor (Reg. No. 73,912)
Mark Oda (Reg. No. 76,659)
Baker Botts L.L.P.
101 California St, Suite 3600
San Francisco, CA 94111
Tel: 415.291.6202
Jeremy.Taylor@BakerBotts.com
Mark.Oda@bakerbotts.com

By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner
RapidPulse, Inc.*