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Paper 7
Entered: February 21, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PENUMBRA, INC.,
Petitioner,

v.

RAPIDPULSE, INC.,
Patent Owner.

IPR2024-01261
Patent 11,406,402 B2

Before JOHN G. NEW, JASON W. MELVIN, and JAMIE T. WISZ, *Administrative Patent Judges*.

WISZ, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Penumbra, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–20 of U.S. Patent No. 11,406,402 B2 (Ex. 1001, "the '402 patent"). RapidPulse, Inc. ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

Under 35 U.S.C. § 314(a), the Board "may not authorize an *inter partes* review to be instituted unless . . . the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." After considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 1–20 of the '402 patent, based on all of the grounds identified in the Petition.

The following findings of fact and conclusions of law are not final, but are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the full trial record, including any response timely filed by Patent Owner. Any arguments not raised by Patent Owner in a timely-filed Response may be deemed waived or forfeited, even if they were presented in the Preliminary Response.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 1. Patent Owner identifies itself as the real party-in-interest. Paper 4, 1.

B. Related Matters

The parties note that the '402 patent is a continuation of U.S. Patent Application No. 16/899,514, currently pending before the USPTO, which is a continuation of U.S. Patent No. 10,722,253 B2 ("the '253 patent"), which is a continuation of U.S. Patent No. 10,531,883 B1 ("the '883 patent"). Pet. 1; Paper 4, 1. The parties further note that the '883 patent and the '253 patent were subject to IPR proceedings IPR2021-01466 and IPR2022-00608, respectively, in which all claims were found to be unpatentable for both patents. Pet. 1; Paper 4, 1. IPR2021-01466 and IPR2022-00608 are currently pending on appeal before the Federal Circuit in cases CAFC-2024-1130 and CAFC-2024-1131. *Id.*

C. The '402 Patent (Ex. 1001)

The '402 patent, titled "Aspiration Thrombectomy System and Methods for Thrombus Removal with Aspiration Catheter," is directed to an aspiration thrombectomy system that may be used for treatment of ischemic strokes caused by a blood clot that blocks or plugs a blood vessel in the brain. Ex 1001, code (54), 1:43–3:20. We reproduce Figure 47 from the '402 patent below.

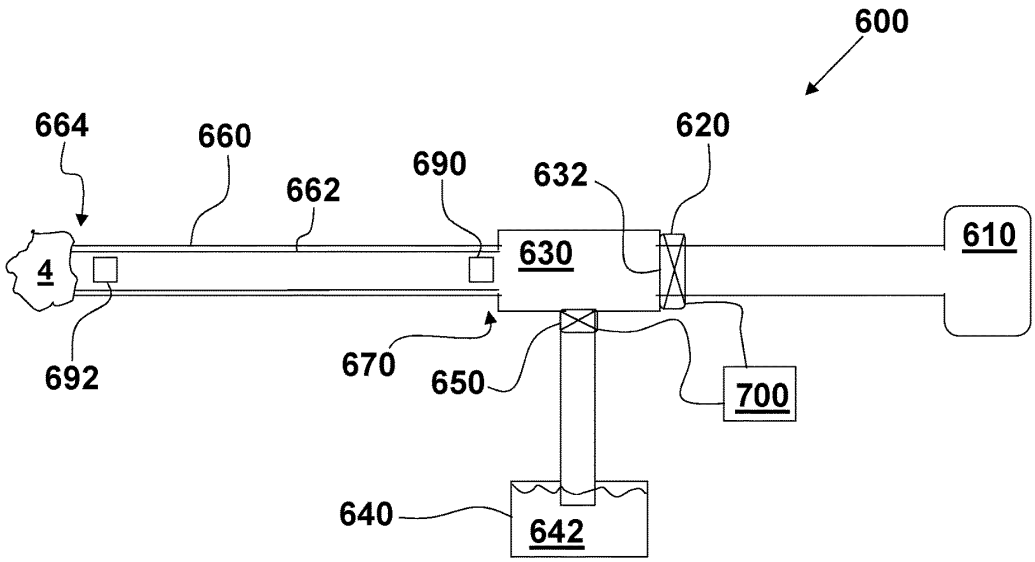

FIG. 47

Figure 47 illustrates an embodiment of the aspiration thrombectomy system 600 of the '402 patent that operates in a Rapid Onset Aspiration Repeater ("ROAR") mode. Ex. 1001, 39:34–36; 41:32–35; Fig 47. The system includes a vacuum source 610 fluidically connected to the input of a controllable vacuum valve 620, which in turn is fluidically connected to the vacuum input of a manifold 630. *Id.* at 41:35–41. A vent fluid source 640 containing a vent liquid 642 is fluidically connected to a controllable vent valve 650. *Id.* at 41:42–44. A ROAR catheter 660, configured to operate in relatively small vessels, "defines a working lumen 662 fluidically connecting a distal end 664 thereof to a proximal manifold connector assembly 670 at a proximal end of the ROAR catheter."[1] *Id.* at 42:1–4.

Operation of the aspiration thrombectomy system 600 occurs through a controller 700 that "selectively opens and closes the vacuum and vent

[1] Throughout this Decision, we omit bolding of reference numbers from the challenged patent and prior art references.

valves 620, 650 such that, when the vacuum valve 620 is opened, the vacuum source 610 is fluidically connected to the liquid column in the lumen 662 and, when the vent valve 650 is opened, vent liquid 642 is fluidically connected to the liquid column in the lumen 662." Ex. 1001, 42:52–58. Controller 700 controls the timing of these valves to "change a level of vacuum at the distal end 664 and prevent the distal portion of the liquid column in the lumen 662 from exiting the distal end 664—substantially no forward flow." *Id.* at 42:58–62.

During a ROAR cycle, "suction is applied to the clot by rapidly opening a valve, causing a rapid rise in vacuum pressure." Ex. 1001, 46:45–47. The source of suction is then turned off and a vent fluid source is rapidly opened, which "relieves the vacuum present in the catheter 660, which again rapidly changes the pressure applied to the clot." *Id.* at 46:47–50. In some embodiments of the ROAR cycle, both the vacuum valve 620 and the vent valve 650 are closed at the same time before the vent valve is opened. *Id.* at 10:6–11, 49:30–50:23, Tables 1, 4, 5. "The vent valve 650 is then rapidly closed and the vacuum valve 620 is rapidly opened." *Id.* at 46:50–51. "This cycle is repeated multiple times per second." *Id.* at 46:52.

In some embodiments, when the distal end of the catheter is clogged by a thrombus, "[t]he controller 10 is actuated to cause the fluid column to shift distally to the shift distance." Ex. 1001, 26:17–19. "This imparts a controlled reversal of flow to the fluid column within the vacuum channel 3 that slightly translates the thrombus to a prescribed shift distance 70 distally relative to the distal opening of the vacuum channel." *Id.* at 26:19–23. "The controller 10 is used to unclog the vacuum channel 3 and displace the thrombus 4 distally out from the distal opening." *Id.* at 27:18–20. Then, "the controller 10 re-applies vacuum," "and the thrombus 4 accelerates back

into the vacuum channel." *Id.* at 27:20–23. According to the '402 patent, "[t]he flow of fluid forward in this exemplary embodiment is intentional, which is in contrast to other exemplary embodiments herein where substantially no forward flow occurs." *Id.* at 36:67–37:2.

D. Challenged Claims

Petitioner challenges claims 1–20 of the '402 patent. Pet. 8. Claim 1, which is an independent claim, is illustrative of the challenged claims, and is reproduced below:

1. [1-Pre] An aspiration thrombectomy system, comprising:

[1-A] an aspiration catheter having a proximal portion, a distal end and a lumen extending through the catheter;

[1-B] a vacuum source fluidically coupled to the catheter;

[1-C] a vacuum valve connected between the vacuum source and the proximal portion of the catheter to control a vacuum flow in the catheter lumen;

[1-D] a vent valve fluidically coupled to the proximal portion of the catheter, the vent valve being configured to control a flow of a vent fluid in the catheter lumen; and

[1-E] a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle

[1-F] to change a level of vacuum at the distal end of the catheter

[1-G] and to control fluid flow in and out from the distal end of the catheter.

Ex. 1001, 61:16–30 (annotated with bracketed claim number and letters). Challenged claims 2–20 depend from claim 1, either directly or indirectly.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–20 of the '402 patent ("the challenged claims") are unpatentable in view of the following grounds. Pet. 8–9.

Ground	Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1	1–8, 10–20	103	Yang,[3] Mullins[4]
2	5, 6, 18, 19	103	Yang, Mullins, Rubinstein[5]
3	9	103	Yang, Mullins, Matteo[6]
4	1–8, 10–20	103	Ofek,[7] Mullins
5	5, 6, 18, 19	103	Ofek, Mullins, Rubinstein
6	9	103	Ofek, Mullins, Matteo

Petitioner relies on the Declarations of Brian Brown (Ex. 1005) and Ian Ross, M.D. (Ex. 1023) in support of its contentions. Patent Owner relies on the Declaration of Brad Culbert (Ex. 2001) in support of its Preliminary Response.

III. ANALYSIS

A. Person of Ordinary Skill in the Art

"The level of skill in the art is a factual determination" that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John*

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. § 103, effective on March 16, 2013. Because the application from which the '402 patent issued was filed after this date and does not claim priority to any application filed before this date, the AIA version of § 103 applies to this proceeding.
[3] Yang et al., US 2017/0238953 A1, published Aug. 24, 2017 (Ex. 1012, "Yang").
[4] Mullins et al., U.S. Patent No. 11,197,977 B2, filed Mar. 13, 2020, issued Dec. 14, 2021 (Ex. 1008, "Mullins").
[5] Rubinstein, U.S. Patent No. 3,955,574, issued May 11, 1976 (Ex. 1011, "Rubinstein").
[6] Matteo, US 2012/0138833 A1, published June 7, 2012 (Ex. 1013, "Matteo").
[7] Ofek et al., U.S. Patent No. 10,322,230 B2, filed June 9, 2017, issued June 18, 2019 (Ex. 1007, "Ofek").

Deere Co., 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner, relying on the testimony of Mr. Brown, contends that a person of ordinary skill in the art ("POSA" or "POSITA") as of the relevant date would be either:

> (1) a person with a B.S. in engineering or an equivalent field, with two-four years of academic or industry experience in aspiration embolectomy and thrombectomy or comparable industry experience who would, where appropriate, work or consult with others, including a physician, to develop embolectomy or thrombectomy devices; or (2) an interventional neurosurgeon with at least three years of experience developing and/or using medical devices in embolectomy or thrombectomy procedures, and who would, where appropriate, work or consult with others, including an engineer, to develop such a medical device.

Pet. 11 (citing Ex. 1005 ¶ 48). Petitioner also contends that, "[a] person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard." *Id.* Patent Owner states that for purposes of its Preliminary Response, it accepts Petitioner's proposed definition of POSA, but "reserves the right to propose its own description of a POSA if the Board institutes review." Prelim. Resp. 8 n.3.

For purposes of this Decision, we adopt Petitioner's characterization because it is consistent with the level of skill in the art at the time of the invention as reflected by the '402 patent and the cited prior art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown"

(quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2024). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner provides a proposed construction for the term "[limited/limiting] to a positive amount of exit flow" recited in claims 3, 4, 13, and 15, as "the maximum permitted amount of positive exit flow in the distal direction, including no exit flow." Pet. 15–16.

Patent Owner asserts that "Petitioner's proposed construction of 'a positive amount of exit flow' as 'including no exit flow' is plainly wrong." Prelim. Resp. 9 (citing Pet. 15–16). Patent Owner also asserts that to the extent Petitioner "view[s] the claim term 'flow in and out' as encompassing only flow in or no flow at all, that would be plainly wrong too." *Id.* Having evaluated the arguments and evidence before us on this record, we determine that construction of "[limited/limiting] to a positive amount of exit flow" is not necessary for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

Turning to a different claim term, we note that neither party provided an explicit construction for the limitation in claim 1 of "control[ling] fluid

flow in and out from the distal end of the catheter." We invite the parties to address the proper claim construction for this term and to specifically discuss what is encompassed by "flow . . . out from the distal end." We note that in the related cases (IPR2021-01466 and IPR2022-00608), we construed the term, "forward flow" to mean "an amount of liquid in the lumen that exits the distal end in the distal direction that is greater than 6 microliters of fluid." Ex. 2007, 15; Ex. 2011, 13–14.

Upon review of the parties' arguments and the evidence of record, we determine that no terms require express construction for purposes of this Decision. *See Nidec Motor Corp*, 868 F.3d at 1017.

C. Asserted Obviousness of Claims 1–8 and 10–20 over Yang and Mullins

Petitioner contends that claims 1–8 and 10–20 are rendered obvious over Yang and Mullins. Pet. 16–53. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 10–50.

1. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention, as a whole, would have been obvious before the effective filing date to a person having ordinary skill in the art to which the claimed invention pertains. *See also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective evidence

of non-obviousness, i.e., secondary considerations.[8] *See Graham*, 383 U.S. at 17–18.

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416. "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417. It is generally obvious to those skilled in the art to substitute one known equivalent for another. *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1374 (Fed. Cir. 2007) ("[T]his court finds no . . . error in [the] conclusion that it would have been obvious to one skilled in the art to substitute one ARC [alkaline reactive compound] for another."); *see also Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (the combination of known elements and substitution of one well known agent for another is obvious).

2. Yang (Ex. 1012)

Yang, titled "Telescoping Neurovascular Catheter with Active Distal Tip," is directed to a telescoping catheter for "distal neurovascular aspiration or access" including a control for advancing the distal section into the patient's vasculature. Ex 1012, codes (54), (57), Figs. 1, 3A, 3B. The catheter can connect to "a controller for applying intermittent vacuum to the lumen" using combinations of vacuum pulses and "spaces of neutral pressure," higher negative pressure or lower negative pressure. *Id.* ¶ 14,

[8] We note that Patent Owner has not presented any evidence of secondary considerations of nonobviousness at this stage of the proceeding.

Figs. 14, 25A–C. Yang also discloses ranges of catheter inner diameters. *Id.* ¶ 68.

Figure 14 of Yang is reproduced below.

FIG. 14

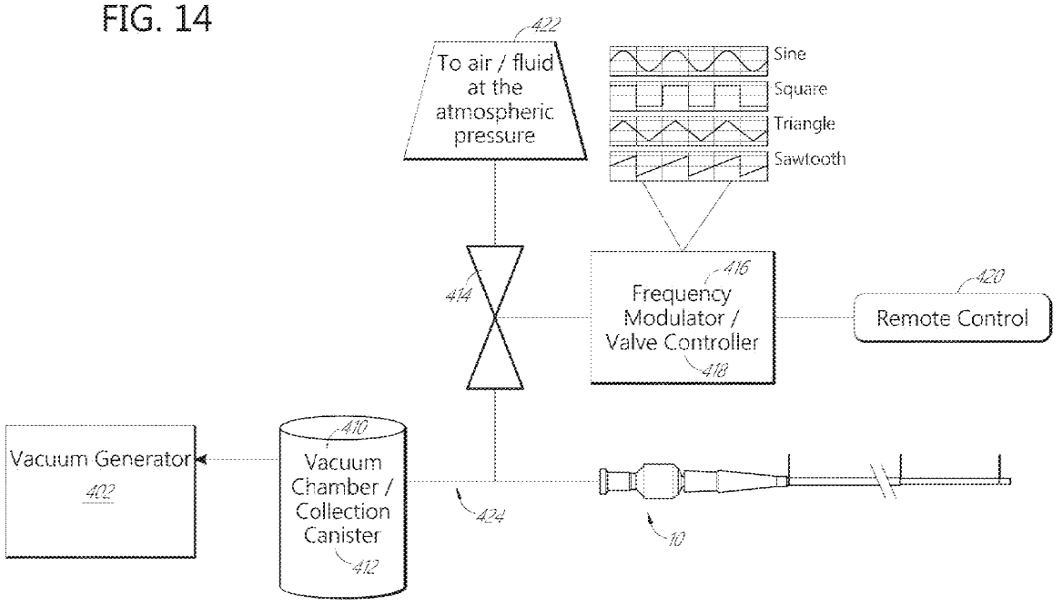

Figure 14 depicts an "aspiration system configured to apply pulsatile negative pressure through the aspiration catheter." Ex. 1012 ¶ 29. According to Yang, this aspiration system

> modulates pressure in the catheter 10 by allowing pressure to vary from vacuum to atmospheric pressure. When the solenoid valve 414 is open to the air/fluid reservoir 422 at the atmospheric pressure, the vacuum pressure in the aspiration line 424 decreases to the atmospheric pressure. When the solenoid valve 414 is closed, it increases the vacuum pressure in the aspiration line 424.

Id. ¶ 131. Referring to Figures 25A–25C, Yang also explains that "an interrupted vacuum can help aspirating a corked clot stuck at the distal end . . . of the catheter . . . by loosening the clot and reshaping it to fit into the catheter . . . after each vacuum and release cycle" and that "[c]ompletely releasing (venting to atmospheric pressure) the vacuum and allowing the clot

to relax before reapplying a vacuum is found to aspirate the corked clot most efficiently." *Id.* ¶ 168.

Yang was published on August 24, 2017, and Petitioner contends that it qualifies as prior art "at least because it was published prior to the filing date of the '402 Patent." Ex. 1012, code (43); Pet. 12. Patent Owner does not contest that Yang is prior art to the '402 patent.

3. Mullins (Ex. 1008)

Mullins, titled "Catheters and Devices and Systems Incorporating Such Catheters," is directed to "providing a catheter with improved properties for desired flexural stiffness and flexibility, to thereby allow use in difficult locations such as where there are significant curves and small dimensions in the patient vessels." Ex. 1008, code (54), 1:45–49.

Figure 45 of Mullins is reproduced below.

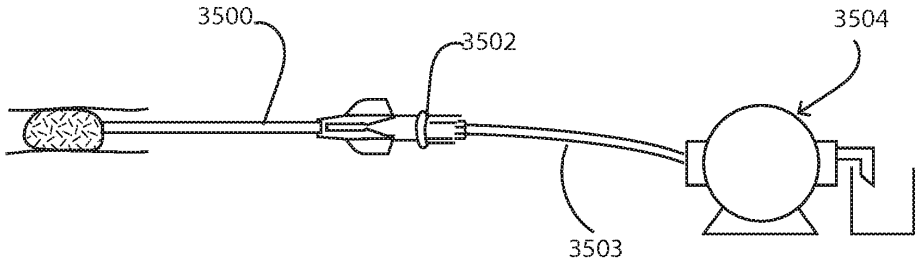

Fig.45

Figure 45 depicts an aspiration device having a catheter 3500, a guide 3502, tubing 3503, and a pump and reservoir assembly 3504. Ex. 1008, 26:20–22. Mullins explains that its invention uses "control and/or, variation of the vacuum pressure and/or, fluid displacement during aspiration to improve the efficiency of aspiration." *Id.* at 26:23–25. According to Mullins, "[t]he pump 3504 may provide a negative fluid displacement thereby decreasing pressure (enabling a vacuum) or positive displacement, thereby increasing pressure." *Id.* at 26:31–33. Mullins describes that "[t]he pump incorporates

a sensor which measures the pressure in the catheter lumen" and "[b]ased on the measured pressure, the pump may change direction hence altering the pressure and fluid displacement." *Id*. at 26:35–37, 26:40–42. Mullins further describes "the ability of the pump to measure the condition in the pump (e.g. pressure or fluid displacement), and continue or alter its behaviour." *Id*. at 27:50–53.

While Mullins was filed on March 13, 2020, and issued on December 14, 2021, Petitioner contends that Mullins qualifies as prior art at least because it claims priority to provisional applications, each of which was filed prior to the earliest effective filing date of the '402 patent, and because the disclosure of Mullins that is relied upon in the Petition is fully supported by the provisional applications. Ex. 1008, codes (22), (45), (60); Pet. 13 (citing Exs. 1009.1, 1009.2, 1009.3). Patent Owner states that it "reserves the right to show that any content in Mullins that Petitioner relies on was not disclosed in Mullins's provisional applications (Ex. 1009), and thus is not prior art, but this issue need not be addressed at the institution stage." Prelim. Resp. 16 n.5.

4. Claim 1

Petitioner, with supporting testimony from Mr. Brown, provides evidence as to where Yang and Mullins disclose the limitations of claim 1 of the '402 patent. Pet. 16–35. At this stage of the proceeding, Patent Owner only contests whether Petitioner has sufficiently shown that Yang and Mullins disclose or render obvious the limitations of "control[ling] fluid flow . . . out from the distal end of the catheter" using "a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle" (limitations [1-G] and [1-E], respectively). Prelim. Resp. 20–50. We review the parties' positions below.

a) Petitioner's Position

Petitioner asserts that Yang alone or in view of Mullins renders obvious the limitation of "control[ling] fluid flow in and out from the distal end of the catheter." Pet. 33–35. Specifically, Petitioner points to Yang's disclosure that the "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." *Id.* at 33 (citing Ex. 1012 ¶¶ 108, 135, 168). According to Petitioner, a "POSA would have understood that this reciprocation would cause fluid to move partially in and out of the distal end." *Id.* (citing Ex. 1005 ¶¶ 149–151).

Petitioner further contends that Mullins "teaches controlling distal fluid flow via measured pressure levels and predetermined cycles." Pet. 34 (citing Ex. 1008, 3:46–4:11, 26:23–64 ("The invention utilises control and/or, variation of the vacuum pressure and/or, fluid displacement . . .," which "help achieve . . . maceration and deformation of the clot.")). According to Petitioner, "Mullins's controller uses positive/negative pressure to control flow of clot and fluid in/out at the distal tip" and a "POSA would understand that the cyclical application of positive/negative pressure to the catheter would control fluid flow in and out from the distal end." *Id.* at 34–35 (citing Ex. 1005 ¶¶ 153–157; Ex. 1008, Figs. 47(a)-(n)).

b) Patent Owner's Position

First, Patent Owner contends that Petitioner has not shown that Yang alone discloses or renders obvious "control[ling] fluid flow in and out from the distal end of the catheter." Prelim. Resp. 21–32. Patent Owner contends that "introducing a positive pressure pulse (e.g., through the water hammer effect) does ***not*** mean that there will be an overall positive pressure within the catheter that would result in flow out from the distal end." *Id.* at 22–23

(citing Ex. 2007, 51 n.12; Ex. 2001 ¶¶ 53–54). According to Patent Owner, introducing a positive pulse does not cause flow out where the catheter remains in an overall vacuum state and Petitioner has not identified any disclosure in "Yang that the catheter is *not* in an overall vacuum state such that there would be sufficient overall positive pressure to cause flow out." *Id.* at 25 (citing Ex. 2005 ¶ 60; Ex. 2007, 43).

Patent Owner further contends that "to have flow out of the catheter's distal end when it is in a patient, the pressure in the catheter not only needs to be positive, but further needs to exceed mean arterial pressure," and that, "even if the pressure in the catheter is above mean arterial pressure, there may not be flow out of the catheter if a clot is corking the end of the catheter." Prelim. Resp. 26–27 (citing Ex. 2001 ¶¶ 59–60; Ex. 2010, 126:15–21, 126:23–127:5). According to Patent Owner, the disclosures in Yang relied on by Petitioner to show obviousness teach "allowing the clot to 'relax' by varying pressure from vacuum to atmospheric pressure at the high end, rather than pushing the corked clot off the catheter using flow out from the distal end." *Id.* at 30 (citing Pet. 22–33; Ex. 1012 ¶ 131 ("Figure 14 involves 'allowing pressure to vary from vacuum to atmospheric pressure;'" Ex. 1012 ¶ 168 ("[c]ompletely releasing (venting to atmospheric pressure)")).

Patent Owner further contends that Yang does not render obvious controlling flow out from the distal end because Yang "focuses on producing axial vibration of the catheter, mainly to ease advancing the catheter to reach the clot" and a "POSA would recognize that having flow out from the distal end while the catheter is being advanced toward the clot would be undesirable, and seek to avoid it, because it would risk pushing the clot distally into the vasculature." Prelim. Resp. 31 (citing Ex. 1012 ¶¶ 108,

135–136; Ex. 2010, 126:2–5; Ex. 2006, 24:10–22). According to Patent Owner, rather than using flow out from the distal end in order to remove clots, Yang discloses other approaches such as using a "moveable jaw or rotatable agitator" to facilitate ingesting clots. *Id.* (citing Ex. 1012, Abstract, ¶¶ 11–13, 77–80; Fig. 4; Ex. 2001 ¶ 68).

Patent Owner also argues that Petitioner failed to identify an adequate motivation to combine Yang and Mullins. Prelim. Resp. 32–41. First, Patent Owner contends that Yang and Mullins are entirely different systems because Yang discloses a two-valve system while Mullins uses a pump, resulting in systems that operate in distinct and incompatible ways. *Id.* at 33–34 (citing Ex. 1008, 26:31–33; Ex. 1012 ¶ 170; Ex. 2001 ¶ 72). According to Patent Owner, "Yang cannot be combined with Mullins without altering Yang's principles of operation, such as Yang's having both vacuum and vent pressure applied at the same time." *Id.* at 34 (citing Ex. 1012 ¶ 170; Ex. 2001 ¶¶ 72–73). Patent Owner also contends that Petitioner does not explain why a POSA would look at the pump-based approach of Mullins to improve the valve-based approach of Yang and that the proposed combination impermissibly relies on hindsight. *Id.* at 34–35. Patent Owner further argues that Petitioner does not identify why a POSA would have been motivated to implement Mullins's disclosures of forward flow into Yang and does not identify any teachings in Mullins that forward flow is desirable. *Id.* at 36–37.

According to Patent Owner, even if the disclosures of Yang and Mullins were combined, the combination would not yield the claimed invention because "modifying Yang's system to use Mullins's pressure sensor and vary aspiration pressure based on the sensed pressure would not result in a system having 'a controller [1] configured to open and close the

vacuum valve and the vent valve in a *predetermined* cycle … [2] *to control fluid flow in and out* from the distal end of the catheter.'" Prelim. Resp. 41 (citing Ex. 1001) (alterations in original). According to Patent Owner, the timing of the cyclical pressure variation in Mullins varies depending on feedback from the sensor, which is affected by factors such as the amount of blood flow entering the catheter, the size of the clot, and the density and consistency of the clot. *Id.* (citing 2001 ¶ 84). Thus, Patent Owner contends, Mullins "teaches that an advantage of implementing Mullins's feedback from pressure sensors is that the cyclic behavior of the pump is ***not*** predetermined." *Id.* at 42 (citing Ex. 2001 ¶ 83).

Lastly, Patent Owner contends that Petitioner does not articulate how the combination of Yang and Mullins would account for and control the water hammer effect in Yang's two-valve system. Prelim. Resp. 45 (citing Pet. 33–35). According to Patent Owner, Mullins's sensor is at the proximal end of the catheter rather than the distal end and Petitioner does not account for the fact that "there can be a tremendous difference between pressure measured at the proximal and distal ends." *Id.* at 48–49 (citing Ex. 1008, 26:35–37; Ex. 2001 ¶¶ 94–96).

c) Analysis

On the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood that the subject matter of claim 1 would have been obvious over the combined disclosures of Yang and Mullins. First, Patent Owner asserts that Yang does not disclose the limitation of "a controller . . . to control fluid flow in and out from the distal end." Prelim. Resp. 21– 32. On the current record, we agree with Patent Owner that introducing a positive pressure pulse such as through the water hammer effect does not *necessarily* mean that there will be an overall

positive pressure within the catheter that would result in flow out from the distal end. *See* Ex. 2001 ¶¶ 53–54; Ex. 2005 ¶ 60; Ex. 2007, 51 n.12. This is especially true if an overall vacuum state is maintained in the catheter. *See* Ex. 2001 ¶ 56; Ex. 2007, 43; Ex. 2010, 125:11–18. Further, on the current record, we credit the testimony of Patent Owner's declarant, Mr. Culbert, that to have flow out of the catheter's distal end when it is in a patient, the pressure in the catheter needs to exceed mean arterial pressure. *See* Ex. 2001 ¶ 59; Ex. 2010, 126:15–21. Therefore, on the current record, we agree with Patent Owner that Yang may not explicitly disclose flow out from the distal end of the catheter. Whether Yang alone renders this limitation obvious may be explored further on a full trial record; however, because this limitation appears to be taught by Mullins and Petitioner has shown on this record that a POSA would have been motivated to combine the disclosures of Yang and Mullins, we are sufficiently persuaded that Petitioner has met its burden to show a reasonable likelihood that this limitation is rendered obvious by the combined disclosures of Yang and Mullins.

We find that, on the current record, Petitioner has sufficiently shown that Mullins teaches "control[ling] fluid flow in and out from the distal end of the catheter." Mullins discloses controlling distal flow using different pressure levels. *See* Ex. 1008, 3:46–4:11, 26:23–64 ("The invention utilises control and/or, variation of the vacuum pressure and/or, fluid displacement . . .," which "help achieve . . . maceration and deformation of the clot."). Mullins further discloses:

> The controller may have defined upper and lower limits of pressure of 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.

Id. at 3:60–65 (emphasis added); *see also id.* at 26:43–49 (describing use of a pump with defined upper and lower limits that "enable the catheter to cyclically ingest and if required expel, at least some of the clot," which "improves the efficiency of the aspiration, and prevents clogging of the catheter"). Thus, the current record supports that Mullins's controller uses positive and negative pressure flow in and out of the distal end of the catheter. *See, e.g.*, Ex. 1008, Figs. 47(a)–(n); Ex. 1005 ¶¶ 153–157.

We also find, on the current record, that Petitioner has persuasively shown that a POSA would have been motivated to combine the teachings of Yang and Mullins and would have done so with a reasonable expectation of success. We agree with Petitioner that Yang and Mullins "address similar problems related to conventional aspiration thrombectomy," "share the common objective of improving the efficiency of removing blood clots," and "teach similar solutions involving using a positive pressure state to provide cyclical changes in pressure to efficiently remove blood clots." Pet. 16. We also agree that Yang and Mullins "[b]oth describe a similar approach of creating a dynamic aspiration force to more effectively clear clots in a blood vessel" and "[b]oth utilize an aspiration thrombectomy system to vary fluid flow and pressure to at least partially cyclically relieve the system's vacuum pressure to create an acceleration force on the clot for optimal clot aspiration." *Id.* at 16–17 (citing Ex. 1005 ¶ 98; Ex. 1012 ¶¶ 14, 67, 91, 123–128, 131, 135–136, 168–170; Ex. 1008, 1:53–2:2, 3:29–38, 3:46–59, 26:31–37, 26:43–49, 26:65–27:17; Ex. 1009.2, 2–10).

We are not persuaded by Patent Owner's argument that because Yang uses valves and Mullins uses a pump, one of skill in the art would not have been motivated to combine the disclosures of these two references.

> The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

In re Keller, 642 F.2d 413, 425 (CCPA 1981). On this record, we agree with Petitioner that a "POSA would have been motivated to implement Mullins's disclosures of forward flow and improvements in unsticking clots to modify Yang's system, which already includes a catheter aspiration system, to provide efficient and effective cyclical aspiration of blood clots." Pet. 17 (citing Ex. 1005 ¶ 100; Ex. 1012 ¶¶ 131, 168–170; Ex. 1008, 3:29–4:11, 26:17–28:64). Thus, although Mullins uses a pump, and Yang uses valves, a POSA would have been motivated to implement Mullins's teachings of using positive pressure to unstick clots. We credit Petitioner's declarant's testimony that this could be achieved by applying a positive pressure using the vent fluid source disclosed in Yang, sufficient to cause forward flow out the distal end of the catheter, as disclosed by Mullins. *See* Ex. 1005 ¶¶ 163–166.

Yang discloses the use of various levels of positive pressure such as "atmospheric pressure" or "slight positive pressure," such that a POSA would be able to adjust the pressure in Yang's device to be sufficient to cause flow out of the distal end of the catheter without altering Yang's principle of operation. *See* Ex. 1005 ¶¶ 163–170. We are sufficiently persuaded, on this record, that a POSA would have been motivated to apply

Mullins's teaching of using positive pressure to unstick clots to Yang's device because Mullins describes this technique of controlling flow out the distal end of the catheter as "improv[ing] [the] efficiency of the aspiration, and prevent[ing] clogging of the catheter." Ex. 1008, 3:64–65, 26:47–49.

We are also not persuaded by Patent Owner's assertions that combining Yang and Mullins would not yield the claimed invention because the combination lacks a "predetermined cycle" for opening and closing the vacuum and vent valves. Patent Owner's argument is based on the assertion that the variable cycle disclosed by Mullins is based on feedback from the pressure sensor, and is, therefore, not "predetermined." Prelim. Resp. 41–44. However, even if this is correct, the current record supports that Yang discloses a valve controller to control the vacuum and vent valves in a "predetermined cycle" as required by the language of the claims. *See* Pet. 28–30. More particularly, Yang discloses a valve controller to control the vacuum and vent valves. Ex. 1012 ¶¶ 123, 128, 131, 169, Figs. 13, 14 ("Valve controller 318 modulates the solenoid valve 314 on and off.") ("This system modulates pressure in the catheter 10 by allowing pressure to vary from vacuum to atmospheric pressure"). Yang also discloses the controller repeatedly cycling the vacuum and vent valves. *Id.* ¶¶ 168, 170, Figs. 25A–25C ("The period of each vacuum and release cycle may be equal to or greater than about 0.1, 0.5, 1, . . . 9, or 10 seconds.") ("In the first step . . . the release valve 2514 is closed, and the vacuum valve 2516 is open . . . . Then . . . the release valve 2514 is opened while the vacuum valve 2516 stays open. . . . Finally, . . . the vacuum valve 2516 is shut off . . . . Then, another cycle . . . begins . . . ."). We are sufficiently persuaded by Petitioner's argument, supported by the testimony of Mr. Brown, that a "POSA would understand this [disclosure] to be opening and closing the

valves [in a] predetermined cycle." Pet. 30 (citing Ex. 1005 ¶¶ 128–129). On the current record, we also agree with Petitioner that a "POSA would have had a reasonable expectation of success in combining Yang and Mullins because Yang's system is already computer-controlled" and that "it would have been well within a POSA's level of skill to modify the logic of Yang's controller to implement Mullins's teachings, and/or to incorporate well-known mechanical components, if needed, to carry out the functionality described in Mullins." Pet. 18 (citing Ex. 1005 ¶ 101).

Lastly, on the current record, we are not persuaded by Patent Owner's arguments that the combination of Yang and Mullins does not control "flow in and out" from the distal end of the catheter because the proposed combination does not address controlling Yang's water hammer effect. As discussed above, Petitioner has made a reasonable showing that a POSA would have been motivated by the teachings of Mullins to use the system of Yang to apply a positive pressure to the distal end of the catheter tip in order to more efficiently aspirate the clot. We credit the testimony of Mr. Brown that "Yang's disclosure invites a POSA to experiment with different levels of positive pressure . . . that would most efficiently aspirate a given clot." Ex. 1005 ¶ 166. Although this issue can be further explored on a full trial record, on the current record, we are persuaded by Petitioner's arguments that a POSA would have been able to conduct such experimentation to determine the optimal amount of pressure needed in order to control the water hammer effect.

Accordingly, having considered the parties' respective evidence and arguments at this stage of the proceeding, we find on this record that Petitioner has shown a reasonable likelihood of prevailing on its assertion

that claim 1 of the '402 patent would have been unpatentable as obvious over the combination of Yang and Mullins.

5. Claims 2–8 and 10–20

Petitioner, with supporting testimony from Mr. Brown, provides evidence as to where Yang and Mullins disclose the limitations of claims 2–8 and 10–20 of the '402 patent. Pet. 35–53. Other than the arguments regarding the combination of Yang and Mullins discussed above, Patent Owner does not dispute Petitioner's contentions. *See generally* Prelim. Resp. We find that Petitioner sufficiently shows for purposes of institution that the disclosures of Yang and Mullins would have rendered these limitations obvious. *See* Pet. 35–53. Thus, on the current record, Petitioner has demonstrated a reasonable likelihood that the subject matter of claims 2–8 and 10–20 of the '402 patent would have been obvious over the combined disclosures of Yang and Mullins.

D. Asserted Obviousness of Claims 5, 6, 18, and 19 over Yang in view of Mullins and Rubinstein[9]

Petitioner contends that claims 5, 6, 18, and 19 are rendered obvious over Yang in view of Mullins and Rubinstein. Pet. 53–64. Other than the arguments regarding the combination of Yang and Mullins discussed above, Patent Owner does not dispute Petitioner's contentions. *See generally* Prelim. Resp.

[9] We note that the heading for Ground 2 in the Petition lists the challenged claims as "Claims 4-6 and 9-13" (Pet. 53); however, the discussion in that section pertains to claims 5, 6, 18, and 19. *See* Pet. 53–64. We provide our analysis for claims 5, 6, 18, and 19 in this section of our Decision.

1. Rubinstein (Ex. 1011)

Rubinstein, titled "Pumping System for Catheter Suction Units," discloses an "improved pumping system for use with catheter suction units" "for drawing fluids and other viscous materials from a body" during medical procedures. Ex. 1011, codes (54), (57), 1:7–14. Rubinstein discloses applying cyclical reversals of positive and negative pressure to create a "self-cleaning" catheter. *Id.* at 1:10–14, 1:64–68. Rubinstein also discloses using "a time controlled valve which is operated at predetermined time intervals to have suction through the catheter interrupted by a predetermined period of positive pressure to cause a reversal of the fluid flow therethrough." *Id.* at 2:1–8.

Rubinstein issued on May 11, 1976, and Petitioner contends that it qualifies as prior art at least because it was patented prior to the earliest effective filing date of the '402 patent. Ex. 1011, code (45); Pet. 14. Patent Owner does not contest that Rubinstein is prior art to the '402 patent.

2. Analysis

We find on this record that Petitioner has shown sufficiently for institution that the combination of Yang, Mullins, and Rubinstein teaches or suggests each limitation of claims 5, 6, 18, and 19 for the reasons stated by Petitioner (*see* Pet. 53–64), which we adopt for purposes of our Decision. Thus, we determine that Petitioner has demonstrated a reasonable likelihood that the subject matter of these claims would have been obvious over the combined disclosures of Yang, Mullins, and Rubinstein.

E. Asserted Obviousness of Claim 9 over Yang in view of Mullins and Matteo[10]

Petitioner contends that claim 9 is rendered obvious over Yang in view of Mullins and Matteo. Pet. 64–67. Other than the arguments regarding the combination of Yang and Mullins discussed above, Patent Owner does not dispute Petitioner's contentions. *See generally* Prelim. Resp.

1. Matteo (Ex. 1013)

Matteo, titled "Multi-Function Eccentrically Actuated Microvalves and Micropumps," is directed to a microfluidics system with "one cylindrical cam controlling several actuator balls and several microvalves" for use in various chemical, biological, and biomedical applications, including "medical and scientific instrumentation." Ex. 1013, codes (54), (57), ¶¶ 6, 12, 29, Figs. 11, 12. Matteo discloses that "[c]am-driven pinch-style microvalves are useful for serving as on/off valve devices for a microfluidic system." *Id.* ¶ 10. Matteo teaches that "[a] cam-driven actuator activates a microvalve by pressing on the elastomeric layer, deforming the elastomeric layer so that it meets a second layer at a location within the channel, thereby either partially or completely obstructing the flow of liquid through the channel at that location, i.e. 'pinching' the channel." *Id.* at code (57).

Matteo was published on June 7, 2012, and Petitioner contends that it qualifies as prior art at least because it was published prior to the earliest

[10] We note that the heading for Ground 3 in the Petition lists the challenged claims as "Claims 15 and 16" (Pet. 64); however, the discussion in that section pertains to claim 9. *See* Pet. 64–67. We provide our analysis for claim 9 in this section of our Decision.

effective filing date of the '402 patent. Ex. 1013, code (43); Pet. 14. Patent Owner does not contest that Matteo is prior art to the '402 patent.

2. Analysis

We find on this record that Petitioner has shown sufficiently for institution that the combination of Yang, Mullins, and Matteo teaches or suggests each limitation of claim 9 for the reasons stated by Petitioner (*see* Pet. 64–67), which we adopt for purposes of our Decision. Thus, we determine that Petitioner has demonstrated a reasonable likelihood that the subject matter of claim 9 would have been obvious over the combined disclosures of Yang, Mullins, and Matteo.

F. Asserted Obviousness of Claims 1–8 and 10–20 over Ofek and Mullins

Petitioner contends that claims 1–8 and 10–20 are rendered obvious over Ofek and Mullins. Pet. 67–103. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 51–65.

1. Ofek (Ex. 1007)

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

Figure 1 of Ofek is reproduced below.

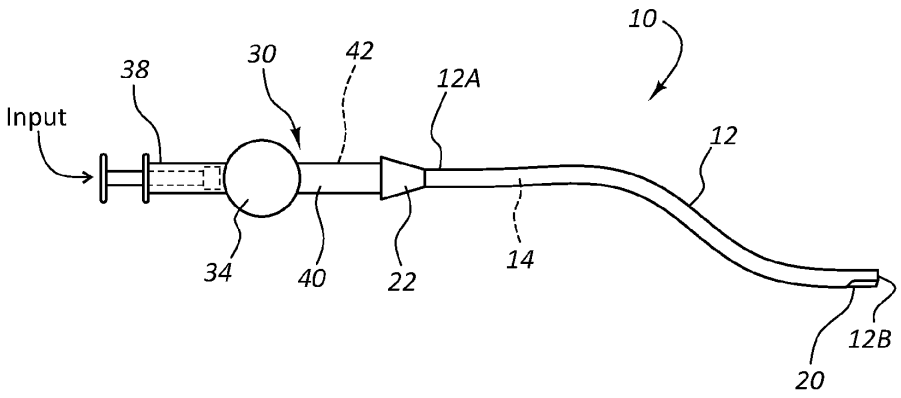

Fig. 1

Figure 1 depicts a catheter 10 including "an elongate catheter tube 12 that defines a lumen 14 extending between a proximal end 12A and a distal end 12B of the catheter tube." Ex. 1007, 2:42–44. Figure 1 also depicts "a patency device 30 configured to operably connect on a temporary basis with the catheter 10 and provide patency to the catheter tube lumen 14." *Id*. at 2:56–59. Ofek describes that

> the patency device 30 includes a fluid reservoir 34 that is configured, together with a pressure input portion 38, to provide one or more relatively short-duration impulses, also referred to herein as positive pressure impulses, of high-pressure fluid to the lumen 14 of the catheter tube 12. Such impulses, when performed periodically, are configured to prevent the formation of thrombus or other occlusion in the lumen 14, especially at the distal end thereof. These short-duration, high pressure impulses can also be used to clear the lumen after occlusions have formed therein.

Id. at 2:59–3:2.

Figure 2 of Ofek is reproduced below.

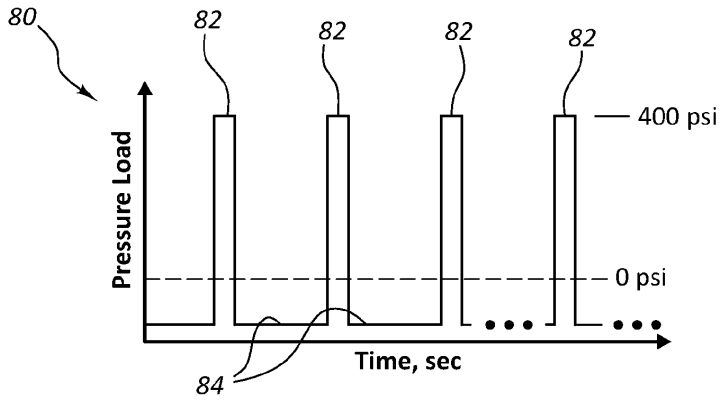

Fig. 2

Figure 2 depicts a time-dependent pressure profile 80 produced by the patency device 30 during operation. Ex. 1007, 3:43–47. Ofek describes that

> the patency device 30 provides short-duration, relatively high-pressure impulses through the fluid present in the catheter tube lumen 14 interspersed by relatively longer rest periods 84 of negative baseline pressure provided to the catheter tube lumen.

Id. at 3:47–51. According to Ofek,

> [t]he occlusion is dislodged by the high-pressure impulses, which are strong enough to dislodge the occlusion but are not of sufficient duration to push it out the distal end 12B of the catheter tube 12. The subsequent negative pressure rest period following each impulse can act to prevent escape of the clot from the catheter tube 12, in one embodiment. In addition, a suction process can be performed by the patency device 30 to withdraw the clot proximally from the catheter tube 12 and catheter 10 and into the patency device, where it may be disposed of. In this way, any clot or occlusion present in the catheter 10 can be acceptably removed.

Id. at 4:33–44.

Ofek was filed June 9, 2017, and issued on June 18, 2019, and Petitioner contends that it qualifies as prior art at least because it has an effective filing date earlier than that of the '402 patent. Ex. 1007, code (22);

Pet. 12. Patent Owner does not contest that Ofek is prior art to the '402 patent.

2. Claim 1

Petitioner, with supporting testimony from Mr. Brown, provides evidence as to where Ofek and Mullins disclose the limitations of claim 1 of the '402 patent. Pet. 67–86. At this stage of the proceeding, Patent Owner only contests whether Petitioner has sufficiently shown for institution that Ofek discloses an "aspiration catheter" (limitation [1-A]) and whether Ofek in combination with Mullins discloses or renders obvious the limitation reciting, "to control fluid flow . . . out from the distal end of the catheter" using "a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle" (limitations [1-G] and [1-E], respectively). Prelim. Resp. 20–50. We review the parties' positions below.

a) Petitioner's Position

Petitioner contends that the combination of Ofek and Mullins would have rendered obvious claim 1. Pet. 64–86. According to Petitioner, "Ofek teaches a catheter (e.g., an 'arterial' catheter) which has 'a lumen 14 extending between a proximal end 12A and a distal end 12B of the catheter tube,' and is used for aspirating 'thrombus [] in the lumen 14, especially at the distal end thereof.'" Pet. 72 (citing Ex. 1007, 2:38–3:2, 8:38–49, Figs. 1, 3, 5; Ex. 1005 ¶¶ 372–378).

Petitioner further contends that Ofek discloses "'controller 170' to 'precisely control the opening/closing of . . . valve 140 and . . . valve 150 so as to provide the impulses and the negative baseline pressure to the lumen 14 as desired' in a 'predetermined pattern.'" Pet. 81 (citing Ex. 1007, 4:62–5:7, 5:34–7:17, 8:23–49, Figs. 3, 5, 10). According to Petitioner, Ofek also discloses "the controller changing levels of vacuum in the catheter, including

at the distal tip via impulses." Pet. 84 (citing Ex. 1007, 2:56–3:60, 4:21–44, 5:49–6:8; Fig. 2). "The impulses are propagated distally down the lumen 14, which is fluid-filled . . . ." Ex. 1007, 5:59–62. "Such impulses, when performed periodically, are configured to prevent the formation of thrombus . . . in the lumen 14, especially at the distal end . . . ." Ex. 1007, 2:64–67.

Petitioner further contends that "Ofek permits control of fluid flow at the distal end," and cites to Ofek's disclosure that "[t]he subsequent negative pressure . . . prevent[s] escape of the clot from the catheter tube" (Ex. 1007, 4:37–39). Pet. 85 (citing Ex. 1007, 2:56–3:2, 3:43–4:44). According to Petitioner:

> A POSA would find it obvious that Ofek's use of impulses and vacuum control over clots at the distal end of the catheter means that it is controlling the flow of material and fluid at the distal end, at least because Ofek utilizes negative pressure in conjunction with the impulses to prevent clots from escaping the distal end and entering the bloodstream.

Id. (citing Ex. 1005 ¶¶ 403–404). Petitioner also contends that Ofek teaches that the controller can customize the pressure/vacuum cycles and includes specific examples of manipulating the pressure impulses to have substantially high pressure peaks such as at 400 psi. *Id.* (citing Ex. 1007, 3:43–4:20). According to Petitioner:

> A POSA would recognize and find obvious, based on Ofek's customizable characteristics (e.g., number of impulses, level of pressure, frequency, etc.) along with the substantially high 400 psi pressure disclosed, that Ofek's system may result in controlled flow of fluid and/or clot out from the distal end of the catheter.

Id. (citing Ex. 1005 ¶¶ 405–406). Petitioner contends that this is further obvious in view of Mullins's additional teachings about controlling flow at the distal end of the catheter. *Id.* at 86 (citing Ex. 1005 ¶¶ 407–409).

b) Patent Owner's Position

Patent Owner first contends that Ofek does not disclose an "aspiration catheter" in the context of aspiration thrombectomy systems. Prelim. Resp. 54–58. According to Patent Owner, Ofek does not disclose any catheter to vacuum clots out of a blood vessel but, rather, only discusses vacuuming a thrombus that is "in the lumen" of the catheter itself. *Id.* at 55–57 (citing Ex. 1005 ¶ 53; Ex. 2001 ¶ 106; Pet. 72).

Patent Owner also contends that Ofek does not render obvious "controlling fluid flow in and out from the distal end of the catheter." Prelim. Resp. 59–61. According to Patent Owner, "Ofek teaches ***against*** creating flow out from the distal end that would cause a clot/occlusion within the catheter to escape from the distal end and risk that it enters the bloodstream." *Id.* (citing Ex. 2001 ¶ 110). Patent Owner asserts that "[n]either Petitioner nor Mr. Brown explain why a POSA would want to modify Ofek to have a clot shift out from the distal end, risking that it may enter the bloodstream, rather than prevent the clot from exiting the distal end in the first place, as Ofek discloses." *Id.* at 61 (citing Pet. 85–86; Ex. 1005 ¶¶ 405–406).

Patent Owner next contends that Petitioner fails to identify a motivation to combine the teachings of Ofek and Mullins, especially because Ofek does not address "aspiration thrombectomy," does not have an "objective of improving the removal of blood clots," and does not use an "aspiration catheter." Prelim. Resp. 62 (citing Pet. 67). Thus, Patent Owner contends that "both Petitioner and Mr. Brown fail to explain why a POSITA would have been motivated to modify Ofek's 'patency device' (Ex. 1007, 1:16–18) in view of Mullins's 'aspiration device.'" *Id.* (citing Ex. 1008, 2:47–49) (emphasis omitted).

Lastly, Patent Owner contends that the combination of Ofek and Mullins would lack "a controller configured to open and close the vacuum valve and the vent valve in a ***predetermined*** cycle," and would not "control fluid flow in and out from the distal end." Prelim. Resp. 63–65.

c) Analysis

We find that, on the current record, Petitioner has demonstrated a reasonable likelihood that the subject matter of claim 1 would have been obvious over the combined disclosures of Ofek and Mullins.

With regard to Patent Owner's argument that Ofek does not disclose an "aspiration catheter," the current record supports that Ofek teaches a catheter that has a proximal end, a distal end, and a lumen extending within the catheter between the proximal and distal ends. *See* Pet. 72 (citing Ex. 1007, 2:38–3:2, 8:38–49, Figs. 1, 3, 5; Ex. 1005 ¶¶ 372–378). Ofek explains that the catheter can be used for aspirating a thrombus at the distal end of the catheter. Ex. 1007, 2:56–3:2; Ex. 1005 ¶ 374. Ofek also states that the catheter in the embodiments of the patent can include different "catheter types, such as dialysis, CVC, PIV, urinary, arterial, balloon catheter, etc." and that "the discussion [] is not intended to be limiting." Ex. 1007, 2:53–55. Although Ofek may not specifically use the term "aspiration catheter" to describe the catheters of the invention, it does describe catheters that may have a thrombus in the lumen and can include arterial catheters. On the current record, and as supported by the Declaration of Mr. Brown, we find that, based on the disclosure of Ofek, one of skill in the art would understand that Ofek discloses or at least renders obvious an aspiration catheter as recited in claim 1. *See* Ex. 1005 ¶ 378.

We are similarly not persuaded by Patent Owner's assertion that Ofek does not disclose or render obvious "a controller . . . to control fluid flow in

and out from the distal end of the catheter." Although Ofek discloses "preventing the dislodged occlusion from entering the bloodstream from the distal end [] of the catheter tube," it also teaches that the controller can customize the pressure/vacuum cycles, and includes specific examples of manipulating the pressure impulses to have substantially high pressure peaks such as 400 psi. Ex. 1007, 3:43–4:20. At this stage of the proceeding, on the current record, we credit the testimony of Mr. Brown that:

> 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. In such a case, a POSA would also find it obvious, consistent with the teachings and stated purpose of Ofek, that negative pressure characteristics could similarly be configured in the operation cycles and pressure profiles to prevent the clot from escaping into the bloodstream even if some portion of it had shifted out from the distal end of the catheter due to the positive pressure impulses.

Ex. 1005 ¶ 406. Further, even if Ofek does not explicitly disclose controlling flow out of the distal end of the catheter, this limitation appears to be taught by Mullins (as discussed above), and Petitioner has demonstrated sufficiently that a POSA would have been motivated to combine the disclosures of Ofek and Mullins such that this limitation is rendered obvious by the combined disclosures of Ofek and Mullins.

On the current record, we agree with Petitioner that a POSA would have been motivated to combine the teachings of Ofek and Mullins because they both address similar problems related to aspiration thrombectomy and

share the common objective of removal of blood clots using dynamic aspiration catheters. *See* Pet. 67 (citing Ex. 1007, 2:56–3:42, 4:21–44, 5:63–6:45, 8:38–49, Figs. 2, 3; Ex. 1008, 3:29–4:1, 26:17–27:67, Figs. 46–49; Ex. 1009.2, 3–10, Figs. 3–8). We further agree with Petitioner and Mr. Brown that:

> A POSA would have been motivated to implement Mullins's disclosures of controlling levels of vacuum and fluid flow in and out of the distal end of the catheter to modify Ofek's system, which already includes a catheter aspiration system utilizing positive and negative pressure sources to control vacuum in the catheter, to provide efficient and effective cyclical aspiration of blood clots.

Id. at 68 (citing Ex. 1005 ¶ 356; Ex. 1007, Abs., 1:16–33, 2:38–3:2, 3:43–4:6, 4:45–6:19; Ex. 1008, 3:29–4:11, 26:17–28:64).

Further, on the current record, we are persuaded that a POSA would have been motivated to apply Mullins's teachings of using positive pressure to unstick clots to the device of Ofek because Mullins describes this technique of controlling flow out the distal end of the catheter as "improv[ing] [the] efficiency of aspiration and prevent[ing] clogging of the catheter." Ex. 1008, 3:64–65, 26:47–49. We are also persuaded that a POSA would have had a reasonable expectation of success in combining Ofek and Mullins because Ofek discloses a computer-controlled system that has similar sources of positive and negative pressure to manipulate vacuum within a catheter and "it would have been well within the level of skill in the art to modify the logic of Ofek's controller to implement Mullins's teachings." Ex. 1005 ¶ 360.

On the current record, we also agree with Petitioner that a "POSA would have had a reasonable expectation of success in combining Ofek and Mullins [b]ecause Ofek's system is already computer-controlled," and "it

would have been well within a POSA's level of skill to modify the logic of Ofek's controller to implement Mullins's teachings, and/or to incorporate well-known mechanical components, if needed, to carry out the functionality described in Mullins." Pet. 68 (citing Ex. 1005 ¶ 360).

We are also not persuaded by Patent Owner's assertions that combining Ofek and Mullins would not yield the claimed invention because the combination lacks a "predetermined cycle" for opening and closing the vacuum and vent valves. Patent Owner's argument is based on the assertion that the variable cycle disclosed by Mullins is based on feedback from the pressure sensor, and is, therefore, not "predetermined." Prelim. Resp. 63. However, even if this is correct, we find on the current record that Ofek discloses a valve controller to control the vacuum and vent valves in a predetermined cycle. *See* Pet. 81–83. Ofek discloses "controller 170" to "precisely control the opening/closing of . . . valve 140 and . . . valve 150 so as to provide the impulses and the negative baseline pressure to the lumen 14 as desired" in a "predetermined pattern." Ex. 1007, 4:62–5:7, 5:34–7:17, 8:23–49, Figs. 3, 5, 10. "The controller 170 determines the number, frequency, rest periods, etc., of the impulses to be delivered . . . . [V]alve 140 is opened and close [sic] repeatedly at predetermined time intervals to provide a series of fluid impulses . . . ." *Id.* at 5:49–55.

Lastly, on the current record, we are not persuaded by Patent Owner's arguments that the combination of Ofek and Mullins does not control "flow in and out" from the distal end of the catheter. As discussed above, we credit Petitioner's assertions that a POSA would have been motivated by the teachings of Mullins to use the system of Ofek to apply a positive pressure to the distal end of the catheter tip in order to more efficiently aspirate the clot. Although this issue can be further explored on a full trial record, on the

current record, we are persuaded by Petitioner's argument and evidence that a POSA would have been able to conduct experimentation to determine the optimal amount of pressure needed in order to effectively control fluid flow in and out from the distal end of the catheter.

Accordingly, having considered the parties' respective evidence and arguments at this stage of the proceeding, we find on this record that Petitioner has shown a reasonable likelihood of prevailing on its assertion that claim 1 of the '402 patent would have been unpatentable as obvious over the combination of Ofek and Mullins.

3. Claims 2–8 and 10–20

Petitioner, with supporting testimony from Mr. Brown, provides evidence as to where Ofek and Mullins disclose the limitations of claims 2–8 and 10–20 of the '402 patent. Pet. 86–103. Other than the arguments regarding the combination of Ofek and Mullins discussed above, Patent Owner does not dispute Petitioner's contentions. *See generally* Prelim. Resp. We find that Petitioner sufficiently shows for institution that the disclosures of Ofek and Mullins render these limitations obvious. *See* Pet. 86–103. Thus, on the current record, Petitioner has demonstrated a reasonable likelihood that the subject matter of claims 2–8 and 10–20 of the '402 patent would have been obvious over the combined disclosures of Ofek and Mullins.

G. Asserted Obviousness of Claims 5, 6, 18, and 19 over Ofek in view of Mullins and Rubinstein

Petitioner contends that claims 5, 6, 18, and 19 would have been obvious over Ofek in view of Mullins and Rubinstein. Pet. 103–106. Other than the arguments regarding the combination of Ofek and Mullins discussed above, Patent Owner does not dispute Petitioner's contentions.

See generally Prelim. Resp. We find on this record that Petitioner has shown sufficiently for institution that the combination of Ofek, Mullins, and Rubinstein teaches or suggests each limitation of claims 5, 6, 18, and 19 for the reasons stated by Petitioner (*see* Pet. 103–106), which we adopt for purposes of our Decision. Thus, we determine that Petitioner has demonstrated a reasonable likelihood that the subject matter of these claims would have been obvious over the combined disclosures of Ofek, Mullins, and Rubinstein.

H. Asserted Obviousness of Claim 9 over Ofek in view of Mullins and Matteo

Petitioner contends that claim 9 is rendered obvious over Ofek in view of Mullins and Matteo. Pet. 106–107. Other than the arguments regarding the combination of Ofek and Mullins discussed above, Patent Owner does not dispute Petitioner's contentions. *See generally* Prelim. Resp. We find on this record that Petitioner has shown sufficiently for institution that the combination of Ofek, Mullins, and Matteo teaches or suggests each limitation of claim 9 for the reasons stated by Petitioner (*see* Pet. 106–107), which we adopt for purposes of our Decision. Thus, we determine that Petitioner has demonstrated a reasonable likelihood that the subject matter of claim 9 would have been obvious over the combined disclosures of Ofek, Mullins, and Matteo.

IV. CONCLUSION

For the forgoing reasons, Petitioner has demonstrated a reasonable likelihood that at least one challenged claim of the '402 patent would have been obvious over the prior art of record. Accordingly, we institute an *inter partes* review on claims 1–20 for all grounds set forth in the Petition.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted on claims 1–20 for all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review of the '402 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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