UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PENUMBRA, INC.,

Petitioner,

v.

RAPIDPULSE, INC.,

Patent Owner.

Case No. IPR2024-01261
Patent No. 11,406,402

PETITIONER'S NOTICE OF APPEAL

Notice is hereby given, pursuant to 35 U.S.C. §§ 141, 142, 319, and 37 C.F.R. §§ 90.2 and 90.3, that Petitioner Penumbra, Inc. ("Petitioner" or "Penumbra") appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision by the Patent Trial and Appeal Board's ("Board") in IPR2024-01261, entered on February 17, 2026 (Paper 39) ("Final Written Decision"), a copy of which is attached hereto as **Exhibit A**. This notice is timely filed under 37 C.F.R. § 90.3(a)(1) within 63 days of the Final Written Decision.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Petitioner states that the issues on appeal may include, without limitation:

- The Board's claim construction of the claim term "predetermined cycle."
- The Board's conclusion that no challenged claims were shown to be unpatentable.
- Any Board finding, determination, judgment, or order supporting or related to the foregoing and/or to the Final Written Decision and decided adversely to Petitioner.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2, this Notice is being filed with the Director of the United States Patent and Trademark Office, and a copy of this Notice is being concurrently filed with the Board. In addition, a copy of the

Notice of Appeal is being filed with the Clerk of Court for the United States Court of Appeals for the Federal Circuit, along with the required docketing fee.

Dated: April 17, 2026

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CERTIFICATE OF FILING

I hereby certify that, in addition to being filed electronically through the Patent Trial and Appeal Board's P-TACTS system, a true and correct copy of the above-captioned **PETITIONER'S NOTICE OF APPEAL** is also being filed pursuant to 37 C.F.R. § 90.2(a) with the Director of the United States Patent and Trademark Office, on April 17, 2026, by electronic mail to efileSO@uspto.gov, which is the email address indicated on the United States Patent and Trademark Office's web page for the Office of the General Counsel, <https://www.uspto.gov/about-us/organizational-offices/office-general-counsel>.

I also hereby certify that a true and correct copy of the above-captioned **PETITIONER'S NOTICE OF APPEAL**, along with the filing fee, is being filed via CM/ECF with the Clerk's Office of the United States Court of Appeals for the Federal Circuit on April 17, 2026.

Dated: April 17, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of April, 2026, **PETITIONER'S NOTICE OF APPEAL** was served by email on the following counsel of record for Patent Owner:

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Exhibit A

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Paper 39
Date: February 17, 2026

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 ROBERT L. KINDER, DAVID COTTA, and JAMIE T. WISZ, *Administrative Patent Judges.*

WISZ, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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"). Petitioner supported its Petition with the Declarations of Brian Brown and Ian Ross, MD (Exs. 1005, 1023). RapidPulse, Inc. ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.") along with the Declaration of Brad Culbert (Ex. 2001). Upon consideration of the Petition, the Preliminary Response, and the preliminary evidence of record, we determined that Petitioner had demonstrated a reasonable likelihood that it would prevail with respect to at least one of the challenged claims of the '402 patent (Paper 7, "Institution Decision" or "Inst. Dec."). Thus, we instituted review with respect to all of the challenged claims.

Patent Owner filed a Patent Owner's Response (Paper 15, "PO Resp.") with an additional Declaration from Mr. Culbert (Ex. 2014). Patent Owner also filed an Unopposed Motion to Submit Supplemental Information (Paper 19), which we granted (Paper 23) so that Patent Owner could file the European Patent Office Opposition filed by Petitioner (Ex. 2035), which opposes Patent Owner's European Patent No. 3823686. Petitioner filed a Reply (Paper 24, "Pet. Reply"), supported by the Supplemental Declaration of Brian Brown (Ex. 1035), and Patent Owner filed a Sur-Reply (Paper 34, "PO Sur-Reply").

An oral hearing was held on December 10, 2025, and a transcript of the hearing is included in the record (Paper 38, "Tr.").

We have jurisdiction under 35 U.S.C. § 6. After considering the parties' arguments and supporting evidence, we conclude that Petitioner has

not demonstrated by a preponderance of the evidence that any of claims 1–20 of the '402 patent are unpatentable. 35 U.S.C. § 318(a).

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. The decisions in IPR2021-01466 and IPR2022-00608 were affirmed by the Federal Circuit in cases CAFC-2024-1130 and CAFC-2024-1131.

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.

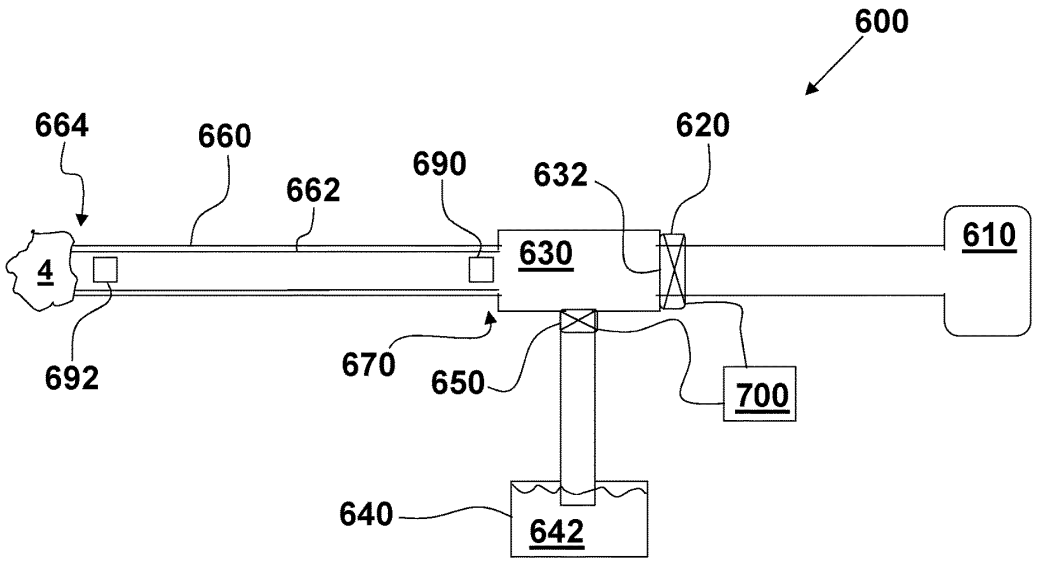


FIG. 47

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. In some embodiments, 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. Instituted Grounds

We instituted trial to determine whether the challenged claims are unpatentable based on the following grounds:

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

III. ANALYSIS

A. Principles of Law

To prevail in its challenges to the patentability of all claims of the '402 patent, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid. Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); *see also* 35 U.S.C. § 312(a)(3) (requiring *inter partes*

[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").

review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim"). That burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015); *see also In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375–78 (Fed. Cir. 2016) (discussing the burden of proof in *inter partes* review).

B. 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 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 PO Response, it "accepts

Petitioner's description of a POSA." PO Resp. 8 (citing Pet. 11, Ex. 2014 ¶ 44).

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))).

C. 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.*

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention" and "after reading the entire patent" and its prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 1321 (Fed. Cir. 2005) (en banc). Although extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises can be consulted, extrinsic evidence is less significant than the intrinsic record. *Id.* at 1312–17. Usually, the specification is dispositive, and is the single best guide to the meaning of a disputed term. *Id.* at 1315.

Below, we discuss the term, "predetermined cycle," as construed by the parties.

1. "predetermined cycle"

Claim 1 recites "a controller configured to open and close the vacuum valve and the vent valve in a *predetermined cycle* to change a level of vacuum at the distal end of the catheter." Ex. 1001, 61:26–29 (emphasis added). The parties arguments with regard to the limitation of a "predetermined cycle" are described below.

a) Parties' Arguments

Patent Owner construes "predetermined cycle" to mean 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." PO Sur-Reply 7. According to Patent Owner, "[t]he specification uses the term consistent with this plain meaning, referring to 'a fixed cycle' and 'predetermined' timing of valve operation." *Id.* at 7–8 (citing Ex. 1001, 9:9–14, 11:1–5, 58:34–38). Patent Owner also contends that this construction is consistent with how the Examiner interpreted "predetermined cycle," as demonstrated by the Examiner's statement in the Notice of Allowance that the prior art Garrison reference[8] "discloses a similar device, but the controller disclosed in [0113] changed the cycle of opening and closing the valves based on feedback from sensors and is not a pre-determined pattern." PO Resp. 6–7, 25–26 (citing Ex. 1004, 86); PO Sur-Reply 7–8.

Petitioner construes "predetermined cycle" to mean "the 'cycle' of opening and closing the valves, in an established sequence, with no restriction on sensor usage to making timing adjustments to the cycle."

[8] Garrison et al., US 2016/0220741 A1, published Aug. 4, 2016 (Ex. 2015, "Garrison").

Pet. Reply 15 (citing Ex. 1035 ¶¶ 68–70). According to Petitioner, this construction "is consistent with the plain meaning of 'cycle,' which is a complete sequence of repeating events or states (e.g., 'cycle of life')." *Id.* Petitioner argues that Patent Owner's construction of "predetermined cycle" includes an "unstated negative limitation prohibiting sensor usage to tune system operation," which is legally erroneous. *Id.* at 14–15 (citing PO Resp. 24–31; Ex. 2014 ¶¶ 60–82). According to Petitioner, Patent Owner's reliance on the Examiner's statement in the Notice of Allowance is misplaced because the Applicant expressly refused to agree with the Examiner's statement such that there was no disclaimer. *Id.* at 15 (citing Ex. 1004, 29). Petitioner further contends that the Examiner's statement is technically incorrect because the Examiner failed to recognize that Garrison discloses embodiments where the cycle timing is controlled only by the user, not sensor feedback. *Id.* at 15–16 (citing Ex. 2015 ¶ 114).

In arguing that the proper construction of "predetermined cycle" does not exclude the use of sensors, Petitioner also contends that the '402 patent specification explicitly includes sensors similar to those in the prior art. Pet. Reply 15 (citing Ex. 1001, 32:55–33:7, 40:66–41:5, 44:9–29 (discussing controller use of data from "sensors" including "pressure measurement devices" to "time the valves properly")). Further, at the Oral Hearing, Petitioner raised (for the first time), additional disclosure from the '402 specification regarding use of the controller to "tune" the system either "statically or dynamically," wherein "dynamic tuning" refers to "tun[ing] during operation." Tr. 50:10–51:5 (citing Ex. 1001, 48:19–36, 49:7, 49:15–17).

Patent Owner responds that Petitioner's proposed construction is erroneous because it reads "predetermined" out of the phrase "predetermined

cycle." PO Sur-Reply 7. According to Patent Owner, "[a]ny cycle has 'an established sequence'; indeed, Petitioner admits that a 'cycle' 'is a complete sequence of repeating events or states.'" *Id.* (citing Pet Reply 15). Patent Owner also contends that Petitioner's arguments about the prosecution history are "misplaced" because Patent Owner's position does not turn on a "disclaimer" or whether the Examiner understood Garrison correctly but, rather, "[t]he 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.'" *Id.* at 8 (citing *Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1289 (Fed. Cir. 2021)).

In response to Petitioner's arguments regarding the "sensors" disclosed in the '402 patent, Patent Owner responds that at least one of the sensors disclosed in the '402 patent specification is used to "trigger" the predetermined cycle and, regardless, disclosure of different embodiments is not a basis for rewriting the claims to encompass them all. PO Sur-Reply 8 (citing Ex. 1001, 32:55–66). During the Oral Hearing, Patent Owner further argued that the sensors described in the '402 patent do not "control[] the timing of the cycle," but, rather, are used to detect the presence of blood (discussing Ex. 1001, 40:66–41:5), or to show how the pressure changes during the method as shown in Figures 50 and 51 of the patent (discussing Ex. 1001, 44:9–29). Tr. 36:14–25. According to Patent Owner, these sensors are not used "to control performance of the claim[ed] method." *Id.*; *see also id.* at 40:13–22 (arguing that there is no adjustment being made to the cycle based on the sensed pressure from these sensors)). With regard to the discussion of "dynamic tuning" in the patent, Patent Owner's counsel responded that, "[t]o the extent Petitioner is saying that dynamic tuning

means that you use the sensor to perform adjustments to the cycle timing during operation of the cycle, that is indeed an unclaimed embodiment." *Id.* at 56:3–6.

b) Analysis

We look to the intrinsic record to determine the construction of "predetermined cycle." *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) ("In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.") (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc)).

Patent Owner directs us to three portions of the '402 patent specification in support of their assertion that the patent uses the term "predetermined cycle" consistent with its plain meaning of a "fixed cycle" and "predetermined" timing of valve operation. PO Sur-Reply 7–8 (citing Ex. 1001, 9:9–14, 11:1–5, 58:34–38). First, they point to a statement that, "[i]n accordance with an exemplary embodiment, the clot removal system comprises a ***fixed cycle*** with plurality of pinch valves and plurality of cams mechanically coupled to the valves so that orientations of the cams cannot be changed." Ex. 1001, 9:9–14 (emphasis added). Although this excerpt does not use the term "predetermined," it does indicate that in certain embodiments, there is a fixed cycle of opening and closing the vent and vacuum valves. Patent Owner also cites to another part of the specification as shown below:

> In accordance with another feature, the controller is configured to open and close the vent and vacuum valves in a repeated ***cycle*** of the ***pre-determined pattern*** and prevent

> forward flow of the distal portion out from the distal end during each cycle by ***regulating timing*** of the vent valve.

Id. at 11:1–5 (emphasis added). Although this excerpt refers to an embodiment in which forward flow is prevented, it does indicate that "predetermined" in the context of a "cycle" refers to a predetermined *pattern and timing* for opening and closing of the vent and vacuum valves. Lastly, Patent Owner cites to the excerpt shown below:

> The controller 700 will then alternatively open one or both of the control valves for a ***predetermined time and sequence*** to pull the sterile fluid through the extension line 674 and valves and displace all the air that may have been in the system.

Id. at 58:34–38 (emphasis added). Although this excerpt is included in a discussion of purging the system of air prior to its use in the clot removal process (*see id.* at 58:28–49), we find that it still provides guidance as to the use of the term "predetermined" in the context of the patent. Specifically, the term "predetermined" includes a predetermined (or set) *time and sequence* for opening and closing of the valves.

As discussed above, Petitioner contends that the '402 patent specification explicitly includes sensors similar to those in the prior art in support of their argument that the claimed "predetermined cycle" must not exclude the use of such sensors. Pet. Reply 15 (citing Ex. 1001, 32:55–33:7, 40:66–41:5, 44:9–29). We reviewed the portions of the specification cited by Petitioner. We agree with Patent Owner that one excerpt discussing sensor use appears to be directed to triggering the predetermined cycle rather than causing timing changes during the cycle itself (Ex. 1001, 32:55–66) (describing use of a pressure sensor to "determine when the vacuum channel 3 is clogged by a thrombus and automatically perform the unclogging procedures described herein"), while another excerpt discusses a sensor that

detects the presence of blood. Ex. 1001, 40:66–41:5. We also agree with Petitioner that the '402 patent discusses the use of sensors to "tune" the system and that such "tuning" can be done statically (setting the cycle timing in advance) or dynamically (adjusting the timing during the cycle itself). *See* Ex. 1001, 48:19–49:50. Overall, we find that these disclosures involving sensors demonstrate that sensors may be used in various ways in different embodiments. However, none of these disclosures explicitly discuss the use of sensors in conjunction with a "pre-determined cycle." Therefore, we find that the '402 patent specification's discussion of "sensors" are not particularly informative as to the appropriate construction of a "predetermined cycle" and do not outweigh the other explicit disclosures of "predetermined cycle" in the patent.

We next turn to the other intrinsic evidence discussed by the parties — the prosecution history. As discussed by Patent Owner, in the Notice of Allowance, the Examiner found that Garrison did not teach or suggest a "predetermined cycle" because Garrison's controller "changed the cycle of opening and closing the valves based on feedback from sensors." Ex. 1004, 86. We acknowledge that the patent applicant filed subsequent comments during prosecution in which they stated that they "do[] not concede that the Examiner's characterizations of the terms of the claims and the prior art are correct." *Id.* at 29. However, we agree with Patent Owner that the importance of the Examiner's statement in the Notice of Allowance does not rely on it being an express disclaimer (a standard which it does not meet). PO Sur-reply 8. We also considered Petitioner's contention that the Examiner's interpretation of Garrison may have been in error (PO Resp. 16); however, even if this were true, the Examiner's statement still provides helpful insight into how the Examiner was interpreting the term

"predetermined cycle." Specifically, the Examiner found that the use of sensors to change the opening and closing of valves during a cycle was not a "predetermined cycle." *Id.* at 86.

In sum, we find that Patent Owner's proposed construction is consistent with the usage of the term "predetermined cycle" in the '402 patent specification and prosecution history. Thus, after considering all of the cited evidence, we construe "predetermined cycle" to mean 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."

2. Other Terms

The parties also provided proposed constructions for the limitations of "[limited/limiting] to a positive amount of exit flow" and "control[ling] fluid flow in and out from the distal end of the catheter." *See* Pet. 15–16; Pet. Reply 1–8; PO Resp. 22–24; PO Sur-Reply 2–6. However, having evaluated the arguments and evidence before us, we determine that construction of these terms 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.")).

D. 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. PO Resp. 24–72; PO Sur-Reply 6–25.

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

Figure 14 of Yang is reproduced below.

FIG. 14

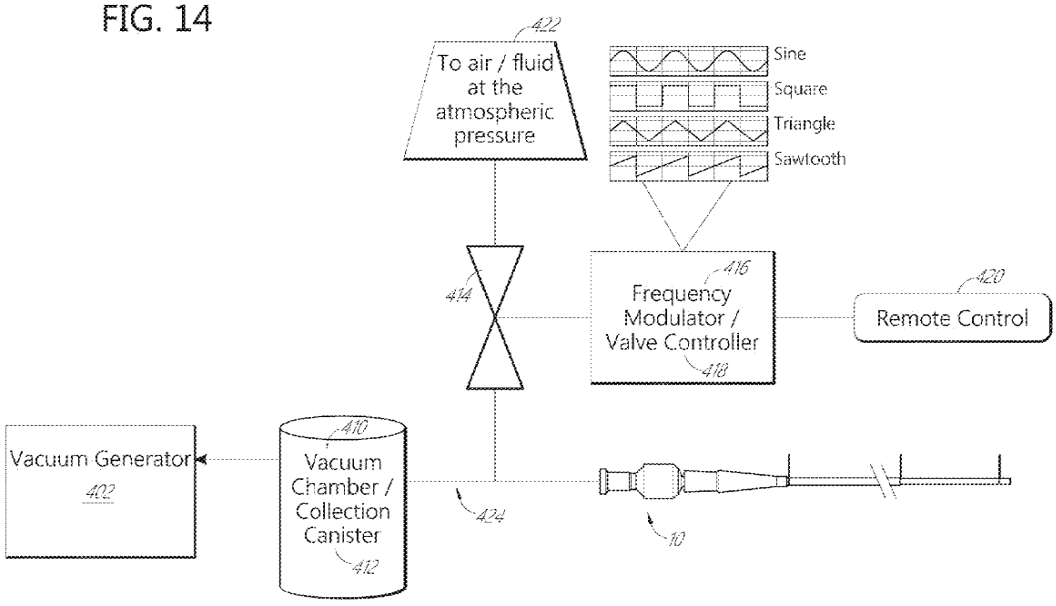


Figure 14 depicts an "aspiration system configured to apply pulsatile negative pressure through the aspiration catheter." Ex. 1012 ¶ 29. According to Yang, this aspiration system

> 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.

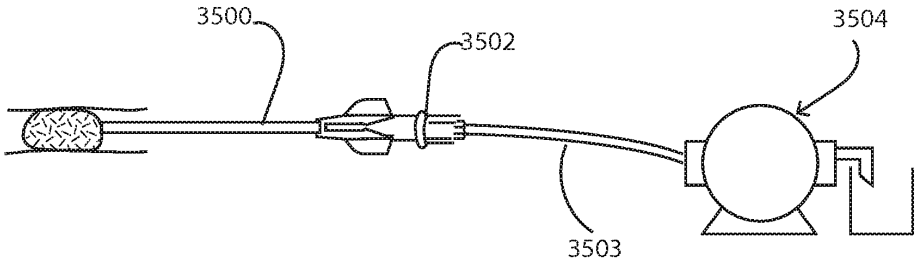


Fig.45

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 does not contest that Mullins is prior art to the '402 patent.

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. Patent Owner contends that Petitioner fails to show that the combination of Yang and Mullins discloses "a controller

configured to open and close the vacuum valve and the vent valve in a ***predetermined cycle*** to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter." PO Resp. 24–30. We discuss the parties' positions regarding this limitation below.

a) Petitioner's Position

Petitioner asserts that Yang alone or in view of Mullins renders obvious "a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter." Pet. 28–35.

With regard to the "controller"/"predetermined cycle" limitation, Petitioner points to Yang's disclosure of a valve controller to control the vacuum and vent valves. *Id.* at 28 (citing Ex. 1012 ¶¶ 123, 128, 131, Fig. 13 ("FIG. 13 shows…Valve controller 318 modulates the solenoid valve 314 on and off."); *see also id.* at ¶¶ 131, 169 ("[A]spiration system may comprises [sic] a vacuum generator 402…a valve controller 418… this system modulates pressure in the catheter 10 by allowing pressure to vary from vacuum to atmospheric pressure.")). According to Petitioner, "Yang further illustrates the controller repeatedly cycling the vacuum and vent valves: 'each vacuum and release cycle may be equal to or greater than about 0.1, 0.5, 1,… 9, or 10 seconds.'" *Id.* at 29–30 (citing Ex. 1012 ¶¶ 168, 170, Figs. 25A–25C). "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, allowing the vacuum to be completely released and the clot to relax. Then, another cycle…begins." Ex. 1012 ¶ 170. Petitioner contends

that "[a] POSA would understand this to be opening and closing the valves [in a] predetermined cycle." *Id.* at 30 (citing Ex. 1005 ¶¶ 128–129).

According to Petitioner, Mullins also discloses a cycling controller that "varies aspiration pressure according to sensed pressure within the catheter lumen." Pet. 30–31 (citing Ex. 1008, 3:46–59, 4:5–11 ("The controller may increase a vacuum to ingest more of a clot and reverse at a low limit of pressure defined such that during vacuum, a portion of the clot has been aspirated but not so much that the clot has become irreversibly clogged")). Petitioner cites to Mullins's disclosure that the controller works "***cyclically***" to aspirate the clot. *Id.* at 31 (citing Ex. 1008, 3:60–4:4, 27:40–28:10, 28:59–64 ("the applied pressure signal incorporates an oscillation or 'shake' signal [involving] application of pulse cycling between two pressure limits")). According to Petitioner, this involves "positive and negative fluid displacement to alternately infuse and aspirate the catheter" controlled using an "infuse-to-aspirate cycle" ratio. *Id.* Petitioner concludes that, a "POSA would recognize Mullins' 'pulse cycling' and 'infuse-to-aspirate cycles' are predetermined cycles." *Id.* (citing Ex. 1005 ¶ 134).

With regard to the "control[ling] fluid flow in and out limitation," 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." Pet. at 34–35 (citing Ex. 1005 ¶¶ 153–157; Ex. 1008, Figs. 47(a)-(n)).

In response to arguments by Patent Owner that Mullins does not disclose a "predetermined cycle" to "control fluid flow in and out" because it uses sensors to alter the cycle, Petitioner contends that Mullins discloses "pulse cycling between two pressure limits" and also "discloses various different embodiments which don't require or discuss sensor-based feedback." Pet. Reply 16, 17 (citing Ex. 1008, 26:43–49, 27:54–65, 28:1–10 ("the shake signal may be initiated for a predefined number of cycles"), 28:49–52, Figs. 46–49; Ex. 1035 ¶¶ 81–82). Petitioner further contends that "Mullins discloses controlling fluid displacement cycles with a peristaltic pump, and a POSA would recognize that a fixed timing cycle of operation in each pump direction would produce Mullins' predetermined cycles." *Id.* at 17 (citing Ex. 1035 ¶¶ 81–82; Ex. 1008, 28:59–29:12 (discussing "ratio of the infuse-to-aspirate cycle")).

b) Patent Owner's Position

Patent Owner contends that Petitioner fails to show that the combined disclosures of Yang and Mullins teach or render obvious "a controller configured to open and close the vacuum valve and the vent valve in a ***predetermined cycle*** to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter," as required by independent claim 1. PO Resp. 24–30.

Specifically, Patent Owner argues that, because Petitioner's Yang/Mullins combination uses Mullins's sensor, it means that the combination does not have a "predetermined cycle." *Id.* at 26 (citing Pet. 17–18, 34, 51). According to Patent Owner, "Petitioner's repeated arguments relying on inclusion of Mullins's pressure sensor in the Yang/Mullins combination confirms that there would be no 'predetermined cycle' because the controller would vary the applied pressure based on the pressure sensed by the sensor." *Id.* at 26–27. Patent Owner contends that "Petitioner admits that Mullins's 'cycling controller … '***varies*** aspiration pressure according to sensed pressure within the catheter lumen.'" *Id.* at 27 (citing Pet. 30 (quoting Ex. 1008, 3:36–59)). According to Patent Owner, Petitioner does not propose any combination of Yang and Mullins that does not include Mullin's pressure sensor in order "to control fluid flow in and out from the distal end of the catheter." PO Resp. 27–29.

c) Analysis

After carefully considering the arguments and evidence, we determine that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '402 patent would have been obvious over Yang and Mullins. We agree with Patent Owner that, under the proper construction of the term "predetermined cycle," Petitioner has not shown that that the combination of Yang and Mullins discloses a "predetermined cycle" to "control fluid flow in and out."

As discussed above, we construed "predetermined cycle" to mean "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." In contrast, Mullins describes using "a sensor" to measure the pressure and, "[b]ased on the measured pressure, the pump may change

direction hence altering the pressure and fluid displacement." Ex. 1008, 26:35–37, 26:40–42. As stated in the Petition, Mullins discloses a "cycling controller that '***varies*** aspiration pressure according to sensed pressure within the catheter lumen.'" Pet. 30 (citing Ex. 1008, 3:4–59) (emphasis added). We agree with Patent Owner that this is the type of system that the Examiner distinguished as not having a "predetermined cycle." Ex. 1004, 86 ("the cycle of opening and closing the valves based on feedback from sensors [] is not a pre-determined pattern").

We also find that Mullins's disclosure of "pulse cycling between two pressure limits" is not a "predetermined cycle" because the cycling is based on when the sensed pressure reaches a limit. Ex. 1008, 27:54–65, 26:43–49, Figs. 46–49. Similarly, Mullins's "shake signal … initiated for a predefined number of cycles," cited by Petitioner, also involves "application of pulse cycling between two pressure limits," which is not a "predetermined cycle." *See* Ex. 1008, 28:1–10, 27:54–57; Ex. 2014 ¶ 126; Ex. 1035 ¶ 77. We further find that Mullins's disclosure of a "predefined number of cycles" is different than a "predetermined cycle" itself. *Id.* at 28:1–10. With regard to Mullins's "infuse-to-aspirate cycle" ratios, such as "between 0.01 and 0.99," cited by Petitioner, we credit the testimony of Mr. Culbert that this is not disclosure of "fixed timing," but rather of boundaries for Mullins's sensor feedback-based approach. *See* Pet. Reply 17 (quoting Ex. 1008, 28:59–29:12); 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").

Although we found in our Institution Decision that Yang discloses a "predetermined cycle" (Inst. Dec. 22–23), we agree with Patent Owner that Petitioner's contentions rely on the combination of Yang and Mullins to

disclose a "predetermined cycle" to "control fluid flow in and out." Specifically, Petitioner incorporates Mullins's controller, which uses pressure sensor feedback, in combination with Yang. *See* Tr. 9:23–10:1 (Counsel for Petitioner stating that, "[Mullins is] relied on primarily in the petition for its control features because it does go into great detail about how these catheter valves could be controlled in order to ensure that you're effectively aspirating the clot by first breaking it up and then ingesting it into the system."). Further, in arguing the motivation to combine Yang and Mullins, Petitioner contends that a "POSA would recognize Yang could be configured to achieve the benefits, as taught by Mullins, of cyclical pressure changes, including the ***use of a pressure sensor***." Pet. 17–18, 34 (emphasis added).

Petitioner's declarant, Mr. Brown also argues that it would have been obvious to combine the disclosures of Yang and Mullins based, at least in part, on Mullins's pressure sensor in stating:

> A POSA would find it obvious to implement Mullins' disclosures of forward flow and improvements in unsticking clots to modify Yang's system, which includes a catheter aspiration system that is ready for improvement by Mullins's techniques …. The methods of cyclical pressure changes described by Mullins are consistent with and improve on the aspiration cycles that Yang discloses to provide effective cyclical aspiration thrombectomy. . . Additionally, ***using the pressure sensor provided by Mullins on Yang's device would help implement the most efficient pressure changes*** to the catheter to reduce the risk of complications from aspiration thrombectomy, including clogged catheters and excessive forward flow of material out of the distal end of the catheter into the patient's blood stream, as ***explicitly taught by Mullins***.

Ex. 1005 ¶ 100 (emphasis added). Mr. Brown further discusses using the pressure sensor of Mullins in combination with Yang in stating:

> A POSA would also find it obvious to implement monitoring the level of vacuum pressure change at the distal end of the aspiration catheter contemplated by Mullins within Yang's aspiration thrombectomy system. … Mullins discloses that a lumen pressure sensor and ***a controller can be used to monitor the pressure in the system, and builds on the concept of altering vacuum pressure levels by utilizing a pressure sensor. A POSA would have recognized the benefit of monitoring the vacuum pressure levels*** at various points throughout the aspiration system, … as disclosed in Mullins, in the context of Yang, ***and it would have been trivial to implement these within Yang's aspiration thrombectomy system.***

Id. at ¶ 102 (emphasis added). Further, in discussing use of Mullins's controller in the combined disclosures of Yang and Mullins, Mr. Brown explains that "Mullins describes measuring the pressure in the catheter with a pressure sensor" and "discusses the controller utilizing pressure and fluid displacement at the catheter tip to aspirate clots based on the measured pressure levels." Ex. 1005 ¶¶ 153, 155.

We agree with Patent Owner that neither Petitioner nor Mr. Brown propose any combination of Yang and Mullins that does not include Mullins's pressure sensor in order "to control fluid flow in and out from the distal end of the catheter." Indeed, in addressing the "predetermined cycle" limitation, Mr. Brown contends that Mullins discloses a "cycling controller that 'varies aspiration pressure according to sensed pressure within the catheter lumen.'" Ex.1005 ¶¶ 131–32 (citing, *e.g.*, Ex.1008, 27:40–28:20 ("[a] novel aspect of this pump system is the incorporation of feedback into the pump algorithm in order to produce more effective pressure cycling")). This use of a sensor to change pressure during a cycle, is not a "predetermined cycle" under our construction.

Petitioner argues that "Mullins' relevance in the prior art combinations is its discussion of distal end flow control, not for its sensors." Pet. Reply 17 (citing Ex. 1035 ¶ 83). However, Petitioner's obviousness grounds rely on the combination of Yang and Mullins, especially with regard to Mullins's disclosure of "a controller" in order "to control fluid flow in and out." As discussed above, Mullins relies on the sensor-feedback approach in order to control flow and we find that Petitioner has not presented persuasive evidence of how the combined disclosures of Yang and Mullins would control flow without using Mullins's sensor feedback approach. *See 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").

Therefore, we determine that Petitioner has not sufficiently shown that the combination of Yang and Mullins discloses or renders obvious "a controller configured to open and close the vacuum valve and the vent valve in a ***predetermined cycle*** to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter." Accordingly, having considered the parties' respective evidence and arguments, we find that Petitioner has not shown by a preponderance of the evidence 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. However, because claims 2–8 and 10–20 all depend, either directly or indirectly, from claim 1, they all

include the "predetermined cycle" limitation. Therefore, for the reasons discussed above, we find that Petitioner has not shown by a preponderance of the evidence that claims 2–8 and 10–20 of the '402 patent would have been unpatentable as obvious over the combination of Yang and Mullins.

E. 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. Patent Owner argues all of the Yang/Mullins grounds (Grounds 1–3) together. *See* PO Resp. 24–30.

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

[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.

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

Because claims 5, 6, 18, and 19 all depend, either directly or indirectly, from claim 1, they all include the "predetermined cycle" limitation. Petitioner relies on the combination of Yang and Mullins from Ground 1 to disclose the limitations of claim 1, as incorporated into these dependent claims. *See* Pet. 55, 63. Therefore, for the reasons discussed above, we find that Petitioner has not shown by a preponderance of the evidence that claims 5, 6, 18, and 19 of the '402 patent would have been unpatentable as obvious over the combination of Yang, Mullins, and Rubinstein.

F. 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. Patent Owner argues all of the Yang/Mullins grounds (Grounds 1–3) together. *See* PO Resp. 24–30.

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),

[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.

(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 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

Because claim 9 depends from claim 1, it includes the "predetermined cycle" limitation. Petitioner relies on the combination of Yang and Mullins from Ground 1 to disclose the limitations of claim 1, as incorporated into dependent claim 9. *See* Pet. 65. Therefore, for the reasons discussed above, we find that Petitioner has not shown by a preponderance of the evidence that claim 9 of the '402 patent would have been unpatentable as obvious over the combination of Yang, Mullins, and Matteo.

G. 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. PO Resp. 24–72; PO Sur-Reply 6–25.

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.

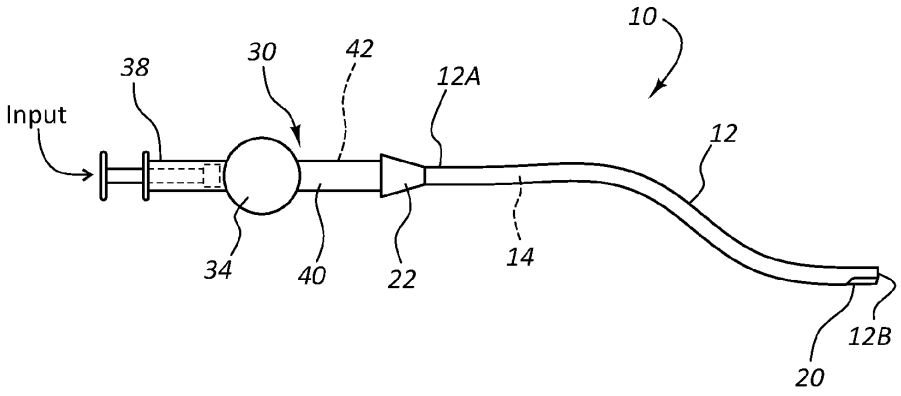


Fig. 1

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.

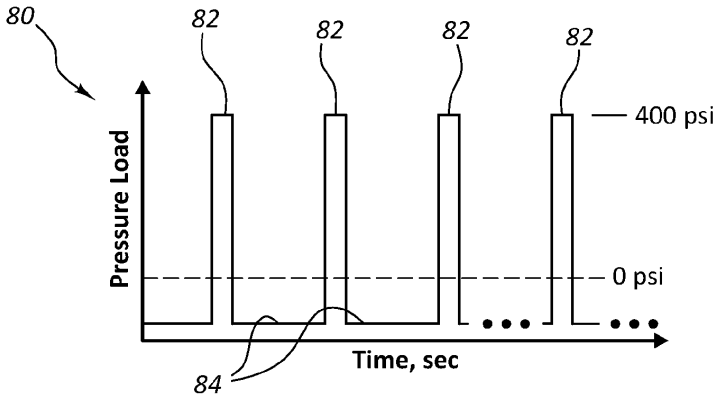


Fig. 2

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. As with the Yang prior art grounds, Patent Owner contends that Petitioner fails to show that the combination of Ofek and Mullins discloses "a controller configured to open and close the vacuum valve and the vent valve in a ***predetermined cycle*** to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter." PO Resp. 24–26, 30–31. We discuss the parties' positions regarding this limitation below.

a) Petitioner's Position

Petitioner asserts that the combination of Ofek and Mullins renders obvious "a controller configured to open and close the vacuum valve and the vent valve in a predetermined cycle to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter." Pet. 81–86.

With regard to the "controller"/"predetermined cycle" limitation, Petitioner contends that Ofek discloses a "'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). Petitioner cites to Ofek's disclosure that, "[t]he controller 170 determines the number, frequency, rest periods, etc., of the impulses to be delivered…valve 140 is opened and close [sic] repeatedly at predetermined time intervals to provide a series of fluid impulses." *Id.* (citing Ex. 1007m 5:49–62).

With regard to the "control[ling] fluid flow in and out limitation," Petitioner 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 systems, as explained in the Yang grounds. *Id.* at 86 (citing Pet. 33–35; Ex. 1005 ¶¶ 407–409).

b) Patent Owner's Position

As with the Yang grounds, Patent Owner contends that Petitioner fails to show that the combined disclosures of Ofek and Mullins teaches or renders obvious "a controller configured to open and close the vacuum valve and the vent valve in a ***predetermined cycle*** to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter," as required by independent claim 1. PO Resp. 24–26, 30–31. Specifically, Patent Owner argues that, because Petitioner's Ofek/Mullins combination uses Mullins's sensor and pressure-feedback approach for the control of fluid flow, the combination does not have a predetermined cycle. *Id.* at 30 (citing Pet. 67). Patent Owner concludes that, "[t]hus, like the Yang/Mullins combination, the Ofek/Mullins combination does not use 'a predetermined cycle' to control fluid flow, as the claims require." *Id.* at 31.

c) Analysis

After carefully considering the arguments and evidence, we determine that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '402 patent would have been obvious over Ofek and Mullins. We agree with Patent Owner that, under our construction of the term "predetermined cycle," Petitioner has not shown that that the combination of Ofek and Mullins discloses a "predetermined cycle" to "control fluid flow in and out."

As discussed above, we find that Mullins's use of a pressure sensor in its pressure-feedback approach for the control of fluid flow is not a "predetermined cycle" as required by claim 1. Although we found in our institution decision that Ofek discloses a "predetermined cycle" (Inst. Dec. 36), we agree with Patent Owner that Petitioner's contentions rely on the combination of Ofek and Mullins to disclose a "predetermined cycle" to "control fluid flow in and out." Specifically, for the limitation of "control[ling] fluid flow in and out," Petitioner relies on Mullins's teachings regarding controlling flow at the distal end of the catheter and cites to their arguments regarding Mullins in the Yang/Mullins grounds. *See* Pet. 86 (citing to Pet. 33–35 (discussing Mullins's use of "measured pressure levels"); Ex. 1005 ¶¶ 407–409); *see also* Tr. 9:23–10:1 (Petitioner's counsel stating at the oral hearing that Mullins is relied on in the prior art grounds "for its control features"). Further, in arguing the motivation to combine Ofek and Mullins, Mr. Brown contends that:

> A POSA would also find it obvious to implement monitoring the level of vacuum pressure change at the distal end of the aspiration catheter contemplated by Mullins within Ofek's aspiration system. Consistent with Ofek's use of a pressure transducer to measure pressure of the catheter, monitoring pressure inside the aspiration catheter and vacuum system was a known concept that was used to improve the knowledge available to clinicians about the ongoing aspiration procedure and allow for more effective aspiration techniques, …. ***Mullins discloses that a lumen pressure sensor and a controller can be used to monitor the pressure in the system, and builds on the concept of altering vacuum pressure levels by utilizing a pressure sensor. A POSA would have recognized the benefit of controlling the vacuum pressure levels and fluid flow*** at the distal tip of the catheter, ***as disclosed in Mullins***, in the context of Ofek, which also includes a pressure transducer, and it would

> have been trivial to implement these within Ofek's aspiration thrombectomy system.

Ex. 1005 ¶ 361 (emphasis added). Similarly, Petitioner cites to Mullins's disclosure of "a sensor used to determine fluid displacement and vary pressure" in discussing the combination of Ofek and Mullins for claim 14. Pet. 101.

In sum, Petitioner's obviousness grounds rely on the combination of Ofek and Mullins, especially with regard to Mullins's disclosure of "control[ling] fluid flow in and out." As discussed above, Mullins relies on the sensor-feedback approach in order to control flow and we find that Petitioner has not presented persuasive evidence of how the combined disclosures of Ofek and Mullins would control flow without using Mullins's sensor feedback approach. *See W.L. Gore*, 721 F.2d at 1550 (Fed. Cir. 1983).

Therefore, we determine that Petitioner has not sufficiently shown that the combination of Ofek and Mullins discloses or renders obvious "a controller configured to open and close the vacuum valve and the vent valve in a ***predetermined cycle*** to change a level of vacuum at the distal end of the catheter and to control fluid flow in and out from the distal end of the catheter." Accordingly, having considered the parties' respective evidence and arguments, we find that Petitioner has not shown by a preponderance of the evidence 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. However, because claims 2–8

and 10–20 all depend, either directly or indirectly, from claim 1, they all include the "predetermined cycle" limitation. Therefore, for the reasons discussed above, we find that Petitioner has not shown by a preponderance of the evidence that claims 2–8 and 10–20 of the '402 patent would have been unpatentable as obvious over the combination of Ofek and Mullins.

H. 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. Patent Owner argues all of the Ofek/Mullins grounds (Grounds 4–6) together. *See* PO Resp. 24–26, 30–31.

Because claims 5, 6, 18, and 19 all depend, either directly or indirectly, from claim 1, they all include the "predetermined cycle" limitation. Petitioner relies on the combination of Ofek and Mullins from Ground 4 to disclose the limitations of claim 1, as incorporated into these dependent claims. *See* Pet. 104–106. Therefore, for the reasons discussed above, we find that Petitioner has not shown by a preponderance of the evidence that claims 5, 6, 18, and 19 of the '402 patent would have been unpatentable as obvious over the combination of Ofek, Mullins, and Rubinstein.

I. 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. Patent Owner argues all of the Ofek/Mullins grounds (Grounds 4–6) together. *See* PO Resp. 24–26, 30–31.

Because claim 9 depends from claim 1, it includes the "predetermined cycle" limitation. Petitioner relies on the combination of Yang and Mullins

from Ground 4 to disclose the limitations of claim 1, as incorporated into dependent claim 9. *See* Pet. 107. Therefore, for the reasons discussed above, we find that Petitioner has not shown by a preponderance of the evidence that claim 9 of the '402 patent would have been unpatentable as obvious over the combination of Ofek, Mullins, and Matteo.

IV. CONCLUSION

For the forgoing reasons, we determine that Petitioner has not established by a preponderance of the evidence that claims 1–20 of the '402 patent are unpatentable.[11] This determination is shown in the following table.

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–8, 10–20	103	Yang, Mullins		1–8, 10–20
5, 6, 18, 19	103	Yang, Mullins, Rubinstein		5, 6, 18, 19
9	103	Yang, Mullins, Matteo		9
1–8, 10–20	103	Ofek, Mullins		1–8, 10–20
5, 6, 18, 19	103	Ofek, Mullins, Rubinstein		5, 6, 18, 19
9	103	Ofek, Mullins, Matteo		9
Overall Outcome				1–20

[11] We note that Patent Owner makes additional arguments as to why the claims are not rendered obvious by the cited art, including presenting evidence of secondary considerations of non-obviousness; however, because we find that Petitioner has failed to show by a preponderance of the evidence that the art renders obvious the "predetermined cycle" limitation, we need not address those other arguments.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not established, by a preponderance of the evidence that claims 1–20 of the '402 patent are unpatentable;

FURTHER ORDERED that because this is a Final Written Decision, parties to the proceeding seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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