

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PENUMBRA, INC.,  
Petitioner,

v.

RAPIDPULSE, INC.,  
Patent Owner.

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IPR2021-01466  
Patent 10,531,883 B1

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Before CHRISTOPHER G. PAULRAJ, 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 2, “Pet.”) requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 10,531,883 B1 (Ex. 1001, “the ’883 patent”). RapidPulse, Inc. (“Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314, which provides that an *inter partes* review may be instituted only upon a showing that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). 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 all challenged claims of the ’883 patent, based on all of the grounds identified in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included 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, even if they were presented in the Preliminary Response.

### A. The '883 Patent

The '883 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), 1:28–3:6. We reproduce Figure 47 from the '883 patent below.

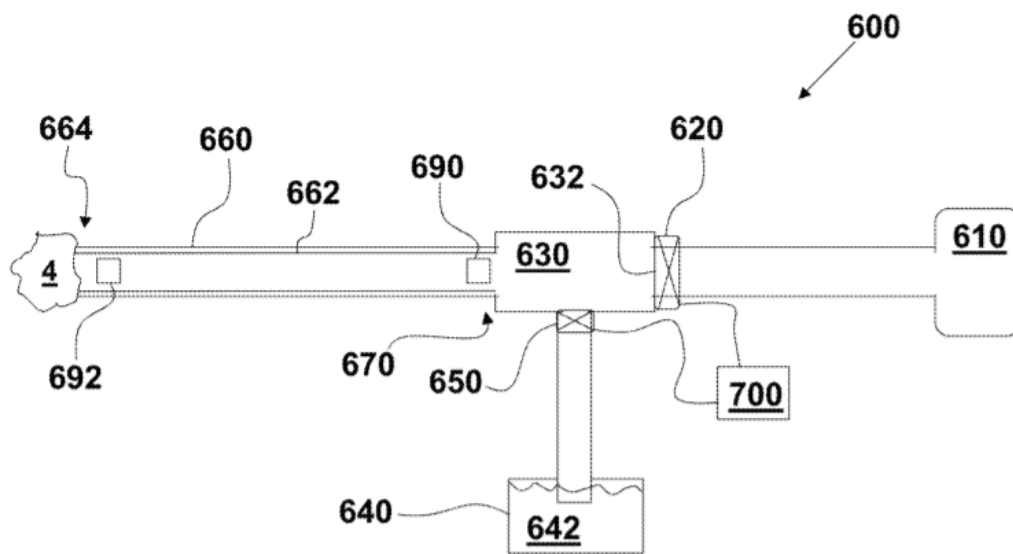


FIG. 47

Figure 47 illustrates an embodiment of the aspiration thrombectomy system 600 of the '883 patent that operates in a Rapid Onset Aspiration Repeater (“ROAR”) mode. Ex. 1001, 33:22–24; 35:19–22; 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 35:22–28. A vent fluid source 640 containing a vent liquid 642 is fluidically connected to a controllable vent valve 650. *Id.* at 35:29–31. 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.” *Id.* at 35:55–58.

Operation of the aspiration thrombectomy system 600 occurs through a controller 700 that “selectively opens and closes the vacuum and vent 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, 36:39–45. 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 36:45–49.

During a ROAR cycle, “suction is applied to the clot by rapidly opening a valve, causing a rapid rise in vacuum pressure.” Ex. 1001, 40:32–34. 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 40:34–37. 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 6:11–17, 43:17–44:10, Tables 1, 4, 5. “The vent valve 650 is then rapidly closed and the vacuum valve 620 is rapidly opened.” *Id.* at 40:37–38. “This cycle is repeated multiple times per second.” *Id.* at 40:39.

According to the ’883 patent, the “ROAR effect overcomes the static friction of a clot that is fixed or ‘stuck’ on the catheter tip while under constant suction” by “provid[ing] an oscillating/alternating displacement that

causes the clot shuttle' back and forth to overcome static frictional force.” Ex. 1001, 7:9–14. And with ROAR, “there is a morcellation of the clot that overcomes different clot morphologies as well as overriding volume and diameter constraints of the small, fixed luminal volume dictated by the micro-anatomic environment.” *Id.* at 7:14-18.

*B. The '883 Patent Priority Date*

The application that issued as the '883 patent was filed on July 18, 2019, and claims priority to U.S. Provisional App. Nos. 62/750,011 (“the '011 provisional”), filed October 24, 2018, and 62/701,086 (“the '086 provisional”), filed July 20, 2018. Ex 1001, codes (22), (60).

Petitioner contends that the claims of the '883 patent are entitled to a priority date no earlier than its July 18, 2019 filing date because neither provisional application describes or enables the claims. Pet. 8. Patent Owner disagrees with Petitioner’s contention that the '883 patent is not entitled to the benefit of its provisional applications and reserves the right to challenge this contention; however, they do not provide arguments or evidence to support priority to the provisional applications in their Preliminary Response. Prelim. Resp. 9 n.1.

Thus, on this record, for purposes of institution, we use July 18, 2019, as the priority date of the '883 patent. *In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011) (“[A] patent’s claims are not entitled to an earlier priority date because the patentee claims priority. Rather, for a patent’s claims to be entitled to an earlier priority date, the patentee must demonstrate that the claims meet the requirements of 35 U.S.C. § 120.” (citations omitted)); *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870–71 (Fed. Cir. 2010); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327–29

(Fed. Cir. 2008); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305–06 (Fed. Cir. 2008).

*C. Illustrative Claim*

Petitioner challenges claims 1–18 of the '883 patent. Claim 1, which is an independent claim, is illustrative of the challenged claims, and is reproduced below:

1. A clot removal system, comprising:
  - [a] a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion;
  - [b] a controllable vacuum valve;
  - [c] a vacuum source fluidically connected to the vacuum valve;
  - [d] a controllable vent valve having a vent liquid input;
  - [e] a vent fluid source containing a vent liquid and fluidically connected to the vent valve to retain the vent liquid at the vent fluid input;
  - [f] a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen: to the vacuum source through the vacuum valve; and to the vent fluid source through the vent valve;
  - [g] a controller connected to the vacuum valve and the vent valve and configured to selectively open and close the vacuum valve and the vent valve such that: responsive to opening the vacuum valve, the vacuum source is fluidically connected to the liquid column in the lumen; and responsive to opening the vent valve, the vent fluid source is fluidically connected to the liquid column in the lumen,
  - [h] the controller configured to cyclically open and close the vacuum valve and the vent valve to: change a level of vacuum at the distal end; and
  - [i] and prevent forward flow of the distal portion out from the distal end during each cycle.

Ex. 1001, 55:5–35 (annotated with bracketed letters). Challenged claims 2–17 depend from claim 1, either directly or indirectly.

Challenged claim 18 is independent.

*D. The Asserted Grounds of Unpatentability*

Petitioner contends claims 1–18 of the '883 patent are unpatentable in view of the following grounds. Pet. 9.

| Ground | Claims Challenged | 35 U.S.C. § | Reference(s)/Basis                     |
|--------|-------------------|-------------|----------------------------------------|
| 1      | 1–12, 15, 16, 18  | 103         | Teigen, <sup>1</sup> Grey <sup>2</sup> |
| 2      | 2, 3, 6–9, 18     | 103         | Teigen, Grey, Rubenstein <sup>3</sup>  |
| 3      | 13, 14            | 103         | Teigen, Grey, Yang <sup>4</sup>        |
| 4      | 17                | 103         | Teigen, Grey, Matteo <sup>5</sup>      |

Petitioner submits the Declarations of Brian Brown (Ex. 1005) and Ian Ross, M.D. (Ex. 1023) in support of institution of *inter partes* review. Patent

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<sup>1</sup> Teigen et al., US 11,096,712 B2, issued Aug. 24, 2021 (Ex. 1007, “Teigen”).

<sup>2</sup> Grey et al., WO 2014/151209 A1, published Sept. 25, 2014 (Ex. 1010, “Grey”).

<sup>3</sup> Morton K. Rubenstein, US 3,955,574, issued May 11, 1976 (Ex. 1011, “Rubenstein”).

<sup>4</sup> Yang et al., US 2017/0238953 A1, published Aug. 24, 2017 (Ex. 1012, “Yang”).

<sup>5</sup> Joseph Matteo, US 2012/0138833 A1, published June 7, 2012 (Ex. 1013, “Matteo”).

Owner relies on the Declarations of Ender Finol, Ph.D. (Ex. 2001) and Michael Chen, M.D. (Ex. 2003) in support of its Preliminary Response.

## II. ANALYSIS

### *A. Person of Ordinary Skill in the Art*

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

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 to four years of academic or industry experience in aspiration embolectomy and thrombectomy or comparable industry experience who would, where necessary or desired, 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 necessary, work or consult with others, including an engineer, to develop such a medical device.

Pet. 15 (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 does not address the definition of a POSA in its Preliminary Response.<sup>6</sup> *See* Prelim. Resp.

Because Petitioner’s proposed definition is unopposed at this stage and is consistent with the level of skill reflected in the cited prior art, we adopt it for the purposes of this Decision.

*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) (2019). 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 proposed constructions for the terms, “the change in the level of vacuum at the distal end is greater than approximately [15]/[20]/[25] in Hg and no greater than approximately [50]/[30]/[20] ms.” Pet. 21–23. Patent Owner does not address claim construction in its Preliminary Response.<sup>7</sup> *See* Prelim. Resp.

Upon review of the parties’ arguments and the evidence of record, we determine that the terms provided by Petitioner do not require express

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<sup>6</sup> The Declaration of Dr. Finol expresses some disagreement with Petitioner’s definition of a POSA; however, the Preliminary Response does not address the definition nor does it cite to the discussion of a POSA in the Finol Declaration. *See* Ex. 2001 ¶¶ 38–39.

<sup>7</sup> The Declaration of Dr. Finol does not dispute the constructions proposed by Petitioner, but Patent Owner does not cite this testimony or otherwise address claim construction in the Preliminary Response. *See* Ex. 2001 ¶¶ 34–36.

construction for purposes of this Decision. We do, however, construe the term “forward flow” in the analysis below. *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.”)).

*C. Asserted Obviousness of Claims 1–12, 15, 16, and 18 over Teigen in view of Grey*

Petitioner contends that the subject matter of claims 1–12, 15, 16, and 18 of the ’883 patent are obvious over the disclosure of Teigen in view of Grey. Pet. 23–63. Patent Owner disputes Petitioner’s contentions. Prelim. Resp. 25–50.

*1. Principles of Law*

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the subject matter sought to be patented and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *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 v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“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 Litigation*, 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. *Teigen (Ex. 1007)*

*Teigen*, titled “Aspiration Thrombectomy System and Methods for Thrombus Removal with Aspiration Catheter,” is directed to devices and methods for controlling clot removal from a patient’s vasculature by aspiration thrombectomy. *Ex. 1007*, code (54), 1:17–21. *Teigen* discloses a vacuum aspiration control system for use with a vacuum source and an aspiration catheter. *Id.*, code (57).

*Teigen* further discloses that its vacuum aspiration system comprises a connecting tube, on-off valve, sensing unit, controller, fluid introduction unit, three-point junction, and fluid injection valve for pulsed aspiration. *Ex. 1007*, 3:60–4:17, 14:61–18:7. *Teigen* discloses that the controller is configured to receive signals from pressure sensors in the system, and opens and closes the vacuum and fluid injection valves to “clear occlusions in an aspiration catheter or to facilitate the aspiration of clot that are large or

otherwise hard to aspirate.” *Id.* at 3:60–4:17, 14:61–18:7. Teigen teaches that the pressure pulse can create a force impulse that breaks static friction momentarily, allowing a lower dynamic friction to ingest thrombus. *Id.* at 14:61–15:9. Teigen also discloses that, in one example, “pressure is generated by introducing fluid into the catheter, where the fluid is at a pressure between full vacuum and ambient pressure, at ambient pressure, at systolic pressure, or above systolic pressure.” *Id.* at 15:37–40.

In some embodiments of Teigen, “the controller may modulate a vacuum valve [] and a pressure valve [], whereby the closing of the vacuum valve [] and the opening of the pressure valve [] may result in a relative increase in pressure at a distal tip of an aspiration catheter.” Ex. 1007, 17:45–49. Further, “[a]lternatively, the opening of the vacuum valve [] and the closing of the pressure valve [] may result in a relative decrease in pressure at the distal tip of the aspiration catheter [].” *Id.* at 17:50–52.

### 3. *Teigen Priority Date*

Teigen issued on August 24, 2021, from U.S. Patent Application No. 16/988,556 (“the ’556 application”), filed August 7, 2020. Ex. 1007, codes (21), (22), (45). The ’556 application is a continuation of PCT/US2019/043095 (“the ’095 PCT application”), filed on July 23, 2019. *Id.* at code (63). The ’095 PCT application claims the benefit of priority to U.S. Provisional Application Nos. 62/778,708 (“the ’708 provisional”), filed December 12, 2018, and 62/702,804 (“the ’804 provisional”), filed July 24, 2018. *Id.* at code (60).

Petitioner contends that Teigen qualifies as prior art under 35 U.S.C. §§ 102(a)(2) and 102(d)(2) because the subject matter of Teigen is fully supported by both provisional applications such that Teigen has a priority

date of July 24, 2018 (i.e., the filing date of the '804 provisional). Pet. 16. Patent Owner contends that Petitioner failed to establish that Teigen is prior art. Prelim. Resp. 8–24.

*a. Petitioner's Position*

Petitioner asserts that Teigen should get priority to its provisional applications because a representative claim from Teigen is described and enabled by both provisional applications and because the disclosure relied on from Teigen in the Petition is also fully supported by both provisional applications. Pet. 16 (citing Ex. 1005 ¶¶ 84–95). Petitioner cites to the Brown Declaration to support these contentions. *Id.* Mr. Brown opines that claim 1 of Teigen is fully supported and enabled by the disclosure of the '804 provisional application and provides citations to the '804 provisional to support this assertion. Ex. 1005 ¶¶ 84–95. Mr. Brown also opines that both provisional applications adequately describe and support the relevant subject matter of Teigen relied upon in the Petition and provides cross cites to the provisional applications when discussing the obviousness arguments. *See id.*, e.g., ¶¶ 84–85, 105–238.

*b. Patent Owner's Position*

First, Patent Owner argues that Petitioner did not establish that Teigen should get the benefit of the '095 PCT application because they did not show that: “(1) the Teigen PCT application designated the United States and was entitled to its filing date in accordance with PCT Article 11; (2) the Teigen PCT application was filed during the pendency of the international application; or (3) the Teigen patent provides a specific reference to the Teigen PCT application.” Prelim. Resp. 9–10.

Next, Patent Owner asserts that Petitioner failed to show that Teigen should get the benefit of the provisional applications because the Petition improperly incorporates arguments from the Brown Declaration to make this showing. Prelim. Resp. 11–14. Similarly, Patent Owner argues that the Petition fails to show that several portions of Teigen relied on in the Petition are supported by the provisional applications. *Id.* at 21–25.

Lastly, Patent Owner contends that the Brown Declaration does not cure the deficiencies of the Petition because it fails to show that certain limitations of claim 1 of Teigen are supported by the provisional applications. Prelim. Resp. 15–21.

*c.* Analysis

With regard to Patent Owner’s arguments regarding Petitioner’s failure to show that Teigen can properly claim the benefit of the ’095 PCT application, we note that Teigen is a continuation of the ’095 PCT application, and, therefore, cannot include any new matter. Ex. 1007, code (63); Manual of Patent Examining Procedure § 211.05, I.B. (“The disclosure of a continuation or divisional application cannot include anything which would constitute new matter if inserted in the prior-filed application.”). Patent Owner cites no authority for the contention that Petitioner must separately show that Teigen meets the procedural requirements for claiming priority to the ’095 PCT application, especially where Patent Owner has not identified any discrepancies between the Teigen disclosure and the ’095 PCT application. Further, Teigen and the ’095 PCT application themselves, on their face, provide sufficient evidence that the ’095 PCT application designated the United States, that the ’095 PCT application was filed during the pendency of the international application (i.e., the provisional

applications), and that Teigen provides a specific reference to the '095 PCT application. *See* Ex. 1007, code (63), 1:5–13; Ex. 2005, codes (22), (30), (81). Thus, on the current record, we are not persuaded that Petitioner has failed to show that Teigen is entitled to the priority of the '095 PCT application.

With regard to the incorporation by reference arguments, the Petition states that the relevant subject matter relied on in Teigen is fully supported by both provisional applications and that a representative claim of Teigen is described and enabled by the provisional applications. Pet. 16. While it is true that Petitioner cites to paragraphs 84–95 of the Brown Declaration to provide support for a representative claim of Teigen being described and enabled by the provisional applications, we do not find this citation to be unreasonable under the circumstances. We also do not find it unreasonable under the circumstances for the Petition to cite to the Brown Declaration to provide cross-cites to the portions of the provisional applications that provide support for the disclosure relied on in Teigen to show obviousness.

As recognized by the Board and the Federal Circuit, the prohibition against incorporation by reference set forth in 37 C.F.R. § 42.6(a)(3) “minimizes the chance that an argument would be overlooked and eliminates abuses that arise from incorporation and combination,” and is intended to prevent the situation where “the Board would be forced to ‘play archeologist with the record’ for arguments that might have been made outside the parties’ briefing.” *3M Co. v. Evergreen Adhesives, Inc.*, 860 F. App’x 724, 725 (Fed. Cir. 2021). Here, both Patent Owner and the Board were provided sufficient notice of Petitioner’s reliance on the cited portions of the Brown Declaration concerning support in the provisional applications for Teigen’s

disclosure and representative claim. As such, there was no need to “play archeologist with the record.” We find this case to be distinguishable from the Board case cited by Patent Owner in which footnotes were used to cite to large portions of an expert declaration, which itself cited to additional claim charts. *See Cisco Sys., Inc. v. C-Cation Techs., LLC*, No. IPR2014-00454, Paper 12 (PTAB Aug. 29, 2014).

We now turn to Patent Owner’s argument that the Brown Declaration fails to show that certain limitations of claim 1 of Teigen are supported by the provisional applications. Claim 1 of Teigen is shown below:

1. A clot removal system, comprising:
  - [a] a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion;
  - [b] a controllable vacuum valve;
  - [c] a vacuum source fluidically connected to the vacuum valve;
  - [d] a controllable vent valve having a vent liquid input;
  - [e] a vent fluid source containing a vent liquid and fluidically connected to the vent valve to retain the vent liquid at the vent fluid input;
  - [f] a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen: to the vacuum source through the vacuum valve; and to the vent fluid source through the vent valve;
  - [g]<sup>8</sup> a controller connected to the vacuum valve and the vent valve and configured to selectively open and close the vacuum valve and the vent valve such that: responsive to opening the vacuum valve, the vacuum source is fluidically

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<sup>8</sup> The Brown Declaration uses the label [e] for two different claim limitations; however, we have assigned the label [g] to the second occurrence of [e]. *See* Ex. 1005 ¶¶ 92, 94.

connected to the liquid column in the lumen; and responsive to opening the vent valve, the vent fluid source is fluidically connected to the liquid column in the lumen,

**the controller configured to cyclically open and close the vacuum valve and the vent valve to: change a level of negative and positive pressure at the distal end; and control flow of the distal portion in and out from the distal end during each cycle.**

Ex. 1007, 23:2–33 (bracketed letters and emphasis added). Patent Owner asserts that Mr. Brown fails to show that the provisional applications provide support for the bolded claim language from limitation [1g] above. Prelim. Resp. 15–21.

In asserting that the '804 provisional application supports these limitations, the Brown Declaration states that “[t]he '804 Provisional explains that during dynamic/pulsed aspiration, the on-off valves including the vacuum source valve and the pressure source valve are modulated by the controller by alternating between opening and closing the valves to generate pressure differentials within the lumen of the aspiration catheter,” citing to paragraphs 63–65 of the '804 provisional application. Ex. 1005 ¶ 94. Patent Owner contends that the paragraphs cited by Mr. Brown do not mention changing a level of negative and positive pressure at the distal end and, “at best, disclose a method for ‘applying a vacuum, followed by reducing that vacuum with saline, and then reapplying full vacuum’ using an on-off valve and a saline injection valve.” Prelim. Resp. 17–19. According to Patent Owner, “there cannot be a ‘positive pressure’ . . . if the vacuum is merely ‘partially’ relieved or reduced.” *Id.* at 18 (citing Ex. 2001 ¶ 50). We address these claim limitations below.

The '804 provisional application discloses pulsated aspiration in which, at times, the valve to the vacuum pump is closed and the valve to the saline injection unit is open in order to more efficiently digest a clot that is large or otherwise difficult to aspirate. Ex. 1008 ¶¶ 65, 69. According to the '804 provisional, “[s]aline pulsated aspirations provide a ‘dynamic’ aspiration force” because “[i]nstead of aspirating clots with a static (constant) vacuum force, pulsated aspiration introduces an acceleration component to the mass transfer force which can help break up larger clots so that they can better fit in the catheter lumen.” *Id.* ¶ 64. We recognize that the '804 provisional does not specifically mention “positive pressure.” Nonetheless, based on the present record, we understand that a positive pressure could result at the distal end of the catheter when the vacuum pump is turned off and the saline injection unit is open to create an influx of saline into the catheter. Our understanding is confirmed by the disclosure of the '708 provisional application which, in discussing pulsated aspiration, expressly states that, “[a]n influx of fluid will create a positive pressure or partially relieve the vacuum.” Ex. 1009 ¶ 67.<sup>9</sup>

The '804 provisional application also discloses that, after a short period of time, the system will close the valve to the saline injection unit and reopen the valve of the vacuum to reestablish the aspiration vacuum.

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<sup>9</sup> Although the Brown Declaration only provides citations to the '804 provisional application to establish priority for Teigen, it also states that the '708 provisional provides support for Teigen. Ex. 1005 ¶ 85. We note that the '708 provisional application, which was filed on December 12, 2018, also has an earlier filing date than the July 18, 2019 priority date of the '883 patent. As such, we have also considered the disclosure of the '708 provisional in assessing the issue of Teigen's priority.

Ex. 1008 ¶ 65. Thus, on the current record, we find that the '804 provisional application provides support for the claim limitation of “chang[ing] a level of negative and positive pressure at the distal end” of claim 1 of Teigen. Changing the pressure level at the distal end also results in “control[ing] flow of the distal portion in and out from the distal end,” thus, we find that this limitation is also supported by the '804 provisional application. *See id.* at ¶ 63 (“in some instances, it will be desirable to ‘pulsate’ the aspiration pressure to reduce clogging and promote flow of the clot and thrombus through the aspiration catheter.”). The '804 provisional application also discloses that the pulsed aspiration “process is repeated as necessary for a system stuck in clot,” providing support for the claim limitations reciting the cyclical opening and closing of the vent valve and vacuum valve. Ex. 1008 ¶¶ 65, 69 (“While aspiration is cycled off, saline injection is cycled on until aspiration is turned back on.”).

Accordingly, on the present record, we find that Petitioner has sufficiently shown that the '804 provisional application provides support for limitation [1g] of the Teigen patent. Patent Owner does not contest support for any other limitations of claim 1 of Teigen at this time and we find that Petitioner and Mr. Brown sufficiently show that the '804 provisional application also provides support for these limitations. *See* Ex. 1005 ¶¶ 85–95. Thus, on the current record, for purposes of this decision, we find that Petitioner has sufficiently shown that Teigen can claim priority to the July 24, 2018 filing date of the '804 provisional application and is prior art to the '833 patent.

4. *Grey (Ex. 1010)*

Grey, titled “Dynamic Aspiration Methods and Systems,” is directed to “an aspiration system” including “a catheter[], an aspiration source providing a negative pressure in the catheter, and a device which repetitively changes the negative pressure to produce a dynamic suction force at a distal end of the catheter.” Ex 1010, codes (54), (57), 5:1–4. Grey discloses that “negative pressure and negative pressure oscillations are delivered by a fluid medium,” and that, in some embodiments, a “second aspiration fluid may be provided at a positive pressure.” *Id.* at 3:22–24, 8:24–25. Grey teaches that “dynamic aspiration as taught [] may cause fracture and break-up of a clot applying smaller suction forces which are repetitively varied to induce material fatigue.” *Id.* at 10:17–19.

Grey also discloses that “[o]ne very serious risk is the escape and travel of occlusive material from the initial site of occlusion to a distal portion of the lumen or to another lumen branching therefrom.” *Id.* at 7:10–12. According to Grey, “[p]roviding a non-zero suction force in the catheter at all times reduces the risk of occlusive material breaking free of a clot and traveling distally in the vessel.” *Id.* at 13:7–11.

Grey was published on September 25, 2014 and Petitioner contends that it qualifies as prior art at least under §102(a)(1) because it was published prior to the effective filing date of the ’883 Patent. Ex. 1010, code (43); Pet. 18. Patent Owner does not contest that Grey is prior art to the ’833 patent.

5. *Claims*

Petitioner contends that the subject matter of claims 1–12, 15, 16, and 18 of the '883 patent would have been obvious over Teigen in view of Grey. Pet. 23–62.

a. Claim 1

Petitioner, with supporting testimony from Mr. Brown, provides evidence as to where Teigen and Grey disclose the limitations of claim 1 of the '833 patent. Pet. 25–41. At this stage of the proceeding, Patent Owner only contests whether Petitioner has sufficiently shown that Teigen discloses limitation [1i] of the '883 patent: “the controller configured to cyclically open and close the vacuum valve and the vent valve to: . . . prevent forward flow of the distal portion out from the distal end during each cycle.” Prelim. Resp. 25–35. We review the parties’ positions below.

(1) *Petitioner’s Position*

Petitioner cites to three portions of Teigen to support their argument that Teigen discloses limitation [1i] of the '883 patent. Pet. 25–31. First, Petitioner cites to claim 1 of Teigen which states, “the controller configured to cyclically open and close the vacuum valve and the vent valve to: . . . control flow of the distal portion in and out from the distal end during each cycle.” *Id.* at 40 (citing Ex. 1007, claim 1). Next, Petitioner cites to the portion of Teigen, which discloses that during the pulsed extraction cycle:

a controller may close vacuum valve [] and open pressure valve [] for a small period of time, thus allowing ***a minimal volume of fluid*** from the pressure source [] to be introduced into a proximal end of the aspiration catheter [] ***to increase the relative pressure at the distal end of the aspiration catheter*** [] before reverting to vacuum by re-opening vacuum valve [] and closing pressure valve.

*Id.* (citing Ex. 1007, 17:55–62). Petitioner further contends that “Teigen also discloses that the fluid introduced into the catheter from the fluid source is ‘at a pressure between full vacuum and ambient pressure,’ such as to partially relieve the vacuum in the catheter.” *Id.* (citing Ex. 1007, 15:34–43; Ex. 1005 ¶ 155).

In addition, according to Petitioner, to the extent that Teigen alone does not disclose limitation [1i] of the ’833 patent, then the combination of Teigen and Grey does. Pet. 40–41 (citing Ex. 1005 ¶¶ 155–159). Petitioner asserts that Grey discloses that a “second aspiration fluid may be provided at a positive pressure” for dynamic aspiration and recognizes that “one very serious risk is the escape and travel of occlusive material from the initial site of occlusion to a distal portion of the lumen or to another lumen branching therefrom.” *Id.* at 41 (citing Ex. 1010, 8:24–25, 7:10–12). Thus, according to Petitioner, Grey teaches that “the magnitude of the baseline pressure is preferably maintained above zero (i.e., a vacuum is maintained)” and that “providing a non-zero suction force in the catheter at all times reduces the risk of occlusive material breaking free of a clot and traveling distally in the vessel.” *Id.* (citing Ex. 1010, 13:7–11).

Petitioner, with supporting testimony from Mr. Brown, contends that “[a] POSA would have recognized that Grey teaches the prevention of forward flow out of the distal end of the catheter as described in the ’883 Patent.” Pet. 41 (citing Ex 1005 ¶ 158; Ex 1001, 2:60–3:4 (defining forward flow)). According to Petitioner, “[a] POSA would have been motivated in view of Grey to operate the dynamic aspiration system of Teigen in a manner that maintains ‘a non-zero suction force’ to prevent forward flow of the distal portion out from the distal end during each cycle in order [to]

reduce the risk of a clot travelling distally, as taught in Grey.” *Id.* Petitioner also contends that a POSA would have had a reasonable expectation of success in doing so because Grey discloses “a plurality of parameters” that “control/influence the pressure realized in a catheter and to which an occlusion is subjected.” *Id.* at 42 (citing Ex. 1010, 10:22–31). According to Petitioner, “[a] POSA would have been able to follow the directions provided in Grey to ‘optimize[] treatment efficacy’ using Teigen’s system, including to prevent forward flow, using no more than routine experimentation.” *Id.* (citing Ex. 1005 ¶ 159).

*(2) Patent Owner’s Position*

Patent Owner contends that neither the disclosure of Teigen alone, nor the combined disclosures of Teigen and Grey, teaches or suggests limitation [1i] of claim 1 of the ‘833 patent. Prelim. Resp. 26–35. First, Patent Owner contends that Petitioner does not provide cross-citations to the provisional applications for support of claim 1 of Teigen. *Id.* at 27–28. Patent Owner also contends that claim 1 of Teigen does not disclose preventing forward flow of the distal portion out from the distal end because the claim language describes flow out from the distal end, which is “in direct contradiction to Petitioner’s argument that Teigen claim 1 discloses preventing forward flow.” *Id.* at 28 (citing Ex. 2001 ¶ 54).

Patent Owner further contends that the disclosure at lines 17:17–18:7 of Teigen does not describe “preventing forward flow” and also asserts that the concept of a “minimal volume of fluid ... to increase relative pressure at the distal end of the aspiration catheter” is first disclosed only in the ‘095 PCT application and not in either of the provisional applications. Prelim.

Resp. 29. Thus, according to Patent Owner, this disclosure cannot be used as prior art against the '833 patent. *Id.*

With regard to the argument that Teigen discloses that “the fluid introduced into the catheter from the fluid source is ‘at a pressure between full vacuum and ambient pressure,’ such as to partially relieve the vacuum in the catheter,” Patent Owner argues that Petitioner fails to disclose how this “prevent[s] forward flow of the distal portion out from the distal end during each cycle.” Prelim. Resp. 29–30 (citing Pet. 40 (citing Ex. 1007, 15:34–43)). Patent Owner, along with supporting testimony from Dr. Finol, asserts that “quickly closing the vacuum valve causes a forward moving pressure pulse (i.e., water hammer effect) or introducing a vent fluid at ambient pressure while the vacuum source is cut off causes the expansion of the catheter creating a forward pressure pulse in the fluid column.” *Id.* at 30 (citing Ex. 2001 ¶¶ 56–58).

Patent Owner further contends that the disclosure of Grey in combination with Teigen does not disclose limitation [1i] because none of the citations referenced by Petitioner explicitly disclose forward flow. Prelim. Resp. 33. According to Patent Owner, Grey does not teach the combination of a vacuum valve, a vent valve, and cyclically opening and closing the vacuum valve and the vent valve to “prevent forward flow at the distal end.” *Id.* at 34 (citing Ex. 2001 ¶ 74). Patent Owner, with supporting testimony from Dr. Finol, also asserts that Grey discloses a system in which the vacuum sources always apply a non-zero vacuum force in the catheter and, thus, it “cannot disclose preventing forward flow during the pulse of vent fluid **while a vacuum valve is closed during each cycle.**” *Id.* at 34–35 (citing Ex. 2001 ¶ 67). Patent Owner contends that Petitioner does not

explain how “Grey’s concept of ‘providing a non-zero suction force in the catheter at all times’ is implemented in a system in which a vacuum valve is closed to shut off the vacuum force and a vent valve is opened to relieve the vacuum pressure.” *Id.* at 35.

Lastly, Patent Owner asserts that Petitioner fails to establish a motivation to combined Teigen with Grey because Petitioner’s arguments are too generic and “[i]t would not have been clear to a POSITA at the time of the invention of the ’883 patent how ‘providing a non-zero suction force in the catheter at all times,’ including while providing a ‘positive pressure’ to cause the distal portion to flow ‘out from the distal end’ as required by the Teigen patent, would enhance the efficiency and effectiveness of Teigen’s system.” Prelim. Resp. 37–40 (citing Pet. 24; Ex. 2001 ¶ 85). Patent Owner further contends that “modifying the ‘positive pressure’ pulse in Teigen that produces the flow ‘out from the distal end’ of the catheter by ‘providing a non-zero suction force at all times’ to reduce the risk of distal migration would render Teigen’s system inoperable.” *Id.* at 41. Patent Owner, with supporting testimony from Dr. Finol, concludes that a POSA would not have had a reasonable expectation of success in modifying Teigen based on the teachings of Grey. *Id.* at 43 (citing Ex. 2001 ¶ 83). Patent Owner also contends that the motivation to combine Teigen and Grey to achieve limitation [1i] fails to provide the rational underpinnings necessary to support obviousness and is driven by improper hindsight bias. Prelim. Resp. 43–46.

### *(3) Analysis*

First, as discussed above regarding cross-citations to the Teigen provisional applications, we find that the Brown Declaration provides

sufficient cross-cites to the disclosures in the provisional applications that provide support for the teachings of Teigen that have been relied upon to allege obviousness of limitation [1i] of the '833 patent. *See* Ex. 1005 ¶ 155 (citing Ex. 1007, 3:60–4:26, 5:4–22, 6:6–21, 11:1–25, 14:61–18:22; Ex. 1008 ¶¶ 12, 13, 17, 20, 57, 61–65; Ex. 1009 ¶¶ 14, 15, 19, 22, 59, 63–69).

Next, in analyzing whether Teigen and Grey disclose limitation [1i], we find it useful to construe the term, “forward flow,” as recited in claim 1 of the '833 patent. The '833 patent defines forward flow as “an amount of liquid in the lumen . . . that exits the distal end . . . in the distal direction” and “is defined as greater than 6 microliters of fluid.” Ex. 1001, 36:18–22.

With this definition in mind, we turn to the disclosures from Teigen and Grey relied on by Petitioner to show obviousness of “prevent[ing] forward flow of the distal portion out from the distal end during each cycle.”<sup>10</sup> Claim 1 of Teigen recites that “the controller [is] configured to cyclically open and close the vacuum valve and the vent valve to: . . . control flow of the distal portion in and out from the distal end during each cycle.” Ex. 1007, 23:28–33. Further, Teigen discloses a controller configured to cyclically open and close its vacuum and fluid injection valves to change a level of vacuum at the distal end of the catheter during each extraction cycle in order to more effectively digest blood clots at the distal end of the

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<sup>10</sup> We agree with Patent Owner, that, on the current record, it does not appear that the provisional applications specifically disclose the allowance of a “minimal volume of fluid . . . to increase relative pressure at the distal end of the aspiration catheter.” *See* Prelim. Resp. 28–29. Therefore, we will not consider this disclosure in determining whether the disclosures of Teigen and Grey render limitation [1i] of the '833 patent obvious.

aspiration catheter. *See* Pet. 37–38; Ex. 1005 ¶ 150 (citing Ex. 1007, 3:60–4:26, 5:4–22, 6:6–21; 11:1–25, 14:61–18:22; Ex. 1008 ¶¶ 12, 13, 17, 20, 57, 61–65; Ex. 1009 ¶¶ 14, 15, 19, 22, 59, 63–69). Teigen also discloses that the fluid introduced into the catheter from the fluid source can be “at a pressure between full vacuum and ambient pressure,” such as to partially relieve the vacuum in the catheter. Pet. 40 (citing Ex. 1005 ¶ 155; Ex. 1007, 15:28–43).

We find that, based on the disclosure in Teigen, one of ordinary skill in the art would understand that the level of vacuum and amount of fluid injected into the distal end of the catheter could be adjusted in order to more effectively remove a clot. Grey provides further disclosure which describes the “very serious risk [of] the escape and travel of occlusive material from the initial site of occlusion to a distal portion of the lumen or to another lumen branching therefrom.” Ex. 1010, 7:10–12. To minimize this risk, Grey teaches that “the magnitude of the baseline pressure is preferably maintained above zero (i.e., a vacuum is maintained)” and that “providing a non-zero suction force in the catheter at all times reduces the risk of occlusive material breaking free of a clot and traveling distally in the vessel.” *Id.* at 13:7–11.

Based on these disclosures, we find that, on the current record, it would have been obvious to a POSA to operate the controller of Teigen in such a way as to prevent forward flow out from the distal end of the catheter in order to reduce the risk of portions of the clot from breaking free and traveling distally in the vessel. This could be done, for example, by introducing the fluid into the catheter “at a pressure between full vacuum and ambient pressure,” thereby providing a non-zero suction force, as disclosed in Teigen and Grey. Ex. 1007, 15:37–40; Ex. 1010, 13:7–11. We

note Patent Owner and Dr. Finol's discussion of the "water hammer effect" but it is not clear if such an effect would occur if the fluid pressure is only increased at a pressure between full vacuum and ambient pressure (i.e., partially relieving the vacuum). This issue will be resolved on a complete trial record.

Patent Owner further argues that, because the Teigen claim language recites flow out from the distal end then, by definition, it cannot be preventing forward flow. *See* Prelim. Resp. 28 (citing Ex. 2001 ¶ 54). We are not persuaded by this argument for two reasons. First, the Teigen claim recites that the controller "control[s] flow . . . in and out from the distal end." Controlling flow out of the distal end encompasses preventing forward flow. Also, as discussed above, "forward flow," as defined in the '833 patent, does allow for a minimal amount of fluid (i.e., up to 6 microliters of fluid), to exit the distal end. *See* Ex. 1001, 36:18–22. Thus, Teigen's disclosure of controlling flow out from the distal end could include allowing up to 6 microliters of fluid to exit the distal end.

Patent Owner's argument that Grey does not teach the combination of a vacuum valve, a vent valve, and cyclically opening and closing the vacuum valve and the vent valve to "prevent forward flow at the distal end" is also unavailing because Teigen teaches this combination of valves and Grey provides the motivation to prevent forward flow at the distal end. *See* Prelim. Resp. 34 (citing Ex. 2001 ¶ 74).

We further find that, on the current record, Petitioner has provided sufficient evidence of motivation to combine the disclosures of Teigen and Gray. We agree with Petitioner and Mr. Brown that a POSA would have been motivated to combine the teachings of Teigen and Grey because they

“address similar problems related to convention aspiration thrombectomy and share the common objective of improving aspiration efficiency.” Pet. 23 (citing Ex. 1005 ¶¶ 104–111). We also agree that both Teigen and Grey “teach similar solutions involving a liquid source to temporarily vent/relieve vacuum within the catheter to create an accelerated suction force to efficiently remove blood clots from a patient’s blood vessel into the device.” *Id.* Teigen and Grey both discuss issues with clogged catheters and the limitations of static aspiration technologies for controlled clot aspiration. *Id.* at 24 (citing Ex. 1007, 1:57–2:23, 2:46–52, 3:12–32, 14:61–15:33; Ex. 1010, 1:7–9, 1:15–2:3). Both references also describe a similar approach of creating a dynamic aspiration force to more effectively clear clots from a clogged catheter. *Id.* (citing Ex. 1007, 2:24–64, 3:12–48, 14:61–18:7; Ex. 1010, 2:24–3:24).

Further, on this record, we agree with Petitioner and Mr. Brown that “[c]ombining the teachings of Teigen and Grey would have been well within the skill of a POSA because it is nothing more than combining known vacuum aspiration technologies described in these references to perform their intended functions with described benefits and predictable results.” *Id.* at 24 (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007)); Ex. 1005 ¶ 107. We also find that a POSA would have had a reasonable expectation of success in combining the disclosures of Teigen and Grey because “it would have been well within a POSA’s level of skill to modify the logic of Teigen’s controller to implement Grey’s teachings, and/or to incorporate well-known mechanical components, if needed, to carry out the functionality described in Grey.” Pet. 25 (citing Ex. 1005 ¶ 109).

On the current record we are also not persuaded by Patent Owner's argument that it would not have been clear to a POSA how "'providing a non-zero suction force in the catheter at all times,' including while providing a 'positive pressure' to cause the distal portion to flow 'out from the distal end' as required by the Teigen patent, would enhance the efficiency and effectiveness of Teigen's system." Prelim. Resp. 37–40 (citing Pet. 24; Ex. 2001 ¶ 85). We disagree that the disclosure of the Teigen patent requires a positive pressure which causes the distal portion to flow out from the distal end. As discussed above, Teigen's recitation of controlling flow in and out from the distal portion does not preclude preventing forward flow out of the distal end. Further, under the '833 patent's definition of "forward flow," a small amount of liquid is allowed to flow out of the distal end. Thus, we also do not agree that "modifying the 'positive pressure' pulse in Teigen that produces the flow 'out from the distal end' of the catheter by 'providing a non-zero suction force at all times' to reduce the risk of distal migration would render Teigen's system inoperable," because there is no disclosure in Teigen that requires there to be flow out of the distal end. *Id.* at 41. In fact, Teigen states that the pressure generated by introducing the fluid into the catheter can be "at a pressure between full vacuum and ambient pressure," which would not result in forward flow. Ex. 1007, 15:37–39; Ex. 1009 ¶ 67.

Upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner sufficiently explains why a POSA would have found it obvious to implement Grey's disclosure of "a non-zero suction force" in the system of Teigen in order to reduce the risk of a clot travelling distally. Accordingly, on this record, Petitioner has demonstrated a

reasonable likelihood that the subject matter of limitation [1i] would have been obvious over the combined disclosures of Teigen and Grey. At this time, Patent Owner does not contest that Teigen and Grey disclose the other limitations of claim 1 of the '833 patent, and we find that Petitioner sufficiently shows that the disclosures of Teigen and Grey render these limitations obvious. *See* Pet. 23–42. Thus, on the current record, Petitioner has demonstrated a reasonable likelihood that the subject matter of claim 1 of the '833 patent would have been obvious over the combined disclosures of Teigen and Grey.

*b.* Claims 4, 5, 10–12, 15, and 16

Patent Owner also does not currently contest that Teigen and Grey disclose the other limitations of dependent claims 4, 5, 10–12, 15, and 16, and we find that Petitioner sufficiently shows that the disclosures of Teigen and Grey render these limitations obvious. *See* Pet. 44–61. Thus, on the current record, Petitioner has demonstrated a reasonable likelihood that the subject matter of claims 4, 5, 10–12, 15, and 16 of the '833 patent would have been obvious over the combined disclosures of Teigen and Grey.

*c.* Claims 2, 3, and 6–9

Petitioner, with supporting testimony from Mr. Brown, provides evidence as to where Teigen and Grey disclose the limitations of dependent claims 2, 3, and 6–9 of the '833 patent. Pet. 42–46, 49–54. At this stage of the proceeding, Patent Owner only contests whether Petitioner has sufficiently shown that Teigen discloses the limitations which recite that the controller of claim 1 “is configured to cyclically open and close the vacuum valve and the vent valve in a repeated cycle [limitation [2a]] comprising a double-closed state in which the vacuum valve is closed and the vent valve

is closed [limitation [2b]],” and “wherein the controller is configured to selectively open and close the vacuum valve and the vent valve cycle in a repeated cycle comprising ... a first double-closed state in which the vacuum valve is closed and the vent valve is closed [limitation [6c]] ... and a second double-closed state in which the vacuum valve is closed and the vent valve is closed [limitation [6e]].” Prelim. Resp. 47–50. These limitations are also recited in claims 3 and 7–9 based on their dependency on claims 2 and 6. We refer to these limitations as the “double-closed state” and review the parties’ positions below.

*(1) Petitioner’s Position*

To support its contention that Teigen discloses a “double-closed state,” Petitioner cites to claim 2 of Teigen which recites “a repeated cycle comprising a closed state in which the vacuum valve is closed and the vent valve is closed.” Pet. 42 (citing Ex. 1005 ¶¶ 162–165; Ex. 1007, claim 2). Petitioner also cites to Teigen’s teaching sequences of opening and closing the vacuum and vent valves including where “both valves are closed for at least short periods of time.” *Id.* at 43 (citing Ex 1007, 16:51-18:7).

Petitioner further argues that, “[t]o the extent that Teigen does not explicitly disclose a double-closed state in which the vacuum valve and vent valve are both closed, a POSA would have found a double-closed state an obvious manner of implementing the dynamic aspiration sequence disclosed in Teigen.” *Id.* (citing Ex 1005 ¶¶ 163–64). According to Petitioner, “[a] POSA would have found it obvious, in actual execution, to conduct the valve operation in serial to yield effective pulsing, e.g. closing the vacuum valve first and then opening the vent valve to generate the positive pulse” because “[t]his would have been an efficient way to build [a] positive

pressure pulse.” *Id.* at 43 (citing Ex. 1005 ¶164). Petitioner contends that, if the vacuum valve remained open during this period, some of the positive pulse introduced by opening the vent valve would be reduced by the vacuum.” *Id.* Thus, according to Petitioner, “[b]ecause of the nature of serial operation, it would be obvious to have a finite delay (e.g. for confirming the state of the valve) between the closing of the vacuum valve and the opening of the vent valve, which leads to at least a brief period where both the vacuum valve and the vent valve are closed, i.e. the double-closed state.” *Id.* at 43–44.

*(2) Patent Owner’s Position*

First, Patent Owner contends that neither claim 2 of Teigen nor the quote cited from Teigen at col. 17, lines 5–7 have written description support in the provisional applications. Prelim. Resp. 47–49. Patent Owner also argues that Petitioner’s theories regarding obviousness of claim 2 are inconsistent with Petitioner’s arguments for combining the disclosures of Teigen and Gray for claim 1 because “having a double-closed state to more efficiently ‘build a positive pressure pulse’ . . . directly vitiates Petitioner’s argument that a ‘POSA would have been motivated in view of Grey to operate the dynamic aspiration system of Teigen in a manner that maintains a ‘non-zero suction force’ to prevent forward flow of the distal portion out from the distal end. . . [to] reduce the risk of a clot traveling distally, as taught in Grey’ for claim 1.” *Id.* at 49–50 (citing Pet. 43; Ex. 2001 ¶¶ 79, 81). According to Patent Owner, “[a] ‘double-closed’ state would cut off the vacuum source such that the ‘positive pressure pulse’ to produce ‘positive pressure at the distal end’ during the subsequent open state of the vent valve would eliminate the ‘non-zero suction force at all times in the catheter’

required by the combination of Teigen and Grey.” *Id.* at 50 (citing Ex. 2001 ¶ 81).

*(3) Analysis*

First, on the current record, we agree with Patent Owner that neither claim 2 of Teigen nor the quote cited from Teigen at col. 17, lines 5–7 have written description support in the provisional applications. Therefore, we will not consider these disclosures in our analysis of the “double-closed state” claim limitations.

Teigen discloses dynamic aspiration by opening and closing vacuum and vent valves to generate pressure pulses to improve clot removal efficiency. Ex. 1007, 15:10–33, 17:17–18:7; Ex. 1008 ¶¶ 63–65, Ex. 1009 ¶¶ 65–67. We have considered the testimony of Mr. Brown that “[a] POSA would have found it obvious and typical to conduct the valve operation in serial to yield effective pulsing, e.g. closing the vacuum valve first and then opening the vent valve to generate the positive pulse.” Ex. 1005 ¶ 164. However, we agree with Dr. Finol that Petitioner’s arguments for the “double-closed stated” limitations appear to be in tension with their arguments regarding the combination of Teigen and Grey for claim 1. *See* Prelim. Resp. 49–50; Ex. 2001 ¶¶ 79–81. For example, Petitioner argues that “[a] POSA would have been motivated in view of Grey to operate the dynamic aspiration system of Teigen in a manner that maintains ‘a non-zero suction force’ to prevent forward flow of the distal portion out from the distal end during each cycle in order [to] reduce the risk of a clot travelling distally, as taught in Grey.” Pet. 41. On the current record, we are persuaded by the testimony of Dr. Finol that a POSA would understand that a “double-closed” state would fluidically disconnect the vacuum source such

that the “non-zero suction force at all times in the catheter” would be eliminated. Ex. 2001 ¶ 81.

In view of the foregoing, on the current record, we are somewhat skeptical as to whether a POSA would have combined the disclosures of Teigen and Grey to implement a “double-closed” state as recited in claims 2, 3, and 6–9 of the ’833 patent. Pursuant to *SAS* and *PGS*, however, when instituting on the basis that Petitioner has demonstrated a reasonable likelihood with respect to at least one challenged claim, we must institute on all claims and all grounds challenged in the Petition. *See SAS*, 138 S. Ct. at 1359–60; *PGS*, 891 F.3d at 1360. Thus, this issue will be resolved on a complete trial record.

*d.* Claim 18

Patent Owner contends that Petitioner fails to establish a reasonable likelihood of prevailing on claim 18 for the same reasons as discussed for claims 1 and 2. Prelim. Resp. 51. Because claim 18 includes the “double-closed state” limitation, as discussed above, we are somewhat skeptical as to whether Petitioner has sufficiently demonstrated that this claim is rendered obvious by the combined disclosures of Teigen and Grey. Pursuant to *SAS* and *PGS*, however, when instituting on the basis that Petitioner has demonstrated a reasonable likelihood with respect to at least one challenged claim, we must institute on all claims and all grounds challenged in the Petition. *See SAS*, 138 S. Ct. at 1359–60; *PGS*, 891 F.3d at 1360. Thus, this issue will be resolved on a complete trial record.

*D. Asserted Obviousness of Claims 2, 3, 6–9, and 18 over Teigen in view of Grey and Rubenstein*

Petitioner contends that the subject matter of claims 2, 3, 6–9, and 18 of the '883 patent are obvious over the disclosure of Teigen in view of Grey and Rubenstein. Pet. 63–69. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 51–54.

*1. Rubenstein (Ex. 1011)*

Rubenstein, 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. Rubenstein discloses applying cyclical reversals of positive and negative pressure to create a "self-cleaning" catheter. *Id.* at 1:10–14, 1:64–68. Rubenstein 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 fluid flow therethrough." *Id.* at 2:1–8.

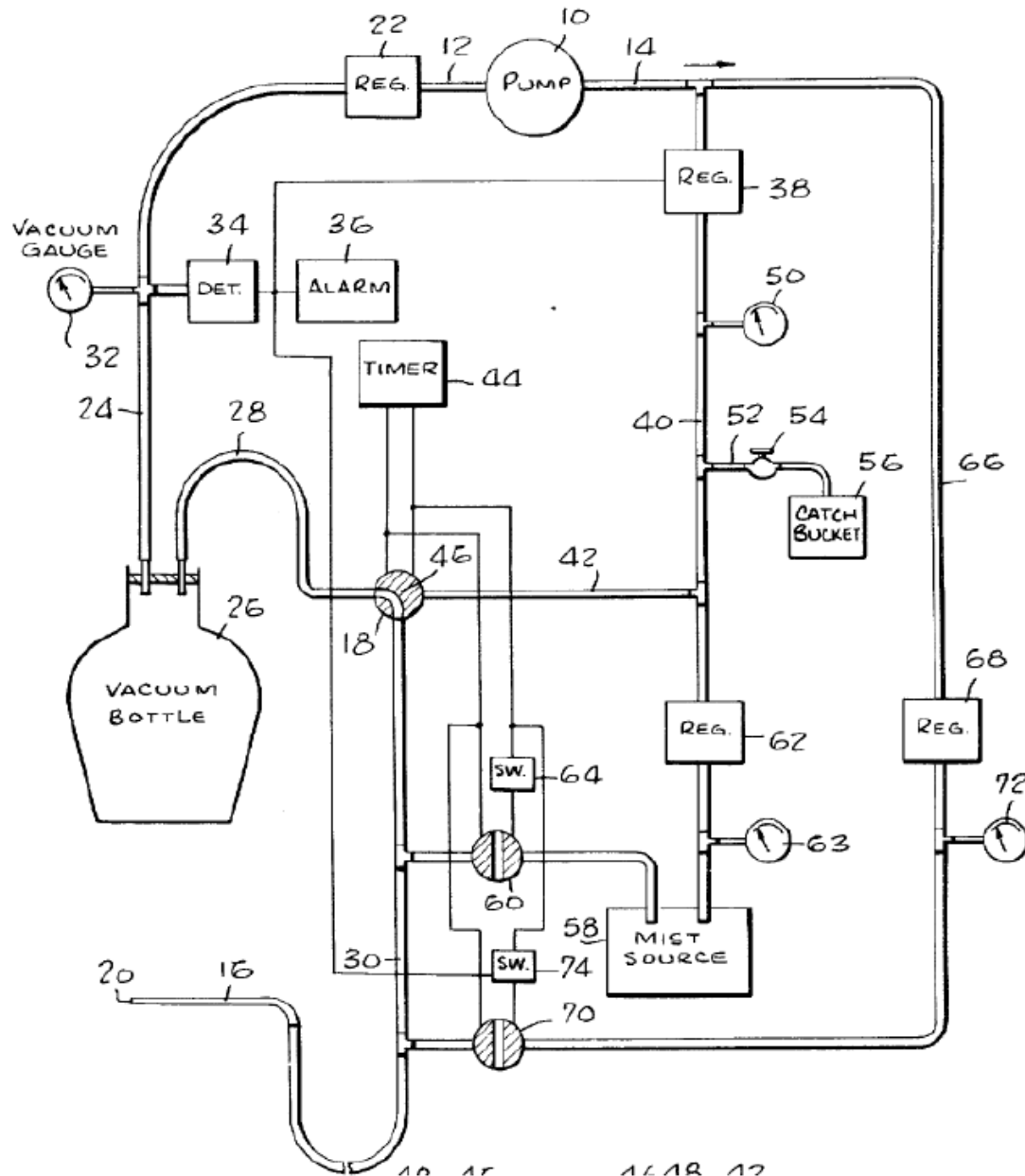
Rubenstein issued on May 11, 1976 and Petitioner contends that it qualifies as prior art at least under §102(a)(1) because it was patented prior to the effective filing date of the '883 Patent. Ex. 1011, code (45); Pet. 19. Patent Owner does not contest that Rubenstein is prior art to the '833 patent.

*2. Petitioner's Position*

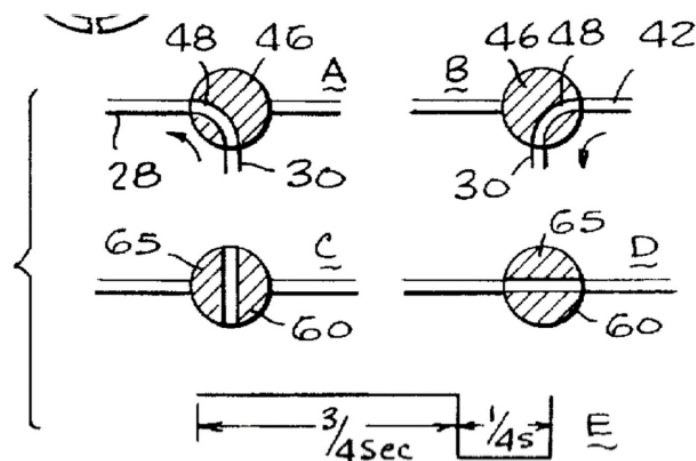
As discussed above, Petitioner contends that Teigen in view of Grey discloses or renders obvious a "double-closed state" in which the vacuum valve is closed, and the vent valve is closed. Petitioner also contends that

Rubenstein further discloses and renders this limitation obvious. Pet. 65 (citing Ex. 1005 ¶¶ 254–63).

Petitioner discusses figures 1 and 2 of Rubenstein shown below in asserting that Rubenstein discloses a double-closed state.



Ex. 1011, Fig. 1. Figure 1 of Rubenstein shown above is a schematic functional block diagram illustrating a pumping system for catheter suction units. *Id.* at 2: 15–16.



*Id.*, Fig. 2. Figure 2 of Rubenstein shown above is a series of graphic diagrams that illustrate the different possible positions of the movable plugs of the pumping system for catheter suction units. *Id.* at 2:18, 3:26–31, 4:19–21.

Petitioner contends that a POSA would have understood the mist source valve (60) and the suction valves (18) to be a vent valve and vacuum valve, respectively. Pet. 68 (citing Ex. 1005 ¶ 259). Petitioner also asserts that a POSA would have understood that the time it would take to rotate the movable plugs within the valves would not be instantaneous and there would, therefore, be a period when both valves are closed during the rotation of the plugs as the system transitions from its suction to blowing modes. *Id.* According to Petitioner, “a POSA would have found it an obvious design choice, when implementing the combination of Teigen and Grey, to use the controllable valves operated in the sequence described in Rubenstein to accomplish the dynamic aspiration taught by Teigen and Grey including ‘a double-closed state in which the vacuum valve is closed, and the vent valve is closed.’” *Id.* at 68–69 (citing Ex. 1005 ¶ 262).

### 3. *Patent Owner's Position*

Patent Owner contends that Rubenstein is non-analogous art and that Petitioner did not provide an adequate motivation to combine Teigen and Grey with Rubenstein. Prelim. Resp. 52–54. Patent Owner also asserts that Rubenstein does not disclose a double-closed state because “Rubenstein does not disclose or suggest a double-closed state in which a vacuum valve and a vent valve are both closed to concurrently fluidically disconnect both the vacuum source and the vent fluid source from the catheter.” *Id.* at 54 (citing Ex. 2001 ¶ 103).

### 4. *Analysis*

On the current record, we agree with Patent Owner that Rubenstein does not appear to disclose a double-closed state.<sup>11</sup> We credit the testimony of Dr. Finol that, “for Petitioner’s argument to stand, the alleged ‘double-closed’ state would require the mist valve 60 to be closed ([see, i.e.,] state ‘C’ of Figure 2 [of Rubenstein]) to fluidically disconnect the positive pressure outlet 14 from the catheter 16 and the rotary valve 18/46 to be positioned to fluidically disconnect the vacuum source from the catheter 16 ([i.e.,] state ‘B’ in Figure 2).” Ex. 2001 ¶ 103. We further credit Dr. Finol’s opinion that “[h]owever, in state ‘B,’ the rotary valve 18/46 ... fluidically connect[s] the positive pressure outlet 14 to the catheter [16] such that even

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<sup>11</sup> We also note that, on the current record, we find that Rubenstein is analogous art because, even, assuming *arguendo*, that it is not in the same field of endeavor as the ’833 patent, it is at least reasonably pertinent to the particular problem with which the inventor is involved because it describes issues with clogged catheters and using alternative cycling of negative and positive pressure to overcome these problems. Ex. 1011, 1:10–14, 1:26–27, 1:64–68; *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986).

when valve 60 is closed and the vacuum source is fluidically disconnected from the catheter 16, positive pressure fluid still flows to the catheter 16.”

*Id.* Therefore, it does not appear that Rubenstein discloses a system in which the vacuum valve and the vent valve are both closed.

In view of the foregoing, on the current record, we are somewhat skeptical as to whether a POSA would have combined the disclosures of Teigen, Grey, and Rubenstein to implement a “double-closed” state as recited in claims 2, 3, 6–9, and 18 of the ’883 patent. Pursuant to *SAS* and *PGS*, however, when instituting on the basis that Petitioner has demonstrated a reasonable likelihood with respect to at least one challenged claim, we must institute on all claims and all grounds challenged in the Petition. *See SAS*, 138 S. Ct. at 1359–60; *PGS*, 891 F.3d at 1360. Thus, this issue will be resolved on a complete trial record.

*E. Asserted Obviousness of Claims 13 and 14 over Teigen in view of Grey and Yang*

Petitioner contends that the subject matter of claims 13 and 14 of the ’883 patent are obvious over the disclosures of Teigen in view of Grey and Young. Pet. 69–73. Patent Owner disputes Petitioner’s contentions. Prelim. Resp. 55.

*1. 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.

Yang was published on August 4, 2017 and Petitioner contends that it qualifies as prior art at least under §102(a)(1) because it was published prior to the effective filing date of the ’883 Patent. Ex. 1012, code (43); Pet. 19. Patent Owner does not contest that Yang is prior art to the ’833 patent.

## *2. Petitioner’s Position*

As discussed above, Petitioner contends that Teigen in view of Grey discloses or renders obvious claim 1 of the ’833 patent. Petitioner also contends that the disclosure of Teigen in view of Grey and Yang renders the limitations of dependent claims 13 and 14 obvious. Pet. 71–73.

Limitation 13[a] recites the system of claim 1, wherein “the lumen has an internal diameter of between approximately 0.038” and approximately 0.106”.” Ex. 1001, 56:16–18. Petitioner contends that Yang discloses the inner diameter of the distal section of the catheter to be “between about 0.030 inches and about 0.112 inches,” which renders this limitation obvious. Pet. 72 (citing Ex. 1012 ¶ 68; Ex. 1005 ¶¶ 291–292; Ex. 1023 ¶¶ 13–14). Limitation 13[b] recites that “the controller is configured to cyclically open and close the vacuum valve and the vent valve at a frequency of between 2 and 16 Hz.” Ex. 1001, 56:19–21. Petitioner asserts that Teigen in view of Grey and Yang render this limitation obvious for the same reasons provided for claim 8 of Ground 1. Pet. 72 (citing Pet. 53–54).

Limitation 14[a] of claim 14 recites the system of claim 1, wherein “the lumen has an internal diameter of between approximately 0.068” and approximately 0.088”.” Ex. 1001, 56:22–24. Petitioner contends that Yang

discloses catheter lumen internal diameters between 0.030 inches and 0.112 inches, which overlaps with and renders obvious the claimed range. Pet. 72 (citing Ex. 1005 ¶¶ 295–297; Ex. 1023 ¶¶ 13–14). Limitation 14[b] recites that “the controller is configured to cyclically open and close the vacuum valve and the vent valve at a frequency of between 2 and 16 Hz.” Ex. 1001, 56:25–27. Petitioner asserts that Teigen in view of Grey and Yang render this limitation obvious for the same reasons provided for claim 8 of Ground 1. Pet. 73 (citing Pet. 53–54).

### *3. Patent Owner’s Position*

Patent Owner contends that this ground fails because Petitioner fails to make the necessary showing that the combination of Teigen and Grey renders claim 1 obvious. Prelim. Resp. 55. Patent Owner also contends that “Petitioner makes broad, conclusory statements regarding the reasons for its combination without any support” such that “the motivations to combine presented for each ground lack the requisite rational underpinnings to support a conclusion of obviousness.” *Id.*

### *4. Analysis*

As discussed above, 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 Teigen and Grey. We also find, on the current record, that Petitioner has sufficiently shown that the limitations of claims 13 and 14 are rendered obvious by the combined disclosures of Teigen, Grey, and Yang.

On this record, and upon review of Petitioner’s arguments and supporting evidence, we determine that Petitioner sufficiently explains why a POSA would have found it obvious when implementing the combination

of Teigen and Grey to select catheters with internal diameters as taught in Yang. *See* Pet. 69–70. Other than a general statement that Petitioner’s motivations to combine lack the requisite rational underpinnings to support a conclusion of obviousness, Patent Owner has not made any specific arguments regarding Petitioner’s motivation to combine contentions. *See* Prelim. Resp. 55. Accordingly, Petitioner has demonstrated a reasonable likelihood that the subject matter of claims 13 and 14 would have been obvious over the combined disclosures of Teigen, Grey, and Yang.

*F. Asserted Obviousness of Claim 17 over Teigen in view of Grey and Matteo*

Petitioner contends that the subject matter of claim 17 of the ’883 patent is obvious over the disclosures of Teigen in view of Grey and Matteo. Pet. 73–78. Patent Owner disputes Petitioner’s contentions. Prelim. Resp. 55.

*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 (65), (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 under §102(a)(1) because it was published prior to the effective filing date of the ’883 Patent. Ex. 1013, 1; Pet. 20. Patent Owner does not contest that Matteo is prior art to the ’833 patent.

## *2. Petitioner’s Position*

As discussed above, Petitioner contends that Teigen in view of Grey discloses or renders obvious claim 1 of the ’833 patent. Petitioner also contends that the disclosure of Teigen in view of Grey and Matteo renders the limitations of dependent claim 17 obvious. Pet. 75–78.

Claim 17 recites “[t]he system of claim 1, which further comprises a shaft and the vacuum valve and the vent valve are mounted together on the shaft.” Ex. 1001, 56:37–39. Petitioner contends that Matteo teaches that “a single cam, controlled by ***a single position-control mechanism, is able to control multiple microvalves.***” Pet. 78 (citing Ex. 1013, code (57), ¶¶ 10, 11, Figs. 11, 12). According to Petitioner, “[a] POSA would have understood that disclosures of the ‘single cam, controlled by a single position-control mechanism’ in Matteo to be a shaft with mounted valves because the cam disclosed in Matteo is used to move the cam actuators in and out of position to open and close their respective valves.” *Id.* Petitioner, with supporting testimony from Mr. Brown concludes that, “[i]t would have been obvious for a POSA and required no undue experimentation to implement the valve operations and controls taught by Teigen and Grey with the cam-driven valves disclosed in Matteo to achieve the desired dynamic aspiration.” *Id.* (citing Ex. 1005 ¶ 311).

3. *Patent Owner's Position*

Patent Owner contends that this ground fails because Petitioner fails to make the necessary showing that the combination of Teigen and Grey renders claim 1 obvious. Prelim. Resp. 55. Patent Owner also contends that “Petitioner makes broad, conclusory statements regarding the reasons for its combination without any support” such that “the motivations to combine presented for each ground lack the requisite rational underpinnings to support a conclusion of obviousness.” *Id.*

4. *Analysis*

As discussed above, 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 Teigen and Grey. We also find, on the current record, that Petitioner has sufficiently shown that the limitations of claim 17 are rendered obvious by the combined disclosures of Teigen, Grey, and Matteo.

On this record, and upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner sufficiently explains why a POSA would have found it an obvious design choice, when implementing the combination of Teigen and Grey, to place the vacuum and vent valves together on a shaft, as taught in Matteo. *See* Pet. 73–75. Other than a general statement that Petitioner's motivations to combine lack the requisite rational underpinnings to support a conclusion of obviousness, Patent Owner has not made any specific arguments regarding Petitioner's contentions regarding a motivation to combine. *See* Prelim. Resp. 55. Accordingly, Petitioner has demonstrated a reasonable likelihood that the subject matter of

claim 17 would have been obvious over the combined disclosures of Teigen, Grey, and Matteo.

*G. Objective indicia of non-obvious*

In determining whether a claim is obvious in light of the prior art, we also consider any relevant evidence of secondary considerations of non-obviousness. *See Graham*, 383 U.S. at 17. Notwithstanding what the teachings of the prior art would have suggested to one of ordinary skill in the art at the time of the invention, the totality of the evidence submitted, including objective evidence of non-obviousness, may lead to a conclusion that the challenged claims would not have been obvious to one of ordinary skill. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). Patent Owner presents evidence of long-felt need and failure of others. *See* Prelim. Resp. 55–56.

Patent Owner argues that “a long-felt and persistent need existed to improve aspiration-based thrombectomy systems to improve the low first-pass recanalization rates” and that RapidPulse succeeds in overcoming the problems plaguing aspiration techniques to improve patient outcomes. Prelim. Resp. 56. Patent Owner contends that the claimed ROAR system of the ’833 patent was implemented by RapidPulse and presents data allegedly showing that the ROAR system has nearly a 300% better clot ingestion rate and performs much better than conventional systems as the hardness of the occlusive material increases. *Id.* at 56–57. Patent Owner concludes that, “[t]he invention of the ’833 patent, embodied in RapidPulse’s product, addressed a long-felt need for effective treatment for patients with ischemic stroke.” *Id.* at 57.

Objective evidence of nonobviousness is relevant only if there is a nexus between this evidence and the claimed invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). A presumption of nexus applies if the asserted objective evidence “is tied to a specific product and that product ‘embodies the claimed features, and is coextensive with them.’” *Id.* (quoting *Polaris Indus., Inc. v. Artic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018)). To the extent that a presumption of nexus does not apply, Patent Owner may still prove nexus “by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)).

Although Patent Owner asserts that the invention of the ’833 patent is “embodied in RapidPulse’s product,” and “addressed a long-felt need for an effective treatment of patients with ischemic stroke,” Patent Owner provides no description of the RapidPulse product compared to the claims of the ’883 patent. Absent this information, Patent Owner does not establish the required nexus connecting the ’883 patent claims to the RapidPulse product. Prelim. Resp. 57.

For these reasons, on the current record, we are not persuaded by Patent Owner’s arguments that failure of others and long-felt need weigh toward the non-obviousness of the claimed subject matter.

### III. DISCRETIONARY ISSUES

#### A. Rule 42.24

Patent Owner argues that Petitioner abused the process by circumventing the Board’s word count rule and, therefore, the Board should exercise its discretion to deny institution or, alternatively, cut at least 1000

words from the end of the Petition. Prelim. Resp. 57–63 (citing 37 C.F.R. § 42.24). Specifically, Patent Owner contends that Petitioner deleted spaces in its citations, which reduced the word count by well over 600 words. *Id.* at 58–61. Patent Owner also contends that Petitioner incorporated Figure labels into images so that the words would not be counted by the word processing system, which reduced the word count by another 200 words. *Id.* at 61–62. Patent Owner further asserts that “Petitioner randomly deleted words in statement and trimmed citations to further reduce[] the word count.” *Id.* at 62. Lastly, Patent Owner contends that Petitioner’s extensive incorporation by reference potentially resulted in “the reductions of thousands and thousands of words from its final total” word count. *Id.* at 63.

We agree with Patent Owner that the better practice would be to use spaces between the abbreviation for “exhibit” and the exhibit numbers and between the exhibit numbers themselves. However, we determine that Petition’s failure to do so was not so extraordinary or so excessive as to warrant the extreme remedy of discretionarily denying the Petition or cutting out words from the Petition. This is not to say we condone the approach taken by Petitioner here. Petitioner should refrain from using unusual spacing in citations going forward.

We also reviewed Petitioner’s use of figures and find that the provided annotations are helpful in the understanding of the figures. We do agree with Patent Owner that the figure labels themselves should have been included in the text, rather than in the figures, but again, find that this practice was not particularly extraordinary or excessive. We discussed Patent Owner’s incorporation by reference arguments above and do not find such incorporation to be improper in this case. Thus, we decline to exercise

our discretion to deny the petition due to Petitioner's alleged violation of the word count rule.

*B. 35 U.S.C. § 325(d)*

Patent Owner asserts that we should deny the Petition under 35 U.S.C. § 325(d) because the same or substantially the same art was previously presented to the Office and Petitioner failed to make any showing of material error. *See* Prelim. Resp. 63–65.

We have discretion to deny review when “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d) (“Section 325(d)"). In that respect, Section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the Office.<sup>12</sup> *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*").

In evaluating the exercise of discretion to deny institution under Section 325(d), the Board uses the following two-part framework: (1) determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics*, Paper 6 at 8.

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<sup>12</sup> The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

In applying the two-part framework, we consider several non-exclusive factors, including:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art or patent owner distinguishes the prior art;
- (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

*Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) (“*Becton, Dickinson*”).

Factors (a), (b), and (d) of the *Becton, Dickinson* factors relate to whether the art or arguments presented in the Petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, Paper 6 at 10. Factors (c), (e), and (f) “relate to whether the petitioner has demonstrated a material error by the Office” in its prior consideration of that art or arguments. *Id.* Only if the same or substantially the same art or arguments were previously presented to the Office do we then consider whether petitioner has demonstrated a material error by the Office. *Id.*

*1. Same or Substantially the Same Art or Arguments Previously Presented to the Office*

We first consider whether Petitioner asserts the same or substantially the same art or arguments that previously were presented to the Office. *Advanced Bionics*, Paper 6 at 8.

Patent Owner argues that Grey was cited in an Information Disclosure Statement (IDS) during prosecution. Prelim. Resp. 64. Petitioner acknowledges that Grey was cited on an IDS containing 180 references but was not substantively examined during prosecution. Pet. 14.

Under *Advanced Bionics*, “[p]reviously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.” *Advanced Bionics*, Paper 6 at 7–8. Because Grey was cited on an IDS, it was previously before the Office.

However, the other references cited in the Petition, including Teigen, which is the primary reference relied on by Petitioner for all of the grounds, was not cited during prosecution. Because Teigen and the other cited references (i.e., Rubenstein, Yang, and Matteo), were not cited during prosecution, we find that the same or substantially the same art was not previously presented and the first prong of the *Advanced Bionics* framework is not satisfied. Thus, we decline to exercise our discretion to deny the Petition under 35 U.S.C. § 325(d).

IV. CONCLUSION

For the forgoing reasons, Petitioner has demonstrated a reasonable likelihood that at least one challenged claim of the ’883 patent would have

been obvious over the prior art of record. Accordingly, we institute an *inter partes* review on all claims and all grounds set forth in the Petition.

V. ORDER

It is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted on all claims and 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 '883 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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