

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

IPR2022-00991
Patent 9,867,955 B2

Before JAMES A. TARTAL, ARTHUR M. PESLAK, and
ALYSSA A. FINAMORE, *Administrative Patent Judges*.

PESLAK, *Administrative Patent Judge*.

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

I. INTRODUCTION

ResMed, Inc. (“Petitioner”) filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–6, 8, 11, 12, 16–26, 30, and 31 (“the challenged claims”) of U.S. Patent No. 9,867,955 B2 (“the ’955 patent,” Ex. 1001). Paper 1. Petitioner filed a Declaration of Dr. Khosrow Behbehani in support of the Petition. Ex. 1003. Subsequently, Petitioner filed a Motion to Correct the Petition, which New York University (“Patent Owner”) opposed. Papers 10, 11. We granted Petitioner’s motion. Paper 12. Petitioner then filed a Corrected Petition. Paper 15 (“Pet.”).¹ Patent Owner filed a Preliminary Response. Paper 14 (“Prelim. Resp.”). With our authorization, Petitioner filed a Reply to the Preliminary Response. Paper 17 (“Pet. Reply”). Patent Owner filed a Sur-reply. Paper 18 (“Sur-reply”).

We have authority, acting on the designation of the Director, to determine whether to institute an *inter partes* review under 35 U.S.C. § 314(a). *See* 37 C.F.R. § 42.4(a) (2021) (“The Board institutes the trial on behalf of the Director.”). Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the Petition shows “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Considering the Petition, the Preliminary Response, as well as all supporting evidence, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in its challenge of at least one claim of the ’955 patent as unpatentable.

¹ Further references herein to “Petition” are to the Corrected Petition, Paper 15, unless stated otherwise.

Pursuant to 35 U.S.C. § 314, we hereby institute an *inter partes* review of all challenged claims of the '955 patent on all grounds stated in the Petition.

Our factual findings, claim construction, and legal conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This decision to institute trial is not a final decision as to the unpatentability of the claims for which *inter partes* review is instituted. Our final decision will be based on the full record developed during trial.

A. Related Matters

The parties identify the '955 patent as a subject of *New York University v. ResMed, Inc.*, No. 1:21-cv-00813-JPM (D. Del. 2021). Pet. 1; Paper 5, 2.

Petitioner also states that they have filed petitions challenging claims of the following related patents: U.S. Patent Nos. 6,988,994 B2 (IPR2022-00993); No. 9,108,009 B2 (IPR2022-00988); 9,168,344 B2 (IPR2022-00994); 9,427,539 B2 (IPR2022-00889); 9,533,115 B2 (IPR2022-00990); and 10,384,024 B2 (“the '024 patent”) (IPR2022-00992). Pet. 2.

B. Real Parties in Interest

Petitioner and Patent Owner each identifies itself and no others as a real party in interest. Pet. 1; Paper 5, 2.

C. The '955 Patent

The '955 patent is titled “System and Method for Diagnosis and Treatment of a Breathing Pattern of a Patient.” Ex. 1001, code (54). The '955 patent issued on January 16, 2018, from Application No. 14/633,535, which was filed on February 27, 2015 and claims priority through a series of continuation and continuation-in-part applications to Application No. 10/642,459, filed August 14, 2003. *Id.* at codes (45), (21), (22), (63).

As background, the '955 patent explains that “[o]bstructive sleep apnea syndrome (OSAS) is a well recognized disorder which may affect as much as 1-5% of the adult population.” Ex. 1001, 1:25–28. According to the '955 patent:

OSAS is associated with many conditions in which there is an anatomic or functional narrowing of the patient’s upper airway, and is characterized by an intermittent obstruction of the upper airway occurring during sleep. The obstruction results in a spectrum of respiratory disturbances ranging from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring), despite continued respiratory efforts.

Id. at 1:31–38. The '955 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS.” *Id.* at 1:54–58. The '955 patent describes that “PAP therapy is directed to maintaining pressure in the collapsible portion of the airway at or above the critical tissue pressure at all times” and is applied via a tight fitting nasal mask worn during sleep. *Id.* at 1:54–57, 2:7–9.

The '955 patent provides that “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” Ex. 1001, 1:61–63. Specifically, “conventional PAP therapy has not taken sleep/wake state into account, and conventional PAP systems apply pressure unnecessarily when the patient is awake.” *Id.* at 2:14–17. The '955 patent further provides that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:29–30.

The '955 patent describes system 1 (shown in Figure 1) that includes mask 20 connected via tube 21 for receiving an airflow of a particular

pressure from flow generator 22. *Id.* at 3:51–54. Figure 1 of the '955 patent is reproduced below:

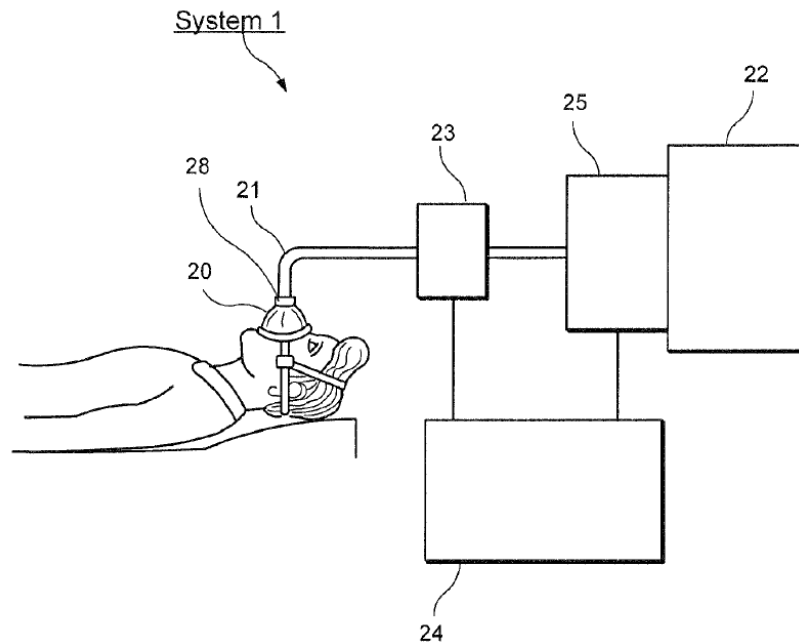


FIG. 1

Figure 1 illustrates an embodiment of the claimed invention. *Id.* at 3:20–21. As shown in Figure 1, conventional flow sensors 23 that are coupled to tube 21 and detect the rate of airflow to/from the patient and/or a pressure supplied to the patient via generator 22. *Id.* at 3:59–62. The '955 patent states that “[s]ignals corresponding to the airflow and/or the pressure are provided to a processing arrangement 24 for processing” and “[t]he processing arrangement 24 outputs a signal to a conventional flow control device 25 to control a pressure applied to the flow tube 21 by the flow generator 22.” *Id.* at 3:63–67.

The '955 patent also describes a method that uses system 1. Ex. 1001, 3:22–24. “[S]ystem 1 initiates a real-time monitoring procedure of the

patient's breathing patterns.” *Id.* at 4:12–13, 4:16–17. The '955 patent explains that “[t]he monitoring procedure is performed by the processing arrangement 24 which may utilize pre-stored patient data along with current data provided by the sensors 23 regarding the airflow to and from the patient and/or the applied pressure.” *Id.* at 4:17–21. The '955 patent states that “[d]uring the monitoring procedure, the processing arrangement 24 makes a determination as to a current state of the patient (e.g., whether the patient is asleep, awake and breathing regularly or awake and breathing irregularly due to distress or anxiousness).” *Id.* at 4:22–26. According to the '955 patent, this “determination can be made based on a number of different measurements,” such as “the patient's heart rate, blood pressure, EEG data, breathing patterns, etc.” *Id.* at 4:26–30. The '955 patent further describes breathing patterns that indicate quiet, regular, and relaxed breathing during PAP therapy; sleep disordered breathing; and when the patient is awake and anxious or distressed. *Id.* at 4:33–35, 4:42–57.

The '955 patent describes processing arrangement 24 as determining whether there has been a change in the patient's state and adjusting pressure to correspond to the patient's current state. Ex. 1001, 5:58–62. The '955 patent further describes an embodiment in which “system 1 may include a neural network coupled to the processing arrangement 24 and the sensors 23 for identifying the state of the patient.” *Id.* at 7:47–50.

D. Illustrative Claim

Claims 1 and 19 are independent claims. Claim 1 is representative of the claimed subject matter and is reproduced below:

1. A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's

airways in order to assist in treating a sleeping disorder in a patient, the positive airway pressure system comprising:

- a flow generator which supplies a positive treatment pressure flow of breathable gases to the entrance of a tube, the tube directing the flow of breathable gases to the airway of a patient to provide the patient with the positive treatment pressure flow of breathable gases;

- a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and

- a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns, the processing arrangement also determines whether to alter the pressure supplied to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and a lesser positive treatment pressure in an awake state, wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state, the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system.

Ex. 1001, 9:47–10:11.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–6, 8, 11, 12, 16–26, 30, and 31 would have been unpatentable on the following grounds (Pet. 3–4):

Claims Challenged	35 U.S.C. §	References/Basis
1–5, 8, 11, 12, 16–22, 24–26, 30, 31	103(a)	Sullivan995, ² Sullivan460 ³
6, 23	103(a)	Sullivan995, Sullivan460, Matthews ⁴
1–5, 8, 11, 12, 16–22, 24–26, 30, 31	103(a)	Rapoport502, ⁵ Sullivan460
6, 23	103(a)	Rapoport502, Sullivan460, Matthews

II. ANALYSIS

A. Discretionary Denial of Institution Under 35 U.S.C. § 325(d)

Patent Owner contends we should exercise our discretion under 35 U.S.C. § 325(d) and deny institution because Petitioner relies on prior art that was previously considered by the office. Prelim. Resp. 18–25. Patent Owner bases this contention on the fact that the applicant disclosed Sullivan995 and Rapoport502 on an Information Disclosure Statement (“IDS”) submitted during the prosecution of U.S. Patent No. 6,988,994 B2 (“the ’994 patent”) from which the ’955 patent claims priority. *Id.* at 20; *see also id.* at 6 (detailing the prosecution history of the ’994 patent (citing Ex. 2003, 74–75)). Patent Owner further contends Sullivan995 and

² U.S. Patent No. 5,245,995 (issued Sept. 21, 1993) (Ex. 1005, “Sullivan995”).

³ WO 01/05460 A1, published Jan. 25, 2001 (Ex. 1006, “Sullian460”).

⁴ U.S. Patent No. 7,168,429 B2 (issued Jan. 30, 2007) (Ex. 1007, “Matthews”).

⁵ U.S. Patent No. 5,490,502 (issued Feb. 13, 1996) (Ex. 1008, “Rapoport502”).

Rapoport502 “fall squarely within the definition of previously presented prior art, which ‘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.’” *Id.* at 20 (quoting *Advanced Bionics, LLC v. Med-el Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 at 7–8 (PTAB Feb. 13, 2020) (precedential)).

Patent Owner next contends that “Sullivan460 must also be considered previously presented prior art because it shared the same disclosure as Sullivan995 and, in addition, expressly states that it ‘incorporates Sullivan995 by reference.’” Prelim. Resp. 21 (citing Ex. 1006, 6:22–25; Pet. 17–18, 34).

Patent Owner next contends that “Petitioner fails to provide any argument that the Examiner erred by failing to consider the Petitioner’s asserted prior art during prosecution.” Prelim. Resp. 23. According to Patent Owner, “Petitioner disingenuously and incorrectly states that ‘none of the asserted references was considered during prosecution’ and that ‘substantially the same art and arguments have never been presented to or considered by the Office.’” *Id.* at 23–24.

Petitioner, in turn, contends the “majority of the claims [in the ’995 patent] were allowable because determination of an ‘awake state’ using breathing patterns was not in the prior art.” Pet. Reply 6 (citing Ex. 1002, 100–03, 154). Petitioner further contends that “Sullivan460 discloses this ‘awake state’ limitation . . . and its disclosures were never presented to the Office.” *Id.* (citing Ex. 1006, 6:30–7:12; Pet. 14–16, 40–42–35).

Petitioner next contends that Sullivan995 was never considered during the '955 patent prosecution. Pet. Reply 7. According to Petitioner, “the initialed IDS in the '994 prosecution cannot be extended to the '955 patent, which differs in claim scope” because “the '994 patent does not include the distinguishing ‘awake state’ limitation.” *Id.* (citing *Peloton Interactive, Inc. v. iFit, Inc.*, IPR2021-01597, Paper 10 at 54–55 (PTAB Apr. 22, 2022); *Nuna Baby Essentials, Inc. v. Britax Child Safety, Inc.*, IPR2019-00663, Paper 8 at 7–20 (PTAB Sept. 4, 2019)).

Petitioner next contends “Sullivan460 does not share the same disclosure as Sullivan995. Rather, Sullivan460 incorporates Sullivan995 by reference and additionally describes improvements on the device disclosed in Sullivan995.” Pet. Reply 7 (citing Ex. 1006, 6:22–32). According to Petitioner, “there are no material similarities between the specifications of Sullivan460 and Sullivan995, and [Patent Owner] points to none.” *Id.*

Petitioner next contends that there is no overlap between Petitioner’s arguments and those made during prosecution of the '955, '994, or any related patents. Pet. Reply 8. According to Petitioner, “the Office never had an opportunity to assess the patentability of the '955 patent over any combinations that include Sullivan460.” *Id.*

Petitioner alternately argues that, in the event we find that the same or substantially the same art was previously presented to the Office, the Office overlooked the “awake state” disclosure in Sullivan460. Pet. Reply 8–10. Petitioner notes that the Examiner of the '994 application “provided no explanation or analysis of either Sullivan995 or Rapoport502. Nor did any rejection rest on either.” *Id.* at 8–9. Petitioner further contends “the Petition establishes that the Office materially erred by ‘overlooking something

persuasive’—namely, Sullivan995 or Rapoport502 as modified by Sullivan460 renders obvious each and every limitation of the challenged independent claims.” *Id.* at 9 (citing *Advance Bionics*, Paper 8 at 8). According to Petitioner, “the asserted prior art discloses the limitation that the Examiner identified as the inventive feature of the claims.” *Id.* at 10 (citing Ex. 1002, 99–101).

In the Sur-reply, Patent Owner contends “[d]uring prosecution of a child application, the Examiner ‘will consider information which has been considered by the Office in the parent application’ and ‘a listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.’” Sur-reply 6 (citing *Google LLC v. Kewazinga Corp.*, IPR2019-00527, Paper 16 at 11 (PTAB Aug. 21, 2021) (citing MPEP § 609.02)). Patent Owner further contends that “Petitioner’s ‘ancestral application’ prosecution arguments fail” because the ’115 patent is a child patent of the ’994 patent and “[t]he Examiner has to consider the materials from the ’994 Patent when assessing the ’955 Patent.” *Id.* at 7. Patent Owner also notes that the same Examiner reviewed both the ’994 and the ’955 patent applications. *Id.* Patent Owner reiterates its contention that we should find that Sullivan460 was presented to the Office during prosecution of the ’994 patent, not because it was disclosed on an IDS, but because it incorporates Sullivan995 by reference and Sullivan995 was disclosed on an IDS. *Id.*

Patent Owner contends we should admonish Petitioner for failing to state in the Petition how the Examiner erred under *Advanced Bionics*. Sur-reply 8. Patent Owner further contends that Petitioner’s argument that “the Examiner did not properly evaluate the art because the Examiner provided

no explanation or analysis of Sullivan⁹⁹⁵ or Rapoport⁵⁰²” is “incorrect and illogical.” *Id.* at 9. According to Patent Owner, we should “infer that since there is no Office Action or argument regarding a specific reference, the Examiner *did* consider the reference and found it not a bar to patentability.” *Id.*

Patent Owner next contends we should not consider several arguments raised by Petitioner because the arguments “are all substantive new arguments not mentioned anywhere in the 990 Petition.” Sur-reply 10. The alleged new arguments are “that the Examiner erred in failing to consider Sullivan⁴⁶⁰’s specific teaching of the ‘awake state’; the difference in claim scope between the ’994 and ’955 Patents; and that the Patent Office material erred by ‘overlooking something persuasive.’” *Id.* (citing Pet. Reply 5–10).

i. Analytical Framework Under 35 U.S.C. § 325(d)

The statute provides that “the Director may take into account whether, and reject the petition . . . because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). Our Consolidated Trial Practice Guide (“CTPG”) indicates that the decision whether to deny institution on this basis “is a fact-dependent decision, in which the Board balances the petitioner’s desire to be heard against the interest of the patent owner in avoiding duplicative challenges to its patent.” Patent Trial and Appeal Board Consolidated Trial Practice Guide, 62 (Nov. 2019), available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf>.

We use a two-part framework to analyze a request to exercise discretion to deny institution under § 325(d). First, we determine “whether the same or substantially the same art previously was presented to the Office

or whether the same or substantially the same arguments were previously presented to the Office.” *Advanced Bionics*, Paper 6 at 8. Second, “if either condition of the first part of the framework is satisfied, then we consider “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims.” *Id.* In applying this framework, we refer to the non-exclusive factors delineated in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first para.). These factors are: a) the similarities and material differences between the asserted art and the prior art involved during examination; b) the cumulative nature of 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 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. *Id.* at 17–18.

These factors “should be read broadly . . . to apply to any situation in which a petition relies on the same or substantially the same art or arguments previously presented to the Office during a proceeding pertaining to the challenged patent.” *Advanced Bionics*, Paper 6 at 10. If, after review of factors (a), (b), and (d), we determine the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e),

and (f) relate to whether the petitioner demonstrates that the Office erred in a manner material to patentability of the challenged claims. *Id.*

The '955 patent application was filed February 27, 2015, and claims priority through three intervening continuation and continuation-in-part applications to the '994 patent application, which was filed on August 14, 2003. Ex. 1001, code (63).

The Examiner provided the following description of the allowable subject matter in the '955 patent application:

Neither Burton nor the prior art of record teaches the following: the processing arrangement applies a greater positive treatment pressure in an asleep state and a lesser positive treatment pressure in an awake state, wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state, the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system.

Ex. 1002, 101. As explained in detail below in connection with Ground 1, Petitioner relies on Sullivan460 for these claim limitations. Pet. 40 (citing Ex. 1006, 6:30–7:19).

Patent Owner has not shown that Sullivan460 was disclosed during prosecution or otherwise considered by the Examiner. *See generally* Ex. 1002. Sullivan995 and Rapoport502 were both disclosed on an IDS filed by the applicants and initialed by the Examiner during prosecution of the '994 patent application. Ex. 2003, 74–75. Sullivan460 was not listed on the Examiner initialed IDS submitted during prosecution of the '994 patent application. *Id.* Patent Owner does not direct us to any evidence in the record that Sullivan460 was considered by the Examiner during the prosecution of the '955 patent application. Prelim. Resp. 8–13, 21; Sur-reply 5–8. Nonetheless, Patent Owner contends that Sullivan460 should be

considered as “previously presented prior art because it shares the same disclosure as Sullivan995 and, in addition expressly states that it ‘incorporates Sullivan995 by reference.’” Prelim. Resp. 21. This argument is unavailing because Patent Owner does not point to disclosure in Sullivan995 that corresponds to the disclosure in Sullivan460 of the awake state relied on by Petitioner. *Id.* We also disagree with Patent Owner’s argument that, because Sullivan460 incorporates Sullivan995, Sullivan460 was previously considered during examination. Even assuming Sullivan995 was before the Examiner, it is not Sullivan995 that incorporates by reference Sullivan460; rather, Sullivan460 (which was not submitted to the Examiner) incorporates Sullivan995 by reference.

After considering Patent Owner’s arguments and evidence, we find, in connection with *Becton Dickinson* factor (a) that Sullivan460 was not presented to the Office during the prosecution of the ’994 patent application nor was it presented to the Office during prosecution of the ’955 patent application. In connection with *Becton Dickinson* factor (d), we find that there is no overlap between Petitioner’s arguments here and during prosecution of the ’955 patent. In fact, the prosecution histories of the ’955 and the ’994 patents both silent with respect to the combinations of Sullivan995, Rapoport502, with Sullivan460 asserted by Petitioner because there are no rejections based on the combination of references asserted here. For the foregoing reasons, we determine that the first prong of the *Advanced Bionics* framework is not satisfied. Because the first prong of the *Advanced Bionics* framework is not satisfied, we need not reach the second prong of

the *Advanced Bionics* framework. Accordingly, we decline to exercise our discretion to deny institution under § 325(d).⁶

B. 35 U.S.C. § 315(b) Time Bar

Patent Owner contends that the “Petition [is] time-barred under 35 U.S.C. § 315(b) because [it] fails to provide specific claim construction arguments for any claim terms.” Prelim. Resp. 14–15. According to Patent Owner, the “Petition is fatally flawed because Petitioner first merely argues that ‘the prior art meets each of the claim limitations under any reasonable construction’ [without] providing specific claim constructions for any of the independent claims and all but one dependent claim. *Id.* at 17 (citing Pet. 18). Patent Owner further contends it “would be clearly prejudiced if the . . . Petition was not time-barred” and it “should not be penalized for the Petitioner’s calculated indecision and failure to endorse a single claim construction.” *Id.* at 18.

Petitioner, in turn, contends there is no requirement to propose express construction of claim terms and points to the CTPG, which provide “that ‘a petitioner may include a statement that the ***claim terms require no express construction.***’” Pet. Reply 3 (citing CTPG 44). Petitioner contends that its statement that “[t]his Petition establishes the prior art meets each of the claim limitation under any reasonable construction” (Pet. 20) is equivalent to stating that no claim term requires express construction. Pet. Reply at 3–4.

⁶ We note that Patent Owner’s contention that Petitioner improperly raised new arguments in the Reply is directed to Petitioner’s contentions with respect to the second prong of the *Advanced Bionics* framework. Because we do not reach the second prong of the *Advanced Bionics* framework, we need not address Patent Owner’s contention. However, Patent Owner’s reliance on the CTPG at 73 is misplaced because that provision is directed to post institution petitioner replies.

Petitioner further points to its proposed construction of the term “troubled wakefulness” as fulfilling the requirement of 37 C.F.R. § 42.104(b)(3). *Id.* at 3. Petitioner further contends that Patent Owner has not shown prejudice because it “admits ‘no claim terms are in controversy.’” *Id.* at 4 (citing Prelim. Resp. 10).

In the Sur-reply, Patent Owner contends the CTPG “states that a petition must either ‘provide a claim construction for the challenged claims’ or rely on the plain and ordinary meaning by stating that the ‘claim terms require no express construction.’” Sur-reply 3. Patent Owner contends “Petitioner [fails to] meet either requirement.” *Id.*

Patent Owner next contends that contrary to Petitioner’s “assertions, the [Patent Owner] is not required to submit claim constructions in order for the Board to deny institution.” Sur-reply 4. According to Patent Owner, the “Preliminary Response is wholly irrelevant to whether Petitioner met its required obligations in properly identifying challenges in its Petition under Rule 42.104(b).” *Id.*

For the following reasons, Patent Owner’s contention that the Petition is time-barred under § 315(b) is unavailing.

Sections 42.104(b)(3) and (b)(4) of Title 37 of the Code of Federal Regulations require a petitioner to state in its petition “[h]ow the challenged claim is to be construed” and “specify where each element of the claim is to be found in the prior art patents or printed publications relied upon.” The Petition states “[t]he Board construes the claims ‘using the same claim construction standard that would be used’ in district courts.” Pet. 18. We disagree that our rules or the CTPG requires Petitioner to make any specific statement if it takes the position that no express construction of claim terms

is required. Rather, the CTPG states that “a petitioner *may* include a statement that the claim terms require no express construction.” CTPG 44 (emphasis added). In this case, Petitioner requests an express construction of one term, “troubled wakefulness” which is recited in claims 6 and 23 but submits no express construction of any other term. Pet. 18.

Petitioner maps the asserted art against the claims using what appears, based on our review of the Petition and the Preliminary Response, to be the plain and ordinary meaning of the claim limitations. *See* Ex. 1003 ¶ 87 (applying “plain meaning” of claim terms). As the Federal Circuit notes, “[i]n some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly used words.” *Phillips v. AWG Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) (citing *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001)). Under these circumstances, it would require us to exalt form over substance to accept Patent Owner’s contention that Petitioner’s failure to use an optional phrase from the CTPG, not required by our rules, mandates denial of institution.

Patent Owner relies on two non-precedential Board decisions *Volkswagen Group of America, Inc., v. Michigan Motor Techs., LLC*, IPR2020-00229, Paper 13 (PTAB July 6, 2020), and *EiKO Global, LLC v. Blackbird Tech LLC*, IPR2018-00980, Paper 16 (PTAB Sept. 1, 2017). Prelim. Resp. 16. In *Volkswagen*, however, the petitioner argued for the plain and ordinary meaning of “temporal characteristics,” which the patent owner explained was expressly defined in the patent at issue. *Volkswagen*, Paper 13 at 10. The petition provided “no explanation for disregarding and

failing to address the express definition of an important claim term.” *Id.* Here, Patent Owner does not direct us to any express definitions from the Specification of the ’955 patent not addressed by Petitioner. In *EiKO Global*, the petitioner failed to properly address certain claim constructions from a parallel district court proceeding. *EiKO Global*, Paper 16 at 35–36. In particular, the petitioner made “the proper construction and application of the claim term ‘housing’ a moving target” by first endorsing a construction of the term and then “not apply[ing] this construction in arguing how the asserted prior art renders claim 12 unpatentable.” *Id.* at 36. Here, Petitioner has not taken any inconsistent positions concerning the construction of any claim term. Although Patent Owner is not required to offer any claim constructions or even file a Preliminary Response, it did file a Preliminary Response and did not point to any specific claim construction issue in Petitioner’s mapping of the prior art to the claims which, as noted above, appears to be based on the plain and ordinary meaning of all claim terms other than “troubled wakefulness.”

For these reasons, and because the claim language can be readily understood, we determine the Petition complies with 37 C.F.R. § 42.104(b). Consequently, Patent Owner’s contention that the Petition is time-barred under 35 U.S.C. § 315(b) is unavailing.

C. Overview

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter 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 indicia of non-obviousness (i.e., secondary considerations).⁷ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

D. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art “in 2003 would have had at least a bachelor’s degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience” and “[a]dditional experience could substitute for less education, and additional education could likewise substitute for less experience.” Pet. 17 (citing Ex. 1003 ¶ 84). Petitioner further states that the “Petition does not turn on this precise definition, and the challenged claims would be unpatentable from the perspective of any reasonable person of ordinary skill in the art at the relevant time.” *Id.* at 18 (citing Ex. 1003 ¶ 85). Patent Owner, at this stage of the proceeding, does not dispute Petitioner’s definition of the person of ordinary skill in the art. Prelim. Resp. 13.

For the purposes of this Decision, we apply Petitioner’s proffered level of skill in the art because it appears consistent with the problems addressed in the ’955 patent and the prior art.

⁷ No evidence of secondary considerations has been presented at this stage of the proceeding.

E. Claim Construction

We apply the same claim construction standard used by Article III federal courts and the International Trade Commission, both of which follow *Phillips*, 415 F.3d 1303 and its progeny. 37 C.F.R. § 42.100(b) (2019). Accordingly, we construe each challenged claim of the '955 patent to generally be “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 contends that the term “troubled wakefulness,” in claims 6 and 23, “means ‘state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.’” Pet. 18 (citing Ex. 1003 ¶ 88).⁸ Petitioner asserts that “[t]his term is not an industry standard term and was coined in the [’955] Patent.” *Id.* (citing Ex. 1003 ¶ 89).⁹ According to Petitioner, the ’955 Patent “describes ‘troubled wakefulness’ as a state ‘in which the breathing pattern is characterized by irregularity variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient’s airflow tracing indicating that the patient is awake and either anxious or uncomfortable.’” *Id.* at 18–19 (citing Ex. 1001, 4:59–64, Fig. 7). Petitioner further argues that “[t]he specification further confirms that ‘Patient’s discomfort during wakefulness is often associated with changes from a regular breathing pattern ... and frequently occur when the patient is distressed by the PAP system.’” *Id.* at 19 (alteration in original) (citing Ex. 1001, 2:40–47).

⁸ Petitioner cites to Exhibit 1003 ¶ 91 which appears to be a typographical error.

⁹ In this sentence, Petitioner refers to the ’024 patent and Exhibit 1003 ¶ 92 which appear to be typographical errors.

Patent Owner does not contest Petitioner's proposed construction.
Prelim. Resp. 13–14.

We determine that an express construction of this or any other claim term is not necessary for purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

F. Ground 1: Alleged Obviousness of Claims 1–5, 8, 11, 12, 16–22, 24–26, 30, and 31 over Sullivan995 and Sullivan460

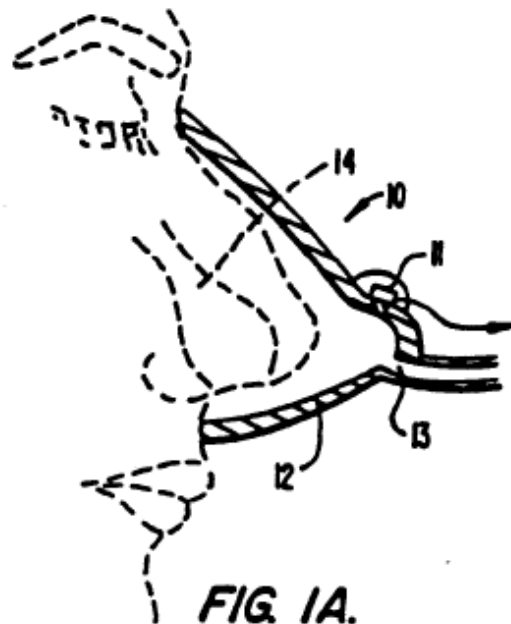
Petitioner contends claims 1–5, 8, 11, 12, 16–22, 24–26, 30, and 31 would have been obvious over Sullivan995 and Sullivan460. Pet. 19–57. Petitioner supports its contentions with the Declaration of Dr. Behbehani. Ex. 1003. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 14–18, 26–43.

We begin with brief summaries of Sullivan995 and Sullivan460 and then address the parties' respective contentions.

1. Sullivan995 (Ex. 1005)

Sullivan995 is titled “Device and Method for Monitoring Breathing During Sleep, Control of CPAP Treatment, and Preventing of Apnea.” Ex. 1005, code (54). Sullivan995 is directed “to the diagnosis and treatment of partial or complete upper airway occlusion, a condition where the upper airway collapses, particularly under the reduced pressure generated by inhalation.” *Id.* at 1:14–18.

Sullivan995's Figure 1A depicts snoring detection device 10, which is reproduced below. *Id.* at 8:47.



Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a nose mask.” *Id.* at 8:47–49. Sullivan995 explains that “[a]ir, being inhaled by the patient, enters the nasal passageways 14 through the opening 13 in the nose mask 12 and is exhaled in the reverse direction” and this arrangement focuses and concentrates snoring and breathing sounds. *Id.* at 8:49–52, 8:57–59.

Sullivan995 describes using detection device 10 in a diagnostic device or a feedback control. Ex. 1005, 8:61–62. For instance, an electronic processor/recorder may be connected to microphone 11 to record signals “either on a time basis or after preprogrammed processing so as to record for example tables of indexes such as the number of apneic episodes, their duration, etc.” and “[t]he recorded data can then be reviewed by the physician for diagnosis.” *Id.* at 8:62–9:2.

Sullivan995's Figure 3, reproduced below, shows a CPAP apparatus.
Ex. 1005, 9:57–58.

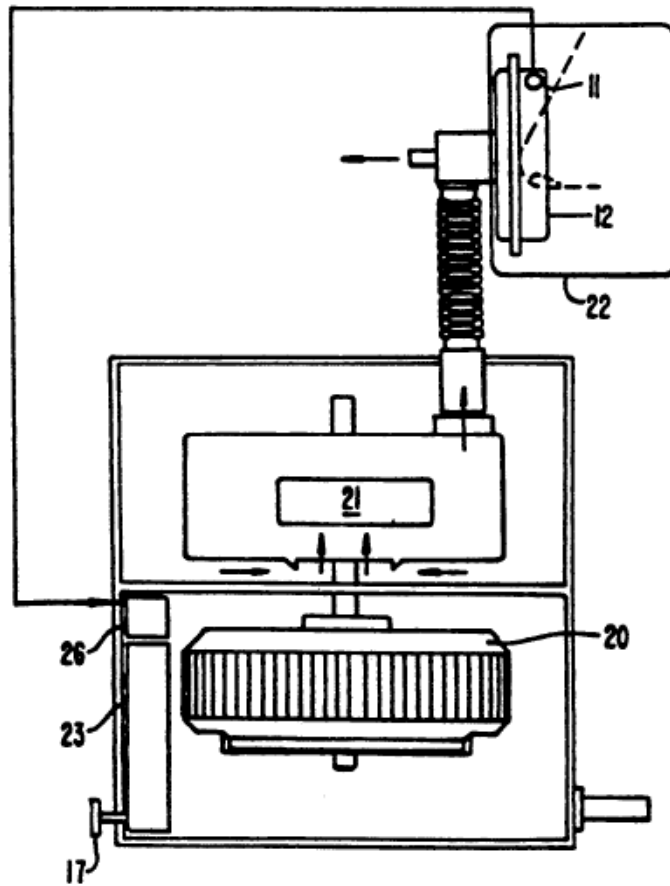


FIG. 3

The CPAP apparatus shown in Figure 30 includes motor 20 that drives blower 21. *Id.* at 9:58–59. Sullivan995 explains that “[t]he speed of the motor 20 is controlled by an electronic speed control unit 23.” *Id.* at 9:59–60. The CPAP apparatus further includes snoring detection means 22 that uses microphone 11 to detect sounds. *Id.* at 9:64–66. Sullivan995 states that “snoring detection means 22 is conveniently in the form of the previously described device 10” and that “[i]n its most general form, the snoring

detection means 22 is a pressure detection means and microphone 11 is a differential pressure sensor.” *Id.* at 9:66–3. Sullivan995 explains that:

Electrical impulses are fed from said microphone 11 to an amplifier/filter/processor unit 26 which generates an electrical signal when snoring sounds occur. The motor speed control means is electrically connected to the snoring detection device 22 and increases the speed of the electric motor 20 by an analogue means in response to the electrical signal generated by the snoring detection device. Accordingly, the output pressure of the CPAP unit increases in response to detection of snoring.

Id. at 10:3–12.

Sullivan995 describes that a patient connects themselves to the CPAP unit and goes to sleep. Ex. 1005, 10:47–48. The CPAP unit operates at an initial pressure but, some time after going to sleep, the patient’s body relaxes and the patient’s airway will become unstable and the patient will snore. *Id.* at 10:48–54. Detection apparatus 22 responds to a snore or snore pattern and, via processor 26, increases motor speed so that the CPAP unit’s pressure increases. *Id.* at 10:55–58.

Sullivan995's Figure 12 is reproduced below.

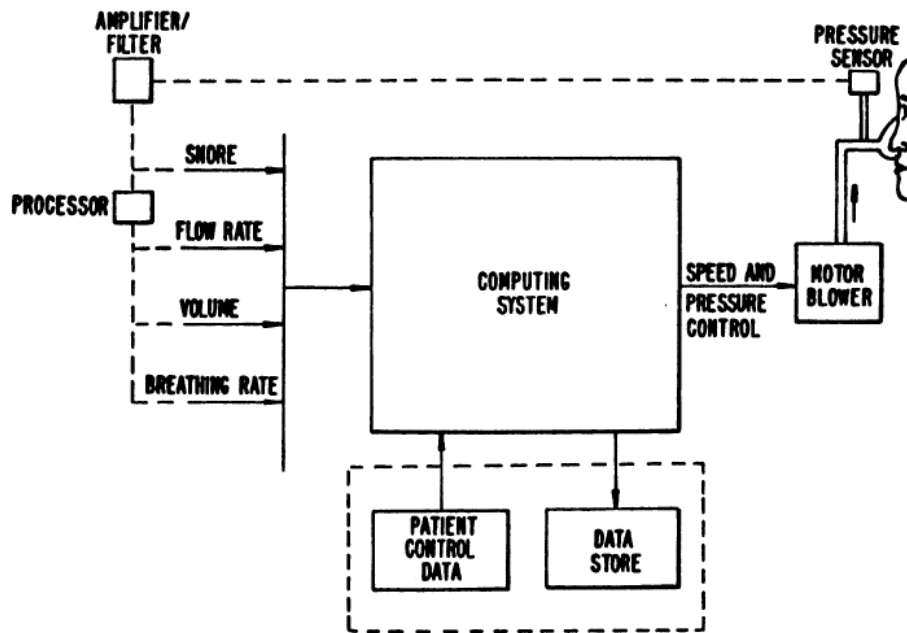


FIG. 12.

Figure 12 shows schematically the circuitry of Sullivan995's feedback system. Ex. 1005, 8:36–39, 17:3–4.

Sullivan995 states that:

A pressure detection apparatus is provided either integral with or attached to the CPAP mask worn by the patient. The electrical signals from the pressure transducer are amplified and filtered to provide pressure waves of the desired frequencies indicative of snoring and breathing. The pressure wave indicative of breathing is further processed to generate signals indicative of flow rate, volume and breathing rate. Any or all signals are fed to a computing system which analyses the signals for deviation from predetermined values or patterns. The computing system may itself calculate control values of patterns for each patient based on moving average values or such values or patterns will be pre-programmed into the computing system.

Id. at 17:4–18.

2. *Sullivan460 (Ex. 1006)*

Sullivan460 is titled “Apparatus and Method for the Treatment of an Upper Airway Flow Limitation.” Ex. 1006, code (54). Sullivan460 is directed to “an apparatus and method for the treatment of an upper airway flow limitation in a patient” and particularly “an apparatus and method of treating hypertension caused by pre-eclampsia.” Ex. 1006, 1:5–8. Sullivan460 describes an embodiment in which a “treatment means is a device which applies Continuous Positive Airway Pressure (CPAP), more preferably nasal- Continuous Positive Airway Pressure (nCPAP), to the airway of the patient.” *Id.* at 6:17–20. Sullivan460 also describes an embodiment in which “the flow rate measurement means and the treatment means may be constructed together as part of one apparatus. Such as the AutoSet product from ResMed described in US Patent No 5245995 [Sullivan 995].” *Id.* at 6:22–24.

Sullivan460’s “Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia.” Ex. 1006, 10:7–8. Figure 2 is reproduced below.

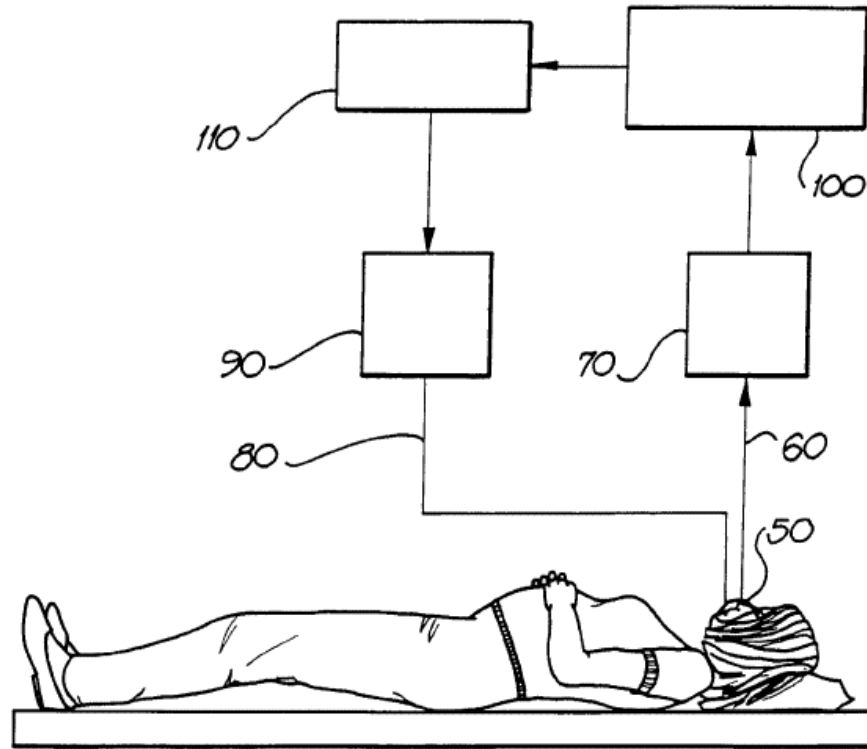


FIG. 2

In Figure 2, patient 30 is lying on bed 40 and wears mask 50 over her nose. *Id.* at 10:8–9. Mask 50 is connected via 80 to nCPAP apparatus 90. *Id.* at 9–10. Sullivan460 states that “flow rate measurement means 70 detects the rate at which the patient breathes in air, and generates a signal which is sent to a central controller 100.” *Id.* at 10–12. Sullivan460 explains that “[w]hen the flow rate measurement means 70 detects the interruptions to inspiratory flow 10, the controller 100 activates a switch 110 which activates the nCPAP apparatus 90 to supply air to the patient 30 at a pressure which

ameliorates or eliminates the upper airway flow limitation for that patient.”

Id. at 10:12–16.

Sullivan460 explains:

[T]he treatment means may operate with two modes of delivery, a first mode for use when the patient is awake, and a second mode for use when the patient is asleep. In the first mode of air delivery, the treatment means provides a minimally intrusive air and pressure delivery to the patient, and hence is more comfortable. In the second mode of air delivery, the treatment means provides a relatively greater air and pressure delivery to the patient than in the first mode, which is sufficient to treat an air flow limitation.

Ex. 1006, 6:30–7:2. Sullivan460 describes an embodiment in which “the treatment means may additionally include a sleep sensor which senses whether or not the patient is asleep, and may also include a switching means which responds to the sleep sensor and automatically switches the treatment means between the two modes of air delivery.” *Id.* at 7:3–7. Sullivan460 also describes an embodiment in which a “detection means is adapted to detect the occurrence of at least two or more interruption cycles in the upper inspiratory flow rate and the treatment means treats the airway limitation on detection of said at least two interruption cycles.” *Id.* at 3:20–23.

3. *Claim 1*

Petitioner provides a limitation-by-limitation analysis of independent claim 1 mapping the prior art to the claim limitations. Pet. 23–43. Petitioner also provides contentions concerning motivation to combine and reasonable expectation of success. *Id.* at 19–22.

Patent Owner contends that Sullivan995 and Sullivan460 fail to teach the requirements “that the system indicates when the patient transitions either to or from an awake state” (Prelim. Resp. 28), Sullivan460 teaches

away from the claimed invention (*id.* at 33), and Petitioner cannot establish motivation to combine or reasonable expectation of success because the Petition does not establish all claim limitations (*id.* at 38).

With this background, we analyze the parties' respective contentions.

Preamble: A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's airways in order to assist in treating a sleeping disorder in a patient, the positive airway pressure system comprising:

Petitioner contends "Sullivan995 discloses a 'continuous positive airway pressure (CPAP)' system which is *a positive airway pressure system.*" Pet. 23 (footnote omitted) (citing Ex. 1005, Abstract, 1:33–36, 2:15–19, 9:57–58, Fig. 3). Petitioner further contends "Sullivan995's CPAP system 'deliver[s] appropriate airway pressure' to the patient's airway passages and is therefore *for delivery of a flow of breathable gas.*" *Id.* (citing Ex. 1005, 2:15–16). Petitioner further contends that one of ordinary skill in the art "would have understood, CPAP delivers 'positive' airway pressure relative to atmospheric pressure, so that the breathable gas delivered by Sullivan995's CPAP system is *at a positive treatment pressure with respect to ambient air pressure.*" *Id.* (citing Ex. 1003 ¶ 101).

Petitioner further contends Sullivan995's CPAP system includes nose mask 12 "for delivery of air to the patient's nasal passages,' meaning the CPAP system delivers the elevated air pressure *to an entrance of a patient's airways.*" *Id.* at 22–23 (citing Ex. 1005, 5:12–34, 11:1–4, 11:23–43, claim 6, Fig. 3). Petitioner further contends Sullivan995's CPAP system provides "air pressure at a certain level to 'prevent the onset of apnea' in the patient, where Sullivan995 characterizes sleep apnea as a complete occlusion of the

upper airway during sleep, which is a *sleeping disorder*.” *Id.* at 24 (citing Ex. 1003 ¶ 103; Ex. 1005, 1:20–31, 1:32–48, 10:31–35, 11:15–20).

Patent Owner does not address the preamble in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution. Therefore, we need not address whether the preamble is limiting.

1[a] a flow generator which supplies a positive treatment pressure flow of breathable gases to the entrance of a tube, the tube directing the flow of breathable gases to the airway of a patient to provide the patient with the positive treatment pressure flow of breathable gases;

Petitioner contends that “Sullivan995’s CPAP system includes a motor 20 with a variable speed that drives a blower 21” which “*supplies a positive treatment pressure flow of breathable gases* by providing pressurized air to the patient.” Pet. 25 (citing Ex. 1003 ¶ 104; Ex. 1005, 9:57–64). Petitioner further contends that “blower 21 supplies pressurized air through an air line (*to the entrance of a tube*). The air line connects from blower 21 to the nose piece.” *Id.* (citing Ex. 1005, 7:13–25, 7:29–41, Fig. 3). Petitioner further contends that one of ordinary skill in the art “would understand that the connection of the air line (*tube*) from blower 21 to the nose piece is *directing the flow of breathable gases to the airway of a patient to provide the patient with the positive treatment pressure flow of breathable gases*.” *Id.* (citing Ex. 1003 ¶ 106).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[b] a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and

Petitioner contends Sullivan995's "system includes a differential pressure sensor (microphone 11), which is a *flow sensor*." Pet. 26 (citing Ex. 1003 ¶ 107; Ex. 1005, 9:64–66, Fig. 3). Petitioner further contends that "Sullivan995 explains that the microphone is a sound transducer that 'consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the *rate of breathing*, inhaled air flow or inhaled *air flow rate*.'" *Id.* at 26–27 (citing Ex. 1005, Abstract, 3:21–30). Petitioner further contends that Figure 3 of Sullivan995 illustrates that "microphone 11 is located within the snoring detection means 22, and is therefore *located in a flow path of the positive treatment pressure flow of breathable gases*." *Id.* at 27 (citing Ex. 1003 ¶ 109; Ex. 1005, 8:52–57).

Petitioner next contends that Sullivan995's snoring detection means 22 can be located in device 10. Pet. 28 (citing Ex. 1005, 10:1–3, Figs. 1A, 1B, 2A, 2B). Petitioner further contends Sullivan995 discloses that microphone 11 is "located 'in sound communication with the container 12 of [the] nose mask' and 'an 'enclosed airway,' which 'extends from the source of snoring sounds within the patient's body, through the nasal passages 14 and out of the opening 13 in the nasal mask.'" *Id.* at 28–29 (citing Ex. 1005, 8:47–59). According to Petitioner "[t]hat enclosed airway includes air 'being inhaled by the patient' that 'enters the nasal passageways' and therefore forms a *flow path of the positive treatment pressure flow of breathable gases*." *Id.* at 29 (citing Ex. 1003 ¶ 111; Ex. 1005, 8:49–59).

Petitioner next contends Sullivan995’s “microphone 11 (*flow sensor*) performs a ‘form of measurement’ by ‘detecting snoring sounds’ and ‘other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate.’” Pet. 29 (citing Ex. 1005, 3:26–33). According to Petitioner, by doing these things, “microphone 11 . . . *measure[es] data that is indicative of the patient’s breathing patterns.*” *Id.* (citing Ex. 1003 ¶ 112; Ex. 1005, 11:5–20, Fig. 3); *see also id.* at 30–32 (contending that Sullivan995’s Figures 2A and 8–12 disclose data indicative of the patient’s breathing patterns).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[c1] a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor,
Petitioner contends “[t]he combination of an amplifier/filter/processor unit 26 with a speed control unit 23 depicted in Figure 3 and described in part as the computing system in Figure 12” corresponds to the recited processing arrangement. Pet. 32–33 (footnotes omitted). Petitioner further contends Sullivan995’s “microphone 11 (*flow sensor*) provides its *measured data* to processor unit 26.” *Id.* at 33 (citing Ex. 1005, 10:3–6, 10:37–66). Petitioner further contends “Sullivan995 states ‘[t]he electrical signals from the pressure transducer are amplified and filtered to provide pressure waves of the desired frequencies indicative of snoring and breathing. The pressure wave indicative of breathing is further processed to generate signals indicative of flow rate,

volume and breathing rate.” *Id.* at 35 (alteration in original) (citing Ex. 1005, 17:6–12). Based on this, Petitioner contends “Sullivan995’s *processing arrangement receives the measured data corresponding to the flow of breathable gases from the flow sensor.*” *Id.*

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[c2] [the processing arrangement] analyzes the data to determine the patients breathing patterns,

Relying on its contentions for limitations 1[b] and 1[c1], Petitioner contends Sullivan995’s computing system “‘analyzes and records signals from the pressure sensor,’ and analyzes ‘the sound and breathing patterns’ to record ‘indexes such as the number of apneic episodes, the number of hypopneas, their duration, etc.’” Pet. 36 (citing Ex. 1005, 12:67–13:8, Fig. 12). Petitioner further contends these actions by the computing system correspond to the recited “analyz[ing] the data to determine the patient’s breathing patterns.” *Id.*

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[c3] the processing arrangement also determines whether to alter the pressure supplied to the airway of the patient based, at least in part, of the determined breathing patterns of the patient,

Petitioner contends in Sullivan995, “[i]n response to the electrical signal generated when snoring sounds occur, a motor speed control means

‘increases the speed of the electronic motor 20,’ which ‘increases the blower speed,’ thereby ‘increas[ing] the output air pressure of the blower 21.’” Pet. 36 (citing Ex. 1005, 9:60–64, 10:6–12, 10:40–46, 10:55–58). Petitioner further contends that “‘in the absence of an electronic signal from the microphone 11,’ meaning the patient is not snoring, Sullivan995’s processor unit 26 ‘achieve[s]’ a decrease in CPAP pressure by ‘continuously gradually reducing the blower speed over a period of time.’” *Id.* (citing Ex. 1003 ¶ 126; Ex. 1005, 10:37–46). According to Petitioner, increasing or decreasing the blower speed corresponds to the recited “alter[ing] [of] the pressure supplied by the blower to the airway of the patient” and “is based on ‘when snoring sounds occur.’” *Id.* (emphasis omitted) (citing Ex. 1003 ¶ 126). Petitioner further contends “[t]he determination to increase the output air pressure in Sullivan995 is made when ‘respond[ing] to a snore, or a snore *pattern*,’ and is therefore *based, at least in part, on the determined breathing patterns of the patient.*” *Id.* at 37 (citing Ex. 1005, 10:55–58).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[d1] wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and;

Petitioner contends that “[a]s Sullivan995 explains for Figure 3, ‘the output pressure of the CPAP unit increases in response to detection of snoring.’” Pet. 38 (citing Ex. 1005, 10:10–12). Petitioner further contends

that one of ordinary skill in the art “would understand that the detection of snoring indicates that the patient is in an asleep state.” *Id.* (citing Ex. 1003 ¶ 139; Ex. 1005, 10:47–61). Petitioner further contends that Figure 13 of Sullivan995 illustrates that “the computing system maintains a constant pressure until the first snore is detected. In response to the first snore, and each subsequent snore, the computing system increases the pressure.” *Id.* at 39 (citing Ex. 1003 ¶ 141).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[d2] [the processing arrangement applies] a lesser positive treatment pressure in an awake state

Petitioner contends “Sullivan995 increases pressure to the patient when a snore is detected” but concedes that “Sullivan995 does not explicitly disclose that *a lesser positive treatment pressure* is applied *in an awake state*.” Pet. 39 (citing Ex. 1003 ¶¶ 143–145; Ex. 1005, 10:10–12, 14:17–20, Fig. 3). Nonetheless, Petitioner contends this is taught by Sullivan460 and “the modified CPAP system taught by Sullivan995 in view of Sullivan460 would have rendered this limitation obvious.” *Id.* at 39–40 (citing Ex. 1003 ¶ 146).

Petitioner next contends that “Sullivan460 discloses ‘sleep sensor [that] is adapted to register that the patient is asleep when there is a reduced average airflow in the patient’s upper airway.’” Pet. 40 (citing Ex. 1006, 7:17–19). Petitioner further contends Sullivan460 discloses switching means “which respond[] to the sleep sensor and automatically

switch[] the treatment means between [] two modes of air delivery,’ where ‘a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep’” and the second mode provides a higher pressure than the first mode. *Id.* (citing Ex. 1003 ¶¶ 147–148; Ex. 1006, 6:30–7:12, claims 22–28, 43–46).

Petitioner next contends it would have been obvious to one of ordinary skill in the art to modify Sullivan995’s processing arrangement to apply “a lesser pressure when the patient is in an awake state, and determine[] that the patient has transitioned between an awake state and an asleep state, as taught by Sullivan460.” Pet. 19 (citing Ex. 1003 ¶ 91). Petitioner further contends one of ordinary skill “would have been motivated to implement this modification to cause Sullivan995’s CPAP system to apply a lower pressure upon detecting the patient’s awake state.” *Id.*

Petitioner next contends that one of ordinary skill in the art “would have recognized the advantages of using the same CPAP system to treat both sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught by Sullivan460.” Pet. 19 (citing Ex. 1003 ¶ 93; Ex. 1006, 7:3–12). Petitioner further contends that modifying “Sullivan995’s CPAP system would allow for detection of inaudible low frequency vibrations, including those associated with pre-eclampsia, so that the patient may be treated with high pressure.” *Id.* at 20 (citing Ex. 1006, 2:19–22, 4:33–34, 6:3–34, 9:31–10:6). According to Petitioner, Sullivan995 suggests “such modifications would be desirable, as its CPAP system is not limited to treating apnea and snoring, but also apply to other upper airway disorders which [one of ordinary skill in the art] would have understood to include vibrations related to pre-eclampsia.” *Id.* (citing Ex. 1005, 1:14–31, 4:36–45).

Petitioner next contends a skilled artisan “would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment.” Pet. 20. Petitioner further contends “Sullivan995 strongly suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period).” *Id.* (citing Ex. 1005, 10:13–46, 14:45–64). Petitioner further contends “Sullivan995 explains, prior to Sullivan995, therapy pressure was often delivered at levels higher than necessary for substantial periods causing discomfort . . . and Sullivan 995 partially solves the problem by reducing the pressure at the beginning of therapy, when the patient connects herself to the CPAP system.” *Id.* at 21(citing Ex. 1003 ¶ 96; Ex. 1005, 4:21–25).

Petitioner next contends that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Sullivan995. Pet. 21 (citing Ex. 1003 ¶ 97). Petitioner points to the fact that “Sullivan460 explicitly recognizes the combination of Sullivan995 with the teachings in Sullivan460.” *Id.* (citing Ex. 1003 ¶ 98). In particular, Petitioner points to the disclosure in Sullivan460 that “expressly states that Sullivan995 may be modified to include features of Sullivan460, such as ‘sens[ing] an upper airway flow limitation characterized by a least one decrease in upper airway inspiratory flow rate followed by at least one increase in flow rate.’” *Id.* (citing Ex. 1006, 6:22–29). Petitioner further contends one of ordinary skill in the art “would have had a reasonable expectation of success in performing this modification because Sullivan460 already describes Sullivan995 as being used to sense flow limitations, and Sullivan460 further explains that

flow data may be used to determine an awake/sleep state.” *Id.* at 21–22 (citing Ex. 1003 ¶ 98).

Petitioner next contends Sullivan995 and Sullivan 460 both “describe CPAP systems that include flow sensors and flow generators” and both “disclose[] a flow rate measurement means . . . located in the flow path for detecting the rate at which the patient breathes.” Pet. 22 (citing Ex. 1006, 10:10–12). Because of this and other similarities, Petitioner contends that Sullivan995 and Sullivan460 are analogous art. *Id.* (citing Ex. 1003 ¶ 99).

Petitioner next contends that the modification of Sullivan995 “would simply be a change in programming . . . involv[ing] a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.” Pet. 22 (citing Ex. 1003 ¶ 100).

Patent Owner¹⁰ responds that Sullivan995 and Sullivan460 “fail to teach that the system indicates when the patient transitions either to or from an awake state.” Prelim. Resp. 28. According to Patent Owner, “Sullivan995 and Sullivan460 do not disclose the claimed application of applying lesser positive treatment pressure in an awake state because Sullivan 995 teaches a system that preferably and continuously decreases CPAP pressure unless snoring or apnea symptoms occur.” *Id.* at 29 (citing Ex. 1005, 11:5–8, 16:22–23, 16:60–63). Patent Owner contends that this

¹⁰ Patent Owner generally asserts that we “should incorporate the Examiners’ findings and analysis during prosecution of the ’955 and ’994 Patents.” Prelim. Resp. 27. However, as discussed above in connection with our analysis under 35 U.S.C. § 325(d), Sullivan460 was not disclosed to the Office and the Examiner made no findings concerning Sullivan 460 or the proposed combinations of Sullivan995 and Rapoport502 with Sullivan460.

teaching is contrary to the claimed invention which requires that “the processing arrangement [to] appl[y] a lesser positive pressure in an awake state,” and “a greater amount of pressure” when the patient is asleep. *Id.* (alterations in original) (citing Ex. 1001, claims 1, 19, Fig. 12).

Patent Owner’s contention is unavailing because it attacks Sullivan995 in isolation. Petitioner’s challenge is based on the combined teaching of Sullivan995 and Sullivan460. In particular, Petitioner relies on Sullivan460 for disclosing that a lesser treatment pressure is applied “when the processing arrangement determines the patient is in an awake state.” Pet. 40 (emphasis omitted).

Sullivan460 discloses that its system “senses whether or not the patient is asleep and may also include a switching means which responds to the sleep sensor and automatically switches between the two modes of air delivery.” Ex. 1006, 7:4–7. Sullivan460 further discloses that the first mode is “for use when the patient is awake” and the second mode is “for use when the patient is asleep.” *Id.* at 6:31–32. Sullivan460 further discloses that in the second mode, “the treatment means provides a relatively greater air and pressure delivery to the patient than in the first mode, which is sufficient to treat an air flow limitation.” *Id.* at 6:34–7:2.

Based on this disclosure and the parties’ respective contentions, Petitioner sufficiently establishes that Sullivan460 discloses that a lesser treatment pressure is applied when the processing arrangement determines the patient is in an awake state.

Patent Owner next contends that Sullivan460 teaches away from the claimed invention “because it does not teach detection of sleep apnea breathing patterns.” Prelim. Resp. 33. According to Patent Owner,

Sullivan460 “was intended not to treat and detect apneas but rather to detect airway patterns resulting from substantial blood pressure elevations exhibited by patients with pre-eclampsia.” *Id.* at 34 (citing Ex. 1006, 6). For the following reasons, this contention is unavailing based on the current record.

“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *Ricoh Co. v. Quanta Comput. Inc.*, 550 F.3d 1325, 1332 (Fed. Cir. 2008)). Indeed, a reference must be considered for all it discloses, both disclosure that teaches away from the invention at issue as well as disclosure that points toward and teach the invention. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 296 (Fed. Cir. 1985).

We initially note that the preamble of the claims refers to “treating a sleeping disorder,” not sleep apnea. Patent Owner does not argue that pre-eclampsia is not a sleeping disorder. Patent Owner does not point to any disclosure in Sullivan460 that could reasonably be read as discouraging an ordinary skilled artisan from following the path set out in the claimed invention. *See* Prelim. Resp. 34–36. Further, Patent Owner studiously avoids Sullivan460’s explicit disclosure that “the flow measurement means and the treatment means may be constructed together as part of one apparatus, such as the AutoSet product from ResMed described in” Sullivan995. Ex. 1006, 6:22–24. This disclosure clearly points toward

modifying Sullivan995, which is directed to treating sleep apnea, with the teachings of Sullivan460.

Patent Owner next contends that Petitioner cannot establish motivation to combine “because it failed to meet its burden of proving that the asserted art disclosed all the claim limitations of, at the very least the independent claims.” Prelim. Resp. 38–39. The only claim limitations that Patent Owner contends are not disclosed is the determining the transition from an awake state to an asleep state and decreasing the pressure when the patient is in the awake state. *Id.* at 40–41. As discussed above, based on the current record, Petitioner sufficiently establishes that Sullivan460 discloses these limitations.

Based on our review of the evidence and arguments cited by Petitioner, and after considering Patent Owner’s arguments, we find Petitioner sufficiently establishes on the current record that the combined teachings of Sullivan995 and Sullivan460 disclose this limitation and that one of ordinary skill in the art would have had a motivation to combine Sullivan995 and Sullivan460 and would have had a reasonable expectation of success in doing so.

1[e1] wherein the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state

Petitioner contends Sullivan995 discloses “the output pressure of the CPAP unit increases in response to detection of snoring,” and “the pressure is decreased ‘if an extended period of snore free breathing occurs’ by ‘intentionally reducing the CPAP pressure at a gradual rate as long as snoring is not detected.’” Pet. 41 (citing Ex. 1005, 10:10–12, 10:31–46, 10:47–61, 14:17–20, Figs. 3, 13). Petitioner concedes “Sullivan995 does not

explicitly disclose that the increase occurs when the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state has occurred.” *Id.* (emphasis omitted) (citing Ex. 1003 ¶ 152). Nonetheless, Petitioner contends “this limitation would have been obvious from Sullivan995 in view of Sullivan460.” *Id.*

Petitioner next contends “Sullivan460 discloses determin[ing] that the patient has transitioned between at least an awake state and an asleep state by describing embodiments in which ‘a sleep sensor [] senses whether or not the patient is asleep’ by determining ‘when there is a reduced average airflow in the patient’s upper airway.’” Pet. 42 (alterations in original) (emphasis omitted) (citing Ex. 1003 ¶ 152; Ex. 1006, 7:3–7, 7:10–12, 7:17–19).

Petitioner relies on its motivation to combine and reasonable expectation of success contentions discussed above.

We interpret Patent Owner’s contentions for limitation 1[d2] as applicable to this limitation as well.

For the reasons discussed above in connection with limitation 1[d2], we find Petitioner sufficiently establishes that the combined teachings of Sullivan995 and Sullivan460 disclose this limitation and that one of ordinary skill in the art would have had a motivation to combine Sullivan995 and Sullivan460 and would have had a reasonable expectation of success in doing so.

1[e2] the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system.

Petitioner contends Sullivan995 discloses that its “processing arrangement automatically controls the flow generator to increase a

positive treatment pressure supplied to the entrance of the tube incrementally with each snore that is detected.” Pet. 43 (citing Ex. 1005, 14:17–20, Fig. 13). According to Petitioner, one of ordinary skill in the art “would have readily recognized, the incremental increase depicted in Figure 13 is using a ramp system because the incremental increases occur at different times, upon detection of each snore.” *Id.* (citing Ex. 1003 ¶ 155, Ex. 1006, 11:55–12:6, Figs. 4–6).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

Summary of Claim 1

For all the foregoing reasons, we determine that Petitioner has shown a reasonable likelihood that claim 1 would have been unpatentable over Sullivan995 and Sullivan460.

4. Claims 2–5, 8, 11, 12, and 16–18

These claims depend from claims 1. Ex. 1001, 10:12–11:11. Petitioner sets forth evidence and argument as to why Sullivan995 and Sullivan460 allegedly render claims 2–5, 8, 11, 12, and 16–18 unpatentable. Pet. 43–52.

Patent Owner does not address these claims in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed Petitioner’s evidence and arguments and determine that Petitioner has sufficiently shown a reasonable likelihood that these dependent claims would have been unpatentable over Sullivan995 and Sullivan460.

5. *Claim 19*

Independent claim 19 contains many limitations substantially similar to claim 1. Ex. 1001, 11:12–44. For those limitations, Petitioner relies on its contentions and evidence for claim 1. Pet. 52–55. For the remaining limitations, Petitioner provides contentions supported by evidence from Sullivan995, Sullivan460, and Dr. Behbehani. *Id.*

Patent Owner does not provide any separate contentions for the patentability of claim 19. *See generally* Prelim. Resp.

We reviewed the Petitioner’s additional evidence and arguments for claim 19 and determine that Petitioner has sufficiently shown a reasonable likelihood that claim 19 would have been unpatentable over Sullivan995 and Sullivan460.

6. *Claims 20–22, 24–26, 30, and 31*

These claims depend from claim 19. Ex. 1001, 12:1–42. Petitioner sets forth evidence and argument as to why Sullivan995 and Sullivan460 allegedly render claims 20–22, 24–26, 30, and 31 unpatentable. Pet. 55–57.

Patent Owner does not address these claims in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed Petitioner’s evidence and arguments and determine that Petitioner has sufficiently shown a reasonable likelihood that these dependent claims would have been unpatentable over Sullivan995 and Sullivan460.

G. *Ground 2: Alleged Obviousness of Claims 6 and 23 over Sullivan995, Sullivan460, and Matthews*

Petitioner contends claims 6 and 23 would have been obvious over Sullivan995, Sullivan460, and Matthews. Pet. 57–59. Petitioner supports its contentions with the Declaration of Dr. Khosrow Behbehani (Ex. 1003).

Patent Owner disputes Petitioner's contentions. Prelim. Resp. 14–18, 26–43.

We begin with a brief summary of Matthews and then address the parties' respective contentions.

1. Matthews (Ex. 1007)

Matthews is titled “Auto-Titration Pressure Support System and Method of Using Same.” Ex. 1007, code (54). Matthews is directed to “an auto-titration pressure support system and to a method of automatically titrating a pressure support system to optimize the pressure delivered to the patient to treat the disordered breathing while otherwise minimizing the delivered pressure for patient comfort.” *Id.* at 1:18–22. Matthews describes an auto-CPAP control layer that has a general goal of inducing slow pressure ramps or to provide a pressure hold period (i.e., a therapy pressure). *Id.* at 25:26–29. Matthews explains that “[t]he patient's response to these pressure changes and to the therapy pressure is evaluated by monitoring certain parameters associated with the flow waveform to determine whether the patient flow waveform is improving, degrading, or showing no change.” *Id.* at 25:29–33. Matthews further states that “[w]hen a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable” and “[i]t is, therefore, important to interrupt the auto-CPAP controller if the patient's breathing pattern becomes too variable.” *Id.* at 21:37–42.

2. Claims 6 and 23

Claim 6 depends from claim 1 and recites “wherein the awake state is a troubled wakefulness state.” Ex. 1001, 11:33–34. Claim 23 depends from claim 19 and recites “wherein applying a lower pressure when the patient is

in the awake state comprises applying a low pressure when the patient is in a troubled wakefulness state.” *Id.* at 12:12–15.

Petitioner contends that Matthews “discloses an *awake state is a troubled wakefulness state* by describing ‘[w]hen a patient is awake . . . or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable.’” Pet. 59 (alterations in original) (citing Ex. 1007, 21:34–44, 21:63–22:1). According to Petitioner, “Matthew’s description of erratic breathing when the patient is awake and in distress is consistent with the ’955 Patent’s description of *troubled wakefulness* as ‘awake and anxious or distressed.’” *Id.* at 51–52 (citing Ex. 1001, 4:54–66). Petitioner also provides reasons why one of ordinary skill in the art would have been motivated to modify the system of Sullivan995 and Sullivan 460 with the teachings of Matthews and why the proposed modification would have had a reasonable expectation of success. *Id.* at 57–58.

Patent Owner counters that Matthews “fails to teach the claimed troubled wakefulness state.” Prelim. Resp. 31. Patent Owner contends that Petitioner’s ellipsis in the quoted portion of Matthews obscures the meaning of the quoted sentence by omitting Matthews’ reference to the REM sleep state. *Id.* (citing Ex. 1007, 21:37–41). According to Patent Owner, “[u]nder Matthews, detection of the REM sleep state would require interruption of the auto-CPAP control and decrease pressure. *Id.* at 31–32.

The entire sentence from Matthews relied on by Petitioner for disclosure of the “troubled wakefulness” state is: “[w]hen a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable.” Ex. 1007, 21:37–41. Petitioner and its expert insert an ellipse to interpret the sentence as “when the patient is

awake and in distress.” Pet. 59; Ex. 1003 ¶ 223 (Dr. Behbehani using same interpretation). Petitioner’s use of ellipses does not change the fact that Matthews discloses erratic breathing when the patient is awake and in distress. Based on the present record, Petitioner sufficiently establishes that Matthew discloses the troubled wakefulness state.

Patent Owner next contends that Matthews teaches away from the ’955 patent because it teaches that its CPAP pressure decreases if its system determines “that the rate of leakage of gas from the system reaches a certain threshold” when a patient is asleep by dislodging the mask. Prelim. Resp. 35–36 (citing Ex. 1007, 14:8–10, 14:52–59; Ex. 2005, 29). Patent Owner further contends that “Matthews teaches that the CPAP pressure decrease causes the erratic breathing patterns” but “in the ’955 Patent, it is the pressure increases that cause the patient’s irregular breathing patterns and detection of the troubled wakefulness state, which can only be resolved by decreasing the CPAP pressure.” *Id.* at 38 (citing Ex. 1007, 24:16–18).

This contention does not undercut Petitioner’s showing at this stage of the proceeding because it does not show why an ordinary skilled artisan would be discouraged from proceeding along the path of the claimed invention.

Based on Petitioner’s evidence and arguments, cited by Petitioner and after considering Patent Owner’s contentions, we determine that Petitioner has shown a reasonable likelihood that claims 6 and 23 are unpatentable.

H. Ground 3: Alleged Obviousness of Claims 1–5, 8, 11, 12, 16–22, 24–26, 30, and 31 over Rapoport502 and Sullivan460

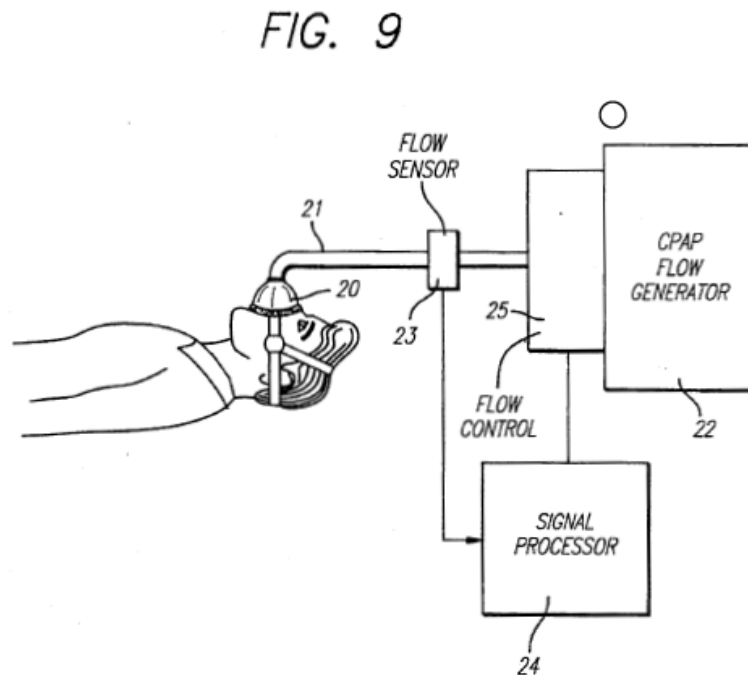
Petitioner contends claims 1–5, 8, 11, 12, 16–22, 24–26, 30, and 31 would have been obvious over Rapoport502 and Sullivan460. Pet. 59–78. Petitioner supports its contentions with the Declaration of Dr. Behbehani

(Ex. 1003). Patent Owner disputes Petitioner’s contentions. Prelim. Resp. 14–18, 26–43.

We begin with a brief summary of Rapoport502 and then address the parties’ respective contentions.

1. Rapoport502 (Ex. 1008)

Rapoport502 is titled “Method and Apparatus for Optimizing the Continuous Positive Airway Pressure for Treating Obstructive Sleep Apnea.” Ex. 1008, code (54). Rapoport502 is directed “to a method and apparatus for adjusting the positive airway pressure of a patient to an optimum value in the treatment of obstructive sleep apnea.” *Id.* at 1:14–18. Rapoport502’s Figure 9 depicts a block diagram of a system and is reproduced below. *Id.* at 4:11–12.



The system of Figure 9 includes CPAP mask 20 connected via tube 21 to receive air from CPAP flow generator 22. *Id.* at 5:51–53. Rapoport502 explains that “[a] conventional flow sensor 23 is coupled to the tube 21, to

provide an electric output signal corresponding to the waveform of the airflow in the tube 21” and “[t]his signal is applied to a signal processor 24, which detects the existence in the waveforms of conditions that indicate flow limitation.” *Id.* at 5:56–61. According to Rapoport502, “[t]he signal processor 24 outputs a signal to a conventional flow control 25 for controlling the pressure applied by the flow generator to the tube 21.” *Id.* at 5:61–63.

Rapoport502 explains that, “[a]fter the CPAP mask has been fitted to a patient and the CPAP generator has been connected to the mask (step 40), the CPAP pressure is set at a starting pressure,” a pressure at which flow limitation does not occur for the patient. *Id.* at 6:2–7. The flow signal is then analyzed. *Id.* at 6:7–8. Rapoport502 states that, “[i]f it is determined that flow limitation has occurred (step 43) and that the CPAP pressure is less than the maximum allowed (step 44), then the CPAP pressure is increased.” *Id.* at 6:9–11. If it is determined that a flow limitation is not present, then it is determined whether a predetermined time has elapsed since the last change in CPAP pressure. *Id.* at 6:17–20. If there is a determination that the predetermined amount of time has elapsed, there is a determination of whether the CPAP pressure is greater than a minimum allowed pressure. *Id.* at 6:23–25. If so, the CPAP pressure is decreased. *Id.* at 6:25–27.

2. Claim 1

Petitioner provides a limitation-by-limitation analysis of independent claim 1 mapping the prior art to the claim limitations. Pet. 63–70. Petitioner also provides contentions concerning motivation to combine and reasonable expectation of success. *Id.* at 59–63.

Patent Owner contends that Rapoport502 and Sullivan460 fail to teach the requirements “that the system indicates when the patient transitions either to or from an awake state” (Prelim. Resp. 28), Sullivan460 teaches away from the claimed invention (*id.* at 32), and Petitioner cannot establish motivation to combine or reasonable expectation of success because the Petition does not establish all claim limitations (*id.* at 38).

With this background, we analyze the parties’ respective contentions.

Preamble: A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient’s airways in order to assist in treating a sleeping disorder in a patient, the positive airway pressure system comprising:

Petitioner contends “Rapoport502 discloses a continuous *positive airway pressure system* in the same manner as the ’955 Patent.” Pet. 63 (citing Ex. 1003 ¶ 234; Ex. 1008, 1:16–22, Fig. 9).

Patent Owner does not address the preamble in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution. Therefore, we need not address whether the preamble is limiting.

1[a] a flow generator which supplies a positive treatment pressure flow of breathable gases to the entrance of a tube, the tube directing the flow of breathable gases to the airway of a patient to provide the patient with the positive treatment pressure flow of breathable gases;

Petitioner contends that “Rapoport502’s CPAP system includes a *flow generator 22 . . . which supplies air to the patient . . . via a patient worn CPAP mask 20.*” Pet. 63 (citing Ex. 1008, 5:51–53, Fig. 9).

According to Petitioner, one of ordinary skill in the art “would have

understood that the air supplied to the patient is *a positive treatment pressure flow of breathable gases.*” *Id.* at 64 (citing Ex. 1003 ¶ 235).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[b] a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient’s breathing patterns; and

Petitioner contends that “Rapoport502’s CPAP system includes a conventional *flow sensor 21 . . . ‘coupled to the tube 21,’* which defines the *flow path of the positive treatment pressure flow of breathable gases* from the flow generator 22 to the patient worn CPAP mask 20.” Pet. 64 (citing Ex. 1008, Fig. 9). Petitioner further contends “Rapoport502 discloses that ‘the blower [i.e., flow generator 22] ***supplies air through the flow sensor*** to the patient via a hose and nasal coupling’ of the CPAP mask 20” which “illustrate the flow sensor being in the flow path in the same manner as the ’955 Patent.” *Id.* (citing Ex. 3:34–36). Petitioner further contends “Rapoport502’s ‘conventional flow sensor 23 . . . provide[s] an electric output signal corresponding to the waveform of the airflow in the tube 21. The signal is applied to a signal processor 24, which detects the existence in the waveforms of conditions that indicate flow limitation.” *Id.* (alterations in original) (citing Ex. 1008, 5:56–61). According to Petitioner, one of ordinary skill in the art “would have understood that the conventional flow sensor 23 *measures data corresponding* to the ‘air through the flow sensor,’ and the measured data

in the form of a waveform is *indicative of the patient's breathing patterns* analyzed by the processor 24.” *Id.* at 64–65 (citing Ex. 1003 ¶ 238; Ex. 1008, 3:24–26).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[c1] a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor,
Petitioner contends that “Rapoport502’s CPAP system includes a signal processor 24 . . . corresponding to a *processing arrangement*.” Pet. 65. Petitioner further contends Rapoport502’s signal processor 24 is connected in the same manner as in the ’955 patent and “uses the term ‘signal processor’ which had a well-understood structure to [one of ordinary skill] akin to an arrangement of elements that performs processing.” *Id.* (citing Ex. 1003 ¶ 239). Petitioner further contends “signal processor 24 receives the measured data corresponding to the flow of breathable gases from the flow sensor.” *Id.* at 66.

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[c2] [the processing arrangement] analyzes the data to determine the patients breathing patterns,
Petitioner contends Rapoport502’s “processor 24 *analyzes the data to determine the patient’s breathing patterns* by ‘detect[ing] the existence in the waveforms [supplied by the flow generator 23] of conditions that

indicate flow limitation’ of the patient.” Pet. 66 (alterations in original) (citing Ex. 1003 ¶ 242; Ex. 1005, 5:59–61).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[c3] the processing arrangement also determines whether to alter the pressure supplied to the airway of the patient based, at least in part, of the determined breathing patterns of the patient,

Petitioner contends that “signal processor 24 outputs a signal to a conventional flow control 25 for controlling the pressure applied by the flow generator to the tube 21.” Pet. 66 (citing Ex. 1008, 5:61–63). Petitioner further contends Rapoport502 discloses if processor 24 determines that a “flow limitation has occurred . . . and that the CPAP pressure is less than the maximum allowed . . . then the CPAP pressure is increased” based on the control signal output of processor 24. *Id.* at 67 (citing Ex. 1003 ¶ 243; Ex. 1008, 6:9–13).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

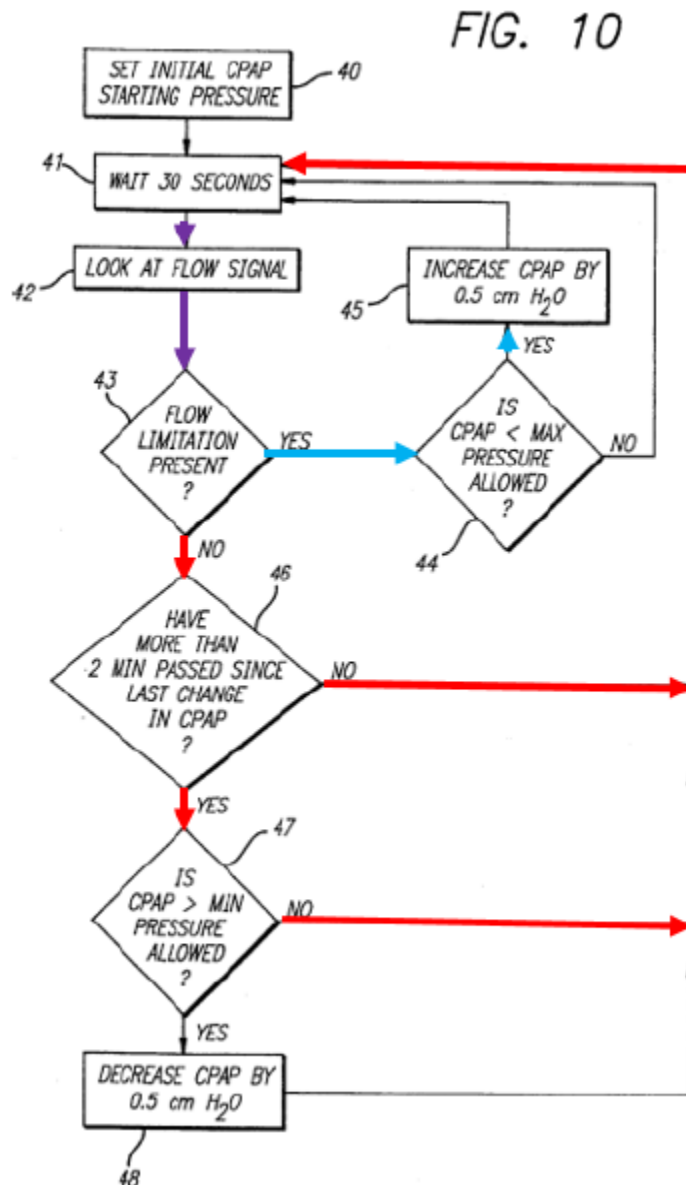
We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[d1] wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and;

Petitioner contends Rapoport502 increases “pressure upon determining a flow limitation for the patient.” Pet. 67 (citing Ex. 1008, Fig. 10). Petitioner further contends Rapoport502’s Figure 10 represents an “‘automatic adjustment mode’ effectuated by the *processing arrangement* in

which ‘several input parameters . . . are used in the determination of the action to be taken’ including applying a delay before onset of a pressure increase to the patient.” *Id.* at 68 (citing Ex. 1008, 7:6–8).

Petitioner provides the following annotated version of Rapoport502’s Figure 10:



Pet. 68. Figure 10 of Rapoport502 “is a flow diagram illustrating one technique for adjusting CPAP pressure.” Ex. 1008, 4:13–14. In Petitioner’s

annotated version, Petitioner adds blue arrows between blocks 43 and 44 and between blocks 44 and 45. Pet. 68. Petitioner contends that “[a]s seen in (blue), after completion of the delay and the signal processor 24 determines ‘YES’ for a flow limitation (Step 43), it applies *a pressure increase to the patient* of 0.5 cm H₂O (Step 45) provided that the current CPAP pressure is less than the maximum allowed (step 44).” *Id.* at 69 (citing Ex. 1003 ¶ 241; Ex. 1008, 6:9–13).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[d2] [the processing arrangement applies] a lesser positive treatment pressure in an awake state

Petitioner contends Rapoport502 in view of Sullivan460 renders this limitation obvious. Pet. 69 (citing Ex. 1003 ¶ 248)¹¹. Petitioner relies on its contentions regarding the teachings of Sullivan460 discussed above in connection with this limitation in Ground 1. *Id.* Petitioner concedes that Rapoport502 does not “disclose applying *a lesser positive treatment pressure in an awake state.*” *Id.* Nonetheless, Petitioner contends this would have been obvious in light of the teachings of Sullivan460. *Id.* (citing Ex. 1003 ¶ 248). Petitioner relies on its contentions concerning Sullivan460 discussed above in connection with limitation 1[d2] in Ground 1. *Id.*

Petitioner next contends it would have been obvious to one of ordinary skill in the art to modify Rapoport502’s processing arrangement so

¹¹ The Petition also refers to Matthews as teaching this limitation. Pet. 69. This appears to be a typographical error as Matthews is not relied on in this ground and the Petition specifically refers to the teachings of Sullivan460.

that it applies *a lesser pressure when the patient is in an awake state, and determines that the patient has transitioned between at least an awake state and an asleep state.*” Pet. 59–60 (citing Ex. 1003 ¶ 227). Petitioner further contends that one of ordinary skill in the art “would have recognized the advantages of using the same PAP system to treat both sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught by Sullivan460.” *Id.* (citing Ex. 1003 ¶ 228; Ex. 1006, 7:3–12). Petitioner further contends that modifying “Rapoport502’s PAP system would allow for detection of inaudible low frequency vibrations, including those associated with pre-eclampsia, so that the patient may be treated with high pressure.” *Id.* at 60 (citing Ex. 1006, 2:19–22, 4:33–34, 6:3–34, 9:31–10:6). According to Petitioner, Rapoport502 suggests “such modifications would be desirable, as it acknowledges that obstructive sleep apnea syndrome . . . is not limited to any particular disorder, but rather ‘is associated with all conditions in which there is anatomic or functional narrowing of the patient’s upper airway’” which one of ordinary skill in the art “would have understood to include vibrations related to pre-eclampsia.” *Id.* (citing Ex. 1003 ¶ 228; Ex. 1008, 1:29–33).

Petitioner next contends that one of ordinary skill in the art “would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment.” Pet. 61 (citing Ex. 1003 ¶ 229). Petitioner further contends

“[b]oth Dr. Rapoport and Dr. Sullivan¹² recognized that a major limitation with CPAP therapy was non-compliance due to discomfort” and “that lowering pressure when the patient is in an awake state could improve compliance.” *Id.* (citing Ex. 1012, 5; Ex. 1014, 5). Petitioner further contends that “the modified CPAP system would apply a low pressure whenever the sensor detects the patient is awake. Reverting to a low pressure upon wake-up would add to patient comfort and decrease the likelihood the patient will remove the mask due to uncomfortably high pressure.” *Id.* (citing Ex. 1003 ¶ 229).

Petitioner next contends that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Rapoport502. Pet. 61 (citing Ex. 1003 ¶ 230). Petitioner contends that like Rapoport502, “Sullivan460 discloses a flow rate measurement means 70 . . . located in the flow path for detecting the rate at which the patient breathes” and “when Sullivan460 senses interruptions 10 in the patient’s ‘breathing patterns’ or determines the patient is asleep, a controller 100 activates a switch 110, which activates the nCPAP apparatus 90 to supply air to the patient 30 at a higher pressure to ameliorate or eliminate the patient’s upper airway flow limitation.” *Id.* at 61–62 (citing Ex. 1006, 10:3–16).

Petitioner next contends that “Dr. Rapoport was familiar with Dr. Sullivan’s work, and acknowledged that Dr. Sullivan and his colleagues were ‘a few months ahead of the rest of us.’” Pet. 62 (citing Ex. 1003 ¶ 232; Ex. 1012, 3). According to Petitioner, one of ordinary skill in the art “would

¹² Dr. Rapoport is a named inventor on the ’955 patent and Rapoport502. Ex. 1001, code (72); Ex. 1008, code (75). Dr. Sullivan is a named inventor on Sullivan995 and Sullivan460. Ex. 1005, code (75); Ex. 1006, code (75).

have naturally looked at the pioneer in CPAP machines for algorithms for different air pressure setting that could improve compliance,” and “Dr. Rapoport [] repeatedly cites to Dr. Sullivan’s work in his own published work.” *Id.* at 54–55 (citing Ex. 1003, ¶ 232; Ex. 1016, 7–8).

Petitioner next contends that the modification of Rapoport502 “involves a simple change in the programming algorithm, it is nothing more than a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.” Pet. 62–63 (citing Ex. 1003 ¶ 233).

Patent Owner responds that Rapoport502 “fails to teach or disclose the claimed increase in CPAP pressure supplied to the patient upon an indication that the patient’s breathing patterns have changed from an awake state to an asleep state.” Prelim. Resp. 30. Patent Owner contends “Rapoport 502 teaches, ‘if no flow limitation is detected for an interval of time, then the controlled positive pressure is lowered to test for the development of flow limitation’” and “[i]n other words Rapoport502 teaches that if there are no obstructions in the patient’s breathing patterns while the patient sleeps, then the system will lower the pressure until such obstructions are detected.” *Id.* (citing Ex. 1008, 10:49–52, claims 1, 14, 15, 19, and 34). According to Patent Owner, the teaching of Rapoport502 “is contrary to the ’955 Patent’s teachings, which states that CPAP pressure is increased when the patient is asleep and has normal breathing patterns.” *Id.* (citing Ex. 1001, claims 1, 12, 21). Patent Owner further contends that Rapoport502 is silent as to its system operation when a patient awakens and “cannot

determine an awake state, much less decrease the applied CPAP pressure the patient awakens.” *Id.* at 30–31 (citing Ex. 1008, 5:11–12).

Patent Owner’s contention is unavailing because it attacks Rapoport502 in isolation. Petitioner’s challenge, however, is based on the combined teaching of Rapoport502 and Sullivan460. In particular, Petitioner relies on Sullivan460 for disclosing applying a lesser pressure when the patient is awake. *See* Pet. 69. As discussed above in connection with limitation 1[d2] in Ground 1, Petitioner sufficiently establishes, on the current record, that Sullivan460 discloses switching between two modes where a lower pressure is applied in the second mode when the patient is awake.

Patent Owner next contends that Petitioner cannot establish motivation to combine “because it failed to meet its burden of proving that the asserted art disclosed all the claim limitations of, at the very least the independent claims.” Prelim. Resp. 40. Patent Owner argues that Rapoport502 fails to teach “the system detecting when a user’s breathing patterns transition from the sleep state to the awake state” and “in response to transition detection, adjusting the pressure, such as decreasing the pressure when the patient is in the awake state.” *Id.* at 40–41. As discussed above, based on the current record, Petitioner sufficiently establishes that Sullivan460 discloses these limitations.

Patent Owner next contends that Petitioner relies on its expert to supply “missing claim limitations solely by concluding that it would have been common knowledge and obvious to [one of ordinary skill in the art] that a system would detect a transition between the awake asleep state.” Prelim. Resp. 41. In support of this contention, Patent Owner cites to

paragraphs 164, 167 and 251 of Dr. Behbehani’s declaration testimony. *Id.* We find these citations not persuasive based on the current record, because paragraphs 164 and 167 address claims 3 and 4 in Ground 1 and paragraph 264 relates to claim 4 in this Ground, not claim 1, which we consider here.

Based on our review of the evidence and arguments cited by Petitioner, and after considering Patent Owner’s arguments,¹³ we find Petitioner sufficiently establishes that the combined teachings of Rapoport502 and Sullivan460 disclose this limitation and that one of ordinary skill in the art would have been motivated to combine Rapoport502 and Sullivan460 and would have had a reasonable expectation of success in doing so.

1[e1] wherein the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state

Petitioner contends that “Rapoport502 in view of Sullivan460 renders obvious this limitation.” Pet. 69 (citing Ex. 1003 ¶¶ 254–258). Petitioner further contends that Rapoport502 discloses when the CPAP pressure is greater than the minimum pressure, processor 24 detects a “transition[] between a flow limitation state and a no flow limitation state, and *lowers pressure applied to airway of patient* by 0.5 cm H₂O” in the no flow state. *Id.* at 69–70 (citing Ex. 1008, 6:17–29). Petitioner concedes that “Rapoport502 does not expressly disclose the patient is in an awake state when there is no flow limitation present” but relies on Sullivan460 for this. *Id.* at 70 (citing Ex. 1003 ¶ 256). Petitioner refers us to its contentions concerning the teachings of Sullivan460 for limitation 1[e1] in Ground 1 and

¹³ We addressed Patent Owner’s argument that Sullivan460 teaches away from the claimed invention in connection with Ground 1.

its contentions concerning Motivation to Combine and Reasonable Expectation of Success discussed above in connection with limitation 1[d][2] in this Ground.

Patent Owner does not provide any contentions specific to this claim limitation. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

1[e2] the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system.

Petitioner contends “Rapoport502 discloses this limitation . ‘[T]he controlled positive *pressure* could be changed’ . . . ‘automatically via an automated system, either in response to feedback control or *using* pre-set *ramps* or steps in the controlled positive pressure throughout the night. . . .” Pet. 70 (first alteration in original) (citing Ex. 1008, 11:44–46).

Patent Owner does not address this limitation in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed the evidence cited by Petitioner and find it sufficient for institution.

Summary of Claim 1

For all the foregoing reasons, we determine that Petitioner has shown a reasonable likelihood that claim 1 would have been unpatentable over Rapoport502 and Sullivan 460.

3. Claims 2–5, 8, 11, 12, and 16–18

These claims depend from claim 1. Ex. 1001, 10:12–11:11. Petitioner sets forth evidence and argument as to why Rapoport502 and

Sullivan460 allegedly render claims 2–5, 8, 11, 12, and 16–18 unpatentable. Pet. 71–75.

Patent Owner does not address these claims in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed Petitioner’s evidence and arguments and determine that Petitioner has sufficiently shown a reasonable likelihood that these dependent claims would have been unpatentable over Rapoport502 and Sullivan460.

4. *Claim 19*

Independent claim 19 contains many limitations substantially similar to claim 1. Ex. 1001, 11:12–44. For those limitations, Petitioner relies on its contentions and evidence for claim 1. Pet. 75–77. For the remaining limitations, Petitioner provides contentions supported by evidence from Rapoport502, Sullivan460, and Dr. Behbehani. *Id.*

Patent Owner does not provide any separate contentions for the patentability of claim 19. *See generally* Prelim. Resp.

We reviewed Petitioner’s additional evidence and arguments for claim 19 and determine that Petitioner has sufficiently shown a reasonable likelihood that claim 19 would have been unpatentable over Rapoport502 and Sullivan460.

5. *Claims 20–22, 24–26, 30, and 31*

These claims depend from claim 19. Ex. 1001, 12:1–42. Petitioner sets forth evidence and argument as to why Sullivan995 and Sullivan460 allegedly render claims 20–22, 24–26, 30, and 31 unpatentable. Pet. 77–78.

Patent Owner does not address these claims in the Preliminary Response. *See generally* Prelim. Resp.

We reviewed Petitioner’s evidence and arguments and determine that Petitioner has sufficiently shown a reasonable likelihood that these dependent claims would have been unpatentable over Rapoport502 and Sullivan460.

I. Ground 4: Alleged Obviousness of Claims 6 and 23 over Rapoport502, Sullivan460, and Matthews

Petitioner contends claims 6 and 23 would have been obvious over Rapoport502, Sullivan460, and Matthews. Pet. 69–72. Petitioner relies on Matthews to disclose the “troubled wakefulness” state recited in claims 6 and 23. *Id.* at 72. Patent Owner relies on its arguments discussed in Ground 2 that Matthews does not teach the troubled wakefulness state and teaches away from the claimed invention. Prelim. Resp. 31–33. For the same reasons discussed above in connection with Ground 2, Patent Owner’s arguments do not undercut Petitioner’s showing. Thus, we determine that Petitioner’s showing is sufficient for institution.

III. CONCLUSION

Based on the present record, we determine that Petitioner demonstrates a reasonable likelihood that it would prevail in establishing that at least one challenged claim of the ’955 patent is unpatentable. We, thus, institute an *inter partes* review of all challenged claims of the ’955 patent based on all grounds in the Petition. At this stage of the proceeding, we have not made a final determination under 35 U.S.C. § 318(a) with respect to the unpatentability of any challenged claim.¹⁴

¹⁴ Patent Owner is cautioned that any arguments not raised in the Patent Owner Response may be deemed waived. *See In re NuVasive, Inc.*, 842 F.3d 1376, 1379–82 (Fed. Cir. 2016) (holding that a patent owner waived an

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of the '955 patent is instituted with respect to challenged claims 1–6, 8, 11, 12, 16–26, 30, and 31 and Grounds 1–4 as set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4(b), *inter partes* review of the '955 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

argument addressed in a preliminary response by not raising the same argument in the patent owner response).

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