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Paper 64
Date: December 4, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

IPR2022-00988
Patent 9,108,009 B2

Before BART A. GERSTENBLITH, JAMES A. TARTAL, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

ORDER
Denying Patent Owner's Motion to Exclude (Paper 44) and
Denying Petitioner's Motion to Exclude (Paper 45)
37 C.F.R. § 42.64(c)

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We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) (2018) and 37 C.F.R. § 42.73 (2021). ResMed, Inc. (“Petitioner”) bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to New York University (“Patent Owner”). See 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). For the reasons discussed below, we determine Petitioner has shown by a preponderance of the evidence that claims 1–30 (“the Challenged Claims”) of U.S. Patent No. 9,108,009 B2 (Ex. 1001, “the ’009 patent”) are unpatentable.

I. INTRODUCTION

A. Summary of Procedural History

Petitioner filed a Petition (Paper 1, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of the Challenged Claims.¹ We instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 10. Patent Owner filed a Response.² Paper 27 (“PO Resp.”). Petitioner filed a Reply to the Patent Owner Response. Paper 37 (“Pet. Reply”). Patent Owner filed a Sur-reply in support of the Patent Owner Response. Paper 40 (“PO Sur-reply”).

¹ Petitioner identifies no additional real parties in interest. Pet. 1.

² Patent Owner identifies no additional real parties in interest. Paper 4, 2.

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Following oral argument, we entered a transcript of the hearing in the record.³ Paper 59 (“Tr.”).

Additionally, Patent Owner filed a Motion to Exclude Exhibits 1035, 1049, 1051, and 1056–1059, and portions of Exhibits 1003, 1046, and 1052. Paper 44 (“PO MTE”), 1; *see also* Paper 48 (Petitioner’s Opposition to Patent Owner’s Motion to Exclude (“PO MTE Opp.”)); Paper 49 (Patent Owner’s Reply in Support of Its Motion to Exclude (“PO MTE Reply”). As explained below, we deny Patent Owner’s Motion to Exclude. *See infra* Section III.

Petitioner filed a Motion to Exclude portions of Exhibit 1053. Paper 45 (“Pet. MTE”); *see also* Paper 47 (Patent Owner’s Opposition to Petitioner’s Motion to Exclude (“Pet. MTE Opp.”); Paper 50 (Petitioner’s Reply in Support of Its Motion to Exclude (“Pet. MTE Reply”)). As explained below, we deny Petitioner’s Motion to Exclude. *See infra* Section IV.

B. Related Matters

The Parties identify the ’009 patent as a subject of *New York University v. ResMed, Inc.*, No. 1:21-cv-00813-JPM (D. Del. 2021). Pet. 1; Paper 4, 2. Petitioner also states that it filed petitions challenging claims of the following related patents: U.S. Patent No. 9,427,539 B2 (the ’539 patent”) (IPR2022-00989), U.S. Patent No. 9,533,115 B2 (IPR2022-00990), U.S. Patent No. 9,867,955 B2 (IPR2022-00991), U.S. Patent No. 10,384,024

³ The Parties both filed objections to the other party’s demonstrative exhibits and hearing arguments, and responses to the objections. Papers 56, 57, 60–63. Demonstrative exhibits and hearing arguments are not evidence and are not relied on as a basis of this Decision. Accordingly, the objections are denied as moot.

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B2 (IPR2022-00992), U.S. Patent No. 6,988,994 B2 (“the ’994 patent”) (IPR2022-00993), and U.S. Patent No. 9,168,344 B2 (“the ’344 patent”) (IPR2022-00994). Pet. 1–2.

C. The ’009 Patent

The ’009 patent is titled “System and Method for Diagnosis and Treatment of a Breathing Pattern of a Patient.” Ex. 1001, code (54). The ’009 patent issued on August 18, 2015, from Application No. 14/583,005 (“the ’005 Application”), which was filed on December 24, 2014. *Id.* at codes (45), (21), (22). The ’005 Application is a continuation in a series of applications dating back to August 14, 2003. *Id.* at code (63). Petitioner does not dispute that the priority date of the ’009 patent is August 14, 2003, for purposes of this proceeding. Pet. 7 n.5.

The ’009 patent explains as background 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, 1:23–25. According to the ’009 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 1:29–36. The ’009 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS.” *Id.* at 1:52–55. The ’009 patent describes that “PAP therapy is directed to maintaining pressure in the collapsible portion of the airway at or

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above the critical tissue pressure at all times” and is applied via a tight-fitting nasal mask worn during sleep. *Id.* at 1:52–55, 2:5–7.

The '009 patent states 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.” *Id.* at 1:59–61. 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 2:13–15. The '009 patent also states that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:27–28.

Figure 1 of the '009 patent is reproduced below.

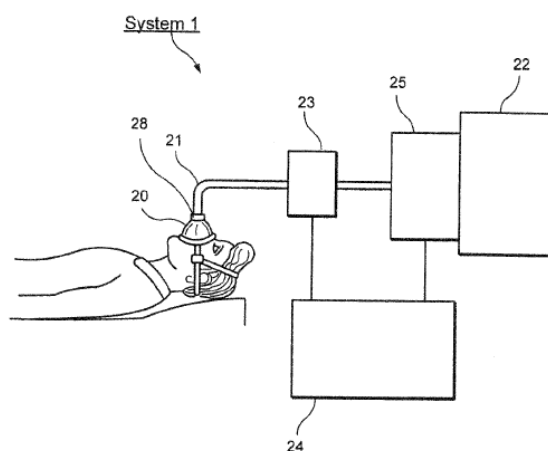


FIG. 1

Figure 1 “shows an exemplary embodiment of a system according to” the '009 patent. *Id.* at 3:17–18. System 1, shown in Figure 1, includes mask 20 connected via tube 21 for receiving an airflow of a particular pressure from flow generator 22. *Id.* at 3:47–50. The '009 patent describes 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 3:55–59. The '009 patent states that “[s]ignals

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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 3:59–64.

The ’009 patent also describes a method that uses system 1. *Id.* at 3:19–21. “[S]ystem 1 initiates a real-time monitoring procedure of the patient’s breathing patterns.” *Id.* at 4:9–10, 4:13–14. The ’009 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 4:14–18. The ’009 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 4:19–23. According to the ’009 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 4:23–27. The ’009 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 4:30–32, 4:38–54.

The ’009 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. *Id.* at 5:55–57. The ’009 patent further describes an embodiment in which “system 1 may include a neural

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network coupled to the processing arrangement 24 and the sensors 23 for identifying the state of the patient.” *Id.* at 7:37–40.

D. Illustrative Claim of the '009 Patent

Petitioner challenges claims 1–30 of the '009 patent. Pet. 1. Claims 1, 14, and 24 are independent. Ex. 1001, 9:34–12:34. Claim 1 is illustrative 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 be supplied to a patient;
 - 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 by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state, wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state, wherein the processing arrangement determines the patient has transitioned between an awake state and an asleep state when a combination of obstructions are detected.

Ex. 1001, 9:34–61.

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E. References and Testimony

Below we provide an abbreviated summary of the qualifications of Dr. Jason Kirkness, who offered testimony in support of Petitioner in place of Dr. Khosrow Behbehani.⁴ We also provide an abbreviated summary of the qualifications Dr. Jason H. T. Bates, who offered testimony in support of Patent Owner. Additionally, in the table below we identify the primary references relied upon by Petitioner, as well as the exhibits corresponding to the declarations and deposition testimony in the record for Dr. Behbehani, Dr. Kirkness, and Dr. Bates.

Dr. Kirkness indicates he is “the Senior Vice President of Medical and Clinical Affairs” at a medical technology company and that his “career has focused on technology and devices to diagnose, monitor, and treat chronic respiratory-related diseases and disorders, including obstructive sleep apnea, chronic obstructive airway diseases, and acute respiratory diseases.”

Ex. 1046 ¶ 2. Dr. Kirkness indicates he received a Bachelor of Science degree in Biology from the University of Western Sydney, Kingwood,

⁴ The Petition was originally supported by a declaration from Dr. Behbehani. In his declaration, Dr. Behbehani stated he is “a Professor in the Bioengineering Department at the University of Texas at Arlington, specializing in the design of sleep apnea therapy equipment, the design of CPAP systems for flow delivery, and biosignal process algorithms.” Ex. 1003 ¶ 3. After institution, Petitioner informed the Board that Dr. Behbehani was unable to continue to serve as an expert in this proceeding (Paper 23), and, with our authorization (Paper 26), Petitioner replaced Dr. Behbehani with Dr. Kirkness, who adopted substantially the entirety of Dr. Behbehani’s prior opinions. Ex. 1046 ¶¶ 1, 28 (adopting paragraphs 20–28, 32–80, and 84–280 of Dr. Behbehani’s Declaration (Exhibit 1003)). In this Decision we cite to the Declaration of Dr. Behbehani (Ex. 1003) with the understanding that the opinions expressed were adopted and, therefore, are attributable to Dr. Kirkness.

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Australia in 1996, a Bachelor of Science degree in Physiology from the University of Western Sydney, Australia in 1997, and a Ph.D. in Medicine from the University of Sydney, Camperdown, Australia in 2003. *Id.* ¶¶ 3–5. Dr. Kirkness states he was part of the faculty at the School of Medicine at John Hopkins University from 2009 until 2017, and then worked at or served as a consultant, and continues to work at various healthcare/medical companies. *Id.* ¶¶ 11–13, 16, 17. He states he is “a named inventor on two patent applications for quantifying inspiratory and expiratory airflow,” and has published over 50 articles in peer-reviewed journals, including “findings relating to medical devices and systems and methods for assessing the physiological characteristics of breathing during wakefulness and sleep.” *Id.* ¶¶ 15, 19.

Dr. Bates states that he is a “Professor of Medicine, Molecular Physiology & Biophysics, and Electrical & Biomedical Engineering at the University of Vermont.” Ex. 2005 ¶ 1. Dr. Bates indicates he received a Bachelor of Science degree in Physics from the University of Canterbury, Christchurch, New Zealand in 1978; a Ph.D. degree in Medicine from the University of Otago, Dunedin, New Zealand in 1981; and a D.Sc. degree from the University of Canterbury, Christchurch, New Zealand in 1994. *Id.* ¶¶ 5, 6, 8. He states he has spent “nearly 40 years focusing on research into lung mechanics and pathophysiology,” and that his “more than 330 published scientific papers focus on this subject, including sleep.” *Id.* ¶ 4. In addition to his research work at various universities, Dr. Bates states he is named on ten issued patents and patent applications, seven of which concern methods for controlling and/or measuring breathing. *Id.* ¶¶ 4, 14. Dr. Bates states he has designed studies on constant positive airway pressure

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(“CPAP”) in patients, developed software and supervised research relating to “the computational analysis of breathing patterns.” *Id.* ¶¶ 10–12.

The table below identifies the exhibits corresponding to the asserted references and witness testimony.

References and Witness Testimony⁵	Date	Ex. No.
U.S. Patent No. 5,245,995 (“Sullivan995”)	Sept. 21, 1993	1005
WO 01/05460 A1 (“Sullivan460”)	Jan. 25, 2001	1006
U.S. Patent No. 7,168,429 B2 (“Matthews”)	Jan. 30, 2007	1007
U.S. Patent No. 5,490,502 (“Rapoport502”)	Feb. 13, 1996	1008
Declaration of Dr. Khosrow Behbehani	May 31, 2022	1003
Declaration of Dr. Jason P. Kirkness	Mar. 8, 2023	1046
Declaration of Dr. Kirkness in Support of Reply	July 28, 2023	1051
Deposition Transcript of Dr. Kirkness, Vol. I	Mar. 29, 2023	2012
Deposition Transcript of Dr. Kirkness, Vol. II	Mar. 30, 2023	2013
Declaration of Dr. Jason Bates ⁶	Apr. 21, 2023	2005
Deposition Transcript of Dr. Bates, Vol. I	June 22, 2023	1052
Deposition Transcript of Dr. Bates, Vol. II	June 23, 2023	1053

⁵ The table identifies only a select number of documents particularly pertinent to this Decision. *See, e.g.*, Paper 55 (Patent Owner’s Updated List of Exhibits); Paper 58 (Petitioner’s Updated Exhibit List). A complete identification of the papers and exhibits that form the record of this case is available in the docket of this proceeding.

⁶ Dr. Bates provided corrections to citations in his declaration. Ex. 1048.

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F. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds (Pet. 3–4):

Claims Challenged	35 U.S.C. §	References/Basis
1–11, 13–21, 23–28, 30	103(a)	Sullivan995, Sullivan460
12, 22, 29	103(a)	Sullivan995, Sullivan460, Matthews
1–11, 13–21, 23–28, 30	103(a)	Rapoport502, Sullivan460
12, 22, 29	103(a)	Rapoport502, Sullivan460, Matthews

II. ANALYSIS

A. Legal Standard of Obviousness

Petitioner contends under four grounds that the Challenged Claims would have been obvious.⁷ Pet. 3–4. 35 U.S.C. § 103(a) sets forth as follows:

[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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

⁷ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because an application related to the application from which the ’009 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of § 103 applies. *See* Ex. 1001, code (63). No issue in this proceeding turns on the applicable version of the statute and the outcome of this Decision would be the same regardless of which version of the statute applies.

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differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re Nuvasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016); *see also Pers. Web Tech., LLC, v. Apple, Inc.*, 848 F.3d 987, 993–94 (Fed. Cir. 2017) (“[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention”) (alteration in original) (quoting *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)).

B. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Petitioner contends that a person of ordinary skill in the art would have had “at least a bachelor’s degree in mechanical engineering, biomedical

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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. 13 (citing Ex. 1003 ¶ 81). 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.* (citing Ex. 1003 ¶ 82). Patent Owner does not dispute Petitioner’s definition of the person of ordinary skill in the art. PO Resp. 12.

We find that the ’009 patent and the cited prior art references reflect the appropriate level of skill at the time of the claimed invention and that the level of appropriate skill reflected in these references and in the ’009 patent is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Claim Construction

In this *inter partes* review, claims are construed using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.100(b) (2021). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing claims in accordance with their ordinary and customary meaning, we take into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

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If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thorner v. Sony Comput. Entm’t Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only 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)).

Petitioner asserts that “the prior art meets each of the claim limitations under any reasonable construction.” Pet. 14. Petitioner proposes no express construction for any claim term with respect to the alleged obviousness of the Challenged Claims. *See id.* Patent Owner argues several claim terms require construction: “troubled wakefulness,” “analyzes the data to determine the patient’s breathing patterns,” and “analyzing . . . the indication of the patient’s breathing patterns to determine the sleep state of a patient.” PO Resp. 29–33. We address each of these terms below.

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I. “troubled wakefulness”

Dependent claims 12 and 22 each recite, “wherein the awake state is a troubled wakefulness state.” Ex. 1001, 10:26–27; 11:17–18. Dependent claim 29 recites, “wherein applying a lower pressure when the patient is in an awake state comprises applying a lower pressure when the patient is in a troubled wakefulness state.” *Id.* at 12:28–31.

In the Petition, Petitioner did not expressly construe “troubled wakefulness,” but did analyze and address the prior art to identify the teachings of the prior art that Petitioner contends teach these limitations of the claims. *See, e.g.*, Pet. 22–27. In the Patent Owner Response, Patent Owner argues that “troubled wakefulness” is a “state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.” PO Resp. 30. Patent Owner’s proposed construction is supported by the Specification of the ’009 patent, which describes the breathing pattern for “troubled wakefulness” as “characterized by irregular[] 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.” Ex. 1001, 4:54–59. Petitioner agrees with Patent Owner’s proposed construction. Pet. Reply 16 (citing PO Resp. 30); *see also* Tr. 11:22–24 (Petitioner stating during oral argument that “[b]oth parties agree that troubled wakefulness is a state in which the breathing pattern is irregular, indicating that the patient is both awake and either anxious or uncomfortable”). We adopt Patent Owner’s undisputed construction of “troubled wakefulness” because it is consistent with the Specification of the ’009 patent.

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2. *“analyzes the data to determine the patient’s breathing patterns”*

Claims 1 and 14 each recite “analyzes the data to determine the patient’s breathing patterns.” Ex. 1001, 9:34–61, 10:30–58. In claims 1 and 14, “the data” is “data corresponding to the flow of breathable gases directed to the patient and indicative of the patient’s breathing patterns.” *Id.*

In the Petition, Petitioner did not expressly construe “analyzes the data to determine the patient’s breathing patterns,” but did analyze and address the prior art to identify the teachings of the prior art that Petitioner contends teach this limitation. *See, e.g.*, Pet. 26–27. In the Patent Owner Response, Patent Owner argues that “analyzes the data to determine the patient’s breathing patterns” should be construed to mean “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.”⁸ PO Resp. 30–31. Patent Owner also refers to “the values of the parameters and the order which they appear in time” in its proposed construction as “both the amplitude structure and the temporal structure of a breath-by-breath parameter time series.” *Id.* at 2. As borne out through Patent Owner’s

⁸ Patent Owner also includes what it describes as the “Entire Claim with Claim Constructions” in which Patent Owner inserts its proposed construction into the language of claim 1 and states that “[s]hould the Board adopt the above constructions, including that proposed by Patent Owner, independent claim 1 would read as follows.” PO Resp. 33–34. To be clear, Patent Owner could have filed a motion to amend the claim language, but did not do so. *See* 37 C.F.R. § 42.121 (“Amendment of the Patent”). Thus, the notion that claim 1 would “read” as Patent Owner suggests if its proposed construction were adopted is misplaced, because construing claim language does not equate to rewriting the claim.

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arguments in response to Petitioner’s challenges and as further elaborated in Patent Owner’s Sur-reply, Patent Owner contends that “analyzing the breathing patterns” requires analysis of “both the amplitude and temporal structures.” PO Resp. 41; *see also id.* at 3, 9–10, 37–38; PO Sur-reply 3–7 (asserting that the Challenged Claims require analysis of both amplitude structure and temporal structure). Petitioner disputes this proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2. For the reasons that follow, we agree with Petitioner.

a. Arguments Presented by the Parties

To explain why “analyzing the breathing patterns” should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the [S]pecification” of the ’994 patent.⁹ PO Resp. 31 (citing Ex. 2005 ¶ 138); *see also* PO Sur-reply 13 (Patent Owner argues that, according to Dr. Bates, “‘breathing pattern’ has no ordinary meaning and ‘is an extremely general term.’”) (citing Ex. 1052, 108:25–109:7). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apneas and hypopneas in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters and the order in which they appear in time.” PO Resp. 31 (citing Ex. 2005 ¶ 138).

⁹ Patent Owner cites the “’994 Patent, 2:12–19,” which we understand was intended to be a citation to the ’009 patent (4:38–47) at issue in this proceeding. Patent Owner makes the same mistake multiple times elsewhere in its Response, which we understand also were intended to refer to the ’009 patent. *See* PO Resp. 31–32. We do not include Patent Owner’s incorrect citations in this Decision, but have considered the corresponding correct portions of the ’009 patent in our evaluation of Patent Owner’s arguments.

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Patent Owner points to the description of Figures 7 and 8 of the '009 patent in support of its construction. *Id.* at 31–32 (citing Ex. 2005 ¶¶ 139–140). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient's airflow, but no periodic irregularity in breath size. Ex. 1001, 4:54–61. Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. *Id.* at 5:17–30.

According to Patent Owner, “[t]his methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns” and focuses “on a determination of ‘the sequence of parameters of a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time.’” PO Resp. 32 (citing Ex. 2005 ¶ 139); *see also* PO Sur-reply 4 (citing Ex. 1001, 4:54–61; Ex. 2005 ¶ 139) (asserting that the '009 patent describes Figure 7 as showing “[b]oth amplitude and temporal structures are likewise described when examining specific flow waveforms”). Patent Owner further argues that the description of Figure 8 in the Specification “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 32 (citing Ex. 2005 ¶ 140); PO Sur-reply 1, 5–12; Ex. 2005 ¶¶ 67–76.

Additionally, Patent Owner suggests the Specification's discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the

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patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. PO Resp. 32–33 (citing Ex. 2005 ¶ 142).

Turning to the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’009 [p]atent.” PO Sur-reply 3; *see also id.* at 7–16 (arguing that distinguishing troubled wakefulness from REM sleep requires assessing both amplitude and temporal structure). First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” PO Sur-reply 3–4 (quoting Ex. 1001, 4:38–46) (citing Ex. 2005 ¶ 138). Patent Owner maintains that the descriptions of the waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of waveforms. *Id.* at 4–6 (citing Ex. 1001, 4:54–61, 5:25–34, 6:33–39; Ex. 1052, 81:17–23, 180:1–15; Ex. 2005 ¶¶ 138–140). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’009 [p]atent,” but contends that they “are not obligatory.” *Id.* at 5. Patent Owner asserts that the ’009 patent’s “enablement hinges on its ability to distinguish between all awake and asleep states,” and, otherwise, “incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 6.

Second, Patent Owner asserts that during the prosecution of the related ’344 patent, the applicant responded to a rejection by arguing that the prior art, in that instance, “failed to discern between regular wakefulness and troubled wakefulness.” PO Sur-reply 7. Patent Owner argues that it is

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necessary to integrate “both amplitude and temporal structure analyses to distinguish all awake and asleep states.” *Id.*

Third, Patent Owner argues that “a patentee does not need to rigidly define terms, but can imply their own meaning.” *Id.* Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by Figure 7 – a flow waveform indicating troubled wakefulness.” *Id.* at 7 (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the Specification “provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “since ‘analyzes the data’ is followed by ‘to determine the patient’s breathing patterns,’ some of which occur in the asleep state and some of which occur in the awake state, this further implies that these states can be separated from one another.” *Id.* at 7–8 (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22). Patent Owner contends that, “[g]iven the separation between awake and asleep states discussed in the ’009 [p]atent, [Patent Owner’s] construction is integral for discerning the difference and applying the correct pressure,” because, without doing so, it “could result in inappropriate pressure administration.” *Id.* (citing Ex. 1052, 179:23–25; Ex. 2005 ¶ 140).

Patent Owner also argues that extrinsic evidence supports its proposed construction. PO Sur-reply 8–13. Based on Dr. Bates’s testimony, Patent Owner asserts that “[b]y assessing *only amplitude*” the waveforms of troubled wakefulness and REM sleep “appear indistinguishable,” but “their temporal structure (order in time) . . . offers differentiation.” *Id.* at 10 (citing Ex. 2005 ¶ 75). Patent Owner contends it proves its argument by showing that if the “temporal structure” of the REM sleep waveform is “rearranged in

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time,” then the resulting “time series has a random appearance that *cannot be distinguished* from troubled wakefulness.” *Id.* at 10 (citing Ex. 2005 ¶ 76). Patent Owner reasons that “amplitude structure and temporal structure convey independent information” and both must be considered in an analysis or “the awake state can be confused with an asleep state.” *Id.* at 11 (citing Ex. 2005 ¶ 69). According to Patent Owner, it is “Dr. Bates[’s] illustrations [that] clearly present the problem solved by the ’009 [p]atent.” *Id.* at 11–12.

According to Patent Owner, construing “analyzing breathing patterns” to include “*any type*” of breathing pattern analysis, as suggested by Dr. Kirkness, is “impractical, as it might even encompass using a mirror to check for breaths.” PO Sur-reply 13 (citing Ex. 1051 ¶ 16).¹⁰ Specifically, Patent Owner argues as follows:

Dr. Bates examined the specification to determine what breathing characteristics were crucial to analyzing the breathing pattern with respect to the invention’s essence. [Ex. 1052], 24:20-25, 25:1-13. He determined that a [person of ordinary skill in the art], after reading the ’994 [p]atent, would understand that analyzing breathing patterns, with respect to the ’009 [p]atent, would need to confer the ability to distinguish between troubled wakefulness and REM sleep. *Id.*, 111:22-25 – 112:1-21. [Patent Owner’s] construction evidences the understanding of a [person

¹⁰ Patent Owner also states that “Dr. Kirkness argues that the ’009 [p]atent is indefinite, especially regarding the measurement of airflow waveforms and temporal/amplitude aspects,” and that “Petitioner has never directly raised indefiniteness.” PO Sur-reply 12. We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths.” *Id.* at 13.

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of ordinary skill in the art] – that analyzing breathing patter[n]s requires analysis of amplitude and temporal structures.

Id. at 13–14.

Petitioner proposes that we construe “analyzes the data to determine the patient’s breathing patterns” in accordance with its plain and ordinary meaning because “nothing in the intrinsic record” limits the term “to analysis of either or both amplitude and temporal structures—instead, the claims, specification, and prosecution history all use these terms in accordance with their plain and ordinary meaning.” Pet. Reply 4–6 (citing *CCS Fitness*, 288 F.3d at 1366). Petitioner asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the specification or during prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” *Id.* at 6 (quoting *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* at 6–7. Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, the patentee must ‘clearly express an intent’ to redefine the term.” *Id.* at 7 (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends “[n]o such intent exists here” and Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* (citing Ex. 1051 ¶ 24).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner’s] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as proposing “a lengthy construction” and then construing “its own construction to inject two arbitrary requirements: that the processor must analyze (1) ‘the value of the

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parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.* at 3–4 (citing PO Resp. 8–10, 30–33; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert decided based on his personal experience, as opposed to that of a [person of ordinary skill in the art].” *Id.* at 4 (citing Ex. 1053, 271:10–14).

Responding to Patent Owner’s citations to the Specification, Petitioner contends that the Specification “further confirms that the terms encompass any type of breathing pattern analysis” and “states that ‘[t]here are a number of characteristics of the patient’s breathing patterns that may be taken into account in making such a determination’ . . . and does not limit the analysis to any particular characteristic.” Pet. Reply 5 (citing Ex. 1001, 2:35–38, 4:19–30, 4:54–59, 5:27–30, Figs. 3–8; Ex. 1051 ¶¶ 16–24; Ex. 1052, 28:4–30:21; Ex. 2005 ¶¶ 47–48, 139–141). Petitioner also contends that “[t]he [S]pecification further states that the flow sensors ‘detect the rate of airflow’ to and from the patient, and provide ‘[s]ignals corresponding to the airflow’ to a processing arrangement for processing.” *Id.* (second alteration in original) (citing Ex. 1001, 3:55–61). Thus, Petitioner asserts the Specification “confirms that analyzing temporal structures is not required.” *Id.*

Petitioner also addresses the prosecution history of patents related to the ’009 patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5–6. Petitioner asserts that, in responding to different office actions, the applicant

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did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1009, 404; Ex. 1002, 91, 128).

Next, Petitioner contends Patent Owner’s extrinsic evidence, in the form of Dr. Bates’s testimony, contradicts the intrinsic record and should be disregarded. Pet. Reply 6–11. Petitioner asserts Dr. Bates “performed a ‘crude’ analysis by ‘approximating’ the amplitudes of each breath in the figures ‘estimat[ing] by eye . . . the size of those individual breaths.’” *Id.* at 7 (first alteration in original) (citing Ex. 1052, 75:11–76:14, 78:16–79:19). Petitioner argues that Dr. Bates’s “analysis has no basis in the patent.” *Id.* at 8. Petitioner presents five arguments in rebuttal in regard to the testimony of Dr. Bates:

(1) Dr. Bates’s analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the ’009 [p]atent would have derived [Patent Owner’s] construction.” *Id.* at 8 (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* (citing Ex. 1052, 75:11–76:14; 78:16–79:19; 90:8–91:11).

(2) Dr. Bates’s analysis is based on his own expertise in “digital signal processing,” not from the viewpoint of a person of ordinary skill in the art who would not necessarily have such experience. *Id.* at 8–9 (citing Ex. 1052, 25:3–27:6, 52:2–25, 64:4, 208:16–21; Ex. 1053, 240:8–242:8; 243:3–8).

(3) Dr. Bates’s analysis contradicts the ’009 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM

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sleep without requiring temporal analysis. *Id.* at 9 (citing Ex. 1001, 4:47–54; 5:27–30; Ex. 1056, 9:55–10:3 (claim 5), 10:20–24 (claim 8); Ex. 1051 ¶¶ 25–33).

(4) “Dr. Bates admitted the waveforms of Figures 7–8 are merely exemplary.” *Id.* (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do not limit the broader claim terms of the patent.” *Id.* at 9–10 (citing *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004)).

(5) Dr. Bates “could not explain ‘parameter’ or provide an objective basis to define a ‘sequence’ and ‘series’ used in [Patent Owner’s] proposed construction” and “admitted that [Patent Owner’s] construction would exclude breathing patterns recited in dependent claims.” *Id.* at 10–11 (citing Ex. 1052, 182:1–184:19, 247:5–11; Ex. 1053, 288:14–289:3). Thus, Petitioner asserts we “should discount []expert testimony that is clearly at odds . . . with the written record of the patent.” *Id.* at 11 (quoting *Phillips*, 415 F.3d at 1318).

b. Analysis of the Claim Language

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14. Claims 1 and 14 recite, in relevant part, “a processing arrangement” which “analyzes the data to determine the patient’s breathing patterns.” Ex. 1001, 9:34–61, 10:31–58. As reflected, claims 1 and 14 do not recite “a sequence of parameters” or “a series of breaths” or “examining the values of the parameters and the order in which they appear in time” or any analysis of amplitude or temporal structure. *See id.* Claims 1 and 14 do not recite distinguishing between “troubled wakefulness” and “REM sleep” or between “all awake and asleep states,” and does not require applying “the

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correct pressure” under all circumstances. Rather, the relevant portions of claims 1 and 14 recite that the processing arrangement analyzes data, without specifically reciting how the analysis is performed. The phrase in each of claims 1 and 14, however, does recite the purpose of the analysis—to determine the patient’s breathing patterns—but does not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a significant number of limitations not recited expressly nor suggested by “analyzes the data to determine the patient’s breathing patterns.”

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citation omitted). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech.*, 923 F. 3d at 1044 (Fed. Cir. 2019).

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of claims 1 and 14, nor does Patent Owner argue that it explicitly defined “analyzes the data to determine the patient’s breathing patterns” in the Specification. *See, e.g.*, PO Resp. 30–33. We determine that there is no disavowal nor any explicit lexicographic definition of “analyzing the breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we

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should construe the phrase as Patent Owner proposes. PO Sur-reply 3, 7–8 (citing, *inter alia*, *AstraZeneca AB v. Mut. Pharm. Co., Inc.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004)). We disagree.

In *AstraZeneca AB*, the United States Court of Appeals for the Federal Circuit reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d at 1339–40 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors “deliberately acted as their own lexicographers” to limit the claim term “solubilizer” to surfactants, the Federal Circuit explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The Federal Circuit rejected AstraZeneca’s argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

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The Specification of the '009 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner's proposed construction, the Specification makes no reference to "a sequence of parameters" (PO Resp. 30–31) or an analysis of "the amplitude and *temporal* structures of a breath-by-breath time series" (*id.* at 4) or any of the other terms set forth in the proposed construction. *See id.* at 30–33. Further, it is undisputed that words like "amplitude" and "temporal" do not appear in the Specification. *See* Pet. Reply 7 ("The terms 'amplitude' and 'temporal' do not appear anywhere."); PO Sur-reply 5 ("Petitioner rightly observes that terms like 'amplitude' and 'temporal' are not explicitly named in the '009 [p]atent."); Ex. 1051 ¶ 24 (Dr. Kirkness stating that "amplitude," "temporal," and "sequence" do not appear anywhere in the '009 patent, which "describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures"). Patent Owner directs us to portions of the Specification for what Patent Owner characterizes as the process of analyzing breathing patterns. PO Resp. 31 (quoting Ex. 1001, 4:38–47). The portion of the Specification Patent Owner relies upon describes "[i]ndices of sleep disordered breathing." Ex. 1001, 4:38–47. The cited text does not describe analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how "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

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due to distress or anxiousness).” Ex. 1001, 4:19–23. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns, etc. in the determining the patient’s state.” *Id.* at 4:23–27. There is no mention that analyzing breathing patterns requires analysis of a sequence of parameters and the order in which they appear in time or an analysis of amplitude and temporal aspects of the waveform.

The Specification further describes, in an embodiment, “processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern.” Ex. 1001, 7:10–13. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal aspects of the waveform.

Patent Owner also relies on the description of Figures 7 and 8 of the ’009 patent in support of its construction. PO Resp. 31–32; PO Sur-reply 4–10. Figures 7 and 8 illustrate airflow waveforms from a patient indicative of a period of troubled wakefulness and a period of REM sleep with irregular breathing, respectively. Ex. 1001, 3:32–36, 4:47–59, 5:18–21. Patent Owner relies on Figures 7 and 8 to support its argument that “an analysis of both the amplitude and temporal structures of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.” PO Resp. 45; *see also* PO Sur-reply 9 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Figures 7 and 8, however, depict one particular example of an awake state (i.e., troubled wakefulness) and one particular example of a sleep state (i.e., REM sleep), respectively.

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Ex. 1001, 3:33–37. But Patent Owner’s analysis does not address Figures 3–6 of the ’009 patent. PO Resp. 30–33; PO Sur-reply 1–15. Figures 3 and 4 show waveforms of a patient during “regular wakefulness” and “regular sleep,” respectively. *Id.* at 3:22–26. Figures 5 and 6 show waveforms from a sleeping patient indicative of “hypopnea” and “repetitive obstructive apnea,” respectively. *Id.* at 3:27–31. Patent Owner provides no evidence or explanation why amplitude and temporal aspects of a waveform are required to distinguish regular wakefulness from regular sleep or hypopnea or repetitive obstructive apnea.¹¹

Claims 1 and 14 recite “analyzes the data to determine the patient’s breathing patterns.” Ex. 1001, 9:34–61, 10:30–59. Claims 1 and 14 are not limited to distinguishing *solely* between troubled wakefulness and REM sleep, but rather encompass other states, such as those shown in Figures 3–6. Thus, even if we were to agree with Patent Owner that an analysis of one or both of the amplitude and temporal structures of a waveform is required to distinguish between troubled wakefulness and REM sleep, that determination, alone, would be insufficient to narrow the scope of claims 1 and 14, which by their own terms are broad enough to include specific types of awake or sleep states other than troubled wakefulness and REM sleep. For the same reasons, we are not persuaded that the additional limitations Patent Owner seeks to read into the claims are necessary to “fully enable” the claims, as Patent Owner asserts.

¹¹ Nor does Patent Owner direct us to any portion of the prosecution history of the ’009 patent that it contends supports its proposed construction of “analyzes the data to determine the patient’s breathing patterns.” *See generally* PO Resp.

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Having reviewed the intrinsic evidence, we next consider the extrinsic evidence, and specifically the testimony of Dr. Bates.¹² Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 30–33 (citing Ex. 2005 ¶¶ 138–140, 142). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. *See* Ex. 2005 ¶¶ 138–140, 142. Rather, Dr. Bates reads portions of the Specification and extrapolates (by taking several unsupported leaps) that the ’009 patent “implicitly demands certain parameter measurements.” PO Sur-reply 7 (citing Ex. 1052, 44:6–20).

Although expert testimony is legitimate to consider when construing claims, the Federal Circuit has cautioned that because it “is generated at the time of and for the purpose of litigation,” it “can suffer from bias that is not present in intrinsic evidence.” *Phillips*, 415 F.3d at 1318. And, extrinsic evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* at 1317 (internal quotations and citations omitted). In the context presented here, Dr. Bates’s testimony is not supported sufficiently by the intrinsic record or other extrinsic evidence (e.g., objective extrinsic evidence) and, therefore, even though we have considered it fully, we give it little weight.

¹² Although the Parties briefly address the prosecution history of patents related to the ’009 patent, we do not find the discussion thereof informative on this specific issue.

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For the reasons explained above, we determine that Patent Owner did not implicitly define the phrase “analyzes the data to determine the patient’s breathing patterns,” as proposed, because Patent Owner has failed to show any sufficient evidence that the ’009 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner’s contentions in light of all the evidence of record, we do not adopt Patent Owner’s proposed construction; instead, we apply the plain and ordinary meaning of “analyzes the data to determine the patient’s breathing patterns” in our consideration of the issues before us.

3. *“analyzing ... the indication of the patient’s breathing patterns to determine the sleep state of a patient”*

Claim 24 recites, in relevant part, “analyzing ... the indication of the patient’s breathing patterns to determine the sleep state of a patient.” Ex. 1001, 11:21–12:18. Patent Owner treats this limitation for purposes of its proposed claim construction, without further explanation, as though it were identical to the “analyzes the data to determine the patient’s breathing patterns” limitation of claims 1 and 14 discussed above.¹³ See PO Resp. 30–33. However, claim 24 is directed to analyzing “the indication of the

¹³ Petitioner states that “[e]ach independent claim [of the ’009 patent] requires a processing arrangement that analyzes a patient’s breathing patterns.” Pet. Reply 2. That, however, does not resolve the issue here, which is whether the language of claim 24 varies from claims 1 and 14 in a material way. For purposes of our subsequent analysis, we consider whether Petitioner has shown how the prior art renders obvious each of the Challenged Claims, not whether the varying claim language means exactly the same thing.

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patient’s breathing patterns,” not analyzing “the data to determine the patient’s breathing patterns” as recited by claims 1 and 14. To the extent Patent Owner’s proposed construction for claims 1 and 14 of “analyzes the data to determine the patient’s breathing patterns” applies to the “analyzing ... the indication of the patient’s breathing patterns to determine the sleep state of a patient” limitation of claim 24, as Patent Owner suggests, we disagree with Patent Owner’s arguments at least for the same reasons discussed above with regard to claims 1 and 14.

4. *Additional Claim Terms*

The Parties do not dispute the construction of any other claim terms and we find that no other claim terms require express construction for purposes of rendering 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.*, 200 F.3d 795 at 803)).

D. *Scope and Content of the Asserted Prior Art*

Petitioner relies on Sullivan995, Sullivan460, Matthews, and Rapoport502 to show that the Challenged Claims are unpatentable. Pet. 9–13. Each of these references is summarized in relevant part below.

1. *Summary of Sullivan995*

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.

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Figure 1A of Sullivan995 is reproduced below.

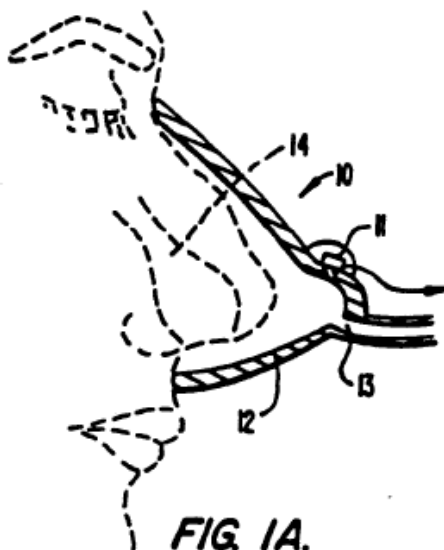


Figure 1A depicts snoring detection device 10. *Id.* at 8:47. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a nose mask.” *Id.* at 8:47–49. Sullivan995 explains that “[a]ir, being inhaled by the patient, enters the nasal passageways 14 through 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.

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Figure 3 of Sullivan995 is reproduced below.

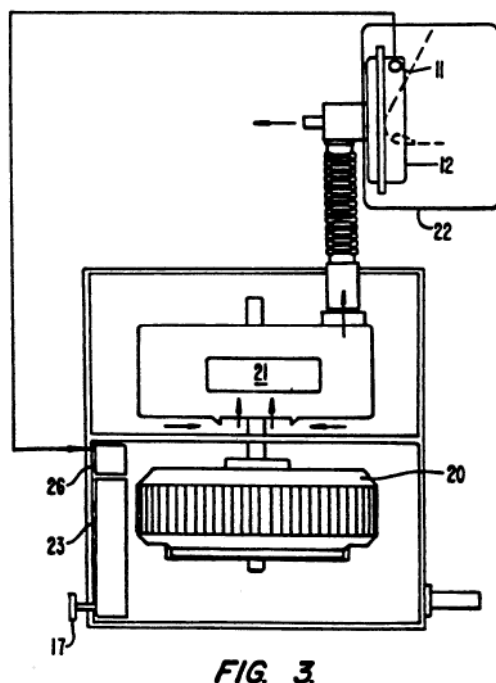


Figure 3 of Sullivan995 shows a CPAP apparatus. Ex. 1005, 9:57–58. The CPAP apparatus shown in Figure 30 includes motor 20 that drives blower 21. *Id.* at 9:58–59. Sullivan995 explains that “[t]he speed of the motor 20 is controlled by an electronic speed control unit 23.” *Id.* at 9:59–60. The CPAP 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 9:66–10:3. 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

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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, 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.

Figure 12 of Sullivan995 is reproduced below.

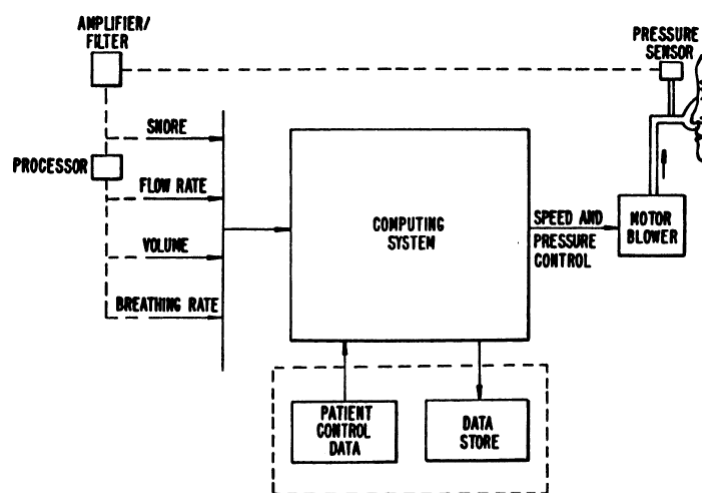


FIG. 12.

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

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,

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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. *Summary of Sullivan460*

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.” *Id.* at 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 [Sullivan 995].” *Id.* at 6:22–24.

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Figure 2 of Sullivan460 is reproduced below.

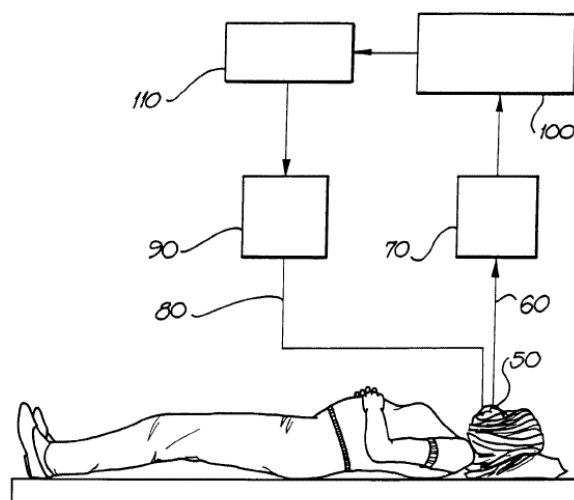


FIG. 2

Sullivan460's "Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia." Ex. 1006, 10:7–8. In Figure 2, patient 30 is lying on bed 40 and wears mask 50 over her nose 50. *Id.* at 10:8–9. Mask 50 is connected via 80 to nCPAP apparatus 90. *Id.* at 10:9–10. 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 10:10–12. 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 as follows:

[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

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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.

Patent Owner argues that “Sullivan460 is not enable, and not prior art.” PO Resp. 18 (citing *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1354 (Fed Cir. 2003). Enablement “is not a requirement to prove invalidity under §103.” *Amgen*, 314 F.3d at 1357 (under §103, “a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein”).

3. *Summary of Matthews*

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

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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 AutoCPAP 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.

4. *Summary of Rapoport502*

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.

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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 a 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.

E. Alleged Obviousness over Sullivan995 and Sullivan460

Petitioner contends that the subject matter of claims 1–11, 13–21, 23–28, and 30 of the ’009 patent would have been obvious over the combination of Sullivan995 and Sullivan460, and presents a limitation-by-limitation analysis of each claim (other than claim 17), along with reasons supporting both the asserted combination and a reasonable expectation of success. Pet. 14–52. Petitioner’s contentions are supported by the declaration testimony of Dr. Kirkness. Ex. 1046 ¶ 28 (adopting the opinions set forth in Ex. 1003 ¶¶ 85–195).

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Patent Owner argues, with support from Dr. Bates, that Sullivan995 and Sullivan460 fail to teach various claim limitations of the Challenged Claims, that “there is neither a motivation to combine these references nor a reasonable expectation of success that any combination would yield a successful result,” and that “secondary considerations, in particular a long felt but unresolved need, support a finding of non-obviousness.” PO Resp. 35–36; Ex. 2005 ¶¶ 143–214. Below we address differences between the prior art and the Challenged Claims, beginning with claim 1 as Petitioner argues in the Petition, and then we turn to the rationale in support of the combination and objective evidence of nonobviousness. For the reasons that follow we determine that Petitioner has shown by a preponderance of the evidence that the subject matter of claims 1–11, 13–21, 23–28, and 30 would have been obvious over the combination of Sullivan995 and Sullivan460.

1. Differences Between the Subject Matter of Claims 1–11, 13–21, 23–28, and 30 and the Combination of Sullivan995 and Sullivan460

Petitioner shows that the combination of Sullivan995 and Sullivan460 teaches each of the limitations of claims 1–11, 13–21, 23–28, and 30. Pet. 14–52. We adopt Petitioner’s analysis as our own findings and conclusions as to these claims. *Id.* Consistent with Petitioner’s discussion in the Petition, we begin with an analysis of Petitioner’s contentions concerning each of the limitations of independent claim 1, followed by the remaining claims challenged. We further focus our discussion below on the reasons why we disagree with Patent Owner’s arguments in opposition, which likewise focus on claim 1. *See In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016) (noting that “[t]he Board, having found the only

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disputed limitations together in one reference, was not required to address undisputed matters”); *see also* PO Resp. 35–44 (presenting no additional opposition arguments directed specifically to claims 2, 5–11, 13–21, 23–28, and 30 aside from the arguments directed to claim 1).

a. Claim 1

Petitioner contends the subject matter of claim 1 would have been obvious over the combination of Sullivan995 and Sullivan460. Pet. 24–36. We address each of the limitations of claim 1 below and determine Petitioner has shown by a preponderance of the evidence how each was suggested or taught by the asserted art.

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 shows that Sullivan995 teaches a CPAP system that corresponds to a positive airway pressure system for delivery of a flow of breathable gas and that a person of ordinary skill in the art would have understood that “CPAP delivers ‘positive’ airway pressure relative to atmospheric pressure.” Pet. 18 (citing Ex. 1005, Abstract, 1:33–36, 2:15–19, 9:57–58, Fig. 3). Petitioner also shows that “Sullivan995’s CPAP system includes a nose mask 12 ‘fluidly sealable to the [patient’s] nasal air passages’ and is ‘for delivery of air to the patient’s nasal passages’ and thereby assists in treating a sleeping disorder in a patient by providing air pressure at a level “to ‘prevent the onset of apnea.’” *Id.* at 18–19 (citing Ex. 1005, 1:20–48, 5:12–34, 10:31–35, 10:67–11:4, 11:15–20, 11:23–43, claim 6); *see also* Ex. 1003 ¶¶ 95–97. Patent Owner does not dispute

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Petitioner's contentions as to the preamble of claim 1.¹⁴ See PO Resp. 36–40.

a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient;

Petitioner shows that “Sullivan995’s CPAP system includes a variable speed motor 20 that drives a blower 21,” corresponding to the recited flow generator. Pet. 19 (citing Ex. 1003 ¶ 98; Ex. 1005, 9:57–64). Patent Owner does not dispute Petitioner’s contentions as to this limitation. See PO Resp. 36–40.

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 shows that microphone 11 of Sullivan995 is a differential pressure sensor corresponding to the recited flow sensor. Pet. 19–22 (citing Ex. 1003 ¶¶ 99–100; Ex. 1005, 9:64–66, Fig. 3). Petitioner further shows that microphone 11 “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 19 (emphasis omitted) (quoting Ex. 1005, 3:21–30). Petitioner relies on Figure 3 of Sullivan995 to illustrate that microphone 11 may be “*located in a flow path of the positive treatment pressure flow of breathable gases.*” *Id.* at 20 (citing, e.g., Ex. 1003 ¶¶ 101–103; Ex. 1005, 10:1–3, Figs. 3, 7).

Petitioner also shows that Sullivan995’s microphone 11 “performs a ‘form

¹⁴ Patent Owner states in its Response in regard to claim 1 that “the missing claim limitations are highlighted in red,” yet Patent Owner’s replication of claim 1 in its Response contains no red highlighting. PO Resp. 36–37.

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of measurement’ (*measuring data*) by ‘detecting snoring sounds’ and ‘other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate (*indicative of the patient’s breathing patterns*).’” *Id.* at 22 (citing Ex. 1003 ¶ 104; Ex. 1005, 3:21–33, 11:5–20, 15:56–64, Fig. 3); *see also id.* at 23–24 (contending that Sullivan995’s Figures 2A and 9 disclose data indicative of a patient’s breathing patterns) (citing, e.g., Ex. 1003 ¶¶ 105–109; Ex. 1005, 13:10–21, 18:27–31, 18:50–53). Patent Owner does not dispute Petitioner’s contentions as to this limitation. *See* PO Resp. 36–40.

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,

Petitioner shows that Sullivan995’s “combination of an amplifier/filter/processor unit 26 and speed control unit 23” corresponds to the recited processing arrangement. Pet. 24 (citing Ex. 1005, Figs. 3, 12). Petitioner also shows that “microphone 11 (flow sensor) provides its *measured data* to processor unit 26,” and processor unit 26 “generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.” *Id.* at 24–26 (citing Ex. 1003 ¶¶ 110, 112, 113; Ex. 1005, 10:3–6, 10:37–66, 11:55–62, 17:3–4, 17:6–12). Petitioner also shows from Sullivan995 that in “generating this control signal, the processor unit 26 (included in the *processing arrangement*) therefore *analyzes data [from the sensor] to determine the patient’s breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.” *Id.* at 26–27 (emphasis omitted) (citing Ex. 1005, 12:67–13:8) (further stating that the “computing system (including processing unit 26 and speed controller 23)

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‘analyses 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.’”); Ex. 1003 ¶ 114. We address all of Patent Owner’s arguments regarding the recited “processing arrangement” below.

the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient,

Petitioner shows that Sullivan995 teaches that “[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. 27 (citing Ex. 1005, 9:58–64, 10:6–12, 10:40–46, 10:55–58). Petitioner further shows that Sullivan995 teaches 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.* at 28 (citing Ex. 1005, 10:37–46). As Petitioner explains, because Sullivan995’s determination to increase the output air pressure “is made when ‘respond[ing] to a snore, or a snore pattern,’” the determination is “made based, at least in part, on the determined breathing patterns of the patient,” as required by the above limitation of claim 1. *Id.* (emphasis omitted) (citing Ex. 1005, 10:55–58). We address all of Patent Owner’s arguments regarding the recited “processing arrangement” below.

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wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state, wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state,

Petitioner shows that Sullivan995 teaches that “the output pressure of the CPAP unit increases in response to detection of snoring,” and that “the pressure is decreased ‘if an extended period of snore free breathing occurs’ by ‘automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected.’” Pet. 29–32 (citing Ex. 1005, 10:10–16, 10:31–46, 10:47–61; 14:17–20, Figs. 3, 13). Petitioner relies on Sullivan460 as teaching that “‘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.’” *Id.* at 30 (alteration in original) (citing Ex. 1003 ¶ 134; Ex. 1006, 7:3–7, 7:10–12, 7:17–19). Petitioner further shows that Sullivan460’s “switching means responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery,” and that “‘a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep,’ where the pressure for the second mode is higher than the pressure for the first mode.” *Id.* (alterations in original) (citing Ex. 1006, 6:30–7:12, claims 22–28, 43–46). Petitioner further explains, and we agree, that “[b]ecause Sullivan460 only enters the higher-pressure second mode when the patient is asleep, Sullivan460 discloses automatically delay[ing] the onset of a pressure increase to the patient upon a determin[ation] that the patient is in an awake state.” *Id.* at 30–31 (alterations in original) (emphasis omitted) (citing Ex. 1003 ¶ 34). Thus, Petitioner shows that Sullivan995’s CPAP system, as

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modified by the teaching of Sullivan460, “changes from a low pressure to a higher pressure when an asleep state is detected, meaning that *the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.*” *Id.* at 32 (citing Ex. 1003 ¶ 139; Ex. 1006, 6:30–7:22, 10:8–16, 14:7–36). We address all of Patent Owner’s arguments regarding the recited “processing arrangement” below.

wherein the processing arrangement determines the patient has transitioned between an awake state and an asleep state when a combination of obstructions are detected.

Petitioner shows that Sullivan995 teaches when a “‘sequence of snores is detected,’ a signal is generated so that the speed control unit 23 increases the speed of the fan motor and the output pressure is increased,” and “expressly illustrates that four (4) snores . . . are detected,” corresponding to a combination of obstructions. Pet. 33 (citing Ex. 1005, 8:36–44, 10:13–28, 14:17–20, 14:48–15:15, Fig. 13). Petitioner further shows that Sullivan460 teaches that “flow rate measurement means 70 detects multiple ‘interruptions,’ . . . and are a *combination of obstructions.*” *Id.* at 35 (citing Ex. 1006, 10:12–16, Fig. 1). Petitioner explains, and we agree, that “Sullivan460 detects the occurrence of ‘two or more interruption cycles’ (which are regularly-spaced obstructions) in the upper inspiratory flow rate and the treatment means treats the airway limitation on the detection of said at least two interruption cycles.” *Id.* (citing Ex. 1003 ¶¶ 147–148; Ex. 1006, 3:20–23).

We now turn to all of Patent Owner’s arguments regarding the recited “processing arrangement” limitations. Patent Owner argues that “[w]ithout considering both the amplitude and temporal structures based on the

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parameters and examining the values of the parameters and the order which they appear in time, such as the two states – troubled wakefulness and REM sleep – cannot be distinguished.” PO Resp. 38 (citing Ex. 2005 ¶ 78).

Patent Owner further argues that “Sullivan995 does not teach the signal processing necessary to distinguish between sleep and awake states, because making this distinction requires consideration of both the amplitude structure and temporal structure of a time series of breath-by-breath parameters derived from the flow waveform.” *Id.* (citing Ex. 2005 ¶¶ 77, 78, 144, 152–154); Ex. 2012, 79:3–23). According to Patent Owner, “a snoring pattern is not a breathing pattern,” because “[b]reathing patterns are used to determine if a subject is awake or asleep,” and Sullivan995 cannot make that determination since the “criteria that Sullivan995 uses to increase pressure all involve a single parameter value or an average of a parameter over a time interval,” and “these are aspects of the amplitude structure of a time series composed of the parameter from breath to breath and as such they are insufficient to determine the state of the patient.” *Id.* at 38–39 (citing Ex. 2005 ¶¶ 155, 163, 164; Ex. 2012, 73:20–22); *see also* PO Sur-reply 16 (arguing that “snoring sounds . . . are not breathing patterns). Patent Owner also argues that “the ‘snore’, ‘flow rate’, ‘breathing rate’ or ‘time interval’, and ‘volume’ data in Sullivan995 are all single parameters which, by themselves, do not constitute a breathing pattern,” because they “are all aspects of the amplitude structure of a breath-by-breath parameter time series and cannot on their own provide the ability to determine an awake state versus an asleep state.” PO Resp. 39 (citing Ex. 2005 ¶ 166).

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Additionally, Patent Owner argues as follows:

Sullivan460 does not teach how to transition between an awake state and an asleep state because it discloses only the analysis of the amplitude structure of the time series, i.e. how to make decisions based on average values derived from inspiratory flow within a single breath. *See* EX2005, ¶ 183, citing Sullivan460, 7:18-19. The detection of a combination of obstructions by the CPAP system in Sullivan995 does not mean that the patient has transitioned between an awake state and an asleep state, as paragraph 148 of the Kirkness Declaration contends. *See* EX2005, ¶ 184. The patient may already have been asleep for some time before the obstructions were detected, meaning the transition could have happened an arbitrary time previously. Sullivan460 does not teach if, during the pre-obstruction phase, the patient was awake or asleep because Sullivan460 does not teach how to distinguish between an awake state and an asleep state as claimed. *Id.*

Id. at 39–40.

In its Reply, Petitioner argues that Patent Owner’s arguments are based on Patent Owner’s “erroneous proposed claim construction,” and that Sullivan460 discloses “a sleep sensor which senses whether or not the patient is asleep,” which can “register that a patient is asleep when there is a reduced average airflow in the patient’s upper airway.” Pet. Reply 11–12 (quoting Ex. 1006, 7:4, 7:17–19). Petitioner further argues that “Dr. Bates agreed that amplitude is a parameter extracted from a flow waveform, and Sullivan995’s analysis is ‘an example of a kind of analysis of a breathing

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pattern you could do.””¹⁵ *Id.* at 12 (citing Ex. 1052, 74:11–24, 184:20–185:7; Ex. 1005, Fig. 8).

We agree with Petitioner that Patent Owner’s arguments do not distinguish claim 1 from the combined teachings of Sullivan995 and Sullivan460 because the arguments are premised on Patent Owner’s proposed claim construction for “analyzing the breathing patterns,” which we do not accept for the reasons provided above. *See supra* Section II.C.2. Further, Patent Owner’s arguments are not commensurate with the scope of claim 1, which does not require distinguishing between troubled wakefulness and REM sleep. *See* PO Resp. 37–40. We find Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches each of the limitations of claim 1.

b. Claims 2–11, 13–16, 18–21, 23–28, and 30

Petitioner asserts that the subject matter of claims 2–11, 13–16, 18–21, 23–28, and 30 would have been obvious over Sullivan995 and Sullivan460 and provides a detailed analysis of each of these claims with argument and evidence in support thereof. Pet. 14–52. Patent Owner does not raise any arguments directed specifically to claims 2–11, 13–21, 23–28, and 30 aside from the arguments Patent Owner directs to claim 1. *See generally* PO Resp. For the same reasons explained above in our discussion

¹⁵ Petitioner argues in its Reply that the combination of Sullivan995 and Sullivan460 teaches a “processing arrangement,” as recited in claim 1, “[e]ven if ‘analyzing the breathing patterns’ in the challenged claims required analysis of both amplitude and temporal structures.” Pet. Reply 13–14. Because we find that claim 1 does not require analysis of both amplitude and temporal structures, we need not address Petitioner’s alternative arguments or Patent Owner’s opposition on this particular issue in its Sur-reply.

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of claim 1, we determine that Petitioner shows by a preponderance of the evidence that the combination of Sullivan995 and Sullivan 460 teaches each limitation of claims 2–11, 13–16, 18–21, 23–28, and 30. We adopt Petitioner’s arguments and cited evidence as to these claims and limitations as our own determination and basis. *See* Pet. 14–52.

c. Claim 17

Claim 17 depends from claim 14 and further recites “wherein the three or more obstructions are a regular period of three or more obstructions.” Ex. 1001, 10:63–65. Petitioner contends the subject matter of claim 17 would have been obvious over Sullivan995 and Sullivan460, but does not otherwise specifically address claim 17 in detail in the Petition. *See* Pet. 3 (stating “Ground 1: Claims 1-11, 13-21, 23-28, and 30 are obvious under 35 U.S.C. § 103 over Sullivan995 in view of Sullivan460” (footnotes omitted)). Thus, Patent Owner was provided notice in the Petition that Petitioner asserts the subject matter of claim 17 would have been obvious over the combination of Sullivan995 and Sullivan460.

The additional subject matter of claim 17 is substantively the same as subject matter recited in claims 2, 3, and 27. Ex. 1001, 9:62–65, 10:63–65, 12:22–24. Petitioner specifically explains how the combination of Sullivan995 and Sullivan460 teaches the subject matter of claims 2, 3, and 27. Pet. 36–40, 51. Patent Owner does not dispute the sufficiency of Petitioner’s showing with regard to the additional limitations of any of claims 2, 3, 17, or 27, beyond the arguments Patent Owner provides with regard to claim 1. *See generally* PO Resp.

In particular, claim 2 recites “wherein the combination of obstructions are a regular period of obstructions,” claim 3 recites “wherein the

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combination of obstructions are three or more obstructions,” and both claims 2 and 3 depend from claim 1. *Id.* at 9:62–65. Claim 27, which depends from claim 24, recites “wherein pattern of at least three obstructions are a regular period of three or more obstructions.” Ex. 1001, 12:22–24. In its contentions specifically addressing claim 27, Petitioner refers back to its contentions directed to claims 2 and 3. Pet. 51.

In particular, Petitioner shows that Sullivan995 depicts a “sequence of snores,” which corresponds to a combination of obstructions, and illustrates the four snores in Figure 13 as “spaced evenly apart in time,” corresponding to a regular period of obstructions. Pet. 36–37 (citing Ex. 1003 ¶ 152; Ex. 1005, 14:65–15:1). Thus, Petitioner has shown in the Petition how Sullivan995 teaches “the three or more obstructions are a regular period of three or more obstructions,” as required by claim 17. *See id.* Although we acknowledge claim 17 is not separately addressed in detail in the Petition, Petitioner specifically addresses the subject matter of claim 17 in the Petition through its discussion of claims 2, 3, and 27, and, for the reasons provided above, shows by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches the subject matter of claim 17, which Patent Owner has not disputed. *Id.*

2. *Reasons Supporting Obviousness Over Sullivan995 and Sullivan460*

In support of the combination of the teachings of Sullivan995 and Sullivan460, Petitioner states that “Sullivan460 incorporates Sullivan995 by reference and states that its ‘flow rate measurement means and [] treatment means may be constructed together as part of one apparatus [with Sullivan995].” Pet. 30 (first two alterations in original) (citing Ex. 1003 ¶ 133; Ex. 1006, 6:22–29); *see also id.* at 14–17 (discussing motivations

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supporting the asserted combination of teachings from Sullivan995 and Sullivan460, as well as why a person of ordinary skill in the art would have had a reasonable expectation of success). According to Petitioner, the asserted combination advantageously “would apply a low pressure upon wake-up, adding to patient comfort and decreasing the likelihood the patient will remove the mask” due to uncomfortably high pressure as suggested by Sullivan995, which explains “that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period).” *Id.* at 15 (citing Ex. 1005, 10:13–46, 14:45–64). Also, according to Petitioner, the asserted combination advantageously “would have resulted in higher therapeutic pressure being permitted as soon as the patient goes to sleep,” because “without such sleep detection” the “CPAP system may begin activating the higher pressure” either “too early . . . when the patient is still awake” or “too late . . . well after the patient has fallen asleep.” *Id.* at 32–33 (citing Ex. 1003 ¶¶ 140–141). Further, according to Petitioner, “[b]oth Sullivan995 and Sullivan460 suggest using multiple obstructions as a trigger for treatment,” obstructions “typically occur in groups during sleep,” and “verifying a sleep state would have avoided false positives that would occur when only a single obstruction is detected.” *Id.* at 35–36 (citing Ex. 1003 ¶¶ 149–151; Ex. 1005, 10:13–30, 14:65–15:17, Figs. 2, 9, 13; Ex. 1006, 3:20–23, Fig. 1).

Additionally, Petitioner contends that a person 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 16 (citing

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Ex. 1003 ¶ 92). We find Petitioner’s reasoning above supports the asserted combination of features from Sullivan995 and Sullivan460. We further consider Patent Owner’s arguments in opposition and do not agree with Patent Owner for the reasons provided below. *See* PO Resp. 40–42; PO Sur-reply 19–21.

First, Patent Owner argues that a person of ordinary skill “would not have recognized certain advantages with applying higher therapeutic pressure as soon as the patient goes to sleep, because Sullivan995 teaches ‘[l]ow airway pressures are also desirable before and during the early stages of each sleep period.’” PO Resp. 41–42 (citing Ex. 2005 ¶ 177, quoting Ex. 1005, 2:43–44). The portion of Sullivan995 relied on by Patent Owner, however, is discussing the background in the art, not the system taught by Sullivan995. Sullivan995 proceeds to state that “[p]resently available CPAP units do not address” the problems identified in Sullivan995, and that “there is a need to provide a CPAP device which will be more acceptable to the patient before and during initial sleep by operating at an initially low pressure but automatically increasing to an appropriate therapeutic pressure before apnea occurs.” Ex. 1005, 2:56–61; *see also id.* at 10:13–21 (“When a snore or sequence of snores is detected by the snoring detection means 22 a signal is generated. The speed control unit 23 increases the speed of the fan motor and the output pressure is increased.”). Sullivan995 also teaches that snoring “is a warning signal of the imminence of upper airway occlusion in patients that suffer obstructive sleep apnea,” and increases pressure when snoring is detected. Ex. 1005, 10:13–21; *see also* Ex. 1001, 9:59–61, 4:64–5:3 (describing a system that “determines the patient has transitioned

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between an awake state and an asleep state when a combination of obstructions are detected”).

Patent Owner argues that Sullivan460 teaches a CPAP system with sleep detection that “may begin activating the higher pressure *too early* because it cannot distinguish between an awake or an asleep state by analyzing a breathing pattern such as between troubled wakefulness and REM sleep.” PO Resp. 42 (citing Ex. 2005 ¶ 177). Patent Owner asserts that this “means the patient would be awake when the higher pressure is activated, causing discomfort and reducing the likelihood of compliance.” *Id.* Patent Owner further reasons that “the system should thus only apply pressure when the patient[] shows signs of becoming obstructed,” and a person of ordinary skill in the art “would not have recognized that Sullivan460 solved the problem of determining the proper time to increase pressure, because Sullivan460 does not teach how to detect an awake state versus an asleep state as claimed.” *Id.* (citing Ex. 2005 ¶¶ 178, 185–187).

We disagree with Patent Owner’s argument because it is premised on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns” requiring analysis of both the amplitude structure and the temporal structure, which we do not adopt for the reasons provided above. Moreover, the claims do not require distinguishing between troubled wakefulness and REM sleep, and Sullivan460 expressly teaches two modes of air delivery, explaining that as “soon as the patient goes to sleep (as determined by an appropriate sensing algorithm in the treatment means), the second treatment mode is activated.” Ex. 1006, 7:3–12. Patent Owner’s argument that Sullivan460’s “patient would be awake when the

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higher pressure is activated, causing discomfort and reducing the likelihood of compliance,” is contrary to the express disclosure of Sullivan460.

Based on our review of the arguments and evidence cited by Petitioner, and after considering Patent Owner’s arguments, we find Petitioner shows that one of ordinary skill in the art would have had sufficient reason with rational underpinning to combine Sullivan995 and Sullivan460 as asserted and would have had a reasonable expectation of success in doing so.¹⁶

3. *Objective Evidence of Nonobviousness*

The fourth *Graham* factor instructs that we must consider—apart from what the prior art itself would have suggested—whether objective evidence of nonobviousness (i.e., secondary considerations) may lead to a conclusion that the Challenged Claims would not have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (instructing that evidence of secondary considerations, when present, must always be considered in determining obviousness). Objective evidence of nonobviousness may include evidence of commercial success, licensing,

¹⁶ Patent Owner improperly argues for the first time in its Sur-reply that the asserted combination would have required “undue experimentation.” PO Sur-reply 20–21. Patent Owner’s alleged “undue experimentation” was not raised in Patent Owner’s Response. Petitioner did not have notice of the argument and was deprived of an opportunity to respond in its Reply. Accordingly, Patent Owner’s argument is improper and the issue is deemed waived. *See* Paper 17, 9 (stating that “Patent Owner is cautioned that any arguments not raised in the response may be deemed waived”); *see also* 37 C.F.R. § 42.23(b) (“A sur-reply may only respond to arguments raised in the corresponding reply.”). Moreover, we disagree with Patent Owner’s “undue experimentation” argument because it is premised on Patent Owner’s proposed construction requiring analysis of “both amplitude and temporal structure,” which we do not adopt for the reasons provided above.

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copying, praise by others, long felt but unresolved need, and failure or skepticism of others. *Graham*, 383 U.S. at 17–18. But, secondary considerations are only a part of the “totality of the evidence”; their mere existence does not control the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). Objective evidence of nonobviousness “may often be the most probative and cogent evidence in the record” and “may often establish that an invention appearing to have been obvious in light of the prior art was not.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

Patent Owner argues that evidence of nonobviousness exists in the form of long-felt need. PO Resp. 42–44. According to Patent Owner, since 1991 there has been “a need for patients to increase compliance with usage of their CPAP machines,” with patients complaining about “nocturnal awakenings” and “nasal issues.” *Id.* at 43 (citing Ex. 1036, 1, 5). Patent Owner further argues as follows:

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients’ compliance with CPAP treatment by noting that “the conventional PAP therapy [had] not taken sleep/wake state into account” and “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” ’994 Patent, 1:44-46, 65–65. Further, before the development of the claimed invention in the ’009 Patent, self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. *Id.* at 2:31-35. In fact, as of 2002, a [person of ordinary skill] was “not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters.” *See* Ex. 1010, 2:33–37. As such, the claimed invention solved a long felt but unresolved need – better

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compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 43–44 (first and second alterations in original).

Patent Owner further argues that conventional CPAP treatment “had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control.” PO Sur-reply 24–25 (citing Ex. 1001, 2:12–14; Ex. 1053, 296:22–297:15). According to Patent Owner, Dr. Bates’s testimony explained that “[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states.” *Id.* at 25 (citing Ex. 1052, 113:3–11, 115:22–116:10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by the ’009 patent’s “ability to distinctly identify when a patient is awake or asleep,” because a person of ordinary skill in the art “prior to the 994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and awake.” *Id.* at 25–26 (alteration in original) (citing Ex. 1052, 202:23–203:3).

a. Nexus

Objective evidence of nonobviousness “is only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). A “nexus” is a legally and factually sufficient connection between the objective evidence and the claimed invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*,

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938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 32–33 (PTAB Jan. 24, 2020) (precedential), *aff’d sub nom. Zaxcom, Inc. v. Lectrosonics, Inc.*, 2022 WL 499848 (Fed. Cir. Feb. 18, 2022). We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* at 32. If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 33 (quoting *Fox Factory*, 944 F.3d at 1373–75). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Id.* (citing *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011)). There is no requirement that the objective evidence of non-obviousness be tied exclusively to claim elements that are not disclosed in the prior art, and the claimed combination as a whole may serve as a nexus for the objective evidence. *Id.* (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)).

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Petitioner argues that “for secondary considerations to be accorded substantial weight, [Patent Owner] bears the burden of showing that a nexus exists between the claimed features of the invention and the evidence offered to show non-obviousness.” Pet. Reply 23 (citing *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). According to Petitioner, Patent Owner does not meet this burden because: 1) Patent Owner did not establish “a presumption of nexus” since Patent Owner did not identify any product tied to the objective evidence; 2) Patent Owner did not “demonstrate a nexus by showing that long-felt need was met as a ‘direct result of the unique characteristics of the claimed invention’”; 3) Patent Owner did not identify “any failed efforts to solve the problem before the invention”; and 4) Patent Owner does not point to disclosure in the ’009 patent that the “prior art recognized the need to analyze temporal and amplitude structures.” *Id.* at 23–25 (citations omitted).

Patent Owner purports to show nexus by asserting a long-felt need for the claimed system of the ’009 patent. First, Patent Owner has not argued that the presumption of nexus applies and we agree with Petitioner that Patent Owner is not entitled to a presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the Challenged Claims. Second, we address Patent Owner’s evidence of long-felt, but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the ’009 patent, absent the presumption.

b. Long-felt Need

In order to show a long-felt, but unmet, need *for the claimed invention*, the objective evidence must show that the need was a persistent

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one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). “Evidence of a long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would not have persisted had the solution been obvious.” *WBIP*, 829 F.3d at 1332.

Here, Patent Owner suggests increasing the comfort of the CPAP system is a goal to improve patient compliance with CPAP therapy. Patent Owner does not explain, however, why Sullivan460’s treatment means which “addresses ... the comfort of CPAP,” and “is an improvement over the prior art” because of the two modes of air delivery, does not meet the long-felt need identified by Patent Owner. *See* Ex. 1006, 7:7–16; *see also* Pet. 9–11. Thus, we agree with Petitioner that “[t]o the extent that any need existed, it was already satisfied.” Pet. Reply 24 (citations omitted).

Additionally, Patent Owner’s Response fails to identify any failed efforts to solve the problem before the invention and similarly fails to provide sufficient evidence that the ’009 patent satisfied the alleged need. Dr. Bates’s redirect testimony, which Patent Owner almost exclusively relied on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to “little or no weight.” 37 C.F.R. § 42.65(a). Patent Owner’s additional arguments regarding a supposed need for better compliance with CPAP therapy by detecting troubled wakefulness (*see* PO Resp. 43–44; PO Sur-reply 25–26) are not persuasive because detecting troubled wakefulness is not a requirement of any of claims 1–11, 13–21, 23–28, and 30. We agree with Petitioner that Patent Owner “did not provide any evidence that the claimed invention . . . resulted in better compliance in comparison with prior art

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systems,” and the prior art addressed the need for improved therapies “by detecting sleep and wake states, and lowering the pressure during wakefulness.” Pet. Reply 24 (citing Ex. 1006, 7).

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt need. As a result, we accord little weight to Patent Owner’s evidence of long-felt need.

4. *Collective Considerations of the Graham Factors*

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches each limitation of claims 1–11, 13–21, 23–28, and 30, that an ordinarily skilled artisan would have had a reason to combine features of both Sullivan995 and Sullivan460 as asserted to arrive at the claimed invention with a reasonable expectation of success when doing so, and that Petitioner’s evidence of unpatentability significantly outweighs the marginal evidence of long felt need provided by Patent Owner. On the whole, we find that the information provided in consideration of the *Graham* factors collectively demonstrates that Petitioner has shown by a preponderance of the evidence that claims 1–11, 13–21, 23–28, and 30 of the ’009 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Sullivan995 and Sullivan460.

F. *Alleged Obviousness over Sullivan995, Sullivan460, and Matthews*

Petitioner contends that the subject matter of claims 12, 22, and 29 would have been obvious over the combination of Sullivan995, Sullivan460, and Matthews. Pet. 52–55; Pet. Reply 16–18. Petitioner’s contentions are supported by the declaration testimony of Dr. Kirkness. Ex. 1046 ¶ 28 (adopting the opinions set forth in Ex. 1003 ¶¶ 196–206).

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Patent Owner argues, with support from Dr. Bates, that Petitioner’s proposed combination of Sullivan995 based on Sullivan460 and Matthews does not teach the limitations at issue, would not have been obvious, is unsupported by any motivation, and lacks a reasonable expectation of success. PO Resp. 44–50; PO Sur-reply 21–23; Ex. 2005 ¶¶ 215–235.

1. Differences Between the Subject Matter of Claims 12, 22, and 29 and the Combination of Sullivan995, Sullivan460, and Matthews

Claim 12, which depends from claims 1 and 11, and claim 22, which depends from claim 14, both further recite “wherein the awake state is a troubled wakefulness state.” Ex. 1001, 10:26–27, 11:17–18. Claim 29, which depends from claim 24, recites “wherein applying a lower pressure when the patient is in an awake state comprises applying a lower pressure when the patient is in a troubled wakefulness state.” *Id.* at 12:28–31.

Petitioner relies on Matthews as teaching the additional limitations of claims 12, 22, and 29.¹⁷ Pet. 52–55 (citing Ex. 1003 ¶¶ 196–206). In particular, Petitioner shows 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

¹⁷ Petitioner states that it relies on Matthews “[t]o the extent *the awake state is a troubled wakefulness state* would not have been obvious from Sullivan995 in view of Sullivan460” (Pet. 54), but Petitioner provides no substantive analysis in the Petition to show that claims 12, 22, or 29 would have been obvious over Sullivan995 only in view of Sullivan460. *See* Pet. 3 (identifying “Ground 1: Claims 1-11, 13-21, 23-28, and 30 are obvious under 35 U.S.C. § 103 over Sullivan995 in view of Sullivan460”). Accordingly, to the extent Petitioner’s challenge could be interpreted, in the alternative, as based on Sullivan995 and Sullivan460 (without Matthews), Petitioner has not shown that claims 12, 22, or 29 would have been obvious over Sullivan995 only in view of Sullivan460.

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becomes unstable.” *Id.* at 54 (citing Ex. 1007, 21:34–44, 21:63–22:1). According to Petitioner, “Matthews’s description of erratic breathing when the patient is awake and in distress is consistent with the ’009 [p]atent’s description of *troubled wakefulness* as ‘awake and anxious or distressed.’” *Id.* (citing Ex. 1001, 4:47–59). Petitioner further explains that in Matthews, when erratic breathing is detected, the “operation of the auto-CPAP controller” is interrupted and “the pressure delivered to the patient” is decreased. *Id.* at 54–55 (citing Ex. 1007, 21:57–61, 23:67–24:1).

Patent Owner argues that “Sullivan 460 and Matthews” do not render obvious “wherein the awake state is a troubled wakefulness state.” PO Resp. 45 (citing Ex. 2005 ¶¶ 220–225). Patent Owner, however, offers no evidence that Matthews fails to teach “a troubled wakefulness state,” as shown by Petitioner. *See id.* at 44–51. Instead, Patent Owner returns to its arguments based on its proposed claim construction, asserting that “Sullivan995 does *not* disclose” certain features because “Sullivan995 cannot distinguish between all the various breathing patterns when analyzing the breathing patterns, including REM sleep versus troubled wakefulness.” *Id.* at 45 (citing Ex. 2005 ¶ 221). Patent Owner again argues that “amplitude structure . . . is not enough,” and that “an analysis of both the amplitude and temporal structures . . . is required to distinguish between troubled wakefulness and REM sleep.” *Id.* at 46. According to Patent Owner, Matthews “cannot distinguish between an awake or asleep state by analyzing breathing patterns, let alone troubled wakefulness from REM sleep,” because “[d]istinguishing between troubled wakefulness and REM sleep requires the analysis of both the amplitude and temporal structures of a time series.” *Id.* at 47–48 (citing Ex. 2005 ¶¶ 227, 228). Patent Owner suggests

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that Matthews could confuse “erratic breathing” during REM sleep with “erratic breathing” during “troubled wakefulness,” potentially resulting in “pressure being increased in troubled wakefulness.” *Id.* at 48. To the extent Patent Owner’s arguments have any bearing on whether Petitioner has shown how Matthews teaches “troubled wakefulness,” we do not agree with Patent Owner’s arguments for the same reasons provided above, namely, because we do not adopt Patent Owner’s claim construction requiring an analysis of amplitude and temporal structure. We have reviewed Petitioner’s evidence in light of the Parties’ agreed-on construction of “troubled wakefulness” and find that Petitioner has shown how Matthews teaches the limitations of claims 12, 22, and 29. Ex. 1003 ¶¶ 201–206; Ex. 1007, Abstract, 21:34–44, 21:57–22:1, 23:67–24:1, 24:2–6; 25:23–25, 40:25–30; Ex. 1051 ¶¶ 37–47.

2. *Reasons Supporting Obviousness over Sullivan995, Sullivan460, and Matthews*

In support of the combination of the teachings of Sullivan995, Sullivan460, and Matthews, Petitioner contends a person of ordinary skill in the art would have been motivated to modify the system of Sullivan995 and Sullivan460 in view of Matthews so that the processing arrangement in Sullivan995 delays the onset of a pressure increase when the patient has a troubled wakefulness state and lowers the pressure when a patient transitions to a troubled wakefulness state. Pet. 52 (citing Ex. 1003 ¶ 96). According to Petitioner, a person of ordinary skill would have recognized the advantages of detecting troubled wakefulness corresponding to erratic breathing to “allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* at 53 (citing Ex. 1003 ¶ 197). Petitioner notes that Sullivan995 is

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“concerned with the patient’s comfort, and already discloses it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible.” *Id.* (citing Ex. 1005, 2:31–39).

Petitioner next contends that there would be a reasonable expectation of success in combining Sullivan995, Sullivan460, and Matthews *Id.* at 53–54. Petitioner explains that because data from Matthews’ flow sensor “are monitored to control the pressure” and Sullivan460 discloses lowering the pressure in an awake state, a person of ordinary skill in the art “would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient.” *Id.* at 53 (citing Ex. 1003 ¶¶ 198–199). According to Petitioner, the modification to Sullivan995 and Sullivan460 “is a combination of 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.” *Id.* at 54 (citing Ex. 1003 ¶ 200).

In opposition, Patent Owner does not address the reasons and motivations advanced by Petitioner in support of the asserted combination. *See* PO Resp. 44–50. Instead, Patent Owner argues that there would have been no motivation “to combine the teaching of Matthews,” because “distinguishing between troubled wakefulness and REM sleep requires the analysis of both the amplitude and temporal structures of a breath-by-breath parameter time series.” *Id.* at 48 (citing Ex. 2005 ¶ 229). Patent Owner also argues “there is no reasonable expectation of success,” because a person of ordinary skill “would not have known that determining a troubled wakefulness state” and “distinguishing it from REM sleep, would have

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required the analysis of both the amplitude and temporal structures of a time series,” that Sullivan995 “does not teach how to distinguish between REM sleep and troubled wakefulness,” and “implementing” the limitations of claims 12, 22, and 29 would have required “methods of digital signal processing that go beyond a combination of known prior art elements.” *Id.* at 49–50 (citing Ex. 2005 ¶¶ 218, 219, 232–235). These arguments are unavailing because they turn on Patent Owner’s proposed claim construction, which we do not adopt for the reasons provided above. *See supra* Sections II.C.2 and II.E.2. Based on our review of the arguments and evidence cited by Petitioner, and after considering Patent Owner’s arguments and evidence cited by Patent Owner, we find Petitioner shows that one of ordinary skill in the art would have had sufficient reason with rational underpinning to combine Sullivan995, Sullivan460, and Matthews, as asserted, and would have had a reasonable expectation of success in doing so.

3. *Objective Evidence of Nonobviousness*

Patent Owner relies on the same evidence and arguments concerning objective evidence of nonobviousness, and specifically long-felt need, with regard to obviousness over the combination of Sullivan995, Sullivan460, and Matthews as Patent Owner argues in regard to obviousness over the combination of Sullivan995 and Sullivan460, discussed above. *See* PO Resp. 50. We considered Patent Owner’s arguments and evidence in the context of obviousness over Sullivan995 and Sullivan460. We also indicated that Patent Owner includes arguments on long-felt need specifically tied to detecting troubled wakefulness. In addition to the reasoning discussed in the context of obviousness over Sullivan995 and

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Sullivan460 above, which we incorporate herein, we add that, as shown by Petitioner, Matthews already taught detecting troubled wakefulness and thus, in the context of claims 12, 22, and 29, Patent Owner has not explained why the alleged long-felt need was not met by Matthews. Moreover, for the reasons discussed above (*see supra* Section II.E.3) we determine the record evidence shows minimal, if any, evidence of long-felt need. As a result, we accord little weight to Patent Owner's evidence of long-felt need.

4. *Collective Considerations of the Graham Factors*

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews teaches each limitation of claims 12, 22, and 29, that an ordinarily skilled artisan would have had reasons with rational underpinning to combine features of Sullivan995, Sullivan460, and Matthews as asserted to arrive at the claimed invention with a reasonable expectation of success when doing so, and that Petitioner's evidence of unpatentability significantly outweighs the marginal evidence of long-felt need provided by Patent Owner. On the whole, we find that the information provided in consideration of the *Graham* factors collectively demonstrates that Petitioner has shown by a preponderance of the evidence that claims 12, 22, and 29 of the '009 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Sullivan995, Sullivan460, and Matthews.

G. *Alleged Obviousness over Rapoport502, Sullivan460, and Matthews*

Petitioner contends that the subject matter of claims 1–11, 13–21, 23–28, and 30 would have been obvious over Rapoport502 and Sullivan460, and that the subject matter of claims 12, 22, and 29 would have been obvious

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over Rapoport502, Sullivan460, and Matthews. Pet. 55–76. We determined, as discussed above, that the Challenged Claims were shown to be unpatentable by a preponderance of the evidence based on obviousness over the combination of Sullivan995 and Sullivan460 and the combination of Sullivan995, Sullivan460, and Matthews. *See supra* Sections II.E and II.F. As a result, we do not reach the merits of obviousness over Rapoport502 and Sullivan460 or over Rapoport502, Sullivan460, and Matthews, and we make no determination of whether Petitioner has shown the unpatentability of any of the Challenged Claims as obvious over these references.

III. PATENT OWNER’S MOTION TO EXCLUDE

Patent Owner seeks to exclude Exhibits 1035, 1049, 1051, and 1056–1059, portions of Exhibits 1003, 1046, and 1052, as well as portions of the record relying on these disputed exhibits, *e.g.*, in the Petition and Reply. PO MTE 1–11; PO MTE Reply 1–5. Petitioner opposes the motion. PO MTE Opp. 1–12. For the following reasons we deny Patent Owner’s Motion to Exclude.

A. Exhibits 1003 and 1046

Exhibit 1003 is the declaration of Petitioner’s original declarant, Dr. Behbehani, and Exhibit 1046 is the substitute declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s Declaration. *See* Ex. 1046 ¶ 28. Patent Owner argues that certain portions of Exhibit 1003 should be excluded and that the same portions of Exhibit 1003 that Dr. Kirkness adopts should be excluded. PO MTE 2–5; PO MTE Reply 1. More specifically, Patent Owner seeks to exclude paragraphs 38, 39, 42, 45, 49, 71, and 212 of Exhibit 1003 on the premise that they are

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based upon hearsay and “not any independent analysis.” PO MTE 2–5. Further, according to Patent Owner, hearsay may not be a basis for an expert opinion when “the expert adds nothing to the out-of-court statements other than transmitting them to the factfinder.” *Id.* at 4. In opposition, Petitioner argues, among other things, that “[a]n expert such as Dr. Kirkness may base an opinion on any facts or data that the expert ‘has been made aware of or personally observed,’” that “the facts or data ‘need not be admissible’ if an expert in the particular field would ‘reasonably rely’ on those kinds of facts or data,” and that Dr. Kirkness “would certainly rely on peer-reviewed articles regarding the results of a study testing a CPAP machine.” PO MTE Opp. 3. Because we do not rely on the challenged portions of Exhibit 1003 in rendering this Decision, we deny Patent Owner’s Motion to Exclude as to these portions of Exhibit 1003 and the corresponding portions of Exhibit 1046, as moot.

B. Exhibits 1035 and 1059

Exhibit 1035 is an article titled “Continuous positive airway pressure: new generations,” published Clinics in Chest Medicine in 2003. Patent Owner argues that Dr. Kirkness relied on Exhibit 1035 to show that “machines for delivering PAP therapy were on the market that included one or more sensors and a central processing unit that could detect breathing patterns and adjust pressure as appropriate based on those breathing patterns.” PO MTE 6–7 (citing Ex. 1003 ¶ 47 (citing Ex. 1035, 2)).

Exhibit 1059 is an article titled “Control of breathing during sleep” published in Clinical Science in 1984. Patent Owner argues that Dr. Kirkness relied on Exhibit 1059 to show that a person of ordinary skill in the art “knew ‘that a processor could be programmed to analyze breathing

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patterns that fall below or above certain preset levels of airflow rate to indicate awake or asleep states’ and that analysis of temporal structures was not necessary.” PO MTE 9–10 (quoting Ex. 1051 ¶¶ 12, 32).

According to Patent Owner, any use of Exhibit 1035 or Exhibit 1059 “is therefore an improper incorporation by reference” through Exhibit 1003 or Exhibit 1051, “violating 37 C.F.R. § 42.6(a)(3), which prohibits incorporating arguments by reference from one document into another document.” PO MTE 6, 9. Patent Owner’s argument has no merit.

Petitioner explains in opposition that the Petition cites to the portions of the testimony of Dr. Kirkness that discusses Exhibit 1035 as an “overview of the technology of the challenged patent,” and is relevant to the state of the art. PO MTE Opp. 8.

In reply, Patent Owner argues that such a citation to Exhibit 1035 is “akin to an improper incorporation.” PO MTE Reply 3. Patent Owner also argues in reply that Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply 5. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his reply declaration were relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” PO MTE Opp. 12.

As Petitioner notes, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and neither Exhibit 1035 nor Exhibit 1059 is “an argument.” PO MTE Opp. 8–9, 12. Because Patent Owner shows no persuasive basis to

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exclude Exhibit 1059, Patent Owner's Motion to Exclude as to Exhibit 1059 is denied.

C. Exhibits 1056–1058

Exhibit 1056 is the '344 patent. Exhibit 1057 is the '539 patent. Exhibit 1058 is the '994 patent. Each of these patents is at issue in related matters. *See supra* Section I.B. Patent Owner argues that Petitioner relies on these exhibits “to support its claim construction arguments for ‘analyzing the breathing patterns,’” and that they were introduced as “new evidence” with Petitioner's Reply. PO MTE 5. According to Patent Owner, the '539 patent issued after the '009 patent “negating any probative value and rendering the evidence highly irrelevant and prejudicial.” Further, according to Patent Owner, the exhibits are “inadmissible under 37 C.F.R. § 42.61(a)” and “subject to exclusion under F.R.E. 403.” *Id.*; *see also* PO MTE Reply 2 (arguing that Petitioner could have used these exhibits in its Petition “but did not” and they should, therefore, be excluded).

In the Petition, Petitioner argued for “‘using the same claim construction standard that would be used’ in district courts,” i.e., the ordinary and customary meaning. Pet. 13. In its Response, Patent Owner argued that the language of the term “analyzes the data to determine the patient's breathing patterns” should be construed as “‘determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 30–31. Petitioner's first and only opportunity to respond to Patent Owner's construction is in its Reply. And Petitioner's Reply does not change the theory, prior art, or evidence relied upon to challenge the subject claims as

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compared to that which was presented in the Petition. Therefore, Petitioner properly relies on Exhibits 1056–1058 in support of its contention in the Petition that the plain and ordinary meaning of the claim term “analyzing the breathing patterns” should be applied. *See* PO MTE Opp. 6–7; Pet. 13. We therefore deny Patent Owner’s Motion to Exclude as to Exhibits 1056–1058.

D. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2. Patent Owner argues that the priority date of this patent is after the priority date of the ’009 patent and should be excluded as irrelevant and “not prior art.” PO MTE 6–7; PO MTE Reply 4. Patent Owner also argues it should have been introduced prior to Petitioner’s Reply. PO MTE 7. Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. PO MTE Opp. 9–10. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates’s credibility, not as prior art, and find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision and deny Patent Owner’s Motion to Exclude as to Exhibit 1049 as moot.

E. Exhibit 1051

Exhibit 1051 is the Declaration of Dr. Kirkness in support of Petitioner’s Reply. Patent Owner argues that Exhibit 1051 should be excluded because it raises “new issues” and “new evidence that could have been presented in a prior filing.” PO MTE 7–8; PO MTE Reply 1–2. The only “example,” provided by Patent Owner in support of its argument is that Dr. Kirkness “uses Exhibits 1049 and 1056–1058 in the exact same manner” as they are used in Petitioner’s Reply and should therefore be excluded for

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the same reasons discussed above. PO MTE 7–8. For the reasons discussed above for Exhibits 1049 and 1056–1058, we deny the Motion to Exclude as to Exhibit 1051.

F. Exhibit 1052

Exhibit 1052 is the transcript of Dr. Bates’s deposition testimony. Patent Owner argues that the portions of Exhibit 1052 “focusing on patent eligible subject matter and whether certain products, such as processors, infringe by meeting the limitations of the ’009 [p]atent should be excluded as irrelevant.” PO MTE 8–9 (citing Ex. 1052, 62:7–23, 63:15–25, 64:1–5, 117:9–25, 118:1–11, 146:4–12); PO MTE Reply 4–5. Petitioner argues that the testimony of Dr. Bates is relevant to obviousness issues in this proceeding, that there was “no discussion of ‘infringement’ or ‘patentable subject matter,’” and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 10–11. We agree with Petitioner for the same reasons provided by Petitioner and deny Patent Owner’s Motion to Exclude as to the challenged portions of Exhibit 1052.

IV. PETITIONER’S MOTION TO EXCLUDE

Petitioner seeks to exclude portions of Exhibit 1053, the deposition testimony of Dr. Bates. Pet. MTE 1–10; Pet. MTE Reply 1–5. Specifically, Petitioner moves to exclude parts of the redirect deposition testimony of Dr. Bates concerning secondary considerations of nonobviousness. Pet. MTE 1–2. Petitioner argues that the redirect testimony of Dr. Bates “was outside the scope of Petitioner’s cross-examination in contravention of [Federal Rule of Evidence] 611(b) and 37 C.F.R. § 42.53 (d)(5)(ii).” *Id.* at 1. Petitioner does not seek to exclude the entirety of Dr. Bates’s redirect testimony concerning secondary considerations but only the specific

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portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes the Motion. Pet. MTE Opp. 1–10. For the following reasons, we deny Petitioner’s Motion to Exclude.

Petitioner contends that it “did not cross-examine Dr. Bates about any secondary considerations and timely objected to [Patent Owner’s] line of questioning during redirect as being outside the scope.” Pet. MTE 1–2 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9); *id.* at 4 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9). Petitioner further contends that Patent Owner’s “introduction of belated expert testimony into the record via the Sur-Reply is improper and the evidence must be excluded.” *Id.* at 2 (citing *Comcast Cable Commc’ns, LLC v. Rovi Guides, Inc.*, IPR2019-01413, Paper 34 at 4 (PTAB Sept. 16, 2020); *IBM v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 15 at 5 (PTAB Feb. 2, 2015)); *see also id.* at 5–6 (identifying portions of the Sur-reply citing to the disputed testimony). Further, according to Petitioner, “Dr. Bates’ declaration included no discussion of secondary considerations.” *Id.*

Petitioner argues that “FRE 611(b) prohibits redirect examination that goes beyond the scope of cross-examination questions and testimony” and Patent Owner’s “redirect examination did just that.” Pet. MTE 8. Petitioner next argues that “the portions of Dr. Bates’ redirect testimony that Petitioner seeks to exclude from the record . . . have no bearing on ‘matters affecting the witness’s credibility.’” *Id.* (citations omitted). According to Petitioner, Patent Owner “does not rely on Dr. Bates’ testimony to counter a challenge to his credibility.” *Id.* at 9. Petitioner also contends that 37 C.F.R. § 42.53(d)(5)(ii) “similarly prevents a party from expanding the scope of redirect examination beyond that of cross-examination.” *Id.*

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In opposition, Patent Owner argues Petitioner's Motion to Exclude is improper for two reasons. First, Patent Owner argues that the PTAB Consolidated Trial Practice Guide provides that "[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or *otherwise exceeds the proper scope* of reply or sur-reply, it may request authorization to file a motion to strike." Pet. MTE Opp. 2 (citing PTAB Consolidated Trial Practice Guide ("CTPG") 80 (PTAB Nov. 2019)). Patent Owner contends that "Petitioner's counsel reserved that right to strike Dr. Bates' redirect testimony" but "failed to preserve this right because it failed to file a motion to strike within one week of [Patent Owner] submitting its Sur-Reply." *Id.* at 2–3 (citing CTPG 80–81). Second, Patent Owner contends that Petitioner "never argues that this testimony is, in fact *inadmissible*," only that it "should be excluded (not stricken) because it is beyond the scope of its cross-examination." *Id.* at 4. According to Patent Owner, "Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections." *Id.* (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends "Petitioner's counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner's] redirect was beyond the scope." *Id.* at 5–6 (citing Ex. 1053, 242:12–25).

In reply, Petitioner contends it "properly focused its motion to exclude on the portions of Dr. Bates' inadmissible re-direct deposition testimony cited in [the] Sur-Reply," and that Patent Owner "uses its Sur-Reply as no more than a 'vehicle' to enter new evidence into the record." Pet. MTE Reply 1. Petitioner contends that it "timely objected at the deposition" once

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Patent Owner began “improperly elicit[ing] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Federal Rule of Evidence 611(b). *Id.*

For the following reasons, we deny Petitioner’s Motion to Exclude. The CTPG provides that “[a] motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay)” but should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.” CTPG 79. Further, the CTPG clearly distinguishes a motion to exclude evidence from a motion to strike evidence. The CTPG states that, “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike.” *Id.* at 80. As an alternative to a motion to strike, “a party may request authorization for further merits briefing . . . to address the merits of newly-raised arguments or evidence.” *Id.* A party must seek authorization to file a motion to strike within one week of the allegedly improper submission. *Id.* at 81.

As noted in the CTPG, motions to strike are intended to address, *inter alia*, whether a brief raises new issues or exceeds the proper scope of a sur-reply. Here, Petitioner argues that the redirect testimony is inadmissible under Rule 611(b) and/or 37 C.F.R. § 42.53(d)(5)(ii) as exceeding the scope of cross-examination. But, Petitioner does not seek to exclude all redirect testimony on secondary considerations, only the testimony relied on by Patent Owner in the Sur-reply. Pet. MTE 5 n.2.

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The issue presented here borders on the proper scope of a motion to exclude as compared to a motion to strike. The goal of Petitioner's Motion is clearly to undercut arguments raised in Patent Owner's Sur-reply directed to objective indicia of nonobviousness. By limiting its Motion to only the portions of Dr. Bates's redirect examination actually relied on in Patent Owner's Sur-reply, Petitioner's arguments reflect this goal. *See, e.g.*, Pet. MTE 5 n.2 ("Although all of Dr. Bates' redirect testimony on secondary considerations was outside the scope of Petitioner's cross-examination, Petitioner narrowly focuses this motion on excluding only those portions that [Patent Owner] relies on in its Sur-Reply."). One way in which Petitioner could have challenged the arguments raised in Patent Owner's Sur-reply is by requesting authorization to file a motion to strike, which, as noted above, is intended for the purpose of addressing arguments a party believes exceeds the proper scope of sur-reply. *See* CTPG 80. Petitioner did not request such authorization. Instead, by seeking to exclude some of Dr. Bates's redirect testimony on objective indicia (i.e., the portions relied on in Patent Owner's Sur-reply), Petitioner seeks to undercut the arguments raised in Patent Owner's Sur-reply on objective indicia by effectively removing the primary evidentiary support for those arguments. Were we to grant Petitioner's Motion to Exclude, we would be faced with determining what to do with Patent Owner's arguments in the Sur-reply, which would remain of record because they are not the subject of Petitioner's Motion to Exclude (nor could they be based on the CTPG) and (as previously noted) Petitioner did not also file a motion to strike those arguments. The best course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike

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after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Rule 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination (just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony¹⁸), Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of nonobviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the circumstances presented here and in light of the little weight to which Patent Owner's argument and Dr. Bates's redirect is entitled, we determine that the better course is to deny Petitioner's Motion to Exclude.

¹⁸ There are exceptions, e.g., questions pertaining to a witness's credibility. See Fed. R. Evid. 611(b).

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V. CONCLUSION

The outcome for the Challenged Claims in this proceeding is set forth in summary as follows:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–11, 13–21, 23–28, 30	103(a)	Sullivan995, Sullivan460	1–11, 13–21, 23–28, 30	
12, 22, 29	103(a)	Sullivan995, Sullivan460, Matthews	12, 22, 29	
1–11, 13–21, 23–28, 30	103(a)	Rapoport502, Sullivan460 ¹⁹		
12, 22, 29	103(a)	Rapoport502, Sullivan460, Matthews ²⁰		
Overall Outcome			1–30	

¹⁹ For the reasons explained above, we do not reach this alternative ground, because we determine that the subject matter of claims 1–11, 13–21, 23–28, and 30 would have been obvious over the combination of Sullivan995 and Sullivan460.

²⁰ For the reasons explained above, we do not reach this alternative ground, because we determine that the subject matter of claims 12, 22, and 29 would have been obvious over the combination of Sullivan995, Sullivan460, and Matthews.

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ORDER²¹

Upon consideration of the record before us, it is:

ORDERED that Patent Owner's Motion to Exclude (Paper 45) is denied;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 46) is denied;

FURTHER ORDERED that claims 1–30 of U.S. Patent No. 9,108,009 B2 have been proven by a preponderance of the evidence to be unpatentable; and,

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

²¹ Should Patent Owner wish to pursue amendment of a Challenged Claim in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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Paper 69
Date: December 4, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

IPR2022-00989
Patent 9,427,539 B2

Before BART A. GERSTENBLITH, JAMES A. TARTAL, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

ORDER

Denying Patent Owner's Motion to Exclude (Paper 48) and
Denying Petitioner's Motion to Exclude (Paper 51)
37 C.F.R. § 42.64(c)

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We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) (2018) and 37 C.F.R. § 42.73 (2021). ResMed, Inc. (“Petitioner”) bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to New York University (“Patent Owner”). See 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). For the reasons discussed below, we determine Petitioner has shown by a preponderance of the evidence that claims 1, 2, 5–11, 13, and 15–30 (“the Challenged Claims”) of U.S. Patent No. 9,427,539 B2 (Ex. 1001, “the ’539 patent”) are unpatentable.

I. INTRODUCTION

A. Summary of Procedural History

Petitioner filed a petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of the Challenged Claims. Paper 1. Subsequently, Petitioner filed a Motion to Correct Petition (Paper 7), which Patent Owner opposed (Paper 8). We granted Petitioner’s Motion to Correct Petition (Paper 10) and Petitioner filed a Corrected Petition (Paper 11, “Petition” or “Pet.”).¹ We instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 16. Patent Owner filed a Response.² Paper 33 (“PO Resp.”). Petitioner filed a Reply to the Patent Owner Response. Paper 41 (“Pet. Reply”). Patent Owner filed a Sur-reply in support of the Patent Owner

¹ Petitioner identifies no additional real parties in interest. Pet. 1.

² Patent Owner identifies no additional real parties in interest. Paper 4, 2.

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Response. Paper 44 (“PO Sur-reply”). Following oral argument, we entered a transcript of the hearing in the record.³ Paper 64.

Additionally, Patent Owner filed a Motion to Exclude Exhibits 1009, 1018, 1019, 1033, 1049, 1051, 1054–1056, 1058, and 1059, and portions of Exhibits 1003, 1046, and 1052. Paper 48 (“PO MTE”), 1; *see also* Paper 53 (Petitioner’s Opposition to Patent Owner’s Motion to Exclude (“PO MTE Opp.”)); Paper 54 (Patent Owner’s Reply in Support of Its Motion to Exclude (“PO MTE Reply”). As explained below, we deny Patent Owner’s Motion to Exclude. *See infra* Section III.

Petitioner filed a Motion to Exclude portions of Exhibit 1053. Paper 51 (“Pet. MTE”); *see also* Paper 52 (Patent Owner’s Opposition to Petitioner’s Motion to Exclude (“Pet. MTE Opp.”); Paper 55 (Petitioner’s Reply in Support of Its Motion to Exclude (“Pet. MTE Reply”)). As explained below, we deny Petitioner’s Motion to Exclude. *See infra* Section IV.

B. Related Matters

The Parties identify the ’539 patent as a subject of *New York University v. ResMed, Inc.*, No. 1:21-cv-00813-JPM (D. Del. 2021). Pet. 1; Paper 4, 2. Petitioner also states that it filed petitions challenging claims of the following related patents: U.S. Patent No. 9,108,009 B2 (IPR2022-00988), U.S. Patent No. 9,533,115 B2 (IPR2022-00990), U.S. Patent No. 9,867,955 (IPR2022-00991), U.S. Patent No. 10,384,024 B2 (IPR2022-

³ The Parties both filed objections to the other party’s demonstrative exhibits and hearing arguments, and responses to the objections. Papers 61, 62, 65–68. Demonstrative exhibits and hearing arguments are not evidence and are not relied on as a basis of this Decision. Accordingly, the objections are denied as moot.

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00992), U.S. Patent No. 6,988,994 B2 (“the ’994 patent”) (IPR2022-00993), and U.S. Patent No. 9,168,344 B2 (“the ’344 patent”) (IPR2022-00994).
Pet. 2.

C. The ’539 Patent

The ’539 patent is titled “System and Method for Diagnosis and Treatment of a Breathing Pattern of a Patient.” Ex. 1001, code (54). The ’539 patent issued on August 30, 2016, from Application No. 15/015,944 (“the ’944 Application”), which was filed on February 4, 2016. *Id.* at codes (45), (21), (22). The ’944 Application is a continuation in a series of applications dating back to August 14, 2003. *Id.* at code (63). Petitioner does not dispute that the priority date of the ’539 patent is August 14, 2003, for purposes of this proceeding. Pet. 12 n.4.

The ’539 patent explains as background 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, 1:29–32. According to the ’539 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 1:35–42. The ’539 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS.” *Id.* at 1:58–61. The ’539 patent describes that “PAP therapy is directed to maintaining pressure in the collapsible portion of the airway at or

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above the critical tissue pressure at all times” and is applied via a tight-fitting nasal mask worn during sleep. *Id.* at 1:58–61, 2:11–13.

The '539 patent states 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.” *Id.* at 1:65–67. 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 2:18–21. The '539 patent also states that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:32–33.

Figure 1 of the '539 patent is reproduced below.

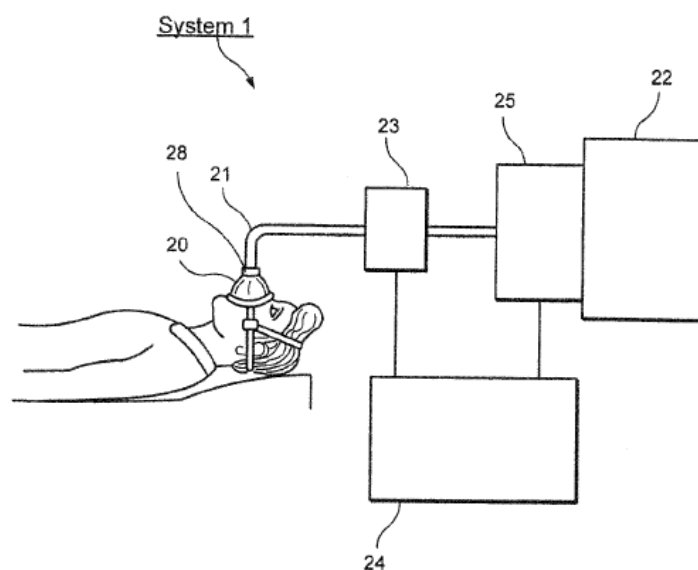


FIG. 1

Figure 1 “shows an exemplary embodiment of a system according to” the '539 patent. *Id.* at 3:22–23. System 1, shown in Figure 1, includes mask 20 connected via tube 21 for receiving an airflow of a particular pressure from flow generator 22. *Id.* at 3:52–56. The '539 patent describes

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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 3:61–64. The ’539 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 3:65–4:2.

The ’539 patent also describes a method that uses system 1. *Id.* at 3:24–26. “[S]ystem 1 initiates a real-time monitoring procedure of the patient’s breathing patterns.” *Id.* at 4:14–15, 4:18–19. The ’539 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 4:19–23. The ’539 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 4:24–28. According to the ’539 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 4:28–32. The ’539 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 4:35–37, 4:44–59.

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The '539 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. *Id.* at 5:60–62. The '539 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 7:49–52.

D. Illustrative Claim of the '539 Patent

Petitioner challenges claims 1, 2, 5–11, 13, and 15–30 of the '539 patent. Pet. 1. Claims 1, 11, and 24 are independent. Ex. 1001, 9:34–12:34. Claim 24 is illustrative of the claimed subject matter and is reproduced below.

24. A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:

- a generator supplying airflow and applying a pressure to an airway of a patient;
- a sensor measuring data corresponding to patient's breathing patterns from data indicate of the airflow supplied to the patient using at least one of a flow sensor or pressure sensor; and
- a hardware processor analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state have occurred.

Ex. 1001, 11:36–12:7.

E. References and Testimony

Below we provide an abbreviated summary of the qualifications of Dr. Jason Kirkness, who offered testimony in support of Petitioner in place

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of Dr. Khosrow Behbehani.⁴ We also provide an abbreviated summary of the qualifications Dr. Jason H. T. Bates, who offered testimony in support of Patent Owner. Additionally, in the table below we identify the primary references relied upon by Petitioner, as well as the exhibits corresponding to the declarations and deposition testimony in the record for Dr. Behbehani, Dr. Kirkness, and Dr. Bates.

Dr. Kirkness indicates he is “the Senior Vice President of Medical and Clinical Affairs” at a medical technology company and that his “career has focused on technology and devices to diagnose, monitor, and treat chronic respiratory-related diseases and disorders, including obstructive sleep apnea, chronic obstructive airway diseases, and acute respiratory diseases.”

Ex. 1046 ¶ 2. Dr. Kirkness indicates he received a Bachelor of Science degree in Biology from the University of Western Sydney, Kingwood, Australia in 1996, a Bachelor of Science degree in Physiology from the University of Western Sydney, Australia in 1997, and a Ph.D. in Medicine from the University of Sydney, Camperdown, Australia in 2003. *Id.* ¶¶ 3–5.

⁴ The Petition was originally supported by a declaration from Dr. Behbehani. In his declaration, Dr. Behbehani stated he is “a Professor in the Bioengineering Department at the University of Texas at Arlington, specializing in the design of sleep apnea therapy equipment, the design of CPAP systems for flow delivery, and biosignal process algorithms.” Ex. 1003 ¶ 3. After institution, Petitioner informed the Board that Dr. Behbehani was unable to continue to serve as an expert in this proceeding (Paper 29), and, with our authorization (Paper 32), Petitioner replaced Dr. Behbehani with Dr. Kirkness, who adopted substantially the entirety of Dr. Behbehani’s prior opinions. Ex. 1046 ¶¶ 1, 28 (adopting paragraphs 20–28, 32–76, and 80–258 of Dr. Behbehani’s Declaration (Exhibit 1003)). In this Decision we cite to the Declaration of Dr. Behbehani (Ex. 1003) with the understanding that the opinions expressed were adopted by and, therefore, are attributable to Dr. Kirkness.

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Dr. Kirkness states he was part of the faculty at the School of Medicine at John Hopkins University from 2009 until 2017, and then worked at or served as a consultant, and continues to work at various healthcare/medical companies. *Id.* ¶¶ 11–13, 16, 17. He states he is “a named inventor on two patent applications for quantifying inspiratory and expiratory airflow,” and has published over 50 articles in peer-reviewed journals, including “findings relating to medical devices and systems and methods for assessing the physiological characteristics of breathing during wakefulness and sleep.” *Id.* ¶¶ 15, 19.

Dr. Bates states that he is a “Professor of Medicine, Molecular Physiology & Biophysics, and Electrical & Biomedical Engineering at the University of Vermont.” Ex. 2005 ¶ 1. Dr. Bates indicates he received a Bachelor of Science degree in Physics from the University of Canterbury, Christchurch, New Zealand in 1978; a Ph.D. degree in Medicine from the University of Otago, Dunedin, New Zealand in 1981; and a D.Sc. degree from the University of Canterbury, Christchurch, New Zealand in 1994. *Id.* ¶¶ 5, 6, 8. He states he has spent “nearly 40 years focusing on research into lung mechanics and pathophysiology,” and that his “more than 330 published scientific papers focus on this subject, including sleep.” *Id.* ¶ 4. In addition to his research work at various universities, Dr. Bates states he is named on ten issued patents and patent applications, seven of which concern methods for controlling and/or measuring breathing. *Id.* ¶¶ 4, 14. Dr. Bates states he has designed studies on constant positive airway pressure (“CPAP”) in patients, developed software and supervised research relating to “the computational analysis of breathing patterns.” *Id.* ¶¶ 10–12.

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The table below identifies the exhibits corresponding to the asserted references and witness testimony.

References and Witness Testimony⁵	Date	Ex. No.
U.S. Patent No. 5,245,995 (“Sullivan995”)	Sept. 21, 1993	1005
WO 01/05460 A1 (“Sullivan460”)	Jan. 25, 2001	1006
U.S. Patent No. 5,490,502 (“Rapoport502”)	Feb. 13, 1996	1008
Declaration of Dr. Khosrow Behbehani	May 31, 2022	1003
Declaration of Dr. Jason P. Kirkness	Mar. 8, 2023	1046
Declaration of Dr. Kirkness in Support of Reply	July 28, 2023	1051
Deposition Transcript of Dr. Kirkness, Vol. I	Mar. 29, 2023	2014
Deposition Transcript of Dr. Kirkness, Vol. II	Mar. 30, 2023	2015
Declaration of Dr. Jason Bates ⁶	Apr. 21, 2023	2005
Deposition Transcript of Dr. Bates, Vol. I	June 22, 2023	1052
Deposition Transcript of Dr. Bates, Vol. II	June 23, 2023	1053

F. Petitioner’s Asserted Grounds for Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds (Pet. 3–4):

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1, 2, 5–11, 13, 15–30	103(a)	Sullivan995, Sullivan460
1, 2, 5–11, 13, 15–30	103(a)	Rapoport502, Sullivan460
1, 2, 5–11, 13, 15–30	102(b)	Sullivan995
1, 2, 5–11, 13, 15–30	102(b)	Rapoport502

⁵ The table identifies only a select number of documents particularly pertinent to this Decision. *See, e.g.*, Paper 60 (Patent Owner’s Updated List of Exhibits); Paper 59 (Petitioner’s Updated Exhibit List). A complete identification of the papers and exhibits that form the record of this case is available in the docket of this proceeding.

⁶ Dr. Bates provided corrections to citations in his declaration. Ex. 1048.

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II. ANALYSIS

A. *Legal Standards of Anticipation and Obviousness*

Petitioner contends under two grounds that the Challenged Claims are anticipated. Pet. 3–4. A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim.

Orion IP, LLC v. Hyundai Motor Am., 605 F.3d 967, 975 (Fed. Cir. 2010).

“A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed.

Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

Petitioner contends under two grounds that the Challenged Claims would have been obvious.⁷ Pet. 3–4. 35 U.S.C. § 103(a) sets forth as follows:

[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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

⁷ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because an application related to the application from which the ’539 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of § 103 applies. *See* Ex. 1001, code (63). No issue in this proceeding turns on the applicable version of the statute and the outcome of this Decision would be the same regardless of which version of the statute applies.

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differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re Nuvasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016); *see also Pers. Web Tech., LLC, v. Apple, Inc.*, 848 F.3d 987, 993–94 (Fed. Cir. 2017) (“[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention”) (alteration in original) (quoting *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)).

B. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Petitioner contends that a person of ordinary skill in the art would have had “at least a bachelor’s degree in mechanical engineering, biomedical

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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. 19 (citing Ex. 1003 ¶ 77). 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.* (citing Ex. 1003 ¶ 78). Patent Owner does not dispute Petitioner’s definition of the person of ordinary skill in the art. PO Resp. 15–16.

We find that the ’539 patent and the cited prior art references reflect the appropriate level of skill at the time of the claimed invention and that the level of appropriate skill reflected in these references and in the ’539 patent is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Claim Construction

In this *inter partes* review, claims are construed using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.100(b) (2021). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing claims in accordance with their ordinary and customary meaning, we take into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

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If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thorner v. Sony Comput. Entm’t Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only 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)).

Petitioner asserts that “the prior art meets each of the claim limitations under any reasonable construction.” Pet. 20. Petitioner proposes no express construction for any claim term with respect to the alleged obviousness of the Challenged Claims. *See id.* Petitioner however, does address the meaning of “awake state” in regard to its allegations of anticipation. *Id.* at 68–70.

Patent Owner discusses “analyzes the measured data to determine whether a patient breathing pattern,” as recited in claim 1; “analyzing...the measured data to determine whether the data includes breathing patterns,” as

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recited in claim 11; and “analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state,” as recited in claim 24. PO Resp. 30. We discuss each of these terms below.

1. “*awake state*”

Claim 24 recites, in part, “to determine whether breathing patterns indicate an asleep state or an awake state.” Ex. 1001, 11:36–12:7; *see also id.* at 9:49–64 (claim 1 reciting “between an awake state and an asleep state”), 10:42–56 (claim 11 reciting “at least one of an awake state or an asleep state”). In regard to its allegations of obviousness, Petitioner’s arguments suggest an “awake state” ordinarily means when a patient is not asleep. Pet. 36–37, 42. By contrast, with regard to its allegations of anticipation, Petitioner argues that under Patent Owner’s “implied construction of ‘an awake state’ based on [Patent Owner’s] infringement allegations” in district court, “the patient is in an awake state when there is an absence of obstructions or other breathing patterns indicative of sleep.” *Id.* at 68–70 (citing, e.g., Ex. 1018 ¶¶ 2, 158, 159).

Petitioner provides no further support for this “implied construction” purportedly taken from Patent Owner’s district court allegations. *Id.* Dr. Kirkness, in support of Petitioner, applied the plain meaning of all terms and phrases. *See, e.g.*, Ex. 1003 ¶ 80. In regard to supporting Petitioner’s allegations of anticipation, Dr. Kirkness merely assumed Patent Owner’s purported district court claim construction “position to be true.” Ex. 1003 ¶ 253.

In this proceeding Patent Owner does not propose an express meaning for “awake state.” *See* PO Resp. 29–33. More generally, Patent Owner states that the ’539 patent “teaches how to distinguish between an awake

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state and an asleep state.” *Id.* at 8. From the arguments of the Parties, we discern no dispute in this proceeding that a plain and ordinary meaning of an “awake state” is a state in which a patient is not asleep. *See* Ex. 1001, 3:1–5 (distinguishing between “a wake state” and “a sleep state”), 7:22–24 (describing an embodiment with a processing arrangement that “may determine whether the patient is in a sleep state or a wake state based on the breathing pattern”).⁸ We apply the plain and ordinary meaning of “awake state” in this proceeding and further determine that Petitioner has not shown by a preponderance of the evidence that an awake state means “an absence of obstructions or other breathing patterns indicative of sleep.”

2. *“analyzing the breathing patterns” (claim 24)*

Claim 24 recites “a hardware processor analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state have occurred.” Ex. 1001, 12:5–7. In the Petition, Petitioner did not expressly construe this phrase, but did analyze and address the prior art to identify the teachings of the prior art that Petitioner contends teach this limitation. *See, e.g.*, Pet. 30–35. In the Patent Owner Response, Patent Owner argues that “analyzing the breathing patterns” means “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the

⁸ The term “awake state” appears only in the claims of the ’539 patent and the phrase “a wake state” appears only in the Specification of the ’539 patent outside of the claims; however, neither Party suggests any material distinction between “awake state” and “a wake state.”

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parameters and the order which they appear in time.”⁹ PO Resp. 30. Patent Owner also refers to “the values of the parameters and the order which they appear in time” in its proposed construction as “both the amplitude structure and the temporal structure of a time series of breath-by-breath parameters calculated from a flow waveform.” *Id.* at 2. As borne out through Patent Owner’s arguments in response to Petitioner’s challenges and as further elaborated in Patent Owner’s Sur-reply, Patent Owner contends that “analyzing the breathing patterns” requires an analysis of “both the amplitude and the temporal structure.” PO Resp. 36; *see also id.* at 2, 10–11, 37–38, 40, 47–49, 51; PO Sur-reply 1–7 (asserting that Challenged Claims require analysis of both amplitude structure and temporal structure). Petitioner disputes this proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2. For the reasons that follow, we agree with Petitioner.

a. Arguments Presented by the Parties

To explain why “analyzing the breathing patterns” should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the [S]pecification” of the ’539 patent. PO Resp. 30 (citing Ex. 1001, 4:44–51; Ex. 2005 ¶ 119); *see*

⁹ Patent Owner also includes what it describes as the “Entire Claim with Claim Constructions” in which Patent Owner inserts its proposed construction into the language of claim 1 and states that “[s]hould the Board adopt the above constructions, including that proposed by Patent Owner, independent claim 1 would read as follows.” PO Resp. 33. To be clear, Patent Owner could have filed a motion to amend the claim language, but did not do so. *See* 37 C.F.R. § 42.121 (“Amendment of the Patent”). Thus, the notion that claim 1 would “read” as Patent Owner suggests if its proposed construction were adopted is misplaced, because construing claim language does not equate to rewriting the claim.

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also PO Sur-reply 13 (Patent Owner argues that, according to Dr. Bates, “‘breathing pattern’ has no ordinary meaning and ‘is an extremely general term.’”) (citing Ex. 1052, 108:25–109:7). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apneas and hypopneas in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters and the order in which they appear in time.” PO Resp. 31 (citing Ex. 2005 ¶ 120).

Patent Owner points to the description of Figures 7 and 8 of the ’539 patent in support of its construction. *Id.* at 31–32 (citing Ex. 1001, 4:59–66; 5:23–29; Ex. 2005 ¶¶ 121–123). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient’s airflow, but no periodic irregularity in breath size. Ex. 1001, 4:59–66. Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. *Id.* at 5:23–36.

According to Patent Owner, “[t]his methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns” and focuses “on a determination of ‘the sequence of parameters of a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.’” PO Resp. 31 (citing Ex. 2005 ¶ 122); *see also* PO Sur-reply 4 (citing Ex. 1001, 4:59–66; Ex. 2005 ¶ 121) (asserting that the ’539 patent describes Figure 7 as showing “[b]oth amplitude and temporal

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structures are described when examining flow waveforms”). Patent Owner further argues that the description of Figure 8 in the Specification “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 32 (citing Ex. 1001, 5:23–29; Ex. 2005 ¶ 123); PO Sur-reply 3–12; Ex. 2005 ¶¶ 63–72).

Additionally, Patent Owner suggests the Specification’s discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. PO Resp. 32 (citing Ex. 1001, 6:41–48; Ex. 2005 ¶ 124).

Turning to the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’539 [p]atent.” PO Sur-reply 2; *see also id.* at 7–15 (arguing that distinguishing troubled wakefulness from REM sleep requires assessing both amplitude and temporal structure). First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” PO Sur-reply 3 (quoting Ex. 1001, 4:44–51) (citing Ex. 2005 ¶ 119). Patent Owner maintains that the descriptions of the waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of waveforms. *Id.* at 4–6 (citing Ex. 1001, 4:59–66, 5:30–39, 6:41–48; Ex. 1052, 81:17–23, 180:1–15; Ex. 2005 ¶¶ 120–124). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’539 [p]atent,” but contends that they “are not

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obligatory.” *Id.* at 5. Patent Owner asserts that the ’539 patent’s “enablement hinges on its ability to distinguish between all awake and asleep states,” and “[o]therwise, incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 6.

Second, Patent Owner asserts that during the prosecution of the related ’344 patent, the applicant responded to a rejection by arguing that the prior art, in that instance, “failed to discern between regular wakefulness and troubled wakefulness.” PO Sur-reply 6. Patent Owner argues that it is necessary to integrate “both amplitude and temporal structure analyses to distinguish all awake and asleep states.” *Id.*

Third, Patent Owner argues that “a patentee does not need to rigidly define terms, but can imply their own meaning.” *Id.* Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by the flow waveform indicating troubled wakefulness in Figure 7.” *Id.* at 7 (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the Specification “provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “[s]ince ‘analyzes the data’ is followed by ‘to determine the patient’s breathing patterns,’ some of which occur in the asleep state and some of which occur in the awake state, this further implies that these states can be separated from one another.” *Id.* (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22). Patent Owner contends that, “[g]iven the separation between awake and asleep states discussed in the ’539 [p]atent, [Patent Owner’s] construction is integral for discerning the difference and applying the correct pressure,” because, without doing so, it “could result in

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inappropriate pressure administration.” *Id.* (citing Ex. 1052, 179:23–25; Ex. 2005 ¶ 124).

Patent Owner also argues that extrinsic evidence supports its proposed construction. PO Sur-reply 7–12. Based on Dr. Bates’s testimony, Patent Owner asserts that “[b]y assessing *only amplitude*” the waveforms of troubled wakefulness and REM sleep “appear indistinguishable,” but “their temporal structure (order in time) . . . offers differentiation.” *Id.* at 9–10 (citing Ex. 2005 ¶ 71). Patent Owner contends it proves its argument by showing that if the “temporal structure” of the REM sleep waveform is “rearranged in time,” then the resulting “time series has a random appearance that *cannot be distinguished* from troubled wakefulness.” *Id.* at 10 (citing Ex. 2005 ¶ 72). Patent Owner reasons that “amplitude structure and temporal structure convey independent information” and both must be considered in an analysis or “the awake and asleep states can be confused.” *Id.* at 11 (citing Ex. 2005 ¶ 65). According to Patent Owner, it is “Dr. Bates[’s] illustrations [that] clearly present the problem solved by the ’539 [p]atent.” *Id.*

According to Patent Owner, construing “analyzing breathing patterns” to include “any type” of breathing pattern analysis, as suggested by Dr. Kirkness, is “nonsensical, as it might even encompass using a mirror to

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check for breaths.” PO Sur-reply 12–13 (citing Ex. 1051 ¶ 16).¹⁰

Specifically, Patent Owner argues as follows:

Dr. Bates examined the specification to determine which breathing characteristics were crucial to analyzing the breathing pattern with respect to the invention’s essence. [Ex. 1052], 24:20-25, 25:1-13. He determined that a [person of ordinary skill in the art], after reading the ’994 [p]atent, would understand that analyzing breathing patterns, with respect to the ’539 [p]atent, would need to confer the ability to distinguish between troubled wakefulness and REM sleep. *Id.*, 111:22-25 – 112:1-21. [Patent Owner’s] construction evidences the understanding of a [person of ordinary skill in the art] – that analyzing breathing patter[n]s requires analysis of amplitude and temporal structures.

Id. at 13.

Petitioner proposes that we construe “analyzing the breathing patterns” in accordance with its plain and ordinary meaning because “[n]othing in the intrinsic record limits the ‘analyzing the breathing patterns’ terms to analysis of either or both amplitude and temporal structures— instead, the claims, specification, and prosecution history all use these terms in accordance with their plain and ordinary meaning.” Pet. Reply 4, 6 (citing *CCS Fitness*, 288 F.3d at 1366). Petitioner asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the specification or during

¹⁰ Patent Owner also states that “Dr. Kirkness argues that the ’539 [p]atent is indefinite, especially regarding the measurement of airflow waveforms and temporal/amplitude aspects,” and that “Petitioner has never raised indefiniteness.” PO Sur-reply 12. We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths.” *Id.* at 12–13.

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prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” *Id.* at 6 (quoting *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* at 6–7. Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, ‘the patentee must clearly express an intent to redefine the term.’” *Id.* at 7 (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends “[n]o such intent exists here” and Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* (citing Ex. 1051 ¶ 24).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner’s] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as proposing “a lengthy construction” and then construing “its own construction to inject two arbitrary requirements: that the processor must analyze (1) ‘the value of the parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.* at 3–4 (citing PO Resp. 9–11, 30–31; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record, or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert decided based on his personal experience, as opposed to that of a” person of ordinary skill in the art. *Id.* at 4 (citing Ex. 1053, 271:10–14).

Responding to Patent Owner’s citations to the Specification, Petitioner contends that the Specification “further confirms that the terms encompass any type of breathing pattern analysis” and “states that ‘[t]here

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are a number of characteristics of the patient’s breathing patterns that may be taken into account in making such a determination’ . . . and does not limit the analysis to any particular characteristic.” Pet. Reply 5 (citing Ex. 1001, 2:40–43, 4:18–32, 4:59–64, 5:32–36, Figs. 3–8; Ex. 1051 ¶¶ 16–24; Ex. 1052, 28:4–30:21; Ex. 2005 ¶¶ 46–47, 121–123). Petitioner also contends that “[t]he [S]pecification further states that the flow sensors ‘detect the rate of airflow’ to and from the patient, and provide ‘[s]ignals corresponding to the airflow’ to a processing arrangement for processing.” *Id.* (second alteration in original) (citing Ex. 1001, 3:60–66). Thus, Petitioner asserts the Specification “confirms that analyzing temporal structures is not required.” *Id.*; *see also id.* at 4 (arguing that “claim 3 of the ’539 [p]atent expressly recites that ‘the hardware processor determines the breathing patterns using the measured airflow rate” (emphasis omitted)).

Petitioner also addresses the prosecution history of patents related to the ’539 patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5–6. Petitioner asserts that, in responding to different office actions, the applicant did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1009, 404; Ex. 1054, 91, 128).

Next, Petitioner contends Patent Owner’s extrinsic evidence, in the form of Dr. Bates’s testimony, contradicts the intrinsic record and should be disregarded. Pet. Reply 6–11. Petitioner asserts Dr. Bates “performed a ‘crude’ analysis by ‘approximating’ the amplitudes of each breath in the figures ‘estimat[ing] by eye . . . the size of those individual breaths.’” *Id.* at 7 (first alteration in original) (citing Ex. 1052, 75:11–76:14, 78:16–79:19).

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Petitioner argues that Dr. Bates’s “analysis has no basis in the patent.” *Id.* at 7–8. Petitioner presents five arguments in rebuttal in regard to the testimony of Dr. Bates:

(1) Dr. Bates’s analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the ’539 [p]atent would have derived [Patent Owner’s] construction.” *Id.* at 8 (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* (citing Ex. 1052, 75:11–76:14; 78:16–79:19; 90:8–91:11).

(2) Dr. Bates’s analysis is based on his own expertise in “digital signal processing,” not from the viewpoint of a person of ordinary skill in the art who would not necessarily have such experience. *Id.* at 8–9 (citing Ex. 1052, 25:3–27:6, 52:2–25, 64:4, 208:16–21; Ex. 1053, 240:8–242:8; 243:3–8).

(3) Dr. Bates’s analysis contradicts the ’539 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM sleep without requiring temporal analysis. *Id.* at 9 (citing Ex. 1001, 4:52–59; 5:32–36; Ex. 1056, 9:55–10:3 (claim 5), 10:20–24 (claim 8); Ex. 1051 ¶¶ 25–33).

(4) “Dr. Bates admitted the waveforms of Figures 7–8 are merely exemplary.” *Id.* (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do not limit the broader claim terms of the patent.” *Id.* at 9–10 (citing *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004)).

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(5) Dr. Bates “could not explain ‘parameter’ or provide an objective basis to define a ‘sequence’ and ‘series’ used in [Patent Owner’s] proposed construction” and “admitted that [Patent Owner’s] construction would exclude breathing patterns recited in dependent claims.” *Id.* at 10–11 (citing Ex. 1052, 182:1–184:19, 247:5–11; Ex. 1053, 288:14–289:3). Thus, Petitioner asserts we “should discount []expert testimony that is clearly at odds . . . with the written record of the patent.” *Id.* at 11 (quoting *Phillips*, 415 F.3d at 1318).

b. Analysis of the Claim Language

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14. As stated above, claim 24 recites, in relevant part, “a hardware processor analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state have occurred.” Ex. 1001, 12:5–7. As reflected, claim 24 does not recite “a sequence of parameters” or “a series of breaths” or “examining the values of the parameters and the order in which they appear in time” or any analysis of amplitude or temporal structure. *See id.* Claim 24 does not recite distinguishing between “troubled wakefulness” and “REM sleep” or between “all awake and asleep states,” and does not require applying “the correct pressure” under all circumstances. Rather, this portion of claim 24 recites that the processor analyzes the breathing patterns, without specifically reciting how the analysis is performed. The claim phrase, however, does recite the purpose of the analysis—to determine whether breathing patterns indicate an asleep or an awake state—but does not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a significant number

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of limitations not recited expressly nor suggested by “analyzing the breathing patterns.”

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citation omitted). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech.*, 923 F. 3d at 1044.

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of claim 24, nor does Patent Owner argue that it explicitly defined “analyzing the breathing patterns” in the Specification. *See, e.g.*, PO Resp. 29–32. We determine that there is no disavowal nor any explicit lexicographic definition of “analyzing the breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we should construe the phrase as Patent Owner proposes. PO Sur-reply 2, 6–7 (citing, *inter alia*, *AstraZeneca AB v. Mut. Pharm. Co., Inc.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004)). We disagree.

In *AstraZeneca AB*, the United States Court of Appeals for the Federal Circuit reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d at 1339–40

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(quoting *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors “deliberately acted as their own lexicographers” to limit the claim term “solubilizer” to surfactants, the Federal Circuit explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The Federal Circuit rejected AstraZeneca’s argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

The Specification of the ’539 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to “a sequence of parameters” (PO Resp. 30) or an “analysis of both the amplitude and the temporal structure of a breath-by-breath time series” (*id.* at 2–4, 36) or any of the other terms set forth in the proposed construction. See *id.* at 29–32. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. See Pet. Reply 7 (“The terms ‘amplitude’ and ‘temporal’ do not appear anywhere”); PO Sur-reply 5

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(“Petitioner rightly observes that terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’539 [p]atent.”); *see also* Ex. 1051 ¶ 24 (Dr. Kirkness stating that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’539 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures”). Patent Owner directs us to portions of the Specification for what Patent Owner characterizes as the process of analyzing breathing patterns. PO Resp. 30–31 (quoting Ex. 1001, 4:44–51). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” Ex. 1001, 4:44–51. The cited text does not describe analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how “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).” Ex. 1001, 4:24–28. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns, etc. in the determining the patient’s state.” *Id.* at 4:28–32. There is no mention that analyzing breathing patterns requires analysis of a sequence of parameters and the order in which they appear in time or an analysis of amplitude and temporal aspects of the waveform.

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The Specification further describes, in an embodiment, “processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern.” Ex. 1001, 7:22–24. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal aspects of the waveform.

Patent Owner also relies on the description of Figures 7 and 8 of the ’539 patent in support of its construction. PO Resp. 31–32; PO Sur-reply 3–9. Figures 7 and 8 illustrate airflow waveforms from a patient indicative of a period of troubled wakefulness and a period of REM sleep with irregular breathing, respectively. Ex. 1001, 3:38–41, 4:52–64, 5:23–26. Patent Owner relies on Figures 7 and 8 to support its argument that “an analysis of both the amplitude and the temporal structure of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.” PO Resp. 36; *see also* PO Sur-reply 8 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Figures 7 and 8, however, depict one particular example of an awake state (i.e., troubled wakefulness) and one particular example of a sleep state (i.e., REM sleep), respectively. Ex. 1001, 3:37–41. But Patent Owner’s analysis does not address Figures 3–6 of the ’539 patent. PO Resp. 29–32; PO Sur-reply 1–15. Figures 3 and 4 show waveforms of a patient during “regular wakefulness” and “regular sleep,” respectively. *Id.* at 3:27–31. Figures 5 and 6 show waveforms from a sleeping patient indicative of “hypopnea” and “repetitive obstructive apnea,” respectively. *Id.* at 3:32–36. Patent Owner provides no evidence or explanation why amplitude and temporal aspects of

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a waveform are required to distinguish regular wakefulness from regular sleep or hypopnea or repetitive obstructive apnea.¹¹

Claim 24 recites “analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state.” Ex. 1001, 12:5–7. Claim 24 is not limited to distinguishing *solely* between troubled wakefulness and REM sleep, but rather encompasses other states, such as those shown in Figures 3–6. Thus, even if we were to agree with Patent Owner that an analysis of one or both of the amplitude and temporal structures of a waveform is required to distinguish between troubled wakefulness and REM sleep, that determination, alone, would be insufficient to narrow the scope of claim 24, which by its own terms is broad enough to include specific types of awake or sleep states other than troubled wakefulness and REM sleep. For the same reasons, we are not persuaded that the additional limitations Patent Owner seeks to read into the claims are necessary to “fully enable” the claims, as Patent Owner asserts.

Having reviewed the intrinsic evidence, we next consider the extrinsic evidence, and specifically the testimony of Dr. Bates.¹² Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 30–32 (citing Ex. 1001, 4:44–51,

¹¹ Nor does Patent Owner direct us to any portion of the prosecution history of the ’539 patent that it contends supports its proposed construction of “analyzing the breathing patterns.” See *generally* PO Resp.

¹² Although the Parties briefly address the prosecution history of patents related to the ’539 patent, we do not find the discussion thereof informative on this specific issue.

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4:59–66, 5:23–29, 6:41–48; Ex. 2005 ¶¶ 119–124). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. *See* Ex. 2005 ¶¶ 119–124. Rather, Dr. Bates reads portions of the Specification and extrapolates (by taking several unsupported leaps) that the ’539 patent “implicitly demands certain parameter measurements.” PO Sur-reply 7 (citing Ex. 1052, 44:6–20); *see also* PO Sur-reply 6 n.6 (stating that “[a]l of the patents in the ’994 [p]atent family share virtually the same specification”).

Although expert testimony is legitimate to consider when construing claims, the Federal Circuit has cautioned that because it “is generated at the time of and for the purpose of litigation,” it “can suffer from bias that is not present in intrinsic evidence.” *Phillips*, 415 F.3d at 1318. And, extrinsic evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* at 1317 (internal quotations and citations omitted). In the context presented here, Dr. Bates’s testimony is not supported sufficiently by the intrinsic record or other extrinsic evidence (e.g., objective extrinsic evidence) and, therefore, even though we have considered it fully, we give it little weight.

For the reasons explained above, we determine that Patent Owner did not implicitly define the phrase “analyzing breathing patterns,” as proposed, because Patent Owner has failed to show any sufficient evidence that the ’539 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner’s contentions in light of all the evidence of record, we do not adopt Patent Owner’s proposed construction; instead, we apply the plain and

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ordinary meaning of “analyzing breathing patterns” in our consideration of the issues before us.

3. *“analyzes the measured data” (claim 1) and “analyzing the measured data” (claim 11)*

Claim 1 recites, in relevant part, “flow sensors measuring data corresponding to the supplied airflow . . . wherein the hardware processor analyzes the measured data to determine whether a patient breathing pattern indicative [sic] at least one transition between an awake state and an asleep state has occurred.” Ex. 1001, 9:49–64. Claim 11 recites, in relevant part, “measuring data corresponding to changes in flow or pressure of the airflow” and “analyzing . . . the measured data to determine whether the data includes breathing patterns indicative of at least one of an awake state or an asleep state.” *Id.* at 10:42–56. Patent Owner treats these limitations for purposes of its proposed claim construction, without further explanation, as though they were identical to the “analyzing the breathing patterns” limitation of claim 24 discussed above.¹³ See PO Resp. 30–32. However, claim 1 is directed to analyzing “data corresponding to the supplied airflow,” and claim 11 is directed to analyzing “data corresponding to changes in flow or pressure of the airflow,” not “analyzing the breathing patterns” as recited by claim 24. To the extent Patent Owner’s proposed construction directed to “analyzing the breathing patterns” of claim 24 applies to the limitations of

¹³ Petitioner states that “[e]ach independent claim [of the ’539 patent] requires a processor that analyzes a patient’s breathing patterns.” Pet. Reply 2. That, however, does not resolve the issue here, which is whether the language of claims 1, 11, and 24 varies in a material way. For purposes of our subsequent analysis, we consider whether Petitioner has shown how the prior art renders obvious each of the Challenged Claims, not whether the varying claim language means exactly the same thing.

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claims 1 and 11, as Patent Owner suggests, we find those arguments not persuasive at least for the same reasons discussed above with regard to claim 24.

4. *Additional Claim Terms*

The Parties do not dispute the construction of any other claim terms and we find that no other claim terms require express construction for purposes of rendering 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.*, 200 F.3d at 803)).

D. *Scope and Content of the Asserted Prior Art*

Petitioner relies on Sullivan995, Sullivan460, and Rapoport502 to show that the Challenged Claims are unpatentable. Pet. 13–19. Each of these references is summarized in relevant part below.

1. *Summary of Sullivan995*

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.

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Figure 1A of Sullivan995 is reproduced below.

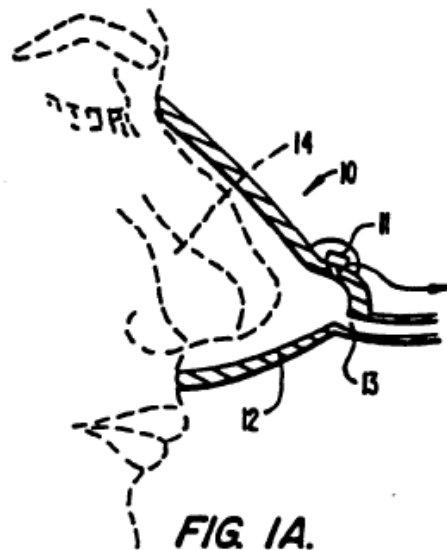


Figure 1A depicts snoring detection device 10. *Id.* at 8:47. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a nose mask.” *Id.* at 8:47–49. Sullivan995 explains that “[a]ir, being inhaled by the patient, enters the nasal passageways 14 through 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.

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Figure 3 of Sullivan995 is reproduced below.

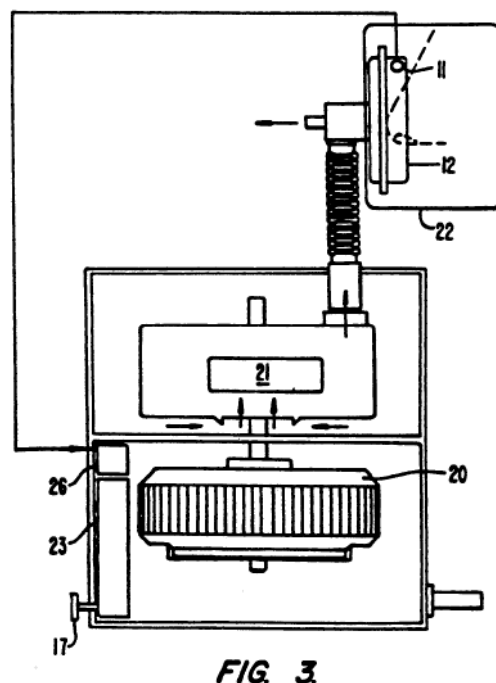


Figure 3 of Sullivan995 shows a CPAP apparatus. Ex. 1005, 9:57–58. The CPAP apparatus shown in Figure 30 includes motor 20 that drives blower 21. *Id.* at 9:58–59. Sullivan995 explains that “[t]he speed of the motor 20 is controlled by an electronic speed control unit 23.” *Id.* at 9:59–60. The CPAP 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

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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, 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.

Figure 12 of Sullivan995 is reproduced below.

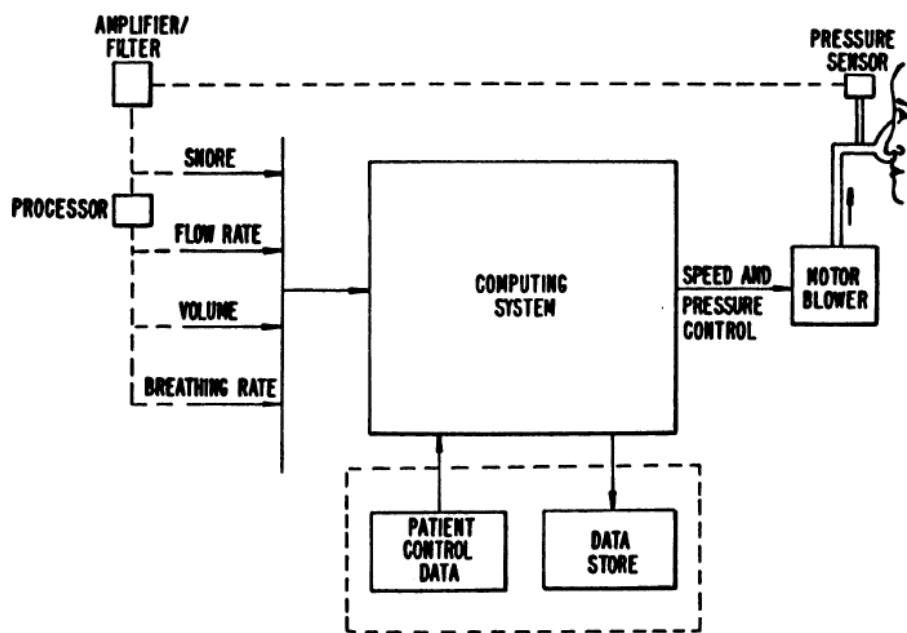


FIG. 12.

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

A pressure detection apparatus is provided either integral with or attached to the CPAP mask worn by the patient. The electrical

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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. *Summary of Sullivan460*

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.” *Id.* at 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 [Sullivan 995].” *Id.* at 6:22–24.

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Figure 2 of Sullivan460 is reproduced below.

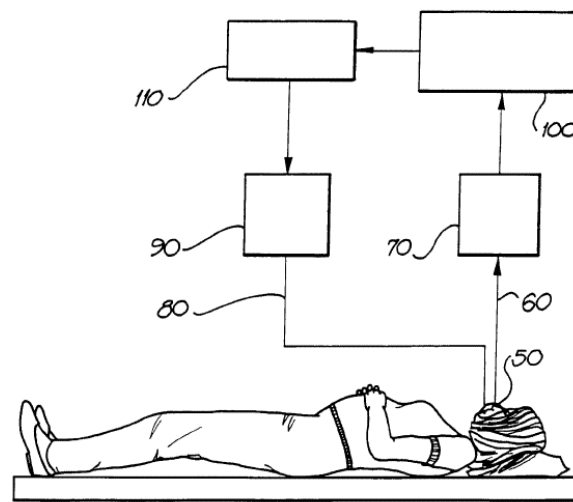


FIG. 2

Sullivan460's "Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia." Ex. 1006, 10:7–8. In Figure 2, patient 30 is lying on bed 40 and wears mask 50 over her nose 50. *Id.* at 10:8–9. Mask 50 is connected via 80 to nCPAP apparatus 90. *Id.* at 10:9–10. 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 10:10–12. 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 as follows:

[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

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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. *Summary of Rapoport502*

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

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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 a 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.

E. Alleged Obviousness over Sullivan995 and Sullivan460

Petitioner contends that the subject matter of claims 1, 2, 5–11, 13, and 15–30 of the ’539 patent would have been obvious over the combination of Sullivan995 and Sullivan460, and presents a limitation-by-limitation analysis of each claim, along with reasons supporting both the asserted combination and a reasonable expectation of success. Pet. 20–50. Petitioner’s contentions are supported by the declaration testimony of

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Dr. Kirkness. Ex. 1046 ¶ 28 (adopting the opinions set forth in Ex. 1003 ¶¶ 81–192).

Patent Owner argues, with support from Dr. Bates, that Sullivan995 and Sullivan460 fail to teach various claim limitations of the Challenged Claims, that “there is neither a motivation to combine these references nor a reasonable expectation of success that any combination would yield a successful result,” and that “secondary considerations, in particular a long felt but unresolved need, support a finding of non-obviousness.”¹⁴ PO Resp. 34–45; Ex. 2005 ¶¶ 125–195. Below we address differences between the prior art and the Challenged Claims, beginning with claim 24 as Petitioner argues in the Petition, and then we turn to the rationale in support of the combination and objective evidence of nonobviousness. For the reasons that follow we determine that Petitioner has shown by a preponderance of the evidence that the subject matter of claims 1, 2, 5–11, 13, and 15–30 would have been obvious over the combination of Sullivan995 and Sullivan460.

¹⁴ Patent Owner also improperly states in its Response that Petitioner fails to prove that the Challenged Claims would have been obvious over the combination of Sullivan995 and Sullivan460 due to “the additional reasons provided by Dr. Bates in his Declaration, EX2005, which is incorporated here in its entirety.” PO Resp. 39. Our Rules expressly state that “[a]rguments must not be incorporated by reference from one document into another document.” 37 C.F.R. § 42.6(a)(3). Further, Patent Owner was expressly informed in our Scheduling Order as follows: “Patent Owner is cautioned that any arguments not raised in the response may be deemed waived.” Paper 17, 9. Accordingly, we deem waived all arguments based on unidentified “additional reasons” in Dr. Bates’s declaration purported by Patent Owner to have been incorporated by reference with its Response.

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1. *Differences Between the Subject Matter of the Challenged Claims and the Combination of Sullivan995 and Sullivan460*

Petitioner shows that the combination of Sullivan995 and Sullivan460 teaches each of the limitations of claims 1, 2, 5–11, 13, and 15–30. Pet. 20–50. We adopt Petitioner’s analysis as our own findings and conclusions as to these claims. *Id.* Consistent with Petitioner’s discussion in the Petition, we begin with an analysis of Petitioner’s contentions concerning each of the limitations of independent claim 24. We further focus our discussion below on the reasons why we disagree with Patent Owner’s arguments in opposition, which likewise focus on claim 24. *See In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016) (noting that “[t]he Board, having found the only disputed limitations together in one reference, was not required to address undisputed matters”); *see also* PO Resp. 34–45 (presenting no additional opposition arguments directed specifically to claims 1, 2, 5–11, 13, 15–23, and 25–30 aside from the arguments directed to claim 24).

a. *Claim 24*

Petitioner contends the subject matter of claim 24 would have been obvious over the combination of Sullivan995 and Sullivan460. Pet. 24–36. We address each of the limitations of claim 24 below and determine Petitioner has shown by a preponderance of the evidence how each was suggested or taught by the asserted art.

A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:

Petitioner shows that Sullivan995 teaches a CPAP system that corresponds to a positive airway pressure system that one of ordinary skill in the art would have understood “delivers ‘positive’ airway pressure relative to atmospheric pressure.” Pet. 24 (citing Ex. 1003 ¶ 95; Ex. 1005, Abstract,

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1:33–36, 2:15–19, 9:57–58, Fig. 3). Petitioner shows that Sullivan995’s CPAP system “includes a nose mask 12 or nasal prongs that are ‘fluidly sealable to the nasal air passages of a patient’ and are ‘for delivery of air to the patient’s nasal passages’” and thereby assists in treating a sleeping disorder in a patient by providing air pressure at a level “to ‘prevent the onset of apnea.’” *Id.* at 24–25 (citing Ex. 1005, 1:20–48, 5:12–34, 10:31–35, 10:67–11:4, 11:15–20, 11:23–43, claim 6, Fig. 3); *see also* Ex. 1003 ¶¶ 95–97. Patent Owner does not dispute Petitioner’s contentions as to the preamble of claim 24. *See* PO Resp. 36.

a generator supplying airflow and applying a pressure to an airway of a patient;

Petitioner shows that “Sullivan995’s CPAP system includes a motor 20 with a variable speed that drives a blower 21,” corresponding to the recited generator supplying airflow. Pet. 26 (citing Ex. 1003 ¶ 98; Ex. 1005, 9:57–64). Patent Owner does not dispute Petitioner’s contentions as to this limitation. *See* PO Resp. 36.

a sensor measuring data corresponding to patient’s breathing patterns from data indicate of the airflow supplied to the patient using at least one of a flow sensor or pressure sensor; and

Petitioner shows that microphone 11 of Sullivan995 is a differential pressure sensor corresponding to the recited flow sensor. Pet. 26 (citing Ex. 1003 ¶ 99; Ex. 1005, 9:64–66, Fig. 3). Petitioner further shows that microphone 11 “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.* (emphasis omitted) (quoting Ex. 1005, 3:21–30). Petitioner relies on Sullivan995’s Figures 2A and 9 to illustrate that “microphone 11 (*sensor*) performs a ‘form

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of measurement’ by ‘detecting snoring sounds’ and ‘other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate’ (*measuring data corresponding to patient’s breathing patterns*).” *Id.* at 27 (citing Ex. 1003 ¶ 104; Ex. 1005, 3:21–33, 11:5–20, 15:56–64); *see also id.* at 27–28 (contending that Sullivan995’s Figures 2A and 9 disclose data indicative of the patient’s breathing patterns) (citing, e.g., Ex. 1005, 13:10–21, 18:27–31, 18:50–53). Patent Owner does not dispute Petitioner’s contentions as to this limitation. *See* PO Resp. 36.

a hardware processor analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state have occurred.

Petitioner shows that Sullivan995’s “combination of an amplifier/filter/processor unit 26 with a speed control unit 23” corresponds to the recited hardware processor. Pet. 30 (footnotes and emphasis omitted) (citing Ex. 1005, Figs. 3, 12). Petitioner also shows that “microphone 11 (*flow sensor*) provides its *measured data* to processor unit 26,” and processor unit 26 “generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.” *Id.* at 30–31 (citing Ex. 1005, 10:3–6, 10:37–66, 11:55–62). Petitioner also shows from Sullivan995 that in “generating this control signal, the processor unit 26 (included in the *hardware processor*) therefore *analyzes the data [from the sensor]* to determine the patient’s breathing patterns, which are the snoring patterns or predetermined patterns in Sullivan995.” *Id.* at 32–33 (emphasis omitted) (citing Ex. 1005, 12:67–13:8) (further stating that “the computing system (including processing unit 26 and speed controller 23) ‘analyses and records signals from the pressure sensor,’ and analyzes ‘the sound and

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breathing patterns’ to record ‘indexes such as the number of apneic episodes, the number of hypopneas, their duration, etc.’”).

Petitioner shows that Sullivan995 teaches detecting a breathing pattern because “Sullivan995 describes detecting ‘a snore, or snoring pattern or abnormal breathing pattern’ after the patient has gone to sleep, and then increasing the CPAP pressure in response.” *Id.* at 33–34 (citing Ex. 1003 ¶¶ 112, 117; Ex. 1005, 16:17–22); *see also id.* at 34–35 (explaining that Figure 2A of Sullivan995 discloses data indicative of a patient’s breathing patterns) (citing, e.g., Ex. 1003 ¶¶ 120–121; Ex. 1005, 9:16–32).

As to the hardware processor determining whether the breathing patterns indicate an awake state, Petitioner relies on Sullivan460 and explains as follows:

Sullivan460 discloses determining *whether breathing patterns indicate an awake 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 According to Sullivan460, “a switching means responds to the sleep sensor and automatically switches 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,” where the pressure for the second mode is higher than the pressure for the first mode.

Id. at 36 (alterations, except for ellipses, in original) (citing Ex. 1003 ¶ 124; Ex. 1006, 6:30–7:12, 7:10–12, 7:17–19, claims 22–28, 43–46).

Patent Owner argues in regard to “a hardware processor analyzing the breathing patterns” that “an analysis of both the amplitude and the temporal structure of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.” PO Resp. 36 (citing Ex. 2005 ¶¶ 126–127). According to Patent Owner, the combination of Sullivan995 and

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Sullivan460 does not teach the hardware processor recited in claim 24 because “Sullivan995 cannot distinguish between all the various breathing patterns, including REM sleep versus troubled wakefulness” and “neither Sullivan995 nor Sullivan460 teaches how to detect an awake state versus an asleep state as claimed.” *Id.* at 36–37 (citing Ex. 2005 ¶¶ 125–196). Patent Owner’s arguments do not distinguish claim 24 from the combined teachings of Sullivan995 and Sullivan460 because the arguments are premised on Patent Owner’s proposed claim construction for “analyzing the breathing patterns,” which we do not accept for the reasons provided above. *See supra* Section II.C.2. Further, Patent Owner’s arguments directed to distinguishing between troubled wakefulness and REM sleep are not commensurate with the scope of claim 24, which is directed to determining “whether breathing patterns indicate an asleep state or an awake state.” *See* PO Resp. 36–42; Ex. 1001, 11:36–12:7. We find Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches a “a hardware processor analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state have occurred,” as recited by claim 24.¹⁵

¹⁵ Petitioner argues in its Reply that the combination of Sullivan995 and Sullivan460 teaches a “hardware processor,” as recited in claim 24, “[e]ven if ‘analyzing the breathing patterns’ in the challenged claims required analysis of both amplitude and temporal structures.” Pet. Reply 13–14. Because we find that claim 24 does not require analysis of both amplitude and temporal structures, we need not address Petitioner’s alternative arguments or Patent Owner’s opposition on this particular issue in its Sur-reply.

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b. Claims 1, 2, 5–11, 13, 15–23, and 25–30

Petitioner asserts that the subject matter of claims 1, 2, 5–11, 13, 15–23, and 25–30 would have been obvious over Sullivan995 and Sullivan460 and provides a detailed analysis of each of these claims with argument and evidence in support thereof. Pet. 36–50. Patent Owner does not raise any arguments directed specifically to claims 1, 2, 5–11, 13, 15–23, and 25–30 aside from the arguments Patent Owner directs to claim 24. *See generally* PO Resp. For the same reasons explained above in our discussion of claim 24, we determine that Petitioner shows by a preponderance of the evidence that the combination of Sullivan995 and Sullivan 460 teaches each limitation of claims 1, 2, 5–11, 13, 15–23, and 25–30. We adopt Petitioner’s arguments and cited evidence as to these claims and limitations as our own determination and basis. *See* Pet. 36–50.

2. Reasons Supporting Obviousness over Sullivan995 and Sullivan460 and Reasonable Expectation of Success

In support of the combination of the teachings of Sullivan995 and Sullivan460, Petitioner states that “Sullivan460 incorporates Sullivan995 by reference and refers to Sullivan995 as describing a ‘flow rate measurement means and [a] treatment means [as being] constructed together as part of one apparatus [with Sullivan995].” Pet. 35 (first two alterations in original) (citing Ex. 1003 ¶ 123; Ex. 1006, 6:22–29); *see also id.* at 20–24 (discussing motivations supporting the asserted combination of teachings from Sullivan995 and Sullivan460, as well as why a person of ordinary skill in the art would have had a reasonable expectation of success). According to Petitioner, the asserted combination advantageously “would apply a low pressure upon wake-up, adding to patient comfort and decreasing the likelihood the patient will remove the mask due to uncomfortably high

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pressure,” as suggested by Sullivan995, which explains “that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period).” *Id.* at 21–22 (citing Ex. 1005, 10:13–46, 14:45–64). Additionally, Petitioner contends that a person 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 23 (citing Ex. 1003 ¶ 91). We find Petitioner’s reasoning above supports the asserted combination of features from Sullivan995 and Sullivan460. We further consider Patent Owner’s arguments in opposition and do not agree with Patent Owner for the reasons provided below. *See* PO Resp. 42–43; PO Sur-reply 18–20.

First, Patent Owner argues that there is “no motivation to combine Sullivan995 with Sullivan460” to “*determine whether breathing patterns indicate an asleep state or an awake state have occurred*,” because “Sullivan460 focuses exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to distinguish between an awake state and an asleep state.” PO Resp. 42–43 (emphasis omitted) (citing Ex. 2005 ¶¶ 125–26). We disagree with Patent Owner’s argument because it is premised on Patent Owner’s proposed construction of “analyzing the breathing patterns” as requiring analysis of both the amplitude structure and the temporal structure, which we do not adopt for the reasons provided above. Further, Patent Owner’s argument that the asserted combination “makes it impossible . . . to distinguish between an awake state and an asleep state” is contrary to the

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disclosure of Sullivan460, which describes two modes of air delivery, one at a higher pressure than the other, as well as “a sleep sensor which senses whether or not the patient is asleep” and “switching means” so that treatment may be switched to a higher pressure mode “as soon as the patient goes to sleep (as determined by an appropriate sensing algorithm in the treatment means).” Ex. 1006, 7:3–12.

Second, Patent Owner argues that there is “no motivation to combine,” because Sullivan460 teaches that “the preset level is a single value of a flow rate, but Dr. Kirkness does not know how this would be calculated.” PO Resp. 43 (citing Ex. 2014, 48:6–20). Specifically, Dr. Kirkness was asked “[h]ow would you calculate a single value of a flow rate?” and responded “[s]o in my – I don’t know how this would be – it doesn’t describe, for me, in this sentence how that level is.” Ex. 2014, 48:6–20. Elsewhere in its Response, Patent Owner implies, in regard to a *different* alleged ground of unpatentability, that Sullivan460 is not enabled. PO Resp. 50 (asserting no motivation to combine Rapport502 and Sullivan460) (citing *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1354 (Fed Cir. 2003), for the proposition that “to qualify as prior art, it must be enabled”). Further, Patent Owner makes the same allegation but directed to the combination of Sullivan995 with Sullivan460 for the first time in its Sur-reply, asserting that “[t]here is no motivation to combine any reference with Sullivan460 because it is not enabling”). PO Sur-reply 18 (citing Ex. 2014, 48:6–20).

We disagree with Patent Owner’s arguments—that Petitioner fails to show any motivation to combine and that Sullivan460 is not enabled—merely because Dr. Kirkness indicated in a deposition that he did not know

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how a preset level is calculated from a sentence in Sullivan460. As Petitioner explains, enablement “is not a requirement to prove invalidity under §103.” *Amgen*, 314 F.3d at 1357 (under §103, “a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein”). Moreover, we agree with Petitioner that the Challenged Claims do not require any preset level for a flow rate, and a person of ordinary skill “would have understood that a preset level is established from previously-acquired data or data from a previous window of time, such as an average level, for example, as taught in Sullivan995.” Pet. Reply 15 (citing Ex. 2014, 38:2–16; Ex. 1005, 17:3–27, Fig. 12). Patent Owner responds that Petitioner’s assertion is unsupported, and that “Petitioner is obligated to address this challenge, and failed to do so.” PO Sur-reply 18–19 (citing *In re Morsa*, 713 F.3d 104, 110 (Fed. Cir. 2013)). We find Petitioner’s arguments persuasive because they are supported by the asserted references. Sullivan995 discloses that the computing system may “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.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22. Based on this disclosure, and given that Sullivan460 incorporates Sullivan995 by reference, we agree with Petitioner that Sullivan460’s disclosure of detecting that the flow rate has fallen below a preset level would have informed a person of ordinary skill that this level was predetermined, so that “the controller 100 activates the nCPAP apparatus 90

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to supply air to the patient 30 at a pressure which ameliorates or eliminates the upper airway flow limitation.”¹⁶ Ex. 1006, 10:17–21.

Third, Patent Owner argues a person of ordinary skill would have had no reasonable expectation of success combining the teachings of Sullivan995 with Sullivan460 because “Sullivan995 is not configured to monitor breathing patterns while the patient is asleep to determine a patient’s pressure flow needs” and “Sullivan995 does not teach how to distinguish [an] awake state and an asleep state, which have opposite implications for pressure and flow.” PO Resp. 43 (citing Ex. 2005 ¶¶ 126–130). We disagree with Patent Owner’s arguments because they are directed to the references individually and not to what the references in combination would have taught a person of ordinary skill. For example, Petitioner relies on Sullivan460 not Sullivan995 to distinguish between an awake state and an asleep state. *See* Pet. 35–36.

Finally, Patent Owner argues that “the proposed modification to Sullivan995’s CPAP system would require methods of digital signal processing that go beyond a combination of known prior art elements,” and “would require the use of methods that analyze the temporal structure of a time series.” PO Resp. 43 (citing Ex. 2005 ¶ 130). To the contrary, Petitioner has shown by a preponderance of the evidence that the Challenged Claims “do not require analysis of temporal structures of a time series,” and that a person of ordinary skill “would have understood that asleep and awake

¹⁶ Sullivan460 refers to a “present level,” which we understand in the full context of the paragraph was a typographical error intended to be “preset level.” *See, e.g.*, Ex. 1006, 10:21–24 (stating that “[w]hen the flow rate measurement means 70 detects that the flow rate increases above the preset level, the controller activates the switch”).

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states could be determined without analysis of temporal structures.” Pet. Reply 17 (citing Ex. 1051 ¶¶ 21–22).

Based on our review of the arguments and evidence cited by Petitioner, and after considering Patent Owner’s arguments, we find Petitioner shows that one of ordinary skill in the art would have had sufficient reason with rational underpinning to combine Sullivan995 and Sullivan460 as asserted and would have had a reasonable expectation of success in doing so.¹⁷

3. *Objective Evidence of Nonobviousness*

The fourth *Graham* factor instructs that we must consider—apart from what the prior art itself would have suggested—whether objective evidence of nonobviousness (i.e., secondary considerations) may lead to a conclusion that the Challenged Claims would not have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (instructing that evidence of secondary considerations, when present, must always be considered in determining obviousness). Objective evidence of nonobviousness may include evidence of commercial success, licensing,

¹⁷ Patent Owner improperly argues for the first time in its Sur-reply that the asserted combination would have required “undue experimentation.” PO Sur-reply 19. Patent Owner’s alleged “undue experimentation” was not raised in Patent Owner’s Response. Petitioner did not have notice of the argument and was deprived of an opportunity to respond in its Reply. Accordingly, Patent Owner’s argument is improper and the issue is deemed waived. *See* Paper 17, 9 (stating that “Patent Owner is cautioned that any arguments not raised in the response may be deemed waived”); *see also* 37 C.F.R. § 42.23(b) (“A sur-reply may only respond to arguments raised in the corresponding reply.”). Moreover, we disagree with Patent Owner’s “undue experimentation” argument because it is premised on Patent Owner’s proposed construction requiring analysis of “both amplitude and temporal structure,” which we do not adopt for the reasons provided above.

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copying, praise by others, long felt but unresolved need, and failure or skepticism of others. *Graham*, 383 U.S. at 17–18. But, secondary considerations are only a part of the “totality of the evidence”; their mere existence does not control the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). Objective evidence of nonobviousness “may often be the most probative and cogent evidence in the record” and “may often establish that an invention appearing to have been obvious in light of the prior art was not.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

Patent Owner argues that evidence of nonobviousness exists in the form of long-felt need. PO Resp. 43–45. According to Patent Owner, since 1991 there has been “a need for patients to increase compliance with usage of their CPAP machines,” with patients complaining about “nocturnal awakenings” and “nasal issues.” *Id.* at 44 (citing Ex. 1036, 1, 5). Patent Owner further argues as follows:

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients’ compliance with CPAP treatment by noting that “the conventional PAP therapy [had] not taken sleep/wake state into account” and “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” ’539 Patent, 1:65-67, 2:18-20. Further, before the development of the claimed invention in the ’539 Patent, self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. *Id.* at 2:51-56. In fact, as of 2002, a [person of ordinary skill] was “not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters.” *See* U.S. Patent No. 6,397,845 to Burton (“Burton845”) (EX2016), 2:33-37. As such, the claimed

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invention solved a long felt but unresolved need – better compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 44–45 (first and second alterations in original).

Patent Owner further argues that conventional CPAP treatment “had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control.” PO Sur-reply 22 (citing Ex. 1001, 2:18–20; Ex. 1053, 296:22–297:15). According to Patent Owner, Dr. Bates’s testimony explained that “[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states.” *Id.* (citing Ex. 1052, 113:3–11, 115:22–116:10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by the ’539 patent’s “ability to distinctly identify when a patient is awake or asleep,” because a person of ordinary skill in the art “prior to the 994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and awake.” *Id.* at 23 (alteration in original) (citing Ex. 1052, 202:23–203:3).

c. Nexus

Objective evidence of nonobviousness “is only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). A “nexus” is a legally and factually sufficient connection between the objective evidence and the claimed invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*,

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938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 32–33 (PTAB Jan. 24, 2020) (precedential), *aff'd sub nom. Zaxcom, Inc. v. Lectrosonics, Inc.*, 2022 WL 499848 (Fed. Cir. Feb. 18, 2022). We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* at 32. If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 33 (quoting *Fox Factory*, 944 F.3d at 1373–75). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Id.* (citing *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011)). There is no requirement that the objective evidence of non-obviousness be tied exclusively to claim elements that are not disclosed in the prior art, and the claimed combination as a whole may serve as a nexus for the objective evidence. *Id.* (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)).

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Petitioner argues that “for secondary considerations to be accorded substantial weight, [Patent Owner] bears the burden of showing that a nexus exists between the claimed features of the invention and the evidence offered to show non-obviousness.” Pet. Reply 22 (citing *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). According to Petitioner, Patent Owner does not meet this burden because: 1) Patent Owner did not establish “a presumption of nexus” since Patent Owner did not identify any product tied to the objective evidence; 2) Patent Owner did not “demonstrate a nexus by showing that long-felt need was met as a ‘direct result of the unique characteristics of the claimed invention’”; 3) Patent Owner did not identify “any failed efforts to solve the problem before the invention”; and 4) Patent Owner does not point to disclosure in the ’539 patent that the “prior art recognized the need to analyze temporal and amplitude structures.” *Id.* at 22–24 (citations omitted).

Patent Owner purports to show nexus by asserting a long-felt need for the claimed system of the ’539 patent. First, Patent Owner has not argued that the presumption of nexus applies and we agree with Petitioner that Patent Owner is not entitled to a presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the Challenged Claims. Second, we address Patent Owner’s evidence of long-felt, but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the ’539 patent, absent the presumption.

d. Long-felt Need

In order to show a long-felt, but unmet, need *for the claimed invention*, the objective evidence must show that the need was a persistent

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one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). “Evidence of a long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would not have persisted had the solution been obvious.” *WBIP*, 829 F.3d at 1332.

Here, Patent Owner suggests increasing the comfort of the CPAP system is a goal to improve patient compliance with CPAP therapy. Patent Owner does not explain, however, why Sullivan460’s treatment means which “addresses ... the comfort of CPAP,” and “is an improvement over the prior art” because of the two modes of air delivery, does not meet the long-felt need identified by Patent Owner. *See* Ex. 1006, 7:7–16; *see also* Pet. 13–16. Thus, we agree with Petitioner that “[t]o the extent that any need existed, it was already satisfied.” Pet. Reply 23 (citations omitted).

Additionally, Patent Owner’s Response fails to identify any failed efforts to solve the problem before the invention and similarly fails to provide sufficient evidence that the ’539 patent satisfied the alleged need. Dr. Bates’s redirect testimony, which Patent Owner almost exclusively relied on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to “little or no weight.” 37 C.F.R. § 42.65(a). Patent Owner’s additional arguments regarding a supposed need for better compliance with CPAP therapy by detecting troubled wakefulness (*see* PO Resp. 44–45; PO Sur-reply 22–23) are not persuasive because troubled wakefulness is not a requirement of any of the Challenged Claims. We agree with Petitioner that Patent Owner “did not provide any evidence that the claimed invention . . . resulted in better compliance in comparison with prior art systems,” and the prior art

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addressed the need for improved therapies “by detecting sleep and wake states, and lowering the pressure during wakefulness.” Pet. Reply 23 (citing Ex. 1006, 7).

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt need. As a result, we accord little weight to Patent Owner’s evidence of long-felt need.

4. *Collective Considerations of the Graham Factors*

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches each limitation of claims 1, 2, 5–11, 13, and 15–30, that a person of ordinary skill would have had a reason to combine features of both Sullivan995 and Sullivan460 as asserted with a reasonable expectation of success when doing so, and that Petitioner’s evidence of unpatentability significantly outweighs the marginal evidence of long-felt need provided by Patent Owner. On the whole, we find that the information provided in consideration of the *Graham* factors collectively demonstrates that Petitioner has shown by a preponderance of the evidence that claims 1, 2, 5–11, 13, and 15–30 of the ’539 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Sullivan995 and Sullivan460.

F. *Alleged Obviousness over Rapoport502 and Sullivan460*

Petitioner contends that claims 1, 2, 5–11, 13, and 15–30 would have been obvious over Rapoport502 and Sullivan460. Pet. 50–68. We determine, as discussed above, that the Challenged Claims are shown to be unpatentable by a preponderance of the evidence based on obviousness over the combination of Sullivan995 and Sullivan460. *See supra* Section II.E.

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As a result, we do not reach the merits of obviousness over Rapoport502 and Sullivan460, and make no determination of whether Petitioner has shown the unpatentability of any of the Challenged Claims as obvious over these references.

G. Alleged Anticipation by Sullivan995 or by Rapoport502

Petitioner contends that claims 1, 2, 5–11, 13, and 15–30 are anticipated by Sullivan995 and also are anticipated by Rapoport502. Pet. 68–71. Petitioner premises its contentions on the notion that it is applying a claim construction of “an awake state” that Patent Owner “implied” in district court litigation, but Petitioner neither expressly construes the term nor identifies an express construction advanced by Patent Owner in district court. *Id.* Petitioner provides no limitation-by-limitation analysis of any challenged claim, and instead focuses much of its short discussion on allegations made by Patent Owner in district court. *Id.* According to Petitioner, Sullivan995 and Rapoport502 each disclose “the absence of breathing patterns indicative of sleep, which is indicative of *an awake state* under PO’s implied construction,” rendering claims 1, 2, 5–11, 13, and 15–30 anticipated by Sullivan995 and by Rapoport502. *Id.* at 69. For the reasons addressed above, we do not adopt Petitioner’s proposed construction of “an awake state” to show anticipation. Accordingly, Petitioner fails to show that any of the Challenged Claims is anticipated by Sullivan995 or by Rapoport502.

III. PATENT OWNER’S MOTION TO EXCLUDE

Patent Owner seeks to exclude Exhibits 1009, 1018, 1019, 1033, 1049, 1051, 1054–1056, 1058, and 1059, portions of Exhibits 1003, 1046, and 1052, as well as portions of the record relying on these disputed

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exhibits, *e.g.*, in the Petition and Reply. PO MTE 1–14; PO MTE Reply 1–5. Petitioner opposes the motion. PO MTE Opp. 1–13. For the following reasons, we deny Patent Owner’s Motion to Exclude.

A. Exhibits 1003 and 1046

Exhibit 1003 is the declaration of Petitioner’s original declarant, Dr. Behbehani, and Exhibit 1046 is the substitute declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s Declaration. *See* Ex. 1046 ¶ 28. Patent Owner argues that certain portions of Exhibit 1003 should be excluded and that the same portions of Exhibit 1003 that Dr. Kirkness adopts should be excluded. PO MTE 3–6, 9; PO MTE Reply 1–2. More specifically, Patent Owner seeks to exclude paragraphs 38, 39, 42, 65, 202, and 253–256 of Exhibit 1003 on the premise that they are based upon hearsay, because Dr. Kirkness did not review “the actual infringement allegations upon which his opinion is based,” because they “lack foundation,” or rely on “inadmissible evidence.” PO MTE 3–6. Further, according to Patent Owner, hearsay may not be a basis for an expert opinion when “the expert adds nothing to the out-of-court statements other than transmitting them to the factfinder.” *Id.* at 6. In opposition, Petitioner argues, among other things, that “[a]n expert such as Dr. Kirkness may base an opinion on any facts or data that the expert ‘has been made aware of or personally observed,’” that “the facts or data ‘need not be admissible’ if an expert in the particular field would ‘reasonably rely’ on those kinds of facts or data,” and that Dr. Kirkness “would certainly rely on peer-reviewed articles regarding the results of a study testing a CPAP machine.” PO MTE Opp. 3. Because we do not rely on the challenged portions of Exhibit 1003 in rendering this Decision, we deny Patent Owner’s Motion to Exclude as to

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these portions of Exhibit 1003 and the corresponding portions of Exhibit 1046, as moot.

B. Exhibits 1009 and 1054–1056

Exhibit 1009 is the file history of the '344 patent, and Exhibit 1056 is the '344 patent. Exhibit 1054 is the file history of related U.S. Patent No. 9,108,009 (the '009 patent"), and Exhibit 1055 is the '009 patent. Patent Owner asserts that "Petitioner introduced new evidence in its Reply with these exhibits," contrary to 37 C.F.R. § 42.61(a), which provides that "[e]vidence that is not taken, sought, or filed in accordance with this subpart is not admissible." PO MTE 7; PO MTE Reply 3–4. According to Patent Owner, these exhibits are "subject to exclusion under" Rule 403 of the Federal Rules of Evidence. In opposition, Petitioner argues that these exhibits are proper evidence in support of its Reply, because Patent Owner "proposed a construction for the 'analyzing the breathing patterns' claim terms for the first time in [Patent Owner's] Response." PO MTE Opp. 7.

In the Petition, Petitioner argued for "using the same claim construction standard that would be used' in district courts," i.e., the ordinary and customary meaning. Pet. 20. In its Response, Patent Owner argued that the language of the term "analyzing the breathing patterns," should be construed as "determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time." PO Resp. 30. Petitioner's first and only opportunity to respond to Patent Owner's construction is in its Reply. And Petitioner's Reply does not change the theory, prior art, or evidence relied upon to challenge the subject claims as compared to that which was presented in the Petition. Therefore,

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Petitioner properly relies on Exhibits 1009 and 1054–1056 in support of its contention in the Petition that the plain and ordinary meaning of the claim term “analyzing the breathing patterns” should be applied. *See* PO MTE Opp. 7–8; Pet. 20. We therefore deny Patent Owner’s Motion to Exclude as to Exhibits 1009 and 1054–1056.

C. Exhibits 1018, 1019, and 1033

Exhibit 1018 is Patent Owner’s complaint in the related district court proceeding. Exhibits 1019 and 1033 are exhibits to that complaint. Patent Owner argues that Petitioner relies upon these exhibits “to support its arguments for anticipation,” and that they should be excluded because “[a]ny discussion of infringement is irrelevant in IPRs.” PO MTE 7–8; PO MTE Reply 4. Petitioner argues that these exhibits are relied on in support of and are relevant to Petitioner’s anticipation contentions in this proceeding. We agree with Petitioner that these exhibits are relevant to Petitioner’s contentions. Moreover, we do not rely on Exhibits 1018, 1019, or 1033 in rendering this Decision and deny Patent Owner’s Motion to Exclude as to these exhibits as moot.

D. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2. Patent Owner argues that the priority date of this patent is after the priority date of the ’539 patent and should be excluded as irrelevant and “not prior art.” PO MTE 9–10; PO MTE Reply 4. Patent Owner also argues it should have been introduced prior to Petitioner’s Reply. PO MTE 10. Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. PO MTE Opp. 9–10. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to

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Dr. Bates's credibility, not as prior art, and find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision and deny Patent Owner's Motion to Exclude as to Exhibit 1049 as moot.

E. Exhibit 1051

Exhibit 1051 is the Declaration of Dr. Kirkness in support of Petitioner's Reply. Patent Owner argues that Exhibit 1051 should be excluded because it raises "new issues" and "new evidence that could have been presented in a prior filing." PO MTE 10; PO MTE Reply 2–3. The only "example," provided by Patent Owner in support of its argument is that Dr. Kirkness "uses Exhibits 1049 and 1054–1056 in the exact same manner" as they are used in Petitioner's Reply and should therefore be excluded for the same reasons discussed above. PO MTE 10–11. For the reasons discussed above, we deny the Motion to Exclude as to Exhibit 1051.

F. Exhibit 1052

Exhibit 1052 is the transcript of Dr. Bates's deposition testimony. Patent Owner argues that the portions of Exhibit 1052 "focusing on patent eligible subject matter and whether certain products, such as processors, infringe by meeting the limitations of the '539 [p]atent should be excluded as irrelevant." PO MTE 11–12 (citing Ex. 1052, 62:7–23, 63:15–25, 64:1–5, 117:9–25, 118:1–11, 146:4–12); PO MTE Reply 4–5. Petitioner argues that the testimony of Dr. Bates is relevant to obviousness and anticipation issues in this proceeding, that there was "no discussion of 'infringement' or 'patentable subject matter,'" and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 10–11. We agree with Petitioner for

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the same reasons provided by Petitioner and deny Patent Owner's Motion to Exclude as to the challenged portions of Exhibit 1052.

G. Exhibit 1058

Exhibit 1058 is related U.S. Patent No. 6,988,994 B2. Patent Owner asserts that because "Petitioner does not discuss or cite" this exhibit "in any document filed in this IPR," it is "irrelevant" and "should be excluded." PO MTE 8–9. Because we do not rely on Exhibit 1058 in rendering this Decision, we deny Patent Owner's Motion to Exclude as to Exhibit 1058 as moot.

H. Exhibit 1059

Exhibit 1059 is an article titled "Control of breathing during sleep" published in Clinical Science in 1984 and was cited by Dr. Kirkness in his reply declaration (Exhibit 1051). Patent Owner argues that Dr. Kirkness relied on Exhibit 1059 to show that a person of ordinary skill in the art "knew 'that a processor could be programmed to analyze breathing patterns that fall below or above certain preset levels of airflow rate to indicate awake or asleep states' and that analysis of temporal structures was not necessary." PO MTE 12 (quoting Ex. 1051 ¶¶ 11, 32); PO MTE Reply 5. According to Patent Owner, "[a]ny use of EX1059 is therefore an improper incorporation by reference through EX1051, violating 37 C.F.R. § 42.6(a)(3), which prohibits incorporating arguments by reference from one document into another document." PO MTE 12. Patent Owner's argument has no merit. As Petitioner notes, 37 C.F.R. § 42.6(a)(3) provides that "arguments must not be incorporated by reference from one document into another document," and Exhibit 1059 "is not an argument." PO MTE Opp. 12. Patent Owner also argues in reply that Exhibit 1059 should have

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been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply 5. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his reply declaration were relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” PO MTE Opp. 12. We agree with Petitioner for the same reasons discussed above regarding Exhibits 1009 and 1054–1056. Because Patent Owner shows no persuasive basis to exclude Exhibit 1059, Patent Owner’s Motion to Exclude as to Exhibit 1059 is denied.

IV. PETITIONER’S MOTION TO EXCLUDE

Petitioner seeks to exclude portions of Exhibit 1053, the deposition testimony of Dr. Bates. Pet. MTE 1–9; Pet. MTE Reply 1–5. Specifically, Petitioner moves to exclude parts of the redirect deposition testimony of Dr. Bates concerning secondary considerations of nonobviousness. Pet. MTE 1–2. Petitioner argues that the redirect testimony of Dr. Bates “was outside the scope of Petitioner’s cross-examination in contravention of [Federal Rule of Evidence] 611(b) and 37 C.F.R. § 42.53 (d)(5)(ii).” *Id.* at 1. Petitioner does not seek to exclude the entirety of Dr. Bates’s redirect testimony concerning secondary considerations but only the specific portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes the Motion. Pet. MTE Opp. 1–10. For the following reasons, we deny Petitioner’s Motion to Exclude.

Petitioner contends that it “did not cross-examine Dr. Bates about any secondary considerations and timely objected to [Patent Owner’s] line of questioning during redirect as being outside the scope.” Pet. MTE 1–2

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(citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9); *id.* at 4 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9). Petitioner further contends that Patent Owner’s “introduction of belated expert testimony into the record via the Sur-Reply is improper and the evidence must be excluded.” *Id.* at 2 (citing *Comcast Cable Commc’ns, LLC v. Rovi Guides, Inc.*, IPR2019-01413, Paper 34 at 4 (PTAB Sept. 16, 2020); *IBM v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 15 at 5 (PTAB Feb. 2, 2015)); *see also id.* at 5–6 (identifying portions of the Sur-reply citing to the disputed testimony). Further, according to Petitioner, “Dr. Bates’ declaration included no discussion of secondary considerations.” *Id.*

Petitioner argues that “FRE 611(b) prohibits redirect examination that goes beyond the scope of cross-examination questions and testimony” and Patent Owner’s “redirect examination did just that.” Pet. MTE 7. Petitioner next argues that “the portions of Dr. Bates’ redirect testimony that Petitioner seeks to exclude from the record . . . have no bearing on ‘matters affecting the witness’s credibility.’” *Id.* at 8 (citations omitted). According to Petitioner, Patent Owner “does not rely on Dr. Bates’ testimony to counter a challenge to his credibility.” *Id.* Petitioner also contends that 37 C.F.R. § 42.53(d)(5)(ii) “similarly prevents a party from expanding the scope of redirect examination beyond that of cross-examination.” *Id.* at 9.

In opposition, Patent Owner argues Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner argues that the PTAB Consolidated Trial Practice Guide provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or *otherwise exceeds the proper scope* of reply or sur-reply, it may request authorization to file a motion to strike.” Pet.

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MTE Opp. 2 (citing PTAB Consolidated Trial Practice Guide (“CTPG”) 80 (PTAB Nov. 2019)). Patent Owner contends that “Petitioner’s counsel reserved that right to strike Dr. Bates’ redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of [Patent Owner] submitting its Sur-Reply.” *Id.* at 2–3 (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact *inadmissible*,” only that “it should be excluded (not stricken) because it is beyond the scope of its cross-examination.” *Id.* at 4. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–25).

In reply, Petitioner contends it “properly focused its motion to exclude on the portions of Dr. Bates’ inadmissible re-direct deposition testimony cited in [the] Sur-Reply,” and that Patent Owner “uses its Sur-Reply as no more than a ‘vehicle’ to enter new evidence into the record.” Pet. MTE Reply 1. Petitioner contends that it “timely objected at the deposition” once Patent Owner began “improperly elic[it] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Federal Rule of Evidence 611(b). *Id.*

For the following reasons, we deny Petitioner’s Motion to Exclude. The CTPG provides that “[a] motion to exclude must explain why the

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evidence is not admissible (e.g., relevance or hearsay)” but should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.” CTPG 79. Further, the CTPG clearly distinguishes a motion to exclude evidence from a motion to strike evidence. The CTPG states that, “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike.” *Id.* at 80. As an alternative to a motion to strike, “a party may request authorization for further merits briefing . . . to address the merits of newly-raised arguments or evidence.” *Id.* A party must seek authorization to file a motion to strike “within one-week of the allegedly improper submission.” *Id.* at 81.

As noted in the CTPG, motions to strike are intended to address, *inter alia*, whether a brief raises new issues or exceeds the proper scope of a sur-reply. Here, Petitioner argues that the redirect testimony is inadmissible under Rule 611(b) and/or 37 C.F.R. § 42.53(d)(5)(ii) as exceeding the scope of cross-examination. But, Petitioner does not seek to exclude all redirect testimony on secondary considerations, only the testimony relied on by Patent Owner in the Sur-reply. Pet. MTE 5 n.2.

The issue presented here borders on the proper scope of a motion to exclude as compared to a motion to strike. The goal of Petitioner’s Motion is clearly to undercut arguments raised in Patent Owner’s Sur-reply directed to objective indicia of nonobviousness. By limiting its Motion to only the portions of Dr. Bates’s redirect examination actually relied on in Patent Owner’s Sur-reply, Petitioner’s arguments reflect this goal. *See, e.g.*, Pet. MTE 5 n.2 (“Although all of Dr. Bates’ redirect testimony on secondary

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considerations was outside the scope of Petitioner's cross-examination, Petitioner narrowly focuses this motion on excluding only those portions that [Patent Owner] relies on in its Sur-Reply."'). One way in which Petitioner could have challenged the arguments raised in Patent Owner's Sur-reply is by requesting authorization to file a motion to strike, which, as noted above, is intended for the purpose of addressing arguments a party believes exceeds the proper scope of sur-reply. *See* CTPG 80. Petitioner did not request such authorization. Instead, by seeking to exclude some of Dr. Bates's redirect testimony on objective indicia (i.e., the portions relied on in Patent Owner's Sur-reply), Petitioner seeks to undercut the arguments raised in Patent Owner's Sur-reply on objective indicia by effectively removing the primary evidentiary support for those arguments. Were we to grant Petitioner's Motion to Exclude, we would be faced with determining what to do with Patent Owner's arguments in the Sur-reply, which would remain of record because they are not the subject of Petitioner's Motion to Exclude (nor could they be based on the CTPG) and (as previously noted) Petitioner did not also file a motion to strike those arguments. The best course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Rule 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination (just as each rule expressly limits the scope of cross-examination to the

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scope of the direct examination/testimony¹⁸), Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of nonobviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the circumstances presented here and in light of the little weight to which Patent Owner’s argument and Dr. Bates’s redirect is entitled, we determine that the better course is to deny Petitioner’s Motion to Exclude.

V. CONCLUSION

The outcome for the Challenged Claims in this proceeding is set forth in summary as follows:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 2, 5–11, 13, 15–30	103(a)	Sullivan995, Sullivan460	1, 2, 5–11, 13, 15–30	
1, 2, 5–11, 13, 15–30	103(a)	Rapoport502, Sullivan460 ¹⁹		
1, 2, 5–11, 13, 15–30	102(b)	Sullivan995		1, 2, 5–11, 13, 15–30
1, 2, 5–11, 13, 15–30	102(b)	Rapoport502		1, 2, 5–11, 13, 15–30

¹⁸ There are exceptions, e.g., questions pertaining to a witness’s credibility. *See* Fed. R. Evid. 611(b).

¹⁹ For the reasons explained above, we do not reach this alternative ground, because we determine that the subject matter of all Challenged Claims would have been obvious over the combination of Sullivan995 and Sullivan460.

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Claim(s) Challenged	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
Overall Outcome			1, 2, 5–11, 13, 15–30	

ORDER²⁰

Upon consideration of the record before us, it is:

ORDERED that Patent Owner's Motion to Exclude (Paper 48) is denied;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 51) is denied;

FURTHER ORDERED that claims 1, 2, 5–11, 13, 15–30 of U.S. Patent No. 9,427,539 B2 have been proven by a preponderance of the evidence to be unpatentable; and

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

²⁰ Should Patent Owner wish to pursue amendment of a Challenged Claim in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending ALA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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Paper 68
Date: December 6, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

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Patent 9,533,115 B2

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

PESLAK, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

Determining All Challenged Claims Unpatentable

35 U.S.C. § 318(a)

ORDER

Denying Patent Owner's Motion to Exclude (Paper 48) and

Denying Petitioner's Motion to Exclude (Paper 49)

37 C.F.R. § 42.64(c)

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I. INTRODUCTION

ResMed, Inc. (“Petitioner”) filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1, 3–6, 9–12, 14–24, and 26–29 (“the Challenged Claims”) of U.S. Patent No. 9,533,115 B2 (“the ’115 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 ResMed, Inc. (“Patent Owner”) opposed. Papers 8, 9. We granted Petitioner’s Motion to Correct the Petition. Paper 10. Petitioner then filed a Corrected Petition. Paper 11 (“Pet.”).¹ Patent Owner filed a Preliminary Response. Paper 12. On December 7, 2022, we instituted this *inter partes* review as to all Challenged Claims and all grounds presented in the Petition. Paper 16.

After institution, we granted Petitioner’s unopposed motion to substitute Dr. Jason P. Kirkness for Dr. Behbehani. Paper 32. Dr. Kirkness, adopted substantially the entirety of Dr. Behbehani’s prior opinions. Ex. 1046 ¶¶ 1, 28 (adopting paragraphs 20–28, 32–85, and 89–293 of Dr. Behbehani’s Declaration (Ex. 1003)). In this Decision we cite to the Declaration of Dr. Behbehani (Ex. 1003) with the understanding that the opinions expressed were adopted by and, therefore, are attributable to Dr. Kirkness.

Patent Owner filed a Response to the Petition (“PO Resp.”) supported by the Declaration of Dr. Jason H.T. Bates. Paper 33; Ex. 2006.² Petitioner filed a Reply (“Pet. Reply”) supported by a Declaration of

¹ Further references herein to “Petition” are to the Corrected Petition, Paper 11.

² Dr. Bates provided corrections to certain citations in his Declaration. Ex. 1048.

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Dr. Kirkness. Paper 41; Ex. 1051. Patent Owner filed a Sur-reply (“Sur-reply”). Paper 44. An oral hearing was held on October 2, 2023 and the transcript is entered into the record. Paper 63³

Additionally, Patent Owner filed a Motion to Exclude Exhibits 1009, 1018, 1049, and 1054–1059, and portions of Exhibits 1003, 1046, 1051, and 1052. Paper 48 (“PO MTE”); *see also* Paper 52 (Petitioner’s Opposition to Patent Owner’s MTE (“PO MTE Opp.”)); Paper 53 (Patent Owner’s Reply in Support of Its MTE (“PO MTE Reply”)). As explained below, we deny Patent Owner’s Motion to Exclude. *See infra* Section III.

Petitioner filed a Motion to Exclude portions of Exhibit 1053. Paper 49 (“Pet. MTE”); *see also* Paper 51 (Patent Owner’s Opposition to Petitioner’s Motion to Exclude (“Pet. MTE Opp.”)); Paper 54 (Petitioner’s Reply in Support of Its Motion to Exclude (“Pet. MTE Reply”)). As explained below, we deny Petitioner’s Motion to Exclude. *See infra* Section IV.

We have jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the Challenged Claims of the ’115 patent. For the reasons discussed below, we determine Petitioner establishes by a preponderance of the evidence that all of the Challenged Claims are unpatentable.

³ The Parties both filed objections to the other party’s demonstrative exhibits and hearing arguments, and responses to the objections. Papers 60, 61, 64–67. Demonstrative exhibits and hearing arguments are not evidence and are not relied on as a basis of this Decision. Accordingly, the objections are denied as moot.

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A. Related Matters

The Parties identify the '115 patent as a subject of *New York University v. ResMed, Inc.*, No. 1:21-cv-00813-JPM (D. Del. 2021). Pet. 2; Paper 5, 2.

Petitioner also states that it filed petitions for the following related patents: U.S. Patent No. 6,988,994 B2 (the "'994 patent") (IPR2022-00993), U.S. Patent No. 9,108,009 B2 (IPR2022-00988), U.S. Patent No. 9,168,344 B2 (the "'334 patent") (IPR2022-00994), U.S. Patent No. 9,427,539 B2 (the "'539 patent") (IPR2022-00989), U.S. Patent No. 9,867,955 B2 (the "'955 patent") (IPR2022-00991), and U.S. Patent No. 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. 2; Paper 5, 2.

C. The '115 Patent

The '115 patent is titled "System and Method for Diagnosis and Treatment of a Breathing Pattern of a Patient." Ex. 1001, code (54). The '115 patent issued on January 3, 2017, from Application No. 15/019,347, which was filed on February 9, 2016. *Id.* at codes (45), (21), (22). Application No. 15/019,347 claims priority through a series of continuation and continuation-in-part applications to Application No. 10/642,459, filed August 14, 2003. *Id.* at code (63).

The '115 patent is directed to a system and method for diagnosing and treating the breathing pattern of a patient. Ex. 1001, code (54). As background, the '115 patent explains that "[o]bstructive sleep apnea syndrome (OSAS) is a well recognized disorder which may affect as much

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as 1-5% of the adult population.” *Id.* at 1:31–34. According to the ’115 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 1:37–44. The ’115 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS.” *Id.* at 1:60–63. The ’115 patent describes PAP therapy as a person wearing a tight-fitting nasal mask during sleep and 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.” *Id.* at 1:60–63, 2:13–15.

The ’115 patent states 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, 1:67–2:2. 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 2:20–23. The ’115 patent also states that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:34–35.

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Figure 1 of the '115 patent is reproduced below.

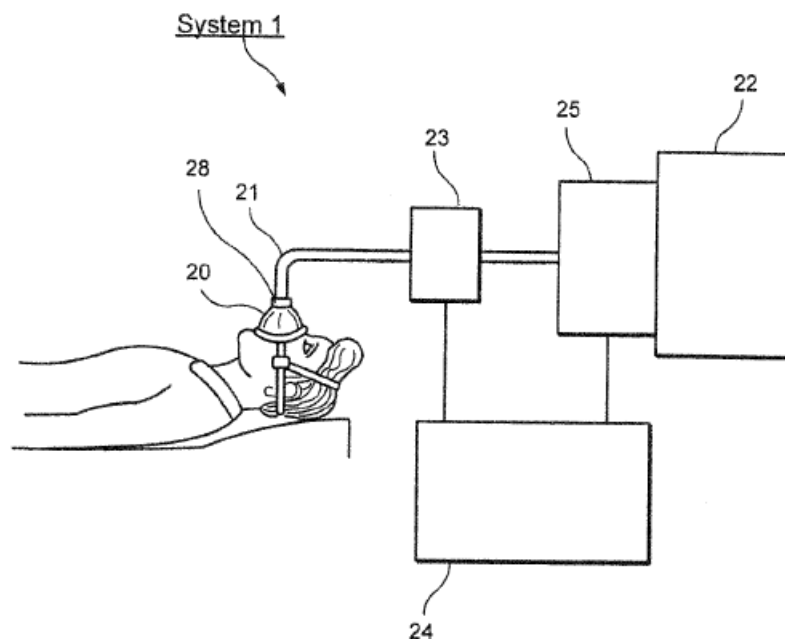


FIG. 1

Figure 1 “shows an exemplary embodiment of a system according to” the '115 patent. Ex. 1001, 3:24–25. System 1, shown in Figure 1, includes mask 20 placed over the face of the patient which is connected via tube 21 for receiving an airflow of a particular pressure from flow generator 22. *Id.* at 3:54–58. The '115 patent describes 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 3:63–66. The '115 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 3:67–4:4.

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The '115 patent also describes a method that uses Figure 1's system 1. Ex. 1001, 3:26–28. “[S]ystem 1 initiates a real-time monitoring procedure of the patient's breathing patterns.” *Id.* at 4:20–21. The '115 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 4:21–25. The '115 patent further explains 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 4:26–30. According to the '115 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 4:30–34. The '115 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 4:37–39, 4:46–61.

The '115 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, 5:62–64. The '115 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 7:50–53.

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D. Illustrative Claims

Claims 1, 15, 21, and 27 are independent claims. Claim 1 is representative of the claimed subject matter and is reproduced below with Petitioner's annotations:

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

[a] a flow generator which generates a flow of breathable gases to be supplied to a patient;

[b] a flow sensor measuring data indicative of the patient's breathing patterns; and

[c1] at least one hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data, [c2] the hardware processor determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the indication of the patient's breathing patterns, [c3] wherein the hardware processor automatically increases a pressure supplied to the patient when the hardware processor determines that an indication of the patient's breathing patterns representative of a change from an awake state to an asleep state has occurred, [c4] the indication of the patient's breathing patterns representative of a change from an awake state to an asleep state including at least one of a regularity of breathing or a regular period of obstructions.

Ex. 1001, 9:51–10:8.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1, 3–6, 9–12, 14–24, and 26–29 would have been unpatentable on the following grounds (Pet. 4–5):

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Pet. Challenge Id.	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
Ground 1	1, 3–6, 9–12, 14–18, 20–24, 26–29	103(a) ⁴	Sullivan995, ⁵ Sullivan460 ⁶
Ground 2	19	103(a)	Sullivan995, Sullivan460, Matthews ⁷
Ground 3	1, 3–6, 9–12, 14–24, 26–29	103(a)	Rapoport502, ⁸ Sullivan460
Ground 4	19	103(a)	Rapoport502, Sullivan460, Matthews

II. ANALYSIS

A. Overview

Petitioner bears the burden of establishing the unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

⁴ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because an application related to the application from which the ’115 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of § 103 applies. *See* Ex. 1001, code (63). No issue in this proceeding turns on the applicable version of the statute, and the outcome of this Decision would be the same regardless of which version of the statute applies.

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

⁶ WO 01/05460 A1, published Jan. 25, 2001 (Ex. 1006, “Sullian460”).

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

⁸ U.S. Patent No. 5,490,502 (issued Feb. 13, 1996) (Ex. 1008, “Rapoport502”).

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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). *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. 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. 20 (citing Ex. 1003 ¶ 86). 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.* (citing Ex. 1003 ¶ 87). Patent Owner does not dispute Petitioner’s definition of the person of ordinary skill in the art. PO Resp. 10.

We apply Petitioner’s level of skill in the art because it appears consistent with the problems addressed in the ’115 patent and the prior art.

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C. 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 v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). 37 C.F.R. § 42.100(b) (2019). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing claims in accordance with their ordinary and customary meaning, we take into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thornerv. Sony Comput. Entm’t. Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs.*,

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Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999)). To determine whether Petitioner has shown that the Challenged Claims are unpatentable, we expressly construe the claim term “troubled wakefulness,” and we discuss the Parties’ contentions for the claim term “analyzes the data to determine the patient’s breathing patterns.”

a. “troubled wakefulness”

Petitioner contends that the term “troubled wakefulness” in claim 19 “means ‘state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.’” Pet. 21 (citing Ex. 1003 ¶ 90). Petitioner asserts that “[t]his term is not an industry standard term and was coined in the [‘115] Patent⁹.” *Id.* (citing Ex. 1003 ¶ 91). According to Petitioner, the ‘115 patent “describes ‘troubled wakefulness’ as a state ‘in which the breathing pattern is characterized by irregular[] 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.* (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.* (second alteration in original) (citing Ex. 1001, 2:40–47).

Patent Owner “agrees with this construction.” PO Resp. 28.

⁹ Petitioner refers to “the ‘024 Patent” and cites to paragraph 91 of Dr. Behbehani’s Declaration. Pet. 21. In paragraph 91, Dr. Behbehani refers to the ‘115 patent. Accordingly, we understand that Petitioner’s reference to the ‘024 patent is a typographical error and that Petitioner is referring the ‘115 patent.

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We adopt Petitioner’s undisputed construction of “troubled wakefulness” because it is supported by and consistent with the Specification of the ’115 patent, which explicitly describes the term. *See, e.g.,* Ex. 1001, 4:59–64.

b. “analyzes the data to determine the patient’s breathing patterns”

Patent Owner proposes that the term “analyzes the data to determine the patient’s breathing patterns” appearing in claim 27 should be construed as “determin[es] a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examin[es] the values of the parameters and the order which they appear in time.” PO Resp. 28.¹⁰ Petitioner contends that this term should be given its plain and ordinary meaning. Pet. Reply 2.

In the Petition, Petitioner did not expressly construe “analyzes the data to determine the patient’s breathing patterns”, but did analyze and address the prior art to identify the teachings of the prior art that Petitioner contends teach this limitation of claim 27. *See, e.g.,* Pet. 29–31 (addressing limitation 27[c1]). In the Patent Owner Response, Patent Owner argues that “analyzes the data to determine the patient’s breathing patterns” means “determin[es] a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examin[es] the

¹⁰ In the Sur-reply, Patent Owner argues that this construction should also be applied to claims 1, 15, and 21 because those claims recite language similar to the phrase recited in claim 27. *See* Sur-reply 3 n.5 (pointing to claim 1’s recitation of “analyzes . . . the breathing patterns”; claim 15’s recitation of “analyzes the indication of the patient’s breathing patterns”; and claim 21’s recitation of “determining . . . one or more indications of the patient’s breathing patterns based on the data indicative of the patient’s breathing patterns”).

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values of the parameters and the order which they appear in time.” PO Resp. 28. Patent Owner also refers to “the values of the parameters and the order which they appear in time” in its proposed construction as “an analysis of both the amplitude structure and the temporal structure of a time series of breath-by-breath parameters calculated from a flow waveform.” *See, e.g., id.* at 2, 6, 10. As borne out through Patent Owner’s arguments in response to Petitioner’s challenges and as further elaborated in Patent Owner’s Sur-reply, Patent Owner contends that “analyzes the data to determine the patient’s breathing patterns” and allegedly similar recitations in claims 1, 15, and 21, require analysis of “both amplitude and temporal structures.” PO Resp. 33–34; PO Sur-reply 4.

Petitioner disputes this proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2; *see id.* at 2–10. For the reasons that follow, we agree with Petitioner.

i. The Parties’ Contentions

To explain why the claim phrase should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the specification” of the ’115 patent. PO Resp. 28 (citing Ex. 1001, 4:46–53; Ex. 2006 ¶ 139); *see also* Sur-reply 14 (Patent Owner arguing that according to Dr. Bates “‘breathing patterns’ has no ordinary meaning and ‘is an extremely general term’”) (citing Ex. 1052, 108:25–109:1–7). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apnea and hypopnea in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters

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and the order in which they appear in time.” PO Resp. at 28–29 (citing Ex. 2006 ¶ 139).

Patent Owner points to the description of Figures 7 and 8 of the ’115 patent in support of its construction. PO Resp. 29–30 (citing Ex. 1001, 4:61–5:1, 5:25–41; Ex. 2006 ¶¶ 140, 142). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient’s airflow, but no periodic irregularity in breath size. Ex. 1001, 4:61–5:1. Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. *Id.* at 5:25–38.

According to Patent Owner, “[t]his methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns” and focuses “on a determination of ‘the sequence of parameters of a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time.’” PO Resp. 29 (citing Ex. 2006 ¶ 140); *see also* Sur-reply 5 (citing Ex. 1001, 4:61–5:1; Ex. 2006 ¶ 140) (asserting that the ’115 patent describes Figure 7 as showing “[b]oth amplitude and temporal structures are likewise described when examining specific flow waveforms”). Patent Owner further argues that the description of Figure 8 in the Specification “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 29 (citing Ex. 1001, 5:25–41; Ex. 2006 ¶ 142); Sur-reply 5–12.

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Additionally, Patent Owner suggests the Specification’s discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. PO Resp. 30 (citing Ex. 1001, 6:41–48; Ex. 2006 ¶ 143).

Turning to the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’115 Patent.” Sur-reply 3; *see also id.* at 9–14 (arguing that distinguishing troubled wakefulness from REM sleep requires assessing both amplitude and temporal structure). First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” Sur-reply 4 (quoting Ex. 1001, 4:46–53) (citing Ex. 2006 ¶ 138). Patent Owner maintains that the descriptions of the waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of waveforms. *Id.* at 5–7 (citing Ex. 1001, 4:61–5:1, 5:32–41, 5:24–33; Ex. 1052, 81:17–23, 180:1–15; Ex. 2006 ¶¶ 140–42). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’115 Patent,” but contends that “these are not obligatory.” *Id.* at 6. Patent Owner asserts that enablement of the ’115 patent “hinges on its ability to distinguish between all awake and asleep states,” and “[i]f not achieved, incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 7.

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Second, Patent Owner asserts that during the prosecution of the related '344 patent, the applicant responded to a rejection by arguing that the prior art, in that instance, “failed to discern between regular wakefulness and troubled wakefulness.” Sur-reply 7–8 (citing Ex. 1009, 404). Patent Owner argues that it is necessary to integrate “both amplitude and temporal structure analyses to distinguish all awake and asleep states.” *Id.* at 8.

Third, Patent Owner argues that “a patentee does not need to rigidly define terms, but can imply their own meaning.” Sur-reply 8. Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by Figure 7 – a flow waveform indicating troubled wakefulness.” *Id.* (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the Specification “provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “[s]ince ‘analyses the data’ is followed by ‘to determine the patient’s breathing patterns,’ some of which occur in the asleep state and some of which occur in the awake state, this further implies that these states can be separated from one another.” *Id.* (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22). Patent Owner contends that, “[g]iven the separation between awake and asleep states discussed in the ’115 Patent, [Patent Owner’s] construction is integral for discerning the difference and applying the correct pressure” because without doing so, it “could result in inappropriate pressure administration.” *Id.* at 8–9 (citing Ex. 1052, 179:23–25; Ex. 2006 ¶ 143).

Patent Owner also argues that extrinsic evidence supports its proposed construction. Sur-reply 9–14. Based on Dr. Bates testimony, Patent Owner asserts that “[b]y assessing *only amplitude*” the waveforms of troubled

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wakefulness and REM sleep “appear indistinguishable,” but “their temporal structure (order in time) . . . offers differentiation.” *Id.* at 10 (citing Ex. 2006 ¶ 74). Patent Owner argues it proves its argument by showing that if the “temporal structure” of the REM sleep waveform is “rearranged in time,” then the resulting “time series has a random appearance that cannot be distinguished from troubled wakefulness.” *Id.* at 11 (citing Ex. 2006 ¶ 75) (emphasis omitted). Patent Owner reasons that “amplitude structure and temporal structure convey independent information” and both must be considered in an analysis or “the awake state can be confused with an asleep state.” *Id.* at 12 (citing Ex. 2006 ¶ 68). According to Patent Owner, it is “Dr. Bates’ illustrations [that] clearly present the problem solved by the ’115 Patent.” *Id.*

According to Patent Owner, construing “analyzing breathing patterns” to include “any type” of breathing pattern analysis, as suggested by Dr. Kirkness, is “nonsensical, as it might even encompass using a mirror to check for breaths.” Sur-reply 14 (citing Ex. 1051 ¶ 16).¹¹

Specifically, Patent Owner argues as follows:

Dr. Bates examined the specification to determine what characteristics of breathing were crucial to analyzing the breathing pattern with respect to the invention’s essence. [Ex. 1052], 24:20-25, 25:1-13. He determined that a [person of ordinary skill in the art], after reading the ’994 Patent, would understand that analyzing breathing patterns, with respect to the

¹¹ Patent Owner also states that “Dr. Kirkness argues that the ’115 Patent is indefinite, especially regarding the measurement of airflow waveforms and temporal/amplitude aspects,” and that “Petitioner has never raised indefiniteness.” Sur-reply 13. We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths.”

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'115 Patent, needs to confer the ability to distinguish between troubled wakefulness and REM sleep. *Id.*, 111:22-25 – 112:1-21. In contrast to the broad construction proposed by Petitioner, [Patent Owner's] construction evidences the understanding of a [person of ordinary skill in the art] – that analyzing breathing patter[n]s requires analysis of amplitude and temporal structures.

Sur-reply 14–15.

Petitioner proposes that we construe the phrase in accordance with its plain and ordinary meaning because “[n]othing in the intrinsic record limits the ‘analyzing the breathing patterns’ terms to analysis of either or both amplitude and temporal structures—instead, the claims, specification, and prosecution history use these terms in accordance with their plain meaning.” Pet. Reply 4 (citing *CCS Fitness*, 288 F.3d 1359 at 1366). Petitioner asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the specification or during prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” *Id.* at 6 (quoting *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, ‘the patentee must clearly express an intent to redefine the term.’” *Id.* (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends “[n]o such intent exists here” and Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* at 6–7 (citing Ex. 1051 ¶ 24).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner's] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as “propos[ing] a lengthy

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construction and then constru[ing] its own construction to inject two requirements: that the processor must analyze (1) ‘the value[s] of the parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.* (third alteration in original) (citing PO Resp. 29; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert decided based on his personal experience, as opposed to that of a” person of ordinary skill in the art. *Id.* (citing Ex. 1053, 271:10–14).

Responding to Patent Owner’s citations to the Specification, Petitioner contends that the Specification “further confirms that the terms encompass any type of breathing pattern analysis” and “states that ‘[t]here are a number of characteristics of the patient’s breathing patterns that may be taken into account in making such a determination’ . . . and does not limit the analysis to any particular characteristic.” Pet. Reply 4–5 (first alteration in original) (citing Ex. 1001, 2:65–67, 4:35–5:41, Figs. 3–8; Ex. 1051 ¶¶ 16–24; Ex. 1052, 28:4–30:21; Ex. 2006 ¶¶ 46–48, 138, 140). Petitioner also contends that “[t]he specification further states the flow sensors ‘detect the rate of airflow’ and provide ‘[s]ignals corresponding to the airflow’ to a processing arrangement for processing.” *Id.* at 5 (second alteration in original) (citing Ex. 1001, 3:63–4:1). Thus, Petitioner asserts the Specification “confirms that temporal analysis is not required.” *Id.*

Petitioner also addresses the prosecution history of patents related to the ’115 patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5. Petitioner

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asserts that, in responding to different office actions, the applicant did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1009, 404; Ex. 1054, 91, 128).

Next, Petitioner contends Patent Owner's extrinsic evidence, in the form of Dr. Bates's testimony, contradicts the intrinsic record and should be disregarded. Pet. Reply 7–10. Petitioner asserts Dr. Bates “performed a ‘crude’ analysis by ‘approximating’ the amplitudes of each breath in the figures ‘estimat[ing] by eye . . . the size of those individual breaths.’” *Id.* at 7 (first alteration in original) (citing Ex. 1052, 75:11–76:14, 78:16–79:19). Petitioner argues that Dr. Bates's “analysis has no basis in the patent.” *Id.* Petitioner presents five arguments in rebuttal in regard to the testimony of Dr. Bates:

(1) Dr. Bates's analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the ’115 patent would have derived [Patent Owner's] construction.” *Id.* (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* (citing Ex. 1052, 75:11–76:14; 78:16–79:19; 90:8–91:11).

(2) Dr. Bates's analysis is based on his own expertise in “digital signal processing,” not from the viewpoint of a person of ordinary skill in the art who would not necessarily have such experience. *Id.* at 8 (citing Ex. 1052, 25:3–27:6, 52:2–25, 64:4, 208:16–21; Ex. 1053, 240:8–242:8; 243:3–8).

(3) Dr. Bates's analysis contradicts the ’115 patent and related patents, which “expressly disclose how to distinguish troubled wakefulness and REM sleep” without requiring temporal analysis. *Id.* (citing Ex. 1001, 4:61–

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5:1; 5:25–41; Ex. 1056, 9:55–10:3 (claim 5), 10:20–24 (claim 8); Ex. 1051 ¶¶ 25–33).

(4) Dr. Bates admitted the waveforms of Figures 7–8 “are merely exemplary.” *Id.* at 9 (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do not limit the broader claim terms of the patent.” *Id.* (citing *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004)).

(5) Dr. Bates “could not explain ‘parameter’ or provide an objective basis to define a ‘sequence’ and ‘series’ used in [Patent Owner’s] construction” and “admitted that [Patent Owner’s] construction would exclude breathing patterns recited in dependent claims.” *Id.* at 10 (citing Ex. 1052, 182:1–184:19, 247:5–11; Ex. 1053, 288:14–289:3). Thus, Petitioner asserts we “should discount [] expert testimony that is clearly at odds . . . with the written record of the patent.” *Id.* (quoting *Phillips*, 415 F.3d at 1318).

ii. Analysis – Claim 27

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14.

In the Patent Owner Response, Patent Owner analyzes only claim 27 which recites “a hardware processor 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.*” Ex. 1001, 12:28–31 (emphasis added). As reflected, claim 27 does not recite “a sequence of parameters” or “a series of breaths” or “examining the values of the parameters and the order in which they appear in time” or any analysis of amplitude or temporal structure. Rather, this portion of claim 27 recites that

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the processor analyzes the data, without specifically reciting how the analysis is performed. The claim phrase does, however, recite the purpose of the analysis—to determine the patient’s breathing patterns—but does not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a significant number of limitations neither expressly recited nor suggested by the specific language of the phrase.

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citation omitted). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech.*, 923 F.3d at 1044.

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of claim 27, nor does Patent Owner argue that it explicitly defined the claim phrase in the Specification. PO Resp. 28–30. We determine that there is no disavowal nor any explicit lexicographic definition of “analyzes the data to determine the patient’s breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we should construe the phrase as Patent Owner proposes. Sur-reply 3, 8–9 (citing, *inter alia*, *AstraZeneca AB v. Mut. Pharm. Co., Inc.*, 384 F.3d 1333 (Fed. Cir. 2004)). We disagree.

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In *AstraZeneca AB*, the United States Court of Appeals for the Federal Circuit reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d 1333, 1339–40 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors “deliberately acted as their own lexicographers” to limit the claim term “solubilizer” to surfactants, the Federal Circuit explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The Federal Circuit rejected AstraZeneca’s argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

The Specification of the ’115 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to “a sequence of parameters” (PO Resp. 28) or an “analysis of both the amplitude

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and the temporal structure of a breath-by breath time series” (*id.* at 33) or any of the other terms set forth in the proposed construction. *See id.* at 28–30. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. *See* Pet. Reply 7 (“[T]he terms ‘amplitude’ and ‘temporal’ do not appear anywhere.”); Sur-reply 6 (“Petitioner rightly observes that terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’115 Patent.”); *see also* Ex. 1051 ¶24 (Dr. Kirkness agrees that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’115 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures”). Patent Owner directs us to portions of the Specification for what Patent Owner characterizes as the process of analyzing breathing patterns. PO Resp. 28 (quoting Ex. 1001, 4:46–53). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” Ex. 1001, 4:46–53. The cited text does not describe analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how “processing arrangement 24 makes a determination as to the 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).” Ex. 1001, 4:26–30. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG

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data, breathing patterns, etc. in determining the patient's state.” *Id.* at 4:30–34. There is no mention that analyzing breathing patterns requires analysis of a sequence of parameters and the order in which they appear in time or an analysis of amplitude and temporal aspects of the waveform. The Specification further describes, in an embodiment, “processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern.” Ex. 1001, 7:23–25. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal aspects of the waveform.

Patent Owner also relies on the description of Figures 7 and 8 of the '115 patent in support of its construction. PO Resp. 29–30. Figures 7 and 8 illustrate airflow waveforms from a patient indicative of a period of troubled wakefulness and a period of REM sleep with irregular breathing, respectively. Ex. 1001, 3:39–43, 4:54–55. Patent Owner relies on Figures 7 and 8 to support its argument that “an analysis of both the amplitude and the temporal structure of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.” PO Resp. 33; Sur-reply 9 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Figures 7 and 8, however, depict one particular example of an awake state (i.e., troubled wakefulness) and one particular example of a sleep state (i.e., REM sleep), respectively. Ex. 1001, 3:30–34. But Patent Owner's analysis does not address Figures 3–6 of the '115 patent. PO Resp. 28–30; Sur-reply 3–17. Figures 3 and 4 show waveforms of a patient during “regular wakefulness” and “regular sleep,” respectively. *Id.* at 3:29–33. Figures 5 and 6 show waveforms from a sleeping patient indicative of

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“hypopnea” and “repetitive obstructive apnea,” respectively. *Id.* at 3:34–38. Patent Owner provides no evidence or explanation why amplitude and temporal aspects of a waveform are required to distinguish regular wakefulness from regular sleep or hypopnea or repetitive obstructive apnea.¹²

Claim 27 recites “analyzes the data to determine the patient’s breathing patterns . . . for indications of a transition between an awake state and an asleep state.” Ex. 1001, 12:30–37. Claim 27 is not limited to distinguishing *solely* between troubled wakefulness and REM sleep, but rather encompasses other states, such as those shown in Figures 3–6. Thus, even if we were to agree with Patent Owner that an analysis of one or both of the amplitude and temporal structures of a waveform is required to distinguish between troubled wakefulness and REM sleep, that determination, alone, would be insufficient to narrow the scope of claim 27, which by its own terms is broad enough to include specific types of types of awake or sleep states other than troubled wakefulness and REM sleep. For the same reasons, we are not persuaded that the additional limitations Patent Owner seeks to read into the claims are necessary to “fully enable” the claims, as Patent Owner asserts.

¹² Patent Owner points to an argument during prosecution of a related patent contending it supports Patent Owner’s claim construction. Sur-reply 6–7. That argument stated that the prior art reference “does not teach or suggest a processing arrangement that distinguishes between regular wakefulness and troubled wakefulness,” but it did not refer to anything even close to resembling the construction proposed by Patent Owner or the concepts of amplitude and temporal structures. Ex. 1009, 404. Thus, this portion of the prosecution history of a related patent does not support Patent Owner’s position here.

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Having reviewed the intrinsic evidence, we next consider the extrinsic evidence, and specifically the testimony of Dr. Bates.¹³ Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 28–30 (citing Ex. 1001, 4:46–53, 4:61–5:1, 5:25–41, 6:41–48; Ex. 2006 ¶¶ 139–143). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. *See* Ex. 2006 ¶¶ 139–143. Rather, Dr. Bates reads portions of the Specification and extrapolates (by taking several unsupported leaps) that the ’115 patent requires, “implicitly demands certain parameter measurements.” Sur-reply 8 (citing Ex. 1052, 44:6–20).

Although expert testimony is legitimate to consider when construing claims, the Federal Circuit has cautioned that because it “is generated at the time of and for the purpose of litigation,” it “can suffer from bias that is not present in intrinsic evidence.” *Phillips*, 415 F.3d at 1318. And, extrinsic evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* at 1317 (internal quotations and citations omitted). In the context presented here, Dr. Bates’s testimony is not supported sufficiently by the intrinsic record or other extrinsic evidence (e.g., objective extrinsic evidence) and, therefore, even though we have considered it fully, we give it little weight.

¹³ Although the Parties briefly address the prosecution history of patents related to the ’115 patent, we do not find the discussion thereof determinative on this specific issue.

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For the reasons explained above, we determine that Patent Owner did not implicitly define the phrase “analyzes the data to determine the patient’s breathing patterns,” as proposed, because Patent Owner has failed to show any sufficient evidence that the ’115 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner’s contentions in light of all the evidence of record, we do not adopt Patent Owner’s proposed construction; instead, we apply the plain and ordinary meaning of “analyzes the data to determine the patient’s breathing patterns” in our consideration of the issues before us.

iii. Analysis – Claims 1, 15, and 21

In the Sur-reply, Patent Owner contends that the construction applies to claims 1, 15, and 21 as well but provides no additional argument or analysis of the specific language of these claims. Sur-reply 3 n.5. Patent Owner contends that Petitioner’s expert, Dr. Kirkness, addressed claims 1, 15, and 21 in his Declaration. *Id.* (citing Ex. 1051 ¶ 9). However, neither Patent Owner nor Dr. Bates separately analyzes the language of these claims or explains why the construction of this phrase appearing only in claim 27 should apply to claims 1, 15, and 21. *See* PO Resp. 28–30; Sur-reply 3–14; Ex. 2006 ¶¶ 136–143.

Claims 1, 15, and 21 recite as follows:

- i.* Claim 1 recites “at least one hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and *analyzes the data*, the hardware processor determines whether to alter the pressure supplied by

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the flow generator to the airway of the patient based, at least in part, on the indication of the patient's breathing patterns." Ex. 1001, 9:60–66 (emphasis added).

- ii. Claim 15 recites "a hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and *analyzes the data for an indication of the patient's breathing patterns.*" *Id.* at 10:57–60 (emphasis added).
- iii. Claim 21 recites "determining using a hardware processor, one or more indications of the patient's breathing patterns based on the data indicative of the patient's breathing patterns including a regularity of breathing or regular period of obstructions." *Id.* at 11:36–40.

Claim 1 does not require analyzing data to determine the patient's breathing pattern, as in claim 27, but merely recites "analyzes the data" and subsequently determines whether to alter the pressure supplied by the flow generator to the airway of the patient based at least in part on the *indication of the patient's breathing patterns*. Claim 15 requires analyzing the data for an *indication* of the patient's breathing patterns. Patent Owner does not address why claims 1 and 15, which do not require analyzing data to determine the patient's breathing pattern, should be construed the same as claim 27. Nor does Patent Owner address why "analyzing an indication of a breathing pattern" in claim 15 should be construed the same as "analyzing the data to determine the patient's breathing pattern" in claim 27. Claim 21 does not even recite "analyz[ing]" data but rather it recites

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“determining . . . one or more indications of the patient’s breathing patterns.”

Thus, for each of these reasons, in addition to the reasons explained above as to why we do not adopt Patent Owner’s proposed construction for claim 27, we do not adopt Patent Owner’s proposed construction in the context of claims 1, 15, and 21. Rather, we apply the plain and ordinary meaning of each of the phrases recited in claims 1, 15, and 21 in our consideration of the issues before us.

D. Ground 1: Alleged Obviousness of Claims 1, 3–6, 9–12, 14–18, 20–24, and 26–29 over Sullivan995 and Sullivan460

Petitioner contends claims 1, 3–6, 9–12, 14–18, 20–24, and 26–29 would have been obvious over Sullivan995 and Sullivan460. Pet. 21–50. Petitioner’s contentions are supported by Dr. Kirkness. Ex. 1046 ¶¶ 28 (adopting the opinions set forth in Ex. 1003 ¶¶ 20–28, 32–85, 89–293). Patent Owner disputes Petitioner’s contentions. PO Resp. 31–39.

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 and is reproduced below. *Id.* at 8:47.

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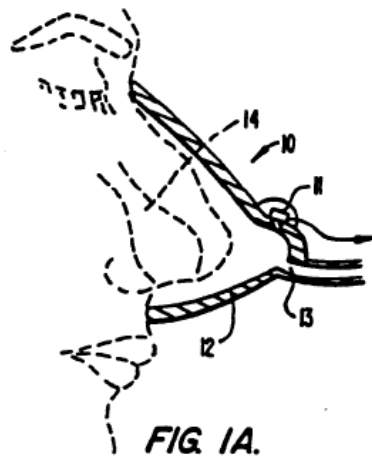
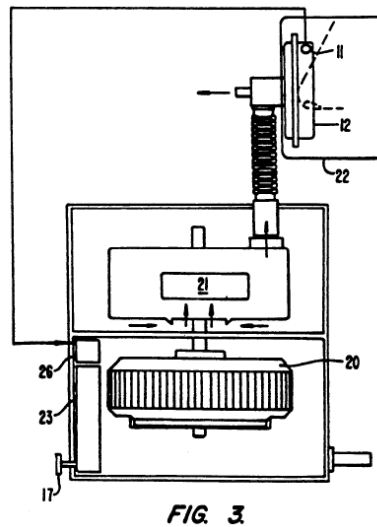


Figure 1A “is a schematic sectional view of one embodiment of a snoring detection apparatus.” *Id.* at 7:66–68. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a nose mask.” *Id.* at 8:47–49. Sullivan995 explains that “[a]ir, being inhaled by 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 example, 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.

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Figure 3 of Sullivan995 is reproduced below.



Sullivan995's Figure 3 shows a CPAP apparatus. Ex. 1005, 9:57–58. The CPAP apparatus 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 9:66–10:3. 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.

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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, at 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 device 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.

Figure 12 of Sullivan995 is reproduced below.

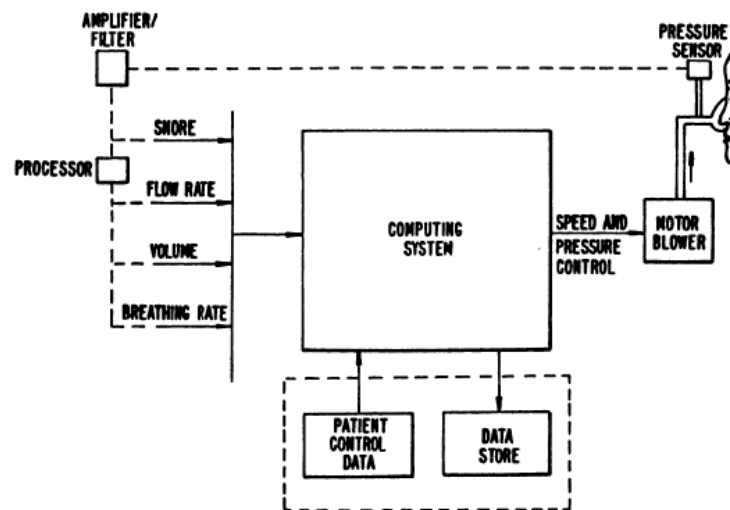


FIG. 12.

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

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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 [Sullivan995].” *Id.* at 6:22–24.

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Figure 2 of Sullivan460 is reproduced below.

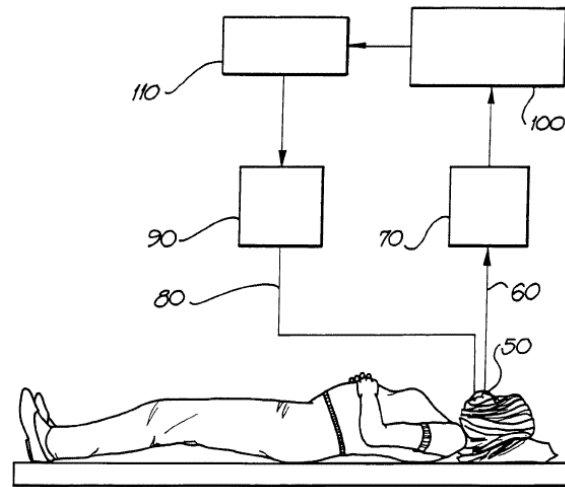


FIG. 2

“Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia.” Ex. 1006, 10:7–8. In Figure 2, patient 30 is laying on bed 40 and wears mask 50 over her nose 50. *Id.* at 10:8–9. Mask 50 is connected via 80 to nCPAP apparatus 90. *Id.* at 10:9–10. 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 10:10–12. 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:

the 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

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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. *Independent Claims 1, 15, and 27*

Petitioner provides a limitation-by-limitation analysis of independent claims 1, 15, and 27, as a group, mapping the prior art to the claim elements.¹⁴ Pet. 25–39. Petitioner also provides contentions concerning motivation to combine and reasonable expectation of success. *Id.* at 21–25.

Patent Owner contends that Sullivan460 fails to teach the limitations “the indication of the patient’s breathing patterns representative of the change from an awake state to an asleep state” (1[c3]) and “a regular period of obstructions as an indication of the transition between awake and asleep” (1[c4]).¹⁵ PO Resp. 34 (emphasis omitted).¹⁶ Patent Owner also contends

¹⁴ For ease of reference, we will refer to claim 1 in our analysis using Petitioner’s claim annotations.

¹⁵ Patent Owner does not provide arguments for the patentability of claims 15 and 27 apart from its arguments for claim 1. PO Resp. 32–38.

¹⁶ Patent Owner reproduces claim 1 and states that the missing claim limitations are highlighted in red. PO Resp. 32–33. However, no limitations

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that “[t]here is no motivation to combine Sullivan995 with Sullivan460 to supply the missing claim limitations” nor is there a reasonable expectation of success. *Id.* at 36–38. Patent Owner also contends that secondary considerations support non-obviousness. *Id.* at 38–39.

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

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

Petitioner contends that, to the extent the preamble is limiting, Sullivan995 discloses a CPAP system that corresponds to a positive airway pressure system for delivery of a flow of breathable gas and that one of ordinary skill in the art would have understood that “CPAP delivers ‘positive’ airway pressure relative to atmospheric pressure.” Pet. 25 (citing Ex. 1003 ¶ 108; Ex. 1005, Abstract, 1:33–36, 2:15–19, 9:57–58, Fig. 3). Petitioner further contends that “Sullivan995’s CPAP system includes a nose mask 12 ‘fluidly sealable to the [patient’s] nasal air passages’ and is ‘for delivery of air to the patient’s nasal passages’ and thereby assists in treating a sleeping disorder in a patient by providing air pressure at a level “to ‘prevent the onset of apnea.’” *Id.* at 26 (citing Ex. 1003 ¶ 110; Ex. 1005, 1:20–48, 5:12–34, 10:31–35, 10:67–11:4, 11:15–20, 11:23–43, claim 6).

Patent Owner does not address the preamble. *See* PO Resp. 31–39.

We reviewed the evidence cited by Petitioner and find Sullivan995 teaches the subject matter of the preamble for the reasons provided by Petitioner, so we need not address whether the preamble is limiting.

are highlighted in red. *Id.* at 33. Nonetheless, we address each of Patent Owner’s arguments below.

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1[a]: a flow generator which generates flow of breathable gases to be supplied to a patient;

Petitioner contends that “Sullivan995’s CPAP system includes a motor 20 with a variable speed that drives a blower 21” that corresponds to the recited flow generator. Pet. 26 (citing Ex. 1003 ¶ 111; Ex. 1005, 9:57–64).

Patent Owner does not address this limitation. See PO Resp. 31–39.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

1[b]: a flow sensor measuring data indicative of the patient’s breathing patterns; and

Petitioner contends “Sullivan995’s CPAP system includes a differential pressure sensor, e.g., microphone 11” that corresponds to the recited flow sensor. Pet. 26–27 (citing Ex. 1003 ¶ 112, Ex. 1005, 9:64–66, Figs. 3, 7). Petitioner further contends microphone 11 “consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as **rate of breathing**, inhaled air flow or inhaled **air flow rate**.” *Id.* at 27 (citing Ex. 1005, Abstract, 3:21–30). Petitioner further contends microphone 11 “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’ (*indicative of the patient’s breathing patterns*).” *Id.* (citing Ex. 1003 ¶ 114; Ex. 1005, 3:21–33, 11:5–20, 15:56–64). Petitioner further contends that Sullivan995’s “Figures 2A and 9 depict the patient’s breathing patterns . . . measured by the microphone 11 without and with, respectively, delivery of air flow from the CPAP system.” *Id.* at 28 (reproducing Sullivan995 Figs. 2A, 9). Petitioner further contends that “Sullivan995’s sensors are

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‘continuously sensing the patient’s breathing [sic] patterns’ including ‘an exhaled air flow volume, an inhaled air flow volume, breathing rate, an exhaled air flow rate, or an inhaled air flow rate.’” *Id.* (citing Ex. 1005, 18:27–31, 18:50–53). According to Petitioner, “[e]ach of these metrics relates to the gas flow delivered to the patient and is *data indicative of the patient’s breathing patterns*.” *Id.* (citing Ex. 1003 ¶ 117).

Patent Owner does not address this limitation. *See* PO Resp. 31–39.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

1[c1]: at least one hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data,

Petitioner contends that Sullivan995’s “combination of an amplifier/filter/processor unit 26 and speed control unit 23” corresponds to the recited hardware processor that “receives the measured data corresponding to the flow of breathable gases from the flow sensor.”

Pet. 29–30 (footnotes omitted) (citing Ex. 1005, 10:3–6, 10:37–66, 11:55–62, Fig. 3, 12). Petitioner further contends Sullivan995’s CPAP system “includes the feedback speed controller 23 illustrated in Figure 12 . . . and includes a computing system.” *Id.* at 30 (citing Ex. 1005, 17:3–6).

Petitioner next contends that in Sullivan995, “electrical signals from the pressure transducer are amplified and filtered to provide pressure waves of the desired frequencies indicative of snoring and breathing [that are] further processed to generate signals indicative of flow rate, volume and breathing rate.” *Id.* at 30–31 (citing Ex. 1005, 17:6–12, Fig. 12). Petitioner further contends that “the processor unit 26, ‘[] generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined

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pattern.” *Id.* at 31 (citing Ex. 1005, 11:55–62). Petitioner also contends that processing unit 26 and speed controller 23 comprise a computing system that “‘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.’” *Id.* at 31 (citing Ex. 1005, 12:67–13:8, Fig. 12).

Patent Owner does not address this limitation. *See* PO Resp. 31–39.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

1[c2]: the hardware processor determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the indication of the patient’s breathing patterns,

Petitioner contends that “[i]n response to the electrical signal generated when snoring sounds occur,” Sullivan995’s “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. 32 (citing Ex. 1005, 9:58–64, 10:6–12, 10:40–46, 10:55–58). Petitioner further contends that “[s]imilarly, ‘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). Petitioner also contends that the process of increasing or decreasing blower speeds corresponds to altering the pressure supplied by the blower to the airway of the patient based on when snoring sounds are detected. *Id.* (citing Ex. 1003 ¶¶ 126–127). According to Petitioner, because the output air pressure is increased when “respond[ing] to a snore, or a snore *pattern*,” the

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determination to increase the pressure is based, at least in part on the indication of the patient's breathing patterns. *Id.* at 33 (citing Ex. 1005, 10:55–58).

Patent Owner does not address this limitation. *See* PO Resp. 31–39.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

1[c3]: wherein the hardware processor automatically increases a pressure supplied to the patient when the hardware processor determines that an indication of the patient's breathing patterns representative of a change from an awake state to an asleep state has occurred,

Petitioner contends that Sullivan995's "hardware processor automatically increases the pressure supplied by the flow generator to the airway of the patient when the hardware processor determines that an indication of a change to an asleep state has occurred." Pet. 33 (citing Ex. 1003 ¶ 139). Petitioner contends Sullivan995 does this by increasing the output pressure of the CPAP unit "in response to detection of snoring." *Id.* (citing Ex. 1005, 10:10–16, 14:17–20, Figs. 3, 13). Petitioner concedes that "Sullivan995 does not explicitly disclose that the increase occurs when the hardware processor determines that an indication of a change from an awake state has occurred." *Id.* at 34 (citing Ex. 1003 ¶ 144) (emphasis omitted). However, Petitioner contends that "this limitation would have been obvious from Sullivan995 in view of Sullivan460." *Id.*

Petitioner contends that "Sullivan460 discloses *determin[ing] that the patient is in an awake 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. 34 (alteration in original) (citing Ex. 1003 ¶¶ 76, 103; Ex. 1006, 7:3–7, 7:10–12, 7:17–19). Petitioner further contends Sullivan460 teaches "'a switching

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means which responds to the sleep sensor and automatically switches 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 pressure is higher in the second mode. *Id.* at 34–35 (alterations in original). According to Petitioner, “[b]ecause Sullivan460 only enters the higher-pressure second mode when the patient is asleep, Sullivan460 discloses *increasing the pressure supplied to the airway of the patient when the hardware processor determines that an indication of a change from an awake state.*” *Id.* at 35 (citing Ex. 1003 ¶¶ 76, 145).

Patent Owner contends that “Sullivan460 only considers mean values of flow, an aspect of the amplitude structure of a time series, in determining sleep versus awake.” PO Resp. 49 (citing Ex. 1005 7:18–19); *see also id.* at 33 (“Sullivan995 in view of Sullivan460 teaches identification of patient state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of a time series.” (citing Ex. 2006 ¶¶ 93(i), 206)). Patent Owner repeats its contention discussed above in our claim construction analysis, that the ’115 patent teaches that “an analysis of both the amplitude and the temporal structure of a breath-by-breath times series is required to distinguish between troubled wakefulness and REM sleep.” *Id.* (citing Ex. 2006 ¶¶ 145–146). According to Patent Owner, “Sullivan995 cannot distinguish between all the various breathing patterns, including REM sleep versus troubled wakefulness.” *Id.* at 33–34 (citing Ex. 2006 ¶¶ 145–146, 151–206). Patent Owner further contends that Sullivan460 does not disclose this limitation because it “focuses exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which

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makes it impossible to distinguish between REM sleep and troubled wakefulness.” *Id.* at 35 (citing Ex. 2006 ¶¶ 148–149).¹⁷

Petitioner, in turn, contends that Patent Owner’s contentions fail because they are based on Patent Owner’s construction for the “analyzing the breathing patterns” terms. Pet. Reply 10–11. Petitioner further contends that Patent Owner effectively concedes that “Sullivan995 in view of Sullivan460 ‘analyz[es] the breathing pattern’ according to its plain meaning, to determine asleep versus awake states.” *Id.* at 11 (alteration in original). Petitioner points to Patent Owner’s statements that Sullivan460 discloses “‘mean values of flow . . . in determining sleep versus awake’ and reduces CPAP when mean airflow increases (i.e., when the patient is awake).” *Id.* (alteration in original) (citing PO Resp. 33, 49; Ex. 1051 ¶¶ 37–39). Petitioner further contends that “Dr. Bates agreed that amplitude is a parameter extracted from a flow waveform, and Sullivan995’s analysis is ‘an example of a kind of analysis of a breathing pattern you could do.’” *Id.* at 12 (citing Ex. 1005, Fig. 8; Ex. 1052, 74:11–24, 184:20–185:7).

Patent Owner’s contentions are unavailing for several reasons.

¹⁷ Patent Owner also argues that claim 1 is not unpatentable for “the additional reasons provided by Dr. Bates in his Declaration, EX2006, which is incorporated here in its entirety.” PO Resp. 36; *see also id.* at 41 (arguing the same for claim 19). Our Rules expressly state that “[a]rguments must not be incorporated by reference from one document into another document.” 37 C.F.R. § 42.6(a)(3). Further, Patent Owner was expressly informed that “arguments not raised in the Patent Owner Response may be deemed waived.” Paper 16, 60 n. 15. Accordingly, we deem waived all arguments based on “additional reasons” in Dr. Bates’s Declaration purported by Patent Owner to have been incorporated by reference into its Response.

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To the extent that Patent Owner relies on its construction of “analyzing the data to determine the patient’s breathing patterns,” the contentions are not persuasive because, as discussed in our claim construction analysis, the claim does not require an analysis of amplitude and temporal structures. Second, Patent Owner’s contention that the combination of Sullivan995 and Sullivan460 does not teach this limitation because it purportedly cannot distinguish between REM sleep and trouble wakefulness (PO Resp. 33–35) is not commensurate with the scope of independent claim 1. Claim 1 does not recite distinguishing between REM sleep and troubled wakefulness, but recites distinguishing between an awake state and an asleep state. Ex. 1001, 10:2–4. Third, Sullivan460’s sleep sensor determines if the patient is asleep “when there is reduced average flow” which aligns with the ’115 patent’s description of “low flow rates” as indicative of REM sleep. Ex. 1001, 5:34–38; *see also* PO Resp. 49 (“Sullivan460 only considers mean values of flow . . . in determining sleep versus awake.” (citing Ex. 1006 7:18–19)).

We have reviewed the evidence cited by Petitioner, and, for the reasons just discussed, we find that the combination of Sullivan995 and Sullivan460 teaches this limitation.

1[c4]: the indication of the patient’s breathing patterns representative of a change from an awake state to an asleep state including at least one of a regularity of breathing or a regular period of obstructions.

Petitioner contends that “Sullivan995 discloses *an indication of transition includes a regular period of obstructions*, by detecting a ‘sequence of snores’ and generating a signal so that the speed control unit 23 increases the speed of the fan motor and the output pressure is increased.” Pet. 35 (citing Ex. 1005, 10:13–28, 14:17–20, 14:56–15:15, Fig. 13).

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Petitioner next contends Sullivan995 “illustrates that four (4) snores (*a regular period of obstructions*) are detected” and recognizes them “as ‘abnormal breathing patterns.’” *Id.* (citing Ex. 1005, 4:28–45, 6:20–24, 7:1–8, 7:29–41, 12:67–13:9, 10:55–58, 14:61–64, 18:9–15, 18:35–42, Figs. 2A, 9). Petitioner further contends “[t]he purpose in Sullivan995 of detecting these *regular periods of obstructions* is to increase pressure to treat sleeping disorders.” *Id.* at 36 (citing Ex. 1003 ¶ 154). Petitioner contends that Sullivan995 “discloses a *regularity of breathing* in an asleep state” where it “describes . . . the waveforms in Figure 2A depict various patient states” including “normal breathing” which according to Petitioner corresponds to the recited “regularity of breathing.” *Id.* (citing Ex. 1003 ¶ 149; Ex. 1005, 9:16–32, Fig. 2A). Petitioner further contends that one of ordinary skill in the art would understand “that a *regularity of breathing* can be used to indicate that the patient has transitioned to a sleep state.” *Id.* (citing Ex. 1003 ¶ 150; Ex. 1034, 5:34–35).

Petitioner alternately contends that “[t]o the extent that Sullivan995 does not expressly state that this *regularity of breathing* is an *indication of a change or transition from an awake state to an asleep state*, this would have been obvious from Sullivan995 in view of Sullivan460.” *Id.* at 37 (citing Ex. 1003 ¶ 155).

Petitioner contends that Sullivan460’s “switching means receives a signal from the sleep sensor, and ‘causes the treatment means to switch from one treatment mode to the other treatment mode.’” Pet. 37 (citing Ex. 1006, claim 27). Petitioner contends this corresponds to switching the treatment mode “upon determining whether the patient is asleep or awake, including a *transition[] between an awake state and an asleep state*.” *Id.* (alteration in

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original) (citing Ex. 1006, claims 44, 45). Petitioner further contends that Sullivan460's "flow rate measurement means 70 detects multiple 'interruptions,' which Fig[ure] 1 depicts, and are *a regular period of obstructions*." *Id.* (citing Ex. 1006, 10:12–16).

Patent Owner contends that "the detection of a combination of obstructions by the CPAP system in Sullivan995 does *not* mean that the patient has transitioned between an awake state and an asleep state." PO Resp. 36 (citing Ex. 2006 ¶ 176). According to Patent Owner, "[t]he patient may already have been asleep for some time before the obstructions were detected, meaning the transition could have happened an arbitrary time previously," and "Sullivan460 does not teach if, during the pre-obstruction phase, the patient is awake or asleep because Sullivan460 does not teach how to distinguish between an awake state and an asleep state as claimed." *Id.*

Patent Owner's contentions are unavailing for several reasons. First, Patent Owner does not address Petitioner's contention that Sullivan995 teaches regularity of breathing in an asleep state which is sufficient to satisfy this limitation. Pet. 35. Second, as discussed above for limitation 1[c3], Petitioner relies on Sullivan460 for the transition from an awake state to an asleep state. *Id.* at 34–35. Consequently, Patent Owner's contention that the detection of obstructions in Sullivan995 does not mean the patient has transitioned between an awake state and asleep state is unavailing because it is an attack on Sullivan995 in isolation. Finally, Patent Owner's contention that Sullivan460 does not teach how to distinguish between an awake state and an asleep state is unavailing for the reasons discussed above for limitation 1[c3].

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We have reviewed the evidence cited by Petitioner, and, for the reasons just discussed, we find that the combination of Sullivan995 and Sullivan460 teaches this limitation.

Motivation to Combine/Reasonable Expectation of Success

In support of the combination of the teachings of Sullivan995 and Sullivan460, Petitioner states that “Sullivan460 incorporates Sullivan995 by reference and refers to Sullivan995 as describing a ‘flow rate measurement means and [a] treatment means [as being] constructed together as part of one apparatus’ [with Sullivan995].” Pet. 34 (first two alterations in original) (citing Ex. 1006, 6:22–29); *see also id.* at 21–25; 38–39 (discussing motivations supporting the asserted combination of teachings from Sullivan995 and Sullivan460, as well as why a person of ordinary skill in the art would have had a reasonable expectation of success). Petitioner contends that “[l]ike Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep.” *Id.* at 34 (citing Ex. 1003 ¶ 76; Ex. 1006, 6:17–29, 7:3–12, 10:9–33, 11:10–12, claims 22–28, 43–46, Figs. 2–4). According to Petitioner, the asserted combination advantageously “would apply a low pressure upon wake-up, adding to patient comfort and decreasing the likelihood the patient will remove the mask due to uncomfortably high pressure,” as suggested by Sullivan995, which explains “that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period).” *Id.* at 23 (citing Ex. 1005, 10:13–46, 14:45–64). Additionally, Petitioner contends that a person 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

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used to sense flow limitations, and Sullivan460 further explains that flow data may be used to determine an awake/sleep state.” *Id.* at 24 (citing Ex. 1003 ¶ 104).

We find Petitioner’s reasoning above supports the asserted combination of features from Sullivan995 and Sullivan460. We further consider Patent Owner’s arguments in opposition and do not agree with them for the reasons provided below. *See* PO Resp. 36–38; Sur-reply 19–22.

First, Patent Owner argues that there is “no motivation to combine Sullivan995 with Sullivan460” to “determine that *an indication of the patient’s breathing patterns is representative of a change or a transition from an asleep state*,” because “Sullivan460 focuses exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to distinguish between . . . an awake state and an asleep state.” PO Resp. 36–37 (alterations in original) (citing Ex. 2006 ¶¶ 145–46). Patent Owner’s argument is unavailing because it is premised on Patent Owner’s proposed construction of “analyzing the data to determine the patient’s breathing patterns” as requiring analysis of both the amplitude structure and the temporal structure, which we do not adopt for the reasons provided above. Further, Patent Owner’s argument that the asserted combination “makes it impossible . . . to distinguish between an awake state and an asleep state” is contrary to the disclosure of Sullivan460, which describes two modes of air delivery, one at a higher pressure than the other, as well as “a sleep sensor which senses whether or not the patient is asleep” and “switching means” so that treatment may be switched to a higher pressure mode “as soon as the patient goes to sleep (as determined by

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an appropriate sensing algorithm in the treatment means).” Ex. 1006, 7:3–12.

Second, Patent Owner argues that there is “no motivation to combine,” because Sullivan460 teaches that “the preset level is a single value of a flow rate, but Dr. Kirkness does not know how this would be calculated.” PO Resp. 37 (citing Ex. 2015,¹⁸ 48:6–20). Specifically, Dr. Kirkness was asked “[h]ow would you calculate a single value of a flow rate?” and responded “[s]o in my – I don’t know how this would be – it doesn’t describe, for me, in this sentence how that level is.” Ex. 2015 48:6–20. Elsewhere in its Patent Owner Response, Patent Owner implies, in regard to a *different* alleged ground of unpatentability, that Sullivan460 is not enabled. PO Resp. 49 (asserting no motivation to combine Rapport502 and Sullivan460) (citing *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1354 (Fed Cir. 2003), for the proposition that “to qualify as prior art, it must be enabled”). Further, Patent Owner makes the same allegation but directed to the combination of Sullivan995 with Sullivan460 for the first time in its Sur-reply, asserting that “[t]here is no motivation to combine any reference with Sullivan460 because it is not enabling”). Sur-reply 20 (citing Ex. 2015, 48:6–20).

We disagree with Patent Owner’s arguments that Petitioner fails to show any motivation to combine and that Sullivan460 is not enabled merely because Dr. Kirkness indicated in a deposition that he did not know how a preset level is calculated from a single sentence in Sullivan460. As Petitioner correctly explains, enablement “is not a requirement to prove

¹⁸ The Patent Owner Response incorrectly refers to the deposition transcript of Dr. Kirkness as Exhibit 2011. PO Resp. 37.

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invalidity under §103.” *Amgen*, 314 F.3d at 1357 (Under §103, “a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein.”). Moreover, we agree with Petitioner that the Challenged Claims do not require any preset level for a flow rate, and a person of ordinary skill “would have understood that a preset level is established from previously-acquired data or data from a previous window of time, such as an average level, for example, as taught in Sullivan995.” Pet. Reply 14–15 (citing Ex. 1005, 17:3–27, Fig. 12; Ex. 2015, 38:2–16). Patent Owner responds that Petitioner’s assertion is unsupported, and that “Petitioner is obligated to address this challenge, and failed to do so.” Sur-reply 20 (citing *In re Morsa*, 713 F.3d 104, 110 (Fed. Cir. 2013)). We find Petitioner’s arguments persuasive because they are supported by the asserted references. Sullivan995 discloses that the computing system may “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.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22. Based on this disclosure, and given that Sullivan460 incorporates Sullivan995 by reference, we agree with Petitioner that Sullivan460’s disclosure of “detect[ing] that the flow rate has fallen below a present [sic] level,” would have informed a person of ordinary skill that this level was predetermined, so that “the controller 100 activates the nCPAP apparatus 90 to supply air to the patient 30 at a pressure which ameliorates or eliminates the upper airway flow limitation.” Pet. 24–25; Ex. 1006, 10:19–21.

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Third, Patent Owner argues a person of ordinary skill would have had no reasonable expectation of success combining the teachings of Sullivan995 with Sullivan460 because “Sullivan995 is not ‘configured to monitor breathing patterns while the patient is asleep to determine a patient’s pressure flow needs’” and “does not teach how to distinguish [an] awake state and an asleep state, which have opposite implications for pressure and flow.” PO Resp. 37 (citing Ex. 2006 ¶¶ 147–150, 170). We disagree with Patent Owner’s argument because it is premised on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns” requiring analysis of both the amplitude structure and the temporal structure, which we do not adopt for the reasons provided above. We also disagree with Patent Owner’s arguments because they are directed to the references, individually, and not to what the references in combination would have taught a person of ordinary skill. For example, Petitioner relies on Sullivan460 not Sullivan995 to distinguish between an awake state and an asleep state. *See* Pet. 34–35.

Finally, Patent Owner argues that “the proposed modification to Sullivan995’s CPAP system would require methods of digital signal processing that go beyond a combination of known prior art elements,” and “would require the use of methods that analyze the amplitude and temporal structures of a time series.” PO Resp. 37–38 (citing Ex. 2006 ¶ 151). To the contrary, Petitioner has shown by a preponderance of the evidence that the Challenged Claims “do not require analysis of temporal structures of a time series,” and that a person of ordinary skill “would have understood that asleep and awake states could be determined without analysis of temporal structures.” Pet. Reply 16 (citing Ex. 1051 ¶¶ 21–22). Petitioner’s

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contentions are supported by the '115 patent which describes that the processor “may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns etc. in the determining the patient’s state” and that “high respiratory rates and low flow rates” are indicative of REM sleep. Ex. 1001, 4:30–34, 5:34–37.

Based on our review of the arguments and evidence cited by Petitioner, and after considering Patent Owner’s arguments, we find Petitioner shows that an ordinarily skilled artisan would have been motivated to combine Sullivan995 and Sullivan460 as asserted, and would have had a reasonable expectation of success in doing so.¹⁹

Claims 15 and 27

As discussed above, Petitioner sets forth contentions for claims 1, 15, and 27 together (Pet. 21–39), and Patent Owner does not provide arguments for claims 15 and 27 apart from those arguments discussed above for claim 1 (PO Resp. 31–38). Consequently, for the same reasons discussed above for claim 1, we find that the combination of Sullivan995 and Sullivan460 teaches every limitation of claims 15 and 27 and that an ordinarily skilled

¹⁹ Patent Owner improperly argues for the first time in its Sur-reply that the asserted combination would have required “undue experimentation.” Sur-reply 21. Patent Owner’s alleged “undue experimentation” was not raised in Patent Owner’s Response, and therefore Petitioner did not have an opportunity to respond to it. Accordingly, Patent Owner’s argument is improper, and the issue is deemed waived. See Paper 16, 60 n.15 (stating that “Patent Owner is cautioned that any arguments not raised in the Patent Owner Response may be deemed waived”). Moreover, we disagree with Patent Owner’s “undue experimentation” argument because it is premised on Patent Owner’s proposed construction requiring analysis of “both amplitude and temporal structure,” which we do not adopt.

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artisan would have been motivated to combine Sullivan995 and Sullivan460 with a reasonable expectation of success.

4. Dependent Claims 3–6, 9–12, 14, 16–18, 20, 28, and 29

Petitioner asserts that claims 3–6, 9–12, 14, 16–18, 20, 28, and 29 would have been obvious over Sullivan995 and Sullivan460 and provides a detailed analysis of each of these claims with argument and evidence in support thereof. Pet. 39–46. Patent Owner does not raise any arguments directed specifically to claims 3–6, 9–12, 14, 16–18, 20, 28, and 29 aside from the arguments Patent Owner directs to claim 1. *See* PO Resp. We have reviewed Petitioner’s evidence and arguments and find that the combination of Sullivan995 and Sullivan460 teaches every limitation of claims 3–6, 9–12, 14, 16–18, 20, 28, and 29 for the reasons provided by Petitioner. *See* Pet. 39–46.

5. Independent Claim 21

For the preamble of claim 21 and the limitations Petitioner identifies as 21[a]–21[c] and 21[e] (Pet. 76), Petitioner relies on its contentions for the substantially similar limitations of claim 1. Pet. 47–48.

For limitation 21[d], Petitioner contends that “Sullivan995’s *hardware processor* reduces pressure ‘if an extended period of snore free breathing occurs’ by ‘automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected.’” Pet. 47–48 (citing Ex. 1005, 10:31–46). According to Petitioner, “[t]his means the blower 21 (*flow generator*) in Sullivan995 *app[lies]* a lower pressure in the absence of snoring.” *Id.* at 48.

Patent Owner does not raise any arguments directed specifically to claim 21 aside from the arguments Patent Owner directs to claim 1. *See* PO Resp.

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We have reviewed Petitioner’s evidence and arguments and find the combination of Sullivan995 and Sullivan460 teaches every limitation of claim 21 and that an ordinarily skilled artisan would have been motivated to combine Sullivan995 and Sullivan460 with a reasonable expectation of success for the reasons provided by Petitioner. *See* Pet. 47–48.

6. Dependent Claims 22–24 and 26

Petitioner asserts that claims 22–24 and 26 would have been obvious over Sullivan995 and Sullivan460 and provides a detailed analysis of each of these claims with argument and evidence in support thereof. Pet. 48–50. Patent Owner does not raise any arguments directed specifically to claims 22–24 and 26 aside from the arguments Patent Owner directs to claim 1. *See* PO Resp. We have reviewed Petitioner’s evidence and arguments and find that the combination of Sullivan995 and Sullivan460 teaches every limitation of claims 22–24 and 26 for the reasons provided by Petitioner. *See* Pet. 48–50.

E. Ground 2: Alleged Obviousness of Claim 19 over Sullivan995, Sullivan460, and Matthews

Petitioner contends claim 19 would have been obvious over Sullivan995, Sullivan460, and Matthews. Pet. 50–52. Patent Owner disputes Petitioner’s contentions. PO Resp. 39–43.

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

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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. Analysis

Claim 19 depends from claim 15 and recites “wherein the awake state is a troubled wakefulness state.” Ex. 1001, 11:20–21.

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. 51 (alterations in original) (citing Ex. 1007, 21:34–44, 21:63–22:1). According to Petitioner, “Matthews’s description of erratic breathing when the patient is awake and in distress is consistent with the ’115 Patent’s description of *troubled wakefulness* as ‘awake and anxious or distressed.’” *Id.* at 51–52 (citing Ex. 1001, 4:54–66).

Patent Owner does not dispute that Matthews teaches the limitation “the awake state is a troubled wakefulness state.” PO Resp. 40–41. Rather,

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Patent Owner argues that “Sullivan995 and Sullivan460 in view of Matthews only teach the identification of patient state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of a time series.” *Id.* (citing Ex. 2006 ¶ 206). Patent Owner then repeats its contention that the ’115 patent requires analysis of amplitude and temporal structures “to distinguish between troubled wakefulness and REM sleep.” *Id.* at 41. This contention is unavailing because we do not adopt Patent Owner’s claim construction requiring an analysis of amplitude and temporal structures.

We have reviewed Petitioner’s evidence in light of the parties’ agreed-on construction of “troubled wakefulness” and find that Matthews teaches the limitations of claim 19. *See* Pet. 50–51 (citing Ex. 1007, 21:34–44, 21:63–22:1).

Motivation to Combine/Reasonable Expectation of Success

Petitioner contends it would have been obvious to an ordinarily skilled artisan “to modify the system of Sullivan995 and Sullivan460 in view of Matthews so that the *hardware processor* in Sullivan995 determines when the patient transitions to a *troubled wakefulness state*.” Pet. 50. According to Petitioner, the ordinarily skilled artisan “would have recognized the advantages of detecting different awake states, including [troubled wakefulness] in which the patient has breathing that becomes ‘erratic,’ as taught [by] Matthews” which “would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* (citing Ex. 1003 ¶ 209). Petitioner notes that Sullivan995 is “concerned with the patient’s comfort, and already discloses

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it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible.” *Id.* (citing Ex. 1005, 2:31–39).

Petitioner next contends that there would be a reasonable expectation of success in combining Sullivan995, Sullivan460, and Matthews. Pet. 50. Petitioner explains that because data from Matthews’s flow sensor “are monitored to control the pressure” and Sullivan460 discloses lowering the pressure in an awake state, a person of ordinary skill in the art “would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient.” *Id.* at 51 (citing Ex. 1003 ¶ 211). According to Petitioner, the modification to Sullivan995 and Sullivan460 “is a combination of 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.” *Id.* (citing Ex. 1003 ¶ 212).

Patent Owner argues that “Sullivan460 and Matthews focus exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to distinguish between REM sleep and troubled wakefulness” and “do not teach how to distinguish between an awake state and an asleep state as claimed.” PO Resp. 42 (citing Ex. 2006 ¶¶ 205–206). Patent Owner again argues that Sullivan460 teaches a preset level that Dr. Kirkness cannot calculate. *Id.* (citing Ex. 2015, 48:6–20). These arguments are unavailing because they are based on Patent Owner’s proposed construction of analyzing the data which we do not adopt and for the reasons discussed above. *See supra* Section II.D.3.

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For reasonable expectation of success, Patent Owner repeats its arguments that Sullivan995 is not configured to monitor breathing patterns while the patient is asleep, Sullivan995 does not teach how to distinguish between troubled wakefulness and REM sleep, and modifying Sullivan995's CPAP would require digital signal processing techniques that go beyond a combination of known prior art elements. PO Resp. 41–42. These arguments are unavailing for the same reasons discussed above. *See supra* Section II.D.3.

We have reviewed Petitioner's contentions and evidence in light of Patent Owner's arguments in opposition and find that Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews teaches the limitations of claim 19 and that an ordinarily skilled artisan would have been motivated to combine Sullivan995, Sullivan460, and Matthews with a reasonable expectation of success. *See* Pet. 50–51.

F. Objective Evidence of Non-obviousness

The fourth *Graham* factor instructs that we must consider—apart from what the prior art itself would have suggested—whether objective evidence of non-obviousness (i.e., secondary considerations) may lead to a conclusion that the challenged claims would not have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (instructing that evidence of secondary considerations, when present, must always be considered in determining obviousness). Objective evidence of non-obviousness may include evidence of commercial success, licensing, copying, praise by others, long felt but unresolved need, and failure or skepticism of others. *Graham*, 383 U.S. at 17–18. But, secondary

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considerations are only a part of the “totality of the evidence”; their mere existence does not control the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). Objective evidence of non-obviousness “may often be the most probative and cogent evidence in the record” and “may often establish that an invention appearing to have been obvious in light of the prior art was not.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

Patent Owner argues that evidence of non-obviousness exists in the form of long-felt need. PO Resp. 38–39, 43. According to Patent Owner, since 1991 there has been “a need for patients to increase compliance with usage of their CPAP machines.” *Id.* at 38 (citing Ex. 1036, 5). Patent Owner further argues as follows:

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients’ compliance with CPAP treatment by noting that “the conventional PAP therapy [had] not taken sleep/wake state into account” and “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” ’994 Patent, 1:44-46, 64–65. Further, before the development of the claimed invention in the ’994 Patent, self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. *Id.*, 2:31-35. In fact, as of 2002, a [person of ordinary skill in the art] was “not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters.” *See* EX2017, 2:33-37. As such, the claimed invention solved a long felt but unresolved need – better compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 39 (first and second alternations in original).

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Patent Owner further argues that conventional CPAP treatment “had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control.” Sur-reply 26 (citing Ex. 1001, 2:20–23, 2:31–35; Ex. 1053, 296:22–297:15). According to Patent Owner, Dr. Bates’s testimony explained that “[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states.” *Id.* at 26–27 (citing Ex. 1052, 113:3–11, 115:22–116:10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by the ’115 patent’s “ability to distinctly identify when a patient is awake or asleep,” because a person of ordinary skill in the art “prior to the 994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and awake.” *Id.* at 27 (alteration in original) (citing Ex. 1052, 202:23–203:3).

(1) *Nexus*

Objective evidence of nonobviousness “is only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). A “nexus” is “a legally and factually sufficient connection” between the objective evidence and the claimed invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented

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invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 32–33 (PTAB Jan. 24, 2020) (precedential), *aff’d sub nom. Zaxcom, Inc. v. Lectrosonics, Inc.*, 2022 WL 499848 (Fed. Cir. Feb. 18, 2022). We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* at 32. If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 33 (quoting *Fox Factory*, 944 F.3d at 1373–75). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Id.* (citing *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011)). There is no requirement that the objective evidence of non-obviousness be tied exclusively to claim elements that are not disclosed in the prior art, and the claimed combination as a whole may serve as a nexus for the objective evidence. *Id.* (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)).

Petitioner argues that “for secondary considerations to be accorded substantial weight, [Patent Owner] bears the burden of showing that a nexus exists between the claimed features of the invention and the evidence offered to show non-obviousness.” Pet. Reply 24 (citing *WMS Gaming, Inc. v. Int’l*

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Game Tech., 184 F.3d 1339, 1359 (Fed. Cir. 1999)). According to Petitioner, Patent Owner does not meet this burden because: 1) Patent Owner did not establish “a presumption of nexus” since Patent Owner did not identify any product tied to the objective evidence; 2) Patent Owner did not “demonstrate a nexus by showing that long-felt need was met as a ‘direct result of the unique characteristics of the claimed invention’”; 3) Patent Owner did not identify “any failed efforts to solve the problem before the invention”; and 4) Patent Owner does not point to disclosure in the ’115 patent that the “prior art recognized the need to analyze temporal and amplitude structures.” *Id.* at 24–26 (citations omitted).

First, Patent Owner has not argued that the presumption of nexus applies, and we agree with Petitioner that Patent Owner is not entitled to a presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the Challenged Claims. Second, we address Patent Owner’s evidence of long-felt, but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the ’115 patent, absent the presumption.

(2) Long-felt Need

In order to show a long-felt but unmet need *for the claimed invention*, the objective evidence must show that the need was a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). “Evidence of long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would have not persisted had the solution been obvious.” *WBIP, LLC*, 829 F.3d 1317 at 1332.

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Here, Patent Owner suggests increasing the comfort of the CPAP system is a goal to improve patient compliance with CPAP therapy. Patent Owner does not explain, however, why Sullivan460's treatment means which "addresses . . . the comfort of CPAP," and "is an improvement over the prior art" because of the two modes of air delivery where the pressure is lower in the awake state, does not meet the long-felt need identified by Patent Owner. *See* Ex. 1006, 7:7–16; *see also* Pet. 17–18. Although Patent Owner argues the importance of detecting the troubled wakefulness state (PO Resp. 34), none of the challenged independent claims recite troubled wakefulness. Thus, we agree with Petitioner that "[t]o the extent that any need existed, it was already satisfied." Pet. Reply 25 (citations omitted).

Additionally, Patent Owner does not identify any failed efforts to solve the problem before the invention and similarly fails to provide sufficient evidence that the invention satisfied the alleged need. Dr. Bates's redirect testimony, which Patent Owner almost exclusively relied on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to "little or no weight." 37 C.F.R. § 42.65(a). Patent Owner's additional arguments regarding a supposed need to analyze temporal and amplitude structures is similarly insufficiently supported because the '115 patent fails to provide any discussion of a need to analyze those structures, as Petitioner persuasively explains (*see* Pet. Reply 26), and because we do not limit the claims to requiring analysis of those structures as proposed by Patent Owner.

Patent Owner relies on the same evidence and arguments concerning objective evidence of nonobviousness, and specifically long-felt need, with regard to obviousness over the combination of Sullivan995, Sullivan460,

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and Matthews as Patent Owner argues in regard to obviousness over the combination of Sullivan995 and Sullivan460, discussed above. *See* PO Resp. 43. In addition to the reasoning just discussed in the context of obviousness over Sullivan995 and Sullivan460, we add that, as shown by Petitioner, Matthews already taught detecting troubled wakefulness and thus, in the context of claim 19, Patent Owner has not explained why the alleged long-felt need was not met by Matthews.

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt need. As a result, we accord little weight to Patent Owner’s evidence of long-felt need because Patent Owner has not shown that the alleged need is tied to the claimed features.

G. Weighing the Graham Factors

We have considered the scope and content of the prior art of record, any differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art. For the reasons discussed in our analysis of Grounds 1 and 2, Petitioner provides persuasive evidence of the unpatentability of the Challenged Claims. Patent Owner’s evidence of long-felt need is entitled to little, if any, weight. On balance, after weighing all of the evidence in the record, we determine that Petitioner has established by a preponderance of the evidence that the Challenged Claims would have been obvious to a person of ordinary skill in the art.

H. Grounds 3 and 4: Alleged Obviousness over Rapoport502, and Sullivan460, and over Rapoport502, Sullivan460 and Matthews

In light of our determination that claims 1, 3–6, 9–12, 14–24, and 26–29 are unpatentable based on Grounds 1 and 2, we do not reach Petitioner’s alternative challenges to these claims set forth in Grounds 3 and 4. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is

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entitled to a final written decision addressing all of the claims it has challenged”); *see also* 35 U.S.C. § 318(a).

III. PATENT OWNER’S MOTION TO EXCLUDE

Patent Owner seeks to exclude Exhibits 1009, 1018, 1049, and 1054–1059, and portions of Exhibits 1003, 1046, 1051, and 1052. PO MTE 1–14; PO MTE Reply 1–5. Petitioner opposes the motion. PO MTE Opp. 1–13. For the following reasons we deny Patent Owner’s Motion to Exclude.

A. Exhibits 1003 and 1046

Exhibit 1003 is the Declaration of Petitioner’s original declarant, Dr. Behbehani, and Exhibit 1046 is the substitute Declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s Declaration. *See* Ex. 1046 ¶ 28. Patent Owner argues that certain portions of Exhibit 1003 should be excluded and that the same portions of Exhibit 1003 that Dr. Kirkness adopts should be excluded. PO MTE 3–6, 10. Because we do not rely on the portions of Exhibit 1003 noted by Patent Owner in rendering this Decision, we deny Patent Owner’s Motion to Exclude as to these portions of Exhibit 1003 and the corresponding portions of Exhibit 1046 as moot.

B. Exhibits 1009 and 1054–1058

Exhibit 1009 is the file history of the related ’344 patent. Exhibit 1054 is the file history of the related ’009 patent. Exhibits 1055–1058 are copies of the ’009 patent, the ’344 patent, the ’539 patent, and the ’994 patent, respectively.

Patent Owner asserts that Petitioner improperly relies on these exhibits in the Reply to support its claim construction, because “Petitioner introduced new evidence in its Reply with these exhibits.” PO MTE 5.

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Petitioner replies that these exhibits are proper evidence in the Reply, because Patent Owner “proposed a construction for the ‘analyzing the breathing patterns’ claim terms for the first time in [the] Response.” PO MTE Opp. 6. We agree.

In its Petition, Petitioner argued for “‘using the same claim construction standard that would be used’ in district courts,” i.e., the ordinary and customary meaning. Pet. 20. In its Response, Patent Owner argued that the language of the term “analyzes the data to determine the patient’s breathing patterns,” which appears in claim 27, should be construed as “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 28. Patent Owner did not raise this claim construction argument (or any other claim construction) in its Preliminary Response to the Petition (Paper 12), but raised it for the first time in its Response. *See* Resp. 28–30. Petitioner’s argument in its Reply responds to Patent Owner’s claim construction position asserted in the Patent Owner Response.

Petitioner adduced Exhibits 1009 and 1054–1058 to demonstrate the plain and ordinary meaning of the claim term “analyzing the data to determine the patient’s breathing patterns,” which was a legitimate response to Patent Owner’s proposed construction in its Patent Owner Response. We therefore deny Patent Owner’s Motion to Exclude as to Exhibits 1009 and 1054–1058.

C. Exhibit 1018

Exhibit 1018 is a copy of Patent Owner’s district court complaint. *See supra* I.B. Patent Owner argues that “Petitioner does not discuss or cite

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Ex. 1018 in any document filed in this IPR” and the exhibit “is therefore irrelevant under F.R.E. 402.” PO MTE 6.

Petitioner responds that Exhibit 1018 “was cited as a related matter to this proceeding, as a concurrent litigation filed on June 2, 2021.” PO MTE Opp. 8.

Because we do not rely on Exhibit 1018 in rendering this decision, we deny Patent Owner’s Motion to Exclude as to Exhibit 1018 as moot.

D. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2. Patent Owner argues that the priority date of this patent is after the priority date of the ’115 patent and should be excluded as irrelevant and “not prior art.” PO MTE 7; PO MTE Reply 4. Patent Owner also argues it should have been introduced prior to Petitioner’s Reply. PO MTE 7.

Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. PO MOT. Opp. 8–9. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates’s credibility, not as prior art, and find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision and deny Patent Owner’s Motion to Exclude as to Exhibit 1049 as moot.

E. Exhibit 1051

Exhibit 1051 is the Declaration of Dr. Kirkness in support of Petitioner’s Reply. Patent Owner argues that portions of Exhibit 1051 “should be excluded for the same reasons as” Exhibits 1003 and 1046. PO MTE 7. The only “example” provided by Patent Owner in support of its argument is that Dr. Kirkness “uses Exhibits 1049 and 1054–1058 in the

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exact same manner as they were challenged above.” *Id.* at 8. For the reasons discussed above for Exhibits 1049 and 1054–1058, we deny the Motion to Exclude as to Exhibit 1051.

F. Exhibit 1052

Exhibit 1052 is the transcript of Dr. Bates’s deposition testimony. Patent Owner argues that the portions of Exhibit 1052 “focusing on patent eligible subject matter and whether certain products, such as processors, infringe by meeting the limitations of the ’115 Patent should be excluded as irrelevant.” PO MTE 8–9 (citing Ex. 1052, 62:7–23, 63:15–25, 64:1–5, 117:9–25, 118:1–11, 146:4–12); PO MTE Reply 4–5. Petitioner argues that the testimony of Dr. Bates is relevant to obviousness issues in this proceeding, that there was “no discussion of ‘infringement’ or ‘patentable subject matter,’” and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 9–10. We agree with Petitioner’s reasons and deny Patent Owner’s Motion to Exclude as to the challenged portions of Exhibit 1052.

G. Exhibit 1059

Exhibit 1059 is an article titled “Control of breathing during sleep” published in Clinical Science in 1984 and was cited by Dr. Kirkness in his Reply Declaration (Exhibit 1051). Patent Owner argues that Dr. Kirkness relied on Exhibit 1059 to show that a person of ordinary skill in the art “knew ‘that a processor could be programmed to analyze breathing patterns that fall below or above certain preset levels of airflow rate to indicate awake or asleep states’ and that analysis of temporal structures was not necessary.” PO MTE 9 (quoting Ex. 1051 ¶¶ 11, 32); PO MTE Reply 5. According to Patent Owner, “[a]ny use of EX1059 is therefore an improper

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incorporation by reference through EX1051, violating 37 C.F.R.

§ 42.6(a)(3), which prohibits incorporating arguments by reference from one document into another document.” PO MTE 9.

Patent Owner’s argument has no merit. As Petitioner notes, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and Exhibit 1059 “is not an argument.” PO MTE Opp. 11. Patent Owner also argues in its Reply that Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply 5. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his Reply Declaration were relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” PO MTE Opp. 11. We agree with Petitioner for the same reasons discussed above regarding Exhibits 1009 and 1054–1058. Because Patent Owner shows no persuasive basis to exclude Exhibit 1059, Patent Owner’s Motion to Exclude as to Exhibit 1059 is denied.

IV. PETITIONER’S MOTION TO EXCLUDE

Petitioner seeks to exclude portions of the deposition testimony of Patent Owner’s declarant, Dr. Bates (Exhibit 1053). Pet. MTE 1–9; Pet. MTE Reply 1–5. Petitioner moves to exclude Dr. Bates’s redirect deposition testimony concerning secondary considerations of non-obviousness. Pet. MTE 1–2. Petitioner argues that the redirect testimony of Dr. Bates “was outside the scope of Petitioner’s cross-examination in contravention of Fed. R. Evid. 611(b) and 37 C.F.R. § 42.53 (d)(5)(ii).” *Id.* at 1. Petitioner does not seek to exclude the entirety of Dr. Bates’s redirect testimony but only the

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specific portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes the motion. Pet. MTE Opp. 1–10. For the following reasons, we deny Petitioner’s Motion to Exclude.

Petitioner contends that it “did not cross-examine Dr. Bates about any secondary considerations and timely objected to PO’s line of questioning during redirect as being outside the scope.” Pet. MTE 1–2 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9); *id.* at 4 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9). Petitioner further contends that Patent Owner’s “introduction of belated expert testimony into the record via the Sur-Reply is improper and the evidence must be excluded.” *Id.* at 2 (citing *Comcast Cable Commc’ns, LLC v. Rovi Guides, Inc.*, IPR2019-01413, Paper 34 at 4 (PTAB Sept. 16, 2020); *Int’l Bus. Machines Corp. v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 15 at 5 (PTAB Feb. 2, 2015); *see also id.* at 5–6 (identifying the portions of Sur-reply citing to the disputed testimony). Petitioner further contends that “Dr. Bates’ declaration included no discussion of secondary considerations.” *Id.* at 2.

Petitioner contends that “FRE 611(b) prohibits redirect examination that goes beyond the scope of cross-examination questions and testimony” and Patent Owner’s “redirect examination did just that.” Pet. MTE 7. Petitioner next contends that “the portions of Dr. Bates’ redirect testimony that Petitioner seeks to exclude from the record . . . have no bearing on ‘matters affecting the witness’s credibility.’” *Id.* at 8 (citations omitted). According to Petitioner, Patent Owner “does not rely on Dr. Bates’ testimony to counter a challenge to his credibility.” *Id.* Petitioner next contends that 37 C.F.R. § 42.53(d)(5)(ii) “similarly prevent a party from

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expanding the scope of redirect examination beyond that of cross-examination.” *Id.* at 9.

Patent Owner contends that Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner argues that the PTAB Consolidated Trial Practice Guide provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or *otherwise exceeds the proper scope* of reply or sur-reply, it may request authorization to file a motion to strike.” Pet. MTE Opp. 2 (citing PTAB Consolidated Trial Practice Guide (“CTPG”) 80 (PTAB Nov. 2019)). Patent Owner contends that “Petitioner’s counsel reserved that right to strike Dr. Bates’ redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of PO submitting its Sur-Reply.” *Id.* (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact, *inadmissible*,” only that it “should be excluded (not stricken) because it is beyond the scope of its cross-examination.” *Id.* at 4. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance of hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at that this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–25).

In the Reply, Petitioner contends it “properly focused its motion on the portions of Dr. Bates’ inadmissible re-direct deposition testimony cited in [the] Sur-Reply” and that Patent Owner “uses its Sur-Reply as no more

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than a ‘vehicle’ to enter new evidence into the record.” Pet. MTE Reply 1. Petitioner contends that it “timely objected at the deposition” once Patent Owner began “improperly elicit[ing] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Federal Rule of Evidence 611(b). *Id.* (citing Pet. MTE, Section II.B.2).

For the following reasons, we deny Petitioner’s Motion to Exclude.

The CTPG provides that “[a] motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay)” but should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.” CTPG 79. Further, the CTPG states that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike.” *Id.* at 80. As an alternative to a motion to strike, “a party may request authorization for further merits briefing . . . to address the merits of any newly-raised arguments or evidence.” *Id.* A party must seek authorization to file a motion to strike “within one week of the allegedly improper submission.” *Id.* at 81.

As noted in the CTPG, motions to strike are intended to address, *inter alia*, whether a brief raises new issues or exceeds the proper scope of a sur-reply. Here, Petitioner argues that the redirect testimony is inadmissible under Rule 611(b) and/or 37 C.F.R. § 42.53(d)(5)(ii) as exceeding the scope of cross-examination. But, Petitioner does not seek to exclude all redirect testimony on secondary considerations, only the testimony relied on by Patent Owner in the Sur-reply. Pet. MTE 5 n.2.

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The issue presented here borders on the proper scope of a motion to exclude as compared to a motion to strike. The goal of Petitioner's Motion is clearly to undercut arguments raised in Patent Owner's Sur-reply directed to objective indicia of non-obviousness. By limiting its Motion to only the portions of Dr. Bates's redirect examination actually relied on in Patent Owner's Sur-reply, Petitioner's arguments reflect this goal. *See, e.g.*, Pet. MTE 5 n.2 ("Although all of Dr. Bates' redirect testimony on secondary considerations was outside the scope of Petitioner's cross-examination, Petitioner narrowly focuses this motion on excluding only those portions that [Patent Owner] relies on in its Sur-Reply."). One way in which Petitioner could have challenged the arguments raised in Patent Owner's Sur-reply is by requesting authorization to file a motion to strike, which, as noted above, is intended for the purpose of addressing arguments a party believes exceeds the proper scope of sur-reply. *See* CTPG 80. Petitioner did not request such authorization. Instead, by seeking to exclude some of Dr. Bates's redirect testimony on objective indicia (i.e., the portions relied on in Patent Owner's Sur-reply), Petitioner seeks to undercut the arguments raised in Patent Owner's Sur-reply on objective indicia by effectively removing the primary evidentiary support for those arguments. Were we to grant Petitioner's Motion to Exclude, we would be faced with determining what to do with Patent Owner's arguments in the Sur-reply, which would remain of record because they are not the subject of Petitioner's Motion to Exclude (nor could they be based on the CTPG) and (as previously noted) Petitioner did not also file a motion to strike those arguments. The best course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike

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after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Rule 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination (just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony²⁰), Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of non-obviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the circumstances presented here and in light of the little weight to which Patent Owner's argument and Dr. Bates's redirect is entitled, we determine that the better course at this stage is to deny Petitioner's Motion to Exclude.

²⁰ There are exceptions, e.g., questions pertaining to a witness's credibility. See Fed. R. Evid. 611(b).

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V. CONCLUSION

The outcome for the Challenged Claims in this proceeding is set forth in summary as follows:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 3–6, 9–12, 14–18, 20–24, 26–29	103(a)	Sullivan995, Sullivan460	1, 3–6, 9–12, 14–18, 20–24, 26–29	
19	103(a)	Sullivan995, Sullivan460, Matthews	19	
1, 3–6, 9–12, 14–18, 20–24, 26–29	103(a)	Rapoport502, Sullivan460 ²¹		
19	103(a)	Rapoport502, Sullivan460, Matthews ²²		
Overall Outcome			1, 3–6, 9–12, 14–24, 26–29	

VI. ORDER²³

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Exclude (Paper 48) is denied;

²¹ We do not reach the merits of this ground.

²² We do not reach the merits of this ground.

²³ Should Patent Owner wish to pursue amendment of a Challenged Claim in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice*

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FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 49) is denied;

FURTHER ORDERED that claims 1, 3–6, 9–12, 14–24, and 26–29 of U.S. Patent No. 9,533,115 B2 have been proven by a preponderance of the evidence to be unpatentable; and

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

Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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Paper 71
Date: December 6, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

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Patent 9,867,955 B2

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

PESLAK, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

ORDER

Denying Patent Owner's Motion to Exclude (Paper 51) and
Denying Petitioner's Motion to Exclude (Paper 52)
37 C.F.R. § 42.64(c)

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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 ResMed, Inc. (“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. On December 7, 2022, we instituted this *inter partes* review as to all Challenged Claims and all grounds presented in the Petition. Paper 19.

After institution, we granted Petitioner’s unopposed motion to substitute Dr. Jason P. Kirkness for Dr. Behbehani. Paper 35. Dr. Kirkness, adopted substantially the entirety of Dr. Behbehani’s prior opinions. Ex. 1046 ¶¶ 1, 28 (adopting paragraphs 20–28, 32–83, and 87–316 of Dr. Behbehani’s Declaration (Ex. 1003)). In this Decision we cite to the Declaration of Dr. Behbehani (Ex. 1003) with the understanding that the opinions expressed were adopted by and, therefore, are attributable to Dr. Kirkness.

Patent Owner filed a Response to the Petition (“PO Resp.”) supported by the Declaration of Dr. Jason H.T. Bates. Paper 36; Ex. 2006.² Petitioner filed a Reply (“Pet. Reply”) supported by a Declaration of Dr. Kirkness.

¹ Further references herein to “Petition” will refer to the Corrected Petition unless stated otherwise.

² Dr. Bates provided corrections to certain citations in his Declaration. Ex. 1048.

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Paper 44; Ex. 1051. Patent Owner filed a Sur-reply (“Sur-reply”). Paper 47. An oral hearing was held on October 3, 2023 and the transcript is entered into the record. Paper 66.³

Additionally, Patent Owner filed a Motion to Exclude Exhibits 1009, 1011, 1018, 1020, 1022, 1049, and 1054–1058, and portions of Exhibits 1003, 1046, 1051, and 1052. Paper 51 (“PO MTE”); *see also* Paper 55 (Petitioner’s Opposition to Patent Owner’s MTE (“PO MTE Opp.”)); Paper 56 (Patent Owner’s Reply in Support of Its MTE (“PO MTE Reply”)). As explained below, we deny Patent Owner’s Motion to Exclude. *See infra* Section III.

Petitioner filed a Motion to Exclude portions of Exhibit 1053. Paper 52 (“Pet. MTE”); *see also* Paper 54 (Patent Owner’s Opposition to Petitioner’s Motion to Exclude (“Pet. MTE Opp.”); Paper 57 (Petitioner’s Reply in Support of Its Motion to Exclude (“Pet. MTE Reply”)). As explained below, we deny Petitioner’s Motion to Exclude. *See infra* Section IV.

We have jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the Challenged Claims of the ’955 patent. For the reasons discussed below, we determine Petitioner establishes by a preponderance of the evidence that all of the Challenged Claims are unpatentable.

³ The Parties both filed objections to the other party’s demonstrative exhibits and hearing arguments and responses to the objections. Papers 63, 64, 67–70. Demonstrative exhibits and hearing arguments are not evidence and are not relied on as a basis of this Decision. Accordingly, the objections are denied as moot.

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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 for the following related patents: U.S. Patent No. 6,988,994 B2 (the "'994 patent") (IPR2022-00993), U.S. Patent No. 9,108,009 B2 (the "'009 patent") (IPR2022-00988), U.S. Patent No. 9,168,344 B2 (IPR2022-00994), U.S. Patent No. 9,427,539 B2 (the "'539 patent") (IPR2022-00889), U.S. Patent No. 9,533,955 B2 (IPR2022-00990), and U.S. Patent No. 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 code (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,

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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 PAP therapy as a person wearing a tight fitting nasal mask during sleep and 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.” *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, 1:63–63. 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.

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Figure 1 of the '955 patent is reproduced below:

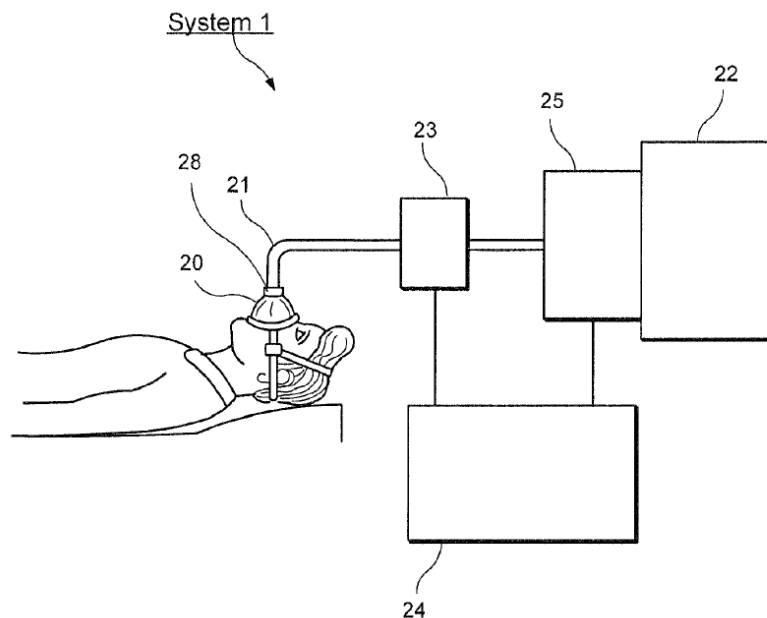


FIG. 1

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 Figure 1's 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

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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 Claims

Claims 1 and 19 are independent claims. Claim 1 is representative of the claimed subject matter and is reproduced below with Petitioner’s annotations:

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

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

[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;

[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

[c1] a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and [c2] analyzes the data to determine the patient's breathing patterns, [c3] 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, [d1] wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and [d2] a lesser positive treatment pressure in an awake state, [e1] wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state, [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.

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):

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Pet. Challenge Id.	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
Ground 1	1–5, 8, 11, 12, 16–22, 24–26, 30, 31	103(a) ⁴	Sullivan995, ⁵ Sullivan460 ⁶
Ground 2	6, 23	103(a)	Sullivan995, Sullivan460, Matthews ⁷
Ground 3	1–5, 8, 11, 12, 16–22, 24–26, 30, 31	103(a)	Rapoport502, ⁸ Sullivan460
Ground 4	6, 23	103(a)	Rapoport502, Sullivan460, Matthews

II. ANALYSIS

A. Overview

Petitioner bears the burden of establishing the unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This burden of persuasion never shifts to Patent Owner.

⁴ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because an application related to the application from which the ’955 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of § 103 applies. *See* Ex. 1001, code (63). No issue in this proceeding turns on the applicable version of the statute, and the outcome of this Decision would be the same regardless of which version of the statute applies.

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

⁶ WO 01/05460 A1, published Jan. 25, 2001 (Ex. 1006, “Sullian460”).

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

⁸ U.S. Patent No. 5,490,502 (issued Feb. 13, 1996) (Ex. 1008, “Rapoport502”).

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Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015).

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). *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. 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 does not dispute Petitioner’s definition of the person of ordinary skill in the art. PO Resp. 10.

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We apply Petitioner’s level of skill in the art because it appears consistent with the problems addressed in the ’955 patent and the prior art.

C. 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 v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). 37 C.F.R. § 42.100(b) (2019). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing claims in accordance with their ordinary and customary meaning, we take into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thornerv. Sony Comput. Entm’t. Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is

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required to construe ‘only those terms . . . that are in controversy, and only 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)). To determine whether Petitioner has shown that the Challenged Claims are unpatentable, we expressly construe the claim term “troubled wakefulness,” and we discuss the Parties’ contentions for the claim term “analyzes the data to determine the patient’s breathing patterns.”

a. “troubled wakefulness”

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 ¶ 91). Petitioner asserts that “[t]his term is not an industry standard term and was coined in the ’024 Patent.” *Id.* (citing Ex. 1003 ¶ 92). According to Petitioner, the ’955 patent “describes ‘troubled wakefulness’ as a state ‘in which the breathing pattern is characterized by irregular[] 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 (second alteration in original) (citing Ex. 1001, 2:40–47).

Patent Owner “agrees with this construction.” PO Resp. 16.

We adopt Petitioner’s undisputed construction of “troubled wakefulness” because it is supported by and consistent with the

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Specification of the '955 patent, which explicitly describes the term. *See, e.g.,* Ex. 1001, 4:59–64.

b. “analyzes the data to determine the patient’s breathing patterns”

Patent Owner proposes that the term “analyzes the data to determine the patient’s breathing patterns” appearing in claim 1 should be construed as “determin[es] a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 17. Petitioner contends that this term should be given its plain and ordinary meaning. Pet. Reply 2.

In the Petition, Petitioner did not expressly construe this phrase, which is recited in claim 1, but did analyze and address the prior art to identify the teachings of the prior art that Petitioner contends teach this limitation of the claims. *See, e.g.,* Pet. 35–36 (addressing limitation 1[c2]). In the Patent Owner Response, Patent Owner argues that “analyzes the data to determine the patient’s breathing patterns” means “determin[es] a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examines the values of the parameters and the order which they appear in time.” PO Resp. 17. Patent Owner also refers to “the values of the parameters and the order which they appear in time” in its proposed construction as “an analysis of both the amplitude structure and the temporal structure of a time series of breath-by-breath parameters calculated from a flow waveform.” *See, e.g., id.* at 2, 7, 9. As borne out through Patent Owner’s arguments in response to Petitioner’s challenges and as further elaborated in Patent Owner’s Sur-reply, Patent Owner contends that “analyzes the data to determine the patient’s breathing patterns” and

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allegedly similar recitations in claim 19, require analysis of “both amplitude and temporal structures.” PO Resp. 22–23; PO Sur-reply 4–5.

Petitioner disputes this proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2; *see id.* at 2–10. For the reasons that follow, we agree with Petitioner.

i. The Parties’ Contentions

To explain why the claim phrase should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the specification” of the ’955 patent. PO Resp. 17 (citing Ex. 1001, 4:42–49; Ex. 2006 ¶ 139); *see also* Sur-reply 13 (Patent Owner arguing that according to Dr. Bates “‘breathing patterns’ has no ordinary meaning and ‘is an extremely general term’”) (citing Ex. 1052, 108:25–109:7). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apnea and hypopnea in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters and the order in which they appear in time.” PO Resp. at 17 (citing Ex. 2006 ¶ 140).

Patent Owner points to the description of Figures 7 and 8 of the ’955 patent in support of its construction. PO Resp. 17–19 (citing Ex. 1001, 4:57–64, 5:21–37; Ex. 2006 ¶¶ 141–143). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient’s airflow, but no periodic irregularity in breath size. Ex. 1001, 4:57–64. Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger

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breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. *Id.* at 5:21–37.

According to Patent Owner, “[t]his methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns” and focuses “on a determination of ‘the sequence of parameters of a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time.’” PO Resp. 18 (citing Ex. 2006 ¶ 142); *see also* Sur-reply 5 (citing Ex. 1001, 4:57–64; Ex. 2006 ¶ 141) (asserting that the ’955 patent describes Figure 7 as showing “both amplitude and temporal structures are likewise described when examining specific flow waveforms”). Patent Owner further argues that the description of Figure 8 in the Specification “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 18–19 (citing Ex. 1001, 5:21–37; Ex. 2006 ¶ 143); Sur-reply 5–13.

Additionally, Patent Owner suggests the Specification’s discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. PO Resp. 19 (citing Ex. 1001, 6:38–45; Ex. 2006 ¶ 144).

Turning to the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’955 Patent.” Sur-reply 3; *see also id.* at 8–16 (arguing that distinguishing troubled wakefulness from REM sleep requires assessing both

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amplitude and temporal structure). First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” Sur-reply 3–4 (quoting Ex. 1001, 4:42–49) (citing Ex. 2006 ¶ 139). Patent Owner maintains that the descriptions of the waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of waveforms. *Id.* at 4–7 (citing Ex. 1001, 4:57–64, 5:28–37, 6:38–45; Ex. 1052, 81:17–23, 180:1–15; Ex. 2006 ¶¶ 139–44). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’955 Patent,” but contends that “these are not obligatory.” *Id.* at 5. Patent Owner asserts that enablement of the ’955 patent “hinges on its ability to distinguish between all awake and asleep states,” and “[i]f not achieved, incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 6.

Second, Patent Owner asserts that during the prosecution of the related ’344 patent, the applicant responded to a rejection by arguing that the prior art, in that instance, “failed to discern between regular wakefulness and troubled wakefulness.” Sur-reply 6–7 (citing Ex. 1009, 404). Patent Owner argues that it is necessary to integrate “both amplitude and temporal structure analyses to distinguish all awake and asleep states.” *Id.* at 7.

Third, Patent Owner argues that “a patentee does not need to rigidly define terms, but can imply their own meaning.” Sur-reply 7. Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by Figure 7 – a flow waveform indicating troubled wakefulness.” *Id.* (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the Specification

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“provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “[s]ince ‘analyses the data’ is followed by ‘to determine the patient’s breathing patterns,’ some of which occur in the asleep state and some of which occur in the awake state, this further implies that these states can be separated from one another.” *Id.* (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22). Patent Owner contends that, “[g]iven the separation between awake and asleep states discussed in the ’955 Patent, [Patent Owner’s] construction is integral for discerning the difference and applying the correct pressure” because without doing so, it “could result in inappropriate pressure administration.” *Id.* at 7–8 (citing Ex. 1052, 179:23–25; Ex. 2006 ¶ 144).

Patent Owner also argues that extrinsic evidence supports its proposed construction. Sur-reply 8–13. Based on Dr. Bates testimony, Patent Owner asserts that “by assessing *only amplitude*” the waveforms of troubled wakefulness and REM sleep “appear indistinguishable,” but “their temporal structure (order in time) . . . offers differentiation.” *Id.* at 9–10 (citing Ex. 2005 ¶ 75). Patent Owner argues it proves its argument by showing that if the “temporal structure” of the REM sleep waveform is “rearranged in time,” then the resulting “time series has a random appearance that cannot be distinguished from troubled wakefulness.” *Id.* at 10 (citing Ex. 2006 ¶ 76) (emphasis omitted). Patent Owner reasons that “amplitude structure and temporal structure convey independent information” and both must be considered in an analysis or “the awake state can be confused with an asleep state.” *Id.* at 11 (citing Ex. 2006 ¶ 69). According to Patent Owner, it is “Dr. Bates’ illustrations [that] clearly present the problem solved by the ’955 Patent.” *Id.*

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According to Patent Owner, construing “analyzing breathing patterns” to include “any type” of breathing pattern analysis, as suggested by Dr. Kirkness, is “nonsensical, as it might even encompass using a mirror to check for breaths.” Sur-reply 13 (citing Ex. 1051 ¶ 16).⁹

Specifically, Patent Owner argues as follows:

Dr. Bates examined the specification to determine what characteristics of breathing were crucial to analyzing the breathing pattern with respect to the invention’s essence. [Ex. 1052], 24:20-25, 25:1-13. He determined that a [person of ordinary skill in the art], after reading the ’994 Patent, would understand that analyzing breathing patterns, with respect to the ’955 Patent, needs to confer the ability to distinguish between troubled wakefulness and REM sleep. *Id.*, 111:22-25 – 112:1-21. In contrast to the broad construction proposed by Petitioner, [Patent Owner’s] construction evidences the understanding of a [person of ordinary skill in the art] – that analyzing breathing patter[n]s requires analysis of amplitude and temporal structures.

Sur-reply 13–14.

Petitioner proposes that we construe the phrase in accordance with its plain and ordinary meaning because “[n]othing in the intrinsic record limits the ‘analyzing the breathing patterns’ terms to analysis of either or both amplitude and temporal structures—instead, the claims, specification, and prosecution history use these terms in accordance with their plain meaning.” Pet. Reply 3–4 (citing *CCS Fitness*, 288 F.3d 1359 at 1366). Petitioner

⁹ Patent Owner also states that “Dr. Kirkness argues that the ’955 Patent is indefinite, especially regarding the measurement of airflow waveforms and temporal/amplitude aspects,” and that “Petitioner has never raised indefiniteness.” Sur-reply 12. We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths.”

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asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the specification or during prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” *Id.* at 6 (quoting *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, ‘the patentee must clearly express an intent to redefine the term.’” *Id.* (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends “[n]o such intent exists here” and Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* (citing Ex. 1051 ¶ 24).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner’s] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as “propos[ing] a lengthy construction and then constru[ing] its own construction to inject two requirements: that the processor must analyze (1) ‘the value[s] of the parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.* (third alteration in original) (citing PO Resp. 16–17; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert decided based on his personal experience, as opposed to that of a” person of ordinary skill in the art. *Id.* (citing Ex. 1053, 271:10–14).

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Responding to Patent Owner’s citations to the Specification, Petitioner contends that the Specification “further confirms that the terms encompass any type of breathing pattern analysis” and “states that ‘[t]here are a number of characteristics of the patient’s breathing patterns that may be taken into account in making such a determination’ . . . and does not limit the analysis to any particular characteristic.” Pet. Reply 4 (first alteration in original) (citing Ex. 1001, 4:18–34 Figs. 3–8; Ex. 1051 ¶¶ 16–24; Ex. 1052, 28:4–30:21; Ex. 2006 ¶¶ 46–47, 121–23). Petitioner also contends that “[t]he specification further states that the flow sensors ‘detect the rate of airflow’ and provide ‘[s]ignals corresponding to the airflow’ to a processing arrangement for processing.” *Id.* at 5 (second alteration in original) (citing Ex. 1001, 3:60–66). Thus, Petitioner asserts the Specification “confirms that temporal analysis is not required.” *Id.*

Petitioner also addresses the prosecution history of patents related to the ’955 patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5. Petitioner asserts that, in responding to different office actions, the applicant did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1009, 404; Ex. 1052, 91, 128).

Next, Petitioner contends Patent Owner’s extrinsic evidence, in the form of Dr. Bates’s testimony, contradicts the intrinsic record and should be disregarded. Pet. Reply 6–10. Petitioner asserts Dr. Bates “performed a ‘crude’ analysis by ‘approximating’ the amplitudes of each breath in the figures ‘estimat[ing] by eye . . . the size of those individual breaths.’” *Id.* at 7 (first alteration in original) (citing Ex. 1052, 75:11–76:14, 78:16–79:19). Petitioner argues that Dr. Bates’s “analysis has no basis in the patent.” *Id.*

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Petitioner presents five arguments in rebuttal in regard to the testimony of Dr. Bates:

(1) Dr. Bates’s analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the ’955 patent would have derived [Patent Owner’s] construction.” *Id.* (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* (citing Ex. 1052, 75:11–76:14; 78:16–79:19; 90:8–91:11).

(2) Dr. Bates’s analysis is based on his own expertise in “digital signal processing,” not from the viewpoint of a person of ordinary skill in the art who would not necessarily have such experience. *Id.* at 8 (citing Ex. 1052, 25:3–27:6, 52:2–25, 64:4, 208:16–21; Ex. 1053, 240:8–242:8, 243:3–8).

(3) Dr. Bates’s analysis contradicts the ’955 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM sleep without requiring temporal analysis. *Id.* at 8–9 (citing Ex. 1001, 4:52–59, 5:32–36; Ex. 1056, 9:55–10:3 (claim 5), 10:20–24 (claim 8); Ex. 1051 ¶¶ 25–33).

(4) “Dr. Bates admitted that Figures 7–8 are merely exemplary.” *Id.* at 9 (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do not limit the broader claim terms of the patent.” *Id.* (citing *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004)).

(5) Dr. Bates “could not explain ‘parameter’ or provide an objective basis to define a ‘sequence’ and ‘series’ used in [Patent Owner’s] construction” and “admitted that [Patent Owner’s] construction would exclude breathing patterns recited in dependent claims.” *Id.* at 10 (citing

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Ex. 1052, 182:1–184:19, 247:5–11; Ex. 1053, 288:14–289:3). Thus, Petitioner asserts we “should discount []expert testimony that is clearly at odds . . . with the written record of the patent.” *Id.* (quoting *Phillips*, 415 F.3d at 1318).

ii. Analysis – Claim 1

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14.

In the Patent Owner Response, Patent Owner analyzes only claim 1 which recites “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.*” Ex. 1001, 9:63–66 (emphasis added). As reflected, claim 1 does not recite “a sequence of parameters” or “a series of breaths” or “examining the values of the parameters and the order in which they appear in time” or any analysis of amplitude or temporal structure. Rather, this portion of claim 1 recites that the processor analyzes the data, without specifically reciting how the analysis is performed. The claim phrase does, however, recite the purpose of the analysis—to determine the patient’s breathing patterns—but does not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a significant number of limitations neither expressly recited nor suggested by the specific language of the phrase.

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citation omitted). “We depart from the plain and ordinary meaning of claim terms

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based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech.* 923 F. 3d at 1044.

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of claim 1, nor does Patent Owner argue that it explicitly defined the claim phrase in the Specification. PO Resp. 28–30. We determine that there is no disavowal nor any explicit lexicographic definition of “analyzes the data to determine the patient’s breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we should construe the phrase as Patent Owner proposes. Sur-reply 3, 8–9 (citing, *inter alia*, *AstraZeneca AB v. Mut. Pharm. Co., Inc.*, 384 F.3d 1333 (Fed. Cir. 2004)). We disagree.

In *AstraZeneca AB*, the United States Court of Appeals for the Federal Circuit reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d 1333, 1339–40 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors “deliberately acted as their own lexicographers” to limit the claim term

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“solubilizer” to surfactants, the Federal Circuit explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The Federal Circuit rejected AstraZeneca’s argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

The Specification of the ’955 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to “a sequence of parameters” (PO Resp. 17) or an “analysis of both the amplitude and the temporal structure of a breath-by breath time series” (*id.* at 22) or any of the other terms set forth in the proposed construction. *See id.* at 17–19. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. *See* Pet. Reply 6 (“[T]he terms ‘amplitude’ and ‘temporal’ do not appear anywhere”); Sur-reply 5 (“Petitioner rightly observes that terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’955 Patent.”); *see also* Ex. 1051 ¶ 24 (Dr. Kirkness agrees that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’955 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures.”). Patent Owner directs us to portions of the Specification for what Patent Owner characterizes as the process of analyzing breathing patterns. PO

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Resp. 17 (quoting Ex. 1001, 4:42–49). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” Ex. 1001, 4:46–53. The cited text does not describe analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how “processing arrangement 24 makes a determination as to the 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).” Ex. 1001, 4:22–26. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns, etc. in determining the patient’s state.” *Id.* at 4:26–30. There is no mention that analyzing breathing patterns requires analysis of a sequence of parameters and the order in which they appear in time or an analysis of amplitude and temporal aspects of the waveform. The Specification further describes, in an embodiment, “processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern.” Ex. 1001, 7:20–23. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal aspects of the waveform.

Patent Owner also relies on the description of Figures 7 and 8 of the ’955 patent in support of its construction. PO Resp. 17–19. Figures 7 and 8 illustrate airflow waveforms from a patient indicative of a period of troubled

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wakefulness and a period of REM sleep with irregular breathing, respectively. Ex. 1001, 3:35–39. Patent Owner relies on Figures 7 and 8 to support its argument that “an analysis of both the amplitude and the temporal structure of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.” PO Resp. 22; Sur-reply 8–9 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Figures 7 and 8, however, depict one particular example of an awake state (i.e., troubled wakefulness) and one particular example of a sleep state (i.e., REM sleep), respectively. Ex. 1001, 3:35–39. But Patent Owner’s analysis does not address Figures 3–6 of the ’955 patent. PO Resp. 16–19; Sur-reply 3–16. Figures 3 and 4 show waveforms of a patient during “regular wakefulness” and “regular sleep,” respectively. Ex. 1001, 3:29–33. Figures 5 and 6 show waveforms from a sleeping patient indicative of “hypopnea” and “repetitive obstructive apnea,” respectively. *Id.* at 3:34–38. Patent Owner provides no evidence or explanation why amplitude and temporal aspects of a waveform are required to distinguish regular wakefulness from regular sleep or hypopnea or repetitive obstructive apnea.¹⁰

¹⁰ Patent Owner points to an argument during prosecution of a related patent contending it supports Patent Owner’s claim construction. Sur-reply 6–7. That argument stated that the prior art reference “does not teach or suggest a processing arrangement that distinguishes between regular wakefulness and troubled wakefulness,” but it did not refer to anything even close to resembling the construction proposed by Patent Owner or the concepts of amplitude and temporal structures. Ex. 1009, 404. Thus, this portion of the prosecution history of a related patent does not support Patent Owner’s position here.

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Claim 1 recites “analyzes the data to determine the patient’s breathing patterns . . . and determines that the patient has transitioned between at least an awake state and an asleep state.” Ex. 1001, 9:65–10:8. Claim 1 is not limited to distinguishing *solely* between troubled wakefulness and REM sleep, but rather encompasses other states, such as those shown in Figures 3–6. Thus, even if we were to agree with Patent Owner that an analysis of one or both of the amplitude and temporal structures of a waveform is required to distinguish between troubled wakefulness and REM sleep, that determination, alone, would be insufficient to narrow the scope of claim 1, which by its own terms is broad enough to include sleep states other than troubled wakefulness and REM sleep states. For the same reasons, we are not persuaded that the additional limitations Patent Owner seeks to read into the claims are necessary to “fully enable” the claims, as Patent Owner asserts.

Having reviewed the intrinsic evidence, we next consider the extrinsic evidence, and specifically the testimony of Dr. Bates.¹¹ Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 16–29 (citing Ex. 1001, 4:42–49, 4:57–64, 5:21–37, 6:38–45; Ex. 2006 ¶¶ 139–144). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. *See* Ex. 2006 ¶¶ 139–144. Rather, Dr. Bates reads portions of the

¹¹ Although the parties briefly address the prosecution history of patents related to the ’955 patent, we do not find the discussion thereof determinative on this specific issue.

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Specification and extrapolates (by taking several unsupported leaps) that the '955 patent "implicitly demands certain parameter measurements." Sur-reply 7 (citing Ex. 1052, 44:6–20).

Although expert testimony is legitimate to consider when construing claims, the Federal Circuit has cautioned that because it "is generated at the time of and for the purpose of litigation," it "can suffer from bias that is not present in intrinsic evidence." *Phillips*, 415 F.3d at 1318. And, extrinsic evidence "is less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* at 1317 (internal quotations and citations omitted). In the context presented here, Dr. Bates's testimony is not supported sufficiently by the intrinsic record or other extrinsic evidence (e.g., objective extrinsic evidence) and, therefore, even though we have considered it fully, we give it little weight.

For the reasons explained above, we determine that Patent Owner did not implicitly define the phrase "analyzes the data to determine the patient's breathing patterns," as proposed, because Patent Owner has failed to show any sufficient evidence that the '955 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner's contentions in light of all the evidence of record, we do not adopt Patent Owner's proposed construction; instead, we apply the plain and ordinary meaning of "analyzes the data to determine the patient's breathing patterns" in our consideration of the issues before us.

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- c. “analyzing, using the processing arrangement, the indication of the patient’s breathing patterns to determine the sleep state of a patient”*

Claims 19 recites “analyzing, using the processing arrangement, the indication of the patient’s breathing patterns to determine the sleep state of a patient.” Ex. 1001, 11:28–30. Patent Owner argues this limitation of claim 19 should be construed to mean the same thing as “analyzes the data to determine the patient’s breathing patterns,” recited in claim 1 and discussed above. PO Resp. 16. Claim 19 does not require analyzing data to determine the patient’s breathing pattern, as in claim 1. Patent Owner does not address why “analyzing . . . the indication of the patient’s breathing patterns” in claim 19 should be construed the same as “analyzing the data to determine the patient’s breathing pattern” in claim 1. Additionally, Patent Owner does not address why “determin[ing] the sleep state of a patient” in claim 19 should be construed the same as “determin[ing] the patient’s breathing patterns” in claim 1.

Thus, for each of these reasons, in addition to the reasons explained above as to why we do not adopt Patent Owner’s proposed construction for claim 1, we do not adopt Patent Owner’s proposed construction in the context of claim 19. Rather, we apply the plain and ordinary meaning of each of the phrases recited in claim 19.

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

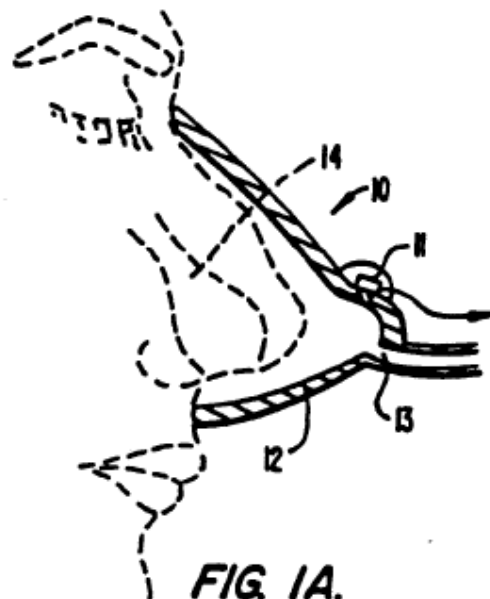
Petitioner contends claims 1–5, 8, 11, 12, 16–22, 24–26, 30, and 31 would have been obvious over Sullivan995 and Sullivan460. Pet. 19–57. Petitioner contentions are supported by Dr. Kirkness. Ex. 1046 ¶ 28 (adopting the opinions set forth in Ex. 1003 ¶¶ 20–28, 32–83, 87–316). Patent Owner disputes Petitioner’s contentions. PO Resp. 20–26.

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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.

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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.

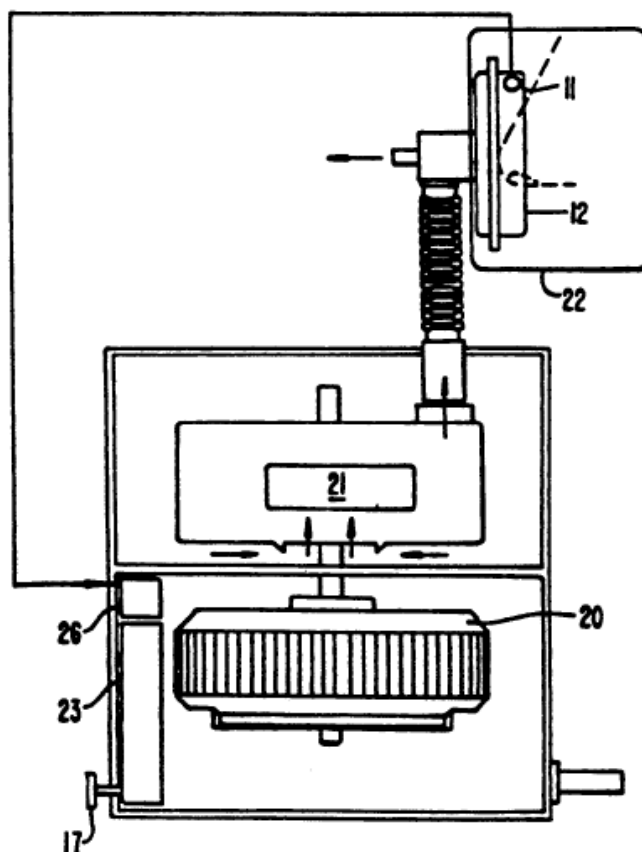


FIG. 3

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

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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.

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Sullivan995's Figure 12 is reproduced below.

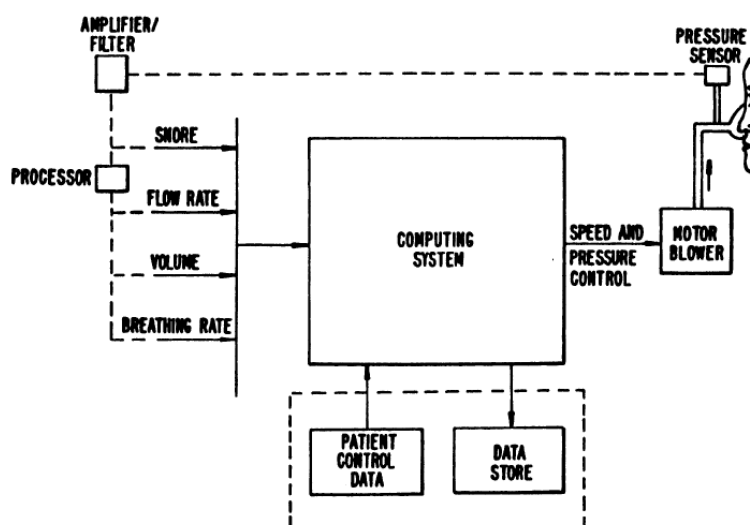


FIG. 12.

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

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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 [Sullivan995].” *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.

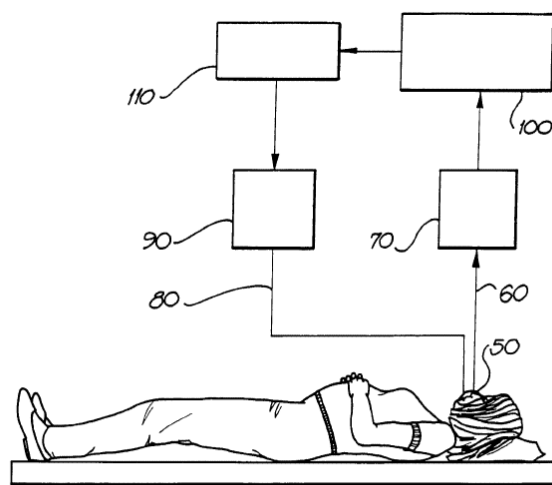


FIG. 2

In Figure 2, patient 30 is laying on bed 40 and wears mask 50 over her nose 50. *Id.* at 10:8–9. Mask 50 is connected via 80 to nCPAP apparatus 90. *Id.*

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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:

the 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.

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3. *Independent Claim 1*

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

Patent Owner contends that the combination of Sullivan995 and Sullivan460 “fails to disclose numerous independent claim limitations . . . highlighted in red.” PO Resp. 21–25.¹² Patent Owner also contends that Petitioner fails to establish motivation to combine or reasonable expectation of success. *Id.* at 25–26. Patent Owner also contends that secondary considerations of non-obviousness support the patentability of the claims. *Id.* at 27–29.

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^[1] which is *a positive airway pressure system.*” Pet. 23 (citing Ex. 1005, Abstract, 1:33–36, 2:15–19, 9:57–58, Fig. 3). Petitioner further contends “Sullivan995’s CPAP system ‘deliver[s]

¹² Patent Owner reproduces claim 1 and highlights a large block of text in red as allegedly not taught by the combination of Sullivan995 and Sullivan460. *See* PO Resp. 22. Patent Owner does not provide arguments for all of the highlighted limitations. We address the specific arguments made by Patent Owner. Further, we note that Patent Owner does not provide separate arguments for independent claim 19 or the dependent claims in this Ground apart from its contentions for claim 1. *Id.* at 21–25.

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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 23–24 (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 passage 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 Patent Owner Response. *See* PO Resp. 21–25.

We reviewed the evidence cited by Petitioner and find Sullivan995 teaches the preamble for the reasons provided by Petitioner. Therefore, we need not address whether the preamble is limiting.

I[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*

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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 Patent Owner Response. *See* PO Resp. 21–25.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

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

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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, and 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 highlights this limitation in red as allegedly not taught by the combination of Sullivan995 and Sullivan460. PO Resp. 22. But,

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Patent Owner does not provide argument directed toward Petitioner's contentions for this limitation. *Id.* at 22–25.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

I[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 (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 highlights this limitation in red as allegedly not taught by the combination of Sullivan995 and Sullivan460. PO Resp. 22. But, Patent Owner does not provide argument directed toward Petitioner's contentions for this limitation. *Id.* at 22–25.

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We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

1[c2] [the processing arrangement] analyzes the data to determine the patient's breathing patterns,

Relying on its contentions for limitations 1[b] and 1[c1], Petitioner contends Sullivan995 “describes various breathing patterns for the patient.” Pet. 35. Petitioner further contends that “Sullivan995’s *processing arrangement* includes the processor unit 26, ‘which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.’” *Id.* at 36 (citing Ex. 1005, 11:55–62, Fig. 4). Petitioner also contends that Sullivan995’s computing system “‘analyses 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.’” *Id.* (citing Ex. 1005, 12:67–18:8, Fig. 12). Petitioner further contends these actions by the computing system correspond to the recited “analyz[ing] the data [from the flow sensor] to determine the patient’s breathing patterns.” *Id.*

Patent Owner highlights this limitation in red as allegedly not taught by Sullivan995 in view of Sullivan460. PO Resp. 22. Patent Owner contends that Sullivan995 does not teach this limitation because it “cannot distinguish between all the various breathing patterns including REM sleep versus troubled wakefulness.”¹³ PO Resp. 22–23 (citing Ex. 2006 ¶¶ 146–

¹³ Patent Owner does not specify whether this contention applies to this claim limitation, but the contention appears to be responsive to Petitioner’s contentions concerning the patient’s breathing patterns. We note that the testimony of Dr. Bates cited by Patent Owner in support of this contention is not directed to this limitation. *See* Ex. 2006 ¶¶ 146–47.

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47). Patent Owner contends that the '955 patent requires “an analysis of both the amplitude and the temporal structure of a breath-by-breath time series . . . to distinguish between troubled wakefulness and REM sleep.” *Id.* at 22 (citing Ex. 2006 ¶¶ 146–47). Patent Owner further contends that “the parameters that Sullivan995 claims to detect are all characteristics of the amplitude structure of a breath-by-breath parameter time series, which is not enough to distinguish between awake and asleep as claimed, let alone REM sleep and troubled wakefulness.” *Id.* at 23 (citing Ex. 2006 ¶ 147).

Petitioner replies that Patent Owner’s “non-obviousness arguments are based on its erroneous proposed construction of the “analyzing the breathing patterns” terms. Pet. Reply 11.

We agree with Petitioner that Patent Owner’s arguments are based on its construction of “analyzing the data to determine the patient’s breathing patterns” which, as discussed above, we do not adopt. Consequently, to the extent that Patent Owner interposed this contention in connection with limitation 1[c2], Patent Owner’s arguments are not commensurate in scope with claim 1, which does not require analysis of both an amplitude and temporal structure of the waveform to determine the patient’s breathing pattern. Further, Dr. Bates’s opinion cited by Patent Owner is not availing because it is based on the same argument that “neither Sullivan995 nor Sullivan460 teaches how to distinguish between an awake state and an asleep state based on an analysis of both the amplitude structure and the temporal structure of a time series of breath-by-breath parameters.” Ex. 2006 ¶ 146.

In the Sur-reply, Patent Owner contends that “Sullivan995 focuses on the analysis of *snoring sounds*, which are not breathing patterns.” Sur-reply

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16 (citing Ex. 2006 ¶ 163). Patent Owner bases this contention on Dr. Bates’s testimony that “[a] snoring signal is not a breathing pattern, so Sullivan995 does not make a determination ‘*based, at least in part on, on the determined breathing patterns of the patient.*’” Ex. 2006 ¶ 163. However, Dr. Bates’s opinion that a snoring signal is not a breathing pattern is explained in paragraphs 157 and 158 of his Declaration where he explains that Sullivan995 records single values that “cannot characterize a breathing pattern which is characterized by a time series of breath-by-breath parameter values arranged in the precise order of the breaths.” *Id.* ¶ 158. Patent Owner’s Sur-reply contention is, thus, unavailing because it relies on Dr. Bates’s testimony which is based on Patent Owner’s claim construction which we do not adopt.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this claim limitation for the reasons provided by Petitioner.

I[c3] 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,

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

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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.* (citing Ex. 1003 ¶ 126) (emphasis omitted). 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 highlights this limitation in red as allegedly not taught by Sullivan995 in view of Sullivan460. PO. Resp. 22. But, Patent Owner does not provide argument directed toward Petitioner’s contentions for this limitation. *Id.* at 22–25.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

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).

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Patent Owner highlights this limitation in red as allegedly not taught by Sullivan995. PO. Resp. 22. But, Patent Owner does not provide argument directed toward Petitioner’s contentions for this limitation. *Id.* at 22–25.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

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 contends that “Sullivan460 discloses [a] ‘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 (second alteration in original) (citing Ex. 1006, 7:17–19). Petitioner further contends Sullivan460 discloses switching means “which responds to the sleep sensor and automatically switches 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

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mode. *Id.* (alterations in original) (citing Ex. 1003 ¶¶ 147–148);
Ex. 1006, 6:30–7:12, claims 22–28, 43–46).

Patent Owner highlights this limitation in red as allegedly not taught by Sullivan995 in view of Sullivan460. PO. Resp. 22. But, Patent Owner does not provide argument directed toward Petitioner’s contentions for this limitation. *Id.* at 22–25.

We reviewed the evidence cited by Petitioner and find that the combination of Sullivan995 and Sullivan460 teaches this limitation for the reasons provided by Petitioner.

I[e] 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.* (citing Ex. 1003 ¶ 152) (emphasis omitted). 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

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reduced average airflow in the patient’s upper airway.” Pet. 42 (alteration in original) (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 which, as we discuss below, are persuasive. Pet. 42.

Patent Owner contends that “Sullivan460 only considers mean values of flow, an aspect of the amplitude structure of a time series, in determining sleep versus awake.” PO Resp. 39 (citing Ex. 1005 7:18–19); *see also id.* at 22 (“Sullivan995 in view of Sullivan460 teaches identification of patient state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of a time series.” (citing Ex. 2006 ¶ 150)). Patent Owner repeats its contention discussed above in our claim construction analysis, that the ’955 patent teaches that “analysis of both the amplitude and temporal structure of a breath-by-breath times series is required to distinguish between troubled wakefulness and REM sleep.” *Id.* at 24. According to Patent Owner, “Sullivan995 cannot distinguish between all the various breathing patterns, including REM sleep versus troubled wakefulness.” *Id.* at 22–23 (citing Ex. 2006 ¶¶ 146–47). Patent Owner further contends that Sullivan460 does not disclose this limitation because it “focuses exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible to distinguish between REM sleep and troubled wakefulness.” *Id.* at 24 (citing Ex. 2006 ¶ 178).¹⁴

¹⁴Patent Owner also argues that claim 1 is unpatentable for “the additional reasons provided by Dr. Bates in his Declaration, EX2006, which is

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Petitioner, in turn, contends that Patent Owner’s contentions fail because they are based on its construction of the “analyzing the breathing patterns” terms. Pet. Reply 10. Petitioner further contends that Patent Owner effectively concedes that “Sullivan995 in view of Sullivan460 ‘analyz[es] the breathing pattern’ according to its plain meaning, to determine asleep versus awake states.” *Id.* at 11 (alteration in original). Petitioner points to Patent Owner’s statements that Sullivan460 discloses “‘mean values of flow . . . in determining sleep versus awake’ and reduces CPAP when mean airflow increases (i.e., when the patient is awake).” *Id.* at 11–12 (alteration in original) (citing PO Resp. 24, 39; Ex. 1051 ¶¶ 37–39). Petitioner further contends that “Dr. Bates agreed that amplitude is a parameter extracted from a flow waveform, and Sullivan995’s analysis is ‘an example of a kind of analysis of a breathing pattern you could do.’” *Id.* at 12 (citing Ex. 1005, Fig. 8; Ex. 1052, 74:11–24, 184:20–185:7).

Patent Owner’s contentions are unavailing for several reasons.

To the extent that Patent Owner relies on its construction of “analyzing the data to determine the patient’s breathing patterns,” the contentions are unavailing because, as discussed in our claim construction analysis, claim 1 does not require an analysis of amplitude and temporal structures of the waveform. Second, Patent Owner’s contentions are not

incorporated here in its entirety.” PO Resp. 25; *see also id.* at 31 (arguing the same for claims 6, 23). Our Rules expressly state that “[a]rguments must not be incorporated by reference from one document into another document.” 37 C.F.R. § 42.6(a)(3). Further, Patent Owner was expressly informed that “arguments not raised in the response may be deemed waived.” Paper 19, 64 n.14. Accordingly, we deem waived all arguments based on “additional reasons” in Dr. Bates’s Declaration purported by Patent Owner to have been incorporated by reference into its response.

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commensurate with the scope of independent claim 1 because it does not recite determining that the patient has transitioned between troubled wakefulness and REM sleep. Rather, claim 1 recites “determin[ing] that the patient has transitioned between at least an awake state and an asleep state.” Ex. 1001, 10:6–6. Third, Sullivan460’s sleep sensor determines if the patient is asleep “when there is reduced average flow” which aligns with the ’955 patent’s description of “low flow rates” as indicative of REM sleep. Ex. 1001, 5:30–34.

We have reviewed the evidence cited by Petitioner and, for the reasons just discussed, we find that the combination of Sullivan995 and Sullivan460 teaches this limitation.

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 Patent Owner Response. PO Resp. 21–25.

We reviewed the evidence cited by Petitioner and find that Sullivan995 teaches this limitation for the reasons provided by Petitioner.

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Motivation to Combine/Reasonable Expectation of Success

In support of the combination of the teachings of Sullivan995 and Sullivan460, Petitioner states that “Sullivan460 . . . incorporates Sullivan995 by reference.” Pet. 15 (citing Ex. 1006, 6:22–29); *see also* Ex. 1003 ¶ 74 (Sullivan460 “incorporates Sullivan995 . . . by reference.”); *see also* Pet. 19–22 (discussing motivations supporting the asserted combination of teachings from Sullivan995 and Sullivan460, as well as why a person of ordinary skill in the art would have had a reasonable expectation of success). Petitioner contends that “[l]ike Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep.” Pet. 15 (citing Ex. 1006, 6:17–29, 7:3–12, 10:9–33, 11:10–12, claims 22–28, 43–46, Figs. 2–4). According to Petitioner, the asserted combination advantageously would apply “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,” as suggested by Sullivan995, which explains “that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period).” *Id.* at 20 (citing Ex. 1005, 10:13–46, 14:45–64). Additionally, Petitioner contends that a person 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).

We find Petitioner’s reasoning above supports the asserted combination of features from Sullivan995 and Sullivan460. We further

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consider Patent Owner’s arguments in opposition and do not agree with them for the reasons provided below. *See* PO Resp. 25–26; Sur-reply 19–21.

First, Patent Owner argues that there is “no motivation to combine Sullivan995 with Sullivan460” to “modify the *processing arrangement* in Sullivan995 to appl[y] a *lesser positive treatment pressure* when the patient is in an awake state, and *determine[] that the patient has transitioned between at least an awake state and an asleep state,*” because “Sullivan460 focuses exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to . . . distinguish between an awake state and an asleep state as claimed.” PO Resp. 25–26 (alterations in original) (citing Ex. 2006 ¶¶ 146–47). Patent Owner’s argument is not persuasive because it is premised on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns” as requiring analysis of both the amplitude structure and the temporal structure, which we do not adopt for the reasons provided above. Further, Patent Owner’s argument that the asserted combination “makes it impossible . . . to distinguish between an awake state and an asleep state” is contrary to the disclosure of Sullivan460, which describes two modes of air delivery, one at a higher pressure than the other, as well as “a sleep sensor which senses whether or not the patient is asleep” and “switching means” so that treatment may be switched to a higher pressure mode “as soon as the patient goes to sleep (as determined by an appropriate sensing algorithm in the treatment means).” Ex. 1006, 7:3–12.

Second, Patent Owner argues that there is “no motivation to combine,” because Sullivan460 teaches that “the preset level is a single value of a flow rate, but Dr. Kirkness does not know how this would be

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calculated.” PO Resp. 26 (citing Ex. 2015, 48:6–20). Specifically, Dr. Kirkness was asked “[h]ow would you calculate a single value of a flow rate?” and responded “[s]o in my – I don’t know how this would be – it doesn’t describe, for me, in this sentence how that level is.” Ex. 2011, 48:6–20. Elsewhere in its Patent Owner Response, Patent Owner implies, in regard to a *different* alleged ground of unpatentability, that Sullivan460 is not enabled. PO Resp. 38 (asserting no motivation to combine Rapport502 and Sullivan460) (citing *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1354 (Fed Cir. 2003), for the proposition that “to qualify as prior art, it must be enabled”). Further, Patent Owner makes the same allegation but directed to the combination of Sullivan995 with Sullivan460 for the first time in its Sur-reply, asserting that “[t]here is no motivation to combine any reference with Sullivan460 because it is not enabling.” Sur-reply 19–20 (citing Ex. 2015, 48:6–20).

We disagree with Patent Owner’s arguments that Petitioner fails to show any motivation to combine and that Sullivan460 is not enabled merely because Dr. Kirkness indicated in a deposition that he did not know how a preset level is calculated from a single sentence in Sullivan460. As Petitioner correctly explains, enablement “is not a requirement to prove invalidity under §103.” *Amgen*, 314 F.3d at 1313 (Under §103, “a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein.”). Moreover, we agree with Petitioner that the challenged claims do not require any preset level for a flow rate, and a person of ordinary skill “would have understood that a preset level is established from previously-acquired data or data from a previous window of time, such as an average level, for example, as taught in Sullivan995.” Pet. Reply 14–15

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(citing Ex. 1005, 17:3–27, Fig. 12; Ex. 2015, 38:2–16). Patent Owner responds that Petitioner’s assertion is unsupported, and that “Petitioner is obligated to address this challenge, and failed to do so.” Sur-reply 20 (citing *In re Morsa*, 713 F.3d 104, 110 (Fed. Cir. 2013)). We find Petitioner’s arguments persuasive because they are supported by the asserted references.

Sullivan995 discloses that the computing system may “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.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22. Based on this disclosure, and given that Sullivan460 incorporates Sullivan995 by reference, we agree with Petitioner that Sullivan460’s disclosure of “detect[ing] that the flow rate has fallen below a present [sic] level,” would have informed a person of ordinary skill that this level was predetermined, so that “the controller 100 activates the nCPAP apparatus 90 to supply air to the patient 30 at a pressure which ameliorates or eliminates the upper airway flow limitation.” Ex. 1006, 11:10–13.

Third, Patent Owner argues a person of ordinary skill would have had no reasonable expectation of success combining the teachings of Sullivan995 with Sullivan460 because “Sullivan995 is not ‘configured to monitor breathing patterns while the patient is asleep to determine a patient’s pressure flow needs’” and “does not teach how to distinguish [an] awake state and an asleep state, let alone between REM sleep and troubled wakefulness which have opposite implications for pressure and flow.” PO

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Resp. 26 (citing Ex. 2005 ¶¶ 149–50, 213). We disagree with Patent Owner’s argument because it is premised on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns” requiring analysis of both the amplitude structure and the temporal structure, which we do not adopt for the reasons provided above. We also disagree with Patent Owner’s arguments because they are directed to the references, individually, and not to what the references in combination would have taught a person of ordinary skill. For example, Petitioner relies on Sullivan460 not Sullivan995 to distinguish between an awake state and an asleep state. *See* Pet. 40.

Finally, Patent Owner argues that “the proposed modification to Sullivan995’s CPAP system would require methods of digital signal processing that go beyond a combination of known prior art elements,” and “would require the use of methods that analyze the temporal structures of a time series.” PO Resp. 26 (citing Ex. 2006 ¶ 150). To the contrary, Petitioner has shown by a preponderance of the evidence that the Challenged Claims “do not require analysis of temporal structures of a time series,” and that a person of ordinary skill “would have understood that asleep and awake states could be determined without analysis of temporal structures.” Pet. Reply 16 (citing Ex. 1051 ¶¶ 21–22). Petitioner contentions are supported by the ’955 patent which describes that the processor “may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns etc. in determining the patient’s state” and that “high respiratory rates and low flow rates” are indicative of REM sleep. Ex. 1001, 4:28–30, 5:32–33.

Based on our review of the arguments and evidence cited by Petitioner, and after considering Patent Owner’s arguments, we find

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Petitioner shows that an ordinarily skilled artisan would have been motivated to combine Sullivan995 and Sullivan460 as asserted, and would have had a reasonable expectation of success in doing so.¹⁵

Summary of Independent Claim 1

For all the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches every limitation of claim 1.

4. Dependent Claims 2–5, 8, 11–12, and 16–18

These claims depend from claim 1. Ex. 1001, 10:12–11:11. Petitioner asserts that these claims would have been obvious over Sullivan995 and Sullivan460 and provides a detailed analysis of each of these claims with argument and evidence in support thereof. Pet. 43–52. Patent Owner does not raise any arguments directed specifically to claims 2–5, 8, 11, 12, and 16–18 aside from the arguments Patent Owner directs to claim 1. *See* PO Resp. 20–26. We have reviewed Petitioner’s evidence and arguments and find that the combination of Sullivan995 and Sullivan460 teaches every limitation of claims 2–5, 8, 11, 12, and 16–18 for the reasons provided by Petitioner.

¹⁵ Patent Owner improperly argues for the first time in its Sur-reply that the asserted combination would have required “undue experimentation.” Sur-reply 20. Patent Owner’s alleged “undue experimentation” was not raised in Patent Owner’s Response and therefore Petitioner did not have an opportunity to respond to it. Accordingly, Patent Owner’s argument is improper and the issue is deemed waived. *See* Paper 19, 64 n. 14 (stating that “Patent Owner is cautioned that any arguments not raised in the Patent Owner Response may be deemed waived”). Moreover, we disagree with Patent Owner’s “undue experimentation” argument because it is premised on Patent Owner’s proposed construction requiring analysis of “both amplitude and temporal structure,” which we do not adopt.

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5. *Independent Claim 19*

Independent claim 19 contains several limitations, identified by Petitioner as limitations 19[e]–19[g], substantially similar to claim 1. *Compare* Ex. 1001, 9:47–10:11, *with id.* at 11:12–44. For these limitations, Petitioner relies on its contentions and evidence for the corresponding limitations of claim 1. Pet. 54–55. For the remaining limitations of claim 19, Petitioner provides contentions supported by evidence from Sullivan995, Sullivan460, and Dr. Behbehani. *Id.* at 52–54. Petitioner relies on the same contentions for motivation to combine and reasonable expectation of success as discussed for claim 1. *Id.* at 19–57.

Patent Owner does not provide contentions for claim 19 apart from its contentions for claim 1. *See* PO Resp. 20–26.

We reviewed the Petitioner’s additional evidence and arguments for claim 19 and determine that Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches every limitation of claim 19 and that an ordinarily skilled artisan would have been motivated to combine Sullivan995 and Sullivan460 with a reasonable expectation of success for the reasons provided by Petitioner.

6. *Dependent Claims 20–22, 24–26, 30, and 31*

These claims depend from claim 19. Ex. 1001, 12:1–42. Petitioner asserts that these claims would have been obvious over Sullivan995 and Sullivan460 and provides a detailed analysis of each of these claims with argument and evidence in support thereof. Pet. 55–57. Patent Owner does not raise any arguments directed specifically to claims 20–22, 24–26, 30, and 31 aside from the arguments Patent Owner directs to claim 1. *See* PO Resp. 20–26. We have reviewed Petitioner’s evidence and arguments and

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find that the combination of Sullivan995 and Sullivan460 teaches every limitation of claims 20–22, 24–26, 30, and 31 for the reasons provided by Petitioner.

E. 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. Patent Owner disputes Petitioner’s contentions. PO Resp. 29–33.

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.” 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-

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CPAP controller if the patient's breathing pattern becomes too variable.” *Id.* at 21:37–42.

2. Analysis

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, 21:35–44, 21:63–22:1). According to Petitioner, “Matthews’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 with ‘erratic breathing.’” *Id.* (citing Ex. 1001, 4:47–59).

Petitioner also provides reasons why one of ordinary skill in the art would have been motivated to modify the system of Sullivan995 and Sullivan460 with the teachings of Matthews and why the proposed modification would have had a reasonable expectation of success. *Id.* at 57–58.

Patent Owner argues that the combination of Sullivan995, Sullivan460, and Matthews does not teach the limitation “the awake state is a troubled wakefulness state.” PO Resp. 30. Patent Owner does not explain why it asserts that Matthews does not teach the recited troubled wakefulness state. *Id.* at 30–31. Rather, Patent Owner argues that “Sullivan995 and Sullivan460 in view of Matthews only teach the identification of patient

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state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of a time series.” *Id.* at 30 (citing Ex. 2006 ¶ 266). Patent Owner then repeats its contention that the ’955 patent requires analysis of amplitude and temporal structure “to distinguish between troubled wakefulness and REM sleep.” *Id.* This contention is unavailing because we do not adopt Patent Owner’s claim construction requiring an analysis of amplitude and temporal structures.

We have reviewed Petitioner’s evidence in light of the parties’ agreed-on construction of “troubled wakefulness” and find that Matthews teaches the limitations of claims 6 and 23. *See* Pet. 59 (citing Ex. 1007, 21:35–44, 21:63–22:1).

Motivation to Combine/Reasonable Expectation of Success

Petitioner contends it would have been obvious to an ordinarily skilled artisan “to modify the system of Sullivan995 and Sullivan460 Matthews so that the *processing arrangement* applies a lower pressure when the patient is in a *troubled wakefulness state*, as taught by Matthews.” Pet. 57 (citing Ex. 1003 ¶ 214). According to Petitioner, the ordinarily skilled artisan “would have recognized the advantages of detecting different awake states, including a distressed state (*troubled wakefulness*) in which the patient has breathing that becomes ‘erratic,’ as taught in Matthews,” which “would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* (citing Ex. 1003 ¶ 215). Petitioner notes that Sullivan995 is “concerned with the patient’s comfort, and already discloses it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible.” *Id.* at 57–58 (citing Ex. 1005, 2:31–39).

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Petitioner next contends that there would be a reasonable expectation of success in combining Sullivan995, Sullivan460 and Matthews. Pet. 58. Petitioner explains that because data from Matthews’s flow sensors “are monitored and used to determine how to control the pressure” and Sullivan460 discloses lowering the pressure in an awake state, a person of ordinary skill in the art “would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient.” *Id.* (citing Ex. 1003 ¶ 217). According to Petitioner, the modification to Sullivan995 and Sullivan460 “is a combination of known prior art elements according to known methods and known techniques to yield predictable results, involves use of a known technique to improve a similar device in the same way.” *Id.* (citing Ex. 1003 ¶ 219).

Patent Owner argues that “Sullivan460 and Matthews focus exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to distinguish between REM sleep and troubled wakefulness” and “do not teach how to distinguish between an awake state and an asleep state as claimed.” PO Resp. 31–32 (citing Ex. 2006 ¶¶ 266–67). Patent Owner argues that Sullivan460 teaches a preset level that Dr. Kirkness cannot calculate. *Id.* at 32 (citing Ex. 2015, 48:6–20). These arguments are unavailing because they are based on Patent Owner’s proposed construction of analyzing the data, which we do not adopt.

For reasonable expectation of success, Patent Owner repeats its arguments that Sullivan995 is not configured to monitor breathing patterns while the patient is asleep, Sullivan995 does not teach how to distinguish

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between troubled wakefulness and REM sleep, and modifying Sullivan995's CPAP would require digital signal processing techniques that go beyond a combination of known prior art elements. PO Resp. 41–42. These arguments are unavailing for the same reasons discussed above. *See supra* Section II.D.3.

We have reviewed Petitioner's contentions and evidence in light of Patent Owner's arguments in opposition and find that the Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews teaches the limitations of claim 19 and that an ordinarily skilled artisan would have been motivated to combine Sullivan995, Sullivan460, and Matthews with a reasonable expectation of success for the reasons provided by Petitioner. *See* Pet. 57–59.

G. Objective Evidence of Non-obviousness

The fourth *Graham* factor instructs that we must consider—apart from what the prior art itself would have suggested—whether objective evidence of non-obviousness (i.e., secondary considerations) may lead to a conclusion that the challenged claims would not have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (instructing that evidence of secondary considerations, when present, must always be considered in determining obviousness). Objective evidence of non-obviousness may include evidence of commercial success, licensing, copying, praise by others, long felt but unresolved need, and failure or skepticism of others. *Graham*, 383 U.S. at 17–18. But, secondary considerations are only a part of the “totality of the evidence;” their mere existence does not control the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). Objective

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evidence of non-obviousness “may often be the most probative and cogent evidence in the record” and “may often establish that an invention appearing to have been obvious in light of the prior art was not.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

Patent Owner argues that evidence of non-obviousness exists in the form of long-felt need. PO Resp. 27–29, 33. According to Patent Owner, since 1991 there has been “a need for patients to increase compliance with usage of their CPAP machines.” *Id.* at 27 (citing Ex. 1036, 5). Patent Owner further argues as follows:

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients’ compliance with CPAP treatment by noting that “the conventional PAP therapy [had] not taken sleep/wake state into account” and “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” ’995 Patent, 1:44-46. Further, before the development of the claimed invention in the ’995 Patent, self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. *Id.*, 2:14-17. In fact, as of 2002, a [person of ordinary skill in the art] was “not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters.” *See* [EX2017, 2:33-37]. As such, the claimed invention solved a long felt but unresolved need – better compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 28–29 (first and second alterations in original).

Patent Owner further argues that conventional CPAP treatment “had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control.” Sur-reply 25 (citing Ex. 1001, 2:13–17, 2:26–29;

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Ex. 1053, 296:22–297:15). According to Patent Owner, Dr. Bates’s testimony explained that “[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states.” *Id.* at 26 (citing Ex. 1052, 113:3–11, 115:22–116:10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by the ’995 patent’s “ability to distinctly identify when a patient is awake or asleep,” because a person of ordinary skill in the art “prior to the 994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and awake.” *Id.* (alteration in original) (citing Ex. 1052, 202:23–203:3).

(1) *Nexus*

Objective evidence of non-obviousness “is only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia of non-obviousness].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). A “nexus” is a legally and factually sufficient connection between the objective evidence and the claimed invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom*,

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Inc., IPR2018-01129, Paper 33 at 32–33 (PTAB Jan. 24, 2020) (precedential), *aff’d sub nom. Zaxcom, Inc. v. Lectrosonics, Inc.*, 2022 WL 499848 (Fed. Cir. Feb. 18, 2022). We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* at 32. If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 33 (quoting *Fox Factory*, 944 F.3d at 1373–75). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Id.* (citing *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011)). There is no requirement that the objective evidence of non-obviousness be tied exclusively to claim elements that are not disclosed in the prior art, and the claimed combination as a whole may serve as a nexus for the objective evidence. *Id.* (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)).

Petitioner argues that “for secondary considerations to be accorded substantial weight, [Patent Owner] bears the burden of showing that a nexus exists between the claimed features of the invention and the evidence offered to show non-obviousness.” Pet. Reply 24 (citing *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). According to Petitioner, Patent Owner does not meet this burden because: 1) Patent Owner did not establish “a presumption of nexus” since Patent Owner did not identify any product tied to the objective evidence; 2) Patent Owner did

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not “demonstrate a nexus by showing that long-felt need was met as a ‘direct result of the unique characteristics of the claimed invention,’” 3) Patent Owner did not identify “any failed efforts to solve the problem before the invention,” and 4) Patent Owner does not point to disclosure in the ’955 patent that the “prior art recognized the need to analyze temporal and amplitude structures.” *Id.* at 24–26 (citations omitted).

First, Patent Owner has not argued that the presumption of nexus applies and we agree with Petitioner that Patent Owner is not entitled to a presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the Challenged Claims. Second, we address Patent Owner’s evidence of long-felt, but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the ’955 patent, absent the presumption.

(2) Long-felt Need

In order to show a long-felt but unmet need *for the claimed invention*, the objective evidence must show that the need was a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). “Evidence of long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would not have persisted had the solution been obvious.” *WBIP*, 829 F.3d at 1332.

Here, Patent Owner suggests increasing the comfort of the PAP system is a goal to improve patient compliance with PAP therapy. PO Resp 27. Patent Owner does not explain, however, why Sullivan460’s treatment means which “addresses ... the comfort of CPAP,” and “is an improvement over the prior art” because of the two modes of air delivery where the

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pressure is lower in the awake state, does not meet the long-felt need identified by Patent Owner. *See* Ex. 1006, 7:7–16; *see also* Pet. 15. Thus, we agree with Petitioner that “[t]o the extent that any need existed, it was already satisfied.” Pet. Reply 25 (citations omitted).

Additionally, Patent Owner does not identify any failed efforts to solve the problem before the invention and similarly fails to provide sufficient evidence that the ’955 patent satisfied the alleged need. Dr. Bates’s redirect testimony, which Patent Owner almost exclusively relied on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to “little or no weight.” 37 C.F.R. § 42.65(a). Patent Owner’s additional arguments regarding a supposed need for better compliance with CPAP therapy by detecting troubled wakefulness (*see* Pet. Reply 26) are only commensurate in scope with dependent claims 6 and 23. Nonetheless, even assuming Patent Owner’s argument is commensurate in scope with each of the Challenged Claims, Patent Owner’s argument still suffers from the other deficiencies identified above, particularly the failure by Patent Owner to show that the ’955 patent satisfied the alleged need.

Patent Owner relies on the same evidence and arguments concerning objective evidence of nonobviousness, and specifically long-felt need, with regard to obviousness over the combination of Sullivan995, Sullivan460, and Matthews as Patent Owner argues in regard to obviousness over the combination of Sullivan995 and Sullivan460 just discussed. *See* PO Resp. 33. In addition, we add that, as shown by Petitioner, Matthews already taught detecting troubled wakefulness and thus, in the context of

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claims 6 and 23, Patent Owner has not explained why the alleged long-felt need was not met by Matthews.

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt, but unmet need met by any of the Challenged Claims. As a result, we accord little weight to Patent Owner's evidence of long-felt need.

H. Weighing the Graham Factors

We have considered the scope and content of the prior art of record, any differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art. For the reasons discussed in our analysis of Grounds 1 and 2, Petitioner provides persuasive evidence of the unpatentability of the Challenged Claims. Patent Owner's evidence of long felt need is entitled to little, if any, weight. On balance, after weighing all of the evidence in the record, we determine that Petitioner has established by a preponderance of the evidence that the Challenged Claims would have been obvious to a person of ordinary skill in the art.

I. Grounds 3 and 4

In light of our determination that claims 1–6, 8, 11, 12, 16–26, and 30–31 are unpatentable based on Grounds 1 and 2, we do not reach Petitioner's alternative challenges to these claims set forth in Grounds 3 and 4. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged.”); *see also* 35 U.S.C. § 318(a).

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner seeks to exclude Exhibits 1009, 1011, 1020, 1022, 1049, and 1054–1058, and portions of Exhibits 1003, 1046, 1051, and 1052.

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PO MTE 1–14; PO MTE Reply 1–5. Petitioner opposes the motion. PO MTE Opp. 1–13. For the following reasons we deny Patent Owner’s Motion to Exclude.

A. Exhibits 1003 and 1046

Exhibit 1003 is the Declaration of Petitioner’s original declarant, Dr. Behbehani, and Exhibit 1046 is the substitute Declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s Declaration. *See* Ex. 1046 ¶ 28. Patent Owner argues that certain portions of Exhibit 1003 should be excluded and that the same portions of Exhibit 1003 that Dr. Kirkness adopts should be excluded. PO MTE 3–5, 6–7. Because we do not rely on the portions of Exhibit 1003 noted by Patent Owner in rendering this Decision, we deny Patent Owner’s Motion to exclude these portions of Exhibit 1003 and the corresponding portions of Exhibit 1046 as moot.

B. Exhibits 1009 and 1054–1058

Exhibit 1009 is the file history of the related ’344 patent. Exhibit 1054 is the file history of the related ’009 patent. Exhibits 1055–1058 are copies of the ’009 patent, the ’344 patent, the ’539 patent, and the ’994 patent respectively.

Patent Owner asserts that Petitioner improperly relies on these exhibits in the Reply to support its claim construction because “Petitioner introduced new evidence in its Reply with these exhibits.” PO MTE 5.

Petitioner replies that these exhibits are proper evidence in the Reply because Patent Owner “proposed a construction for the ‘analyzing the breathing patterns’ claim terms for the first time in [the] Response.” PO MTE Opp. 6. We agree.

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In its Petition, Petitioner argued for ““using the same claim construction standard that would be used’ in district courts,” i.e., the ordinary and customary meaning. Pet. 18. In its Response, Patent Owner argued that the language of the term “analyzing the data to determine the patient’s breathing patterns,” which appears in claim 1, should be construed as “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 17. Patent Owner did not raise this claim construction argument (or any other claim construction) in its Preliminary Response to the Petition (Paper 14), but raised it for the first time in its Response. *See* PO Resp. 16–19. Petitioner’s argument in its Reply responds to Patent Owner’s claim construction position asserted in the Patent Owner Response.

Petitioner adduced Exhibits 1009 and 1054–1058 to demonstrate the plain and ordinary meaning of the claim term “analyzing the data to determine the patient’s breathing patterns,” which was a legitimate response to Patent Owner’s proposed construction in its Patent Owner Response. Therefore, we deny Patent Owner’s Motion to Exclude as to Exhibits 1009 and 1054–1058.

C. Exhibits 1011, 1020, and 1022

Patent Owner argues that these documents are irrelevant under Federal Rule Evidence 402 because Petitioner does not discuss or cite these exhibits in any document filed in this proceeding. PO MTE 6.

For Exhibit 1011 (“Burton852”), Petitioner responds that the documents “meets the threshold for relevance” because it “is cited and discussed during the prosecution history of the ’955 Patent.” PO MTE Opp.

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8 (citing Ex. 1003 ¶ 103 (discussing how applicant obtained allowance over the prior art of record Burton 852)). We agree with Petitioner and deny Patent Owner’s Motion to Exclude as to Exhibit 1011.

For Exhibits 1020 and 1022, Petitioner argues that the Motion to Exclude is moot because Exhibits 1020 and 1022 “were already expunged from the record and they were not cited in the Petition.” PO MTE Opp. 8–9 (citing Paper 12, 4 n.1, 8).

Patent Owner replies that “while the sentence referring to EX1020 was stricken from the Petition, rendering the objection to EX1020 moot, the Board did not expunge Ex. 1022.” PO MTE Reply 3. Because we do not rely on Exhibit 1020, we, thus deny Patent Owner’s Motion to Exclude as to Exhibit 1020 as moot.

We do not rely on Exhibit 1022 in this decision, so we deny the Motion to Exclude as to Exhibit 1022 as moot.

D. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2. Patent Owner argues that the priority date of this patent is after the priority date of the ’955 patent and should be excluded as irrelevant and “not prior art.” PO MTE 7. Patent Owner also argues it should have been introduced prior to Petitioner’s Reply. *Id.*

Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. PO MTE. Opp. 9. Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. *Id.* at 9–10. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates’s

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credibility, not as prior art, and find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision and deny Patent Owner's Motion to Exclude as to Exhibit 1049 as moot.

E. Exhibit 1051

Exhibit 1051 is the Declaration of Dr. Kirkness in support of Petitioner's Reply. Patent Owner argues that portions of Exhibit 1051 "should be excluded for the same reasons as" Exhibits 1003 and 1046. PO MTE 7–8. The only "example," provided by Patent Owner in support of its argument is that Dr. Kirkness "uses Exhibits 1049 and 1054–1058 in the exact same manner as they were challenged above." *Id.* at 8. For the reasons discussed above for Exhibits 1049 and 1054–1058, we deny the Motion to Exclude as to Exhibit 1051.

F. Exhibit 1052

Exhibit 1052 is the transcript of Dr. Bates's deposition testimony. Patent Owner argues that the portions of Exhibit 1052 "focusing on patent eligible subject matter and whether certain products, such as processors, infringe by meeting the limitations of the '995 Patent should be excluded as irrelevant." PO MTE 8–9 (citing Ex. 1052, 62:7–23, 63:15–25, 64:1–5, 117:9–25, 118:1–11, 146:4–12); PO MTE Reply 4–5. Petitioner argues that the testimony of Dr. Bates is relevant to obviousness issues in this proceeding, that there was "no discussion of 'infringement' or 'patentable subject matter,'" and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 10–11. We agree with Petitioner's reasons and deny Patent Owner's Motion to Exclude as to the challenged portions of Exhibit 1052.

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G. Exhibit 1059

Exhibit 1059 is an article titled “Control of breathing during sleep” published in Clinical Science in 1984 and was cited by Dr. Kirkness in his Reply Declaration (Exhibit 1051). Patent Owner argues that Dr. Kirkness relied on Exhibit 1059 to show that a person of ordinary skill in the art “knew ‘that a processor could be programmed to analyze breathing patterns that fall below or above certain preset levels of airflow rate to indicate awake or asleep states’ and that analysis of temporal structures was not necessary.” PO MTE 9–10 (quoting Ex. 1051 ¶¶ 11, 32). According to Patent Owner, “[a]ny use of EX1059 is therefore an improper incorporation by reference through EX1051, violating 37 C.F.R. § 42.6(a)(3), which prohibits incorporating arguments by reference from one document into another document.” *Id.* at 10.

Patent Owner’s argument has no merit. As Petitioner notes, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and Exhibit 1059 “is not an argument.” PO MTE Opp. 12. Patent Owner also argues in its reply that Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply 5. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his Reply Declaration were relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” Pet. MTE Opp. 12. We agree with Petitioner for the same reasons discussed above regarding Exhibits 1009 and 1054–1058. Because Patent Owner shows no

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persuasive basis to exclude Exhibit 1059, Patent Owner's Motion to Exclude as to Exhibit 1059 is denied.

IV. PETITIONER'S MOTION TO EXCLUDE

Petitioner seeks to exclude portions of the deposition testimony of Patent Owner's declarant Dr. Bates, Exhibit 1053. Pet. MTE 1–10; Pet. MTE Reply 1–5. Petitioner moves to exclude Dr. Bates's re-direct deposition testimony concerning secondary considerations of non-obviousness. Pet. MTE 1–2. Petitioner argues that the redirect testimony of Dr. Bates “was outside the scope of Petitioner's cross-examination in contravention of Fed. R. Evid. 611(b) and 37 C.F.R. § 42.53(d)(5)(ii).” *Id.* at 1. Petitioner does not seek to exclude the entirety of Dr. Bates's redirect testimony but only the specific portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes the motion. Pet. MTE Opp. 1–10. For the following reasons, we deny Petitioner's Motion to Exclude.

Petitioner contends that it “did not cross-examine Dr. Bates about any secondary considerations and timely objected to PO's line of questioning during redirect as being outside the scope.” Pet. MTE 1–2 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9), 4 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9). Petitioner further contends that Patent Owner's “introduction of belated expert testimony into the record via the Sur-Reply is improper and the evidence must be excluded.” *Id.* at 2 (citing *Comcast Cable Commc'ns, LLC v. Rovi Guides, Inc.*, IPR2019-01413, Paper 34 at 4 (PTAB Sept. 16, 2020); *Int'l Bus. Machines Corp. v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 15 at 5 (PTAB Feb. 2, 2015); *see also id.* at 5–6 (identifying the portions of Sur-reply citing to the disputed testimony). Petitioner further

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contends that “Dr. Bates’ declaration included no discussion of secondary considerations.” *Id.*

Petitioner contends that “FRE 611(b) prohibits redirect examination that goes beyond the scope of cross-examination questions and testimony” and Patent Owner’s “redirect examination did just that.” Pet. MTE 7. Petitioner next contends that “the portions of Dr. Bates’ redirect testimony that Petitioner seeks to exclude from the record . . . have no bearing on ‘matters affecting the witness’s credibility.’” *Id.* at 8 (citations omitted). According to Petitioner, Patent Owner “does not rely on Dr. Bates’ testimony to counter a challenge to his credibility.” *Id.* Petitioner next contends that 37 C.F.R. § 42.53(d)(5)(ii) “similarly prevents a party from expanding the scope of redirect examination beyond that of cross-examination.” *Id.* at 9.

Patent Owner contends that Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner argues that the PTAB Consolidated Trial Practice Guide provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or ***otherwise exceeds the proper scope*** of reply or sur-reply, it may request authorization to file a motion to strike.” Pet. MTE Opp. 2 (citing PTAB Consolidated Trial Practice Guide (“CTPG”) 80 (PTAB Nov. 2019)). Patent Owner contends that “Petitioner’s counsel reserved that right to strike Dr. Bates’ redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of PO submitting its Sur-Reply.” *Id.* (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact ***inadmissible***,” only that “it should be excluded (not stricken) because it is

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beyond of the scope of its cross-examination.” *Id.* at 3. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* at 4 (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–25).

In the Reply, Petitioner contends it “properly focused its motion to exclude the portions of Dr. Bates’ inadmissible re-direct deposition testimony cited in [the] Sur-Reply” and that Patent Owner “uses its Sur-Reply as no more than a ‘vehicle’ to enter new evidence into the record.” Pet. MTE Reply 1. Petitioner contends that it “timely objected at the deposition” once Patent Owner began “improperly elicit[ing] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Federal Rule of Evidence 611(b). *Id.* at 3 (citing Pet. MTE, Section II.B.2).

For the following reasons, we deny Petitioner’s Motion to Exclude.

The CTPG provides that “[a] motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay)” but should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.” CTPG 79. Further, the CTPG states that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a

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motion to strike.” *Id.* at 80. As an alternative to a motion to strike, “a party may request authorization for further merits briefing . . . to address the merits of newly-raised arguments or evidence.” *Id.* A party must seek authorization to file a motion to strike “within one week of the allegedly improper submission.” *Id.* at 81.

As noted in the CTPG, motions to strike are intended to address, *inter alia*, whether a brief raises new issues or exceeds the proper scope of a sur-reply. Here, Petitioner argues that the redirect testimony is inadmissible under Rule 611(b) and/or 37 C.F.R. § 42.53(d)(5)(ii) as exceeding the scope of cross-examination. But, Petitioner does not seek to exclude all redirect testimony on secondary considerations, only the testimony relied on by Patent Owner in the Sur-reply. Pet. MTE 5 n.2.

The issue presented here borders on the proper scope of a motion to exclude as compared to a motion to strike. The goal of Petitioner’s Motion is clearly to undercut arguments raised in Patent Owner’s Sur-reply directed to objective indicia of non-obviousness. By limiting its Motion to only the portions of Dr. Bates’s redirect examination actually relied on in Patent Owner’s Sur-reply, Petitioner’s arguments reflect this goal. *See, e.g.*, Pet. MTE 5 n.2 (“Although all of Dr. Bates’ redirect testimony on secondary considerations was outside the scope of Petitioner’s cross-examination, Petitioner narrowly focuses this motion on excluding only those portions that [Patent Owner] relies on in its Sur-Reply.”). One way in which Petitioner could have challenged the arguments raised in Patent Owner’s Sur-reply is by requesting authorization to file a motion to strike, which, as noted above, is intended for the purpose of addressing arguments a party believes exceeds the proper scope of sur-reply. *See* CTPG 80. Petitioner did

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not request such authorization. Instead, by seeking to exclude some of Dr. Bates's redirect testimony on objective indicia (i.e., the portions relied on in Patent Owner's Sur-reply), Petitioner seeks to undercut the arguments raised in Patent Owner's Sur-reply on objective indicia by effectively removing the primary evidentiary support for those arguments. Were we to grant Petitioner's Motion to Exclude, we would be faced with determining what to do with Patent Owner's arguments in the Sur-reply, which would remain of record because they are not the subject of Petitioner's Motion to Exclude (nor could they be based on the CTPG) and (as previously noted) Petitioner did not also file a motion to strike those arguments. The best course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Rule 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination (just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony¹⁶), Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of non-obviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the

¹⁶ There are exceptions, e.g., questions pertaining to a witness's credibility. See Fed. R. Evid. 611(b).

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circumstances presented here and in light of the little weight to which Patent Owner's argument and Dr. Bates's redirect is entitled, we determine that the better course at this stage is to deny Petitioner's Motion to Exclude.

V. CONCLUSION

The outcome for the Challenged Claims in this proceeding is set forth in summary as follows:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–5, 8, 11, 12, 16–22, 24–26, 30, 31	103(a)	Sullivan995, Sullivan460	1–5, 8, 11, 12, 16–22, 24–26, 30, 31	
6, 23	103(a)	Sullivan995, Sullivan460, Matthews	6, 23	
1, 3–6, 9–12, 14–18, 20–24, 26–29	102(b)	Rapoport502, Sullivan460 ¹⁷		
19	102(b)	Rapoport502, Sullivan460, Matthews ¹⁸		
Overall Outcome			1–6, 8, 11, 12, 16–26, 30, 31	

¹⁷ We do not reach the merits of this ground.

¹⁸ We do not reach the merits of this ground.

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VI. ORDER¹⁹

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Exclude (Paper 51) is denied;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 52) is denied;

FURTHER ORDERED that claims 1–6, 8, 11, 12, 16–26, 30, and 31 of U.S. Patent No. 9,867,955 B2 have been proven by a preponderance of the evidence to be unpatentable; and

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

¹⁹ Should Patent Owner wish to pursue amendment of a Challenged Claim in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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Paper 67
Date: December 7, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

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Patent 10,384,024 B2

Before BART A. GERSTENBLITH, JAMES A. TARTAL, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

GERSTENBLITH, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

ORDER
Denying Patent Owner's Motion to Exclude (Paper 48) and
Denying Petitioner's Motion to Exclude (Paper 51)
37 C.F.R. § 42.64(c)

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Patent 10,384,024 B2

I. INTRODUCTION

A. Background

ResMed, Inc. (“Petitioner”) filed a Petition (Paper 1) requesting institution of *inter partes* review of claims 1–14 (“the Challenged Claims”) of U.S. Patent No. 10,384,024 B2 (Ex. 1001, “the ’024 patent”). With our prior authorization (Paper 6), Petitioner filed a Motion to Correct the Petition (Paper 7), which New York University (“Patent Owner”) opposed (Paper 8). We granted Petitioner’s Motion to Correct the Petition (Paper 9), and Petitioner filed a Corrected Petition (Paper 10, “Pet.”).¹ Patent Owner filed a Preliminary Response (Paper 11). With our prior authorization, Petitioner filed a Reply to Patent Owner’s Preliminary Response (Paper 13), and Patent Owner filed a Sur-reply (Paper 14). Applying the standard set forth in 35 U.S.C. § 314(a), we instituted an *inter partes* review as to all claims and grounds set forth in the Petition. Paper 15 (“Inst. Dec.”).

After institution, Patent Owner filed a Patent Owner Response (Paper 32, “PO Resp.”), Petitioner filed a Reply (Paper 40, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 43, “Sur-reply”). Additionally, Patent Owner filed a Motion to Exclude (Paper 47, “PO MTE”), Petitioner filed an Opposition (Paper 51, “PO MTE Opp.”), and Patent Owner filed a Reply (Paper 52 “PO MTE Reply”). And Petitioner filed a Motion to Exclude (Paper 48, “Pet. MTE”), Patent Owner filed an Opposition (Paper 50, “Pet. MTE Opp.”), and Petitioner filed a Reply (Paper 53, “Pet. MTE Reply”). A consolidated oral hearing was held for this proceeding as well as six related proceedings, IPR2022-00988, IPR2022-00989,

¹ Further references to “Petition” are to the Corrected Petition (Paper 10), unless otherwise indicated.

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IPR2022-00990, IPR2022-00991, IPR2022-00993, and IPR2022-00994, on October 2, 2023, and the transcript is of record.² Paper 62.

We have jurisdiction pursuant to 35 U.S.C. § 6. This Decision is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of the Challenged Claims. Petitioner bears the burden of proving unpatentability of the Challenged Claims. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2021). Having reviewed the arguments and the supporting evidence, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–14 of the ’024 patent are unpatentable.

B. Related Proceedings

The Parties identify *New York University v. ResMed Inc.*, No. 1:21-cv-00813-JPM (D. Del.), as a related matter. Pet. 1; Paper 4 (Patent Owner’s Mandatory Notices), 2. Petitioner also states that it filed petitions for *inter partes* review challenging claims of several patents related to the ’024 patent in IPR2022-00988, IPR2022-00989, IPR2022-00990, IPR2022-00991, IPR2022-00993, and IPR2022-00994. *See* Pet. 2 (identifying the related patents).

² Each party filed objections to the other party’s demonstrative exhibits and hearing arguments along with responses to those objections. *See* Papers 59, 60, 63–66. Demonstrative exhibits and hearing arguments are not evidence and are not relied on as a basis of this Decision. Accordingly, the objections are denied as moot.

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C. Real Parties in Interest

Petitioner identifies only itself as the real party in interest. Pet. 1.
Patent Owner identifies only itself as the real party in interest. Paper 4, 2.

D. The Asserted Grounds of Unpatentability and Declaration Evidence

Petitioner challenges the patentability of claims 1–14 of the '024 patent on the following grounds:

Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
1–5, 7–14	103(a)	Sullivan995, ⁴ Sullivan460 ⁵
6	103(a)	Sullivan995, Sullivan460, Matthews ⁶
1–5, 7–14	103(a)	Rapoport502, ⁷ Sullivan460
6	103(a)	Rapoport502, Sullivan460, Matthews

Pet. 3–4. Petitioner supports its challenge with a Declaration of Dr. Khosrow Behbehani (Ex. 1003), a Substitute Declaration of Dr. Jason P.

³ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. The '024 patent was filed on October 15, 2019, but asserts priority to several patent applications filed before March 16, 2013. Ex. 1001, codes (22), (63). In this Decision, we assume the asserted priority (which has not been challenged) is correct, so we apply the pre-AIA version of § 103 here.

⁴ U.S. Patent No. 5,245,995, issued Sept. 21, 1993 (Ex. 1005, “Sullivan995”).

⁵ WO 01/05460 A1, published Jan. 25, 2001 (Ex. 1006, “Sullivan460”).

⁶ U.S. Patent No. 7,168,429 B2, filed Oct. 10, 2002, issued Jan. 30, 2007 (Ex. 1007, “Matthews”).

⁷ U.S. Patent No. 5,490,502, issued Feb. 13, 1996 (Ex. 1008, “Rapoport502”).

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Kirkness in support of the Petition⁸ (Ex. 1046), and a Declaration of Dr. Jason P. Kirkness in support of Petitioner's Reply (Ex. 1051). Patent Owner supports its arguments with a Declaration of Dr. James Hamilton Tunstall Bates⁹ (Ex. 2006). Additionally, Petitioner cross-examined Dr. Bates and a two-part transcript of that deposition is of record. Exs. 1052, 1053. And, Patent Owner cross-examined Dr. Kirkness and a two-part transcript of that deposition also is of record. Exs. 2015, 2016.

E. The '024 Patent

The '024 patent is directed to a system and method for diagnosing and treating the breathing pattern of a patient. Ex. 1001, code (54). As background, the '024 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.” *Id.* at 1:29–31. According to the '024 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

⁸ The Petition was originally supported by the Declaration of Dr. Khosrow Behbehani (Ex. 1003). After institution, Petitioner informed the Board that Dr. Behbehani was unable to continue to serve as an expert in this proceeding (Paper 28), and, with our authorization (Paper 31), Petitioner replaced Dr. Behbehani with Dr. Kirkness, who adopted substantially the entirety of Dr. Behbehani's prior opinions. *See* Ex. 1046 ¶¶ 1, 28 (adopting paragraphs 20–28, 32–86, and 90–283 of Dr. Behbehani's Declaration). For consistency with the citations in the Petition, in this Decision we cite to the Declaration of Dr. Behbehani (Ex. 1003) with the understanding that the paragraphs we cite (and opinions expressed therein) were adopted by and, therefore, are attributable to Dr. Kirkness.

⁹ Dr. Bates provided corrections to citations in his declaration via email to Petitioner, which Petitioner then filed as Exhibit 1048.

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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 1:35–42. The '024 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS, and is now the standard of care.” *Id.* at 1:58–61. The '024 patent explains that PAP therapy is applied by a tight-fitting nasal mask worn during sleep (*id.* at 1:58–59), and 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” (*id.* at 2:11–13).

The '024 patent states 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, 1:65–67. 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 2:18–21. The '024 patent also states that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:32–33.

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Figure 1 of the '024 patent is reproduced below.

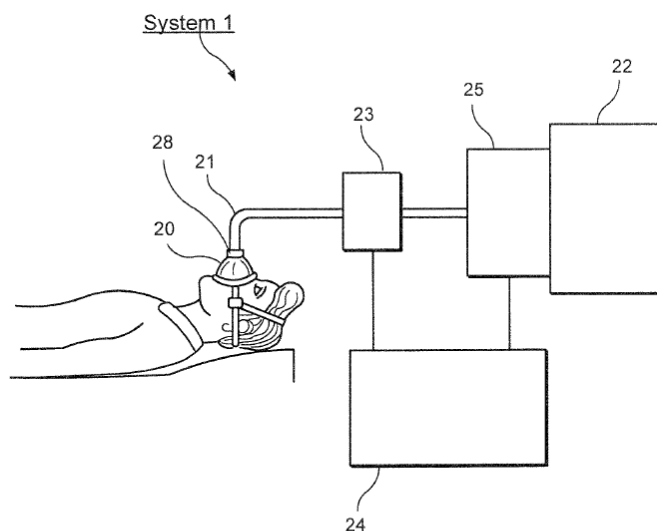


FIG. 1

Figure 1 “shows an exemplary embodiment of a system according to” the '024 patent. Ex. 1001, 3:22–23, 3:52–53. System 1, shown in Figure 1, includes mask 20, placed over the face of the patient, connected via tube 21 to receive airflow of a particular pressure from flow generator 22. *Id.* at 3:53–56. Conventional flow sensors 23 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 3:61–63. The '024 patent states that “[s]ignals corresponding to the airflow and/or the pressure are provided to a processing arrangement 24 for processing” and “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 3:65–4:2.

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Figure 2 of the '024 patent is reproduced below.

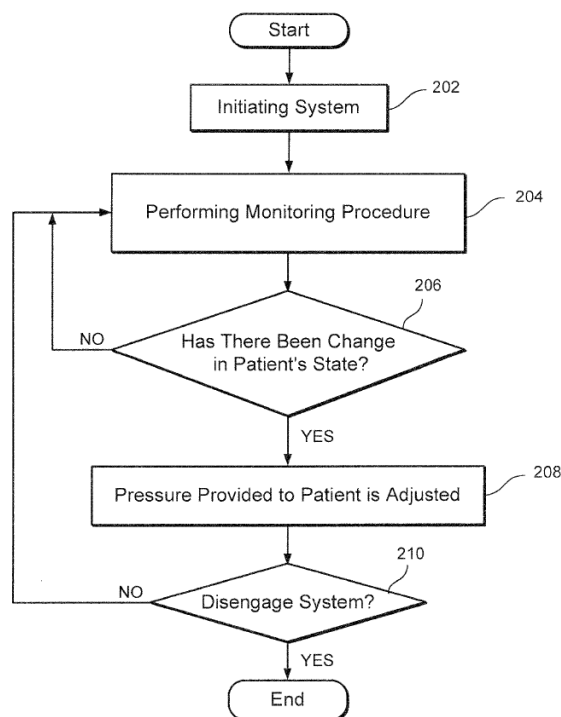


FIG. 2

Figure 2 of the '024 patent “shows an exemplary embodiment of a method . . . which utilizes the system shown in FIG. 1.” Ex. 1001, 3:24–26, 4:13–14. The '024 patent explains the following regarding the method shown in Figure 2. “In step 202, the patient initiates the system 1 by placing the mask 20 over his face and powering up the generator 22, the flow control device 25 and the processing arrangement 24.” *Id.* at 4:13–17. In step 204, “system 1 initiates a real-time monitoring procedure of the patient’s breathing patterns. The 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 4:18–23. The '024 patent teaches that “the processing arrangement 24 makes a

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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 4:24–28. As explained by the ’024 patent, “[s]uch determination can be made based on a number of different measurements. For example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG [electroencephalogram] data, breathing patterns, etc. in the determining the patient’s state.” *Id.* at 4:28–32.

The ’024 patent further explains that, “[i]n step 206, the processing arrangement 24 determines whether there has been a change in the patient’s state.” Ex. 1001, 5:53–54. “For example, the processing arrangement 24 may determine whether the patient was asleep and has been awakened; or the patient was awake and has fallen asleep. If there has been no change, the processing arrangement 24 continues with the monitoring procedures.” *Id.* at 5:54–59. The ’024 patent explains that, “[i]f there has been a change in the patient’s state, the processing arrangement 24 adjusts the pressure to correspond to the patient’s current state (step 208).” *Id.* at 5:60–62. “For example, if the patient has been awakened and the patient’s breathing patterns indicate a period of troubled wakefulness . . . , the processing arrangement 24 may reduce the applied pressure provided to the patient during such period.” *Id.* at 5:62–66. The ’024 patent explains that, “[o]n the other hand, if the patient has fallen asleep, the processing arrangement 24 may instruct the flow control device 25 to elevate the pressure to the level to be applied while the patient is asleep.” *Id.* at 6:9–12. In step 210, “the processing arrangement 24 determines whether instructions to disengage the system 1 have been given,” and, if so, “system 1 shuts down and ends all

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monitoring and flow generating activities. Otherwise, the system 1 continues with the monitoring procedure of step 204.” *Id.* at 6:32–40.

Figure 10 of the '024 patent is reproduced below.

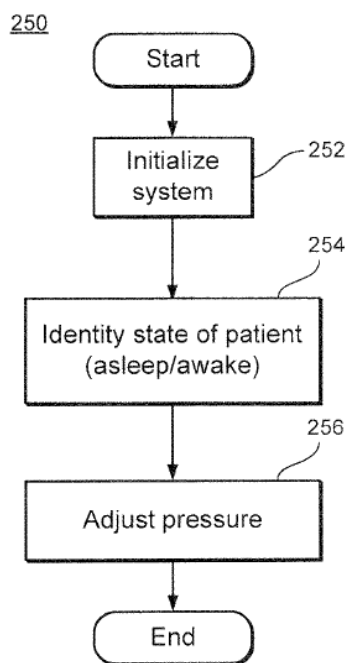


FIG. 10

Figure 10 shows a method identifying a sleep state and a wake state of a patient. Ex. 1001, 3:43–44. The '024 patent explains that, “[i]n a further embodiment . . . , the system 1 may be utilized to detect when the patient is asleep/awake and adjust the pressure based thereon” and method 250 illustrates this embodiment in Figure 10. *Id.* at 7:14–17. In step 252, “system 1 is initialized and coupled to the patient. In step 254, the processing arrangement 24 determines a first state of the patient based on data obtained from the sensors 23 regarding the breathing pattern of the patient.” *Id.* at 7:17–21. The '024 patent explains that, “[i]n this embodiment, the processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern. That

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is, the data may be indicative of a regular breathing state which is generally identified with the sleep state or the wake state.” *Id.* at 7:22–26.

The ’024 patent further explains:

In step 256, the processing arrangement applies supplies [sic] the air pressure as a function of the state. In one embodiment, the CPAP may be applied at a first level for the sleep state and a second level for the wake state. In another embodiment, an automatically adjusting CPAP (“auto-CPAP”) may be applied. In this embodiment, the processing arrangement 24 may adjust the pressure toward the first level when the sleep state is identified, and toward the second level when the wake state is identified. Those of skill in the art will understand that, using this embodiment, a total sleep time of the patient may be determined by the processing arrangement 24 based on identification of the sleep and wake states.

In another embodiment . . . , the system 1 may include a neural network coupled to the processing arrangement 24 and the sensors 23 for identifying the state of the patient. The neural network may obtain data from the sensors 23 and determine the state of the patient based on the data.

Ex. 1001, 7:36–54.

F. Illustrative Claim

Claim 1, the sole independent claim challenged in this proceeding, is illustrative of the claimed subject matter and is reproduced below with Petitioner’s bracketing added for reference (*see* Pet. 78 (Claims App.)):

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] a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient;

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[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

[c] 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, [d] the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, [e] wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state, wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.

Ex. 1001, 9:49–10:12.

G. Level of Ordinary Skill in the Art

Petitioner, supported by Dr. Kirkness's testimony, proposes that a person of ordinary skill in the art at the time of the invention 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." Pet. 16 (citing Ex. 1003 ¶ 87). Petitioner asserts that "[a]dditional experience could substitute for less education, and additional education could likewise substitute for less experience." *Id.* (citing Ex. 1003 ¶ 87).

Patent Owner "does not object to Petitioner's definition of a [person of ordinary skill in the art]," which we adopted preliminarily in our Institution Decision. Inst. Dec. 10.

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Based on the complete record before us, we find (as we did in the Institution Decision) that Petitioner’s uncontested level of ordinary skill in the art is consistent with the level of ordinary skill in the art reflected by the ’024 patent and the prior art of record. *See* Inst. Dec. 10 (citing *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978)). Therefore, we maintain and reaffirm our adoption of Petitioner’s uncontested level of ordinary skill in the art.

II. CLAIM CONSTRUCTION

In this *inter partes* review, claims are construed using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.100(b) (2021). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing claims in accordance with their ordinary and customary meaning, we take into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during

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prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thornerv. Sony Comput. Ent. Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only 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)).

A. “troubled wakefulness”

Petitioner proposes that we construe “troubled wakefulness” to mean a “state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.” Pet. 17 (citing Ex. 1003 ¶ 91). Petitioner contends that “[t]his term is not an industry standard term and was coined in the ’024 Patent.” *Id.* (citing Ex. 1003 ¶ 92). Petitioner explains that the construction of the term “is derived directly from the specification, which describes ‘troubled wakefulness’ as a state ‘in which the breathing pattern is characterized by irregularity [sic] 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.* (quoting Ex. 1001, 4:59–64) (citing Ex. 1001, Fig. 7). Petitioner asserts that “[t]he specification further confirms that [a] ‘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.* (quoting Ex. 1001, 2:40–47).

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Patent Owner agrees with Petitioner's construction, noting that "this term is not in dispute." PO Resp. 29.

We adopt Petitioner's undisputed construction of "troubled wakefulness" because it is supported by and consistent with the Specification's description of the term. *See, e.g.*, Ex. 1001, 4:59–64.

B. "analyzes the data to determine the patient's breathing patterns"

Claim 1 recites, *inter alia*, "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." Ex. 1001, 9:63–10:2. In the Petition, Petitioner did not expressly construe this phrase, but did analyze and address the prior art to identify the teachings of the prior art that Petitioner contends teach this limitation of the claim. *See, e.g.*, Pet. 28–31 (discussing element 1[c]). Patent Owner first proposes this phrase for construction in its Patent Owner Response. PO Resp. 30–32.

In the Patent Owner Response, Patent Owner argues that "analyzes the data to determine the patient's breathing patterns" means "determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time." PO Resp. 30. As borne out through Patent Owner's arguments in response to Petitioner's challenges and as further elaborated in Patent Owner's Sur-reply, Patent Owner contends that "analyzes the data to determine the patient's breathing patterns" requires analysis of "both the amplitude structure and the temporal structure." PO Resp. 36–38; Sur-reply 4–5.

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Petitioner disputes this proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2; *see id.* at 2–11. For the reasons that follow, we agree with Petitioner.

1. The Parties' Contentions

To explain why the claim phrase should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the [S]pecification” of the ’024 patent. PO Resp. 30 (citing Ex. 1001, 4:44–51; Ex. 2006 ¶ 136); *see also* Sur-reply 13 (citing Ex. 1052, 108:25–109:1–7) (arguing that according to Dr. Bates “‘breathing patterns’ has no ordinary meaning and ‘is an extremely general term’”). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apnea and hypopnea in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters and the order in which they appear in time.” *Id.* at 30–31 (citing Ex. 2006 ¶ 137).

Patent Owner points to the description of Figures 7 and 8 of the ’024 patent in support of its construction. *Id.* at 31–32 (citing Ex. 1001, 4:59–66, 5:23–39; Ex. 2006 ¶¶ 138–140). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient’s airflow, but no periodic irregularity in breath size. Ex. 1001, 4:59–66. Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. *Id.* at 5:23–39.

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According to Patent Owner, “[t]his methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns” and focuses “on a determination of ‘the sequence of parameters of a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time.’” PO Resp. 31 (citing Ex. 2006 ¶ 139); *see also* Sur-reply 4 (citing Ex. 1001, 4:59–66; Ex. 2006 ¶ 136) (asserting that “[b]oth amplitude and temporal structures are likewise described when examining specific flow waveforms”). Patent Owner further argues that the description of Figure 8 in the Specification “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 31–32 (citing Ex. 1001, 5:23–39; Ex. 2006 ¶ 140); *see* Sur-reply 5–12.

Additionally, Patent Owner suggests the Specification’s discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. *Id.* at 32 (citing Ex. 1001, 6:41–48; Ex. 2006 ¶ 141).

Turning to the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’024 Patent.” PO Sur-reply 3; *see also id.* at 9–14 (arguing that distinguishing troubled wakefulness from REM sleep requires assessing both amplitude and temporal structure). First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea

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and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” PO Sur-reply 3–4 (quoting Ex. 1001, 4:44–51) (citing Ex. 2006 ¶ 134). Patent Owner maintains that the descriptions of the waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of waveforms. *Id.* at 4–7 (citing Ex. 1001, 4:59–66, 5:30–39, 6:41–48; Ex. 1052, 81:17–23, 180:1–15; Ex. 2006 ¶ 138). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’024 Patent,” but contends that “these are not obligatory.” *Id.* at 5. Patent Owner asserts that enablement of the ’024 patent “hinges on its ability to distinguish between all awake and asleep states,” and “[i]f not achieved, incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 6.

Second, Patent Owner asserts that during the prosecution of a related patent, the applicant responded to a rejection by arguing that the prior art, in that instance, “failed to discern between regular wakefulness and troubled wakefulness.” Sur-reply 6–7 (citing Ex. 1009, 404). Patent Owner argues that it is necessary to integrate “both amplitude and temporal structure analyses to distinguish all awake and asleep states.” *Id.* at 7.

Third, Patent Owner argues that “a patentee does not need to rigidly define terms, but can imply their own meaning.” Sur-reply 7. Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by Figure 7 – a flow waveform indicating troubled wakefulness.” *Id.* (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the Specification “provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “[s]ince ‘analyses the data’ is followed by ‘to

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determine the patient's breathing patterns,' some of which occur in the asleep state and some of which occur in the awake state, this further implies that these states can be separated from one another." *Id.* (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22). Patent Owner contends that, "[g]iven the separation between awake and asleep states discussed in the '024 Patent, [Patent Owner's] construction is integral for discerning the difference and applying the correct pressure" because without doing so, it "could result in inappropriate pressure administration." *Id.* at 7–8 (citing Ex. 1052, 179:23–25; Ex. 2006 ¶ 139).

Patent Owner also argues that extrinsic evidence supports its proposed construction. Sur-reply 8–13. Based on Dr. Bates's testimony, Patent Owner asserts that "by assessing *only amplitude*" the waveforms of troubled wakefulness and REM sleep "appear indistinguishable," but "their temporal structure (order in time) . . . offers differentiation." *Id.* at 9–10 (citing Ex. 2006 ¶ 70). Patent Owner asserts that its argument is correct, alleging that if the "temporal structure" of the REM sleep waveform is "rearranged in time," the resulting "time series has a random appearance that *cannot be distinguished* from troubled wakefulness." *Id.* at 10 (citing Ex. 2006 ¶ 71). Patent Owner reasons that "amplitude structure and temporal structure convey independent information" and both must be considered in an analysis or "the awake state can be confused with an asleep state, leading to application of the wrong CPAP pressure." *Id.* at 11 (citing Ex. 2006 ¶ 64). According to Patent Owner, it is "Dr. Bates' illustrations [that] clearly present the problem solved by the '024 Patent." *Id.*

According to Patent Owner, construing "analyzing breathing patterns" to include "any type" of breathing pattern analysis, as suggested by

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Dr. Kirkness, is “impractical, as it might even encompass using a mirror to check for breaths.” *Id.* at 13 (citing Ex. 1051 ¶ 16).¹⁰

Specifically, Patent Owner argues

Dr. Bates examined the specification to determine what characteristics of breathing were crucial to analyzing the breathing pattern with respect to the invention’s essence. [Ex. 1052], 24:20-25, 25:1-13. He determined that a [person of ordinary skill in the art], after reading the ’994¹¹ [sic] patent, would understand that analyzing breathing patterns, with respect to the ’024 Patent, needs to confer the ability to distinguish between troubled wakefulness and REM sleep. *Id.*, 111:22-25 – 112:1-21. In contrast to the broad construction proposed by Petitioner, [Patent Owner’s] construction evidences the understanding of a [person of ordinary skill in the art] – that analyzing breathing patter[n]s requires analysis of amplitude and temporal structures.

Sur-reply 13–14¹² (footnote added).

¹⁰ Patent Owner also states that “Dr. Kirkness argues that the ’024 Patent is indefinite, especially regarding the measurement of airflow waveforms and temporal/amplitude aspects” and that “Petitioner has never directly raised indefiniteness.” Sur-reply 12. We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths.”

¹¹ U.S. Patent No. 6,988,994 B2 (“the ’994 patent”) is related to the ’024 patent (Ex. 1001, code (63)) and is challenged by Petitioner in related proceeding IPR2022-00993.

¹² In some instances where Patent Owner cites to testimony that carries over to a second page of a transcript, Patent Owner uses a format such as “111:22-25 – 112:1-21.” *See* Sur-reply 13–14 (block quote above). We understand Patent Owner to mean the entire range from 111:22–112:21. In the future, we suggest Patent Owner use the conventional citation form covering the full range to avoid potential confusion.

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Petitioner proposes that we construe the phrase in accordance with its plain and ordinary meaning because “[n]othing in the intrinsic record limits the ‘analyzing the breathing patterns’ term to analysis of either or both amplitude and temporal structures—instead, the claims, specification, and prosecution history use this term in accordance with its plain meaning.” Pet. Reply 3–4 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Petitioner asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the specification or during prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” *Id.* at 6 (quoting *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, ‘the patentee must clearly express an intent to redefine the term.’” *Id.* at 6–7 (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends “[n]o such intent exists here” and Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* at 7 (citing Ex. 1051 ¶ 24).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner’s] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as “propos[ing] a lengthy construction and then constru[ing] its own construction to inject two requirements: that the processor must analyze (1) ‘the value[s] of the parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.*

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(third alteration in original) (citing PO Resp. 9–11, 30–31; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record, or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert decided based on his personal experience, as opposed to that of a” person of ordinary skill in the art. *Id.* (citing Ex. 1053, 271:10–14).

Responding to Patent Owner’s citations to the Specification, Petitioner contends that the Specification “further confirms that the terms encompass any type of breathing pattern analysis” and “states that ‘[t]here are a number of characteristics of the patient’s breathing patterns that may be taken into account in making such a determination’ . . . and does not limit the analysis to any particular characteristic such as amplitude and temporal structures.” Pet. Reply 4–5 (first alteration in original) (citing Ex. 1001, 2:40–43, 4:18–32, 4:32–35, Figs. 3–8; Ex. 1051 ¶¶ 16–24; Ex. 1052, 28:4–30:21; Ex. 2006 ¶¶ 46–47). Petitioner also contends that “[t]he specification further states that the flow sensors ‘detect the rate of airflow’ to and from the patient, and provide ‘[s]ignals corresponding to the airflow’ to a processing arrangement for processing.” *Id.* at 5 (second alteration in original) (citing Ex. 1001, 3:60–66). Thus, Petitioner asserts the Specification “confirms that temporal analysis is not required.” *Id.*

Petitioner also addresses the prosecution history of patents related to the ’024 patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5. Petitioner asserts that, in responding to different office actions, the applicant did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1009, 404; Ex. 1054, 91, 128).

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Next, Petitioner contends Patent Owner’s extrinsic evidence, in the form of Dr. Bates’s testimony, contradicts the intrinsic record and should be disregarded. Pet. Reply 7–11. Petitioner asserts Dr. Bates “performed a ‘crude’ analysis by ‘approximating’ the amplitudes of each breath in the figures ‘estimat[ing] by eye . . . the size of those individual breaths.’” *Id.* at 7 (first alteration in original) (citing Ex. 1052, 75:11–76:14, 78:16–79:19). Petitioner argues that Dr. Bates’s “analysis has no basis in the patent.” *Id.* Petitioner presents five arguments in rebuttal to the testimony of Dr. Bates:

(1) Dr. Bates’s analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the ’024 patent would have derived [Patent Owner’s] construction.” *Id.* (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* at 7–8 (citing Ex. 1052, 75:11–76:14; 78:16–79:19; 90:8–91:11).

(2) Dr. Bates’s analysis is based on his own expertise in “digital signal processing,” not from the viewpoint of a person of ordinary skill in the art who would not necessarily have such experience. *Id.* at 8 (citing Ex. 1052, 25:3–27:6, 52:2–25, 64:4, 208:16–21; Ex. 1053, 240:8–242:8; 243:3–8).

(3) Dr. Bates’s analysis contradicts the ’024 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM sleep without requiring temporal analysis. *Id.* at 8–9 (citing Ex. 1001, 4:52–59; 5:32–36; Ex. 1056, 9:55–10:3 (claim 5), 10:20–24 (claim 8); Ex. 1051 ¶¶ 25–33).

(4) “Dr. Bates admitted Figures 7–8 are merely exemplary.” *Id.* at 9 (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do

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not limit the broader claim terms of the patent.” *Id.* (citing *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004)).

(5) Dr. Bates “could not explain ‘parameter’ or provide an objective basis to define a ‘sequence’ and ‘series’ used in [Patent Owner’s] construction” and “admitted that [Patent Owner’s] construction would exclude breathing patterns recited in dependent claims.” *Id.* at 10 (citing Ex. 1052, 182:1–184:19, 247:5–11; Ex. 1053, 288:14–289:3). Thus, Petitioner asserts we “should discount [] expert testimony that is clearly at odds . . . with the written record of the patent.” *Id.* (first alteration in original) (quoting *Phillips*, 415 F.3d at 1318).

2. Analysis

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14. Claim 1 recites, *inter alia*, “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.*” Ex. 1001, 9:63–10:2 (emphasis added). As reflected, claim 1 does not recite “a sequence of parameters” or “a series of breaths” or “examining the values of the parameters and the order in which they appear in time” or any analysis of amplitude or temporal structure. Rather, this portion of claim 1 recites that the processor analyzes the data, without specifically reciting how the analysis is performed. The claim phrase does, however, recite the purpose of the analysis—to determine the patient’s breathing patterns—but does not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a

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significant number of limitations neither expressly recited nor suggested by the specific language of the phrase.

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citation omitted). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech. LLC v. Iancu*, 923 F. 3d 1032, 1044 (Fed. Cir. 2019).

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of the disputed phrase, nor does Patent Owner argue that it explicitly defined the phrase in the Specification. PO Resp. 30–32. We agree that there is no disavowal nor any explicit lexicographic definition of “analyzes the data to determine the patient’s breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we should construe the phrase as Patent Owner proposes. PO Sur-reply 3, 7–8 (citing, *inter alia*, *AstraZeneca AB v. Mut. Pharm. Co., Inc.*, 384 F.3d 1333 (Fed. Cir. 2004)). We disagree.

In *AstraZeneca AB*, the United States Court of Appeals for the Federal Circuit reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d 1333,

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1339–40 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors “deliberately acted as their own lexicographers” to limit the claim term “solubilizer” to surfactants, the Federal Circuit explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The Federal Circuit rejected AstraZeneca’s argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

The Specification of the ’024 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to “a sequence of parameters” (PO Resp. 30) or an analysis of “both the amplitude structure and the temporal structure of a breath-by-breath parameter time series” (*id.* at 37) or any of the other terms set forth in the proposed construction. See *id.* at 30–32. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. See Pet. Reply 7 (“[T]he terms ‘amplitude’ and ‘temporal’ do not appear

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anywhere.”); Sur-reply 5 (“Petitioner rightly observes that terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’024 Patent.”); *see also* Ex. 1051 ¶ 24 (Dr. Kirkness stating that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’024 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures”). Patent Owner directs us to a portion of the Specification that Patent Owner characterizes as the process of analyzing breathing patterns. PO Resp. 30 (quoting Ex. 1001, 4:44–51). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” *Id.* (citing Ex. 1001, 4:44–51; Ex. 2006 ¶ 136). The cited text does not describe analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how “processing arrangement 24 makes a determination as to the 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).” Ex. 1001, 4:24–28. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns, etc. in determining the patient’s state.” *Id.* at 4:28–32. There is no mention that analyzing the data to determine breathing patterns requires analysis of a sequence of parameters and the order in which they appear in time or an analysis of amplitude and temporal aspects of the

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waveform. The Specification further describes, in an embodiment, “processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern.” *Id.* at 7:22–24. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal aspects of the waveform.

Patent Owner relies on Figures 7 and 8 to support its argument that analysis of “both the amplitude structure and the temporal structure of a breath-by-breath parameter time series” is required to distinguish between an awake state and a sleep state, including troubled wakefulness and REM sleep. PO Resp. 37; Sur-reply 8–9 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Figures 7 and 8, however, depict one particular example of an awake state (i.e., troubled wakefulness) and one particular example of a sleep state (i.e., REM sleep), respectively. Ex. 1001, 3:37–41. But Patent Owner’s analysis does not address Figures 3–6 of the ’024 patent. PO Resp. 30–32; Sur-reply 3–16. Figures 3 and 4 show waveforms of a patient during “regular wakefulness” and “regular sleep,” respectively. *Id.* at 3:27–31. Figures 5 and 6 show waveforms from a sleeping patient indicative of “hypopnea” and “repetitive obstructive apnea,” respectively. *Id.* at 3:32–36. Patent Owner provides no evidence or explanation why amplitude and temporal aspects of a waveform are required to distinguish regular wakefulness from regular sleep or hypopnea or repetitive obstructive apnea.¹³

¹³ Patent Owner points to an argument during prosecution of a related patent contending it supports Patent Owner’s claim construction. Sur-reply 6–7. That argument stated that the prior art reference “does not teach or suggest a

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Claim 1 also recites

the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state, wherein the delay lasts at least until the processor determines that the patient is in an asleep state.

Ex. 1001, 10:2–12. As reflected by the express claim language, claim 1 is *not* limited to distinguishing *solely* between troubled wakefulness and REM sleep, but rather encompasses other states, such as those shown in Figures 3–6. Thus, even if we were to agree with Patent Owner that an analysis of one or both of the amplitude and temporal structures of a waveform is required to distinguish between troubled wakefulness and REM sleep, that determination, alone, is insufficient to narrow the scope of claim 1, which by their own terms are broad enough to include specific types of awake or sleep states other than troubled wakefulness and REM sleep.

For the same reasons, we are not persuaded that the additional limitations Patent Owner seeks to read into the claims are necessary to “fully enable” the claims, as Patent Owner asserts.

processing arrangement that distinguishes between regular wakefulness and troubled wakefulness,” but it did not refer to anything even close to resembling the construction proposed by Patent Owner or the concepts of amplitude and temporal structures. Ex. 1009, 404. Thus, this portion of the prosecution history of a related patent does not support Patent Owner’s position here.

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Having reviewed the intrinsic evidence, we next consider the extrinsic evidence, and specifically the testimony of Dr. Bates.¹⁴ Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 30–32 (citing Ex. 1001, 4:44–51, 4:59–66, 5:23–39, 6:41–48; Ex. 2006 ¶¶ 136–141¹⁵). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. *See* Ex. 2006 ¶¶ 136–141.¹⁶ Rather, Dr. Bates reads portions of the Specification and extrapolates (by taking several unsupported leaps) that the ’024 patent “implicitly demands certain parameter measurements.” Sur-reply 7 (citing Ex. 1052, 44:6–20).

Although expert testimony is legitimate to consider when construing claims, the Federal Circuit has cautioned that because it “is generated at the time of and for the purpose of litigation,” it “can suffer from bias that is not present in intrinsic evidence.” *Phillips*, 415 F.3d at 1318. And, extrinsic evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* at 1317 (internal quotations and citations omitted). In the context presented here, Dr. Bates’s testimony is not supported sufficiently by the intrinsic record or other

¹⁴ Although the Parties briefly address the prosecution history of patents related to the ’024 patent, we do not find the discussion thereof informative on this issue.

¹⁵ It appears that Patent Owner intended to cite paragraphs 133–139 of Dr. Bates’s declaration.

¹⁶ Again, it appears that Patent Owner intended to cite paragraphs 133–139 of Dr. Bates’s declaration.

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extrinsic evidence (e.g., objective extrinsic evidence) and, therefore, even though we have considered it fully, we give it little weight.

For the reasons explained above, we determine that Patent Owner did not implicitly define the phrase “analyzes the data to determine the patient’s breathing patterns,” as proposed, because Patent Owner has failed to show any sufficient evidence that the ’024 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner’s contentions in light of all the evidence of record, we do not adopt Patent Owner’s proposed construction; instead, we apply the plain and ordinary meaning of “analyzes the data to determine the patient’s breathing patterns” in our consideration of the issues before us.

C. *Other Claim Terms*

The Parties do not dispute the construction of any other claim terms, and we find that no other terms require express construction to resolve the controversy between the Parties. Accordingly, we do not construe any other claim terms expressly. *See Realtime Data*, 912 F.3d at 1375 (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs.*, 200 F.3d at 803)).

III. ANALYSIS

A. *Legal Standards – Obviousness*

The United States Supreme Court set forth the framework for applying the statutory language of 35 U.S.C. § 103 in *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966):

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Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

The Supreme Court explained in *KSR International Co. v. Teleflex Inc.* that

[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (alteration in original))).

“Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1327 (Fed. Cir. 2016) (citations omitted). “[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan ‘would have had a reasonable expectation of success from doing so.’” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting

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In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

B. Ground 1: Obviousness over Sullivan995 and Sullivan460

Petitioner asserts that the combination of Sullivan995 and Sullivan460 would have rendered the subject matter of claims 1–5 and 7–14 obvious to one of ordinary skill in the art at the time of the invention. Pet. 18–52. Patent Owner opposes. PO Resp. 34–45.

1. Scope and Content of the Prior Art

a. 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. Figure 1A of Sullivan995 depicts snoring detection device 10 and is reproduced below. *Id.* at 8:47.

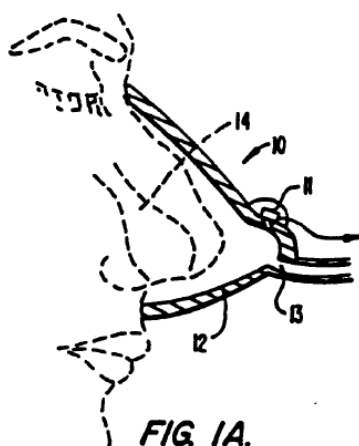


Figure 1A “is a schematic sectional view of one embodiment of a snoring detection apparatus.” *Id.* at 7:66–68. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a

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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 example, 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.

Figure 3 of Sullivan995 is reproduced below.

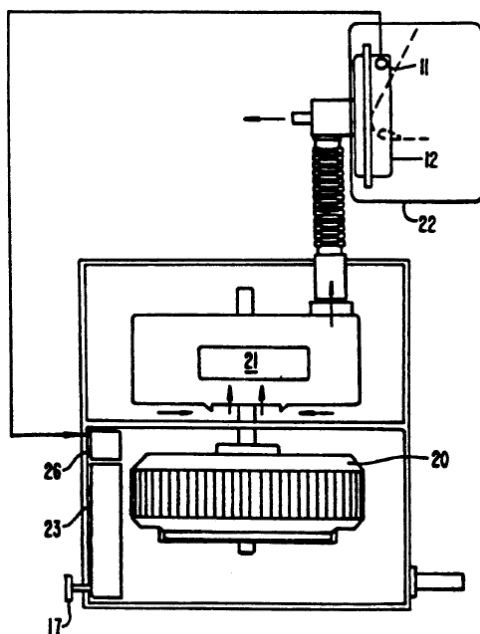


FIG. 3

Figure 3 shows a CPAP apparatus. Ex. 1005, 9:57–58. The CPAP apparatus includes motor 20 that drives blower 21. *Id.* at 9:58–59.

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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 9:66–10:3. Sullivan995 explains,

[e]lectrical 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, at 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 device 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.

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Figure 12 of Sullivan995 is reproduced below.

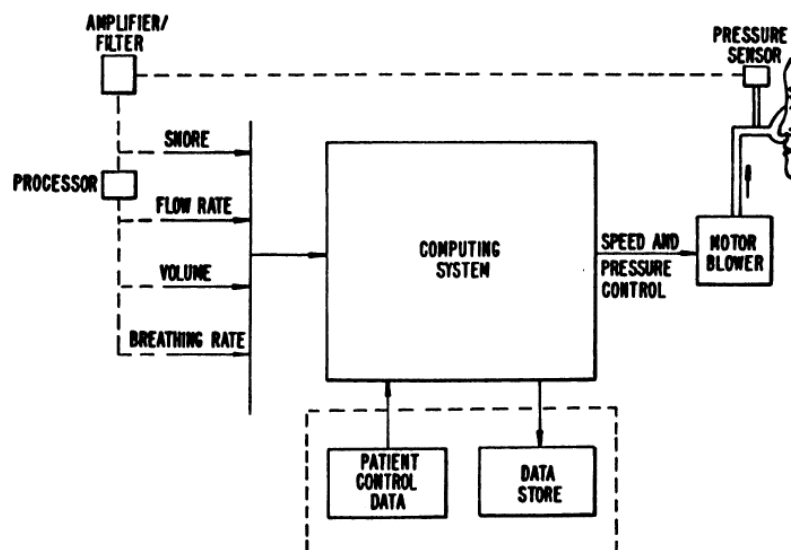


FIG. 12.

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

b. Sullivan460 (Ex. 1006)

Sullivan460 is directed to “an apparatus and method for the treatment of an upper airway flow limitation in a patient” and particularly “an

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apparatus and method of treating hypertension caused by pre-eclampsia.”

Ex. 1006, 1:5–8.¹⁷ Sullivan460 describes an embodiment in which its “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 [Sullivan995].”¹⁸ *Id.* at 6:22–24.

Sullivan460 describes two modes of delivery for the treatment means:

the 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 also 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

¹⁷ For consistency with the citation style of the Parties, citations to Sullivan460 are to the native page numbers of the document, and not the page numbers added by Petitioner in the bottom, right hand corner of each page of Exhibit 1006.

¹⁸ Sullivan460 incorporates Sullivan995 by reference. Ex. 1006, 6:24–25.

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explains that “[t]his feature is an improvement over the prior art because as soon as the patient goes to sleep (as determined by an appropriate sensing algorithm in the treatment means), the second treatment mode is activated.” *Id.* at 7:10–12.

Figure 2 of Sullivan460 is reproduced below.

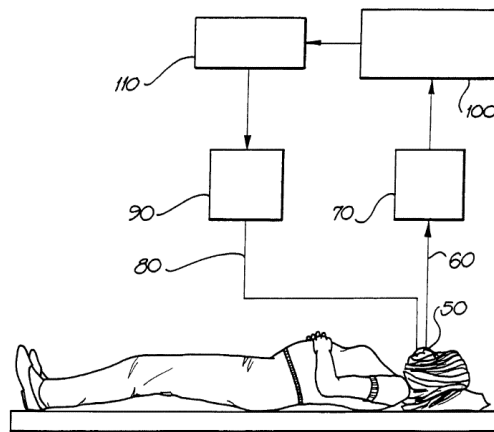


FIG. 2

“Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia.” Ex. 1006, 10:7–8. 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 10:9–10. 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 10:10–12. 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.

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2. *Differences Between the Prior Art and the Claims*

Petitioner sets forth a detailed analysis showing how the combined teachings of the references meet the elements of claims 1–5 and 7–14. Pet. 21–52. In particular, regarding claim 1, Petitioner relies on Sullivan995 as teaching most of the elements of the claim, but relies, in part, on Sullivan460 for elements 1[e] and 1[f]. *See id.*; *see also id.* at 33–37 (addressing elements 1[e] and 1[f]). Additionally, Petitioner contends that it would have been obvious to one of ordinary skill in the art to combine the teachings of Sullivan995 and Sullivan460 with a reasonable expectation of success. *Id.* at 18–21. Patent Owner challenges Petitioner’s analysis of several limitations of the claims, as well as Petitioner’s arguments regarding motivation to combine and reasonable expectation of success.¹⁹ PO Resp. 34–43. Patent Owner also contends objective indicia of nonobviousness support its position that the claimed invention would not have been obvious. *Id.* at 43–45. We address each argument below.

a. *Claim 1*

i. *Preamble*

The preamble of claim 1 recites “[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.” Ex. 1001, 9:49–54. Petitioner

¹⁹ Patent Owner contends “the missing claim limitations [for claim 1] are highlighted in red” (PO Resp. 35–36), but there is no highlighting in Patent Owner’s Response. Nonetheless, we address each of Patent Owner’s arguments below.

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contends, “[t]o the extent the preamble is limiting, Sullivan995 discloses this limitation.” Pet. 21 (citing Ex. 1003 ¶¶ 104–106). Petitioner asserts “Sullivan995 discloses a CPAP system (*a positive airway pressure system*) which ‘deliver[s] appropriate airway pressure’ to the patient’s airway passages (*for delivery of a flow of breathable gas*).” *Id.* (alteration in original) (citing Ex. 1005, Fig. 3, code (57), 1:33–36, 2:15–19, 9:57–58). Petitioner contends one of ordinary skill in the art would have understood “CPAP delivers ‘positive’ airway pressure relative to atmospheric pressure (*a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure*).” *Id.* at 22 (citing Ex. 1003 ¶ 104).

Petitioner asserts Sullivan995’s CPAP system includes “nose mask 12” that is “‘fluidly sealable to the [patient’s] nasal air passages’ and is ‘for delivery of air to the patient’s nasal passages’ (*a flow of breathable gas . . . delivered to an entrance of a patient’s airways*).” Pet. 22 (alterations in original) (citing Ex. 1005, claim 6, 5:12–34, 10:67–11:4, 11:23–43). Petitioner contends “[t]his is *in order to assist in treating a sleeping disorder in a patient* by providing air pressure at a certain level to ‘prevent the onset of apnea’ (*sleeping disorder*) in the patient.” *Id.* (citing Ex. 1005, 1:20–31, 1:32–48, 10:31–35, 11:15–20; Ex. 1003 ¶ 106).

Patent Owner does not challenge Petitioner’s analysis and evidence showing that the preamble of claim 1 is met by Sullivan995. *See generally* PO Resp.

We find Petitioner’s arguments persuasive as to the preamble of claim 1 and supported on the complete record before us, and, therefore, we

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adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that Sullivan995 teaches the preamble of claim 1.²⁰

ii. Element 1[a]

Element 1[a] recites “a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient.” Ex. 1001, 9:55–57. Petitioner contends Sullivan995 discloses element 1[a]. Pet. 22 (citing Ex. 1003 ¶¶ 107–108). Petitioner asserts “Sullivan995’s CPAP system includes a variable speed motor 20 that drives a blower 21 (*flow generator*).” *Id.* (citing Ex. 1005, 9:57–64). Petitioner contends “blower 21 *supplies a positive treatment pressure flow of breathable gases to be supplied to a patient* by providing pressurized air to the patient.” *Id.* (citing Ex. 1005, 9:60–64; Ex. 1003 ¶¶ 107–108).

Patent Owner does not challenge Petitioner’s analysis and evidence showing that element 1[a] is met by Sullivan995. *See generally* PO Resp.

We find Petitioner’s arguments persuasive as to element 1[a] of claim 1 and supported on the complete record before us, and, therefore, we adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that Sullivan995 teaches element 1[a].

iii. Element 1[b]

Element 1[b] recites “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.” Ex. 1001, 9:58–

²⁰ We need not determine whether the preamble of claim 1 is limiting because we find, on the present record, that Petitioner has shown it is taught by Sullivan995.

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62. Petitioner contends Sullivan995 discloses element 1[b]. Pet. 23 (citing Ex. 1003 ¶¶ 109–120). Petitioner asserts “Sullivan995’s CPAP system includes a differential pressure sensor, e.g., microphone 11 (*flow sensor*),” and that “[t]he microphone ‘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.* (quoting Ex. 1005, 3:21–30, code (57)). Petitioner contends Sullivan995 teaches that detection means 22, including microphone 11, can be located in different places, including “*in a flow path of the positive treatment pressure flow of breathable gases*” (e.g., in a nose mask or located within or attached to a nasal prong device). *Id.* at 24–25 (citing Ex. 1005, Figs. 1A, 1B, 2A, 2B, 8:47–61, 10:1–3; Ex. 1003 ¶¶ 110, 111, 113, 114).

Petitioner asserts “microphone 11 (*flow sensor*) performs a ‘form of measurement’ (*measuring data*) by ‘detecting snoring sounds’ and ‘other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate’ (*indicative of the patient’s breathing patterns*).” Pet. 26 (citing Ex. 1005, 3:21–30, 11:5–20, 15:56–64; Ex. 1003 ¶ 114).

Patent Owner does not challenge Petitioner’s analysis and evidence showing that element 1[b] is met by Sullivan995. *See generally* PO Resp.

We find Petitioner’s arguments persuasive as to element 1[b] of claim 1 and supported on the complete record before us, and, therefore, we adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that Sullivan995 teaches element 1[b].

iv. *Elements 1[c]–[f]*

We address these elements together because Patent Owner’s arguments appear to touch on different aspects of these elements.

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a) The Petition

Element 1[c] recites “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.” Ex. 1001, 9:63–10:2. Petitioner contends Sullivan995 discloses element 1[c]. Pet. 28 (citing Ex. 1003 ¶¶ 121–126). Petitioner asserts “[t]he combination of an amplifier/filter/processor unit 26 and speed control unit 23 (depicted in Figure 3 and described in part as the computing system in Figure 12) is *a processing arrangement*.” *Id.* Petitioner contends “microphone 11 (*flow sensor*) provides its *measured data* to processor unit 26.” *Id.* (citing Ex. 1005, 10:3–6, 10:37–66, 11:55–62). Thus, Petitioner argues “processor unit 26 is part of a *processing arrangement that receives the measured data corresponding to the flow of breathable gases from the flow sensor*.” *Id.* at 29.

Additionally, Petitioner asserts “Sullivan995 describes various *breathing patterns* for the patient.” Pet. 30. Pointing to Figure 4, Petitioner contends “Sullivan995’s *processing arrangement* includes the processor unit 26, ‘which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.’” *Id.* (citing Ex. 1005, 11:55–62). Thus, Petitioner argues that, “[i]n generating this control signal, the processor unit 26 (included in the *processing arrangement*) therefore *analyzes the data [from the flow sensor] to determine the patient’s breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.” *Id.*

Further, Petitioner points to Sullivan995’s computing system, which includes processing unit 26 and speed controller 23, contending the

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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. 30–31 (quoting Ex. 1005, 12:67–13:8 (referencing Fig. 12)). Thus, Petitioner asserts Sullivan995’s “computing system is part of the *processing arrangement* and *analyzes the data [from the flow sensor] to determine the patient’s breathing patterns.*” *Id.* at 31.

Element 1[d] recites “the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part on the determined breathing patterns of the patient.” Ex. 1001, 10:2–6. Petitioner contends Sullivan995 discloses element 1[d]. Pet. 31 (citing Ex. 1003 ¶ 127). Petitioner asserts that, as explained for elements 1[b] and 1[c], “Sullivan995 describes various *breathing patterns* for the patient.” *Id.* Petitioner points to Figure 4 contending “Sullivan995’s *processing arrangement* includes the processor unit 26, ‘which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.’” *Id.* (citing Ex. 1005, 11:55–62). Petitioner asserts that, “[i]n generating this control signal, the processor unit 26 (included in the *processing arrangement*) therefore *analyzes the data [from the flow sensor] to determine the patient’s breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.” *Id.*

Additionally, Petitioner points to Figure 12 contending “the computing system (including processing unit 26 and speed controller 23) ‘analyses and records signals from the pressure sensor,’ and analyzes ‘the sound and breathing patterns’ to record ‘indexes such as the number of

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apneic episodes, the number of hypopneas, their duration, etc.” Pet. 31 (citing Ex. 1005, 12:67–13:8). Petitioner asserts that, “[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’ (*flow generator*).” *Id.* at 32 (second alteration in original) (citing Ex. 1005, 9:58–64, 10:6–12, 10:40–46). Petitioner contends the “motor speed control means in Sullivan995 is the same as the speed control unit 23 because it controls the speed of the motor and is therefore part of the *processing arrangement*.” *Id.* (citing Ex. 1005, 9:58–64; Ex. 1003 ¶ 128). Petitioner argues “[s]imilarly, ‘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.* (second alteration in original) (citing Ex. 1005, 10:37–46; Ex. 1003 ¶ 128). Petitioner asserts “[i]ncreasing or decreasing the blower speed results i[n] an *alter[ing] [of] the pressure supplied by the blower (flow generator) to the airway of the patient* and is based on ‘when snoring sounds occur.’” *Id.* (citing Ex. 1003 ¶¶ 128–129).

In sum, Petitioner asserts “[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 made *based, at least in part, on the determined breathing patterns of the patient*.” Pet. 32–33 (second alteration in original) (citing Ex. 1005, 10:55–58). Thus, Petitioner argues that

by describing the speed control unit using the signal from the processor unit 26 to determine whether to increase or decrease the pressure, Sullivan995 describes a *processing arrangement*

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that determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part on the determined breathing patterns of the patient.

Id. at 33 (citing Pet. §§ VIII.C.3 (addressing element 1[b]), VIII.C.4 (addressing element 1[c])).

Element 1[e] recites “wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state.”

Ex. 1001, 10:6–10. Petitioner contends “Sullivan995 renders this limitation obvious either alone or in view of Sullivan460.” Pet. 33 (citing Ex. 1003

¶ 140). Petitioner asserts the following

Sullivan995 discloses *the processing arrangement automatically delays the onset of a pressure increase to the patient* until a snore is detected, meaning the patient has fallen asleep. Specifically, “the output pressure of the CPAP unit increases in response to detection of snoring.” EX1005, 10:10-12, Fig. 3; *see also* 14:17-20, Fig. 13. Also, the pressure is decreased “if an extended period of snore free breathing occurs” by “automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected.” *Id.*, 10:31-47; *see also* Fig. 13. Put simply, because the pressure is reduced automatically in the absence of snoring and is increased in response to snore detection, *the processing arrangement automatically delays the onset of a patient increase to the patient* until snoring is detected. *See also id.* 10:47-61 (it is only “some time after going to sleep [when] the patient’s body relaxes, [and] the airway start[s] to become unstable and the patient start[s] to snore,” and the CPAP pressure increases “via the processor 26,” in response to the “snore, or snore pattern.”).

Pet. 33–34 (alterations in original). Petitioner acknowledges that,

“[a]lthough the patient is awake when he ‘connects himself to the CPAP unit’ when ‘[t]he CPAP pressure is initially at a minimum operating value’ (*id.*, 10:47-58), Sullivan995 does not explicitly disclose that the delay occurs

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when the processing arrangement determines that the patient is in an awake state.” *Id.* at 34 (citing Ex. 1003 ¶ 144). Nonetheless, Petitioner asserts “this limitation would have been obvious from Sullivan995 in view of Sullivan460.” *Id.* (citing Ex. 1003 ¶ 144).

Turning to Sullivan460, Petitioner explains “Sullivan460 incorporates Sullivan995 by reference and refers to Sullivan995 as describing a ‘flow rate measurement means and [a] treatment means [as being] constructed together as part of one apparatus.’” Pet. 34 (citing Ex. 1006, 6:22–29). Petitioner asserts that, “[l]ike Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep.” *Id.* (citing Ex. 1006, 6:17–29, 7:3–12, 10:9–33, 11:10–12, claims 22–28, 43–46, Figs. 2–4; Ex. 1003 ¶ 145).

Petitioner contends the following regarding Sullivan460:

Sullivan460 discloses *determin[ing] that the patient is in an awake 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.” EX1006, 7:3-7, 7:10-12, 7:17-19; [Ex. 1003] ¶146. According to Sullivan460, “a switching means which responds to the sleep sensor and automatically switches 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,” where the pressure for the second mode is higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46. Because Sullivan460 only enters the higher-pressure second mode when the patient is asleep, Sullivan460 discloses *automatically delay[ing] the onset of a pressure increase to the*

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patient upon a determin[ation] that the patient is in an awake state. [Ex. 1003] ¶146.

Pet. 34–35 (second and final alterations added)).²¹

Element 1[f] recites “wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.” Ex. 1001, 10:10–12. Petitioner contends “Sullivan995 alone or in view of Sullivan460 discloses this limitation.” Pet. 35 (citing Ex. 1003 ¶ 148). Pointing to Sullivan995, Petitioner asserts it “delays the onset of a pressure increase to the patient until after a snore is detected” and one of ordinary skill in the art “would have readily understood, because the patient only begins snoring after *the patient is in an asleep state*, this means that Sullivan995 ensures *the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.*” *Id.* at 35–36 (citing Ex. 1003 ¶ 148). Petitioner contends that, “[t]o the extent this limitation is not explicitly disclosed in Sullivan995, the modified CPAP system taught by Sullivan995 in view of Sullivan460 would have rendered this limitation obvious.” *Id.* at 36.

Turning to Sullivan460, Petitioner asserts it “discloses a sleep detection technique based on detection of ‘reduced average airflow,’ and it would have been obvious to use Sullivan460’s sleep detection technique with the modified CPAP system for detecting an asleep state. Pet. 36 (citing Pet. §§ VIII.A (addressing motivation to combine), VIII.B (addressing reasonable expectation of success)). Petitioner contends “Sullivan460’s

²¹ We address motivation to combine and reasonable expectation of success following our discussion of the claim elements and the Parties’ arguments directed thereto.

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awake/asleep determination technique based on ‘reduced average airflow’ would have been easily used in Sullivan995’s CPAP system, especially given Sullivan995’s use of a flow sensor to sense and analyze air flow rate.” *Id.* (citing Ex. 1005, Figs. 10–12, 6:54–68; Ex. 1003 ¶ 150).

Petitioner asserts “[t]he modified CPAP system ‘is an improvement over the prior art because as soon as the patient goes to sleep . . . , the second treatment mode [increased pressure] is activated.’” Pet. 36 (second and third alterations in original) (quoting Ex. 1006, 7:10–12). Petitioner thus contends “the modified CPAP system changes from a low pressure to a higher pressure when an asleep state is detected, meaning that *the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.*” *Id.* (citing Ex. 1006, 6:30–7:22, 10:7–16, 14:7–36, claims 22–31).

b) Patent Owner’s Response

Patent Owner first asserts “Sullivan995 discloses none of the limitations identified by Petitioner.” PO Resp. 38 (citing Ex. 2006 ¶¶ 148–187²²). Specifically Patent Owner asserts that Sullivan995 “does not teach how to distinguish between asleep and awake states because”: (1) “it does not have the signal processing necessary to do so”; (2) “does not have complete waveforms”; and (3) “only considers breathing parameters related to averages, which are aspects of the amplitude structure only, which cannot

²² To the extent Patent Owner seeks to import arguments from *forty paragraphs* of Dr. Bates’s declaration that are not included in Patent Owner’s Response, that attempt is rejected because incorporation by reference is not permitted under our Rules. 37 C.F.R. § 42.6(a)(3). We address the arguments specifically raised in Patent Owner’s Response.

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determine i[f] a patient is asleep.” *Id.* (citing Ex. 2006 ¶¶ 149–155). Patent Owner explains “Sullivan995 also does not disclose these limitations because a snoring pattern is not a breathing pattern as described in the ’024 Patent.” *Id.* (citing Ex. 2006 ¶ 156; Ex. 1001, Figs. 3–8; Ex. 2012, 73:20–22). Patent Owner contends “[b]reathing patterns are used to determine if a subject is awake or asleep, which is something that Sull[iv]an995 does not teach.” *Id.* (citing Ex. 2006 ¶ 155). Patent Owner asserts “snore,” “flow rate,” “breathing rate,” “time interval,” and “volume” data in Sullivan995 “are all single parameters which, by themselves, do not constitute a breathing pattern; these parameters are all aspects of the amplitude structure of a breath-by-breath parameter time series and cannot on their own provide the ability to determine an awake state versus an asleep state.” *Id.* at 39 (citing Ex. 2006 ¶ 156, 167–168).

Turning to Sullivan460, Patent Owner contends “Sullivan460 does not teach how to detect an awake state versus an asleep state, because the Sullivan460 sleep sensor cannot reliably sense that the patient is not asleep.” PO Resp. 39 (citing Ex. 2006 ¶ 169). Patent Owner asserts that Sullivan460’s sleep detection technique, “which is based on detection of ‘reduced average airflow[,]’ is flawed because detecting an awake state versus an asleep state as claimed requires analysis of both the amplitude and temporal structures of a time series composed of breath-by-breath parameters derived from the flow waveform.” *Id.* (citing Ex. 2006 ¶ 173). In contrast, Patent Owner contends “Sullivan460 discloses only the analysis of the amplitude structure of the time series, i.e., how to make decisions based on average flow.” *Id.* (citing Ex. 2006 ¶ 173; Ex. 1006, 7:18–19).

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Referring again to Sullivan995, Patent Owner asserts it “cannot switch from a low pressure to a higher pressure upon detection of an asleep state because it only teaches the analysis of snoring sounds which are not breathing patterns, and the analysis of pressure oscillations during inspiration typical of eclampsia in terms of events taking place within a single breath.” PO Resp. 40 (citing Ex. 2006 ¶ 174). Thus, Patent Owner argues “[t]hese do not teach how to determine an awake state versus an asleep state as claimed.” *Id.* (citing Ex. 2006 ¶ 174).

c) Discussion

We find that Petitioner establishes that the combination of Sullivan995 and Sullivan460 satisfies elements 1[c]–1[f] of claim 1, including Petitioner’s reliance on Sullivan460 in the context of elements 1[e] and 1[f]. Petitioner sets forth a compelling and detailed analysis, as reflected above, which we agree with for the reasons explained by Petitioner. In this discussion, we focus on Patent Owner’s arguments and explain why they do not identify a deficiency in Petitioner’s analysis.

First, Patent Owner’s arguments are substantially based on its proposed construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt for the reasons expressed above. Thus, we disagree with Patent Owner’s arguments attacking Sullivan995 and Sullivan460 based on their alleged focus on amplitude structure. *See* PO Resp. 38–39; *see also* Pet. Reply 11 (noting that Patent Owner’s arguments are based on its proposed claim construction).

Second, we disagree with Patent Owner’s argument that a snoring pattern is not a breathing pattern. PO Resp. 38. Patent Owner’s argument in this regard, focuses not on what a breathing pattern is but rather what it

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contends a “breathing pattern[] [is] used” for. *See id.* (asserting a snoring pattern is not a breathing pattern because “[b]reathing patterns are used to determine if a subject is awake or asleep, which is something that Sullivan995 does not teach”). Patent Owner’s argument is again based on its proposed construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt for the same reasons expressed above.

Third, Sullivan460 explicitly discloses “a sleep sensor which senses whether or not the patient is asleep.” Ex. 1006, 7:4. Thus, Patent Owner’s arguments regarding whether Sullivan460 teaches determining an awake state versus an asleep state are directly contrary to Sullivan460’s express teaching, and we do not agree with those arguments. Additionally, Sullivan460 teaches that its sleep sensor can “register that a patient is asleep when there is a reduced average airflow in the patient’s upper airway.” *Id.* at 7:17–19. We agree with Petitioner that the ’024 patent uses “low flow rate” as one indicator of REM sleep. *See* Pet. Reply 11.

Fourth, we agree with Petitioner that Patent Owner effectively “concedes (as it must) that Sullivan995 in view of Sullivan460 ‘analy[zes] the breathing pattern’ according to its plain meaning, to determine asleep versus awake states.” Pet. Reply 12. Specifically, as Petitioner explains, Patent Owner acknowledges that Sullivan460 teaches “analysis of the amplitude structure of the time series”—“mean values of flow . . . in determining sleep versus awake and reduces CPAP when mean airflow increases (i.e., when the patient is awake).” *Id.* (alteration in original) (citing PO Resp. 39, 50; Ex. 1051 ¶¶ 37–39). We further agree with Petitioner that Patent Owner “thus admits that the combination analyzes breathing patterns

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to determine asleep versus awake state” based on Patent Owner’s statement that “Sullivan460 identifies awake versus sleep only on the basis of average flow, . . . which is an aspect of the amplitude structure of a time series.” *Id.* (quoting PO Resp. 42).

Fifth, Patent Owner’s arguments in its Sur-reply reiterate several of the arguments from the Patent Owner Response and are dependent upon Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing,” which we do not adopt. *See* Sur-reply 16–18 (discussing snoring sounds, temporal analysis, and the alleged requirement of analyzing amplitude structure and temporal structure). Thus, we disagree with those arguments raised by Patent Owner for the reasons explained above.

Accordingly, for the reasons explained above, we find Petitioner has shown that the combination of Sullivan995 and Sullivan460 satisfies elements 1[c]–1[f] of claim 1.

b. Claims 2–5 and 7–14

Claims 2–5 and 7–14 depend, directly or indirectly, from claim 1. Petitioner sets forth a detailed analysis showing how the combined teachings of the references meet the elements of claims 2–5 and 7–14. Pet. 37–52.

Patent Owner does not raise additional argument challenging Petitioner’s analysis and evidence directed to these claims, in its Patent Owner Response,²³ aside from the arguments raised regarding claim 1. *See generally* PO Resp.

²³ Patent Owner states “Petitioner further argues that dependent claims 2–5 and 7–14 are likewise obvious; Petitioner fails for the reasons stated above, and for the additional reasons explained by Dr. Bates. PO Resp. 44–45

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We find Petitioner’s arguments persuasive as to claims 2–5 and 7–14 and supported on the complete record before us, and, therefore, we adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that the combination of Sullivan995 and Sullivan460 satisfies the subject matter of claims 2–5 and 7–14.

3. *Motivation to Combine and Reasonable Expectation of Success*

Petitioner contends one of ordinary skill in the art would have been motivated to modify Sullivan995 “so that the *processing arrangement in Sullivan995 determines that the patient is in an awake state, and in response, automatically delays the onset of a pressure increase to the patient*, as taught in Sullivan460.” Pet. 18 (citing Ex. 1003 ¶¶ 94–103). Petitioner asserts the modification would “cause Sullivan995’s CPAP system to apply a lower pressure or higher pressure upon detecting the patient’s awake state or asleep state, respectively.” *Id.*

Petitioner asserts one of ordinary skill in the art “would have recognized the advantages of using the same CPAP system to treat sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught

(citing Ex. 2006 ¶¶ 178–204). Our Rules do not permit incorporating arguments by reference from one document into another. 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”). Additionally, Patent Owner was expressly informed that “**any arguments not raised in the response may be deemed waived.**” Paper 16 (Scheduling Order), 9. Thus, to the extent Dr. Bates raises additional arguments in response to Petitioner’s challenge to these dependent claims, we do not consider those arguments, and instead we find those arguments waived by virtue of Patent Owner not expressly stating them in its Patent Owner Response.

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in Sullivan460.” Pet. 18 (citing Ex. 1006, 7:3–12; Ex. 1003 ¶ 96).

Petitioner contends “[t]he modification to 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 18–19 (citing Ex. 1006, 2:19–22, 4:33–34, 6:3–7:2, 9:31–10:6). And Petitioner argues “Sullivan995 even suggests that such modifications would be desirable, as its CPAP system is not limited to treating apnea and snoring, but also appl[ies] to other upper airway disorders, including pre-eclampsia.” *Id.* at 19 (citing Ex. 1005, 1:14–31, 4:36–45).

Additionally, Petitioner contends one of ordinary skill in the art “would have recognized that the modification is advantageous” and would “improve[] patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks,” because “[t]he modified CPAP system would apply a low pressure upon wake-up, adding to patient comfort and decreasing the likelihood the patient will remove the mask.” Pet. 19. Petitioner asserts “Sullivan995 suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (e.g., including an awake period). *Id.* (citing Ex. 1005, 10:13–46, 14:45–64). Petitioner also contends Sullivan995 “partially solves the problem” of “therapy pressure . . . [being] delivered at levels higher than necessary for substantial periods, causing discomfort,” “by reducing the pressure at the beginning of therapy.” *Id.* (citing Ex. 1005, 4:21–25; Ex. 1003 ¶ 99).²⁴

²⁴ In the context of element 1[e], Petitioner also provides an additional advantage that it contends would have been recognized by one of ordinary

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In its discussion of reasonable expectation of success, Petitioner critically recognizes that “Sullivan460 expressly states that Sullivan995 may be modified to include features of Sullivan460, such as ‘sens[ing] an upper airway flow limitation characteri[z]ed by at least one decrease in upper airway inspiratory flow rate followed by at least one increase in flow rate.’” Pet. 19–20 (quoting Ex. 1006, 6:26–29). Petitioner asserts 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 20 (citing Ex. 1003 ¶¶ 100, 102).

Additionally, in further support of reasonable expectation of success, Petitioner points to many similarities between Sullivan995 and Sullivan460, which we agree with although we do not repeat here. *See* Pet. 20–21 (citing Ex. 1006, 10:10–12, Figs. 1–2, 9:31–34, 10:3–16). Petitioner asserts that “[g]iven the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements

skill in the art and would have provided additional motivation for modifying Sullivan995 with Sullivan460. Specifically, Petitioner contends that “the modification would have resulted in higher therapeutic pressure being permitted as soon as the patient goes to sleep,” which is an advantage because without such sleep detection, the CPAP system may activate a higher pressure either “(1) too early, so that the higher pressure is activated when the patient is still awake and causes discomfort, or (2) too late, so that the higher pressure is activated well after the patient has fallen asleep and may have already experienced apneic episodes at the lower pressure.” Pet. 37 (citing Ex. 1003 ¶ 153). Petitioner asserts “Sullivan460 solved that problem, which would have been a significant benefit for a patient using Sullivan995’s CPAP system.” *Id.* (citing Ex. 1003 ¶ 154).

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according to known methods and techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.” *Id.* at 21.

Patent Owner challenges Petitioner’s motivation to combine and reasonable expectation of success based entirely on its proposed construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt. *See* PO Resp. 41–43. For example, Patent Owner argues “[t]here is no motivation to combine the teachings of Sullivan995 and Sullivan460 because these references do not teach how to detect an awake state versus an asleep state *as claimed*.” *Id.* at 41 (emphasis added). Patent Owner then continues to describe its proposed claim construction and its alleged requirement to analyze “both the amplitude and temporal structures of a time series,” asserting Sullivan995 and Sullivan460 “disclose only the analysis of the amplitude structure of the time series.” *Id.* (citing Ex. 1005, 6:62, 6:65; Ex. 1006, 7:18–19). Patent Owner’s argument in opposition to Petitioner’s showing on reasonable expectation of success also is based on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns.” *See id.* at 42 (“Sullivan460 cannot distinguish between awake and asleep states in accordance with the *claimed analysis/determination* of breathing patterns *because Sullivan460 does not consider both the amplitude and temporal structures* of a time series composed of breath-by-breath parameters derived from the flow waveform.” (emphases added)).

We disagree with Patent Owner’s arguments for several reasons. First, as noted above, we do not adopt Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns.”

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Second, the combination proposed by Petitioner presents the rare case where the combination is described explicitly in one of the references itself. In other words, at least part of the motivation to combine comes *directly* from Sullivan460. And, Sullivan460 *expressly incorporates Sullivan995 by reference*. Ex. 1006, 6:22–25 (“[T]he 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 [i.e., Sullivan995], the contents of which are incorporated herein by reference.”).

Third, contrary to Patent Owner’s argument regarding whether Sullivan460 can distinguish between awake and asleep states, Sullivan460 *expressly states* that it can and does: “In another embodiment, 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.” Ex. 1006, 7:3–7 (emphasis added). And, Sullivan460 also *expressly states* that when the patient “goes to sleep (as determined by an appropriate sensing algorithm in the treatment means), the second treatment mode is activated” (*id.* at 7:10–12), where the second treatment mode “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 6:30–7:2). Thus, we disagree with Patent Owner’s argument that Sullivan460 cannot distinguish between an awake state and an asleep state because Sullivan460 expressly states that it can and does.

Fourth, we also find that Petitioner has established that one of ordinary skill in the art would have had a reasonable expectation of success

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in achieving the combination proposed. As noted above, Sullivan460 expressly states how to combine Sullivan995. And we find Petitioner’s argument persuasive and supported on the record that “[g]iven the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements according to known methods and techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.”²⁵ Pet. 21.

In its Sur-reply, Patent Owner asserts “[t]here is no motivation to combine Sullivan460 with any reference because Sullivan460 is not enabling.” Sur-reply 19–20. Specifically, Patent Owner asserts that one of ordinary skill in the art would not understand how to determine the preset flow rate in Sullivan460.²⁶ *Id.*

We disagree. As Petitioner correctly explains, enablement “is not a requirement to prove invalidity under § 103.” Pet. 15 (citing *Amgen*, 314 F.3d at 1313 (Under § 103, “a reference need not be enabled; it qualifies as a

²⁵ We disagree with Patent Owner’s one sentence argument contesting Petitioner’s statement (*see* PO Resp. 42–43) because Petitioner’s analysis is supported on the complete record for the reasons explained by Petitioner.

²⁶ Patent Owner raises a new argument in its Sur-reply that combining the teachings of Sullivan995 and Sullivan460 would require “undue experimentation.” Sur-reply 20 (“Since these prior art references lack essential elements, combining them to result in the ’024 Patent’s invention requires undue experimentation, because analyzing both amplitude and temporal structures to determine asleep/awake states was simply not known.”). Aside from the issues pertaining to Patent Owner raising the argument for the first time in its Sur-reply, we disagree with Patent Owner’s argument because, again, it is based on its proposed claim construction for “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt for the reasons discussed above.

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prior art, regardless, for whatever is disclosed therein.”)). Moreover, we agree with Petitioner that the Challenged Claims do not require any preset level for a flow rate, and a person of ordinary skill “would have understood that a preset level is established from previously-acquired data or data from a previous window of time, such as an average level, for example, as taught in Sullivan995.” Pet. Reply 15 (citing Ex. 1005, 17:3–27, Fig. 12; Ex. 2015, 38:2–16). Additionally, Sullivan995 discloses that the computing system may “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.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22. Based on this disclosure, and given that Sullivan460 incorporates Sullivan995 by reference, we agree with Petitioner that Sullivan460’s disclosure of “detect[ing] that the flow rate has fallen below a present²⁷ [sic] level,” would have informed a person of ordinary skill that this level was predetermined, so that “the controller 100 activates the nCPAP apparatus 90 to supply air to the patient 30 at a pressure which ameliorates or eliminates the upper airway flow limitation.” Ex. 1006, 11:10–13 (footnote added).

Inexplicably, Patent Owner also contends one of ordinary skill in the art “would not have readily recognized that Sullivan995 and Sullivan460 are

²⁷ Sullivan460 refers to a “present level,” which we understand in the full context of the paragraph was a typographical error intended to be “preset level.” *See, e.g.*, Ex. 1006, 10:21–24 (stating that “[w]hen the flow rate measurement means 70 detects that the flow rate increases above the preset level, the controller activates the switch”).

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analogous art.” PO Resp. 42 (citing Ex. 2006 ¶ 147). Patent Owner’s reason for this alleged lack of recognition is because “Sullivan460 identifies awake versus asleep only on the basis of average flow . . . which is an aspect of the amplitude structure of a time series.” *Id.* (citing Ex. 2006 ¶ 147).

We disagree with Patent Owner’s argument. Two separate tests are used to define the scope of analogous art: “(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *Netflix, Inc. v. DivX, LLC*, 80 F.4th 1352, 1358 (Fed. Cir. 2023) (citations omitted). As Petitioner explains, Sullivan995 and Sullivan460 are analogous art. Pet. 20. At a minimum, Sullivan995 and Sullivan460 are each in the same field of endeavor as the ’024 patent as each is directed to “CPAP systems that include flow sensors and generators” as Petitioner contends. *Id.* Thus, we disagree with Patent Owner’s argument that Sullivan995 and Sullivan460 are not analogous art to the ’024 patent.

As reflected above, Petitioner’s analysis is persuasive and fully supported on the complete record before us, and we disagree with Patent Owner’s arguments for the reasons explained above. On the complete record, for the reasons discussed above as well as the reasons articulated by Petitioner, which we adopt as our own, we find that Petitioner has established that one of ordinary skill in the art would have had reasons with rational underpinning to combine the teachings of Sullivan995 and

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Sullivan460 as proposed by Petitioner and would have had a reasonable expectation of success in so doing.²⁸

4. *Objective Indicia of Nonobviousness*

Objective evidence of nonobviousness may include evidence of commercial success, licensing, copying, praise by others, long felt but unresolved need, and failure or skepticism of others. *Graham*, 383 U.S. at 17–18. But, secondary considerations are only a part of the “totality of the evidence”; their mere existence does not control the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). Objective evidence of nonobviousness “may often be the most probative and cogent evidence in the record” and “may often establish that an invention appearing to have been obvious in light of the prior art was not.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

Patent Owner argues that evidence of nonobviousness exists in the form of long-felt need. PO Resp. 43–45. According to Patent Owner, since 1991, there has been “a need for patients to increase compliance with usage of their CPAP machines,” with patients complaining about “nocturnal awakenings” and “nasal issues.” *Id.* at 43–44 (citing Ex. 1036, 1, 5). Patent Owner further argues as follows:

²⁸ To the extent Patent Owner’s briefing could be interpreted as raising additional arguments contesting these issues (especially based on Patent Owner’s citations to Dr. Bates’s declaration, which could be interpreted as seeking to incorporate additional arguments by reference although prohibited by our Rules), we find Petitioner’s arguments (in the Petition and Reply) persuasive for the reasons explained by Petitioner and adopt them as our own findings.

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The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients' compliance with CPAP treatment by noting that "the conventional PAP therapy [had] not taken sleep/wake state into account" and "[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy." '994 Patent, 1:44-46, 1:64-65. Further, before the development of the claimed invention in the '024 Patent, self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. *Id.* at 2:31-35. In fact, as of 2002, a [person of ordinary skill in the art] was "not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters." *See* EX2015, at 2:33-37. As such, the claimed invention solved a long felt but unresolved need – better compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 44 (first two alterations in original).

Patent Owner further argues that conventional CPAP treatment "had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control." Sur-reply 25 (citing Ex. 1001, 2:18–21; Ex. 1053, 296:22–25, 297:1–15). According to Patent Owner, Dr. Bates's testimony explained that "[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states." *Id.* at 25–26 (citing Ex. 1052, 113:3–11, 115:22–25, 116:1–10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by the '024 patent's "ability to distinctly identify when a patient is awake or asleep," because a person of ordinary skill in the art "prior to the 994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and

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awake.” *Id.* at 26 (alteration in original) (citing Ex. 1052, 202:23–25, 203:1–3).

a. Nexus

Objective evidence of nonobviousness “is only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (2006)). A “nexus” is a legally and factually sufficient connection between the objective evidence and the claimed invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 32–33 (PTAB Jan. 24, 2020) (precedential), *aff’d sub nom. Zaxcom, Inc. v. Lectrosonics, Inc.*, 2022 WL 499848 (Fed. Cir. Feb. 18, 2022). We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* at 32. If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is

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the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 33 (quoting *Fox Factory*, 944 F.3d at 1373–75). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Id.* (citing *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011)). There is no requirement that the objective evidence of non-obviousness be tied exclusively to claim elements that are not disclosed in the prior art, and the claimed combination as a whole may serve as a nexus for the objective evidence. *Id.* (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)).

Petitioner argues that “for secondary considerations to be accorded substantial weight, [Patent Owner] bears the burden of showing that a nexus exists between the claimed features of the invention and the evidence offered to show non-obviousness.” Pet. Reply 25 (citing *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). According to Petitioner, Patent Owner does not meet this burden because: 1) Patent Owner did not establish “a presumption of nexus” since Patent Owner did not identify any product tied to the objective evidence; 2) Patent Owner did not “demonstrate a nexus by showing that long-felt need was met as a ‘direct result of the unique characteristics of the claimed invention’”; 3) Patent Owner did not identify “any failed efforts to solve the problem before the invention”; and 4) Patent Owner does not point to disclosure in the ’024 patent that the “prior art recognized the need to analyze temporal and amplitude structures.” *Id.* at 25–27 (citations omitted).

First, Patent Owner has not argued that the presumption of nexus applies, and we agree with Petitioner that Patent Owner is not entitled to a

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presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the Challenged Claims. Second, we address Patent Owner's evidence of long-felt but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the '024 patent, absent the presumption.

b. Long-felt but Unmet Need

In order to show a long-felt but unmet need *for the claimed invention*, the objective evidence must show that the need was a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). "Evidence of long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would not have persisted had the solution been obvious." *WBIP*, 829 F.3d at 1332.

Here, Patent Owner suggests increasing the comfort of the PAP system is a goal to improve patient compliance with PAP therapy. Patent Owner does not explain, however, why Sullivan460's treatment means which "addresses ... the comfort of CPAP," and "is an improvement over the prior art" because of the two modes of air delivery, does not meet the long-felt need identified by Patent Owner. *See* Ex. 1007, 7:7–16; *see also* Pet. Reply 25–26. Thus, we agree with Petitioner that "[t]o the extent that any need existed, it was already satisfied," especially in light of the proper construction of "analyzes the data to determine the patient's breathing patterns." Pet. Reply 26 (citations omitted).

Additionally, Patent Owner's Response fails to identify any failed efforts to solve the problem before the invention and similarly fails to provide sufficient evidence that the '024 patent satisfied the alleged need.

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Dr. Bates’s redirect testimony, which Patent Owner almost exclusively relies on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to “little or no weight.” 37 C.F.R. § 42.65(a). Patent Owner’s additional arguments regarding a supposed need for better compliance with CPAP therapy by detecting troubled wakefulness (*see* PO Resp. 44; Sur-reply 25–26) are only commensurate in scope with dependent claim 6 (which is the only claim that expressly recites troubled wakefulness and is discussed in Ground 2 below). Nonetheless, even assuming Patent Owner’s argument is commensurate in scope with each of the Challenged Claims, Patent Owner’s argument still suffers from the other deficiencies identified above, particularly the failure by Patent Owner to show that the ’024 patent satisfied the alleged need.

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt but unmet need met by any of the Challenged Claims. As a result, we accord little weight to Patent Owner’s evidence of long-felt need.

c. Collective Considerations of the Graham Factors

“Once all relevant facts are found, the ultimate legal determination [of obviousness or nonobviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat*, 876 F.3d at 1361. Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches each limitation of claims 1–5 and 7–14 of the ’024 patent, that a person of ordinary skill in the art would have had reasons with rational underpinning to combine features

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of Sullivan995 and Sullivan460 and would have had a reasonable expectation of success in so doing, and that Petitioner's evidence of unpatentability significantly outweighs the marginal evidence of long-felt but unmet need provided by Patent Owner.

On the whole and considering the *Graham* factors collectively, Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 would have rendered the subject matter of claims 1–5 and 7–14 of the '024 patent obvious to one of ordinary skill in the art at the time of the invention.

C. Ground 2: Obviousness over Sullivan995, Sullivan460, and Matthews

Petitioner asserts that the combination of Sullivan995, Sullivan460, and Matthews would have rendered the subject matter of claim 6 obvious to one of ordinary skill in the art at the time of the invention. Pet. 52–55. Patent Owner opposes. PO Resp. 45–48.

1. Scope and Content of the Prior Art

a. 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

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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.” 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. Differences Between the Prior Art and Claim 6

Claim 6 depends from claim 1 and recites “wherein the awake state is a troubled wakefulness state.” Ex. 1001, 10:32–33. Petitioner contends that Matthews “discloses *determining whether a breathing pattern is indicative of a troubled wakefulness state.*” Pet. 54 (citing Ex. 1003 ¶ 215). Specifically, Petitioner contends “Matthews recognizes that ‘[w]hen a patient is awake . . . or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable.’” *Id.* at 55 (alterations in original) (quoting Ex. 1007, 21:37–40). To address potential instability, Petitioner asserts “Matthews discloses ‘a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing.’” *Id.* (quoting Ex. 1007, 40:25–30). Petitioner contends “[t]he breathing control layer ‘performs statistical analysis on the scatter of the trended weighted peak flow data to detect unstable breathing patterns or abrupt changes in patient response,’ similar to those found in Figure 7” of the ’024 patent. *Id.* Thus, Petitioner argues “Matthews’s disclosure of monitoring and detecting erratic or irregular breathing, meets the

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determining whether a breathing pattern is indicative of a troubled wakefulness state claim limitation.” *Id.* (citing Ex. 1003 ¶¶ 217–218).

Patent Owner first challenges whether Sullivan995 and Sullivan460 teach the subject matter of claim 6. PO Resp. 45–46 (citations omitted). Turning to Matthews, Patent Owner asserts Matthews does not teach determining that a patient has transitioned to a troubled wakefulness state from an asleep state because Matthews (and Sullivan995 and Sullivan460) “disclose only the analysis of the amplitude structure of the time series, i.e., how to make decisions based on mean values derived from inspiratory flow within a single breath and the standard deviation of such quantities.” *Id.* at 46 (citing Ex. 2006 ¶ 215).

We disagree with Patent Owner’s argument directed to Matthews because it too is based on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt for the reasons explained above. Patent Owner’s additional arguments in response to Ground 2 are directed to motivation to combine, reasonable expectation of success, and objective indicia of nonobviousness, which we address below. For the reasons discussed above, we find Petitioner’s arguments persuasive as to claim 6 and supported on the complete record before us. Accordingly, we find that the combination of Sullivan995, Sullivan460, and Matthews satisfies the subject matter of claim 6.

3. *Motivation to Combine and
Reasonable Expectation of Success*

We address Petitioner’s arguments regarding the combination of Sullivan995 and Sullivan460 above. Petitioner provides further argument

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regarding motivation to combine Sullivan995 and Sullivan460 with Matthews, which we now address. In particular, Petitioner contends it would have been obvious to one of ordinary skill in the art “to modify the system of Sullivan995 and Sullivan460 in view of Matthews so that the *awake state is a troubled wakefulness state.*” Pet. 52 (citing Ex. 1003 ¶¶ 209–213). Petitioner asserts one of ordinary skill in the art “would have been motivated to implemented this modification to cause Sullivan995’s modified CPAP system to *lower[] the pressure* upon detecting the patient’s *troubled wakefulness state.*” *Id.* (alteration in original) (citing Ex. 1003 ¶¶ 209–210).

Petitioner contends one of ordinary skill in the art “would have recognized the advantages of detecting different awake states, including a distressed state (*troubled wakefulness*) in which the patient has breathing that becomes ‘erratic,’ as taught in Matthews.” Pet. 52 (citing Ex. 1003 ¶ 210). Petitioner asserts the modification to the combined CPAP system of Sullivan995 and Sullivan460 “would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* at 52–53 (also noting that “Sullivan995 is already concerned with the patient’s comfort, and already discloses it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible” (citing Ex. 1005, 2:31–39)).

Turning to reasonable expectation of success, Petitioner contends all three references are “analogous art and describe CPAP systems with flow sensors and generators.” Pet. 53. Petitioner asserts

[l]ike Sullivan995 and Sullivan460, Matthews discloses a “flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34.” Ex., 1007, 7:11-16. The data from

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the flow sensor are monitored to control the pressure. *Id.*, 8:54-9:15. Sullivan460 discloses lowering the pressure upon detecting an awake state (EX1006, 6:30-7:19, cls. 22-28, 43-46), and the [person of ordinary skill in the art] would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient. [Ex. 1003] ¶¶211-212.

Id. Additionally, Petitioner argues “[t]he modification is 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.” *Id.* (citing Ex. 1003 ¶ 213).

Patent Owner’s arguments in response are again based on its proposed claim construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not accept for the reasons discussed above. *See* PO Resp. 47–48 (asserting no motivation to combine because “these references only teach identification of patient state based on mean flow and its standard deviation,” which “is an aspect of the amplitude structure of a time series”; “an analysis of the amplitude and temporal structure of a breath-by-breath time series is required to distinguish between an awake state and a sleep state, including troubled wakefulness and REM sleep”; one of ordinary skill in the art “would not have been motivated to make this combination to specifically reduce pressure upon detection of the troubled wakefulness state, because [one of ordinary skill in the art] would not be able to distinguish between REM sleep and troubled wakefulness and therefore would not know whether to increase or decrease pressure”). Additionally, Patent Owner asserts “there is no reasonable expectation of success, because “[t]his modification requires methods of digital signal processing that go

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beyond a combination of known prior art elements.” *Id.* at 48 (citing Ex. 1003 ¶ 209). As reflected above, Patent Owner’s arguments repeat the arguments raised in the context of Ground 1, which arguments we addressed therein and did not agree with for the reasons explained above and, further, for the reasons explained by Petitioner in its Reply (*see* Pet. Reply 17–19), which we adopt in full as though they were our own.

On the complete record and for the reasons discussed above, we find that Petitioner has established that one of ordinary skill in the art would have had reasons with rational underpinning to combine the teachings of Sullivan995, Sullivan460, and Matthews as proposed by Petitioner and would have had a reasonable expectation of success in so doing.²⁹

4. *Objective Indicia of Nonobviousness*

“Once all relevant facts are found, the ultimate legal determination [of obviousness or nonobviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat*, 876 F.3d at 1361. Patent Owner relies on the same arguments and evidence raised in response to Petitioner’s challenge in Ground 1. *See* PO Resp. 48 (“Patent Owner incorporates the arguments made in Section VI.C. as if fully stated herein.”).

²⁹ To the extent Patent Owner’s briefing could be interpreted as raising additional arguments contesting these issues (especially based on Patent Owner’s citations to Dr. Bates’s declaration, which could be interpreted as seeking to incorporate additional arguments by reference although prohibited by our Rules), we find Petitioner’s arguments (in the Petition and Reply) persuasive for the reasons explained by Petitioner and adopt them as our own findings.

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We considered Patent Owner's arguments and evidence in the context of Ground 1, above. We also indicated that Patent Owner includes arguments on long-felt need specifically tied to detecting troubled wakefulness. In addition to the reasoning discussed in the context of Ground 1, which we incorporated herein, we add that Patent Owner's argument suffers from the same deficiencies identified above, particularly the failure to show that the invention satisfies the alleged need.

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews teaches each limitation of claim 6 of the '024 patent, that a person of ordinary skill in the art would have had reasons with rational underpinning to combine features of Sullivan995, Sullivan460, and Matthews as asserted with a reasonable expectation of success in so doing, and that Petitioner's evidence of unpatentability significantly outweighs the marginal evidence of long-felt but unmet need provided by Patent Owner.

On the whole and considering the *Graham* factors collectively, Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews would have rendered the subject matter of claim 6 of the '024 patent obvious to one of ordinary skill in the art at the time of the invention.

D. Ground 3: Obviousness over Rapoport502 and Sullivan460
Ground 4: Obviousness over Rapoport502, Sullivan460, and Matthews

Petitioner asserts the combination of Rapoport502 and Sullivan460 would have rendered the subject matter of claims 1–5 and 7–14 obvious and

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the combination of Rapoport502, Sullivan460, and Matthews would have rendered the subject matter of claim 6 obvious to one of ordinary skill in the art at the time of the invention. Pet. 55–72 (Ground 3), 72–75 (Ground 4). Patent Owner contests Petitioner’s assertions. *See, e.g.*, PO Resp. 48–51 (Ground 3), 51–54 (Ground 4).

Because we have determined above that Petitioner has established the unpatentability of these same claims based on the combination of Sullivan995 and Sullivan460 (Ground 1) and the combination of Sullivan995, Sullivan460, and Matthews (Ground 2), we need not and do not reach these additional challenges by Petitioner based on the combinations of Rapoport502 and Sullivan460 (Ground 3) and Rapoport502, Sullivan460, and Matthews (Ground 4). *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged.”).

IV. PATENT OWNER’S MOTION TO EXCLUDE

Patent Owner seeks to exclude, either in whole or in part, Exhibits 1003, 1009, 1034, 1046, 1049, 1051, 1052, and 1054–1059 as well as portions of the Petition and Petitioner’s Reply that rely on the allegedly inadmissible exhibits. PO MTE 1; *see* PO MTE Reply. Petitioner opposes Patent Owner’s Motion. PO MTE Opp. For the following reasons, we deny Patent Owner’s Motion to Exclude.

A. Exhibits 1003 and 1046

Exhibit 1003 is the declaration of Petitioner’s original declarant, Dr. Behbehani, and Exhibit 1046 is the substitute declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s Declaration. *See* Ex. 1046 ¶ 28. Patent Owner argues that certain portions of

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Exhibit 1003 should be excluded and that those portions should also be excluded from Exhibit 1046. PO MTE 3–6; PO MTE Reply 1. More specifically, Patent Owner seeks to exclude paragraphs 38, 39, 42, 45, 77, and 224 of Exhibit 1003 on the premise that they are based upon inadmissible hearsay. Patent Owner asserts Dr. Kirkness did not perform any independent analysis and offers testimony for the truth of the matter asserted. PO MTE 3–5. Further, according to Patent Owner, hearsay may not be “a basis for an expert opinion when, in fact, the expert adds nothing to the out-of-court statements other than transmitting them to the factfinder.” *Id.* at 4–5.

In opposition, Petitioner argues, among other things, that “[a]n expert such as Dr. Kirkness may base an opinion on any facts or data that the expert ‘has been made aware of or personally observed,’” that “the facts or data ‘need not be admissible’ if an expert in the particular field would ‘reasonably rely’ on those kinds of facts or data” (PO MTE Opp. 3 (citing Fed. R. Evid. 703)), and that Dr. Kirkness “would certainly rely on peer-reviewed articles regarding the results of a study testing a CPAP machine [Ex. 1012] and manufacturer’s information regarding a commercial CPAP product [Ex. 1028].” PO MTE Opp. 3; *see also id.* at 4 (discussing Dr. Kirkness’s reliance on printed publications to establish the state of the prior art).

Because we do not rely on the challenged portions of Exhibit 1003 in rendering this Decision, we deny Patent Owner’s Motion to Exclude as to these portions of Exhibit 1003 and the corresponding portions of Exhibit 1046 as moot.

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B. Exhibits 1009 and 1054–1058

Exhibit 1009 is the file history of related U.S. Patent No. 9,168,344 B2 (“the ’344 patent”), and Exhibit 1056 is the ’344 patent. Exhibit 1054 is the file history of related U.S. Patent No. 9,108,009 B2 (“the ’009 patent”), and Exhibit 1055 is the ’009 patent. Exhibit 1057 is related U.S. Patent No. 9,427,539 B2, and Exhibit 1058 is the related ’994 patent.

Patent Owner asserts that “Petitioner introduced new evidence in its Reply with these exhibits,” contrary to 37 C.F.R. § 42.61(a), which provides that “[e]vidence that is not taken, sought, or filed in accordance with this subpart is not admissible.” PO MTE 5; PO MTE Reply 2–3. According to Patent Owner, these exhibits are “subject to exclusion under” Federal Rule of Evidence 403. In opposition, Petitioner argues that these exhibits are proper evidence in support of its Reply because Patent Owner “proposed a construction for the ‘analyzing the breathing patterns’ claim terms for the first time in [Patent Owner’s] Response.” PO MTE Opp. 6. Patent Owner contends Petitioner could have used these exhibits in its Petition, but instead “supplemented previous claim construction arguments made in the Petition with these exhibits.” PO MTE Reply 2–3.

We disagree with Patent Owner’s argument. Petitioner proposed one term for construction in the Petition—“troubled wakefulness.” Pet. 17. Patent Owner first presented a construction for “analyzes the data to determine the patient’s breathing patterns” in its Patent Owner Response. PO Resp. 30. Petitioner’s first and only opportunity to respond to Patent Owner’s construction was in its Reply. *See Ancacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380 (Fed. Cir. 2018) (“[T]he petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the

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evidence is a legitimate reply to evidence introduced by patent owner.”). And Petitioner’s Reply does not change the theory, prior art, or evidence relied on to challenge the subject claims as compared to that which was presented in the Petition. Thus, we disagree with Patent Owner’s arguments.

Therefore, Petitioner properly relies on Exhibits 1009 and 1054–1058 in support of its response to Patent Owner’s construction of “analyzes the data to determine the patient’s breathing patterns,” first raised in the Patent Owner Response. Therefore, we deny Patent Owner’s Motion to Exclude as to Exhibits 1009 and 1054–1058.

C. Exhibits 1034 and 1059

Exhibit 1034 is International Publication No. WO 03/075991 A1. Exhibit 1034 was cited by Dr. Kirkness in paragraph 174 of Exhibit 1003. Exhibit 1059 is an article titled “Control of breathing during sleep” published in Clinical Science in 1984 and was cited by Dr. Kirkness in his reply declaration (Exhibit 1051). Patent Owner argues that neither exhibit was cited expressly by Petitioner and therefore the use of each is an improper incorporation of arguments by reference. PO MTE 8–10 (citing 37 C.F.R. § 42.6(a)(3)).

Patent Owner’s argument has no merit. As Petitioner notes, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and neither Exhibit 1034 nor Exhibit 1059 is an argument. PO MTE Opp. 10–11; *see also id.* at 11 (addressing Exhibit 1034 by referencing the same arguments raised in opposition to Patent Owner’s attempt to exclude Exhibit 1059). Patent Owner also argues in its Reply that Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply

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4. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his reply declaration were relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” PO MTE Opp. 10–11. We agree with Petitioner for the same reasons discussed above regarding Exhibits 1009 and 1054–1058. Because Patent Owner shows no persuasive basis to exclude Exhibits 1034 and 1059, we deny Patent Owner’s Motion to Exclude as to Exhibits 1034 and 1059.

D. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2. Patent Owner argues that the priority date of this patent is after the priority date of the ’024 patent and should be excluded as irrelevant and “not prior art.” PO MTE 6; PO MTE Reply 3. Patent Owner also argues that the exhibit should have been introduced prior to Petitioner’s Reply. PO MTE 6. Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. PO MTE Opp. 8–9. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates’s credibility, not as prior art, and find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision, and we deny Patent Owner’s Motion to Exclude as to Exhibit 1049 as moot.

E. Exhibit 1051

Exhibit 1051 is the Declaration of Dr. Kirkness in support of Petitioner’s Reply. Patent Owner argues that Exhibit 1051 should be excluded because it raises “new issues” and “new evidence that could have been presented in a prior filing.” PO MTE 7; PO MTE Reply 1–2. The only

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“example” provided by Patent Owner in support of its argument for exclusion is that Dr. Kirkness “uses Exhibits 1049 and 1054–1058 in the exact same manner” as they are used in Petitioner’s Reply and should therefore be excluded for the same reasons. PO MTE 7. For the same reasons discussed above regarding Exhibits 1049 and 1054–1058, we deny the Motion to Exclude as to Exhibit 1051.

F. Exhibit 1052

Exhibit 1052 is the transcript of the first day of Dr. Bates’s deposition testimony. Patent Owner argues that the portions of Exhibit 1052 “focusing on patent eligible subject matter and whether certain products, such as processors, infringe by meeting the limitations of the ’024 Patent should be excluded as irrelevant.” PO MTE 8 (citing Ex. 1052, 62:7–23, 63:15–25, 64:1–5, 117:9–25, 118:1–11, 146:4–12); PO MTE Reply 3–4. Petitioner argues that the testimony of Dr. Bates is relevant to obviousness issues in this proceeding, that there was “no discussion of ‘infringement’ or ‘patentable subject matter,’” and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 9–10. We agree with Petitioner for the same reasons provided by Petitioner and deny Patent Owner’s Motion to Exclude as to the challenged portions of Exhibit 1052.

V. PETITIONER’S MOTION TO EXCLUDE

Petitioner seeks to exclude portions of Exhibit 1053, the deposition testimony of Dr. Bates. Pet. MTE 1–9; Pet. MTE Reply 1–5. Specifically, Petitioner moves to exclude parts of the redirect deposition testimony of Dr. Bates concerning secondary considerations of nonobviousness. Pet. MTE 1–2. Petitioner argues that the redirect testimony of Dr. Bates “was outside the scope of Petitioner’s cross-examination in contravention of

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Federal Rule of Evidence 611(b) and 37 C.F.R. § 42.53 (d)(5)(ii).” *Id.* at 1. Petitioner does not seek to exclude the entirety of Dr. Bates’s redirect testimony concerning secondary considerations but only the specific portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes Petitioner’s Motion. Pet. MTE Opp. 1–10.

Petitioner contends that it “did not cross-examine Dr. Bates about any secondary considerations and timely objected to PO’s line of questioning during redirect as being outside the scope.” Pet. MTE 1–2 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9); *id.* at 4 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9). Petitioner further contends that Patent Owner’s “introduction of belated expert testimony into the record via the Sur-Reply is improper and the evidence must be excluded.” *Id.* at 2 (citing *Comcast Cable Commc’ns, LLC v. Rovi Guides, Inc.*, IPR2019-01413, Paper 34 at 4 (PTAB Sept. 16, 2020); *Int’l Bus. Machines Corp. v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 15 at 5 (PTAB Feb. 2, 2015)); *see also id.* at 5–6 (identifying portions of the Sur-reply citing the disputed testimony). Further, according to Petitioner, “Dr. Bates’ declaration included no discussion of secondary considerations.” *Id.*

Petitioner argues that Rule “611(b) prohibits redirect examination that goes beyond the scope of cross-examination questions and testimony” and Patent Owner’s “redirect examination did just that.” Pet. MTE 7. Petitioner next argues that “the portions of Dr. Bates’ redirect testimony that Petitioner seeks to exclude from the record . . . have no bearing on ‘matters affecting the witness’s credibility.’” *Id.* at 8 (citations omitted). According to Petitioner, Patent Owner “does not rely on Dr. Bates’ testimony to counter a challenge to his credibility.” *Id.* Petitioner also contends that 37 C.F.R.

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§ 42.53(d)(5)(ii) “similarly prevents a party from expanding the scope of redirect examination beyond that of cross-examination.” *Id.* at 9.

In opposition, Patent Owner argues Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner asserts the Consolidated Trial Practice Guide provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or *otherwise exceeds the proper scope* of reply or sur-reply, it may request authorization to file a motion to strike.” Pet. MTE Opp. 2 (citing PTAB Consolidated Trial Practice Guide (“CTPG”) 80 (PTAB Nov. 2019)). Patent Owner contends that “Petitioner’s counsel reserved the right to strike Dr. Bates’ redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of [Patent Owner] submitting its Sur-Reply.” *Id.* at 2–3 (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact, ***inadmissible***,” only that it “should be excluded (not stricken) because it is beyond the scope of its cross-examination.” *Id.* at 4. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–243:2).

In reply, Petitioner contends it “properly focused its motion to exclude on the portions of Dr. Bates’ inadmissible re-direct deposition testimony cited in [the] Sur-Reply,” and that Patent Owner “uses its Sur-Reply as no

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more than a ‘vehicle’ to enter new evidence into the record.” Pet. MTE Reply 1. Petitioner contends that it “timely objected at the deposition” once Patent Owner began “improperly elicit[ing] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Rule 611(b). *Id.* (citing Pet. MTE § II.B.2 (discussing Fed. R. Evid. 611(b))).

For the following reasons, we deny Petitioner’s Motion to Exclude.

The CTPG provides that “[a] motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay)” but should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.” CTPG 79. Further, the CTPG clearly distinguishes a motion to exclude evidence from a motion to strike evidence. The CTPG states that, “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike.” *Id.* at 80. As an alternative to a motion to strike, “a party may request authorization for further merits briefing . . . to address the merits of any newly-raised arguments or evidence.” *Id.* A party must seek authorization to file a motion to strike “within one week of the allegedly improper submission.” *Id.* at 81.

As noted in the CTPG, motions to strike are intended to address, *inter alia*, whether a brief raises new issues or exceeds the proper scope of a sur-reply. Here, Petitioner argues that the redirect testimony is inadmissible under Rule 611(b) and/or 37 C.F.R. § 42.53(d)(5)(ii) as exceeding the scope of cross-examination. But, Petitioner does not seek to exclude all redirect

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testimony on secondary considerations, only the testimony relied on by Patent Owner in the Sur-reply. Pet. MTE 5 n.2.

The issue presented here borders on the proper scope of a motion to exclude as compared to a motion to strike. The goal of Petitioner's Motion is clearly to undercut arguments raised in Patent Owner's Sur-reply directed to objective indicia of nonobviousness. By limiting its Motion to only the portions of Dr. Bates's redirect examination actually relied on in Patent Owner's Sur-reply, Petitioner's arguments reflect this goal. *See, e.g.*, Pet. MTE 5 n.2 ("Although all of Dr. Bates' redirect testimony on secondary considerations was outside the scope of Petitioner's cross-examination, Petitioner narrowly focuses this motion on excluding only those portions that [Patent Owner] relies on in its Sur-Reply."). One way in which Petitioner could have challenged the arguments raised in Patent Owner's Sur-reply is by requesting authorization to file a motion to strike, which, as noted above, is intended for the purpose of addressing arguments a party believes exceeds the proper scope of a sur-reply. *See* CTPG 80. Petitioner did not request such authorization. Instead, by seeking to exclude some of Dr. Bates's redirect testimony on objective indicia (i.e., the portions relied on in Patent Owner's Sur-reply), Petitioner seeks to undercut the arguments raised in Patent Owner's Sur-reply on objective indicia by effectively removing the primary evidentiary support for those arguments. Were we to grant Petitioner's Motion to Exclude, we would be faced with determining what to do with Patent Owner's arguments in the Sur-reply, which would remain of record because they are not the subject of Petitioner's Motion to Exclude (nor could they be based on the CTPG) and (as previously noted) Petitioner did not also file a motion to strike those arguments. The best

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course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Rule 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination (just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony³⁰), Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of nonobviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the circumstances presented here and in light of the little weight to which Patent Owner's argument and Dr. Bates's redirect is entitled, we determine that the better course at this stage is to deny Petitioner's Motion to Exclude.

VI. SUMMARY

For the reasons discussed above, Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–14 of the '024 patent are unpatentable.

³⁰ There are exceptions, e.g., questions pertaining to a witness's credibility. See Fed. R. Evid. 611(b).

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Our conclusions regarding the Challenged Claims are summarized below:

Claims Challenged	35 U.S.C. §	Reference(s) /Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–5, 7–14	103(a)	Sullivan995, Sullivan460	1–5, 7–14	
6	103(a)	Sullivan995, Sullivan460, Matthews	6	
1–5, 7–14	103(a)	Rapoport502, Sullivan460 ³¹		
6	103(a)	Rapoport502, Sullivan460, Matthews ³²		
Overall Outcome			1–14	

VII. ORDER³³

In consideration of the foregoing, it is:

ORDERED that Patent Owner's Motion to Exclude (Paper 47) is *denied*;

³¹ For the reasons explained above, we do not reach this alternative ground because we determine that claims 1–5 and 7–14 are unpatentable based on Petitioner's first ground, relying on the combination of Sullivan995 and Sullivan460.

³² For the reasons explained above, we do not reach this alternative ground because we determine that claim 6 is unpatentable based on Petitioner's second ground, relying on the combination of Sullivan995, Sullivan460, and Matthews.

³³ Should Patent Owner wish to pursue amendment of a challenged claim in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the Notice Regarding

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FURTHER ORDERED that Petitioner's Motion to Exclude
(Paper 48) is *denied*;

FURTHER ORDERED that claims 1–14 of U.S. Patent
No. 10,384,024 B2 are determined to be unpatentable; and

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

Options for Amendments by Patent Owner Through Reissue or
Reexamination During a Pending AIA Trial Proceeding, 84 Fed.
Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue
application or a request for reexamination of the challenged patent, we
remind Patent Owner of its continuing obligation to notify the Board of any
such related matters in updated mandatory notices. *See* 37 C.F.R.
§§ 42.8(a)(3), (b)(2).

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Paper 69
Date: December 7, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

IPR2022-00993
Patent 6,988,994 B2

Before BART A. GERSTENBLITH, JAMES A. TARTAL, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

GERSTENBLITH, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

ORDER
Denying Patent Owner's Motion to Exclude (Paper 49) and
Denying Petitioner's Motion to Exclude (Paper 50)
37 C.F.R. § 42.64(c)

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I. INTRODUCTION

A. Background

ResMed, Inc. (“Petitioner”) filed a Petition (Paper 1) requesting institution of *inter partes* review of claims 1, 6, 7, 10–14, 19, 20, 23–30, and 32 (“the Challenged Claims”) of U.S. Patent No. 6,988,994 B2 (Ex. 1001, “the ’994 patent”). With our prior authorization (Paper 8), Petitioner filed a Motion to Correct the Petition (Paper 9), which New York University (“Patent Owner”) opposed (Paper 10). We granted Petitioner’s Motion to Correct the Petition (Paper 11), and Petitioner filed a Corrected Petition (Paper 12, “Pet.”).¹ Patent Owner filed a Preliminary Response (Paper 13). With our prior authorization, Petitioner filed a Reply to Patent Owner’s Preliminary Response (Paper 15), and Patent Owner filed a Sur-reply (Paper 16). Applying the standard set forth in 35 U.S.C. § 314(a), we instituted an *inter partes* review as to all claims and grounds set forth in the Petition. Paper 17 (“Inst. Dec.”).

After institution, Patent Owner filed a Patent Owner Response (Paper 34, “PO Resp.”), Petitioner filed a Reply (Paper 42, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 45, “Sur-reply”). Additionally, Patent Owner filed a Motion to Exclude (Paper 49, “PO MTE”), Petitioner filed an Opposition (Paper 53, “PO MTE Opp.”), and Patent Owner filed a Reply (Paper 54, “PO MTE Reply”). And Petitioner filed a Motion to Exclude (Paper 50, “Pet. MTE”), Patent Owner filed an Opposition (Paper 52, “Pet. MTE Opp.”), and Petitioner filed a Reply (Paper 55, “Pet. MTE Reply”). A consolidated oral hearing was held for this proceeding as

¹ Further references to “Petition” are to the Corrected Petition (Paper 12), unless otherwise indicated.

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well as six related proceedings, IPR2022-00988, IPR2022-00989, IPR2022-00990, IPR2022-00991, IPR2022-00992, and IPR2022-00994, on October 2, 2023, and the transcript is of record.² Paper 64.

We have jurisdiction pursuant to 35 U.S.C. § 6. This Decision is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of the Challenged Claims. Petitioner bears the burden of proving unpatentability of the Challenged Claims. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2021). Having reviewed the arguments and the supporting evidence, we determine that Petitioner has shown, by a preponderance of the evidence, that the Challenged Claims of the '994 patent are unpatentable.

B. Related Proceedings

The Parties identify *New York University v. ResMed Inc.*, No. 1:21-cv-00813-JPM (D. Del.), as a related matter. Pet. 1; Paper 6 (Patent Owner's Mandatory Notices), 2. Petitioner also states that it has filed petitions for *inter partes* review challenging claims of several patents related to the '994 patent in IPR2022-00988, IPR2022-00989, IPR2022-00990, IPR2022-00991, IPR2022-00992, and IPR2022-00994. *See* Pet. 1–2 (identifying the related patents).

² Each Party filed objections to the other party's demonstrative exhibits and hearing arguments along with responses to those objections. *See* Papers 61, 62, 65–68). Demonstrative exhibits and hearing arguments are not evidence and are not relied on as a basis of this Decision. Accordingly, the objections are denied as moot.

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C. Real Parties in Interest

Petitioner identifies only itself as a real party in interest. Pet. 1.

Patent Owner identifies only itself as a real party in interest. Paper 6, 2.

D. The Asserted Grounds of Unpatentability and Declaration Evidence

Petitioner challenges the patentability of claims 1, 6, 7, 10–14, 19, 20, 23–30, and 32 of the '994 patent on the following grounds:

Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
1, 6, 7, 10–14, 19, 20, 23–30, 32	103(a)	Rapoport502, ⁴ Sullivan460, ⁵ Matthews ⁶
1, 6, 7, 10–14, 19, 20, 23–30, 32	103(a)	Sullivan995, ⁷ Sullivan460, Matthews
1, 6, 7, 10–14, 19, 20, 23–30, 32	102(a), (b)	Sullivan995

Pet. 3–4. Petitioner supports its challenge with a Declaration of Dr. Khosrow Behbehani (Ex. 1003), a Substitute Declaration of Dr. Jason P.

³ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. §§ 102 and 103 that became effective on March 16, 2013. The '994 patent was filed on May 20, 1994. Ex. 1001, code (22). Accordingly, we apply the pre-AIA versions of §§ 102 and 103 here.

⁴ U.S. Patent No. 5,490,502, issued Feb. 13, 1996 (Ex. 1008, “Rapoport502”).

⁵ WO 01/05460 A1, published Jan. 25, 2001 (Ex. 1006, “Sullivan460”).

⁶ U.S. Patent No. 7,168,429 B2, issued Jan. 30, 2007 (Ex. 1007, “Matthews”).

⁷ U.S. Patent No. 5,245,995, issued Sept. 21, 1993 (Ex. 1005, “Sullivan995”).

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Kirkness in support of the Petition⁸ (Ex. 1046), and a Declaration of Dr. Jason P. Kirkness in support of Petitioner's Reply (Ex. 1051). Patent Owner supports its arguments with a Declaration of Dr. James Hamilton Tunstall Bates⁹ (Ex. 2003). Additionally, Petitioner cross-examined Dr. Bates and a two-part transcript of that deposition is of record. Exs. 1052, 1053. And, Patent Owner cross-examined Dr. Kirkness and a two-part transcript of that deposition also is of record. Exs. 2012, 2013.

E. The '944 Patent

The '994 patent is directed to a system and method for treating a sleeping disorder in a patient. Ex. 1001, code (54). As background, the '994 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." *Id.* at 1:7–10. According to the '994 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

⁸ The Petition was originally supported by the Declaration of Dr. Khosrow Behbehani (Ex. 1003). After institution, Petitioner informed the Board that Dr. Behbehani was unable to continue to serve as an expert in this proceeding (Paper 30), and, with our authorization (Paper 33), Petitioner replaced Dr. Behbehani with Dr. Kirkness, who adopted substantially the entirety of Dr. Behbehani's prior opinions. *See* Ex. 1046 ¶¶ 1, 28 (adopting paragraphs 20–28, 32–89, and 93–280 of Dr. Behbehani's Declaration). For consistency with the citations in the Petition, in this Decision we cite to the Declaration of Dr. Behbehani (Ex. 1003) with the understanding that the paragraphs we cite (and opinions expressed therein) were adopted by and, therefore, are attributable to Dr. Kirkness.

⁹ Dr. Bates provided corrections to citations in his declaration via email to Petitioner, which Petitioner then filed as Exhibit 1048.

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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 1:13–20. The '994 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS, and is now the standard of care.” *Id.* at 1:37–40. The '994 patent explains that PAP therapy is applied by a tight-fitting nasal mask worn during sleep (*id.* at 1:37–38), and 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” (*id.* at 1:57–59).

The '994 patent states 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, 1:44–46. 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 1:64–67. The '994 patent also states that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:11–12.

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Figure 1 of the '994 patent is reproduced below.

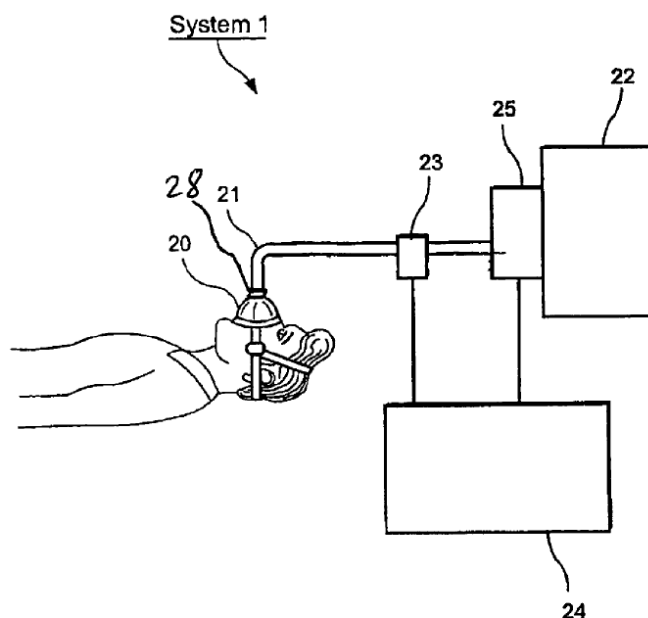


FIG. 1

Figure 1 “shows an exemplary embodiment of a system according to” the '994 patent. Ex. 1001, 2:63–65, 3:19–20. System 1, shown in Figure 1, includes mask 20, placed over the face of the patient, connected via tube 21 to receive airflow of a particular pressure from flow generator 22. *Id.* at 3:20–23. Conventional flow sensors 23 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 3:28–30. The '994 patent states that “[s]ignals corresponding to the airflow and/or the pressure are provided to a processing arrangement 24 for processing” and “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 3:32–36.

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Figure 2 of the '994 patent is reproduced below.

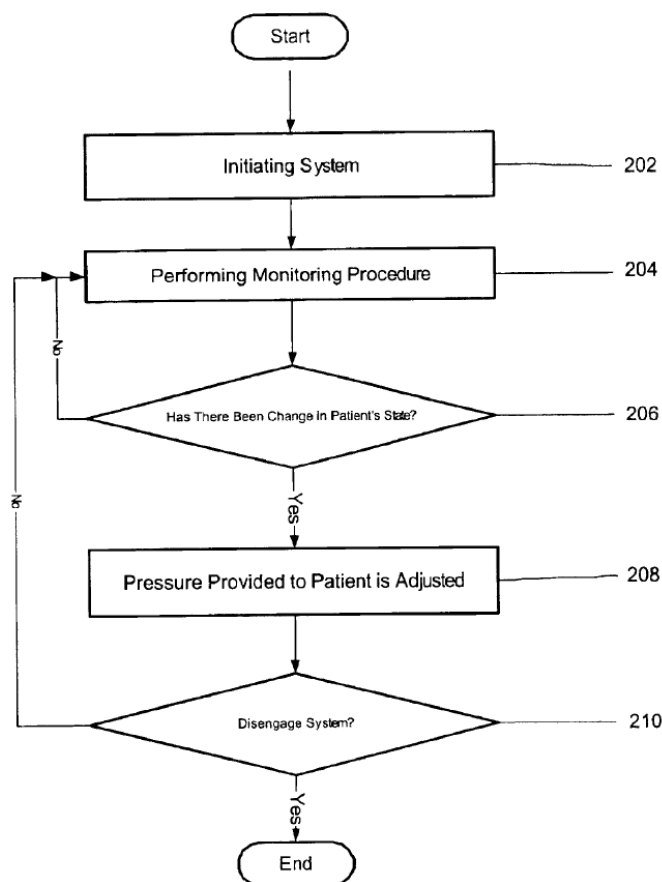


Fig. 2

Figure 2 of the '994 patent “shows an exemplary embodiment of a method . . . which utilizes the system shown in FIG. 1.” Ex. 1001, 2:65–67, 3:48–49. The '994 patent explains the following regarding the method shown in Figure 2. “In step 202, the patient initiates the system 1 by placing the mask 20 over his face and powering up the generator 22, the flow control device 25 and the processing arrangement 24.” *Id.* at 3:49–52. In step 204, “system 1 initiates a real-time monitoring procedure of the patient’s breathing patterns. The 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 3:52–58. The

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'994 patent teaches that “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 3:59–63. As explained by the '994 patent, “[s]uch determination can be made based on a number of different measurements. For example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG [electroencephalogram] data, breathing patterns, etc. in the determining the patient’s state.” *Id.* at 3:63–67.

The '994 patent further explains that, “[i]n step 206, the processing arrangement 24 determines whether there has been a change in the patient’s state.” Ex. 1001, 5:21–22. “For example, the processing arrangement 24 may determine if the patient was asleep and has been awakened; or the patient was awake and has fallen asleep. If there has been no change, the processing arrangement 24 continues with the monitoring procedures.” *Id.* at 5:22–27. The '994 patent explains that, “[i]f there has been a change in the patient’s state, the processing arrangement 24 adjusts the pressure to correspond to the patient’s current state (step 208).” *Id.* at 5:28–30. “For example, if the patient has been awakened and the patient’s breathing patterns indicate a period of troubled wakefulness . . . , the processing arrangement 24 may reduce the applied pressure provided to the patient during such period.” *Id.* at 5:30–34. The '994 patent explains that, “[o]n the other hand, if the patient has fallen asleep, the processing arrangement 24 may instruct the flow control device 25 to elevate the pressure to the level to be applied while the patient is asleep.” *Id.* at 5:44–47. In step 210, “the processing arrangement 24 determines whether instructions to disengage the

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system 1 have been given,” and, if so, “system 1 shuts down and ends all monitoring and flow generating activities. Otherwise, the system 1 continues with the monitoring procedure of step 204.” *Id.* at 5:66–6:6.

F. Illustrative Claim

Claims 1, 14, and 27–30 are the independent claims challenged in this proceeding. Claim 1 is illustrative of the claimed subject matter and is reproduced below with Petitioner’s bracketing added for reference (*see* Pet. 84 (Claims App.)):

1. A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:
 - [a] a generator supplying airflow and applying a pressure to an airway of a patient;
 - [b] a sensor measuring data corresponding to patient’s breathing patterns; and
 - [c1] a processing arrangement analyzing the breathing patterns to determine whether the breathing patterns are indicative of one of the following patient’s states: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state, [c2] the processing arrangement adjusting the applied pressure as a function of the patient’s state,
 - [d1] wherein, when the breathing patterns indicate one of states (i) and (ii) and (iii), the processing arrangement controls the generator to adjust the pressure to a first value and
 - [d2] wherein, when the breathing patterns indicate state (iv), the processing arrangement controls the generator to adjust the pressure to a second value.

Ex. 1001, 6:22–41.

G. Level of Ordinary Skill in the Art

Petitioner, supported by Dr. Kirkness’s testimony, proposes that a person of ordinary skill in the art at the time of the invention would have had

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“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.” Pet. 15 (citing Ex. 1003 ¶ 90). Petitioner asserts that “[a]dditional experience could substitute for less education, and additional education could likewise substitute for less experience.” *Id.* (citing Ex. 1003 ¶ 90).

Patent Owner “does not object” to Petitioner’s definition of a person of ordinary skill in the art, which we adopted preliminarily in our Institution Decision. PO Resp. 12.

Based on the complete record before us, we find (as we did in the Institution Decision) that Petitioner’s uncontested level of ordinary skill in the art is consistent with the level of ordinary skill in the art reflected by the ’994 patent and the prior art of record. *See* Inst. Dec. 9 (citing *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978)). Therefore, we maintain and reaffirm our adoption of Petitioner’s uncontested level of ordinary skill in the art.

II. CLAIM CONSTRUCTION

In this *inter partes* review, claims are construed using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.100(b) (2021). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing claims in accordance with their ordinary and customary meaning, we take

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into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thornerv. Sony Comput. Entm’t. Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only 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))).

A. “troubled wakefulness”

The term “troubled wakefulness” is recited in each of the Challenged Claims either expressly or via dependency. Petitioner proposes that we construe “troubled wakefulness” to mean a “state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.” Pet. 16 (citing Ex. 1003 ¶ 94). Petitioner contends that “[t]his term is not an industry standard term and was coined in the

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'994 Patent.” *Id.* (citing Ex. 1003 ¶ 95). Petitioner explains that the construction of the term “is derived directly from the specification, which describes ‘troubled wakefulness’ as a state ‘in which the breathing pattern is characterized by irregularity [sic] 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.* (quoting Ex. 1001, 4:27–32) (citing Ex. 1001, Fig. 7).

Patent Owner agrees with Petitioner’s construction, noting that “this term is not in dispute.” PO Resp. 30.

We adopt Petitioner’s undisputed construction of “troubled wakefulness” because it is supported by and consistent with the Specification’s description of the term. *See, e.g.*, Ex. 1001, 4:27–32.

B. “when the breathing patterns indicate one of states (i) and (ii) and (iii), . . . adjust the [supplied] pressure to a first value”

Petitioner proposes that we construe this phrase, which is recited expressly in independent claims 1 and 14.¹⁰ Petitioner contends that this phrase means “adjust the [supplied] pressure to a first value when the breathing patterns indicate states (i), (ii), or (iii).” Pet. 16 (alteration in original) (citing Ex. 1003 ¶ 98). Petitioner relies on the Specification of the

¹⁰ Claim 1 recites “adjust the pressure,” whereas claim 14 recites “adjust the supplied pressure.” *Compare* Ex. 1001, 6:38–39 (claim 1), *with id.* at 7:41–42 (claim 14). Neither party suggests any critical difference between this language of each claim, and claim 1 makes it clear that a generator supplies airflow and applies a pressure to an airway of a patient (*id.* at 6:25–26 (“a generator supplying airflow and applying a pressure to an airway of a patient”)), suggesting that the pressure that is adjusted to a first value is the pressure supplied by the generator.

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'994 patent in support of its proposed construction. *Id.* at 16–17 (citing Ex. 1001, 5:58–65, 6:7–14).

Patent Owner agrees with Petitioner's construction, noting that “this term is not in dispute.” PO Resp. 30.

We adopt Petitioner's undisputed construction of this phrase because it is supported by and consistent with the Specification for the reasons explained by Petitioner, which we adopt. *See* Pet. 16–17 (citations omitted).

C. “*analyzing the breathing patterns*”

In the Patent Owner Response, Patent Owner first proposes this phrase for construction and contends that this phrase “appears in Claims 1 and 28.” PO Resp. 30. Patent Owner is correct that this phrase appears in claim 1 (*see* Ex. 1001, 6:29 (“a processing arrangement *analyzing the breathing patterns*” (emphasis added))), but the same phrase is not recited in claim 28. Rather, the same phrase is recited in claim 27 (*see id.* at 8:45), but a different, yet similar, phrase is recited in claim 28 (*see id.* at 8:58 (“analyzing data corresponding to the breathing patterns”)). Claim 14 also recites a similar phrase “analyzing with the processing arrangement the data corresponding to the breathing patterns” (*id.* at 7:31–32), and, although different, we note that Patent Owner considers its arguments applicable in some manner to the following recitations from claim 29 (“a processing arrangement determining whether the breathing patterns” (*see id.* at 9:3–4)) and claim 30 (“determining, based on the data, whether the breathing patterns” (*see id.* at 10:3–4)).¹¹ Sur-reply 2 n.5 (asserting, without

¹¹ In the Patent Owner Response, Patent Owner identifies only claims 1 and 28 as containing this phrase and does not mention any of independent claims 14, 27, 29, and 30. PO Resp. 30. In its Reply, Petitioner points out

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explaining, that the other independent claims also recite similar terms regarding “breathing patterns”).

In the Petition, Petitioner did not expressly construe “analyzing the breathing patterns” or other variations of this phrase recited in the Challenged Claims, but did analyze and address the prior art to identify the teachings of the prior art that Petitioner contends teach these limitations of the claims. *See, e.g.*, Pet. 52–61 (discussing element 1[c1] in the context of Ground 2).

For purposes of analyzing the Parties’ arguments, we consider the language of claim 1, which recites, *inter alia*,

the same omission by Patent Owner, although Petitioner adds claim 14. Pet. Reply 2 n.1 (including claim 14 in its chart with claims 1 and 28, but noting that Patent Owner does not discuss claims 29, 30, and 32). Patent Owner responds in its Sur-reply by identifying (for the first time) claim 14 as reciting “analyzing . . . the breathing patterns,” and asserting that claims 29, 30, and 32 include phrases specifying that “breathing patterns are still analyzed to determine the asleep or awake state.” Sur-reply 2 n.5. It is unclear why Petitioner and Patent Owner identify claim 32 in their lists (as claim 32 depends from claim 30), and yet do not include claim 27 (which is one of the six independent claims). Nonetheless, we disagree with Patent Owner because independent claims 29 and 30 do not include any express recitation of “analyzing” breathing patterns. Rather, each of those claims include “determining” something about the breathing patterns as opposed to “analyzing” them. These differences are not insignificant because each of the other independent claims (i.e., claims 1, 14, 27, and 28) also includes a “determining” clause that follows their recited “analyzing” clauses. Regardless, for purposes of this Decision, we consider Patent Owner’s argument as applicable to each of the independent claims even though a finding of waiver would also be appropriate because Patent Owner did not propose construing any similar terms recited in independent claims 14, 27, 29, and 30 in its Patent Owner Response. *See* Paper 18, 9 (noting that **“Patent Owner is cautioned that any arguments not raised in the response may be deemed waived”**).

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a processing arrangement *analyzing the breathing patterns* to determine whether the breathing patterns are indicative of one of the following patient's states: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state, the processing arrangement adjusting the applied pressure as a function of the patient's state.

Ex. 1001, 6:29–35 (emphasis added).

In the Patent Owner Response, Patent Owner argues that “analyzing the breathing patterns” means “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 30. As borne out through Patent Owner's arguments in response to Petitioner's challenges and as further elaborated in Patent Owner's Sur-reply, Patent Owner contends that “analyzing the breathing patterns” requires analysis of “both the amplitude and the temporal structure.” PO Resp. 37–38; Sur-reply 3–5.

Petitioner disputes this proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2; *see id.* at 2–10. For the reasons that follow, we agree with Petitioner.

1. The Parties' Contentions

To explain why the claim phrase should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the [S]pecification” of the '994 patent. PO Resp. 31 (citing Ex. 1001, 2:12–19; Ex. 2003 ¶ 134); *see also* Sur-reply 13 (arguing that according to Dr. Bates “‘breathing patterns’ has no ordinary meaning and ‘is an extremely general term’”) (citing Ex. 1052, 108:25–

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109:1–7¹²). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apnea and hypopnea in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters and the order in which they appear in time.” *Id.* (citing Ex. 2003 ¶ 135).

Patent Owner points to the description of Figures 7 and 8 of the ’994 patent in support of its construction. PO Resp. 31–32 (citing Ex. 1001, 4:27–35, 2:58–5:7¹³; Ex. 2003 ¶¶ 136–138). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient’s airflow, but no periodic irregularity in breath size. Ex. 1001, 4:27–32. Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. *Id.* at 4:58, 4:65–5:4.

According to Patent Owner, “[t]his methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns” and focuses “on a determination of ‘the

¹² In some instances where Patent Owner cites to testimony that carries over to a second page of a transcript, Patent Owner uses a format such as “108:25 – 109:1-7,” as reflected above. We understand Patent Owner to mean the entire range in each of these instances, e.g., in the citation above, 108:25–109:7. In the future, we suggest Patent Owner use a conventional citation form covering the full range (e.g., 108:25–109:7) to avoid potential confusion.

¹³ Patent Owner includes what it purports to be a block quote from the ’994 patent from column 2, line 58, through column 5, line 7. The actual citation begins at column 4, not column 2.

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sequence of parameters of a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time.” PO Resp. 31–32 (citing Ex. 2003 ¶ 137); *see also* Sur-reply 4 (citing Ex. 1001, 4:27–35; Ex. 2003 ¶ 136) (asserting that “[b]oth amplitude and temporal structures are likewise described when examining specific flow waveforms”). Patent Owner further argues that the description of Figure 8 in the Specification “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 32 (citing Ex. 1001, 2:58–5:7; Ex. 2003 ¶ 138); *see* Sur-reply 5–12.

Additionally, Patent Owner suggests the Specification’s discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. PO Resp. 32–33 (citing Ex. 1001, 6:7–13; Ex. 2003 ¶ 139).

Turning to the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’994 Patent.” Sur-reply 2; *see also id.* at 8–14 (arguing that distinguishing troubled wakefulness from REM sleep requires assessing both amplitude and temporal structure). First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” Sur-reply 3 (quoting Ex. 1001, 4:12–19) (citing Ex. 2003 ¶ 134). Patent Owner maintains that the descriptions of the

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waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of waveforms. *Id.* at 4–7 (citing Ex. 1001, 4:27–35, 4:65–5:7, 6:7–13; Ex. 1052, 30:15–21, 44:6–20, 81:17–23, 108:20–24, 178:24–25, 179:1–22, 179:23–25, 180:1–15; Ex. 2003 ¶¶ 134–139). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’994 Patent,” but contends that “these are not obligatory.” *Id.* at 5. Patent Owner asserts that enablement of the ’994 patent “hinges on its ability to distinguish between all awake and asleep states,” “[o]therwise, incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 6.

Second, Patent Owner asserts that during the prosecution of a related patent, the applicant responded to a rejection by arguing that the prior art, in that instance, “failed to discern between regular wakefulness and troubled wakefulness.” Sur-reply 6 (citing Ex. 1009, 404). Patent Owner argues that it is necessary to integrate “both amplitude and temporal structure analyses to distinguish all awake and asleep states.” *Id.*

Third, Patent Owner argues that “patentees do not need to rigidly define terms, but can imply their own meaning.” Sur-reply 6 (citing *AstraZeneca AB v. Mut. Pharm. Co.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004); *AIA Eng’g, Ltd. v. Magotteaux Int’l S/A*, 657 F.3d 1264, 1276 (Fed. Cir. 2011)). Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by Figure 7 – a flow waveform indicating troubled wakefulness.” *Id.* at 7 (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the Specification “provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “[s]ince

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‘analyses the data’ is followed by ‘to determine the patient’s breathing patterns,’ some of which occur in the asleep state and some of which occur in the awake state, this further implies that these states can be separated from one another.” *Id.* (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22).

Patent Owner contends that, “[g]iven the separation between awake and asleep states discussed in the ’994 Patent, [Patent Owner’s] construction is integral for discerning the difference and applying the correct pressure” because without doing so, it “could result in inappropriate pressure administration.” *Id.* (citing Ex. 1052, 179:23–25; Ex. 2003 ¶ 139).

Patent Owner also argues that extrinsic evidence supports its proposed construction. Sur-reply 7–12. Based on Dr. Bates’s testimony, Patent Owner asserts that “by assessing *only amplitude*” the waveforms of troubled wakefulness and REM sleep “appear indistinguishable,” but “their temporal structure (order in time) . . . offers differentiation.” *Id.* at 9 (citing Ex. 2003 ¶ 69). Patent Owner asserts that its argument is correct, alleging that if the “temporal structure” of the REM sleep waveform is “rearranged in time,” the resulting “time series has a random appearance that *cannot be distinguished* from troubled wakefulness.” *Id.* at 10 (citing Ex. 2003 ¶ 70). Patent Owner reasons that “amplitude structure and temporal structure convey independent information” and both must be considered in an analysis or “the awake and asleep states can be confused.” *Id.* (citing Ex. 2003 ¶ 63). According to Patent Owner, it is “Dr. Bates’ illustrations [that] present the problem solved by the ’994 Patent.” *Id.* at 11.

According to Patent Owner, construing “analyzing breathing patterns” to include “any type” of breathing pattern analysis, as suggested by

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Dr. Kirkness, is “nonsensical, as it might even encompass using a mirror to check for breaths.” Sur-reply 12–13 (citing Ex. 1051 ¶ 16).¹⁴

Specifically, Patent Owner argues

Dr. Bates examined the specification to determine which breathing characteristics were crucial to analyzing the breathing pattern with respect to the invention’s essence. [Ex. 1052], 24:20-25, 25:1-13. He determined that a [person of ordinary skill in the art], after reading the ’994 Patent, would understand that analyzing breathing patterns must confer the ability to distinguish between troubled wakefulness and REM sleep. *Id.*, 111:22-25 – 112:1-21. [Patent Owner’s] construction evidences the understanding of a [person of ordinary skill in the art] – that analyzing breathing patter[n]s requires analysis of amplitude and temporal structures.

Sur-reply 13 (footnote added).

Petitioner proposes that we construe the phrase in accordance with its plain and ordinary meaning because “[n]othing in the intrinsic record limits the ‘analyzing the breathing patterns’ term to analysis of either or both amplitude and temporal structures—instead, the claims, specification, and prosecution history use this term in accordance with their plain meaning.” Pet. Reply 4 (citing *CCS Fitness*, 288 F.3d at 1366). Petitioner asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the

¹⁴ Patent Owner also states that “Dr. Kirkness argues that the ’994 Patent is indefinite, regarding the measurement of airflow waveforms and temporal/amplitude aspects” and that “Petitioner has never raised indefiniteness.” Sur-reply 11 (citing Ex. 1051 ¶¶ 27–30; Pet. Reply 9–10). We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths” (*see* Sur-reply 13).

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specification or during prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” *Id.* at 6 (quoting *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* at 6–7. Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, ‘the patentee must clearly express an intent to redefine the term.’” *Id.* at 7 (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends “[n]o such intent exists here” and Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* (citing Ex. 1051 ¶ 24).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner’s] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as “propos[ing] a lengthy construction . . . and then constru[ing] its own construction to inject two requirements: that the processor must analyze (1) ‘the value[s] of the parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.* (third alteration in original) (citing PO Resp. 8–10, 30–31; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record, or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert decided based on his personal experience, as opposed to that of a” person of ordinary skill in the art. *Id.* (citing Ex. 1053, 271:10–14).

Responding to Patent Owner’s citations to the Specification, Petitioner contends that the Specification “further confirms that the terms encompass any type of breathing pattern analysis” and “states that ‘[t]here

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are a number of characteristics of the patient's breathing patterns that may be taken into account in making such a determination' . . . and does not limit the analysis to any particular characteristic." Pet. Reply 5 (first alteration in original) (citing Ex. 1001, 2:19–22, 3:64–4:3, 4:27–35, 4:67–5:4, Figs. 3–8; Ex. 1051 ¶¶ 16–24; Ex. 1052, 28:4–30:21; Ex. 2003 ¶¶ 48–49). Petitioner also contends that "[t]he specification further states that the flow sensors 'detect the rate of airflow' to and from the patient, and provide '[s]ignals corresponding to the airflow' to a processing arrangement for processing." *Id.* (second alteration in original) (citing Ex. 1001, 3:28–33). Thus, Petitioner asserts the Specification "confirms that temporal analysis is not required." *Id.*

Petitioner also addresses the prosecution history of patents related to the '994 patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5–6. Petitioner asserts that, in responding to different office actions, the applicant did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1009, 404; Ex. 1054, 91, 128).

Next, Petitioner contends Patent Owner's extrinsic evidence, in the form of Dr. Bates's testimony, contradicts the intrinsic record and should be disregarded. Pet. Reply 7–10. Petitioner asserts Dr. Bates "performed a 'crude' analysis by 'approximating' the amplitudes of each breath in the figures 'estimat[ing] by eye . . . the size of those individual breaths.'" *Id.* at 7 (first alteration in original) (citing Ex. 1052, 75:11–76:14, 78:16–79:19). Petitioner argues that Dr. Bates's "analysis has no basis in the patent." *Id.* Petitioner presents five arguments in rebuttal to the testimony of Dr. Bates:

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(1) Dr. Bates’s analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the ’994 patent would have derived [Patent Owner’s] construction.” *Id.* (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* at 8 (citing Ex. 1052, 75:11–76:14, 78:16–79:19, 90:8–91:11).

(2) Dr. Bates’s analysis is based on his own expertise in “digital signal processing,” not from the viewpoint of a person of ordinary skill in the art who would not necessarily have such experience. *Id.* (citing Ex. 1052, 25:3–27:6, 52:2–25, 64:4, 208:16–21; Ex. 1053, 240:8–242:8, 243:3–8).

(3) Dr. Bates’s analysis contradicts the ’994 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM sleep without requiring temporal analysis. *Id.* at 8–9 (citing Ex. 1001, 4:27–35; 4:67–5:4; Ex. 1056, 9:55–10:3 (claim 5), 10:20–24 (claim 8); Ex. 1051 ¶¶ 25–33).

(4) “Dr. Bates admitted Figures 7–8 are merely exemplary.” *Id.* at 9 (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do not limit the broader claim terms of the patent.” *Id.* (citing, *inter alia*, *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004)).

(5) Dr. Bates “could not explain ‘parameter’ or provide an objective basis to define a ‘sequence’ and ‘series’ used in [Patent Owner’s] construction” and “admitted that [Patent Owner’s] construction would exclude breathing patterns recited in dependent claims.” *Id.* at 10 (citing Ex. 1052, 182:1–184:19, 247:5–11, 288:14–289:3). Thus, Petitioner asserts

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we “should discount []expert testimony that is clearly at odds . . . with the written record of the patent.” *Id.* (first alteration in original) (quoting *Phillips*, 415 F.3d at 1318).

2. Analysis

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14. Claim 1 recites, *inter alia*, “a processing arrangement *analyzing the breathing patterns* to determine whether the breathing patterns are indicative of one of the following patient’s states: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state, the processing arrangement adjusting the applied pressure as a function of the patient’s state.” Ex. 1001, 6:29–35 (emphasis added). As reflected, claim 1 does not recite “a sequence of parameters” or “a series of breaths” or “examining the values of the parameters and the order in which they appear in time” or any analysis of amplitude or temporal structure. Rather, this portion of claim 1 recites that the processor analyzes the data, without specifically reciting how the analysis is performed. The claim phrase does, however, recite the purpose of the analysis—to determine whether the breathing patterns are indicative of one of the four recited states—but does not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a significant number of limitations neither expressly recited nor suggested by the specific language of the phrase.

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citation

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omitted). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech.*, 923 F.3d at 1044.

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of the disputed phrase, nor does Patent Owner argue that it explicitly defined the phrase in the Specification. PO Resp. 30–33. We agree that there is no disavowal nor any explicit lexicographic definition of “analyzing the breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we should construe the phrase as Patent Owner proposes. PO Sur-reply 2, 6–7 (citing, *inter alia*, *AstraZeneca AB*, 384 F.3d 1333 (Fed. Cir. 2004)). We disagree.

In *AstraZeneca AB*, the United States Court of Appeals for the Federal Circuit reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d 1333, 1339–40 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors

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“deliberately acted as their own lexicographers” to limit the claim term “solubilizer” to surfactants, the Federal Circuit explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The Federal Circuit rejected AstraZeneca’s argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

The Specification of the ’994 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to “a sequence of parameters” (PO Resp. 30) or an analysis of “both the amplitude structure and the temporal structure of a breath-by-breath parameter time series” (*id.* at 37) or any of the other terms set forth in the proposed construction. *See id.* at 30–32. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. *See* Pet. Reply 7 (“[T]he terms ‘amplitude’ and ‘temporal’ do not appear anywhere.”); Sur-reply 5 (“Petitioner observes that terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’994 Patent.”); *see also* Ex. 1051 ¶ 24 (Dr. Kirkness stating that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’994 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures”). Patent Owner directs us to a portion

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of the Specification that Patent Owner characterizes as the process of analyzing breathing patterns. PO Resp. 31 (quoting Ex. 1001, 2:12–19). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” *Id.* (citing Ex. 1001, 2:12–19; Ex. 2003 ¶ 134). The cited text does not describe analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how “processing arrangement 24 makes a determination as to the 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).” Ex. 1001, 3:59–63. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns, etc. in determining the patient’s state.” *Id.* at 3:63–67. There is no mention that analyzing breathing patterns requires analysis of a sequence of parameters and the order in which they appear in time or an analysis of amplitude and temporal aspects of the waveform. The Specification further describes, in an embodiment, that “processing arrangement 24 [can determine] whether there has been a change in the patient’s state.” *Id.* at 5:21–22. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal aspects of the waveform.

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Patent Owner relies on Figures 7 and 8 to support its argument that analysis of “both the amplitude and temporal structures of a breath-by-breath parameter time series” is required to distinguish between an awake state and a sleep state, including troubled wakefulness and REM sleep. PO Resp. 37; Sur-reply 8 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Figures 7 and 8, however, depict one particular example of an awake state (i.e., troubled wakefulness) and one particular example of a sleep state (i.e., REM sleep), respectively. Ex. 1001, 3:11–16. But Patent Owner’s analysis does not address Figures 3–6 of the ’994 patent. PO Resp. 30–32; Sur-reply 2–15. Figures 3 and 4 show waveforms of a patient during “regular wakefulness” and “regular sleep,” respectively. *Id.* at 3:1–5. Figures 5 and 6 show waveforms from a sleeping patient indicative of “hypopnea” and “repetitive obstructive apnea,” respectively. *Id.* at 3:6–10. Patent Owner provides no evidence or explanation why amplitude and temporal aspects of a waveform are required to distinguish regular wakefulness from regular sleep or hypopnea or repetitive obstructive apnea.¹⁵

¹⁵ Patent Owner points to an argument during prosecution of a related patent contending it supports Patent Owner’s claim construction. Sur-reply 6. That argument stated that the prior art reference “does not teach or suggest a processing arrangement that distinguishes between regular wakefulness and troubled wakefulness,” but it did not refer to anything even close to resembling the construction proposed by Patent Owner or the concepts of amplitude and temporal structures. Ex. 1009, 404. Thus, this portion of the prosecution history of a related patent does not support Patent Owner’s position here.

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Having reviewed the intrinsic evidence, we next consider the extrinsic evidence, and specifically the testimony of Dr. Bates.¹⁶ Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 30–32 (citing Ex. 1001, 2:12–19, 2:58–5:7,¹⁷ 6:7–13; Ex. 2003 ¶¶ 134–139). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. *See* Ex. 2003 ¶¶ 134–139. Rather, Dr. Bates reads portions of the Specification and extrapolates (by taking several unsupported leaps) that the ’994 patent “implicitly demands certain parameter measurements.” Sur-reply 7 (citing Ex. 1052, 44:6–20).

Although expert testimony is legitimate to consider when construing claims, the Federal Circuit has cautioned that because it “is generated at the time of and for the purpose of litigation,” it “can suffer from bias that is not present in intrinsic evidence.” *Phillips*, 415 F.3d at 1318. And, extrinsic evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* at 1317 (internal quotation marks and citations omitted). In the context presented here, Dr. Bates’s testimony is not supported sufficiently by the intrinsic record or other extrinsic evidence (e.g., objective extrinsic evidence) and, therefore, even though we have considered it fully, we give it little weight.

¹⁶ Although the Parties briefly address the prosecution history of patents related to the ’994 patent, we do not find the discussion thereof informative on this issue.

¹⁷ As noted above, this citation should be “4:58–5:7.”

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For the reasons explained above, we determine that Patent Owner did not implicitly define the phrase “analyzing the breathing patterns,” as proposed, because Patent Owner has failed to show any sufficient evidence that the ’994 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner’s contentions in light of all the evidence of record, we do not adopt Patent Owner’s proposed construction; instead, we apply the plain and ordinary meaning of “analyzing the breathing patterns” in our consideration of the issues before us.¹⁸

D. Other Claim Terms

The Parties do not dispute the construction of any other claim terms, and we find that no other terms require express construction to resolve the controversy between the Parties. Accordingly, we do not construe any other claim terms expressly. *See Realtime Data*, 912 F.3d at 1375 (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs.*, 200 F.3d at 803)).

¹⁸ As noted above, we also apply the plain and ordinary meaning to the other independent claims, which recite the same (claim 27), similar (claims 14 and 28), or allegedly similar (claims 29 and 30) language.

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III. ANALYSIS

A. *Legal Standards – Obviousness*

The United States Supreme Court set forth the framework for applying the statutory language of 35 U.S.C. § 103 in *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966):

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

The Supreme Court explained in *KSR International Co. v. Teleflex Inc.* that

[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (alteration in original)).

“Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1327 (Fed. Cir. 2016) (citations omitted).

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“[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan ‘would have had a reasonable expectation of success from doing so.’” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

*B. Ground 2: Obviousness over Sullivan995, Sullivan460, and Matthews*¹⁹

Petitioner asserts that the combination of Sullivan995, Sullivan460, and Matthews would have rendered the subject matter of the Challenged Claims obvious to one of ordinary skill in the art at the time of the invention. Pet. 3, 46–77. Patent Owner contends: the proposed combination fails to teach all of the limitations of the claims, there is no motivation to combine the teachings of the references, one of ordinary skill in the art would not have a reasonable expectation of success in combining the teachings of the references, and objective indicia of nonobviousness supports its arguments as to the patentability of the Challenged Claims. PO Resp. 48–53; Sur-reply 20–24, 25–27.

1. Scope and Content of the Prior Art

a. 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

¹⁹ We briefly address Ground 1 below.

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airway collapses, particularly under the reduced pressure generated by inhalation.” *Id.* at 1:14–18. Figure 1A of Sullivan995 depicts snoring detection device 10 and is reproduced below. *Id.* at 8:47.

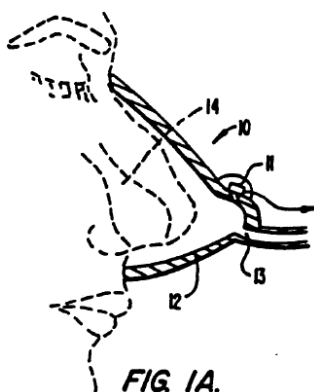


Figure 1A “is a schematic sectional view of one embodiment of a snoring detection apparatus.” *Id.* at 7:66–68. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a nose mask.” *Id.* at 8:47–49. Sullivan995 explains that “[a]ir, being inhaled by 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 example, 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.

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Figure 3 of Sullivan995 is reproduced below.

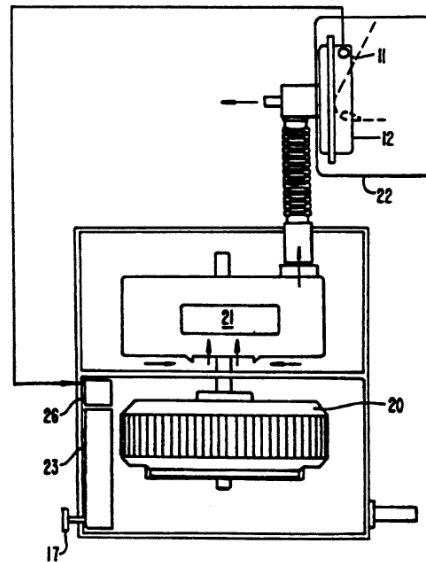


FIG. 3

Figure 3 shows a CPAP apparatus. Ex. 1005, 9:57–58. The CPAP apparatus 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 9:66–10:3. Sullivan995 explains,

[e]lectrical 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.

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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, at 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 device 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.

Figure 12 of Sullivan995 is reproduced below.

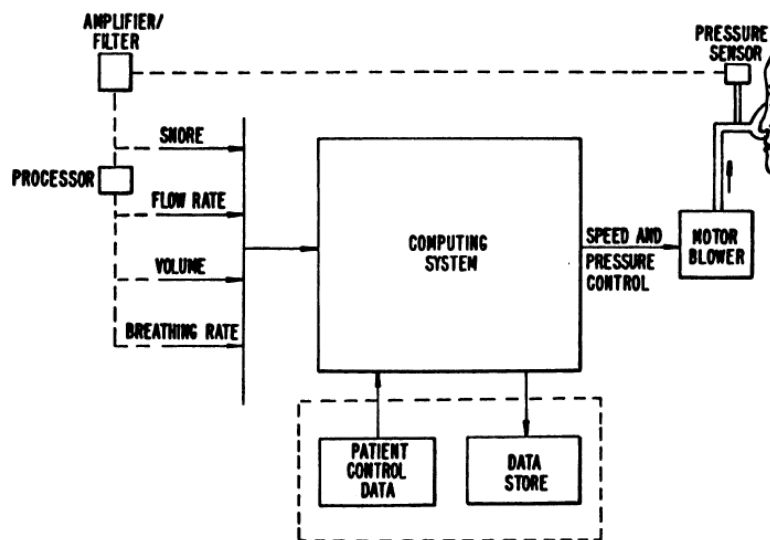


FIG. 12.

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

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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.

b. Sullivan460 (Ex. 1006)

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, 1:5–8.²⁰ Sullivan460 describes an embodiment in which its “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 [Sullivan995].”²¹ *Id.* at 6:22–24.

Sullivan460 describes two modes of delivery for the treatment means:

the 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

²⁰ For consistency with the citation style of the Parties, citations to Sullivan460 are to the native page numbers of the document, and not the page numbers added by Petitioner in the bottom, righthand corner of each page of Exhibit 1006.

²¹ Sullivan460 incorporates Sullivan995 by reference. Ex. 1006, 6:24–25.

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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 also 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 explains that “[t]his feature is an improvement over the prior art because as soon as the patient goes to sleep (as determined by an appropriate sensing algorithm in the treatment means), the second treatment mode is activated.” *Id.* at 7:10–12.

Figure 2 of Sullivan460 is reproduced below.

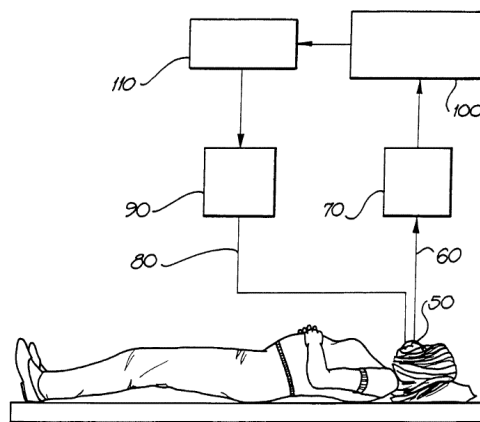


FIG. 2

“Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia.” Ex. 1006, 10:7–8. 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 10:9–10. 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

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10:10–12. 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.

c. 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.” 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.

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2. *Differences Between the Prior Art and the Claims*

a. *Claims 1 and 27*

Petitioner provides a detailed analysis of independent claims 1 and 27 as a group, mapping the teachings of the references to the claim elements.²² Pet. 48–66. Petitioner generally relies on Sullivan995 to disclose most of the recited elements of the claims. More specifically, Petitioner relies on Sullivan995 as teaching the preambles of each claim and Sullivan995’s microphone 11 and blower 21 for teaching the recited flow sensor and generator configured to supply airflow to an airway, respectively. Pet. 48–52 (citations omitted) (discussing the preambles and elements 1[a]/27[a] and 1[b]/27[b]). Patent Owner does not challenge Petitioner’s analysis and evidence showing that the preambles and elements 1[a]/27[a] and 1[b]/27[b] are met by Sullivan995. *See generally* PO Resp.

We find Petitioner’s arguments persuasive as to the preamble²³ and these elements of the claims and supported on the complete record before us, and, therefore, we adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that Sullivan995 teaches the preambles of claims 1 and 27 as well as elements 1[a]/27[a] and 1[b]/27[b].

²² Claim 27 does not recite the same number of elements as claim 1. Specifically, Petitioner analyzes the following clauses of claims 1 and 27 together: preambles, elements 1[a]/27[a], elements 1[b]/27[b], and elements 1[c1]/27[c]. Pet. 48–61. Thereafter, Petitioner addresses elements 1[c2], [1d1], and 1[d2], which do not have corresponding elements in claim 27. *See id.* at 61–66.

²³ We need not determine whether the preambles of claim 1 and 27 are limiting because we find, on the present record, that Petitioner has shown they are taught by Sullivan995.

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For element 1[c1]/27[c] (“a processing arrangement analyzing the breathing patterns to determine whether the breathing patterns are indicative of one of the following patient’s states: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state,”) Petitioner relies on the combined teachings of Sullivan995, Sullivan460, and Matthews.²⁴ Pet. 52–61.

Pointing first to Sullivan995, Petitioner contends it “discloses *a processing arrangement analyzing the breathing patterns*” and “further discloses analyzing *breathing patterns indicative of a regular breathing state and a sleep disorder breathing state.*” Pet. 52 (citing Ex. 1003 ¶ 200) (other citations omitted), 55 (citing Ex. 1003 ¶ 205) (other citations omitted). Specifically, Petitioner asserts “[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 is *a processing arrangement.*” *Id.* at 52–53 (footnotes omitted). Petitioner explains that “microphone 11 (*sensor*) provides its *measured data* to processor unit 26” and processor unit 26 “generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.” *Id.* at 52 (citing Ex. 1005, 10:3–6, 10:37–66, 11:55–62; Ex. 1003 ¶ 201). Petitioner contends Sullivan995’s microphone 11 “is able to detect ‘characteristic patterns of other respiratory parameters such as

²⁴ Petitioner’s arguments regarding the identification of these limitations are the same as its arguments for the identification of these limitations with respect to the asserted ground of unpatentability based on Rapoport502, Sullivan460, and Matthews. Pet. 54 (Petitioner referring to the arguments for these limitations with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews).

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rate of breathing, inhaled/exhaled air volume and inhaled/exhaled air flow rate’ that ‘can also be used for detecting apneas as well as the imminent onset of apneic episodes.’” *Id.* at 55–56 (citing Ex. 1005, 4:31–53).

Additionally, Petitioner points to Figure 2A of Sullivan995 asserting that “Part A of Figure 2A shows ‘normal breathing’ and is therefore (i) *a regular breathing state*” and “Part E of Figure 2A is indicative of sleep apnea and therefore (ii) *a sleep disorder breathing state*.” *Id.* at 57 (citing Ex. 1005, 9:16–32; Ex. 1003 ¶ 208; Ex. 1001, 4:10–14 (“[i]ndices of sleep disordered breathing include apnea”)). And Petitioner contends “Sullivan995 discloses a breathing pattern associated with a REM sleep state shown in Parts B and C of Figure 2A.” *Id.* at 58 (citing Ex. 1005, 16:35–36, 16:26–38, 16:38–40, 16:34–44; Ex. 1003 ¶ 219).

Petitioner then turns to Sullivan460 and Matthews, contending they “teach *determining whether a breathing pattern is indicative of a REM sleep state and a troubled wakefulness state*,” and relies on its arguments and evidence from the same discussion in the context of Ground 1. Pet. 58 (citing Pet. § VIII.C.4.a (discussing elements 1[c1]/27[c] in the context of Ground 1)). In this discussion from Ground 1, Petitioner asserts “Sullivan460 and Matthews together teach *determining the breathing patterns are indicative of a REM sleep state and a troubled wakefulness state*.” *Id.* at 25 (citing Ex. 1003 ¶ 119). Petitioner first points to Sullivan460, contending it teaches using a sleep sensor to determine “a wake state (which a [person of ordinary skill in the art] would have understood includes *a troubled wakefulness state*) and a sleep state (which a [person of ordinary skill in the art] understands includes *a REM sleep state*).” *Id.* (citing Ex. 1006, 7:3–7, 7:10–12, 7:17–19; Ex. 1003 ¶ 119). Petitioner

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asserts Sullivan460 “employs a ‘switching means [to] respond[] to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery’” . . . “a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep.” *Id.* (alterations in original except ellipses) (citing Ex. 1006, 6:30–7:12, claims 22–28, 43–46; Ex. 1003 ¶ 119).

Next, Petitioner turns to Matthews, asserting “Matthews teaches using the detection of erratic breathing to distinguish *a troubled wakefulness state*.” Pet. 25 (citing Ex. 1003 ¶ 120). According to Petitioner, “Matthews recognizes 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 “[t]o address potential instability, Matthews discloses ‘a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing.’” *Id.* at 25–26 (first alteration in original) (citing Ex. 1007, 21:37–40, 40:25–30). Petitioner contends:

Matthews’s disclosure of monitoring and detecting erratic or irregular breathing, meets the *determine whether a breathing pattern is indicative of a non-troubled wake state, a troubled wakefulness state and a REM sleep*. Further, it follows where Matthews detects no erratic breathing in a sleep state (as taught by . . . Sullivan460), Matthews determines *a non-REM sleep state*.

Id. at 26–27 (citing Ex. 1003 ¶¶ 116, 118).

Although we discuss motivation to combine below, Petitioner asserts one of ordinary skill in the art “would have recognized that the teachings of Sullivan460 and Matthews could be combined to modify a *processing arrangement* [i.e., of Sullivan995,] to distinguish between types of wake

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states and sleep states, as taught by Sullivan460, and further modified to detect erratic breathing, as taught by Matthews.” Pet. 27. Petitioner continues, “[i]f the breathing patterns indicate a sleep state and erratic breathing, the *processing arrangement* determines that the breathing patterns indicate the patient is in a *REM sleep state*,” but “[i]f the breathing patterns indicate[] a wake state and erratic breathing, the *processing arrangement* determines that the breathing patterns indicate the patient is in a *troubled wakefulness state*.” *Id.* (citing Ex. 1003 ¶ 122). Thus, Petitioner contends the combination of “Sullivan460 and Matthews teach[es] *breathing patterns indicative of a REM sleep state and a troubled wakefulness state*.” *Id.* (citing Ex. 1003 ¶ 125).

For element 1[c2], Petitioner contends “Sullivan995 discloses this limitation” because Sullivan995 detects “snoring and/or particular deviations in breathing patterns,” which Sullivan995 identifies as likely occurring during REM sleep, and adjusts the CPAP pressure in response and correspondingly, but after REM sleep passes and the high pressure is no longer required, “the CPAP pressure will be gradually reduced until the first sign of snoring and/or unacceptable breathing patterns reoccur[] at which point the pressure will again be increased.” Pet. 61–62 (citing Ex. 1005, 16:6–11, 16:35–44, 16:44–50; Ex. 1003 ¶ 219). In other words, Petitioner asserts “Sullivan995 discloses adjusting the pressure provided by the CPAP based on the patient’s state, as determined by their breathing pattern” and that “the CPAP should operate at a higher pressure immediately before, and during an apnea event or REM sleep, and at a lower pressure at other times.” *Id.* at 62 (citing Ex. 1005, 11:23–35; Ex. 1003 ¶ 220).

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For element 1[d1], Petitioner contends “Sullivan995 in view of the knowledge of a [person of ordinary skill in the art] discloses this limitation.” Pet. 63 (citing Ex. 1003 ¶¶ 222–233). As to knowledge in the art, Petitioner relies, in part, on Sullivan460 as “teach[ing] ‘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,’ where the pressure for the second mode is higher than the pressure for the first mode.” *Id.* (citing Ex. 1006, 6:30–7:12, claims 22–28, 43–46). And, as discussed further below, Petitioner contends it would have been obvious to a person of ordinary skill in the art “to modify Sullivan995 so that the *processing arrangement* adjusts the pressure to a first value when breathing patterns indicate a sleep state (such as regular breathing, disordered breathing, or REM sleep).” *Id.* at 64 (citing Ex. 1003 ¶ 228).

And for element 1[d2], Petitioner contends “Sullivan995 in view of Matthews” teaches this limitation because “[a]s discussed in 1[c2] Sullivan995 teaches *the processing arrangement adjusting the applied pressure as a function of the patient’s state*” (Pet. 65 (citing Pet. § VIII.C.5 (Ground 2, 1[c2]); Ex. 1003 ¶¶ 235–236)), and Matthews teaches adjusting the pressure to a second value when in troubled wakefulness (*id.* at 66 (citing Pet. § VIII.C.7.a (Ground 1, 1[d2], discussing Matthews); Ex. 1003 ¶ 237)).

Patent Owner asserts that the combination of Sullivan995, Sullivan460, and Matthews “fail[s] to disclose numerous independent claim limitations” that are identified in red on page 49 of the Patent Owner Response. PO Resp. 49. Patent Owner’s arguments seeking to distinguish claims 1 and 27 are entirely based on Patent Owner’s proposed construction

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of “analyzing the breathing patterns.” *See id.* at 49–50 (“Sullivan⁹⁹⁵ and Sullivan⁴⁶⁰ in view of Matthews only teach the identification of patient state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of a time series,” whereas “an analysis of both the amplitude and temporal structures of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.”), 50–51 (listing alleged missing limitations and contending that, in accordance with the ’994 patent, “analysis of both the amplitude and temporal structures of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep”), 51 (“The same reasoning applies to the claim limitation when the breathing patterns indicate one of states (i) and (ii) and (iii).”). In conclusion of its arguments regarding allegedly missing limitations, Patent Owner makes the following statement:

Thus due to the above reasons, *and the additional reasons provided by Dr. Bates in his Declaration, EX2003, which is incorporated here in its entirety*, Petitioner has failed to prove that the ’994 Patent is obviousness based on Ground 2. Petitioner further argues that independent claims 14, 28, 29, and 30 and dependent claims 6-7, 10-13, 19-20, 23-26, and 32 are likewise obvious. For the reasons stated above, *and for the additional reasons explained by Dr. Bates, these claims are likewise not obvious. See EX2003, ¶¶ 253-291.*

PO Resp. 52 (emphases added). Petitioner replies that Patent Owner concedes that the references disclose “analyz[ing] the breathing pattern[s]” according to its plain meaning to determine asleep versus awake states, including troubled wakefulness and REM sleep. Pet. Reply 17–18 (citing PO Resp. 51; Ex. 1051 ¶¶ 37–47). Petitioner also replies that, even if “analyzing the breathing patterns” requires an analysis of both amplitude and temporal structures, the combination teaches such analysis. *Id.* at 18–20

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(citations omitted) (discussing the combined teachings of Sullivan995, Sullivan460, and Matthews).

In its Sur-reply, Patent Owner argues Sullivan995’s snoring sounds are not breathing patterns. Sur-reply 21 (citing Ex. 2003 ¶¶ 106(a), 229, 262). And Patent Owner asserts that none of the references teaches analyzing the amplitude and temporal structures of a breathing pattern and that Dr. Kirkness mistakenly equates a temporal structure analysis with a time series. *Id.* at 21–24 (citations omitted).

First, we disagree with Patent Owner’s arguments regarding allegedly missing claim limitations in the combination of Sullivan995, Sullivan460, and Matthews as proposed by Petitioner because Patent Owner’s argument is *entirely* based on its proposed construction of “analyzing the breathing patterns,” which we do not adopt. Similarly, we disagree with Patent Owner’s argument that a snoring pattern is not a breathing pattern (*see, e.g.*, Sur-reply 21) because Patent Owner’s argument in this regard, focuses not on what a breathing pattern is but rather what it contends a breathing pattern is used for and is also based on Patent Owner’s proposed construction. *See, e.g.*, Ex. 2003 ¶¶ 229 (discussing Sullivan995’s use of the snoring sounds detected), 262 (asserting that analysis of both amplitude and temporal structures of a time series is required).

Second, we reject Patent Owner’s attempts to “incorporate” by reference “additional reasons provided by Dr. Bates in his Declaration” directed to claims 1 and 27 *and also* “the additional reasons explained by Dr. Bates” directed to the other Challenged Claims (as identified in the block quote above). *See* PO Resp. 52 (block quote above). Our Rules do not permit incorporating *arguments* by reference from one document into

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another. 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”). Additionally, Patent Owner was expressly informed that “**any arguments not raised in the response may be deemed waived.**” Paper 18 (Scheduling Order), 9. Thus, to the extent Dr. Bates raises additional arguments as to missing limitations in response to Petitioner’s challenge based on Sullivan995, Sullivan460, and Matthews, we do not consider those arguments and instead we find those arguments waived by virtue of Patent Owner not expressly stating them in its Patent Owner Response.

Third, Petitioner provides a detailed analysis with supporting evidence that persuasively shows that the combination of Sullivan995, Sullivan460, and Matthews satisfies the elements of claims 1 and 27. Because Petitioner’s arguments are persuasive and fully supported on the record before us and we disagree with Patent Owner’s arguments for the reasons stated above, we adopt Petitioner’s arguments and reasoning as though they were our own.

b. Claims 6, 7, 10–14, 19, 20, 23–26, 28–30, and 32

As noted above, claims 14, 28, 29, and 30 are independent. Claims 6, 7, and 10–13 depend, directly or indirectly, from claim 1. Claims 19, 20, and 23–26 depend, directly or indirectly, from claim 14. Claim 32 depends from claim 30. Petitioner sets forth a detailed analysis showing how the combined teachings of the references meet the elements of claims 6, 7, 10–14, 19, 20, 23–26, 28–30, and 32. Pet. 66–77. Patent Owner does not raise additional argument challenging Petitioner’s analysis and evidence directed to whether the combination of Sullivan995, Sullivan460, and Matthews satisfies these claims in its Patent Owner Response, aside from the

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arguments raised regarding claims 1 and 27. *See generally* PO Resp.; *see also id.* at 52 (referring to claims 6, 7, 10–14, 19, 20, 23–26, 28, 29, 30, and 32 and stating “[f]or the reasons stated above, and for the additional reasons explained by Dr. Bates, these claims are likewise not obvious” (citing Ex. 2003 ¶¶ 253–291)). And, as noted above, we reject Patent Owner’s attempt to incorporate by reference additional arguments by Dr. Bates directed to these claims and find any such additional arguments waived. 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”); Paper 18 (Scheduling Order), 9 (“**any arguments not raised in the response may be deemed waived**”).

We find Petitioner’s arguments persuasive as to claims 6, 7, 10–14, 19, 20, 23–26, 28–30, and 32 and supported on the complete record before us, and, therefore, we adopt them as our own findings. *See* Pet. 66–77. Accordingly, for the reasons explained by Petitioner, we find that the combination of Sullivan995, Sullivan460, and Matthews satisfies the elements of claims 6, 7, 10–14, 19, 20, 23–26, 28–30, and 32.

3. *Motivation to Combine and
Reasonable Expectation of Success*

Petitioner provides extensive argument, supported by record evidence, showing that one of ordinary skill in the art would have been motivated to modify Sullivan995 in light of Sullivan460 and Matthews. Pet. 46–47, 58–60, 64–65, 66. First, Petitioner contends one of ordinary skill would have been motivated to modify Sullivan995 so that its processing arrangement “determines whether the breathing patterns are indicative of a troubled wakefulness state and to adjust the pressure to a second value, as taught in Matthews” because one of ordinary skill would have “recognized that the

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modification is advantageous . . . [and] improves patient comfort upon wake-up” and “Sullivan995 strongly suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (which would include an awake period).” *Id.* at 46–47 (citations omitted).

Second, Petitioner asserts one of ordinary skill would have been motivated “to modify the *processing arrangement* in Sullivan995 to determine breathing patterns *indicative of a REM sleep state* and a *troubled wakefulness state*, as taught by Sullivan460 and Matthews” because the modification “would have caused Sullivan995’s CPAP system to detect additional breathing states to better tailor the CPAP output to a patient’s needs.” Pet. 59 (citing Pet. § IX.A (motivation to combine for Ground 2)). Importantly, Petitioner contends “Sullivan995 is a part [of] Sullivan460” because “Sullivan460 incorporates Sullivan995 by reference.” *Id.* (citing Ex. 1006, 6:22–29). Thus, Petitioner argues “Sullivan460 itself directs a [person of ordinary skill in the art] to combine the teachings of Sullivan995 and Sullivan460.” *Id.* (citing Ex. 1003 ¶ 212). Turning again to Matthews, Petitioner asserts one of ordinary skill would have been motivated “to combine the teaching of Matthews in detecting [a] *troubled wakefulness state* breathing pattern (i.e., erratic breathing as taught by Matthews)” because one of ordinary skill would “recognize, that one could increase the patient comfort, further than what is taught by Sullivan995, by detecting the transition of the patient from a sleep state to an awake state and lowering the pressure, as it was well known that lower pressure during an awake state would increase patient[] comfort.” *Id.* at 59–60 (citations omitted).

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Third, Petitioner contends one of ordinary skill in the art would have been motivated “to modify Sullivan995 so that the *processing arrangement* adjusts the pressure to a first value when breathing patterns indicate a sleep state (such as regular breathing, disordered breathing, or REM sleep)” because Sullivan460 teaches “a second mode of treatment to be applied when the patient is awake because it ‘provides a greater air and pressure delivery to the patient than in the first mode, which is sufficient to treat an air flow limitation.’” Pet. 64 (citing Ex. 1006, 6:30–7:12; Ex. 1003 ¶¶ 228–229). Petitioner explains that one of ordinary skill understands that “[a] patient’s muscle tone becomes more relaxed as the patient enters deeper levels of sleep” and “that the pressure should be increased to a first value to prevent the airway from collapsing during these stages of sleep.” *Id.* (citing Pet. § IV.A.2 (discussing the relationship between sleep and breathing patterns); Ex. 1003 ¶ 230)).

Additionally, Petitioner asserts one of ordinary skill in the art would have had a reasonable expectation of success in making the modifications discussed above to Sullivan995’s system because “[a]ll references describe CPAP systems with flow sensors and flow generators,” “[t]he data from the flow sensor[s] are monitored and used to determine how to control the pressure delivered to the patient,” and

the proposed modification[s] would simply be a change in programming, [they] merely involve[] a combination of known prior art elements (adjusting pressure based on a patient’s state) according to known methods and known techniques (analyzing breathing patterns to determine whether the patient has an irregular breathing indicative of an awake state) to yield predictable results (lower pressure when the patient has an irregular breathing pattern indicative of an awake state), and

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involves use of a known technique to improve a similar device (CPAP machines) in the same way.

Pet. 48 (citing Ex. 1007, 7:12–16, 8:54–9:15; Ex. 1003 ¶¶ 181–183); *see id.* at 60–61 (asserting reasonable expectation of success in “modifying the *processing arrangement* in Sullivan995 to *determin[e] whether the breathing patterns are indicative of a troubled wakefulness state*” (alteration in original) (citing Ex. 1003 ¶¶ 214–218) because Sullivan460 incorporates Sullivan995 by reference and one of ordinary skill in the art “could have been able to program Sullivan995’s CPAP system to incorporate the erratic flow detection algorithm disclosed in Matthews” (citing Ex. 1005, 10:52–61; Ex. 1007, 15:13–28, Figs. 4A–C, 6)). Further, Petitioner contends one of ordinary skill in the art “would reasonably expect success in modifying Sullivan995 so that the processing arrangement in Sullivan995 adjust[s] the pressure to a first value when the breathing patterns indicate states (i), (ii), or (iii)” because “Sullivan995 is already configured to monitor breathing patterns while the patient is asleep to determine a patient’s pressure flow needs” and one of ordinary skill in the art would have been able “to program Sullivan995’s CPAP system to maintain the same pressure at all three states, as it would just require the change in a variable.” *Id.* at 65 (citing Ex. 1005, 10:52–61; Ex. 1003 ¶¶ 231–232); *see also id.* (reiterating that “the proposed modification would simply be a change in programming, it merely involves 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” (citing Ex. 1003 ¶ 233)).

Patent Owner contends there is no motivation to combine Sullivan995, Sullivan460, and Matthews as Petitioner proposes, and even if

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combined, “there is no reasonable expectation of success.” PO Resp. 52–53;

Sur-reply 24–25. Patent Owner asserts

it would not have been obvious to a [person of ordinary skill in the art] to modify the processing arrangement in Sullivan995 to determine breathing patterns *indicative of a REM sleep state and a troubled wakefulness state*, as Petitioner contends is taught by Sullivan460 and Matthews, because Sullivan460 and Matthews focus exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to distinguish between REM sleep and troubled wakefulness.

PO Resp. 52 (citing Ex. 2003 ¶¶ 220–228). Patent Owner further contends there is a lack of motivation to combine because Dr. Kirkness does not know how to calculate Sullivan460’s preset flow rate level. *Id.* at 53 (citing Ex. 2012, 48:6–20).

In its Sur-reply, Patent Owner raises several additional arguments. First, Patent Owner argues that “Matthews’ pressure adjustments do not differentiate between asleep and awake states”; rather, Matthews “employs an equation that calculates a variable breathing number to assess if the breathing becomes too erratic.” Sur-reply 17–18 (citing Ex. 1052, 173:12–22, 174:12–17).²⁵

Second, Patent Owner also contends Petitioner erroneously equates “erratic breathing” and “troubled wakefulness,” which are not

²⁵ Patent Owner relies on the same arguments directed to motivation to combine and reasonable expectation of success as it raises in response to Petitioner’s challenge in Ground 1. *See* Sur-reply 24 (incorporating arguments from Sur-reply § III.B (“Lack of Motivation to Combine and No Reasonable Expectation of Success” (emphasis omitted))). Thus, our citations to Patent Owner’s Sur-reply are to its arguments directed to Ground 1.

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interchangeable because Matthews cannot differentiate between them.

Sur-reply 18 (citing Ex. 1052, 175:1–5; Ex. 2003 ¶ 119(b)). Patent Owner asserts “Matthews’s ‘erratic’ considers only amplitude, whereas the ‘994 Patent’s ‘irregular’ considers amplitude and temporal elements.” *Id.* (citing Ex. 1052, 175:1–5).

Third, Patent Owner also argues that Petitioner fails to explain how Matthews’s breathing pattern indicative of troubled wakefulness could be integrated into existing systems without accounting for both amplitude and temporal structures. Sur-reply 18 (citing Ex. 2003 ¶ 146).

Fourth, Patent Owner asserts a lack of motivation because “Sullivan460 is not enabling” as it allegedly fails to provide certain details to determine a preset flow rate. Sur-reply 19 (citing Ex. 2003 ¶ 18; Ex. 2012, 48:6–20). Relatedly, Patent Owner also contends combining the teachings of the references “requires undue experimentation because analyzing both amplitude and temporal structures to determine asleep/awake states was not known.” *Id.* at 20.

Patent Owner also contends “there is no reasonable expectation of success because Sullivan995 is not ‘configured to monitor breathing patterns while the patient is asleep to determine a patient’s pressure flow needs’” and “Sullivan995 does not teach how to distinguish between REM sleep and troubled wakefulness, which have opposite implications for pressure and flow.” PO Resp. 53 (citing Ex. 2003 ¶ 227). Additionally, Patent Owner asserts “the proposed modification to Sullivan995’s CPAP system would require methods of digital signal processing that go beyond a combination of known prior art elements” and ‘would require the use of methods that

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analyze both the amplitude and temporal structures of a time series.” *Id.* (citing Ex. 2003 ¶¶ 228, 243–245).

Petitioner provides reasons with rational underpinning as to why one of ordinary skill in the art would have been motivated to modify Sullivan995 as proposed with a reasonable expectation of success. We disagree with Patent Owner’s arguments to the contrary.

First, as with its contentions that the combination of Sullivan995, Sullivan460, and Matthews fails to teach all the claim limitations, Patent Owner’s arguments alleging lack of motivation to combine and reasonable expectation of success are premised on its proffered claim construction of “analyzing the breathing patterns,” which we do not adopt. Thus, we do not agree with Patent Owner’s premise that analysis of both amplitude and temporal structures is required to distinguish a troubled wakefulness state from REM sleep.

Second, we disagree with Patent Owner’s argument regarding enablement. At the outset, we agree with Petitioner that “enablement ‘is not a requirement to prove invalidity under § 103.’” Pet. Reply 21 (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003)). Moreover, we also agree with Petitioner that one of ordinary skill in the art would have understood a preset level is established from previously-acquired data, such as an average level, as Sullivan995 teaches. *Id.* (citing Ex. 1005, 17:3–27, Fig. 12; Ex. 2015, 38:2–16). Sullivan995 discloses the computing system may “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.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values

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or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22.

Third, Patent Owner’s argument that Matthews does not differentiate asleep and awake states does not respond to Petitioner’s proposed combination because Petitioner relies on Sullivan460 to teach determining whether a patient is awake or asleep, and Matthews teaches detecting erratic breathing during wakefulness and sleep. *See* Pet. 52–66. Combining the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes would result in a processing arrangement that determines whether the patient is awake or asleep and whether the patient is breathing erratically. By determining whether the patient is awake or asleep and whether the patient is breathing erratically, the processing arrangement determines whether the patient’s breathing pattern is indicative of “(i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state,” as recited by claim 1 of the ’994 patent. Furthermore, in view of Sullivan995’s disclosure of a generator configured to adjust the airflow pressure as a function of the breathing pattern and the associated patient state and Matthews’s teaching of decreasing pressure after a pressure increase resulted in erratic breathing, Petitioner’s proposed combination would result in a generator configured to adjust the airflow pressure based on the patient’s state and reduce the airflow pressure upon a detection of the patient being awake and breathing erratically, which is indicative of a troubled wakefulness state.

Fourth, Patent Owner improperly argues for the first time in its Sur-reply that Petitioner’s combination of Sullivan995, Sullivan460, and Matthews would have required “undue experimentation because analyzing

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both amplitude and temporal structures to determine asleep/asleep states was not known.” Sur-reply 19–20. Patent Owner’s alleged “undue experimentation” was not raised in Patent Owner’s Response, and therefore Petitioner did not have an opportunity to respond. Accordingly, Patent Owner’s argument is improper, and the issue is deemed waived. *See* Paper 18, 9 (“**Patent Owner is cautioned that any arguments not raised in the response may be deemed waived.**”). Moreover, even if not waived, we disagree with Patent Owner’s “undue experimentation” argument because it is premised on Patent Owner’s proposed construction requiring analysis of “both amplitude and temporal structure,” which we do not adopt.

Fifth, we find Petitioner has shown that one of ordinary skill in the art would have had a reasonable expectation of success in achieving the combination proposed. Specifically, Patent Owner’s arguments are again based on its proposed construction of “analyzing the breathing patterns,” which we do not adopt. Additionally, we agree with Petitioner, for the reasons provided by Petitioner, that one of ordinary skill in the art would have had a reasonable expectation of success in incorporating Matthews’s algorithm to interrupt Sullivan995’s control in the same manner that Matthews teaches for interrupting an auto-CPAP controller.

Thus, we find that Petitioner has established that one of ordinary skill in the art would have had reasons with rational underpinning for combining the teachings of Sullivan995, Sullivan960, and Matthews as proposed and would have had a reasonable expectation of success in so doing.

4. *Objective Indicia of Nonobviousness*

Objective evidence of nonobviousness may include evidence of commercial success, licensing, copying, praise by others, long felt but

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unresolved need, and failure or skepticism of others. *Graham*, 383 U.S. at 17–18. But, secondary considerations are only a part of the “totality of the evidence”; their mere existence does not control the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). Objective evidence of nonobviousness “may often be the most probative and cogent evidence in the record” and “may often establish that an invention appearing to have been obvious in light of the prior art was not.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

Patent Owner argues that evidence of nonobviousness exists in the form of long-felt need. PO Resp. 46–48, 53. According to Patent Owner, since 1991, there has been “a need for patients to increase compliance with usage of their CPAP machines,” with patients complaining about “nocturnal awakenings” and “nasal issues.” *Id.* at 47 (citing Ex. 1036, 1, 5). Patent Owner further argues as follows:

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients’ compliance with CPAP treatment by noting that “the conventional PAP therapy [had] not taken sleep/wake state into account” and “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” ’994 Patent, 1:44-46, 1:64-65. Further, before the development of the claimed invention in the ’994 Patent, self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. *Id.* at 2:31-35. In fact, as of 2002, a [person of ordinary skill in the art] was “not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters.” *See EX2015*, at 2:33-37. As such, the claimed invention solved a long felt but unresolved need – better compliance with CPAP therapy –

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by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 44 (first two alterations in original).

Patent Owner further argues that conventional CPAP treatment “had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control.” Sur-reply 26 (citing Ex. 1001, 1:64–67; Ex. 1053, 296:22–25, 297:1–15). According to Patent Owner, Dr. Bates’s testimony explained that “[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states.” *Id.* at 25–26 (citing Ex. 1052, 113:3–11, 115:22–25, 116:1–10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by the ’994 patent’s “ability to distinctly identify when a patient is awake or asleep,” because a person of ordinary skill in the art “prior to the 994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and awake.” *Id.* at 27 (alteration in original) (citing Ex. 1052, 202:23–25, 203:1–3).

a. Nexus

Objective evidence of nonobviousness “is only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (2006)). A “nexus” is a legally and factually sufficient connection between the objective evidence and the claimed invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*,

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938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 32–33 (PTAB Jan. 24, 2020) (precedential), *aff'd sub nom. Zaxcom, Inc. v. Lectrosonics, Inc.*, 2022 WL 499848 (Fed. Cir. Feb. 18, 2022). We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* at 32. If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 33 (quoting *Fox Factory*, 944 F.3d at 1373–75). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Id.* (citing *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011)). There is no requirement that the objective evidence of non-obviousness be tied exclusively to claim elements that are not disclosed in the prior art, and the claimed combination as a whole may serve as a nexus for the objective evidence. *Id.* (citing *WBIP*, 829 F.3d at 1331).

Petitioner argues that “for secondary considerations to be accorded substantial weight, [Patent Owner] bears the burden of showing that a nexus

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exists between the claimed features of the invention and the evidence offered to show non-obviousness.” Pet. Reply 23 (citing *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). According to Petitioner, Patent Owner does not meet this burden because: 1) Patent Owner did not establish “a presumption of nexus” since Patent Owner did not identify any product tied to the objective evidence; 2) Patent Owner did not “demonstrate a nexus by showing that long-felt need was met as a ‘direct result of the unique characteristics of the claimed invention’”; 3) Patent Owner did not identify “any failed efforts to solve the problem before the invention”; and 4) Patent Owner does not point to disclosure in the ’994 patent that the “prior art recognized the need to analyze temporal and amplitude structures.” *Id.* at 23–25 (citations omitted).

First, Patent Owner has not argued that the presumption of nexus applies, and we agree with Petitioner that Patent Owner is not entitled to a presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the Challenged Claims. Second, we address Patent Owner’s evidence of long-felt but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the ’994 patent, absent the presumption.

b. Long-felt but Unmet Need

In order to show a long-felt but unmet need *for the claimed invention*, the objective evidence must show that the need was a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). “Evidence of long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would

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not have persisted had the solution been obvious.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1332 (Fed. Cir. 2016).

Here, Patent Owner suggests increasing the comfort of the PAP system is a goal to improve patient compliance with PAP therapy. Patent Owner does not explain, however, why Sullivan460’s treatment means which “addresses . . . the comfort of CPAP,” and “is an improvement over the prior art” because of the two modes of air delivery, does not meet the long-felt need identified by Patent Owner. *See* Ex. 1007, 7:7–16; *see also* Pet. Reply 24. Thus, we agree with Petitioner that “[t]o the extent that any need existed, it was already satisfied,” especially in light of the proper construction of “analyzes the data to determine the patient’s breathing patterns.” Pet. Reply 24–25 (citations omitted).

Additionally, Patent Owner’s Response fails to identify any failed efforts to solve the problem before the invention and similarly fails to provide sufficient evidence that the ’994 patent satisfied the alleged need. Dr. Bates’s redirect testimony, which Patent Owner almost exclusively relies on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to “little or no weight.” 37 C.F.R. § 42.65(a).

Patent Owner also assumes a need for better compliance with CPAP therapy *by detecting troubled wakefulness*. PO Resp 47–48; Sur-reply 26–27. But, Patent Owner’s argument suffers from the same deficiencies identified above, particularly the failure by Patent Owner to show that the ’994 patent satisfied the alleged need.

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt but unmet need met by any of the Challenged

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Claims. As a result, we accord little weight to Patent Owner's evidence of long-felt need.

c. Collective Considerations of the Graham Factors

“Once all relevant facts are found, the ultimate legal determination [of obviousness or nonobviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat*, 876 F.3d at 1361. Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews teaches each limitation of the Challenged Claims, that a person of ordinary skill in the art would have had reasons with rational underpinning to combine features of Sullivan995, Sullivan460, and Matthews and would have had a reasonable expectation of success in so doing, and that Petitioner's evidence of unpatentability significantly outweighs the marginal evidence of long-felt but unmet need provided by Patent Owner.

On the whole and considering the *Graham* factors collectively, Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews would have rendered the subject matter of the Challenged Claims obvious to one of ordinary skill in the art at the time of the invention.

C. Ground 1: Obviousness over Rapoport502, Sullivan460, and Matthews

Ground 3: Anticipation by Sullivan995

Petitioner asserts the combination of Rapoport502, Sullivan460, and Matthews would have rendered the subject matter of the Challenged Claims

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obvious to one of ordinary skill in the art at the time of the invention and that the Challenged Claims are anticipated by Sullivan995. Pet. 17–46 (Ground 1), 77–82 (Ground 3). Patent Owner contests Petitioner’s assertions. *See, e.g.*, PO Resp. 34–48 (Ground 1), 53–57 (Ground 3).

Because we have determined above that Petitioner has established the unpatentability of the Challenged Claims based on the combination of Sullivan995, Sullivan460, and Matthews, we need not and do not reach these additional challenges by Petitioner in Grounds 1 and 3. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”).

IV. PATENT OWNER’S MOTION TO EXCLUDE

Patent Owner seeks to exclude, either in whole or in part, Exhibits 1003, 1009, 1018, 1019, 1022, 1033, 1034, 1046, 1049, 1051, 1052, and 1054–1057, and 1059 as well as portions of the Petition and Petitioner’s Reply that rely on the allegedly inadmissible exhibits. PO MTE 1; *see* PO MTE Reply. Petitioner opposes Patent Owner’s Motion. PO MTE Opp. For the following reasons, we deny Patent Owner’s Motion to Exclude.

A. Exhibits 1003 and 1046

Exhibit 1003 is the declaration of Petitioner’s original declarant, Dr. Behbehani, and Exhibit 1046 is the substitute declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s Declaration. *See* Ex. 1046 ¶ 28. Patent Owner argues that certain portions of Exhibit 1003 should be excluded and that those portions should also be excluded from Exhibit 1046. PO MTE 3–6, 9; PO MTE Reply 1–2. More specifically, Patent Owner seeks to exclude paragraphs 38, 39, 42, 45, 82, 97–100, and 265–278 of Exhibit 1003 and the adoption of those paragraphs

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in Exhibit 1046. PO MTE 3–6, 9. Because we do not rely on the challenged paragraphs of Exhibit 1003 in rendering this Decision, we deny Patent Owner’s Motion to Exclude as to these portions of Exhibit 1003 and the corresponding portions of Exhibit 1046 as moot.

B. Exhibits 1009 and 1054–1057

Exhibit 1009 is the file history of related U.S. Patent No. 9,168,344 B2 (“the ’344 patent”), and Exhibit 1056 is the ’344 patent. Exhibit 1054 is the file history of related U.S. Patent No. 9,108,009 B2 (“the ’009 patent”), and Exhibit 1055 is the ’009 patent. Exhibit 1057 is related U.S. Patent No. 9,427,539 B2.

Patent Owner asserts that “Petitioner introduced new evidence in its Reply with these exhibits,” contrary to 37 C.F.R. § 42.61(a), which provides that “[e]vidence that is not taken, sought, or filed in accordance with this subpart is not admissible.” PO MTE 6–7; PO MTE Reply 3. According to Patent Owner, these exhibits are “subject to exclusion under” Federal Rule of Evidence 403. PO MTE 7. In opposition, Petitioner argues that these exhibits are proper evidence in support of its Reply because Patent Owner “proposed a construction for the ‘analyzing the breathing patterns’ claim terms for the first time in [Patent Owner’s] Response.” PO MTE Opp. 7. Patent Owner contends Petitioner could have used these exhibits in its Petition, but instead “supplemented previous claim construction arguments made in the Petition with these exhibits.” PO MTE Reply 3.

We disagree with Patent Owner’s argument. Petitioner proposed two terms for construction in the Petition, neither of which was “analyzing the breathing patterns.” Pet. 16–17. Patent Owner first presented a construction for “analyzing the breathing patterns” in its Patent Owner Response. PO

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Resp. 30. Petitioner’s first and only opportunity to respond to Patent Owner’s construction was in its Reply. *See Ancacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380 (Fed. Cir. 2018) (“[T]he petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by patent owner.”). And Petitioner’s Reply does not change the theory, prior art, or evidence relied on to challenge the subject claims as compared to that which was presented in the Petition. Additionally, we disagree with Patent Owner’s argument that Petitioner “supplemented previous claim construction arguments” in the Petition because neither of the two terms proposed for construction in the Petition were supplemented in Petitioner’s Reply since Patent Owner agreed with each of Petitioner’s proposed constructions. PO Resp. 29–30 (discussing “troubled wakefulness” and “when the breathing patterns indicate one of . . .”). Thus, we disagree with Patent Owner’s arguments.

We find that Petitioner properly relies on Exhibits 1009 and 1054–1057 in support of its response to Patent Owner’s construction of “analyzing the breathing patterns,” first raised in the Patent Owner Response. Therefore, we deny Patent Owner’s Motion to Exclude as to Exhibits 1009 and 1054–1057.

C. Exhibits 1018, 1019, and 1033

Exhibit 1018 is a copy of Patent Owner’s complaint from a related district court action. Exhibits 1019 and 1033 are exhibits to that complaint.

Patent Owner argues these exhibits should be excluded because “[a]ny discussion of infringement is irrelevant in [*inter partes* reviews].” PO MTE 7; PO MTE Reply 3–4. Petitioner argues that these exhibits are relied

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on in support of and are relevant to Petitioner's anticipation contention in this proceeding. PO MTE Opp. 9. We agree with Petitioner that these exhibits are relevant to Petitioner's contentions in this proceeding. Nonetheless, we do not rely on these exhibits in rendering this Decision. We, therefore, deny Patent Owner's Motion to Exclude Evidence as to Exhibits 1018, 1019, and 1033 as moot.

D. Exhibits 1022 and 1034

Exhibit 1022 is U.S. Patent No. 6,427,689 B1. Exhibit 1034 is International Publication No. WO 03/075991 A1. Patent Owner argues that neither exhibit was cited in any document in this proceeding and therefore they are irrelevant under Federal Rule of Evidence 402 and should be excluded. PO MTE 8. Petitioner contends the exhibits should not have been filed and the exhibit numbers should have been listed as "reserved." PO MTE Opp. 10 (citing Ex. 1003, App. A (listing Ex. 1034 as "Reserved")). Petitioner contends Patent Owner will not be prejudiced by leaving them of record because they are not relied on in this proceeding and therefore the filing of the exhibits was harmless error. *Id.*

There is no dispute that Petitioner does not cite to Exhibits 1022 and 1034, and we do not rely on these exhibits in rendering this Decision. Accordingly, we deny Patent Owner's Motion to Exclude Evidence as to Exhibits 1020 and 1034 as moot.

E. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2. Patent Owner argues that the priority date of this patent is after the priority date of the '994 patent and should be excluded as irrelevant and "not prior art." PO MTE 9; PO MTE Reply 4. Patent Owner also argues that the exhibit should have been

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introduced prior to Petitioner’s Reply. PO MTE 9. Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. PO MTE Opp. 10–11. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates’s credibility, not as prior art, and find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision, and we deny Patent Owner’s Motion to Exclude as to Exhibit 1049 as moot.

F. Exhibit 1051

Exhibit 1051 is the Declaration of Dr. Kirkness in support of Petitioner’s Reply. Patent Owner argues that Exhibit 1051 should be excluded because it raises “new issues” and “new evidence that could have been presented in a prior filing.” PO MTE 10; PO MTE Reply 2–3. The only “example” provided by Patent Owner in support of its argument for exclusion is that Dr. Kirkness “uses Exhibits 1049 and 1054–1057 in the exact same manner” as they are used in Petitioner’s Reply and should therefore be excluded for the same reasons. PO MTE 10. For the same reasons discussed above regarding Exhibits 1049 and 1054–1057, we deny the Motion to Exclude as to Exhibit 1051.

G. Exhibit 1052

Exhibit 1052 is the transcript of the first day of Dr. Bates’s deposition testimony. Patent Owner argues that the portions of Exhibit 1052 “focusing on patent eligible subject matter and whether certain products, such as processors, infringe by meeting the limitations of the ’994 Patent should be excluded as irrelevant.” PO MTE 10–11 (citing Ex. 1052, 62:7–23, 63:15–25, 64:1–5, 117:9–25, 118:1–11, 146:4–12); PO MTE Reply 4–5. Petitioner

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argues that the testimony of Dr. Bates is relevant to obviousness issues in this proceeding, that there was “no discussion of ‘infringement’ or ‘patentable subject matter,’” and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 11–12. We agree with Petitioner for the same reasons provided by Petitioner and deny Patent Owner’s Motion to Exclude as to the challenged portions of Exhibit 1052.

H. Exhibit 1059

Exhibit 1059 is an article titled “Control of breathing during sleep” published in Clinical Science in 1984 and was cited by Dr. Kirkness in his reply declaration (Exhibit 1051).

Patent Owner argues Dr. Kirkness relies on Exhibit 1059 to show that a person of ordinary skill in the art “knew ‘that a processor could be programmed to analyze breathing patterns that fall below or above certain preset levels of airflow rate to indicate awake or asleep states’ and that analysis of temporal structures was not necessary.” PO MTE 11–12 (citing Ex. 1051 ¶¶ 11, 32). According to Patent Owner, “[a]ny use of [Exhibit 1059] is therefore an improper incorporation by reference through [Exhibit 1051], violating 37 C.F.R. § 42.6(a)(3), which prohibits incorporating arguments by reference from one document into another document.” *Id.* Patent Owner’s argument has no merit. As Petitioner correctly avers, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and Exhibit 1059 “is not an argument.” PO MTE Opp. 13.

Patent Owner also argues Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply 5. Petitioner, however, explains that the opinions of Dr. Kirkness

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supported by Exhibit 1059 in his reply declaration are relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” PO MTE Opp. 13. We agree with Petitioner for the same reasons discussed above regarding Exhibits 1054–1057. Because Patent Owner shows no persuasive basis to exclude Exhibit 1059, Patent Owner’s Motion to Exclude as to Exhibit 1059 is denied.

V. PETITIONER’S MOTION TO EXCLUDE

Petitioner seeks to exclude portions of Exhibit 1053, the deposition testimony of Dr. Bates. Pet. MTE 1–9; Pet. MTE Reply 1–5. Specifically, Petitioner moves to exclude parts of the redirect deposition testimony of Dr. Bates concerning secondary considerations of nonobviousness. Pet. MTE 1–2. Petitioner argues that the redirect testimony of Dr. Bates “was outside the scope of Petitioner’s cross-examination in contravention of Federal Rule of Evidence 611(b) and 37 C.F.R. § 42.53 (d)(5)(ii).” *Id.* at 1. Petitioner does not seek to exclude the entirety of Dr. Bates’s redirect testimony concerning secondary considerations but only the specific portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes Petitioner’s Motion. Pet. MTE Opp. 1–10.

Petitioner contends that it “did not cross-examine Dr. Bates about any secondary considerations and timely objected to PO’s line of questioning during redirect as being outside the scope.” Pet. MTE 1–2 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9); *id.* at 4 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9). Petitioner further contends that Patent Owner’s “introduction of belated expert testimony into the record via the Sur-Reply is improper and the evidence must be excluded.” *Id.* at 2 (citing *Comcast Cable Commc’ns*,

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LLC v. Rovi Guides, Inc., IPR2019-01413, Paper 34 at 4 (PTAB Sept. 16, 2020); *Int’l Bus. Machines Corp. v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 15 at 5 (PTAB Feb. 2, 2015)); *see also id.* at 5–6 (identifying portions of the Sur-reply citing the disputed testimony). Further, according to Petitioner, “Dr. Bates’ declaration included no discussion of secondary considerations.” *Id.*

Petitioner argues that Rule “611(b) prohibits redirect examination that goes beyond the scope of cross-examination questions and testimony” and Patent Owner’s “redirect examination did just that.” Pet. MTE 7. Petitioner next argues that “the portions of Dr. Bates’ redirect testimony that Petitioner seeks to exclude from the record . . . have no bearing on ‘matters affecting the witness’s credibility.’” *Id.* at 8 (citations omitted). According to Petitioner, Patent Owner “does not rely on Dr. Bates’ testimony to counter a challenge to his credibility.” *Id.* Petitioner also contends that 37 C.F.R. § 42.53(d)(5)(ii) “similarly prevents a party from expanding the scope of redirect examination beyond that of cross-examination.” *Id.* at 9.

In opposition, Patent Owner argues Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner asserts the Consolidated Trial Practice Guide provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or ***otherwise exceeds the proper scope*** of reply or sur-reply, it may request authorization to file a motion to strike.” Pet. MTE Opp. 2 (citing PTAB Consolidated Trial Practice Guide (“CTPG”) 80 (PTAB Nov. 2019)). Patent Owner contends that “Petitioner’s counsel reserved the right to strike Dr. Bates’ redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of [Patent Owner]

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submitting its Sur-Reply.” *Id.* at 2–3 (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact *inadmissible*,” only that it “should be excluded (not stricken) because it is beyond the scope of its cross-examination.” *Id.* at 4. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–25).

In reply, Petitioner contends it “properly focused its motion to exclude on the portions of Dr. Bates’ inadmissible re-direct deposition testimony cited in [the] Sur-Reply,” and that Patent Owner “uses its Sur-Reply as no more than a ‘vehicle’ to enter new evidence into the record.” Pet. MTE Reply 1. Petitioner contends that it “timely objected at the deposition” once Patent Owner began “improperly elicit[ing] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Rule 611(b). *Id.* (citing Pet. MTE § II.B.2 (discussing Fed. R. Evid. 611(b))).

For the following reasons, we deny Petitioner’s Motion to Exclude.

The CTPG provides that “[a] motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay)” but should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.” CTPG 79. Further, the CTPG clearly distinguishes a motion to exclude evidence from a motion to strike evidence.

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The CTPG states that, “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike.” *Id.* at 80. As an alternative to a motion to strike, “a party may request authorization for further merits briefing . . . to address the merits of any newly-raised arguments or evidence.” *Id.* A party must seek authorization to file a motion to strike “within one week of the allegedly improper submission.” *Id.* at 81.

As noted in the CTPG, motions to strike are intended to address, *inter alia*, whether a brief raises new issues or exceeds the proper scope of a sur-reply. Here, Petitioner argues that the redirect testimony is inadmissible under Rule 611(b) and/or 37 C.F.R. § 42.53(d)(5)(ii) as exceeding the scope of cross-examination. But, Petitioner does not seek to exclude all redirect testimony on secondary considerations, only the testimony relied on by Patent Owner in the Sur-reply. Pet. MTE 5 n.2.

The issue presented here borders on the proper scope of a motion to exclude as compared to a motion to strike. The goal of Petitioner’s Motion is clearly to undercut arguments raised in Patent Owner’s Sur-reply directed to objective indicia of nonobviousness. By limiting its Motion to only the portions of Dr. Bates’s redirect examination actually relied on in Patent Owner’s Sur-reply, Petitioner’s arguments reflect this goal. *See, e.g.*, Pet. MTE 5 n.2 (“Although all of Dr. Bates’ redirect testimony on secondary considerations was outside the scope of Petitioner’s cross-examination, Petitioner narrowly focuses this motion on excluding only those portions that [Patent Owner] relies on in its Sur-Reply.”). One way in which Petitioner could have challenged the arguments raised in Patent Owner’s

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Sur-reply is by requesting authorization to file a motion to strike, which, as noted above, is intended for the purpose of addressing arguments a party believes exceeds the proper scope of a sur-reply. *See* CTPG 80. Petitioner did not request such authorization. Instead, by seeking to exclude some of Dr. Bates's redirect testimony on objective indicia (i.e., the portions relied on in Patent Owner's Sur-reply), Petitioner seeks to undercut the arguments raised in Patent Owner's Sur-reply on objective indicia by effectively removing the primary evidentiary support for those arguments. Were we to grant Petitioner's Motion to Exclude, we would be faced with determining what to do with Patent Owner's arguments in the Sur-reply, which would remain of record because they are not the subject of Petitioner's Motion to Exclude (nor could they be based on the CTPG) and (as previously noted) Petitioner did not also file a motion to strike those arguments. The best course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Rule 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination (just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony²⁶), Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of nonobviousness by questioning Dr. Bates about

²⁶ There are exceptions, e.g., questions pertaining to a witness's credibility. *See* Fed. R. Evid. 611(b).

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commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the circumstances presented here and in light of the little weight to which Patent Owner’s argument and Dr. Bates’s redirect is entitled, we determine that the better course at this stage is to deny Petitioner’s Motion to Exclude.

VI. SUMMARY

For the reasons discussed above, Petitioner has demonstrated, by a preponderance of the evidence, that the Challenged Claims of the ’994 patent are unpatentable.

Our conclusions regarding the Challenged Claims are summarized below:

Claims Challenged	35 U.S.C. §	Reference(s) /Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 6, 7, 10–14, 19, 20, 23–30, 32	103(a)	Rapoport502, Sullivan460, Matthews ²⁷		
1, 6, 7, 10–14, 19, 20, 23–30, 32	103(a)	Sullivan995, Sullivan460, Matthews	1, 6, 7, 10–14, 19, 20, 23–30, 32	
1, 6, 7, 10–14, 19, 20, 23–30, 32	102(a), (b)	Sullivan995 ²⁸		

²⁷ For the reasons explained above, we do not reach this alternative ground because we determine that the Challenged Claims are unpatentable based on Petitioner’s second ground, relying on the combination of Sullivan995, Sullivan460, and Matthews.

²⁸ For the reasons explained above, we do not reach this alternative ground because we determine that the Challenged Claims are unpatentable based on

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Claims Challenged	35 U.S.C. §	Reference(s) /Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
Overall Outcome			1, 6, 7, 10–14, 19, 20, 23–30, 32	

VII. ORDER²⁹

In consideration of the foregoing, it is:

ORDERED that Patent Owner's Motion to Exclude (Paper 49) is *denied*;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 50) is *denied*;

FURTHER ORDERED that claims 1, 6, 7, 10–14, 19, 20, 23–30, and 32 of U.S. Patent No. 6,988,994 B2 are determined to be unpatentable; and

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

Petitioner's second ground, relying on the combination of Sullivan995, Sullivan460, and Mathews.

²⁹ Should Patent Owner wish to pursue amendment of a challenged claim in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding, 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

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Paper 68
Entered: December 6, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

IPR2022-00994
Patent 9,168,344 B2

Before BART A. GERSTENBLITH, JAMES A. TARTAL, and
ALYSSA A. FINAMORE, *Administrative Patent Judges*.

FINAMORE, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

ORDER
Denying Patent Owner's Motion to Exclude Evidence (Paper 48) and
Denying Petitioner's Motion to Exclude Evidence (Paper 49)
37 C.F.R. § 42.64(c)

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Patent 9,168,344 B2

I. INTRODUCTION

ResMed, Inc. (“Petitioner”) filed a Corrected Petition (Paper 12, “Pet.”)¹ requesting an *inter partes* review of claims 1, 3, 7, 9, 11, and 13 of U.S. Patent No. 9,168,344 B2 (“the ’344 patent”) (Ex. 1001). We issued a Decision granting institution of an *inter partes* review (Paper 16, “Inst. Dec.”).

During trial, New York University (“Patent Owner”) filed a Response (Paper 33, “PO Resp.”). Petitioner filed a Reply (Paper 41, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 44, “Sur-reply”).

Patent Owner filed a Motion to Exclude Evidence (Paper 48, “PO MTE”). Petitioner filed an Opposition (Paper 52, “PO MTE Opp.”), and Patent Owner filed a Reply (Paper 53, “PO MTE Reply”). Petitioner also filed a Motion to Exclude Evidence (Paper 49, “Pet. MTE”). Patent Owner filed an Opposition (Paper 51, “Pet. MTE Opp.”), and Petitioner filed a Reply (Paper 54, “Pet. MTE Reply”).

An oral hearing took place October 2, 2023.² We entered the transcript (Paper 63, “Tr.”) into the record.

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we conclude Petitioner has proven, by a

¹ Petitioner filed a Petition (Paper 1) and subsequently filed a Motion to Correct the Petition and Filing Date (Paper 8), which New York University opposed (Paper 9). We granted Petitioner’s Motion (Paper 11), and Petitioner then filed the Corrected Petition. All references herein to the “Petition” are to the Corrected Petition.

² The Parties filed objections to the other party’s demonstratives and hearing arguments and responses to those objections (Papers 60, 61, 64–67). Demonstratives and hearing arguments are not evidence and are not relied upon in this Decision. Accordingly, the objections are denied as moot.

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preponderance of the evidence, that claims 1, 3, 7, 9, 11, and 13 of the '344 patent are unpatentable. Furthermore, we deny both Parties' Motions to Exclude Evidence.

A. Related Matters

The Parties identify as a related matter the following district court action: *New York University v. ResMed, Inc.*, No. 1:21-cv-00813-JPM (D. Del. 2021). Pet. 3; Paper 55, 2. The Parties also identify as related matters the following six Board proceedings: IPR2022-00988 (challenging U.S. Patent No. 9,108,009 B2), IPR2022-00989 (challenging U.S. Patent No. 9,427,539 B2), IPR2022-00990 (challenging U.S. Patent No. 9,533,115 B2); IPR2022-00991 (challenging U.S. Patent No. 9,867,955 B2), IPR2022-00992 (challenging U.S. Patent No. 10,384,024 B2), and IPR2022-00993 (challenging U.S. Patent No. 6,988,994 B2). Pet. 3; Paper 55, 2–3.

B. Real Parties in Interest

Petitioner and Patent Owner each identifies itself and no others as a real party in interest. Pet. 3; Paper 5, 2; Paper 27, 2; Paper 34, 2; Paper 55, 2.

C. The '344 Patent (Ex. 1001)

The '344 patent is titled "System and Method for Diagnosis and Treatment of a Breathing Pattern of a Patient." Ex. 1001, code (54). The '344 patent issued on October 27, 2015, from Application No. 12/983,628, which was filed on January 3, 2011. *Id.* at codes (45), (21), (22). Application No. 12/983,628 is a continuation of Application No. 11/240,197, filed on September 30, 2005, which is a continuation-in-part of Application No. 11/210,568, filed on

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August 24, 2005, which is a continuation of Application No. 10/642,459, filed August 14, 2003, now U.S. Patent No. 6,988,994 B2 (“the ’994 patent”) (Ex. 2002).³ *Id.* at code (63).

As background, the ’344 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, 1:22–24. According to the ’344 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 1:28–35. The ’344 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS.” *Id.* at 1:51–54. The ’344 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 1:51–54, 2:4–6.

The ’344 patent states 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.” *Id.* at 1:58–60. Specifically, “conventional PAP therapy has not taken sleep/wake state into account, and

³ Petitioner acknowledges this priority claim and asserts “[f]or the purpose of this Petition, it is unnecessary to break the priority chain to a later date.” Pet. 13 n.5.

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conventional PAP systems apply pressure unnecessarily when the patient is awake.” *Id.* at 2:11–13. The ’344 patent also states that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:25–26.

Figure 1 of the ’344 patent is reproduced below.

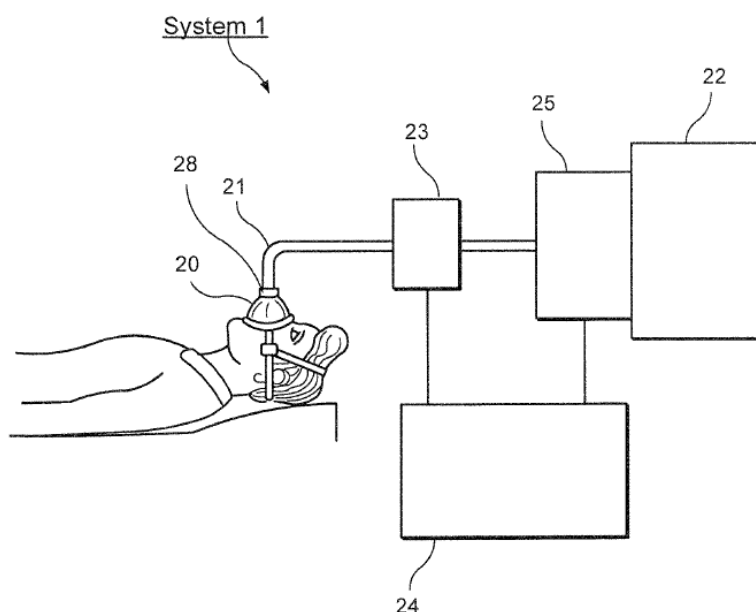


FIG. 1

Figure 1 “shows an exemplary embodiment of a system according to” the ’344 patent. Ex. 1001, 3:15–16. System 1, shown in Figure 1, includes mask 20 which is placed over the face of the patient and connected via tube 21 for receiving an airflow of a particular pressure from flow generator 22. *Id.* at 3:45–48. The ’344 patent describes 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 3:53–56. The ’344 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

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conventional flow control device 25 to control a pressure applied to the flow tube 21 by the flow generator 22.” *Id.* at 3:57–62.

The ’344 patent also describes a method that uses system 1. *Id.* at 4:6–7, Fig. 2. “[S]ystem 1 initiates a real-time monitoring procedure of the patient’s breathing patterns.” Ex. 1001, 4:11–12. The ’344 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 4:12–17. The ’344 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 4:18–22. According to the ’344 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 4:22–26. The ’344 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 4:29–31, 4:38–53.

The ’344 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, 5:55–57. The ’344 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 7:37–40.

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According to the '344 patent, “[o]ne of the advantages of the system 1 according to the present invention is that the pressure supplied to the patient is adjusted (e.g., reduced to zero or a preset low level) when the patient has an irregular breathing pattern that suggests that he is awake and anxious.”

Ex. 1001, 6:33–37. According to the '344 patent, a breathing pattern characterized by “irregular[] variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient’s air flow tracing indicating that the patient is awake and either anxious or uncomfortable” is associated with a “troubled wakefulness state.” *Id.* at 4:53–58.

D. Illustrative Claim

Claims 1 and 7 are independent claims. Ex. 1001, 9:34–46, 10:6–19. Independent claim 1, reproduced below with emphasis added, is representative of the claimed subject matter.

1. A system, comprising:
 - a flow sensor provided in an airflow path and measuring data corresponding to a patient’s breathing patterns; and
 - a processing arrangement configured to *analyze the breathing patterns* to determine whether the breathing patterns are indicative of a troubled wakefulness state; and
 - a generator configured to supply an airflow to an airway of the patient and to reduce a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure.

Id. at 9:34–46 (emphasis added).

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E. Asserted Grounds of Unpatentability

Petitioner asserts the following three grounds of unpatentability for claims 1, 3, 7, 9, 11, and 13 of the '344 patent:

Claims Challenged	35 U.S.C. § ⁴	Reference(s)/Basis
1, 3, 7, 9, 11, 13	103(a)	Sullivan995, ⁵ Sullivan460, ⁶ Matthews ⁷
1, 3, 7, 9, 11, 13	103(a)	Rapoport502, ⁸ Sullivan460, Matthews
1, 3, 7, 9, 11, 13	102(a), (b)	Sullivan995

Pet. 5; *see also id.* at 16 (Petitioner arguing Sullivan995 is prior art under 35 U.S.C. §§ 102(a) and (b)).

In support of the asserted grounds, Petitioner submitted a declaration by Dr. Khosrow Behbehani (Ex. 1003) and declarations by Dr. Jason P.

⁴ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended certain sections of this statute, including §§ 102 and 103, and the effective date of the relevant amendment is March 16, 2013. The filing date of the '344 patent, January 3, 2011, is before the effective date of the amendment. Ex. 1001, code (22). Thus, the pre-AIA version of the statute applies.

⁵ Sullivan et al., US 5,245,995, issued Sept. 21, 1993 (“Sullivan995”) (Ex. 1005).

⁶ Sullivan, WO 01/05460 A1, published Jan. 25, 2001 (“Sullivan460”) (Ex. 1006).

⁷ Matthews et al., US 7,168,429 B2, issued Jan. 30, 2007 (“Matthews”) (Ex. 1007).

⁸ Rapoport et al., US 5,490,502, issued Feb. 13, 1996 (“Rapoport502”) (Ex. 1008).

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Kirkness (Exs. 1046, 1051).⁹ Patent Owner deposed and cross-examined Dr. Kirkness and submitted transcripts of Dr. Kirkness's deposition (Exs. 2015, 2016).

Patent Owner submitted a declaration of Dr. Jason Hamilton Tunstall Bates (Ex. 2006). Dr. Bates provided corrections to citations in his declaration (Ex. 1048). Petitioner deposed and cross-examined Dr. Bates and submitted transcripts of Dr. Bates's deposition (Exs. 1052, 1053).

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

The level of ordinary skill in the art is “a prism or lens” through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). A person of ordinary skill in the art is “a hypothetical person who is presumed to know the relevant prior art.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citing *Custom Accessories, Inc. v. Jeffrey–Allen Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986)). In determining the level of ordinary skill in the art, we may consider certain factors, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made;

⁹ With the Petition, Petitioner filed the declaration of Dr. Behbehani (Ex. 1003). Petitioner then filed the declaration by Dr. Kirkness (Ex. 1046), whereby Dr. Kirkness agrees with and adopts paragraphs 20–28, 32–88, and 92–234 of Dr. Behbehani's declaration, and an Unopposed Motion to Substitute Expert (Paper 29) seeking to substitute Dr. Kirkness for Dr. Behbehani. We granted Petitioner's Motion (Paper 32). In this Decision we cite to the declaration of Dr. Behbehani (Ex. 1003) with the understanding that the opinions expressed were adopted by and, therefore, are attributable to Dr. Kirkness.

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sophistication of the technology; and educational level of active workers in the field.” *Id.* (quoting *Custom Accessories*, 807 F.2d at 962).

Petitioner contends that a person of ordinary skill in the art “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 that “[a]dditional experience could substitute for less education, and additional education could likewise substitute for less experience.” Pet. 23 (citing Ex. 1003 ¶ 89). Petitioner further contends that the “Petition does not turn on this precise definition, and the challenged claim[s] would be unpatentable from the perspective of any reasonable person of ordinary skill in the art at the relevant time.” *Id.* (citing Ex. 1003 ¶ 90). Patent Owner does not object to Petitioner’s definition for the level of ordinary skill in the art. PO Resp. 11.

Petitioner’s definition for the level of ordinary skill in the art is consistent with the problems addressed in the ’344 patent and the prior art. We, therefore, apply Petitioner’s level of ordinary skill in the art in this Decision.

B. Claim Construction

In this *inter partes* review, claims are construed using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.100(b) (2021). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing claims in accordance with their ordinary and customary meaning, we take

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into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thorner v. Sony Comput. Entm’t. Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only 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)). To determine whether Petitioner has shown that the challenged claims are unpatentable, we address the Parties’ proffered constructions for the following three claim terms: “troubled wakefulness,” “configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative,” and “analyze the breathing patterns.”

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1. *“troubled wakefulness”*

Independent claims 1 and 7 recite a “troubled wakefulness” state. Ex. 1001, 9:34–46, 10:6–19. Petitioner argues the claim term “troubled wakefulness” should be construed as “state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.” Pet. 23–24 (citing Ex. 1001, 4:54–58, Fig. 7; Ex. 1003 ¶¶ 93–94). For purposes of this proceeding, Patent Owner agrees with Petitioner’s construction. PO Resp. 18; *see also* Tr. 11:22–24 (Petitioner stating during oral argument that “[b]oth parties agree that troubled wakefulness is a state in which the breathing pattern is irregular, indicating that the patient is both awake and either anxious or uncomfortable”). We adopt Petitioner’s undisputed construction for this claim term because it is consistent with the Specification of the ’344 patent, which explicitly describes the term. *See, e.g.*, Ex. 1001, 4:53–58 (describing the breathing pattern for troubled wakefulness as “characterized by irregular[] 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”).

2. *“configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative”*

Independent claim 7 recites a processing arrangement “configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative.” Ex. 1001, 10:6–19. Petitioner argues the claim term “configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative” means “configured to analyze the breathing patterns to

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determine whether the breathing patterns’ are indicative of the specified states.” Pet. 24–26 (citing Ex. 1001, 4:18–22, 4:27–29, 4:31–32, 4:53–58, 5:26–33; Ex. 1002, 378, 398, 404; Ex. 1003 ¶¶ 95, 106). For purposes of this proceeding, Patent Owner agrees with Petitioner’s construction. PO Resp. 18. We adopt Petitioner’s undisputed construction for this claim term because it is consistent with the claim language and the Specification of the ’344 patent. *See, e.g.*, Ex. 1001, 4:12–29 (describing that processing arrangement 24 monitors a patient’s breathing patterns and determines a current state of the patient, such as whether the patient is asleep, awake and breathing regularly, or awake and breathing irregularly due to distress of anxiousness).

3. *“analyze the breathing patterns”*

Independent claims 1 and 7 recite a processing arrangement configured to “analyze the breathing patterns.” Ex. 1001, 9:34–46, 10:6–19. In the Petition, Petitioner does not expressly construe the term “analyze the breathing patterns”, but does identify the portions of the prior art that Petitioner contends teach the claim limitation including this term. *See, e.g.*, Pet. 53–56 (Petitioner arguing the combined teachings of Sullivan⁴⁶⁰ and Matthews would have resulted in the recited processing arrangement configured to analyze the breathing patterns). In its Response, Patent Owner argues that “analyze the breathing patterns” means “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 19. As borne out through Patent Owner’s arguments in response to Petitioner’s challenges and as further elaborated in Patent Owner’s Sur-reply, Patent Owner contends

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that examining the values of the parameters and the order in which they appear in time, as set forth in its proposed construction, entails analysis of both amplitude and temporal structures of a time series of breath-by-breath parameters from a flow waveform. PO Resp. 2, 10–11; Sur-reply 1, 3–5.

Petitioner disputes Patent Owner’s proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2–10. For the reasons that follow, we agree with Petitioner.

a. The Parties’ Contentions

To explain why the claim term “analyze the breathing patterns” should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the [S]pecification” of the ’344 patent. PO Resp. 19 (citing Ex. 1001, 4:37–45; Ex. 2006 ¶ 145); *see also* Sur-reply 12 (Patent Owner arguing that, according to Dr. Bates, “‘breathing pattern’ has no ordinary meaning and ‘is an extremely general term’”). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apnea and hypopnea in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters and the order in which they appear in time.” *Id.* (citing Ex. 2006 ¶ 146).

Patent Owner points to the description of Figures 7 and 8 of the ’344 patent in support of its construction. *Id.* at 19–21 (citing Ex. 1001, 4:53–60, 5:17–3; Ex. 2006 ¶¶ 147–149). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient’s airflow, but no periodic irregularity in breath size. Ex. 1001, 4:53–60. According to Patent Owner,

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This methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns wherein the focus hinges on a determination of “the sequence of parameters of a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time.”

PO Resp. 20 (citing Ex. 2006 ¶ 148); *see also* Sur-reply 4 (citing Ex. 1001, 4:53–60; Ex. 2006 ¶ 147) (Patent Owner arguing the ’344 patent describes Figure 7 as showing “both amplitude and temporal structures are likewise described when examining specific flow waveforms”). Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. Ex.1001, 5:17–33. Patent Owner argues the description of Figure 8 “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 20 (citing Ex. 1001, 5:17–33; Ex. 2006 ¶ 149); *see also* Sur-reply 4–5 (citing Ex. 1001, 5:24–33; Ex. 1052, 81:17–23, 180:1–15; Ex. 2006 ¶ 149) (Patent Owner arguing that distinguishing REM sleep from wakefulness requires analyzing both amplitude and temporal structures).

Additionally, Patent Owner suggests the Specification’s discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. PO Resp. 21 (citing Ex. 1001, 6:33–39; Ex. 2006 ¶ 150).

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In the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’344 [p]atent.” Sur-reply 2. First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” *Id.* at 3 (quoting Ex. 1001, 4:37–45) (citing Ex. 2006 ¶ 145). Patent Owner maintains that the descriptions of the waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of a waveform. *Id.* at 4–5 (citing Ex. 1001, 4:53–60, 5:24–33; Ex. 1052, 81:17–23, 180:1–15; Ex. 2006 ¶¶ 147–149). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not named in the ’344 [p]atent,” but contends that “these are not obligatory.” *Id.* at 5. Patent Owner asserts that enablement of the ’344 patent “hinges on its ability to distinguish between all awake and asleep states,” and that “[o]therwise, incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 6.

Second, Patent Owner asserts that, during the prosecution of the ’344 patent, Patent Owner argued the prior art “failed to discern between regular wakefulness and troubled wakefulness.” Sur-reply 6 (citing Ex. 1002, 404). According to Patent Owner, “[t]he central argument here is the necessity of integrating both amplitude and temporal structure analyses to distinguish all awake and asleep states.” *Id.*

Third, Patent Owner argues that “patentees do not need to rigidly define terms, but can imply their own meaning.” Sur-reply 6. Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by Figure 7 – a flow

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waveform indicating troubled wakefulness.” *Id.* (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the patent family “provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “[s]ince ‘analyses the data’ is followed by ‘to determine the patient’s breathing patterns,’ some of which occur in the asleep state and some of which occur in the awake state, this implies that these states can be separated from one another.” *Id.* at 6–7 (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22)). Patent Owner contends that, “[g]iven the separation between awake and asleep states discussed in the ’344 [p]atent, [Patent Owner’s] construction is integral for discerning the difference and applying the correct pressure” because, without doing so, it “could result in inappropriate pressure administration.” *Id.* (citing Ex. 1052, 179:23–25; Ex. 2006 ¶ 143).

Patent Owner also argues that extrinsic evidence supports its proposed construction. Sur-reply 7–12. Based on Dr. Bates’s testimony, Patent Owner asserts that “by assessing only amplitude” the waveforms of troubled wakefulness and REM sleep “appear indistinguishable,” but “their temporal structure (order in time) . . . offers differentiation.” *Id.* at 9 (citing Ex. 2006 ¶ 80). Patent Owner argues it proves its argument by showing that if the “temporal structure” of the REM sleep waveform is “rearranged in time,” then the resulting “time series has a random appearance that cannot be distinguished from troubled wakefulness.” *Id.* (citing Ex. 2006 ¶ 81). Patent Owner reasons that “amplitude structure and temporal structure convey independent information” and that both must be considered in an analysis or “the awake and asleep states can be confused.” *Id.* at 10 (citing Ex. 2006

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¶ 74). According to Patent Owner, “Dr. Bates’[s] illustrations present the problem solved by the ’344 [p]atent.” *Id.*

According to Patent Owner, construing “analyzing breathing patterns” to include “any type” of breathing pattern analysis, as suggested by Dr. Kirkness, is “nonsensical, as it might even encompass using a mirror to check for breaths.” Sur-reply 12 (citing Ex. 1051 ¶ 16).¹⁰

Specifically, Patent Owner argues:

Dr. Bates examined the [S]pecification to determine what characteristics of breathing characteristics were crucial to analyzing the breathing pattern with respect to the invention’s essence. He determined that a [person of ordinary skill in the art], after reading the [p]atent, would understand that analyzing breathing patterns must confer the ability to distinguish between troubled wakefulness and REM sleep. [Patent Owner’s] construction evidences the understanding of a [person of ordinary skill in the art] – that analyzing breathing patterns requires analysis of amplitude and temporal structures.

Sur-reply 13 (citations omitted) (citing Ex. 1052, 24:20–25, 25:1–13, 111:22–25, 112:1–21).

Petitioner asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the specification or during prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” Pet. Reply 6 (quoting *Hill-*

¹⁰ Patent Owner also states that “Dr. Kirkness argues that the ’344 [p]atent is indefinite, regarding the measurement of airflow waveforms and temporal/amplitude aspects,” and that “Petitioner has never raised indefiniteness.” Sur-reply 11. We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths.”

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Rom Servs., Inc. v. Stryker Corp., 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, ‘the patentee must clearly express an intent to redefine the term.’” *Id.* (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends that “[n]o such intent exists here” and that Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* at 6 (citing Ex. 1051 ¶¶ 25–33).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner’s] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as “propos[ing] a lengthy construction and then constru[ing] its own construction to inject two requirements: that the processor must analyze (1) ‘the value[s] of the parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.* (third alteration in original) (citing PO Resp. 18–19; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert construed based on his personal experience as opposed to that of a [person of ordinary skill in the art].” *Id.* (citing Ex. 1053, 271:10–14).

Petitioner proposes that we construe the phrase in accordance with its plain and ordinary meaning because “[n]othing in the intrinsic record limits ‘analyzing the breathing patterns’ to analysis of either or both amplitude and temporal structures—instead, the claims, [S]pecification, and prosecution history use these terms in accordance with their plain meaning.” Pet.

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Reply 3–4 (citing *CCS Fitness*, 288 F.3d at 1366). Petitioner argues that the claims of the '344 patent and related patents are dispositive and specifically recite analyses of breathing patterns that do not include analysis of amplitude and temporal structures. *Id.* at 4 (citing Ex. 1001, claims 1, 5, 7, 8, 15; Ex. 1051 ¶¶ 9, 13–15; Ex. 1055, claim 24; Ex. 1057, claim 3; Ex. 1058, claim 4).

Petitioner also contends the Specification “further confirms that the term encompasses any type of breathing pattern analysis.” Pet. Reply 4. According to Petitioner, the '344 patent “states that ‘[t]here are a number of characteristics of the patient’s breathing patterns that may be taken into account in making such a determination’ . . . and does not limit the analysis to any particular characteristic.” *Id.* at 4–5 (first alteration in original) (citing Ex. 1001, 2:41–43, 4:27–29, 4:53–58, 5:25–29, Figs. 3–8; Ex. 1051 ¶¶ 16–20; Ex. 1052, 28–30; Ex. 2006 ¶¶ 47–48, 147–149). Petitioner also contends “[t]he specification further states the flow sensors ‘detect the rate of airflow’ to and from the patient, and provide ‘[s]ignals corresponding to the airflow’ to a processing arrangement for processing.” *Id.* at 5 (second alteration in original) (citing Ex. 1001, 3:55–59). Thus, Petitioner asserts the Specification “confirms that temporal analysis is not required.” *Id.*

Petitioner addresses the prosecution history of the '344 patent and a related patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5. Petitioner asserts that Patent Owner did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1002, 91, 128; Ex. 1009, 404).

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Petitioner additionally contends Patent Owner’s extrinsic evidence, in the form of Dr. Bates’s testimony, contradicts the intrinsic record and should be disregarded. Pet. Reply 7–10. Petitioner asserts Dr. Bates “performed a ‘crude’ analysis by ‘approximating’ the amplitudes of each breath in the figures ‘estimat[ing] by eye . . . the size of those individual breaths.’” *Id.* at 7 (first alteration in original) (citing Ex. 1052, 75:11–76:14, 78:16–79:19). Petitioner argues that Dr. Bates’s “analysis has no basis in the patent.” *Id.* Petitioner presents five arguments in rebuttal in regard to the testimony of Dr. Bates:

(1) Dr. Bates’s analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the ’344 patent would have derived [Patent Owner’s] construction.” *Id.* (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* (citing Ex. 1052, 75:11–76:14; 78:16–79:19, 90:8–91:11).

(2) Dr. Bates’s analysis is based on his own expertise in “digital signal processing,” not from the viewpoint of a person of ordinary skill in the art who would not necessarily have such experience. *Id.* at 8 (citing Ex. 1052, 25:3–27:6, 52:2–25, 64:4, 208:16–21; Ex. 1053, 240:8–242:8, 243:3–8).

(3) Dr. Bates’s analysis contradicts the ’344 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM sleep without requiring temporal analysis. *Id.* at 8–9 (citing Ex. 1001, 4:46–52, 5:26–29, claims 5, 8¹¹; Ex. 1051 ¶¶ 8–24).

¹¹ Petitioner cites “EX1056” for claims 5 and 8 of the ’344 patent. Pet. Reply 8–9. The ’344 patent is Exhibit 1001, and there is no exhibit 1056 in

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(4) “Dr. Bates admitted the waveforms of Figures 7–8 are merely exemplary.” *Id.* at 9 (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do not limit the broader claim terms of the patent.” *Id.* (citing *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004); *N. Telecom Ltd. V. Samsung Elecs. Co.*, 215 F.3d 1281, 1293 (Fed. Cir. 2004)).

(5) Dr. Bates “could not explain ‘parameter’ or provide an objective basis to define a ‘sequence’ and ‘series’ used in [Patent Owner’s] construction” and “admitted that [Patent Owner’s] construction would exclude breathing patterns recited in dependent claims.” *Id.* at 10 (citing Ex. 1052, 182:1–184:19, 247:5–11; Ex. 1053, 288:14–289:3). Thus, Petitioner asserts we “should discount []expert testimony that is clearly at odds . . . with the written record of the patent.” *Id.* (first alteration in original) (quoting *Phillips*, 415 F.3d at 1318).

b. Analysis

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14. Independent claim 1 recites “a processing arrangement configured to *analyze the breathing patterns* to determine whether the breathing patterns are indicative of a troubled wakefulness state,” and independent claim 7 similarly recites “a processing arrangement configured to *analyze the breathing patterns* to determine to which of the following states the detected breathing patterns is indicative: (i) a REM sleep state, (ii) a non-troubled wake states, (iii) a non-REM sleep state and (iv) a troubled wakefulness state.” Ex. 1001, 9:37–39, 10:10–15 (emphases added). As

this proceeding. We understand that Petitioner’s citation to exhibit 1056 is a typographical error and that Petitioner is citing to Exhibit 1001.

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reflected, independent claims 1 and 7 do not recite “a sequence of parameters,” “a series of breaths,” “examining the values of the parameters and the order in which they appear in time,” or an analysis of amplitude and temporal structures. Rather, independent claims 1 and 7 recite that the processing arrangement analyzes the breathing patterns, without specifically reciting how the analysis is performed. The claims do, however, recite the purpose of the analysis—to determine whether the breathing pattern is indicative of the patient’s state—but do not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a significant number of limitations neither expressly recited nor suggested by the specific language of the claims.

Although independent claims 1 and 7 do not provide any further limitations as to the specific requirements of the breathing patterns, claims 5 and 8, which depend from claims 1 and 7, respectively, do provide such further limitations. Ex. 1001, 9:55–10:3, 10:20–24. Claim 5 recites “the breathing patterns that are indicative of the troubled wakeful state^[12] comprises one or more patterns selected from the group consisting of (a) pure mouth breathing, (b) erratic large breaths with varying inspiratory times, and (c) irregularity of intervals between breaths,” and claim 8 recites “the breathing patterns that are indicative of state (i) [a REM sleep state] comprise one or more patterns selected from the group consisting of (a) an

¹² We understand “the troubled wakeful state” recited in claim 5 refers to the “troubled wakefulness state” recited in independent claim 1, and Patent Owner does not argue that the “troubled wakeful state” is different from the “troubled wakefulness state.”

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absence of large breaths, (b) a high respiratory rate, (c) a low flow rate, and (d) a cluster of small breaths.” *Id.* We agree with Petitioner that some of these particular breathing patterns do not require an analysis of amplitude and temporal structures. Pet. Reply 4 (citing Ex. 1001, claims 1, 5, 7, 8, 15; Ex. 1051 ¶¶ 9, 13–15; Ex. 1055, claim 24; Ex. 1057, claim 3; Ex. 1058, claim 4). With respect to the breathing patterns indicative of the troubled wakefulness state recited in claim 5, “pure mouth breathing” does not require an analysis of temporal structure. Similarly, with respect to the breathing patterns associated with REM sleep recited in claim 8, “an absence of large breaths,” “a high respiratory rate,” and “a low flow rate” do not require an analysis of temporal structure. Hence, according to the claims, neither an analysis of amplitude and temporal structures, nor a determination of sequence of parameters and the order in which they appear in time, is necessary to indicate whether the patient is in a troubled wakefulness state or a REM sleep state.

Patent Owner argues that some of the recited breathing patterns include temporal structures, and other recited breathing patterns include amplitude structures (Sur-reply 13), but Patent Owner does not refute that some of the recited breathing patterns may be determined without an analysis of both amplitude and temporal structures. Patent Owner also argues that claims 5 and 8 are not being asserted. Sur-reply 14. The court, however, in *Phillips*, makes clear that “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term.” *Phillips*, 415 F.3d at 1314 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Given that claims 5 and 8 recite breathing patterns

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indicative of a troubled wakefulness state and a REM sleep state that do not require an analysis of both amplitude and temporal structures or a determination of a sequence of parameters and the order in which they appear in time, these claims show the claim term “analyze the breathing pattern” in independent claims 1 and 7 does not include the additional limitations set forth in Patent Owner’s proffered construction.

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citing *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004)). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech.*, 923 F.3d at 1044.

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of “analyze the breathing patterns,” nor does Patent Owner argue that it explicitly defined the claim term in the Specification. We agree that there is no disavowal nor any explicit lexicographic definition of “analyze the breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we should construe the phrase as Patent Owner proposes. PO Sur-reply 6–7 (citing, *inter alia*, *AstraZeneca AB v. Mut. Pharm. Co., Inc.*, 384 F.3d 1333 (Fed. Cir. 2004)). We disagree with Patent Owner that the Specification implies Patent Owner’s construction.

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In *AstraZeneca AB*, the court reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d 1333, 1339–40 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors “deliberately acted as their own lexicographers” to limit the claim term “solubilizer” to surfactants, the court explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The court rejected the argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

The Specification of the ’344 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to an analysis of amplitude and temporal structures, “a sequence of parameters,” “a series of breaths,” “examining the values of the parameters and the order

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in which they appear in time,” or any of the other terms set forth in the proposed construction. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. *See* Pet. Reply 6 (Petitioner arguing “the terms ‘amplitude’ and ‘temporal’ do not appear anywhere”); Sur-reply 5 (Patent Owner asserting “Petitioner rightly observes that terms like ‘amplitude’ and ‘temporal’ are not named in the ’344 [p]atent”); *see also* Ex. 1051 ¶ 24 (Dr. Kirkness stating that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’344 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures”). Patent Owner directs us to a portion of the Specification for what Patent Owner characterizes as the process of analyzing breathing patterns. PO Resp. 19 (quoting Ex. 1001, 4:37–45). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” Ex. 1001, 4:37–45. The cited text does not describe an analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how “processing arrangement 24 makes a determination as to the 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).” Ex. 1001, 4:18–22. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG

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data, breathing patterns, etc. in determining the patient's state.” *Id.* at 4:22–26. There is no mention that analyzing breathing patterns requires analyzing a sequence of parameters and the order in which they appear in time or analyzing amplitude and temporal structures of the waveform. The Specification further describes, in an embodiment, “processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern.” Ex. 1001, 7:11–13. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal structures of the waveform.

Patent Owner relies on the descriptions Figures 7 and 8 to support its argument that an analysis of both the amplitude and temporal structures is required to distinguish between troubled wakefulness and REM sleep and fully enable the claimed invention. Sur-reply 4–6; *see also id.* at 8 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Even if we were to agree with Patent Owner that the descriptions of Figures 7 and 8 describe an analysis of amplitude and temporal structures of the depicted waveforms for troubled wakefulness and REM sleep, respectively, we fail to see how the analysis set forth in each description is something other than an example. The Specification explicitly describes that “[t]here are a number of characteristics of the patient's breathing patterns that may be taken into account in making a determination” as to the current state of the patient. Ex. 1001, 4:27–29. Moreover, with respect to the breathing pattern in Figure 8, the Specification describes:

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This REM associated pattern of breathing may include e.g., the absence of larger breaths, especially after pauses, generally high respiratory rates and low flow rates, and a tendency for clustering of small breaths. These differences in the pattern of the respiratory airflow signal from those seen during troubled wakefulness allow the separation of these states and can be used to make a change in the applied pressure.

Id. at 5:26–34. We are persuaded that some of the breathing patterns indicative of REM sleep, namely “high respiratory rates” and “low flow rates,” do not require an analysis of temporal structures. *See* Pet. Reply 4 (citing Ex. 1001, claims 1, 5, 7, 8, 15; Ex. 1051 ¶¶ 9, 13–15; Ex. 1055, claim 24; Ex. 1057, claim 3; Ex. 1058, claim 4) (Petitioner arguing, *inter alia*, that “a low flow rate” and “a high respiratory rate” require no temporal structure). Given that an analysis of amplitude and temporal structures is simply one way to distinguish troubled wakefulness from REM sleep, Patent Owner’s proposed construction is unnecessary to “fully enable” the claimed invention and would improperly import limitations from the embodiments in the Specification into the claims.

Turning to the prosecution history, Patent Owner relies on an argument that the prior art failed to discern between regular wakefulness and troubled wakefulness to support its proposed construction. Specifically, during prosecution, Patent Owner argued the prior art does not disclose the recited processing arrangement configured to determine whether the detected breathing pattern is indicative of a REM sleep state, a non-troubled wake state, a non-REM sleep state, or a troubled wakefulness state because “the ‘micro-arousals’ cited by the Examiner refer[] to a light stage of sleep that is different from an awake or arousal state, and does not further identify whether the patient is anxious or uncomfortable.” Ex. 1002, 404. Instead of

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distinguishing the prior art based on the particular analysis for differentiating the states, Patent Owner distinguished the claimed invention based on the type of states the processing identifies. Thus, the prosecution history does not support the additional limitations Patent Owner seeks to read into the claim term “analyze the breathing patterns.”

Having considered the intrinsic evidence, we review the extrinsic evidence, and specifically the testimony of Dr. Bates. Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 19–21 (citing Ex. 1001, 4:37–45, 4:53–60, 5:17–33, 6:33–39; Ex. 2006 ¶¶ 145–150). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. Ex. 2006 ¶¶ 145–150. Rather, Dr. Bates reads portions of the Specification and extrapolates, by taking several unsupported leaps, that the ’344 patent “implicitly demands certain parameter measurements.” Sur-reply 6 (citing Ex. 1052, 44:6–20).

Although expert testimony is legitimate to consider when construing claims, the court, in *Phillips*, has cautioned that, because it “is generated at the time of and for the purpose of litigation,” it “can suffer from bias that is not present in intrinsic evidence.” 415 F.3d at 1318. And, extrinsic evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* at 1317 (internal quotation marks and citations omitted). In the context presented here, Dr. Bates’s testimony is not supported sufficiently by the intrinsic record or

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other extrinsic evidence, e.g., objective extrinsic evidence, and, therefore, even though we have considered it fully, we give it little weight.

For the reasons explained above, we determine Patent Owner did not implicitly define the claim term “analyze the breathing patterns,” as proposed, because Patent Owner has failed to show any sufficient evidence that the ’344 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner’s contentions in light of all the evidence of record, we do not adopt Patent Owner’s proposed construction; instead, we apply the plain and ordinary meaning of “analyze the breathing patterns” in our consideration of the issues before us.

C. Obviousness of Claims 1, 3, 7, 9, 11, and 13 over Sullivan995, Sullivan460, and Matthews

Petitioner challenges claims 1, 3, 7, 9, 11, and 13 under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Sullivan995, Sullivan460, and Matthews. Pet. 45–62; Pet.

Reply 18–26. Patent Owner argues the references do not render the claimed subject matter obvious. PO Resp. 35–41; Sur-reply 20–24. Patent Owner contends there is no disclosure of all of the claim limitations, no motivation to combine the teachings of the references, and no reasonable expectation of success in combining the references, and Patent Owner further contends secondary considerations support non-obviousness. PO Resp. 35–41; Sur-reply 20–24.

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We begin our analysis of this asserted ground of unpatentability with an overview of each of the references. We then discuss the Parties' contentions for each of the claims.

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, reproduced below, depicts a snoring detection apparatus. *Id.* at 8:47.

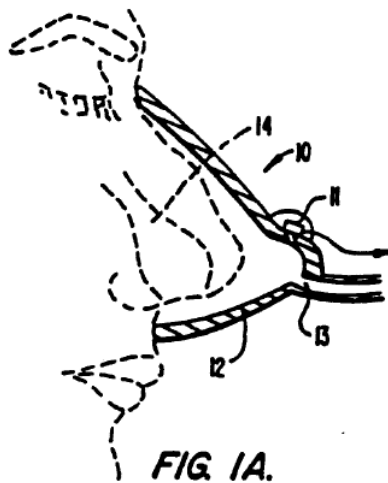


Figure 1A “is a schematic sectional view of one embodiment of a snoring detection apparatus.” *Id.* at 8:66–68. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a nose mask.” *Id.* at 8:47–49. Sullivan995 explains that “[a]ir, being inhaled by the patient, enters the nasal passageways 14 through the opening 13 in the nose mask 12 and is exhaled in the reverse direction” and that this

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arrangement focuses and concentrates snoring and breathing sounds. *Id.* at 8:49–52, 8:57–59.

Sullivan995 describes using detection device 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.

Figure 3 of Sullivan995 is reproduced below.

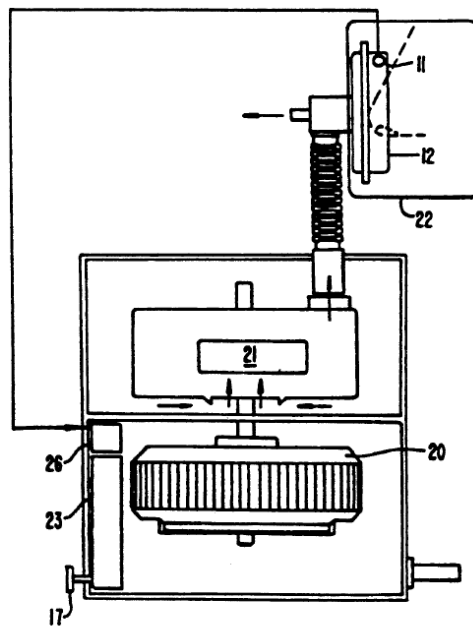


FIG. 3

Sullivan995’s Figure 3 shows a CPAP apparatus. *Id.* at 9:57–58. The CPAP apparatus includes motor 20 that drives blower 21. *Id.* at 9:58–59.

Sullivan995 explains “[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

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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 9:66–10:1. 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, after going to sleep, the patient’s body relaxes, causes the patient’s airway to become unstable, resulting in snoring. *Id.* at 10:48–54. Detection means 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.

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Figure 12 of Sullivan995 is reproduced below.

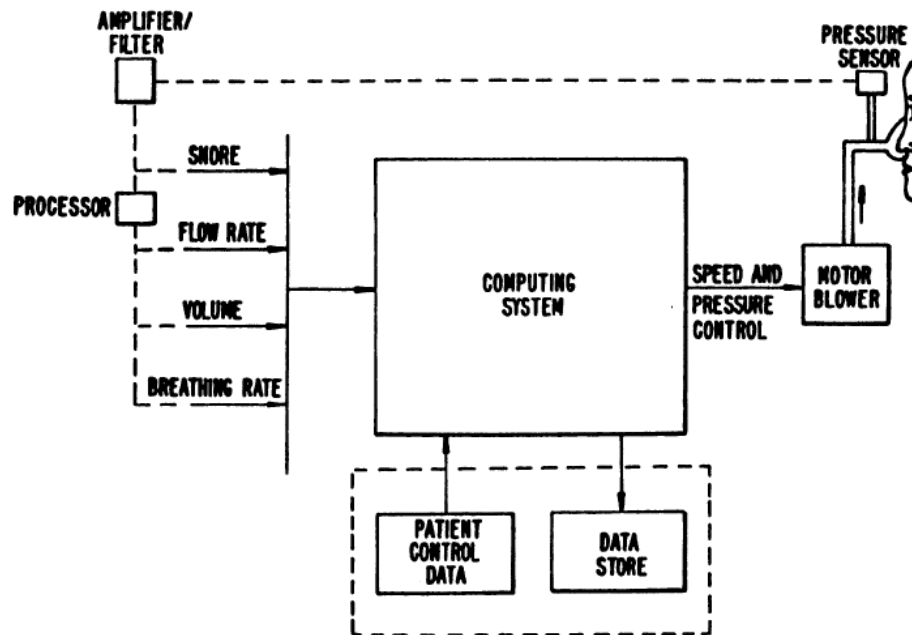


FIG. 12.

Sullivan995's 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

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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.” *Id.* at 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 [Sullivan995].” *Id.* at 6:22–24.

Figure 2 of Sullivan460 is reproduced below.

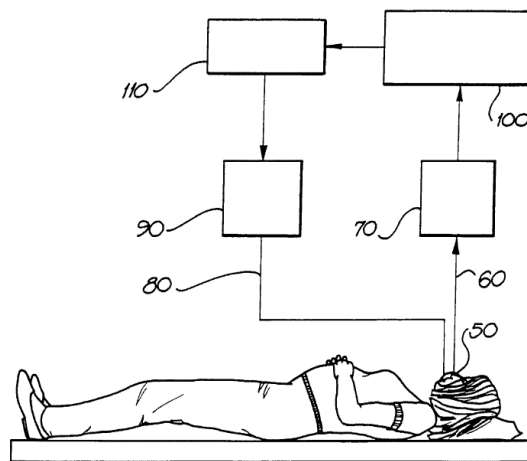


FIG. 2

“Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia.” *Id.* at 10:7–8. 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 by 80 to nCPAP apparatus 90. *Id.* at 10:9–10. 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.*

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at 10:10–12. 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. *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

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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 that “[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.

4. *Independent Claims 1 and 7*

a. *Identification of the Claim Limitations*

Petitioner provides a limitation-by-limitation analysis of independent claims 1 and 7 as a group, mapping the claim limitations to the references. Pet. 47–59. Petitioner generally relies on Sullivan995 to disclose the recited components of the claims. More specifically, Petitioner relies on Sullivan995’s microphone 11, amplifier/filter/processor unit 26, and blower 21 for disclosing the recited flow sensor, processing arrangement configured to analyze breathing patterns, and generator configured to supply airflow to an airway, respectively. Pet. 49–53 (citing Ex. 1003 ¶¶ 178–187; Ex. 1005, Abstract, 3:21–33, 8:47–61, 9:64–66, 10:1–3, 11:5–20, 15:56–64, 18:27–31, 18:50–53, Figs. 1A–B, 2A–B, 3, 7, 9), 53–54 (citing Ex. 1003

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¶¶ 189, 193; Ex. 1005, 9:59–60, 10:3–6, 10:15, 10:37–66, 11:55–64, 14:40–41, 14:50–55, 15:1–3, 15:27–33, 15:59–63, Figs. 3, 4, 12), 57 (citing Ex. 1003 ¶ 202; Ex. 1005, 9:57–64).

For the recited function of the processing arrangement, namely the limitation of independent claim 1 reciting “to determine whether the breathing patterns are indicative of a troubled wakefulness state” and the similar limitation of independent claim 7 reciting “to determine to which of the following states the detected breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state,” Petitioner relies on the combined teachings of Sullivan460 and Matthews.¹³ Pet. 54. Petitioner argues Sullivan460 teaches using a sleep sensor to determine a sleep state and a wake state and two modes of air delivery, namely a first mode for the wake state and a second mode for the sleep state. *Id.* at 34–35 (citing Ex. 1003 ¶ 134; Ex. 1006, 7:3–7, 6:30–7:12, 7:17–19, claims 22–28, 43–46). Petitioner further argues that, for the specific types of wake and sleep states, Matthews teaches using the detection of erratic breathing. *Id.* at 35 (citing Ex. 1003 ¶ 135). According to Petitioner, “Matthews recognizes 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 “[t]o address potential instability, Matthews discloses ‘a variable breathing

¹³ Petitioner’s arguments regarding the identification of these limitations are the same as its arguments for the identification of these limitations with respect to the asserted ground of unpatentability based on Rapoport502, Sullivan460, and Matthews. Pet. 54 (Petitioner referring to the arguments for these limitations with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews).

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control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing.” *Id.* at 35–36 (first alteration in original) (citing Ex. 1007, 21:37–40, 40:25–30). Petitioner contends:

Matthews’s disclosure of monitoring and detecting erratic or irregular breathing, meets the *determine whether a breathing pattern is indicative of a non-troubled wake state, a troubled wakefulness state and a REM sleep*. Further, it follows where Matthews detects no erratic breathing in a sleep state (as taught by Rapoport⁵⁰² and also Sullivan⁴⁶⁰), Matthews determines a *non-REM sleep state*.

Id. at 36 (citing Ex. 1003 ¶ 137).

For the recited function of the generator, namely the limitation of independent claim 1 reciting “to reduce a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of a troubled wakefulness state, the second pressure being lower than the first pressure” and the similar limitation of independent claim 7 reciting “to adjust a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure as a function of a state determined by the processing arrangement,” Petitioner relies on the combined teachings of Sullivan⁹⁹⁵ and Matthews. Pet. 57–59. Petitioner argues “Sullivan⁹⁹⁵’s *generator* is configured to adjust a pressure of the airflow supplied to an airway of the patient as a function of a state determined by the processing arrangement.” *Id.* at 57 (citing Ex. 1003 ¶ 203). According to Petitioner, “Sullivan⁹⁹⁵ describes that . . . the CPAP should operate at a higher pressure immediately before, and during an apnea event or REM sleep, and at a lower pressure at other times.” *Id.* at 58 (citing Ex. 1003 ¶ 207; Ex. 1005, 11:23–25). Although Petitioner contends Sullivan⁹⁹⁵ discloses

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adjusting the pressure as a function of patient state, Petitioner acknowledges Sullivan995 does not disclose a troubled wakefulness state. *Id.* at 58–59 (citing Ex. 1003 ¶ 208). Petitioner contends Matthews discloses a troubled wakefulness state.¹⁴ *Id.* at 59. Petitioner argues Matthews teaches interrupting the auto-CPAP controller and decreasing the pressure delivered to a patient when erratic breathing is detected. *Id.* at 39–40 (citing Ex. 1003 ¶ 153; Ex. 1007, 21:35–44, 21:57–61, 21:63–22:1, 23:67–24:2, claim 1). Petitioner further argues Matthews teaches using the values of previously applied pressures and patient breathing patterns to recognize the patient’s state and then optimize the applied pressure. *Id.* at 40–42 (citing Ex. 1003 ¶¶ 154–155; Ex. 1007, 21:37–39, 23:55–24:10, Fig. 13; Ex. 1016, 1; Ex. 1036, 3).

Patent Owner contends the combination of Sullivan995, Sullivan460, and Matthews does not disclose every claim limitation because the references do not distinguish between a troubled wakefulness state and a REM sleep state. PO Resp. 36–39. Regarding the specific claim limitations, Patent Owner contends the references do not disclose the processing arrangement and generator, particularly, the functions associated therewith, recited in independent claims 1 and 7.¹⁵ *Id.* at 38 (citing Ex. 2006

¹⁴ Petitioner’s arguments regarding the identification of the recited troubled wakefulness state are the same as its arguments for the identification of the recited troubled wakefulness state with respect to the asserted ground of unpatentability based on Rapoport502, Sullivan460, and Matthews. Pet. 59 (Petitioner referring to the arguments for the recited troubled wakefulness state with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews).

¹⁵ In its Response, Patent Owner reproduces independent claim 7, and argues “the missing claim limitations are highlighted in red.” PO Resp. 36.

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¶¶ 209–212, 220–222). According to Patent Owner, “an analysis of both the amplitude structure and temporal structure of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.” *Id.* at 37 (citing Ex. 2006 ¶ 214); *see also id.* at 39 (Patent Owner arguing “[a]s stated by Dr. Bates, the distinction between REM sleep and troubled wakefulness cannot be made purely on the basis of their respective degrees of variability in breath amplitude” (citing Ex. 2006 ¶¶ 226–231)). Patent Owner argues the references “only teach the identification of patient state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of time series.” *Id.* (citing Ex. 2006 ¶ 213); *see also id.* at 39 (Patent Owner arguing “Sullivan460 and Matthews disclose only the analysis of the amplitude structure of the time series.” (citing Ex. 2006 ¶ 206)).

Petitioner replies that Patent Owner concedes that the references disclose “analyze the breathing pattern[s]” according to its plain meaning to determine asleep versus awake states, including troubled wakefulness and REM sleep. Pet. Reply 19. Petitioner also replies that, even if “analyze the breathing patterns” requires an analysis of both amplitude and temporal structures, the references disclose such an analysis. *Id.* at 19–20 (citing

However, there is no highlighting in Patent Owner’s reproduced version of independent claim 7. Patent Owner also argues “neither Sullivan460 nor Matthews teach the following claim limitations which are missing from Sullivan995” and quotes the processing arrangement recited in independent claim 1 and the generator recited in independent claims 1 and 7. *Id.* at 37–38. Given the similarities between independent claims 1 and 7, we understand Patent Owner is arguing that the combination of Sullivan995, Sullivan460, and Matthews does not disclose the processing arrangement and generator recited in independent claims 1 and 7.

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Ex. 1051 ¶¶ 40–41. Petitioner argues Sullivan995 discloses patterns of normal breathing and snoring and increases the pressure in response. *Id.* at 20 (citing Ex. 1005, 9:15–27, 10:55–58, 14:65–15:17, Figs. 2A, 13; Ex. 1051 ¶ 46). Petitioner argues Sullivan460 teaches analyzing the temporal structure of a time series by: sensing an upper airway flow limitation characterized by at least one decrease in upper airway inspiratory flow rate followed by at least one increase in flow rate, determining the asleep state based on reduced average air flow in the patient’s upper airway, and distinguishing vibrations from breaths. *Id.* at 20–21 (citing Ex. 1006, 4:28, 5:22, 6:27–29, 7:17–19, 12:33, 15:22; Ex. 1051 ¶¶ 41–43; Ex. 1052, 49:19–50:2). Petitioner argues Matthews’s air flow time series shown in Figure 8, breath parameters obtained over time shown in Figures 23–24, and sequence of processed breath parameters shown in Figures 10A–B teach analyzing amplitude and temporal structures of a time series. *Id.* at 21 (citing Ex. 1051 ¶ 47).

In its Sur-reply, Patent Owner argues Sullivan995’s snoring sounds are not breathing patterns. Sur-reply 20 (citing Ex. 2006 ¶ 220). Patent Owner further argues that neither Sullivan460 nor Matthews teaches analyzing the amplitude and temporal structures of a breathing pattern because Dr. Kirkness mistakenly equates a temporal structure analysis with a time series. *Id.* at 21–23 (citing Ex. 1007, 4:27–29, 4:33–34, 5:4–8; Ex. 1051 ¶¶ 41–43; Ex. 1052, 46:15–18, 119:7–120:1; Ex. 1053, 247:5–19; Ex. 2006 ¶¶ 63, 72, 74, 77, 80, 93, 99, 220).

Patent Owner’s arguments alleging that the combination of Sullivan995, Sullivan460, and Matthews does not disclose the recited functions of the processing arrangement and generator are premised on its

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proffered claim construction of “analyze the breathing patterns,” which we do not adopt for the reasons set forth above in Section II.B.3. As we discuss in this section, we disagree with Patent Owner that analysis of both amplitude and temporal structures is required to distinguish a troubled wakefulness state from REM sleep. Rather, the ’344 patent describes and claims breathing patterns indicative of a troubled wakefulness state and a REM sleep state that do not require an analysis of amplitude and temporal structures. *See* Ex. 1001, 4:27–29, 5:26–34, claims 5, 8.

Applying the Parties’ agreed-upon constructions and giving the remaining claim terms, including “analyze the breathing patterns,” their plain and ordinary meaning, Petitioner has persuasively identified in its proposed combination of Sullivan995, Sullivan460, and Matthews each limitation of independent claims 1 and 7, including the recited processing arrangement and generator. Regarding the recited processing arrangement, we are persuaded that Sullivan995’s amplifier/filter/processor unit 26, which generates a control signal indicative of a predetermined pattern, discloses a processing unit. Ex. 1003 ¶¶ 188–200, 193; Ex. 1005, 10:3–6, 10:37–66, 11:55–62, Fig. 4. We are also persuaded that Sullivan460 teaches determining whether a patient is awake or asleep (Ex. 1003 ¶ 134; Ex. 1006, 6:30–7:12, 7:17–19, claims 22–28, 43–46) and that Matthews teaches detecting erratic breathing during wakefulness and sleep (Ex. 1003 ¶¶ 135, 137; Ex. 1007, 21:37–40, 40:25–30). Combining the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes would result in a processing arrangement that determines whether the patient is awake or asleep and whether the patient is breathing erratically. By determining whether the patient is awake or asleep and whether the patient is breathing

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erratically, the processing arrangement determines whether the patient's breathing pattern is indicative of the recited states, which include two sleep states that are distinguishable by erratic breathing and two awake states that are distinguishable by erratic breathing. We are persuaded Petitioner's proposed combination of the references would result in a processing arrangement that analyzes the patient's breathing pattern to determine whether a patient's breathing pattern is indicative of the following states: (i) a REM sleep state in which the patient is asleep and breathing erratically, (ii) a non-troubled wake state in which the patient is awake and not breathing erratically, (iii) a non-REM sleep state in which the patient is asleep and not breathing erratically, and (iv) a troubled wakefulness in which the patient is awake and breathing erratically. Accordingly, Petitioner has persuasively identified in its proposed combination of Sullivan995, Sullivan460, and Matthews the processing arrangement recited in independent claims 1 and 7.

Regarding the recited generator, we are persuaded that Sullivan995's motor 20 and blower 21, which are configured to deliver airflow at different pressures based on the patient's breathing patterns, disclose a generator configured to supply an airflow to an airway of the patient from a first pressure to a second pressure and to adjust the pressure of the airflow as a function of the breathing pattern and the state of the patient associated therewith. Ex. 1003 ¶¶ 202–203, 206–207; Ex. 1005, 9:57–64, 10:3–12, 11:23–35; 16:6–11, 16:35–50. We are also persuaded that Matthews teaches adjusting the air flow pressure depending on the patient breathing erratically and further teaches pressure decrease 332 after pressure increase 330 resulted in erratic breathing, as shown by case 2 in Figure 13. Ex. 1003

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¶ 153; Ex. 1007, 21:57–61, 23:67–24:2. Petitioner has persuaded us that combining the teachings of the references as Petitioner proposes would result in a generator configured to adjust the airflow pressure based on the patient’s breathing patterns, which are indicative of the patient’s state, and to reduce the airflow pressure upon a detection of the patient being asleep and breathing erratically, which indicates troubled wakefulness. Accordingly, Petitioner has persuasively identified the generator recited in independent claims 1 and 7 in its proposed combination of the references.

b. Motivation to Combine

Petitioner argues it would have been obvious to modify Sullivan995’s system to determine whether the breathing patterns are indicative of certain states of the patient and to adjust the pressure of the airflow supplied to the patient based on the patient’s state, as Sullivan460 and Matthews teach. Pet. 45–46, 54–56, 59. Petitioner asserts that a person of ordinary skill in the art would have modified Sullivan995’s disclosure to detect different awake states because “[t]he modification to Sullivan995 CPAP system would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* at 46; *see also id.* at 55 (“This modification would have caused Sullivan995’s CPAP system to detect additional breathing states to better tailor the CPAP output to a patient’s needs.” (citing Ex. 1003 ¶ 197)). Petitioner further asserts that a person of ordinary skill in the art “would be motivated to configure the CPAP system of Sullivan995 to determine when a user’s breathing becomes so erratic that auto-CPAP controller is interrupted to alleviate the discomfort of the patient and facilitate compliance.” *Id.* at 56 (citing Ex. 1003 ¶ 198; Ex. 1007, 21:40–44).

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Patent Owner contends there is no motivation to combine Sullivan995, Sullivan460, and Matthews as Petitioner proposes. PO Resp. 40–41; Sur-reply 17–20, 24 (Patent Owner referring to the arguments regarding motivation to combine with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews). Patent Owner argues there is no motivation to combine the teachings of the references because the systems of Sullivan460 and Matthews cannot distinguish between certain states. PO Resp. 40. According to Patent Owner:

It would not have been obvious to a [person of ordinary skill in the art] to modify the processing arrangement in Sullivan995 to determine breathing patterns *indicative of a REM sleep state and a troubled wakefulness state*, as Petitioner contends is taught by Sullivan460 and Matthews, because Sullivan460 and Matthews focus exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to distinguish between an awake and an asleep state such as REM sleep being distinct from troubled wakefulness.

Id. (citing Ex. 2006 ¶¶ 210, 220–221). Patent Owner further argues Petitioner erroneously equates “erratic breathing” and “troubled wakefulness,” which are not interchangeable because Matthews cannot differentiate between them. Sur-reply 18 (citing Ex. 1052, 175:1–5; Ex. 2006 ¶ 130(a)). Patent Owner also argues that Petitioner fails to explain how Matthews’s breathing pattern indicative of troubled wakefulness could be integrated into existing systems without accounting for both amplitude and temporal structures. *Id.* (citing Ex. 2006 ¶ 157).

Petitioner maintains that Patent Owner’s alleged lack of a motivation to combine the teachings of the references is a regurgitation of its argument

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that the prior art does not disclose “analyze the breathing patterns” recited in independent claims 1 and 7. Pet. Reply 22. We agree with Petitioner.

Like its contentions that Sullivan995, Sullivan460, and Matthews fail disclose all the claim limitations, Patent Owner’s arguments alleging a lack of a motivation to combine is premised on its proffered claim construction of “analyze the breathing patterns.” We do not adopt Patent Owner’s proffered claim constructions for the reasons set forth above in Section II.B.3. As we discuss in this section, we disagree with Patent Owner that analysis of both amplitude and temporal structures is required to distinguish a troubled wakefulness state from REM sleep.

Patent Owner also argues there is no motivation to combine the references because Dr. Kirkness did not know how to calculate Sullivan460’s preset level, which is a single value of flow rate. PO Resp. 40–41 (citing Ex. 2015, 48:6–20). Patent Owner further argues that Sullivan460 is not enabling because Sullivan460 fails to provide certain details to determine the preset flow rate. Sur-reply 18–19 (citing Ex. 2006 ¶ 99; Ex. 2015, 48:6–20).

At the outset, we agree with Petitioner that “enablement ‘is not a requirement to prove invalidity under § 103.’” Pet. Reply 23 (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003)). Moreover, we also agree with Petitioner that a person of ordinary skill in the art would have understood a preset level is established from previously-acquired data, such as an average level, as Sullivan995 discloses. *Id.* at 22 (citing Ex. 1005, 17:3–27, Fig. 12; Ex. 2015, 38:2–16). Sullivan995 discloses the computing system may “calculate control values of patterns for each patient based on moving average values or such values

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or patterns will be pre-programmed into the computing system.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22.

Patent Owner additionally argues that “Petitioner simplifies Matthews’s teachings, claiming it advocates decreasing CPAP pressure when erratic breathing is detected” and that “[i]n reality, Matthews adjusts pressure based on the previous CPAP setting.” Sur-reply 17. According to Patent Owner, “Matthews’[s] adjustments to pressure do not differentiate between asleep and awake states, but employ[] an equation that calculates a variable breathing number to assess if the breathing becomes too erratic.” *Id.* at 17–18 (citing Ex. 1052, 173:12–22, 174:12–17). Petitioner, however, is not relying on Matthews for differentiating asleep and awake states, and Patent Owner focuses on Matthews without addressing Petitioner’s proposed combination of Sullivan995, Sullivan460, and Matthews. As we explain above in Section III.C.4.a, Sullivan460 teaches determining whether a patient is awake or asleep, and Matthews teaches detecting erratic breathing during wakefulness and sleep. Combining the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes would result in a processing arrangement that determines whether the patient is awake or asleep and whether the patient is breathing erratically. By determining whether the patient is awake or asleep and whether the patient is breathing erratically, the processing arrangement determines whether the patient’s breathing pattern is indicative of a REM sleep state, a non-troubled wake state, a non-REM sleep state, or a troubled wakefulness state. Furthermore,

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in view of Sullivan995's disclosure of a generator configured to adjust the airflow pressure as a function of the breathing pattern and the associated patient state and Matthews's teaching of decreasing pressure after a pressure increase resulted in erratic breathing, Petitioner's proposed combination would result in a generator configured to adjust the airflow pressure based on the patient's state and reduce the airflow pressure upon a detection of the patient being asleep and breathing erratically, which is indicative of a troubled wakefulness state.

Patent Owner improperly argues for the first time in its Sur-reply that Petitioner's combination of Sullivan995, Sullivan460, and Matthews would have required "undue experimentation because analyzing both amplitude and temporal structures to determine asleep/asleep states was not known." Sur-reply 19–20. Patent Owner's alleged "undue experimentation" was not raised in Patent Owner's Response, and therefore Petitioner did not have an opportunity to respond to it. Accordingly, Patent Owner's argument is improper, and the issue is deemed waived. *See* Inst. Dec. 45 n.10 (stating that "Patent Owner is cautioned that any arguments not raised in the Patent Owner Response may be deemed waived"). Moreover, we disagree with Patent Owner's "undue experimentation" argument because it is premised on Patent Owner's proposed construction requiring analysis of "both amplitude and temporal structure," which we do not adopt.

After considering the Parties' arguments and evidence, we are persuaded a person of ordinary skill in the art would have combined the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes. Petitioner proposes to modify Sullivan995's system to determine whether the breathing patterns are indicative of certain states of the patient and to

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adjust the pressure of the airflow supplied to the patient based on the patient's state, as Sullivan460 and Matthews teach. Pet. 45–46, 54–56, 59. Petitioner reasons that a person of ordinary skill in the art would have combined the teachings of Sullivan995, Sullivan460, and Matthews to “allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* at 46. Petitioner's reason for combining the teachings of the references finds support in Sullivan995, which discloses using the lowest practicable airway pressure to promote the patient's comfort during CPAP therapy. Ex. 1005, 2:31–39; Ex. 1003 ¶ 171. Thus, Petitioner has provided persuasive reasoning for combining the teachings of Sullivan995, Sullivan460, and Matthews.

c. Reasonable Expectation of Success

Petitioner argues a person of ordinary skill in art in the art would have had a reasonable expectation of success in combining the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes. Pet. 46–47, 56, 59. Petitioner asserts that all of the references disclose CPAP systems with flow sensors and flow generators and that, like Sullivan995, Matthews teaches data from the flow sensor is monitored and used to control the pressure delivered to the patient. *Id.* at 46–47 (citing Ex. 1007, 8:54–9:10). According to Petitioner, Sullivan995 is already configured to monitor breathing patterns while a patient is asleep to determine the patient's pressure flow needs. *Id.* at 56 (citing Ex. 1005, 10:52–61). Petitioner asserts a person of ordinary skill in the art would have been able to incorporate Matthews's algorithm to interrupt Sullivan995's control in the same manner that Matthews teaches for interrupting an auto-CPAP

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controller. *Id.* at 56 (citing Ex. 1003 ¶ 199; Ex. 1007, 15:13–28, 21:40–42, Figs. 4A–C, 6).

Patent Owner contends there is no reasonable expectation of success in combining the teachings of Sullivan995, Sullivan460, and Matthews to result in the claimed invention because “Sullivan995 does not teach how to distinguish awake state and an asleep state, let alone between the REM sleep and troubled wakefulness states, which have opposite implications for pressure and flow.” PO Resp. 41 (citing Ex. 2006 ¶¶ 218, 220). Patent Owner further argues that “the proposed modification to Sullivan995’s CPAP system would require methods of digital signal processing that go beyond a combination of known prior art elements” and that the proposed modification “would require the use of methods that analyze the temporal structure of a time series.” *Id.* (citing Ex. 2006 ¶¶ 206, 219, 226–227, 229).

Petitioner replies that claims do not require an analysis of temporal structures of a time series. Pet. Reply 3. We agree with Petitioner.

Patent Owner’s argument that there is no reasonable expectation of success in combining the teachings of the references to result in the claimed invention is premised on its proposed construction of the claim term “analyze the breathing patterns,” which, for the reasons set forth above in Section II.B.3, we do not adopt. Thus, Patent Owner’s arguments alleging there is no reasonable expectation of success are not commensurate with the scope of the claims.

Patent Owner also argues there is no reasonable expectation of success for the same reasons there is no motivation to combine the teachings of the references. Sur-reply 17–20; *see also id.* at 24 (Patent Owner referring to the arguments regarding reasonable expectation of success with

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respect to the asserted ground based on Rapoport⁵⁰², Sullivan⁴⁶⁰, and Matthews). We address these arguments above in Section II.C.4.b.

After considering the Parties’ arguments and evidence, we are persuaded a person of ordinary skill in the art would have combined the teachings of Sullivan⁹⁹⁵, Sullivan⁴⁶⁰, and Matthews with a reasonable expectation of success. Petitioner has persuaded us that Sullivan⁹⁹⁵ is configured to monitor breathing patterns to determine the patient’s pressure flow needs and that a person of ordinary skill in the art would have been able to incorporate Matthews’s algorithm to interrupt Sullivan⁹⁹⁵’s control in the same manner that Matthews teaches for interrupting an auto-CPAP controller. Ex. 1003 ¶ 199; Ex. 1005, 10:52–61; Ex. 1007, 15:13–28, 21:40–42, Figs. 4A–C, 6. Accordingly, Petitioner has shown a reasonable expectation of success in combining the teachings of the references to result in the claimed invention.

d. Secondary Considerations

We must consider—apart from what the prior art itself would have suggested—whether objective evidence of non-obviousness, i.e., secondary considerations, may lead to a conclusion that the challenged claims would not have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (instructing that evidence of secondary considerations, when present, must always be considered in determining obviousness). Objective evidence of non-obviousness may include evidence of commercial success, licensing, copying, praise by others, long felt but unresolved need, and failure or skepticism of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). But, secondary considerations are only a part of the “totality of the evidence”; their mere existence does not control

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the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997).

Patent Owner argues the existence of a long-felt but unresolved need strongly supports the non-obviousness of the challenged claims. PO Resp. 33–35, 41 (Patent Owner referring to the arguments regarding secondary considerations with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews); Sur-reply 25–27. According to Patent Owner, since 1991 there has been “a need for patients to increase compliance with usage of their CPAP machines.” PO Resp. 34 (citing Ex. 1036, 5). Patent Owner further argues:

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients’ compliance with CPAP treatment by noting that “the conventional PAP therapy [had] not taken sleep/wake state into account” and “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” Further, before the development of the claimed invention in the ’994 [p]atent,^[16] self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. In fact, as of 2002, a [person of ordinary skill] was “not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters.” As such, the claimed invention solved a long felt but unresolved need – better compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 34–35 (first and second alterations in original) (citations omitted) (citing Ex. 1010, 2:33–37; Ex. 2002, 1:44–46, 1:64–65, 2:31–35).

¹⁶ The ’344 patent at issue in this proceeding claims priority to the ’944 patent. Ex. 1001, code (63).

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Patent Owner further argues that “[c]onventional CPAP therapy had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control.” Sur-reply 25 (citing Ex. 1001, 2:11–13). According to Patent Owner, Dr. Bates’s testimony explained that “[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states.” *Id.* at 26 (citing Ex. 1052, 113:3–11, 115:22–116:10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by “the ’344 [p]atent’s ability to distinctly identify when a patient is awake or asleep,” because a person of ordinary skill in the art “prior to the [’]994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and awake.” *Id.* at 26–27 (third alteration in original) (citing Ex. 1052, 202:23–203:3, 203:15–204:5).

i. Nexus

Objective evidence of non-obviousness “is only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia of non-obviousness].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). A “nexus” is a legally and factually sufficient connection between the objective evidence and the claimed invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented

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invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 32–33 (PTAB Jan. 24, 2020) (precedential), *aff'd sub nom. Zaxcom, Inc. v. Lectrosonics, Inc.*, 2022 WL 499848 (Fed. Cir. Feb. 18, 2022). We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* at 32. If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 33 (quoting *Fox Factory*, 944 F.3d at 1373–75). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Id.* (citing *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011)). There is no requirement that the objective evidence of non-obviousness be tied exclusively to claim elements that are not disclosed in the prior art, and the claimed combination as a whole may serve as a nexus for the objective evidence. *Id.* (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)).

Petitioner argues that Patent Owner does not meet its burden of proving nexus because: (1) Patent Owner did not identify any product tied to the objective evidence and thus did not establish a “presumption of nexus”; (2) Patent Owner did not “demonstrate a nexus by showing that long-felt

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need was met as a ‘direct result of the unique characteristics of the claimed invention’”; and (3) Patent Owner did not identify “any failed efforts to solve the problem before the invention.” Pet. Reply 24–25.

Patent Owner has not argued that the presumption of nexus applies. We agree with Petitioner that Patent Owner is not entitled to a presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the challenged claims. We address Patent Owner’s evidence of long-felt, but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the ’344 patent, absent the presumption.

ii. Long-felt Need

In order to show a long-felt but unmet need *for the claimed invention*, the objective evidence must show the need was a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). “Evidence of long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would not have persisted had the solution been obvious.” *WBIP*, 829 F.3d at 1332.

Patent Owner suggests increasing the comfort of the CPAP system is a goal to improve patient compliance with CPAP therapy. Patent Owner does not explain, however, why Sullivan460’s system which “addresses . . . the comfort of CPAP,” and “is an improvement over the prior art” because of the two modes of air delivery where the pressure is lower in the awake state, does not meet the long-felt need identified by Patent Owner. Ex. 1006, 7:7–16. Thus, we agree with Petitioner that “[t]o the extent that any need existed, it was already satisfied.” Pet. Reply 25.

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Additionally, Patent Owner does not identify any failed efforts to solve the problem before the invention, and Patent Owner does not provide sufficient evidence that the invention satisfies the alleged need. Dr. Bates's redirect testimony, which Patent Owner almost exclusively relies on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to "little or no weight." 37 C.F.R. § 42.65(a).

Patent Owner also supposes a need for better compliance with CPAP therapy by detecting troubled wakefulness. PO Resp. 35; Sur-reply 26. Patent Owner's argument suffers from the deficiencies identified above, particularly the failure by Patent Owner to show that the invention satisfies the alleged need.

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt need. We, therefore, accord little weight to Patent Owner's evidence of non-obviousness.

e. Conclusion for Independent Claims 1 and 7

We have considered the scope and content of the prior art of record, any differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art. For the reasons discussed in Sections II.C.4.a–c, Petitioner provides persuasive evidence of obviousness for the subject matter of independent claims 1 and 7. As we explain above in Section II.C.4.d, Patent Owner's evidence of long-felt need is entitled to little, if any, weight. On balance, after weighing all of the evidence in the record, we determine that Petitioner has established by a preponderance of the evidence that Sullivan995, Sullivan460, and Matthews render obvious the subject matter of independent claims 1 and 7.

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5. *Claims 3, 9, 11, and 13*

Claim 3 depends from independent claim 1, and claims 9, 11, and 13 depend from independent claim 7. Ex. 1001, 9:49–51, 10:25–27, 10:31–37, 10:40–45. Petitioner sets forth evidence and argument as to why Sullivan995, Sullivan460, and Matthews render these claims unpatentable. Pet. 43–45.

Patent Owner does not raise any arguments directed specifically to claims 3, 9, 11, and 13 aside from its arguments for independent claims 1 and 7. We address these arguments above in Section II.C.4.

Having reviewed the Parties’ arguments and evidence, we are persuaded that the claimed subject matter would have been obvious for the reasons provided by Petitioner. Petitioner has established by a preponderance of the evidence that Sullivan995, Sullivan460, and Matthews render obvious the subject matter of claims 3, 9, 11, and 13.

D. Obviousness Based on Rapoport502, Sullivan460, and Matthews and Anticipation Based on Sullivan460

As set forth above in Section II.C, we determine that Petitioner has shown that all of the claims challenged in the Petition—claims 1, 3, 7, 9, 11, and 13 of the ’344 patent—are unpatentable. In view of this determination, we do not reach Petitioner’s other challenges to the challenged claims. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”).

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III. PATENT OWNER’S MOTION TO EXCLUDE EVIDENCE

Patent Owner seeks to exclude Exhibits 1018–1020, 1033–1034, 1038, 1049, 1051, 1054–1055, and 1057–1059, portions of Exhibits 1003, 1046, and 1052, and portions of the record relying on the disputed exhibits, e.g., the Petition and Reply. PO MTE 1–15; PO MTE Reply 1–5. Petitioner opposes the motion. PO MTE Opp. 1–15. For the following reasons, we deny Patent Owner’s Motion to Exclude Evidence.

A. Exhibits 1003 and 1046

Exhibit 1003 is the declaration of Petitioner’s original declarant, Dr. Behbehani. Exhibit 1046 is the declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s declaration. *See* Ex. 1046 ¶ 28 (Dr. Kirkness agreeing with and adopting paragraphs 20–28, 32–88, and 92–234 of Dr. Behbehani’s declaration). Patent Owner argues paragraphs 38–39, 42, 45, 81, and 219–232 of Exhibit 1003 and Dr. Kirkness’s adoption of those paragraphs in Exhibit 1046 should be excluded. PO MTE 3–6, 9–10. Because we do not rely on these paragraphs of Exhibit 1003 in rendering this Decision, we deny Patent Owner’s Motion to Exclude Evidence as to these paragraphs of Exhibit 1003 and the corresponding portions of Exhibit 1046 as moot.

B. Exhibits 1054–1055 and 1057–1058

Exhibit 1054 is the file history of U.S. Patent No. 9,108,009 B2, which is challenged in a related proceeding, IPR2022-00988, and Exhibit 1055 is this patent. Exhibit 1057 is U.S. Patent No. 9,427,539 B2, which is challenged in a related proceeding, IPR2022-00989. Exhibit 1058 is U.S. Patent No. 6,988,994 B2, which is related via priority to the ’344

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patent (Ex. 1001, code (63)) and challenged in a related proceeding, IPR2022-00993.

Patent Owner asserts that Petitioner improperly relies on these exhibits in the Reply to support its claim construction arguments for the “analyze the breathing patterns.” PO MTE 6. According to Patent Owner, Petitioner does not propose a construction for this claim term in its Petition, and thus introduces new evidence with these exhibits in its Reply. *Id.*

Petitioner replies that these exhibits are proper evidence in the Reply because Petitioner uses the exhibits in response to claim construction arguments raised in Patent Owner’s Response. PO MTE Opp. 7–8. We agree with Petitioner.

In its Response, Patent Owner argues the claim term “analyze the breathing patterns” should be construed as “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 18–19. Petitioner’s first and only opportunity to respond to Patent Owner’s construction is in its Reply. *See* 37 C.F.R. 42.23(b) (“A reply may only respond to arguments raised in the corresponding . . . patent owner response.”). Petitioner properly relies on Exhibits 1054–1055 and 1057–1058 to respond to Patent Owner’s claim construction arguments in its Response. We, therefore, deny Patent Owner’s Motion to Exclude Evidence as to Exhibits 1054–1055 and 1057–1058.

C. Exhibits 1018, 1019, and 1033

Exhibit 1018 is a copy of Patent Owner’s complaint from a related district court action (*see supra* Section I.B). Exhibits 1019 and 1033 are exhibits to that complaint.

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Patent Owner argues these exhibits should be excluded because “[a]ny discussion of infringement is irrelevant in [*inter partes* reviews].” PO MTE 7; PO MTE Reply 3. Petitioner argues that these exhibits are relied on in support of and are relevant to Petitioner’s anticipation contentions in this proceeding. PO MTE Opp. 9–10. We agree with Petitioner that these exhibits are relevant to Petitioner’s contentions in this proceeding. Furthermore, we do not rely on these exhibits in rendering this Decision. We, therefore, deny Patent Owner’s Motion to Exclude Evidence as to Exhibits 1018, 1019, and 1033 as moot.

D. Exhibits 1020 and 1034

Exhibit 1020 is European Patent No. 0 702 978 B1. Exhibit 1034 is International Publication No. WO 03/075991 A1.

Patent Owner argues that Petitioner does not discuss or cite to these exhibits in any paper in this proceeding. PO MTE 8. According to Patent Owner, these exhibits are “irrelevant,” and “the probative value of these exhibits is substantially outweighed by the unfair prejudice resulting from any use of these exhibits at this late stage of the proceedings.” *Id.*

Petitioner responds that “[t]he Board has already noted that these exhibits were not cited in the Petition” and “has already found the listing of these exhibits as ‘harmless.’” PO MTE Opp. 10 (citing Paper 11 at 4 n.1, 8). Patent Owner does not dispute that the Board has already determined the listing of these exhibits is harmless and instead argues “[i]f the exhibits are ‘harmless,’ Petitioner should not object to their exclusion.” PO MTE Reply 3–4.

There is no dispute that Petitioner does not cite to Exhibits 1020 and 1034, and we do not rely on these exhibits in rendering this Decision.

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Accordingly, we deny Patent Owner's Motion to Exclude Evidence as to Exhibits 1020 and 1034 as moot.

E. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2, which lists Dr. Bates as an inventor. Patent Owner argues that the priority date of this patent is after the priority date of the '344 patent and that Exhibit 1049 should be excluded as irrelevant and "not prior art." PO MTE 9; PO MTE Reply 4. Patent Owner also argues the exhibit should have been introduced prior to Petitioner's Reply. PO MTE 9. Petitioner argues the exhibit is not being asserted as prior art, but rather for the credibility of Dr. Bates. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates's credibility, and we find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision. We therefore deny Patent Owner's Motion to Exclude Evidence as to Exhibit 1049 as moot.

F. Exhibit 1051

Exhibit 1051 is the declaration of Dr. Kirkness in support of Petitioner's Reply. Patent Owner argues that Exhibit 1051 "should be excluded for the same reasons as" Exhibits 1003 and 1046. PO MTE 7; PO MTE Reply 2. For the reasons discussed above in Section III.A regarding Exhibits 1003 and 1046, we do not find Patent Owner's arguments persuasive. Patent Owner also argues that Exhibit 1051 should be excluded because it raises "new issues" and "new evidence that could have been presented in a prior filing." PO MTE 10; PO MTE Reply 2–3. The only "example" Patent Owner provides in support of this argument is that Dr. Kirkness's reply declaration "uses Exhibits 1049, 1054–1055,

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and 1057–1058 in the exact same manner” as they are used in Petitioner’s Reply. PO MTE 10. For the reasons discussed above in Section III.B regarding Exhibits 1054–1055 and 1057–1058 and Section III.E regarding Exhibit 1049, we deny Patent Owner’s Motion to Exclude Evidence as to Exhibit 1051.

G. Exhibit 1052

Exhibit 1052 is the transcript of Dr. Bates’s deposition testimony. Patent Owner argues that the portions of Exhibit 1052 including questions regarding patent-eligible subject matter and infringement should be excluded as irrelevant. PO MTE 11 (citing Ex. 1052, 62:7–23, 63:15–64:1–5, 117:9–118:11, 146:4–12); PO MTE Reply 4–5. Petitioner argues that these portions of Dr. Bates’s testimony are relevant to obviousness and anticipation issues in this proceeding, that there was “no discussion of ‘infringement’ or ‘patentable subject matter,’” and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 11–12. We agree with Petitioner and deny Patent Owner’s Motion to Exclude Evidence as to these portions of Exhibit 1052.

H. Exhibit 1059

Exhibit 1059 is an article titled “Control of breathing during sleep” and published in Clinical Science in 1984. Dr. Kirkness cites this article in his reply declaration (Exhibit 1051).

Patent Owner argues Dr. Kirkness relies on Exhibit 1059 to show that “a [person of ordinary skill in the art] knew ‘that a processor could be programmed to analyze breathing patterns that fall below or above certain preset levels of airflow rate to indicate awake or asleep states’ and that analysis of temporal structures was not necessary.” PO MTE 12 (citing

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Ex. 1051 ¶¶ 11, 32). According to Patent Owner, “[a]ny use of [Exhibit 1059] is therefore an improper incorporation by reference through [Exhibit 1051], violating 37 C.F.R. § 42.6(a)(3), which prohibits incorporating arguments by reference from one document into another document.” *Id.* Patent Owner’s argument has no merit. As Petitioner correctly avers, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and Exhibit 1059 “is not an argument.” PO MTE Opp. 13.

Patent Owner also argues Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply 5. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his reply declaration are relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” Pet. MTE Opp. 13. We agree with Petitioner for the same reasons discussed above in Section III.B regarding Exhibits 1054–1055 and 1057–1058. Because Patent Owner shows no persuasive basis to exclude Exhibit 1059, Patent Owner’s Motion to Exclude Evidence as to Exhibit 1059 is denied.

I. Exhibit 1038

Exhibit 1038 as an article titled “Snoring and Sleep Architecture” and published in the American Review of Respiratory Disease in 1991. Dr. Behbehani cites this article in his declaration (Ex. 1003), which Dr. Kirkness adopts in his declaration.

Patent Owner asserts “[Dr. Kirkness] uses [Exhibit 1038] to argue that ‘[t]he well-known correlation between breathing patterns and sleep have

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been used to indicate the sleep-wake state of a patient for decades. This is particularly true of the awake state, the non-REM sleep state (stable breathing), REM state (unstable breathing), and disordered sleep state.” PO MTE 13 (third alteration in original) (citing Ex. 1003 ¶ 53). According to Patent Owner, “[a]ny use of [Exhibit 1038] is therefore an improper incorporation by reference through [Exhibit 1003], violating 37 C.F.R. § 42.6(a)(3) in the same manner as [Exhibit 1059].” *Id.* For the reasons discussed above in Section III.H regarding Exhibit 1059, we do not find Patent Owner’s arguments persuasive, and we deny Patent Owner’s Motion to Exclude Evidence as to Exhibit 1038.

IV. PETITIONER’S MOTION TO EXCLUDE EVIDENCE

Petitioner seeks to exclude portions of Exhibit 1053, the deposition testimony of Dr. Bates. Pet. MTE 1–9; Pet. MTE Reply 1–5. Specifically, Petitioner moves to exclude parts of the redirect deposition testimony of Dr. Bates concerning secondary considerations of non-obviousness. Pet. MTE 1. Petitioner argues that the redirect testimony of Dr. Bates “was outside the scope of Petitioner’s cross-examination in contravention of [Federal Rule of Evidence] 611(b) and 37 C.F.R. § 42.53 (d)(5)(ii).” *Id.* Petitioner does not seek to exclude the entirety of Dr. Bates’s redirect testimony concerning secondary considerations but only the specific portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes the Motion. Pet. MTE Opp. 1–10.

Petitioner contends that it “did not cross-examine Dr. Bates about any secondary considerations and timely objected to [Patent Owner’s] line of questioning during redirect as being outside the scope.” Pet. MTE 1–2

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(citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9); *see also id.* at 4 (Petitioner reiterating the argument). Petitioner further contends that Patent Owner’s “introduction of belated expert testimony into the record via the Sur-[r]epley is improper and the evidence must be excluded.” *Id.* at 2 (citing *Comcast Cable Commc’ns, LLC v. Rovi Guides, Inc.*, IPR2019-01413, Paper 34 at 4 (PTAB Sept. 16, 2020); *IBM Corp. v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 15 at 5 (PTAB Feb. 2, 2015)); *see also id.* at 5–6 (identifying portions of the Sur-repley citing to the disputed testimony). Further, according to Petitioner, “Dr. Bates’[s] declaration included no discussion of secondary considerations.” *Id.* at 2.

Petitioner argues that “[Federal Rule of Evidence] 611(b) prohibits redirect examination that goes beyond the scope of cross-examination questions and testimony” and that Patent Owner’s “redirect examination did just that.” Pet. MTE 7. Petitioner next argues “the portions of Dr. Bates’[s] redirect testimony that Petitioner seeks to exclude from the record have no bearing on ‘matters affecting the witness’s credibility.’” *Id.* at 8 (citations omitted). According to Petitioner, Patent Owner “does not rely on Dr. Bates’[s] testimony to counter a challenge to his credibility.” *Id.* Petitioner also contends that 37 C.F.R. § 42.53(d)(5)(ii) “similarly prevents a party from expanding the scope of redirect examination beyond that of cross-examination.” *Id.* at 9.

In opposition, Patent Owner argues Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner argues the Board’s

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Consolidated Trial Practice Guide¹⁷ provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or *otherwise exceeds the proper scope* of reply or sur-reply, it may request authorization to file a motion to strike.” PO MTE Opp. 2 (quoting CTPG 80). Patent Owner contends that “Petitioner’s counsel reserved that right to strike Dr. Bates’[s] redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of [Patent Owner] submitting its Sur-[r]epley.” *Id.* at 2–3 (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact *inadmissible*,” only that “it should be excluded (not stricken) because it is beyond the scope of its cross examination.” *Id.* at 4. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–25).

In reply, Petitioner contends it “properly focused its [M]otion to [E]xclude on the portions of Dr. Bates’[s] inadmissible re-direct deposition testimony cited in [the] Sur-[r]epley,” and that Patent Owner “uses its Sur-[r]epley as no more than a ‘vehicle’ to enter new evidence into the record.” Pet. MTE Reply 1. Petitioner contends that it “timely objected at the

¹⁷ USPTO, Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019, <https://www.uspto.gov/TrialPracticeGuideConsolidated> (“CTPG”).

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deposition” once Patent Owner began “improperly elicit[ing] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Federal Rule of Evidence 611(b). *Id.* at 3 (citing Pet. MTE 7).

For the following reasons, we deny Petitioner’s Motion to Exclude Evidence.

The Consolidated Trial Practice Guide provides that “[a] motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay)” but should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.” CTPG 79. Further, the CTPG clearly distinguishes a motion to exclude evidence from a motion to strike evidence. The CTPG states that, “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike.” *Id.* at 80. As an alternative to a motion to strike, “a party may request authorization for further merits briefing . . . to address the merits of newly-raised arguments or evidence.” *Id.* A party must seek authorization to file a motion to strike “within one week of the allegedly improper submission.” *Id.* at 81.

As noted in the Consolidated Trial Practice Guide, motions to strike are intended to address, *inter alia*, whether a brief raises new issues or exceeds the proper scope of a sur-reply. Here, Petitioner argues that the redirect testimony is inadmissible under Federal Rule of Evidence 611(b) and/or 37 C.F.R. § 42.53(d)(5)(ii) as exceeding the scope of cross-examination. But, Petitioner does not seek to exclude all redirect

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testimony on secondary considerations, only the testimony relied on by Patent Owner in the Sur-reply. Pet. MTE 5 n.2.

The issue presented here borders on the proper scope of a motion to exclude as compared to a motion to strike. The goal of Petitioner's Motion is clearly to undercut arguments raised in Patent Owner's Sur-reply directed to objective indicia of non-obviousness. By limiting its Motion to only the portions of Dr. Bates's redirect deposition testimony actually relied on in Patent Owner's Sur-reply, Petitioner's arguments reflect this goal. *See, e.g.*, Pet. MTE 5 n.2 ("Although all of Dr. Bates'[s] redirect testimony on secondary considerations was outside the scope of Petitioner's cross-examination, Petitioner narrowly focuses this motion on excluding only those portions that [Patent Owner] relies on in its Sur-[r]epley."). One way in which Petitioner could have challenged the arguments raised in Patent Owner's Sur-reply is by requesting authorization to file a motion to strike, which, as noted above, is intended for the purpose of addressing arguments a party believes exceeds the proper scope of sur-reply. CTPG 80. Petitioner did not request such authorization. Instead, by seeking to exclude some of Dr. Bates's redirect testimony on objective indicia, i.e., the portions relied on in Patent Owner's Sur-reply, Petitioner seeks to undercut the arguments raised in Patent Owner's Sur-reply on objective indicia by effectively removing the primary evidentiary support for those arguments. Were we to grant Petitioner's Motion to Exclude Evidence, we would be faced with determining what to do with Patent Owner's arguments in the Sur-reply, which would remain of record because they are not the subject of Petitioner's Motion to Exclude Evidence, nor could they be based on the CTPG, and, as previously noted, Petitioner did not also file a motion to

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strike those arguments. The best course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Federal Rule of Evidence 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination, just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony,¹⁸ Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of non-obviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the circumstances presented here and in light of the little weight to which Patent Owner's argument and Dr. Bates's redirect is entitled, we determine that the better course is to deny Petitioner's Motion to Exclude Evidence.

¹⁸ There are exceptions, e.g., questions pertaining to a witness's credibility. *See* Fed. R. Evid. 611(b).

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V. CONCLUSION

The outcome for claims 1, 3, 7, 9, 11, and 13 challenged in this proceeding is set forth in summary as follows:

Claims Challenged	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 3, 7, 9, 11, 13	103(a)	Sullivan995, Sullivan460, Matthews	1, 3, 7, 9, 11, 13	
1, 3, 7, 9, 11, 13	103(a)	Rapoport502 Sullivan460, Matthews ¹⁹		
1, 3, 7, 9, 11, 13	102(a), (b)	Sullivan995 ²⁰		
Overall Outcome			1, 3, 7, 9, 11, 13	

VI. ORDER²¹

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Exclude Evidence (Paper 48) is denied;

¹⁹ We do not reach the merits of this ground because, as set forth above in Section II.C, we determine that Petitioner has shown claims 1, 3, 7, 9, 11, and 13 are unpatentable over Sullivan995, Sullivan460, and Matthews.

²⁰ We do not reach the merits of this ground because, as set forth above in Section II.C, we determine that Petitioner has shown claims 1, 3, 7, 9, 11, and 13 are unpatentable over Sullivan995, Sullivan460, and Matthews.

²¹ Should Patent Owner wish to pursue amendment of a challenged claim in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding, 84 Fed.

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FURTHER ORDERED that Petitioner's Motion to Exclude Evidence (Paper 49) is denied;

FURTHER ORDERED that claims 1, 3, 7, 9, 11, and 13 of U.S. Patent No. 9,168,344 B2 have been proven by a preponderance of the evidence to be unpatentable; and

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

Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

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