

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)

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.

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.

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

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.

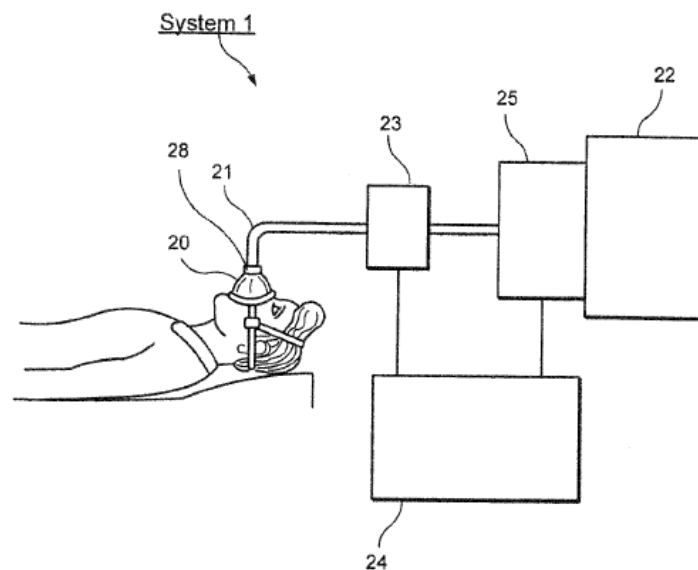


FIG. 1

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

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.

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

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.

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.

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.

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.

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

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.

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

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

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.”

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.

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

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

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

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

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.

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

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).

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)).

(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

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

(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

(“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.

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

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.

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

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.

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.

Figure 1A of Sullivan995 is reproduced below.

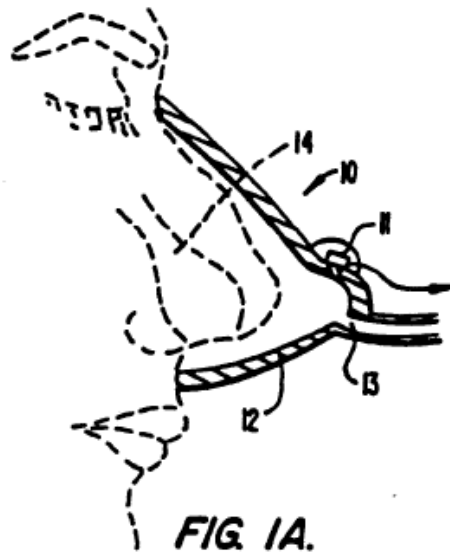


Figure 1A depicts snoring detection device 10. *Id.* at 8:47. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a nose mask.” *Id.* at 8:47–49. Sullivan995 explains that “[a]ir, being inhaled by the patient, enters the nasal passageways 14 through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

Figure 3 of Sullivan995 is reproduced below.

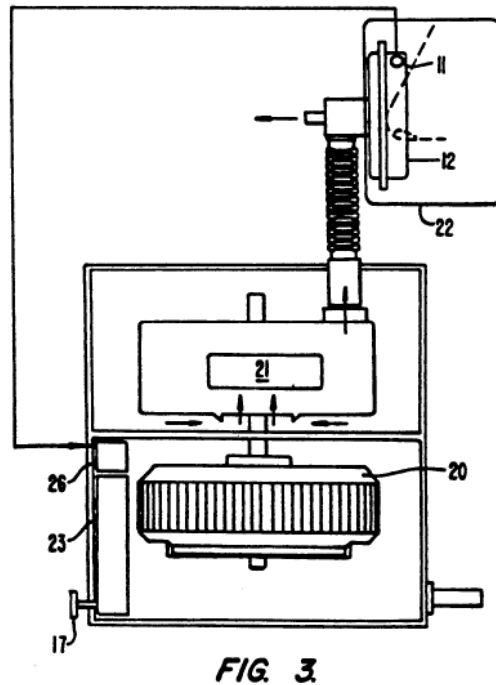


Figure 3 of Sullivan995 shows a CPAP apparatus. Ex. 1005, 9:57–58. The CPAP apparatus shown in Figure 30 includes motor 20 that drives blower 21. *Id.* at 9:58–59. Sullivan995 explains that “[t]he speed of the motor 20 is controlled by an electronic speed control unit 23.” *Id.* at 9:59–60. The CPAP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

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.

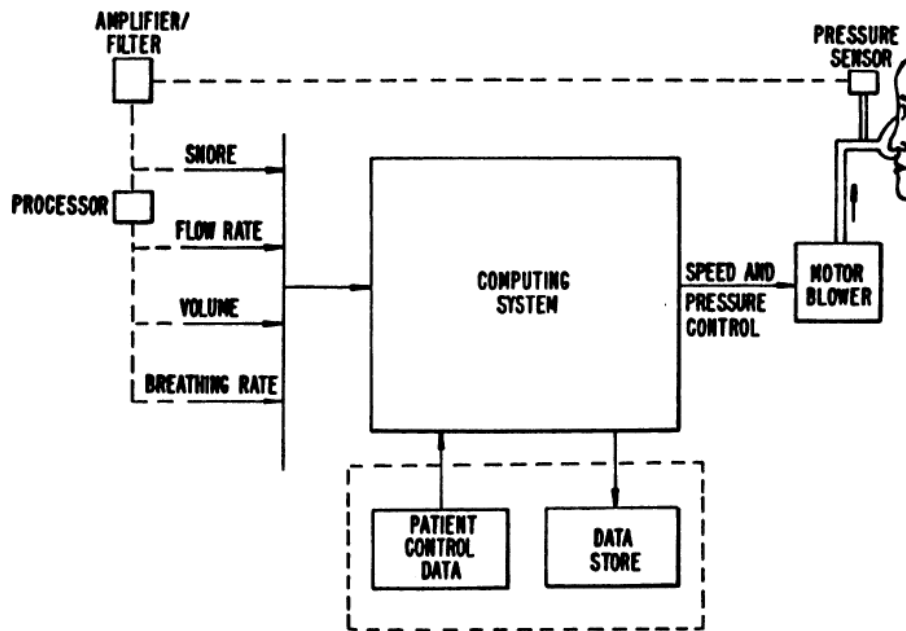


FIG. 12.

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, 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.

Figure 2 of Sullivan460 is reproduced below.

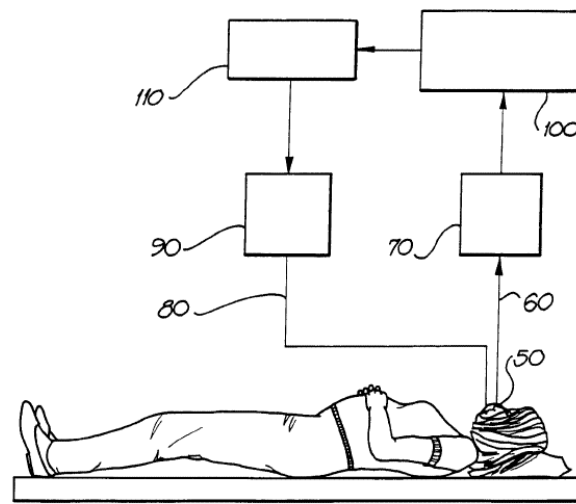


FIG. 2

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

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

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

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.

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,

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

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

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

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.

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

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

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

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

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”).

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.

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

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*,

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)).

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

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

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.

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

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

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,

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

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

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

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

(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.

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]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.

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 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.

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.

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 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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