

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

IPR2022-00991
Patent 9,867,955 B2

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

PESLAK, *Administrative Patent Judge*.

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

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

I. INTRODUCTION

ResMed, Inc. (“Petitioner”) filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–6, 8, 11, 12, 16–26, 30, and 31 (“the Challenged Claims”) of U.S. Patent No. 9,867,955 B2 (“the ’955 patent,” Ex. 1001). Paper 1. Petitioner filed a Declaration of Dr. Khosrow Behbehani in support of the Petition. Ex. 1003. Subsequently, Petitioner filed a Motion to Correct the Petition, which ResMed, Inc. (“Patent Owner”) opposed. Papers 10, 11. We granted Petitioner’s motion. Paper 12. Petitioner then filed a Corrected Petition. Paper 15 (“Pet.”).¹ Patent Owner filed a Preliminary Response. Paper 14. On December 7, 2022, we instituted this *inter partes* review as to all Challenged Claims and all grounds presented in the Petition. Paper 19.

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

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

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

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

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

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

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

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

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

A. Related Matters

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

Petitioner also states that they have filed petitions for the following related patents: U.S. Patent No. 6,988,994 B2 (the "'994 patent") (IPR2022-00993), U.S. Patent No. 9,108,009 B2 (the "'009 patent") (IPR2022-00988), U.S. Patent No. 9,168,344 B2 (IPR2022-00994), U.S. Patent No. 9,427,539 B2 (the "'539 patent") (IPR2022-00889), U.S. Patent No. 9,533,955 B2 (IPR2022-00990), and U.S. Patent No. 10,384,024 B2 (the "'024 patent") (IPR2022-00992). Pet. 2.

B. Real Parties in Interest

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

C. The '955 Patent

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

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

OSAS is associated with many conditions in which there is an anatomic or functional narrowing of the patient's upper airway,

and is characterized by an intermittent obstruction of the upper airway occurring during sleep. The obstruction results in a spectrum of respiratory disturbances ranging from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring), despite continued respiratory efforts.

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

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

The '955 patent describes system 1 (shown in Figure 1) that includes mask 20 connected via tube 21 for receiving an airflow of a particular pressure from flow generator 22. *Id.* at 3:51–54.

Figure 1 of the '955 patent is reproduced below:

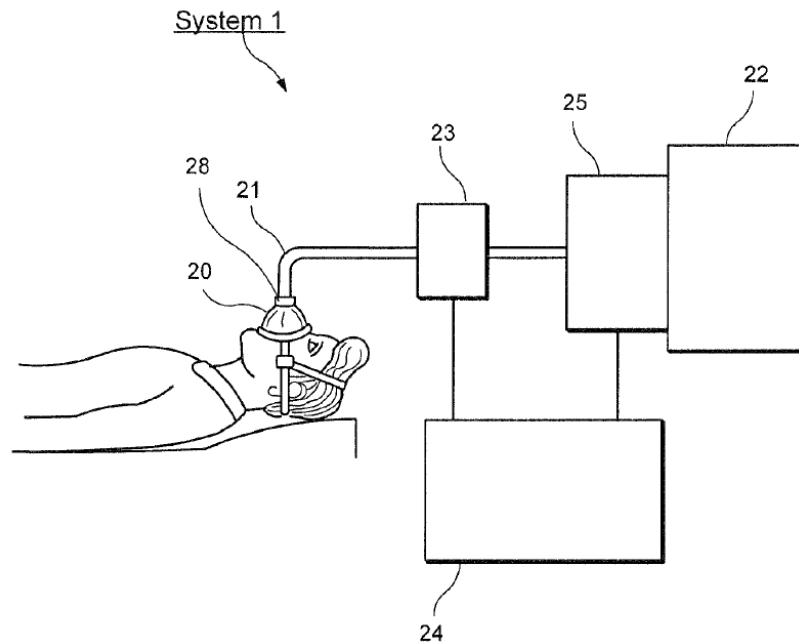


FIG. 1

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

The '955 patent also describes a method that uses Figure 1's system 1. Ex. 1001, 3:22–24. “[S]ystem 1 initiates a real-time monitoring procedure of the patient's breathing patterns.” *Id.* at 4:12–13, 4:16–17. The '955

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

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

D. Illustrative Claims

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

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

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

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

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

[c1] a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and [c2] analyzes the data to determine the patient's breathing patterns, [c3] the processing arrangement also determines whether to alter the pressure supplied to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, [d1] wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and [d2] a lesser positive treatment pressure in an awake state, [e1] wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state, [e2] the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system.

Ex. 1001, 9:47–10:11.

E. Prior Art and Asserted Grounds

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

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

II. ANALYSIS

A. Overview

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

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

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

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

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

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

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

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective indicia of non-obviousness (i.e., secondary considerations). *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art “in 2003 would have had at least a bachelor’s degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience” and “[a]dditional experience could substitute for less education, and additional education could likewise substitute for less experience.” Pet. 17 (citing Ex. 1003 ¶ 84). Petitioner further states that the “Petition does not turn on this precise definition, and the challenged claims would be unpatentable from the perspective of any reasonable person of ordinary skill in the art at the relevant time.” *Id.* at 18 (citing Ex. 1003 ¶ 85). Patent Owner does not dispute Petitioner’s definition of the person of ordinary skill in the art. PO Resp. 10.

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

C. Claim Construction

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

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

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

required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’”)(quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). To determine whether Petitioner has shown that the Challenged Claims are unpatentable, we expressly construe the claim term “troubled wakefulness,” and we discuss the Parties’ contentions for the claim term “analyzes the data to determine the patient’s breathing patterns.”

a. “troubled wakefulness”

Petitioner contends that the term “troubled wakefulness” in claims 6 and 23 “means ‘state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.’” Pet. 18 (citing Ex. 1003 ¶ 91). Petitioner asserts that “[t]his term is not an industry standard term and was coined in the ’024 Patent.” *Id.* (citing Ex. 1003 ¶ 92). According to Petitioner, the ’955 patent “describes ‘troubled wakefulness’ as a state ‘in which the breathing pattern is characterized by irregular[] variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient’s airflow tracing indicating that the patient is awake and either anxious or uncomfortable.’” *Id.* at 18–19 (citing Ex. 1001, 4:59–64, Fig. 7). Petitioner further argues that “[t]he specification further confirms that ‘Patient’s discomfort during wakefulness is often associated with changes from a regular breathing pattern . . . and frequently occur when the patient is distressed by the PAP system.’” *Id.* at 19 (second alteration in original) (citing Ex. 1001, 2:40–47).

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

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

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

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

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

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

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

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

i. The Parties’ Contentions

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

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

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

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

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

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

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

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

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

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

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

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

Specifically, Patent Owner argues as follows:

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

Sur-reply 13–14.

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

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

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

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

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

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

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

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

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

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

(3) Dr. Bates’s analysis contradicts the ’955 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM sleep without requiring temporal analysis. *Id.* at 8–9 (citing Ex. 1001, 4:52–59, 5:32–36; Ex. 1056, 9:55–10:3 (claim 5), 10:20–24 (claim 8); Ex. 1051 ¶¶ 25–33).

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

(5) Dr. Bates “could not explain ‘parameter’ or provide an objective basis to define a ‘sequence’ and ‘series’ used in [Patent Owner’s] construction” and “admitted that [Patent Owner’s] construction would exclude breathing patterns recited in dependent claims.” *Id.* at 10 (citing

Ex. 1052, 182:1–184:19, 247:5–11; Ex. 1053, 288:14–289:3). Thus, Petitioner asserts we “should discount []expert testimony that is clearly at odds . . . with the written record of the patent.” *Id.* (quoting *Phillips*, 415 F.3d at 1318).

ii. Analysis – Claim 1

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

In the Patent Owner Response, Patent Owner analyzes only claim 1 which recites “a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and *analyzes the data to determine the patient’s breathing patterns.*” Ex. 1001, 9:63–66 (emphasis added). As reflected, claim 1 does not recite “a sequence of parameters” or “a series of breaths” or “examining the values of the parameters and the order in which they appear in time” or any analysis of amplitude or temporal structure. Rather, this portion of claim 1 recites that the processor analyzes the data, without specifically reciting how the analysis is performed. The claim phrase does, however, recite the purpose of the analysis—to determine the patient’s breathing patterns—but does not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a significant number of limitations neither expressly recited nor suggested by the specific language of the phrase.

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citation omitted). “We depart from the plain and ordinary meaning of claim terms

based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech.* 923 F. 3d at 1044.

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of claim 1, nor does Patent Owner argue that it explicitly defined the claim phrase in the Specification. PO Resp. 28–30. We determine that there is no disavowal nor any explicit lexicographic definition of “analyzes the data to determine the patient’s breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we should construe the phrase as Patent Owner proposes. Sur-reply 3, 8–9 (citing, *inter alia*, *AstraZeneca AB v. Mut. Pharm. Co., Inc.*, 384 F.3d 1333 (Fed. Cir. 2004)). We disagree.

In *AstraZeneca AB*, the United States Court of Appeals for the Federal Circuit reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d 1333, 1339–40 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors “deliberately acted as their own lexicographers” to limit the claim term

“solubilizer” to surfactants, the Federal Circuit explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The Federal Circuit rejected AstraZeneca’s argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

The Specification of the ’955 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to “a sequence of parameters” (PO Resp. 17) or an “analysis of both the amplitude and the temporal structure of a breath-by breath time series” (*id.* at 22) or any of the other terms set forth in the proposed construction. *See id.* at 17–19. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. *See* Pet. Reply 6 (“[T]he terms ‘amplitude’ and ‘temporal’ do not appear anywhere”); Sur-reply 5 (“Petitioner rightly observes that terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’955 Patent.”); *see also* Ex. 1051 ¶ 24 (Dr. Kirkness agrees that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’955 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures.”). Patent Owner directs us to portions of the Specification for what Patent Owner characterizes as the process of analyzing breathing patterns. PO

Resp. 17 (quoting Ex. 1001, 4:42–49). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” Ex. 1001, 4:46–53. The cited text does not describe analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how “processing arrangement 24 makes a determination as to the current state of the patient (e.g., whether the patient is asleep, awake and breathing regularly or awake and breathing irregularly due to distress or anxiousness).” Ex. 1001, 4:22–26. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns, etc. in determining the patient’s state.” *Id.* at 4:26–30. There is no mention that analyzing breathing patterns requires analysis of a sequence of parameters and the order in which they appear in time or an analysis of amplitude and temporal aspects of the waveform. The Specification further describes, in an embodiment, “processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern.” Ex. 1001, 7:20–23. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal aspects of the waveform.

Patent Owner also relies on the description of Figures 7 and 8 of the ’955 patent in support of its construction. PO Resp. 17–19. Figures 7 and 8 illustrate airflow waveforms from a patient indicative of a period of troubled

wakefulness and a period of REM sleep with irregular breathing, respectively. Ex. 1001, 3:35–39. Patent Owner relies on Figures 7 and 8 to support its argument that “an analysis of both the amplitude and the temporal structure of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.” PO Resp. 22; Sur-reply 8–9 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Figures 7 and 8, however, depict one particular example of an awake state (i.e., troubled wakefulness) and one particular example of a sleep state (i.e., REM sleep), respectively. Ex. 1001, 3:35–39. But Patent Owner’s analysis does not address Figures 3–6 of the ’955 patent. PO Resp. 16–19; Sur-reply 3–16. Figures 3 and 4 show waveforms of a patient during “regular wakefulness” and “regular sleep,” respectively. Ex. 1001, 3:29–33. Figures 5 and 6 show waveforms from a sleeping patient indicative of “hypopnea” and “repetitive obstructive apnea,” respectively. *Id.* at 3:34–38. Patent Owner provides no evidence or explanation why amplitude and temporal aspects of a waveform are required to distinguish regular wakefulness from regular sleep or hypopnea or repetitive obstructive apnea.¹⁰

¹⁰ Patent Owner points to an argument during prosecution of a related patent contending it supports Patent Owner’s claim construction. Sur-reply 6–7. That argument stated that the prior art reference “does not teach or suggest a processing arrangement that distinguishes between regular wakefulness and troubled wakefulness,” but it did not refer to anything even close to resembling the construction proposed by Patent Owner or the concepts of amplitude and temporal structures. Ex. 1009, 404. Thus, this portion of the prosecution history of a related patent does not support Patent Owner’s position here.

Claim 1 recites “analyzes the data to determine the patient’s breathing patterns . . . and determines that the patient has transitioned between at least an awake state and an asleep state.” Ex. 1001, 9:65–10:8. Claim 1 is not limited to distinguishing *solely* between troubled wakefulness and REM sleep, but rather encompasses other states, such as those shown in Figures 3–6. Thus, even if we were to agree with Patent Owner that an analysis of one or both of the amplitude and temporal structures of a waveform is required to distinguish between troubled wakefulness and REM sleep, that determination, alone, would be insufficient to narrow the scope of claim 1, which by its own terms is broad enough to include sleep states other than troubled wakefulness and REM sleep states. For the same reasons, we are not persuaded that the additional limitations Patent Owner seeks to read into the claims are necessary to “fully enable” the claims, as Patent Owner asserts.

Having reviewed the intrinsic evidence, we next consider the extrinsic evidence, and specifically the testimony of Dr. Bates.¹¹ Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 16–29 (citing Ex. 1001, 4:42–49, 4:57–64, 5:21–37, 6:38–45; Ex. 2006 ¶¶ 139–144). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. *See* Ex. 2006 ¶¶ 139–144. Rather, Dr. Bates reads portions of the

¹¹ Although the parties briefly address the prosecution history of patents related to the ’955 patent, we do not find the discussion thereof determinative on this specific issue.

Specification and extrapolates (by taking several unsupported leaps) that the '955 patent "implicitly demands certain parameter measurements." Sur-reply 7 (citing Ex. 1052, 44:6–20).

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

For the reasons explained above, we determine that Patent Owner did not implicitly define the phrase "analyzes the data to determine the patient's breathing patterns," as proposed, because Patent Owner has failed to show any sufficient evidence that the '955 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner's contentions in light of all the evidence of record, we do not adopt Patent Owner's proposed construction; instead, we apply the plain and ordinary meaning of "analyzes the data to determine the patient's breathing patterns" in our consideration of the issues before us.

- c. “analyzing, using the processing arrangement, the indication of the patient’s breathing patterns to determine the sleep state of a patient”

Claims 19 recites “analyzing, using the processing arrangement, the indication of the patient’s breathing patterns to determine the sleep state of a patient.” Ex. 1001, 11:28–30. Patent Owner argues this limitation of claim 19 should be construed to mean the same thing as “analyzes the data to determine the patient’s breathing patterns,” recited in claim 1 and discussed above. PO Resp. 16. Claim 19 does not require analyzing data to determine the patient’s breathing pattern, as in claim 1. Patent Owner does not address why “analyzing . . . the indication of the patient’s breathing patterns” in claim 19 should be construed the same as “analyzing the data to determine the patient’s breathing pattern” in claim 1. Additionally, Patent Owner does not address why “determin[ing] the sleep state of a patient” in claim 19 should be construed the same as “determin[ing] the patient’s breathing patterns” in claim 1.

Thus, for each of these reasons, in addition to the reasons explained above as to why we do not adopt Patent Owner’s proposed construction for claim 1, we do not adopt Patent Owner’s proposed construction in the context of claim 19. Rather, we apply the plain and ordinary meaning of each of the phrases recited in claim 19.

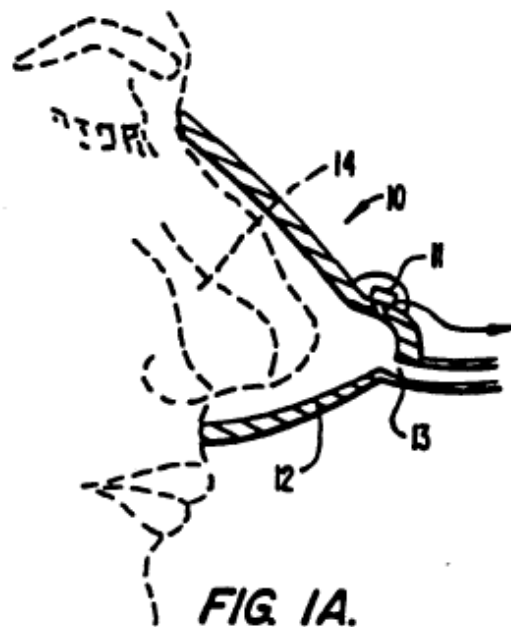
D. Ground 1: Alleged Obviousness of Claims 1–5, 8, 11, 12, 16–22, 24–26, 30, and 31 over Sullivan995 and Sullivan460

Petitioner contends claims 1–5, 8, 11, 12, 16–22, 24–26, 30, and 31 would have been obvious over Sullivan995 and Sullivan460. Pet. 19–57. Petitioner contentions are supported by Dr. Kirkness. Ex. 1046 ¶ 28 (adopting the opinions set forth in Ex. 1003 ¶¶ 20–28, 32–83, 87–316). Patent Owner disputes Petitioner’s contentions. PO Resp. 20–26.

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

1. Sullivan995 (Ex. 1005)

Sullivan995 is titled “Device and Method for Monitoring Breathing During Sleep, Control of CPAP Treatment, and Preventing of Apnea.” Ex. 1005, code (54). Sullivan995 is directed “to the diagnosis and treatment of partial or complete upper airway occlusion, a condition where the upper airway collapses, particularly under the reduced pressure generated by inhalation.” *Id.* at 1:14–18. Sullivan995's Figure 1A depicts snoring detection device 10, which is reproduced below. *Id.* at 8:47.



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

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

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

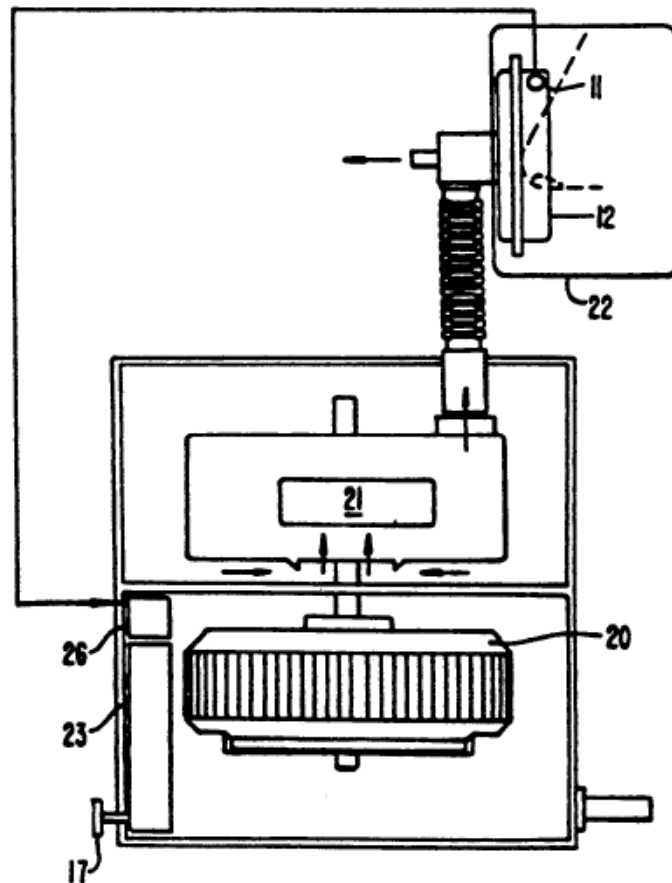


FIG. 3

The CPAP apparatus shown in Figure 30 includes motor 20 that drives blower 21. *Id.* at 9:58–59. Sullivan995 explains that “[t]he speed of the

motor 20 is controlled by an electronic speed control unit 23.” *Id.* at 9:59–60. The CPAP apparatus further includes snoring detection means 22 that uses microphone 11 to detect sounds. *Id.* at 9:64–66. Sullivan995 states that “snoring detection means 22 is conveniently in the form of the previously described device 10” and that “[i]n its most general form, the snoring detection means 22 is a pressure detection means and microphone 11 is a differential pressure sensor.” *Id.* at 9:66–3. Sullivan995 explains that:

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

Id. at 10:3–12.

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

Sullivan995's Figure 12 is reproduced below.

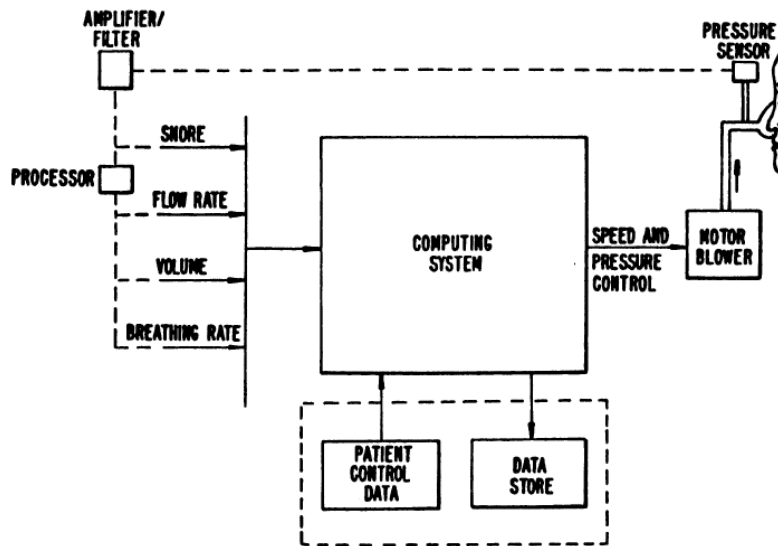


FIG. 12.

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

Sullivan995 states that:

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

Id. at 17:4–18.

2. Sullivan460 (Ex. 1006)

Sullivan460 is titled “Apparatus and Method for the Treatment of an Upper Airway Flow Limitation.” Ex. 1006, code (54). Sullivan460 is

directed to “an apparatus and method for the treatment of an upper airway flow limitation in a patient” and particularly “an apparatus and method of treating hypertension caused by pre-eclampsia.” Ex. 1006, 1:5–8.

Sullivan460 describes an embodiment in which a “treatment means is a device which applies Continuous Positive Airway Pressure (CPAP), more preferably nasal-Continuous Positive Airway Pressure (nCPAP), to the airway of the patient.” *Id.* at 6:17–20. Sullivan460 also describes an embodiment in which “the flow rate measurement means and the treatment means may be constructed together as part of one apparatus. Such as the AutoSet product from ResMed described in US Patent No 5245995 [Sullivan995].” *Id.* at 6:22–24.

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

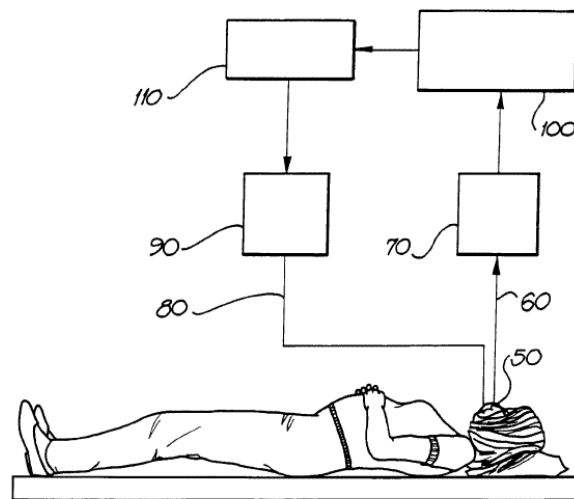


FIG. 2

In Figure 2, patient 30 is laying on bed 40 and wears mask 50 over her nose 50. *Id.* at 10:8–9. Mask 50 is connected via 80 to nCPAP apparatus 90. *Id.*

at 9–10. Sullivan460 states that “flow rate measurement means 70 detects the rate at which the patient breathes in air, and generates a signal which is sent to a central controller 100.” *Id.* at 10–12. Sullivan460 explains that “[w]hen the flow rate measurement means 70 detects the interruptions to inspiratory flow 10, the controller 100 activates a switch 110 which activates the nCPAP apparatus 90 to supply air to the patient 30 at a pressure which ameliorates or eliminates the upper airway flow limitation for that patient.” *Id.* at 10:12–16.

Sullivan460 explains:

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

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

3. *Independent Claim 1*

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

Patent Owner contends that the combination of Sullivan995 and Sullivan460 “fails to disclose numerous independent claim limitations . . . highlighted in red.” PO Resp. 21–25.¹² Patent Owner also contends that Petitioner fails to establish motivation to combine or reasonable expectation of success. *Id.* at 25–26. Patent Owner also contends that secondary considerations of non-obviousness support the patentability of the claims. *Id.* at 27–29.

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

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

Petitioner contends “Sullivan995 discloses a ‘continuous positive airway pressure (CPAP)’ system^[1] which is *a positive airway pressure system.*” Pet. 23 (citing Ex. 1005, Abstract, 1:33–36, 2:15–19, 9:57–58, Fig. 3). Petitioner further contends “Sullivan995’s CPAP system ‘deliver[s]

¹² Patent Owner reproduces claim 1 and highlights a large block of text in red as allegedly not taught by the combination of Sullivan995 and Sullivan460. See PO Resp. 22. Patent Owner does not provide arguments for all of the highlighted limitations. We address the specific arguments made by Patent Owner. Further, we note that Patent Owner does not provide separate arguments for independent claim 19 or the dependent claims in this Ground apart from its contentions for claim 1. *Id.* at 21–25.

appropriate airway pressure’ to the patient’s airway passages and is therefore *for delivery of a flow of breathable gas.*” *Id.* (citing Ex. 1005, 2:15–16).

Petitioner further contends that one of ordinary skill in the art “would have understood, CPAP delivers ‘positive’ airway pressure relative to atmospheric pressure, so that the breathable gas delivered by Sullivan995’s CPAP system is *at a positive treatment pressure with respect to ambient air pressure.*” *Id.* (citing Ex. 1003 ¶ 101). Petitioner further contends Sullivan995’s CPAP system includes nose mask 12 “‘for delivery of air to the patient’s nasal passages,’ meaning the CPAP system delivers the elevated air pressure *to an entrance of a patient’s airways.*” *Id.* at 23–24 (citing Ex. 1005, 5:12–34, 11:1–4, 11:23–43, claim 6, Fig. 3). Petitioner further contends Sullivan995’s CPAP system provides “air pressure at a certain level to ‘prevent the onset of apnea’ in the patient, where Sullivan995 characterizes sleep apnea as a complete occlusion of the upper airway passage during sleep, which is a *sleeping disorder.*” *Id.* at 24 (citing Ex. 1003 ¶ 103; Ex. 1005, 1:20–31, 1:32–48, 10:31–35, 11:15–20).

Patent Owner does not address the preamble in the Patent Owner Response. *See* PO Resp. 21–25.

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

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

Petitioner contends that “Sullivan995’s CPAP system includes a motor 20 with a variable speed that drives a blower 21,” which “*supplies a*

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

Patent Owner does not address this limitation in the Patent Owner Response. *See* PO Resp. 21–25.

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

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

Petitioner contends Sullivan995’s “system includes a differential pressure sensor (microphone 11), which is a *flow sensor.*” Pet. 26 (citing Ex. 1003 ¶ 107; Ex. 1005, 9:64–66, Fig. 3). Petitioner further contends that “Sullivan995 explains that the microphone is a sound transducer that ‘consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the **rate of breathing**, inhaled air flow or inhaled **air flow rate.**’” *Id.* at 26–27 (citing Ex. 1005, Abstract, 3:21–30). Petitioner further contends that Figure 3 of Sullivan995 illustrates that “microphone 11 is located within the snoring

detection means 22, and is therefore *located in a flow path of the positive treatment pressure flow of breathable gases.*” *Id.* at 27 (citing Ex. 1003 ¶ 109; Ex. 1005, 8:52–57).

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

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

Patent Owner highlights this limitation in red as allegedly not taught by the combination of Sullivan995 and Sullivan460. PO Resp. 22. But,

Patent Owner does not provide argument directed toward Petitioner's contentions for this limitation. *Id.* at 22–25.

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

1[c1] a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor,
Petitioner contends “[t]he combination of an amplifier/filter/processor unit 26 with a speed control unit 23 depicted in Figure 3 and described in part as the computing system in Figure 12” corresponds to the recited processing arrangement. Pet. 32–33 (footnotes omitted). Petitioner further contends Sullivan995’s “microphone 11 (*flow sensor*) provides its *measured data* to processor unit 26.” *Id.* at 33 (citing Ex. 1005, 10:3–6, 10:37–66). Petitioner further contends “Sullivan995 states ‘[t]he electrical signals from the pressure transducer are amplified and filtered to provide pressure waves of the desired frequencies indicative of snoring and breathing. The pressure wave indicative of breathing is further processed to generate signals indicative of flow rate, volume and breathing rate.’” *Id.* at 35 (citing Ex. 1005, 17:6–12). Based on this, Petitioner contends “Sullivan995’s *processing arrangement receives the measured data corresponding to the flow of breathable gases from the flow sensor.*” *Id.*

Patent Owner highlights this limitation in red as allegedly not taught by the combination of Sullivan995 and Sullivan460. PO Resp. 22. But, Patent Owner does not provide argument directed toward Petitioner's contentions for this limitation. *Id.* at 22–25.

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

1[c2] [the processing arrangement] analyzes the data to determine the patient's breathing patterns,

Relying on its contentions for limitations 1[b] and 1[c1], Petitioner contends Sullivan995 “describes various breathing patterns for the patient.” Pet. 35. Petitioner further contends that “Sullivan995’s *processing arrangement* includes the processor unit 26, ‘which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.’” *Id.* at 36 (citing Ex. 1005, 11:55–62, Fig. 4). Petitioner also contends that Sullivan995’s computing system “‘analyses and records signals from the pressure sensor,’ and analyzes ‘the sound and breathing patterns’ to record ‘indexes such as the number of apneic episodes, the number of hypopneas, their duration, etc.’” *Id.* (citing Ex. 1005, 12:67–18:8, Fig. 12). Petitioner further contends these actions by the computing system correspond to the recited “analyz[ing] the data [from the flow sensor] to determine the patient’s breathing patterns.” *Id.*

Patent Owner highlights this limitation in red as allegedly not taught by Sullivan995 in view of Sullivan460. PO Resp. 22. Patent Owner contends that Sullivan995 does not teach this limitation because it “cannot distinguish between all the various breathing patterns including REM sleep versus troubled wakefulness.”¹³ PO Resp. 22–23 (citing Ex. 2006 ¶¶ 146–

¹³ Patent Owner does not specify whether this contention applies to this claim limitation, but the contention appears to be responsive to Petitioner’s contentions concerning the patient’s breathing patterns. We note that the testimony of Dr. Bates cited by Patent Owner in support of this contention is not directed to this limitation. *See* Ex. 2006 ¶¶ 146–47.

47). Patent Owner contends that the '955 patent requires “an analysis of both the amplitude and the temporal structure of a breath-by-breath time series . . . to distinguish between troubled wakefulness and REM sleep.” *Id.* at 22 (citing Ex. 2006 ¶¶ 146–47). Patent Owner further contends that “the parameters that Sullivan995 claims to detect are all characteristics of the amplitude structure of a breath-by-breath parameter time series, which is not enough to distinguish between awake and asleep as claimed, let alone REM sleep and troubled wakefulness.” *Id.* at 23 (citing Ex. 2006 ¶ 147).

Petitioner replies that Patent Owner’s “non-obviousness arguments are based on its erroneous proposed construction of the “analyzing the breathing patterns” terms. Pet. Reply 11.

We agree with Petitioner that Patent Owner’s arguments are based on its construction of “analyzing the data to determine the patient’s breathing patterns” which, as discussed above, we do not adopt. Consequently, to the extent that Patent Owner interposed this contention in connection with limitation 1[c2], Patent Owner’s arguments are not commensurate in scope with claim 1, which does not require analysis of both an amplitude and temporal structure of the waveform to determine the patient’s breathing pattern. Further, Dr. Bates’s opinion cited by Patent Owner is not availing because it is based on the same argument that “neither Sullivan995 nor Sullivan460 teaches how to distinguish between an awake state and an asleep state based on an analysis of both the amplitude structure and the temporal structure of a time series of breath-by-breath parameters.” Ex. 2006 ¶ 146.

In the Sur-reply, Patent Owner contends that “Sullivan995 focuses on the analysis of *snoring sounds*, which are not breathing patterns.” Sur-reply

16 (citing Ex. 2006 ¶ 163). Patent Owner bases this contention on Dr. Bates’s testimony that “[a] snoring signal is not a breathing pattern, so Sullivan995 does not make a determination ‘*based, at least in part on, on the determined breathing patterns of the patient.*’” Ex. 2006 ¶ 163. However, Dr. Bates’s opinion that a snoring signal is not a breathing pattern is explained in paragraphs 157 and 158 of his Declaration where he explains that Sullivan995 records single values that “cannot characterize a breathing pattern which is characterized by a time series of breath-by-breath parameter values arranged in the precise order of the breaths.” *Id.* ¶ 158. Patent Owner’s Sur-reply contention is, thus, unavailing because it relies on Dr. Bates’s testimony which is based on Patent Owner’s claim construction which we do not adopt.

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

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

Petitioner contends in Sullivan995, “[i]n response to the electrical signal generated when snoring sounds occur, a motor speed control means ‘increases the speed of the electronic motor 20,’ which ‘increases the blower speed,’ thereby ‘increas[ing] the output air pressure of the blower 21.’” Pet. 36 (citing Ex. 1005, 9:60–64, 10:6–12, 10:40–46, 10:55–58). Petitioner further contends that “‘in the absence of an electronic signal from the microphone 11,’ meaning the patient is not snoring, Sullivan995’s processor unit 26 ‘achieve[s]’ a decrease in CPAP pressure by ‘continuously gradually reducing the blower speed over a period of

time.”” *Id.* (citing Ex. 1003 ¶ 126; Ex. 1005, 10:37–46). According to Petitioner, increasing or decreasing the blower speed corresponds to the recited “alter[ing] [of] the pressure supplied by the blower to the airway of the patient” and “is based on ‘when snoring sounds occur.’” *Id.* (citing Ex. 1003 ¶ 126) (emphasis omitted). Petitioner further contends “[t]he determination to increase the output air pressure in Sullivan995 is made when ‘respond[ing] to a snore, or a snore *pattern*,’ and is therefore *based, at least in part, on the determined breathing patterns of the patient.*” *Id.* at 37 (citing Ex. 1005, 10:55–58).

Patent Owner highlights this limitation in red as allegedly not taught by Sullivan995 in view of Sullivan460. PO. Resp. 22. But, Patent Owner does not provide argument directed toward Petitioner’s contentions for this limitation. *Id.* at 22–25.

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

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

Petitioner contends that, “[a]s Sullivan995 explains for Figure 3, ‘the output pressure of the CPAP unit increases in response to detection of snoring.’” Pet. 38 (citing Ex. 1005, 10:10–12). Petitioner further contends that one of ordinary skill in the art “would understand that the detection of snoring indicates that the patient is in an asleep state.” *Id.* (citing Ex. 1003 ¶ 139; Ex. 1005, 10:47–61). Petitioner further contends that Figure 13 of Sullivan995 illustrates that “the computing system maintains a constant pressure until the first snore is detected. In response to the first snore, and each subsequent snore, the computing system increases the pressure.” *Id.* at 39 (citing Ex. 1003 ¶ 141).

Patent Owner highlights this limitation in red as allegedly not taught by Sullivan995. PO. Resp. 22. But, Patent Owner does not provide argument directed toward Petitioner’s contentions for this limitation. *Id.* at 22–25.

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

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

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

Petitioner contends that “Sullivan460 discloses [a] ‘sleep sensor [that] is adapted to register that the patient is asleep when there is a reduced average airflow in the patient’s upper airway.’” Pet. 40 (second alteration in original) (citing Ex. 1006, 7:17–19). Petitioner further contends Sullivan460 discloses switching means “which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery,’ where ‘a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep”” and the second mode provides a higher pressure than the first

mode. *Id.* (alterations in original) (citing Ex. 1003 ¶¶ 147–148); Ex. 1006, 6:30–7:12, claims 22–28, 43–46).

Patent Owner highlights this limitation in red as allegedly not taught by Sullivan995 in view of Sullivan460. PO. Resp. 22. But, Patent Owner does not provide argument directed toward Petitioner’s contentions for this limitation. *Id.* at 22–25.

We reviewed the evidence cited by Petitioner and find that the combination of Sullivan995 and Sullivan460 teaches this limitation for the reasons provided by Petitioner.

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

Petitioner contends Sullivan995 discloses “the output pressure of the CPAP unit increases in response to detection of snoring,” and “the pressure is decreased ‘if an extended period of snore free breathing occurs’ by ‘intentionally reducing the CPAP pressure at a gradual rate as long as snoring is not detected.’” Pet. 41 (citing Ex. 1005, 10:10–12, 10:31–46, 10:47–61, 14:17–20, Figs. 3, 13). Petitioner concedes “Sullivan995 does not explicitly disclose that the increase occurs when the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state has occurred.” *Id.* (citing Ex. 1003 ¶ 152) (emphasis omitted). Nonetheless, Petitioner contends “this limitation would have been obvious from Sullivan995 in view of Sullivan460.” *Id.*

Petitioner next contends “Sullivan460 discloses determin[ing] that the patient has transitioned between at least an awake state and an asleep state by describing embodiments in which ‘a sleep sensor [] senses whether or not the patient is asleep’ by determining ‘when there is a

reduced average airflow in the patient's upper airway.” Pet. 42 (alteration in original) (citing Ex. 1003 ¶ 152; Ex. 1006, 7:3–7, 7:10–12, 7:17–19).

Petitioner relies on its motivation to combine and reasonable expectation of success contentions which, as we discuss below, are persuasive. Pet. 42.

Patent Owner contends that “Sullivan460 only considers mean values of flow, an aspect of the amplitude structure of a time series, in determining sleep versus awake.” PO Resp. 39 (citing Ex. 1005 7:18–19); *see also id.* at 22 (“Sullivan995 in view of Sullivan460 teaches identification of patient state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of a time series.” (citing Ex. 2006 ¶ 150)). Patent Owner repeats its contention discussed above in our claim construction analysis, that the '955 patent teaches that “analysis of both the amplitude and temporal structure of a breath-by-breath times series is required to distinguish between troubled wakefulness and REM sleep.” *Id.* at 24. According to Patent Owner, “Sullivan995 cannot distinguish between all the various breathing patterns, including REM sleep versus troubled wakefulness.” *Id.* at 22–23 (citing Ex. 2006 ¶¶ 146–47). Patent Owner further contends that Sullivan460 does not disclose this limitation because it “focuses exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible to distinguish between REM sleep and troubled wakefulness.” *Id.* at 24 (citing Ex. 2006 ¶ 178).¹⁴

¹⁴Patent Owner also argues that claim 1 is unpatentable for “the additional reasons provided by Dr. Bates in his Declaration, EX2006, which is

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

Patent Owner's contentions are unavailing for several reasons.

To the extent that Patent Owner relies on its construction of "analyzing the data to determine the patient's breathing patterns," the contentions are unavailing because, as discussed in our claim construction analysis, claim 1 does not require an analysis of amplitude and temporal structures of the waveform. Second, Patent Owner's contentions are not

incorporated here in its entirety." PO Resp. 25; *see also id.* at 31 (arguing the same for claims 6, 23). Our Rules expressly state that "[a]rguments must not be incorporated by reference from one document into another document." 37 C.F.R. § 42.6(a)(3). Further, Patent Owner was expressly informed that "arguments not raised in the response may be deemed waived." Paper 19, 64 n.14. Accordingly, we deem waived all arguments based on "additional reasons" in Dr. Bates's Declaration purported by Patent Owner to have been incorporated by reference into its response.

commensurate with the scope of independent claim 1 because it does not recite determining that the patient has transitioned between troubled wakefulness and REM sleep. Rather, claim 1 recites “determin[ing] that the patient has transitioned between at least an awake state and an asleep state.” Ex. 1001, 10:6–6. Third, Sullivan460’s sleep sensor determines if the patient is asleep “when there is reduced average flow” which aligns with the ’955 patent’s description of “low flow rates” as indicative of REM sleep. Ex. 1001, 5:30–34.

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

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

Petitioner contends Sullivan995 discloses that its “processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube incrementally with each snore that is detected.” Pet. 43 (citing Ex. 1005, 14:17–20, Fig. 13). According to Petitioner, one of ordinary skill in the art “would have readily recognized, the incremental increase depicted in Figure 13 is using a ramp system because the incremental increases occur at different times, upon detection of each snore.” *Id.* (citing Ex. 1003 ¶ 155; Ex. 1006, 11:55–12:6, Figs. 4–6).

Patent Owner does not address this limitation in the Patent Owner Response. PO Resp. 21–25.

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

Motivation to Combine/Reasonable Expectation of Success

In support of the combination of the teachings of Sullivan995 and Sullivan460, Petitioner states that “Sullivan460 . . . incorporates Sullivan995 by reference.” Pet. 15 (citing Ex. 1006, 6:22–29); *see also* Ex. 1003 ¶ 74 (Sullivan460 “incorporates Sullivan995 . . . by reference.”); *see also* Pet. 19–22 (discussing motivations supporting the asserted combination of teachings from Sullivan995 and Sullivan460, as well as why a person of ordinary skill in the art would have had a reasonable expectation of success). Petitioner contends that “[l]ike Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep.” Pet. 15 (citing Ex. 1006, 6:17–29, 7:3–12, 10:9–33, 11:10–12, claims 22–28, 43–46, Figs. 2–4). According to Petitioner, the asserted combination advantageously would apply “a low pressure upon wake-up, would add to patient comfort and decrease the likelihood the patient will remove the mask due to uncomfortably high pressure,” as suggested by Sullivan995, which explains “that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period).” *Id.* at 20 (citing Ex. 1005, 10:13–46, 14:45–64). Additionally, Petitioner contends that a person of ordinary skill in the art “would have had a reasonable expectation of success in performing this modification because Sullivan460 already describes Sullivan995 as being used to sense flow limitations, and Sullivan460 further explains that flow data may be used to determine an awake/sleep state.” *Id.* at 21–22 (citing Ex. 1003 ¶ 98).

We find Petitioner’s reasoning above supports the asserted combination of features from Sullivan995 and Sullivan460. We further

consider Patent Owner's arguments in opposition and do not agree with them for the reasons provided below. *See* PO Resp. 25–26; Sur-reply 19–21.

First, Patent Owner argues that there is “no motivation to combine Sullivan995 with Sullivan460” to “modify the *processing arrangement* in Sullivan995 to appl[y] a *lesser positive treatment pressure* when the patient is in an awake state, and determine[] that the patient has transitioned between at least an awake state and an asleep state,” because “Sullivan460 focuses exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to . . . distinguish between an awake state and an asleep state as claimed.” PO Resp. 25–26 (alterations in original) (citing Ex. 2006 ¶¶ 146–47). Patent Owner's argument is not persuasive because it is premised on Patent Owner's proposed construction of “analyzes the data to determine the patient's breathing patterns” as requiring analysis of both the amplitude structure and the temporal structure, which we do not adopt for the reasons provided above. Further, Patent Owner's argument that the asserted combination “makes it impossible . . . to distinguish between an awake state and an asleep state” is contrary to the disclosure of Sullivan460, which describes two modes of air delivery, one at a higher pressure than the other, as well as “a sleep sensor which senses whether or not the patient is asleep” and “switching means” so that treatment may be switched to a higher pressure mode “as soon as the patient goes to sleep (as determined by an appropriate sensing algorithm in the treatment means).” Ex. 1006, 7:3–12.

Second, Patent Owner argues that there is “no motivation to combine,” because Sullivan460 teaches that “the preset level is a single value of a flow rate, but Dr. Kirkness does not know how this would be

calculated.” PO Resp. 26 (citing Ex. 2015, 48:6–20). Specifically, Dr. Kirkness was asked “[h]ow would you calculate a single value of a flow rate?” and responded “[s]o in my – I don’t know how this would be – it doesn’t describe, for me, in this sentence how that level is.” Ex. 2011, 48:6–20. Elsewhere in its Patent Owner Response, Patent Owner implies, in regard to a *different* alleged ground of unpatentability, that Sullivan460 is not enabled. PO Resp. 38 (asserting no motivation to combine Rapport502 and Sullivan460) (citing *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1354 (Fed Cir. 2003), for the proposition that “to qualify as prior art, it must be enabled”). Further, Patent Owner makes the same allegation but directed to the combination of Sullivan995 with Sullivan460 for the first time in its Sur-reply, asserting that “[t]here is no motivation to combine any reference with Sullivan460 because it is not enabling.” Sur-reply 19–20 (citing Ex. 2015, 48:6–20).

We disagree with Patent Owner’s arguments that Petitioner fails to show any motivation to combine and that Sullivan460 is not enabled merely because Dr. Kirkness indicated in a deposition that he did not know how a preset level is calculated from a single sentence in Sullivan460. As Petitioner correctly explains, enablement “is not a requirement to prove invalidity under §103.” *Amgen*, 314 F.3d at 1313 (Under §103, “a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein.”). Moreover, we agree with Petitioner that the challenged claims do not require any preset level for a flow rate, and a person of ordinary skill “would have understood that a preset level is established from previously-acquired data or data from a previous window of time, such as an average level, for example, as taught in Sullivan995.” Pet. Reply 14–15

(citing Ex. 1005, 17:3–27, Fig. 12; Ex. 2015, 38:2–16). Patent Owner responds that Petitioner’s assertion is unsupported, and that “Petitioner is obligated to address this challenge, and failed to do so.” Sur-reply 20 (citing *In re Morsa*, 713 F.3d 104, 110 (Fed. Cir. 2013)). We find Petitioner’s arguments persuasive because they are supported by the asserted references.

Sullivan995 discloses that the computing system may “calculate control values of patterns for each patient based on moving average values or such values or patterns will be pre-programmed into the computing system.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22. Based on this disclosure, and given that Sullivan460 incorporates Sullivan995 by reference, we agree with Petitioner that Sullivan460’s disclosure of “detect[ing] that the flow rate has fallen below a present [sic] level,” would have informed a person of ordinary skill that this level was predetermined, so that “the controller 100 activates the nCPAP apparatus 90 to supply air to the patient 30 at a pressure which ameliorates or eliminates the upper airway flow limitation.” Ex. 1006, 11:10–13.

Third, Patent Owner argues a person of ordinary skill would have had no reasonable expectation of success combining the teachings of Sullivan995 with Sullivan460 because “Sullivan995 is not ‘configured to monitor breathing patterns while the patient is asleep to determine a patient’s pressure flow needs’” and “does not teach how to distinguish [an] awake state and an asleep state, let alone between REM sleep and troubled wakefulness which have opposite implications for pressure and flow.” PO

Resp. 26 (citing Ex. 2005 ¶¶ 149–50, 213). We disagree with Patent Owner’s argument because it is premised on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns” requiring analysis of both the amplitude structure and the temporal structure, which we do not adopt for the reasons provided above. We also disagree with Patent Owner’s arguments because they are directed to the references, individually, and not to what the references in combination would have taught a person of ordinary skill. For example, Petitioner relies on Sullivan460 not Sullivan995 to distinguish between an awake state and an asleep state. *See* Pet. 40.

Finally, Patent Owner argues that “the proposed modification to Sullivan995’s CPAP system would require methods of digital signal processing that go beyond a combination of known prior art elements,” and “would require the use of methods that analyze the temporal structures of a time series.” PO Resp. 26 (citing Ex. 2006 ¶ 150). To the contrary, Petitioner has shown by a preponderance of the evidence that the Challenged Claims “do not require analysis of temporal structures of a time series,” and that a person of ordinary skill “would have understood that asleep and awake states could be determined without analysis of temporal structures.” Pet. Reply 16 (citing Ex. 1051 ¶¶ 21–22). Petitioner contentions are supported by the ’955 patent which describes that the processor “may analyze the patient’s heart rate, blood pressure, EEG data, breathing patterns etc. in determining the patient’s state” and that “high respiratory rates and low flow rates” are indicative of REM sleep. Ex. 1001, 4:28–30, 5:32–33.

Based on our review of the arguments and evidence cited by Petitioner, and after considering Patent Owner’s arguments, we find

Petitioner shows that an ordinarily skilled artisan would have been motivated to combine Sullivan995 and Sullivan460 as asserted, and would have had a reasonable expectation of success in doing so.¹⁵

Summary of Independent Claim 1

For all the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches every limitation of claim 1.

4. Dependent Claims 2–5, 8, 11–12, and 16–18

These claims depend from claim 1. Ex. 1001, 10:12–11:11. Petitioner asserts that these claims would have been obvious over Sullivan995 and Sullivan460 and provides a detailed analysis of each of these claims with argument and evidence in support thereof. Pet. 43–52. Patent Owner does not raise any arguments directed specifically to claims 2–5, 8, 11, 12, and 16–18 aside from the arguments Patent Owner directs to claim 1. *See* PO Resp. 20–26. We have reviewed Petitioner’s evidence and arguments and find that the combination of Sullivan995 and Sullivan460 teaches every limitation of claims 2–5, 8, 11, 12, and 16–18 for the reasons provided by Petitioner.

¹⁵ Patent Owner improperly argues for the first time in its Sur-reply that the asserted combination would have required “undue experimentation.” Sur-reply 20. Patent Owner’s alleged “undue experimentation” was not raised in Patent Owner’s Response and therefore Petitioner did not have an opportunity to respond to it. Accordingly, Patent Owner’s argument is improper and the issue is deemed waived. *See* Paper 19, 64 n.14 (stating that “Patent Owner is cautioned that any arguments not raised in the Patent Owner Response may be deemed waived”). Moreover, we disagree with Patent Owner’s “undue experimentation” argument because it is premised on Patent Owner’s proposed construction requiring analysis of “both amplitude and temporal structure,” which we do not adopt.

5. *Independent Claim 19*

Independent claim 19 contains several limitations, identified by Petitioner as limitations 19[e]–19[g], substantially similar to claim 1. *Compare* Ex. 1001, 9:47–10:11, *with id.* at 11:12–44. For these limitations, Petitioner relies on its contentions and evidence for the corresponding limitations of claim 1. Pet. 54–55. For the remaining limitations of claim 19, Petitioner provides contentions supported by evidence from Sullivan995, Sullivan460, and Dr. Behbehani. *Id.* at 52–54. Petitioner relies on the same contentions for motivation to combine and reasonable expectation of success as discussed for claim 1. *Id.* at 19–57.

Patent Owner does not provide contentions for claim 19 apart from its contentions for claim 1. *See* PO Resp. 20–26.

We reviewed the Petitioner’s additional evidence and arguments for claim 19 and determine that Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches every limitation of claim 19 and that an ordinarily skilled artisan would have been motivated to combine Sullivan995 and Sullivan460 with a reasonable expectation of success for the reasons provided by Petitioner.

6. *Dependent Claims 20–22, 24–26, 30, and 31*

These claims depend from claim 19. Ex. 1001, 12:1–42. Petitioner asserts that these claims would have been obvious over Sullivan995 and Sullivan460 and provides a detailed analysis of each of these claims with argument and evidence in support thereof. Pet. 55–57. Patent Owner does not raise any arguments directed specifically to claims 20–22, 24–26, 30, and 31 aside from the arguments Patent Owner directs to claim 1. *See* PO Resp. 20–26. We have reviewed Petitioner’s evidence and arguments and

find that the combination of Sullivan995 and Sullivan460 teaches every limitation of claims 20–22, 24–26, 30, and 31 for the reasons provided by Petitioner.

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

Petitioner contends claims 6 and 23 would have been obvious over Sullivan995, Sullivan460, and Matthews. Pet. 57–59. Patent Owner disputes Petitioner’s contentions. PO Resp. 29–33.

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

1. Matthews (Ex. 1007)

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

CPAP controller if the patient's breathing pattern becomes too variable.” *Id.* at 21:37–42.

2. Analysis

Claim 6 depends from claim 1 and recites “wherein the awake state is a troubled wakefulness state.” Ex. 1001, 11:33–34. Claim 23 depends from claim 19 and recites “wherein applying a lower pressure when the patient is in the awake state comprises applying a low pressure when the patient is in a troubled wakefulness state.” *Id.* at 12:12–15.

Petitioner contends that Matthews “discloses an *awake state is a troubled wakefulness state* by describing ‘[w]hen a patient is awake . . . or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable.’” Pet. 59 (alterations in original) (citing Ex. 1007, 21:35–44, 21:63–22:1). According to Petitioner, “Matthews’s description of erratic breathing when the patient is awake and in distress is consistent with the ’955 Patent’s description of *troubled wakefulness* as ‘awake and anxious or distressed with ‘erratic breathing.’” *Id.* (citing Ex. 1001, 4:47–59).

Petitioner also provides reasons why one of ordinary skill in the art would have been motivated to modify the system of Sullivan995 and Sullivan460 with the teachings of Matthews and why the proposed modification would have had a reasonable expectation of success. *Id.* at 57–58.

Patent Owner argues that the combination of Sullivan995, Sullivan460, and Matthews does not teach the limitation “the awake state is a troubled wakefulness state.” PO Resp. 30. Patent Owner does not explain why it asserts that Matthews does not teach the recited troubled wakefulness state. *Id.* at 30–31. Rather, Patent Owner argues that “Sullivan995 and Sullivan460 in view of Matthews only teach the identification of patient

state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of a time series.” *Id.* at 30 (citing Ex. 2006 ¶ 266). Patent Owner then repeats its contention that the ’955 patent requires analysis of amplitude and temporal structure “to distinguish between troubled wakefulness and REM sleep.” *Id.* This contention is unavailing because we do not adopt Patent Owner’s claim construction requiring an analysis of amplitude and temporal structures.

We have reviewed Petitioner’s evidence in light of the parties’ agreed-on construction of “troubled wakefulness” and find that Matthews teaches the limitations of claims 6 and 23. *See* Pet. 59 (citing Ex. 1007, 21:35–44, 21:63–22:1).

Motivation to Combine/Reasonable Expectation of Success

Petitioner contends it would have been obvious to an ordinarily skilled artisan “to modify the system of Sullivan995 and Sullivan460 Matthews so that the *processing arrangement* applies a lower pressure when the patient is in a *troubled wakefulness state*, as taught by Matthews.” Pet. 57 (citing Ex. 1003 ¶ 214). According to Petitioner, the ordinarily skilled artisan “would have recognized the advantages of detecting different awake states, including a distressed state (*troubled wakefulness*) in which the patient has breathing that becomes ‘erratic,’ as taught in Matthews,” which “would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* (citing Ex. 1003 ¶ 215). Petitioner notes that Sullivan995 is “concerned with the patient’s comfort, and already discloses it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible.” *Id.* at 57–58 (citing Ex. 1005, 2:31–39).

Petitioner next contends that there would be a reasonable expectation of success in combining Sullivan995, Sullivan460 and Matthews. Pet. 58. Petitioner explains that because data from Matthews’s flow sensors “are monitored and used to determine how to control the pressure” and Sullivan460 discloses lowering the pressure in an awake state, a person of ordinary skill in the art “would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient.” *Id.* (citing Ex. 1003 ¶ 217). According to Petitioner, the modification to Sullivan995 and Sullivan460 “is a combination of known prior art elements according to known methods and known techniques to yield predictable results, involves use of a known technique to improve a similar device in the same way.” *Id.* (citing Ex. 1003 ¶ 219).

Patent Owner argues that “Sullivan460 and Matthews focus exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to distinguish between REM sleep and troubled wakefulness” and “do not teach how to distinguish between an awake state and an asleep state as claimed.” PO Resp. 31–32 (citing Ex. 2006 ¶¶ 266–67). Patent Owner argues that Sullivan460 teaches a preset level that Dr. Kirkness cannot calculate. *Id.* at 32 (citing Ex. 2015, 48:6–20). These arguments are unavailing because they are based on Patent Owner’s proposed construction of analyzing the data, which we do not adopt.

For reasonable expectation of success, Patent Owner repeats its arguments that Sullivan995 is not configured to monitor breathing patterns while the patient is asleep, Sullivan995 does not teach how to distinguish

between troubled wakefulness and REM sleep, and modifying Sullivan995's CPAP would require digital signal processing techniques that go beyond a combination of known prior art elements. PO Resp. 41–42. These arguments are unavailing for the same reasons discussed above. *See supra* Section II.D.3.

We have reviewed Petitioner's contentions and evidence in light of Patent Owner's arguments in opposition and find that the Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews teaches the limitations of claim 19 and that an ordinarily skilled artisan would have been motivated to combine Sullivan995, Sullivan460, and Matthews with a reasonable expectation of success for the reasons provided by Petitioner. *See* Pet. 57–59.

G. Objective Evidence of Non-obviousness

The fourth *Graham* factor instructs that we must consider—apart from what the prior art itself would have suggested—whether objective evidence of non-obviousness (i.e., secondary considerations) may lead to a conclusion that the challenged claims would not have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (instructing that evidence of secondary considerations, when present, must always be considered in determining obviousness). Objective evidence of non-obviousness may include evidence of commercial success, licensing, copying, praise by others, long felt but unresolved need, and failure or skepticism of others. *Graham*, 383 U.S. at 17–18. But, secondary considerations are only a part of the “totality of the evidence;” their mere existence does not control the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). Objective

evidence of non-obviousness “may often be the most probative and cogent evidence in the record” and “may often establish that an invention appearing to have been obvious in light of the prior art was not.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

Patent Owner argues that evidence of non-obviousness exists in the form of long-felt need. PO Resp. 27–29, 33. According to Patent Owner, since 1991 there has been “a need for patients to increase compliance with usage of their CPAP machines.” *Id.* at 27 (citing Ex. 1036, 5). Patent Owner further argues as follows:

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients’ compliance with CPAP treatment by noting that “the conventional PAP therapy [had] not taken sleep/wake state into account” and “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” ’995 Patent, 1:44-46. Further, before the development of the claimed invention in the ’995 Patent, self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. *Id.*, 2:14-17. In fact, as of 2002, a [person of ordinary skill in the art] was “not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters.” *See* [EX2017, 2:33-37]. As such, the claimed invention solved a long felt but unresolved need – better compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 28–29 (first and second alterations in original).

Patent Owner further argues that conventional CPAP treatment “had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control.” Sur-reply 25 (citing Ex. 1001, 2:13–17, 2:26–29;

Ex. 1053, 296:22–297:15). According to Patent Owner, Dr. Bates’s testimony explained that “[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states.” *Id.* at 26 (citing Ex. 1052, 113:3–11, 115:22–116:10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by the ’995 patent’s “ability to distinctly identify when a patient is awake or asleep,” because a person of ordinary skill in the art “prior to the 994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and awake.” *Id.* (alteration in original)(citing Ex. 1052, 202:23–203:3).

(1) *Nexus*

Objective evidence of non-obviousness “is only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia of non-obviousness].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). A “nexus” is a legally and factually sufficient connection between the objective evidence and the claimed invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom*,

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

Petitioner argues that “for secondary considerations to be accorded substantial weight, [Patent Owner] bears the burden of showing that a nexus exists between the claimed features of the invention and the evidence offered to show non-obviousness.” Pet. Reply 24 (citing *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). According to Petitioner, Patent Owner does not meet this burden because: 1) Patent Owner did not establish “a presumption of nexus” since Patent Owner did not identify any product tied to the objective evidence; 2) Patent Owner did

not “demonstrate a nexus by showing that long-felt need was met as a ‘direct result of the unique characteristics of the claimed invention,’” 3) Patent Owner did not identify “any failed efforts to solve the problem before the invention,” and 4) Patent Owner does not point to disclosure in the ’955 patent that the “prior art recognized the need to analyze temporal and amplitude structures.” *Id.* at 24–26 (citations omitted).

First, Patent Owner has not argued that the presumption of nexus applies and we agree with Petitioner that Patent Owner is not entitled to a presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the Challenged Claims. Second, we address Patent Owner’s evidence of long-felt, but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the ’955 patent, absent the presumption.

(2) Long-felt Need

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

Here, Patent Owner suggests increasing the comfort of the PAP system is a goal to improve patient compliance with PAP therapy. PO Resp 27. Patent Owner does not explain, however, why Sullivan460’s treatment means which “addresses ... the comfort of CPAP,” and “is an improvement over the prior art” because of the two modes of air delivery where the

pressure is lower in the awake state, does not meet the long-felt need identified by Patent Owner. *See* Ex. 1006, 7:7–16; *see also* Pet. 15. Thus, we agree with Petitioner that “[t]o the extent that any need existed, it was already satisfied.” Pet. Reply 25 (citations omitted).

Additionally, Patent Owner does not identify any failed efforts to solve the problem before the invention and similarly fails to provide sufficient evidence that the ’955 patent satisfied the alleged need. Dr. Bates’s redirect testimony, which Patent Owner almost exclusively relied on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to “little or no weight.” 37 C.F.R. § 42.65(a). Patent Owner’s additional arguments regarding a supposed need for better compliance with CPAP therapy by detecting troubled wakefulness (*see* Pet. Reply 26) are only commensurate in scope with dependent claims 6 and 23. Nonetheless, even assuming Patent Owner’s argument is commensurate in scope with each of the Challenged Claims, Patent Owner’s argument still suffers from the other deficiencies identified above, particularly the failure by Patent Owner to show that the ’955 patent satisfied the alleged need.

Patent Owner relies on the same evidence and arguments concerning objective evidence of nonobviousness, and specifically long-felt need, with regard to obviousness over the combination of Sullivan995, Sullivan460, and Matthews as Patent Owner argues in regard to obviousness over the combination of Sullivan995 and Sullivan460 just discussed. *See* PO Resp. 33. In addition, we add that, as shown by Petitioner, Matthews already taught detecting troubled wakefulness and thus, in the context of

claims 6 and 23, Patent Owner has not explained why the alleged long-felt need was not met by Matthews.

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt, but unmet need met by any of the Challenged Claims. As a result, we accord little weight to Patent Owner's evidence of long-felt need.

H. Weighing the Graham Factors

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

I. Grounds 3 and 4

In light of our determination that claims 1–6, 8, 11, 12, 16–26, and 30–31 are unpatentable based on Grounds 1 and 2, we do not reach Petitioner's alternative challenges to these claims set forth in Grounds 3 and 4. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged.”); *see also* 35 U.S.C. § 318(a).

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner seeks to exclude Exhibits 1009, 1011, 1020, 1022, 1049, and 1054–1058, and portions of Exhibits 1003, 1046, 1051, and 1052.

PO MTE 1–14; PO MTE Reply 1–5. Petitioner opposes the motion. PO MTE Opp. 1–13. For the following reasons we deny Patent Owner’s Motion to Exclude.

A. Exhibits 1003 and 1046

Exhibit 1003 is the Declaration of Petitioner’s original declarant, Dr. Behbehani, and Exhibit 1046 is the substitute Declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s Declaration. *See* Ex. 1046 ¶ 28. Patent Owner argues that certain portions of Exhibit 1003 should be excluded and that the same portions of Exhibit 1003 that Dr. Kirkness adopts should be excluded. PO MTE 3–5, 6–7. Because we do not rely on the portions of Exhibit 1003 noted by Patent Owner in rendering this Decision, we deny Patent Owner’s Motion to exclude these portions of Exhibit 1003 and the corresponding portions of Exhibit 1046 as moot.

B. Exhibits 1009 and 1054–1058

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

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

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

In its Petition, Petitioner argued for “‘using the same claim construction standard that would be used’ in district courts,” i.e., the ordinary and customary meaning. Pet. 18. In its Response, Patent Owner argued that the language of the term “analyzing the data to determine the patient’s breathing patterns,” which appears in claim 1, should be construed as “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 17. Patent Owner did not raise this claim construction argument (or any other claim construction) in its Preliminary Response to the Petition (Paper 14), but raised it for the first time in its Response. *See* PO Resp. 16–19. Petitioner’s argument in its Reply responds to Patent Owner’s claim construction position asserted in the Patent Owner Response.

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

C. Exhibits 1011, 1020, and 1022

Patent Owner argues that these documents are irrelevant under Federal Rule Evidence 402 because Petitioner does not discuss or cite these exhibits in any document filed in this proceeding. PO MTE 6.

For Exhibit 1011 (“Burton852”), Petitioner responds that the documents “meets the threshold for relevance” because it “is cited and discussed during the prosecution history of the ’955 Patent.” PO MTE Opp.

8 (citing Ex. 1003 ¶ 103 (discussing how applicant obtained allowance over the prior art of record Burton 852)). We agree with Petitioner and deny Patent Owner’s Motion to Exclude as to Exhibit 1011.

For Exhibits 1020 and 1022, Petitioner argues that the Motion to Exclude is moot because Exhibits 1020 and 1022 “were already expunged from the record and they were not cited in the Petition.” PO MTE Opp. 8–9 (citing Paper 12, 4 n.1, 8).

Patent Owner replies that “while the sentence referring to EX1020 was stricken from the Petition, rendering the objection to EX1020 moot, the Board did not expunge Ex. 1022.” PO MTE Reply 3. Because we do not rely on Exhibit 1020, we, thus deny Patent Owner’s Motion to Exclude as to Exhibit 1020 as moot.

We do not rely on Exhibit 1022 in this decision, so we deny the Motion to Exclude as to Exhibit 1022 as moot.

D. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2. Patent Owner argues that the priority date of this patent is after the priority date of the ’955 patent and should be excluded as irrelevant and “not prior art.” PO MTE 7. Patent Owner also argues it should have been introduced prior to Petitioner’s Reply. *Id.*

Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. PO MTE. Opp. 9. Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. *Id.* at 9–10. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates’s

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

E. Exhibit 1051

Exhibit 1051 is the Declaration of Dr. Kirkness in support of Petitioner's Reply. Patent Owner argues that portions of Exhibit 1051 "should be excluded for the same reasons as" Exhibits 1003 and 1046. PO MTE 7–8. The only "example," provided by Patent Owner in support of its argument is that Dr. Kirkness "uses Exhibits 1049 and 1054–1058 in the exact same manner as they were challenged above." *Id.* at 8. For the reasons discussed above for Exhibits 1049 and 1054–1058, we deny the Motion to Exclude as to Exhibit 1051.

F. Exhibit 1052

Exhibit 1052 is the transcript of Dr. Bates's deposition testimony. Patent Owner argues that the portions of Exhibit 1052 "focusing on patent eligible subject matter and whether certain products, such as processors, infringe by meeting the limitations of the '995 Patent should be excluded as irrelevant." PO MTE 8–9 (citing Ex. 1052, 62:7–23, 63:15–25, 64:1–5, 117:9–25, 118:1–11, 146:4–12); PO MTE Reply 4–5. Petitioner argues that the testimony of Dr. Bates is relevant to obviousness issues in this proceeding, that there was "no discussion of 'infringement' or 'patentable subject matter,'" and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 10–11. We agree with Petitioner's reasons and deny Patent Owner's Motion to Exclude as to the challenged portions of Exhibit 1052.

G. Exhibit 1059

Exhibit 1059 is an article titled “Control of breathing during sleep” published in Clinical Science in 1984 and was cited by Dr. Kirkness in his Reply Declaration (Exhibit 1051). Patent Owner argues that Dr. Kirkness relied on Exhibit 1059 to show that a person of ordinary skill in the art “knew ‘that a processor could be programmed to analyze breathing patterns that fall below or above certain preset levels of airflow rate to indicate awake or asleep states’ and that analysis of temporal structures was not necessary.” PO MTE 9–10 (quoting Ex. 1051 ¶¶ 11, 32). According to Patent Owner, “[a]ny use of EX1059 is therefore an improper incorporation by reference through EX1051, violating 37 C.F.R. § 42.6(a)(3), which prohibits incorporating arguments by reference from one document into another document.” *Id.* at 10.

Patent Owner’s argument has no merit. As Petitioner notes, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and Exhibit 1059 “is not an argument.” PO MTE Opp. 12. Patent Owner also argues in its reply that Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply 5. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his Reply Declaration were relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” Pet. MTE Opp. 12. We agree with Petitioner for the same reasons discussed above regarding Exhibits 1009 and 1054–1058. Because Patent Owner shows no

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

IV. PETITIONER'S MOTION TO EXCLUDE

Petitioner seeks to exclude portions of the deposition testimony of Patent Owner's declarant Dr. Bates, Exhibit 1053. Pet. MTE 1–10; Pet. MTE Reply 1–5. Petitioner moves to exclude Dr. Bates's re-direct deposition testimony concerning secondary considerations of non-obviousness. Pet. MTE 1–2. Petitioner argues that the redirect testimony of Dr. Bates "was outside the scope of Petitioner's cross-examination in contravention of Fed. R. Evid. 611(b) and 37 C.F.R. § 42.53(d)(5)(ii)." *Id.* at 1. Petitioner does not seek to exclude the entirety of Dr. Bates's redirect testimony but only the specific portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes the motion. Pet. MTE Opp. 1–10. For the following reasons, we deny Petitioner's Motion to Exclude.

Petitioner contends that it "did not cross-examine Dr. Bates about any secondary considerations and timely objected to PO's line of questioning during redirect as being outside the scope." Pet. MTE 1–2 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9), 4 (citing Ex. 1053, 296:15–16, 298:8–9, 300:4–9). Petitioner further contends that Patent Owner's "introduction of belated expert testimony into the record via the Sur-Reply is improper and the evidence must be excluded." *Id.* at 2 (citing *Comcast Cable Commc'ns, LLC v. Rovi Guides, Inc.*, IPR2019-01413, Paper 34 at 4 (PTAB Sept. 16, 2020); *Int'l Bus. Machines Corp. v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 15 at 5 (PTAB Feb. 2, 2015); *see also id.* at 5–6 (identifying the portions of Sur-reply citing to the disputed testimony)). Petitioner further

contends that “Dr. Bates’ declaration included no discussion of secondary considerations.” *Id.*

Petitioner contends that “FRE 611(b) prohibits redirect examination that goes beyond the scope of cross-examination questions and testimony” and Patent Owner’s “redirect examination did just that.” Pet. MTE 7.

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

Patent Owner contends that Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner argues that the PTAB Consolidated Trial Practice Guide provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or ***otherwise exceeds the proper scope*** of reply or sur-reply, it may request authorization to file a motion to strike.” Pet. MTE Opp. 2 (citing PTAB Consolidated Trial Practice Guide (“CTPG”) 80 (PTAB Nov. 2019)). Patent Owner contends that “Petitioner’s counsel reserved that right to strike Dr. Bates’ redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of PO submitting its Sur-Reply.” *Id.* (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact ***inadmissible***,” only that “it should be excluded (not stricken) because it is

beyond of the scope of its cross-examination.” *Id.* at 3. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* at 4 (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–25).

In the Reply, Petitioner contends it “properly focused its motion to exclude the portions of Dr. Bates’ inadmissible re-direct deposition testimony cited in [the] Sur-Reply” and that Patent Owner “uses its Sur-Reply as no more than a ‘vehicle’ to enter new evidence into the record.” Pet. MTE Reply 1. Petitioner contends that it “timely objected at the deposition” once Patent Owner began “improperly elicit[ing] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Federal Rule of Evidence 611(b). *Id.* at 3 (citing Pet. MTE, Section II.B.2).

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

The CTPG provides that “[a] motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay)” but should not “address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.” CTPG 79. Further, the CTPG states that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a

motion to strike.” *Id.* at 80. As an alternative to a motion to strike, “a party may request authorization for further merits briefing . . . to address the merits of newly-raised arguments or evidence.” *Id.* A party must seek authorization to file a motion to strike “within one week of the allegedly improper submission.” *Id.* at 81.

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

The issue presented here borders on the proper scope of a motion to exclude as compared to a motion to strike. The goal of Petitioner’s Motion is clearly to undercut arguments raised in Patent Owner’s Sur-reply directed to objective indicia of non-obviousness. By limiting its Motion to only the portions of Dr. Bates’s redirect examination actually relied on in Patent Owner’s Sur-reply, Petitioner’s arguments reflect this goal. *See, e.g.*, Pet. MTE 5 n.2 (“Although all of Dr. Bates’ redirect testimony on secondary considerations was outside the scope of Petitioner’s cross-examination, Petitioner narrowly focuses this motion on excluding only those portions that [Patent Owner] relies on in its Sur-Reply.”). One way in which Petitioner could have challenged the arguments raised in Patent Owner’s Sur-reply is by requesting authorization to file a motion to strike, which, as noted above, is intended for the purpose of addressing arguments a party believes exceeds the proper scope of sur-reply. *See* CTPG 80. Petitioner did

not request such authorization. Instead, by seeking to exclude some of Dr. Bates's redirect testimony on objective indicia (i.e., the portions relied on in Patent Owner's Sur-reply), Petitioner seeks to undercut the arguments raised in Patent Owner's Sur-reply on objective indicia by effectively removing the primary evidentiary support for those arguments. Were we to grant Petitioner's Motion to Exclude, we would be faced with determining what to do with Patent Owner's arguments in the Sur-reply, which would remain of record because they are not the subject of Petitioner's Motion to Exclude (nor could they be based on the CTPG) and (as previously noted) Petitioner did not also file a motion to strike those arguments. The best course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Rule 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination (just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony¹⁶), Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of non-obviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the

¹⁶ There are exceptions, e.g., questions pertaining to a witness's credibility. See Fed. R. Evid. 611(b).

circumstances presented here and in light of the little weight to which Patent Owner's argument and Dr. Bates's redirect is entitled, we determine that the better course at this stage is to deny Petitioner's Motion to Exclude.

V. CONCLUSION

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

Claim(s) Challenged	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–5, 8, 11, 12, 16–22, 24–26, 30, 31	103(a)	Sullivan995, Sullivan460	1–5, 8, 11, 12, 16–22, 24–26, 30, 31	
6, 23	103(a)	Sullivan995, Sullivan460, Matthews	6, 23	
1, 3–6, 9–12, 14–18, 20–24, 26–29	102(b)	Rapoport502, Sullivan460 ¹⁷		
19	102(b)	Rapoport502, Sullivan460, Matthews ¹⁸		
Overall Outcome			1–6, 8, 11, 12, 16–26, 30, 31	

¹⁷ We do not reach the merits of this ground.

¹⁸ We do not reach the merits of this ground.

VI. ORDER¹⁹

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Exclude (Paper 51) is denied;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 52) is denied;

FURTHER ORDERED that claims 1–6, 8, 11, 12, 16–26, 30, and 31 of U.S. Patent No. 9,867,955 B2 have been proven by a preponderance of the evidence to be unpatentable; and

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

¹⁹ Should Patent Owner wish to pursue amendment of a Challenged Claim in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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