

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

IPR2022-00994
Patent 9,168,344 B2

Before BART A. GERSTENBLITH, JAMES A. TARTAL, and
ALYSSA A. FINAMORE, *Administrative Patent Judges*.

FINAMORE, *Administrative Patent Judge*.

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

ORDER
Denying Patent Owner's Motion to Exclude Evidence (Paper 48) and
Denying Petitioner's Motion to Exclude Evidence (Paper 49)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

ResMed, Inc. (“Petitioner”) filed a Corrected Petition (Paper 12, “Pet.”)¹ requesting an *inter partes* review of claims 1, 3, 7, 9, 11, and 13 of U.S. Patent No. 9,168,344 B2 (“the ’344 patent”) (Ex. 1001). We issued a Decision granting institution of an *inter partes* review (Paper 16, “Inst. Dec.”).

During trial, New York University (“Patent Owner”) filed a Response (Paper 33, “PO Resp.”). Petitioner filed a Reply (Paper 41, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 44, “Sur-reply”).

Patent Owner filed a Motion to Exclude Evidence (Paper 48, “PO MTE”). Petitioner filed an Opposition (Paper 52, “PO MTE Opp.”), and Patent Owner filed a Reply (Paper 53, “PO MTE Reply”). Petitioner also filed a Motion to Exclude Evidence (Paper 49, “Pet. MTE”). Patent Owner filed an Opposition (Paper 51, “Pet. MTE Opp.”), and Petitioner filed a Reply (Paper 54, “Pet. MTE Reply”).

An oral hearing took place October 2, 2023.² We entered the transcript (Paper 63, “Tr.”) into the record.

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we conclude Petitioner has proven, by a

¹ Petitioner filed a Petition (Paper 1) and subsequently filed a Motion to Correct the Petition and Filing Date (Paper 8), which New York University opposed (Paper 9). We granted Petitioner’s Motion (Paper 11), and Petitioner then filed the Corrected Petition. All references herein to the “Petition” are to the Corrected Petition.

² The Parties filed objections to the other party’s demonstratives and hearing arguments and responses to those objections (Papers 60, 61, 64–67). Demonstratives and hearing arguments are not evidence and are not relied upon in this Decision. Accordingly, the objections are denied as moot.

preponderance of the evidence, that claims 1, 3, 7, 9, 11, and 13 of the '344 patent are unpatentable. Furthermore, we deny both Parties' Motions to Exclude Evidence.

A. Related Matters

The Parties identify as a related matter the following district court action: *New York University v. ResMed, Inc.*, No. 1:21-cv-00813-JPM (D. Del. 2021). Pet. 3; Paper 55, 2. The Parties also identify as related matters the following six Board proceedings: IPR2022-00988 (challenging U.S. Patent No. 9,108,009 B2), IPR2022-00989 (challenging U.S. Patent No. 9,427,539 B2), IPR2022-00990 (challenging U.S. Patent No. 9,533,115 B2); IPR2022-00991 (challenging U.S. Patent No. 9,867,955 B2), IPR2022-00992 (challenging U.S. Patent No. 10,384,024 B2), and IPR2022-00993 (challenging U.S. Patent No. 6,988,994 B2). Pet. 3; Paper 55, 2–3.

B. Real Parties in Interest

Petitioner and Patent Owner each identifies itself and no others as a real party in interest. Pet. 3; Paper 5, 2; Paper 27, 2; Paper 34, 2; Paper 55, 2.

C. The '344 Patent (Ex. 1001)

The '344 patent is titled "System and Method for Diagnosis and Treatment of a Breathing Pattern of a Patient." Ex. 1001, code (54). The '344 patent issued on October 27, 2015, from Application No. 12/983,628, which was filed on January 3, 2011. *Id.* at codes (45), (21), (22). Application No. 12/983,628 is a continuation of Application No. 11/240,197, filed on September 30, 2005, which is a continuation-in-part of Application No. 11/210,568, filed on

August 24, 2005, which is a continuation of Application No. 10/642,459, filed August 14, 2003, now U.S. Patent No. 6,988,994 B2 (“the ’994 patent”) (Ex. 2002).³ *Id.* at code (63).

As background, the ’344 patent explains that “[o]bstructive sleep apnea syndrome (OSAS) is a well recognized disorder which may affect as much as 1–5% of the adult population.” Ex. 1001, 1:22–24. According to the ’344 patent:

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

Id. at 1:28–35. The ’344 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS.” *Id.* at 1:51–54. The ’344 patent describes that “PAP therapy is directed to maintaining pressure in the collapsible portion of the airway at or above the critical tissue pressure at all times” and is applied via a tight-fitting nasal mask worn during sleep. *Id.* at 1:51–54, 2:4–6.

The ’344 patent states that “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” *Id.* at 1:58–60. Specifically, “conventional PAP therapy has not taken sleep/wake state into account, and

³ Petitioner acknowledges this priority claim and asserts “[f]or the purpose of this Petition, it is unnecessary to break the priority chain to a later date.” Pet. 13 n.5.

conventional PAP systems apply pressure unnecessarily when the patient is awake.” *Id.* at 2:11–13. The ’344 patent also states that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:25–26.

Figure 1 of the ’344 patent is reproduced below.

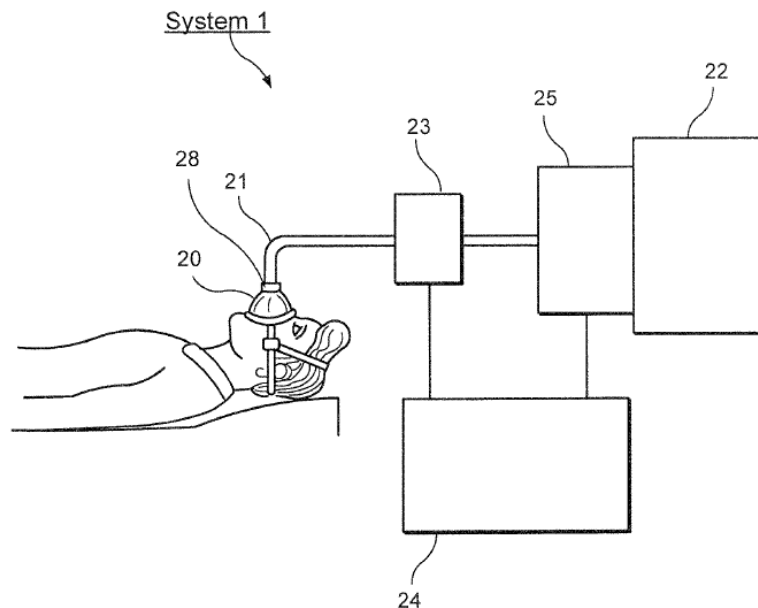


FIG. 1

Figure 1 “shows an exemplary embodiment of a system according to” the ’344 patent. Ex. 1001, 3:15–16. System 1, shown in Figure 1, includes mask 20 which is placed over the face of the patient and connected via tube 21 for receiving an airflow of a particular pressure from flow generator 22. *Id.* at 3:45–48. The ’344 patent describes conventional flow sensors 23 that are coupled to tube 21 and detect the rate of airflow to/from the patient and/or a pressure supplied to the patient via generator 22. *Id.* at 3:53–56. The ’344 patent states that “[s]ignals corresponding to the airflow and/or the pressure are provided to a processing arrangement 24 for processing” and “[t]he processing arrangement 24 outputs a signal to a

conventional flow control device 25 to control a pressure applied to the flow tube 21 by the flow generator 22.” *Id.* at 3:57–62.

The ’344 patent also describes a method that uses system 1. *Id.* at 4:6–7, Fig. 2. “[S]ystem 1 initiates a real-time monitoring procedure of the patient’s breathing patterns.” Ex. 1001, 4:11–12. The ’344 patent explains that “[t]he monitoring procedure is performed by the processing arrangement 24 which may utilize pre-stored patient data along with current data provided by the sensors 23 regarding the airflow to and from the patient and/or the applied pressure.” *Id.* at 4:12–17. The ’344 patent states that “[d]uring the monitoring procedure, the processing arrangement 24 makes a determination as to a current state of the patient (e.g., whether the patient is asleep, awake and breathing regularly or awake and breathing irregularly due to distress or anxiousness).” *Id.* at 4:18–22. According to the ’344 patent, this “determination can be made based on a number of different measurements,” such “the patient’s heart rate, blood pressure, EEG data, breathing patterns, etc.” *Id.* at 4:22–26. The ’344 patent further describes breathing patterns that indicate quiet, regular, and relaxed breathing during PAP therapy; sleep disordered breathing; and when the patient is awake and anxious or distressed. *Id.* at 4:29–31, 4:38–53.

The ’344 patent describes processing arrangement 24 as determining whether there has been a change in the patient’s state and adjusting pressure to correspond to the patient’s current state. Ex. 1001, 5:55–57. The ’344 patent further describes an embodiment in which “system 1 may include a neural network coupled to the processing arrangement 24 and the sensors 23 for identifying the state of the patient.” *Id.* at 7:37–40.

According to the '344 patent, “[o]ne of the advantages of the system 1 according to the present invention is that the pressure supplied to the patient is adjusted (e.g., reduced to zero or a preset low level) when the patient has an irregular breathing pattern that suggests that he is awake and anxious.”

Ex. 1001, 6:33–37. According to the '344 patent, a breathing pattern characterized by “irregular[] variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient’s air flow tracing indicating that the patient is awake and either anxious or uncomfortable” is associated with a “troubled wakefulness state.” *Id.* at 4:53–58.

D. Illustrative Claim

Claims 1 and 7 are independent claims. Ex. 1001, 9:34–46, 10:6–19. Independent claim 1, reproduced below with emphasis added, is representative of the claimed subject matter.

1. A system, comprising:
 - a flow sensor provided in an airflow path and measuring data corresponding to a patient’s breathing patterns; and
 - a processing arrangement configured to *analyze the breathing patterns* to determine whether the breathing patterns are indicative of a troubled wakefulness state; and
 - a generator configured to supply an airflow to an airway of the patient and to reduce a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure.

Id. at 9:34–46 (emphasis added).

E. Asserted Grounds of Unpatentability

Petitioner asserts the following three grounds of unpatentability for claims 1, 3, 7, 9, 11, and 13 of the '344 patent:

Claims Challenged	35 U.S.C. §⁴	Reference(s)/Basis
1, 3, 7, 9, 11, 13	103(a)	Sullivan995, ⁵ Sullivan460, ⁶ Matthews ⁷
1, 3, 7, 9, 11, 13	103(a)	Rapoport502, ⁸ Sullivan460, Matthews
1, 3, 7, 9, 11, 13	102(a), (b)	Sullivan995

Pet. 5; *see also id.* at 16 (Petitioner arguing Sullivan995 is prior art under 35 U.S.C. §§ 102(a) and (b)).

In support of the asserted grounds, Petitioner submitted a declaration by Dr. Khosrow Behbehani (Ex. 1003) and declarations by Dr. Jason P.

⁴ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended certain sections of this statute, including §§ 102 and 103, and the effective date of the relevant amendment is March 16, 2013. The filing date of the '344 patent, January 3, 2011, is before the effective date of the amendment. Ex. 1001, code (22). Thus, the pre-AIA version of the statute applies.

⁵ Sullivan et al., US 5,245,995, issued Sept. 21, 1993 (“Sullivan995”) (Ex. 1005).

⁶ Sullivan, WO 01/05460 A1, published Jan. 25, 2001 (“Sullivan460”) (Ex. 1006).

⁷ Matthews et al., US 7,168,429 B2, issued Jan. 30, 2007 (“Matthews”) (Ex. 1007).

⁸ Rapoport et al., US 5,490,502, issued Feb. 13, 1996 (“Rapoport502”) (Ex. 1008).

Kirkness (Exs. 1046, 1051).⁹ Patent Owner deposed and cross-examined Dr. Kirkness and submitted transcripts of Dr. Kirkness's deposition (Exs. 2015, 2016).

Patent Owner submitted a declaration of Dr. Jason Hamilton Tunstall Bates (Ex. 2006). Dr. Bates provided corrections to citations in his declaration (Ex. 1048). Petitioner deposed and cross-examined Dr. Bates and submitted transcripts of Dr. Bates's deposition (Exs. 1052, 1053).

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

The level of ordinary skill in the art is “a prism or lens” through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). A person of ordinary skill in the art is “a hypothetical person who is presumed to know the relevant prior art.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citing *Custom Accessories, Inc. v. Jeffrey–Allen Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986)). In determining the level of ordinary skill in the art, we may consider certain factors, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made;

⁹ With the Petition, Petitioner filed the declaration of Dr. Behbehani (Ex. 1003). Petitioner then filed the declaration by Dr. Kirkness (Ex. 1046), whereby Dr. Kirkness agrees with and adopts paragraphs 20–28, 32–88, and 92–234 of Dr. Behbehani's declaration, and an Unopposed Motion to Substitute Expert (Paper 29) seeking to substitute Dr. Kirkness for Dr. Behbehani. We granted Petitioner's Motion (Paper 32). In this Decision we cite to the declaration of Dr. Behbehani (Ex. 1003) with the understanding that the opinions expressed were adopted by and, therefore, are attributable to Dr. Kirkness.

sophistication of the technology; and educational level of active workers in the field.” *Id.* (quoting *Custom Accessories*, 807 F.2d at 962).

Petitioner contends that a person of ordinary skill in the art “would have had at least a bachelor’s degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience” and that “[a]dditional experience could substitute for less education, and additional education could likewise substitute for less experience.” Pet. 23 (citing Ex. 1003 ¶ 89). Petitioner further contends that the “Petition does not turn on this precise definition, and the challenged claim[s] would be unpatentable from the perspective of any reasonable person of ordinary skill in the art at the relevant time.” *Id.* (citing Ex. 1003 ¶ 90). Patent Owner does not object to Petitioner’s definition for the level of ordinary skill in the art. PO Resp. 11.

Petitioner’s definition for the level of ordinary skill in the art is consistent with the problems addressed in the ’344 patent and the prior art. We, therefore, apply Petitioner’s level of ordinary skill in the art in this Decision.

B. Claim Construction

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

into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

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

Additionally, only terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). To determine whether Petitioner has shown that the challenged claims are unpatentable, we address the Parties’ proffered constructions for the following three claim terms: “troubled wakefulness,” “configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative,” and “analyze the breathing patterns.”

1. *“troubled wakefulness”*

Independent claims 1 and 7 recite a “troubled wakefulness” state. Ex. 1001, 9:34–46, 10:6–19. Petitioner argues the claim term “troubled wakefulness” should be construed as “state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.” Pet. 23–24 (citing Ex. 1001, 4:54–58, Fig. 7; Ex. 1003 ¶¶ 93–94). For purposes of this proceeding, Patent Owner agrees with Petitioner’s construction. PO Resp. 18; *see also* Tr. 11:22–24 (Petitioner stating during oral argument that “[b]oth parties agree that troubled wakefulness is a state in which the breathing pattern is irregular, indicating that the patient is both awake and either anxious or uncomfortable”). We adopt Petitioner’s undisputed construction for this claim term because it is consistent with the Specification of the ’344 patent, which explicitly describes the term. *See, e.g.*, Ex. 1001, 4:53–58 (describing the breathing pattern for troubled wakefulness as “characterized by irregular[] variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient’s airflow tracing indicating that the patient is awake and either anxious or uncomfortable”).

2. *“configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative”*

Independent claim 7 recites a processing arrangement “configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative.” Ex. 1001, 10:6–19. Petitioner argues the claim term “configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative” means “configured to analyze the breathing patterns to

determine whether the breathing patterns’ are indicative of the specified states.” Pet. 24–26 (citing Ex. 1001, 4:18–22, 4:27–29, 4:31–32, 4:53–58, 5:26–33; Ex. 1002, 378, 398, 404; Ex. 1003 ¶¶ 95, 106). For purposes of this proceeding, Patent Owner agrees with Petitioner’s construction. PO Resp. 18. We adopt Petitioner’s undisputed construction for this claim term because it is consistent with the claim language and the Specification of the ’344 patent. *See, e.g.*, Ex. 1001, 4:12–29 (describing that processing arrangement 24 monitors a patient’s breathing patterns and determines a current state of the patient, such as whether the patient is asleep, awake and breathing regularly, or awake and breathing irregularly due to distress of anxiousness).

3. *“analyze the breathing patterns”*

Independent claims 1 and 7 recite a processing arrangement configured to “analyze the breathing patterns.” Ex. 1001, 9:34–46, 10:6–19. In the Petition, Petitioner does not expressly construe the term “analyze the breathing patterns”, but does identify the portions of the prior art that Petitioner contends teach the claim limitation including this term. *See, e.g.*, Pet. 53–56 (Petitioner arguing the combined teachings of Sullivan⁴⁶⁰ and Matthews would have resulted in the recited processing arrangement configured to analyze the breathing patterns). In its Response, Patent Owner argues that “analyze the breathing patterns” means “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 19. As borne out through Patent Owner’s arguments in response to Petitioner’s challenges and as further elaborated in Patent Owner’s Sur-reply, Patent Owner contends

that examining the values of the parameters and the order in which they appear in time, as set forth in its proposed construction, entails analysis of both amplitude and temporal structures of a time series of breath-by-breath parameters from a flow waveform. PO Resp. 2, 10–11; Sur-reply 1, 3–5.

Petitioner disputes Patent Owner’s proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2–10. For the reasons that follow, we agree with Petitioner.

a. The Parties’ Contentions

To explain why the claim term “analyze the breathing patterns” should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the [S]pecification” of the ’344 patent. PO Resp. 19 (citing Ex. 1001, 4:37–45; Ex. 2006 ¶ 145); *see also* Sur-reply 12 (Patent Owner arguing that, according to Dr. Bates, “‘breathing pattern’ has no ordinary meaning and ‘is an extremely general term’”). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apnea and hypopnea in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters and the order in which they appear in time.” *Id.* (citing Ex. 2006 ¶ 146).

Patent Owner points to the description of Figures 7 and 8 of the ’344 patent in support of its construction. *Id.* at 19–21 (citing Ex. 1001, 4:53–60, 5:17–3; Ex. 2006 ¶¶ 147–149). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient’s airflow, but no periodic irregularity in breath size. Ex. 1001, 4:53–60. According to Patent Owner,

This methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns wherein the focus hinges on a determination of “the sequence of parameters of a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time.”

PO Resp. 20 (citing Ex. 2006 ¶ 148); *see also* Sur-reply 4 (citing Ex. 1001, 4:53–60; Ex. 2006 ¶ 147) (Patent Owner arguing the ’344 patent describes Figure 7 as showing “both amplitude and temporal structures are likewise described when examining specific flow waveforms”). Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. Ex.1001, 5:17–33. Patent Owner argues the description of Figure 8 “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 20 (citing Ex. 1001, 5:17–33; Ex. 2006 ¶ 149); *see also* Sur-reply 4–5 (citing Ex. 1001, 5:24–33; Ex. 1052, 81:17–23, 180:1–15; Ex. 2006 ¶ 149) (Patent Owner arguing that distinguishing REM sleep from wakefulness requires analyzing both amplitude and temporal structures).

Additionally, Patent Owner suggests the Specification’s discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. PO Resp. 21 (citing Ex. 1001, 6:33–39; Ex. 2006 ¶ 150).

In the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’344 [p]atent.” Sur-reply 2. First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” *Id.* at 3 (quoting Ex. 1001, 4:37–45) (citing Ex. 2006 ¶ 145). Patent Owner maintains that the descriptions of the waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of a waveform. *Id.* at 4–5 (citing Ex. 1001, 4:53–60, 5:24–33; Ex. 1052, 81:17–23, 180:1–15; Ex. 2006 ¶¶ 147–149). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not named in the ’344 [p]atent,” but contends that “these are not obligatory.” *Id.* at 5. Patent Owner asserts that enablement of the ’344 patent “hinges on its ability to distinguish between all awake and asleep states,” and that “[o]therwise, incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 6.

Second, Patent Owner asserts that, during the prosecution of the ’344 patent, Patent Owner argued the prior art “failed to discern between regular wakefulness and troubled wakefulness.” Sur-reply 6 (citing Ex. 1002, 404). According to Patent Owner, “[t]he central argument here is the necessity of integrating both amplitude and temporal structure analyses to distinguish all awake and asleep states.” *Id.*

Third, Patent Owner argues that “patentees do not need to rigidly define terms, but can imply their own meaning.” Sur-reply 6. Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by Figure 7 – a flow

waveform indicating troubled wakefulness.” *Id.* (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the patent family “provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “[s]ince ‘analyses the data’ is followed by ‘to determine the patient’s breathing patterns,’ some of which occur in the asleep state and some of which occur in the awake state, this implies that these states can be separated from one another.” *Id.* at 6–7 (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22)). Patent Owner contends that, “[g]iven the separation between awake and asleep states discussed in the ’344 [p]atent, [Patent Owner’s] construction is integral for discerning the difference and applying the correct pressure” because, without doing so, it “could result in inappropriate pressure administration.” *Id.* (citing Ex. 1052, 179:23–25; Ex. 2006 ¶ 143).

Patent Owner also argues that extrinsic evidence supports its proposed construction. Sur-reply 7–12. Based on Dr. Bates’s testimony, Patent Owner asserts that “by assessing only amplitude” the waveforms of troubled wakefulness and REM sleep “appear indistinguishable,” but “their temporal structure (order in time) . . . offers differentiation.” *Id.* at 9 (citing Ex. 2006 ¶ 80). Patent Owner argues it proves its argument by showing that if the “temporal structure” of the REM sleep waveform is “rearranged in time,” then the resulting “time series has a random appearance that cannot be distinguished from troubled wakefulness.” *Id.* (citing Ex. 2006 ¶ 81). Patent Owner reasons that “amplitude structure and temporal structure convey independent information” and that both must be considered in an analysis or “the awake and asleep states can be confused.” *Id.* at 10 (citing Ex. 2006

¶ 74). According to Patent Owner, “Dr. Bates’[s] illustrations present the problem solved by the ’344 [p]atent.” *Id.*

According to Patent Owner, construing “analyzing breathing patterns” to include “any type” of breathing pattern analysis, as suggested by Dr. Kirkness, is “nonsensical, as it might even encompass using a mirror to check for breaths.” Sur-reply 12 (citing Ex. 1051 ¶ 16).¹⁰

Specifically, Patent Owner argues:

Dr. Bates examined the [S]pecification to determine what characteristics of breathing characteristics were crucial to analyzing the breathing pattern with respect to the invention’s essence. He determined that a [person of ordinary skill in the art], after reading the [p]atent, would understand that analyzing breathing patterns must confer the ability to distinguish between troubled wakefulness and REM sleep. [Patent Owner’s] construction evidences the understanding of a [person of ordinary skill in the art] – that analyzing breathing patterns requires analysis of amplitude and temporal structures.

Sur-reply 13 (citations omitted) (citing Ex. 1052, 24:20–25, 25:1–13, 111:22–25, 112:1–21).

Petitioner asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the specification or during prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” Pet. Reply 6 (quoting *Hill-*

¹⁰ Patent Owner also states that “Dr. Kirkness argues that the ’344 [p]atent is indefinite, regarding the measurement of airflow waveforms and temporal/amplitude aspects,” and that “Petitioner has never raised indefiniteness.” Sur-reply 11. We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths.”

Rom Servs., Inc. v. Stryker Corp., 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, ‘the patentee must clearly express an intent to redefine the term.’” *Id.* (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends that “[n]o such intent exists here” and that Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* at 6 (citing Ex. 1051 ¶¶ 25–33).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner’s] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as “propos[ing] a lengthy construction and then constru[ing] its own construction to inject two requirements: that the processor must analyze (1) ‘the value[s] of the parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.* (third alteration in original) (citing PO Resp. 18–19; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert construed based on his personal experience as opposed to that of a [person of ordinary skill in the art].” *Id.* (citing Ex. 1053, 271:10–14).

Petitioner proposes that we construe the phrase in accordance with its plain and ordinary meaning because “[n]othing in the intrinsic record limits ‘analyzing the breathing patterns’ to analysis of either or both amplitude and temporal structures—instead, the claims, [S]pecification, and prosecution history use these terms in accordance with their plain meaning.” Pet.

Reply 3–4 (citing *CCS Fitness*, 288 F.3d at 1366). Petitioner argues that the claims of the '344 patent and related patents are dispositive and specifically recite analyses of breathing patterns that do not include analysis of amplitude and temporal structures. *Id.* at 4 (citing Ex. 1001, claims 1, 5, 7, 8, 15; Ex. 1051 ¶¶ 9, 13–15; Ex. 1055, claim 24; Ex. 1057, claim 3; Ex. 1058, claim 4).

Petitioner also contends the Specification “further confirms that the term encompasses any type of breathing pattern analysis.” Pet. Reply 4. According to Petitioner, the '344 patent “states that ‘[t]here are a number of characteristics of the patient’s breathing patterns that may be taken into account in making such a determination’ . . . and does not limit the analysis to any particular characteristic.” *Id.* at 4–5 (first alteration in original) (citing Ex. 1001, 2:41–43, 4:27–29, 4:53–58, 5:25–29, Figs. 3–8; Ex. 1051 ¶¶ 16–20; Ex. 1052, 28–30; Ex. 2006 ¶¶ 47–48, 147–149). Petitioner also contends “[t]he specification further states the flow sensors ‘detect the rate of airflow’ to and from the patient, and provide ‘[s]ignals corresponding to the airflow’ to a processing arrangement for processing.” *Id.* at 5 (second alteration in original) (citing Ex. 1001, 3:55–59). Thus, Petitioner asserts the Specification “confirms that temporal analysis is not required.” *Id.*

Petitioner addresses the prosecution history of the '344 patent and a related patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5. Petitioner asserts that Patent Owner did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1002, 91, 128; Ex. 1009, 404).

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

(1) Dr. Bates's analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the '344 patent would have derived [Patent Owner's] construction.” *Id.* (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* (citing Ex. 1052, 75:11–76:14; 78:16–79:19, 90:8–91:11).

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

(3) Dr. Bates's analysis contradicts the '344 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM sleep without requiring temporal analysis. *Id.* at 8–9 (citing Ex. 1001, 4:46–52, 5:26–29, claims 5, 8¹¹; Ex. 1051 ¶¶ 8–24).

¹¹ Petitioner cites “EX1056” for claims 5 and 8 of the '344 patent. Pet. Reply 8–9. The '344 patent is Exhibit 1001, and there is no exhibit 1056 in

(4) “Dr. Bates admitted the waveforms of Figures 7–8 are merely exemplary.” *Id.* at 9 (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do not limit the broader claim terms of the patent.” *Id.* (citing *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004); *N. Telecom Ltd. V. Samsung Elecs. Co.*, 215 F.3d 1281, 1293 (Fed. Cir. 2004)).

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

b. Analysis

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14. Independent claim 1 recites “a processing arrangement configured to *analyze the breathing patterns* to determine whether the breathing patterns are indicative of a troubled wakefulness state,” and independent claim 7 similarly recites “a processing arrangement configured to *analyze the breathing patterns* to determine to which of the following states the detected breathing patterns is indicative: (i) a REM sleep state, (ii) a non-troubled wake states, (iii) a non-REM sleep state and (iv) a troubled wakefulness state.” Ex. 1001, 9:37–39, 10:10–15 (emphases added). As

this proceeding. We understand that Petitioner’s citation to exhibit 1056 is a typographical error and that Petitioner is citing to Exhibit 1001.

reflected, independent claims 1 and 7 do not recite “a sequence of parameters,” “a series of breaths,” “examining the values of the parameters and the order in which they appear in time,” or an analysis of amplitude and temporal structures. Rather, independent claims 1 and 7 recite that the processing arrangement analyzes the breathing patterns, without specifically reciting how the analysis is performed. The claims do, however, recite the purpose of the analysis—to determine whether the breathing pattern is indicative of the patient’s state—but do not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a significant number of limitations neither expressly recited nor suggested by the specific language of the claims.

Although independent claims 1 and 7 do not provide any further limitations as to the specific requirements of the breathing patterns, claims 5 and 8, which depend from claims 1 and 7, respectively, do provide such further limitations. Ex. 1001, 9:55–10:3, 10:20–24. Claim 5 recites “the breathing patterns that are indicative of the troubled wakeful state^[12] comprises one or more patterns selected from the group consisting of (a) pure mouth breathing, (b) erratic large breaths with varying inspiratory times, and (c) irregularity of intervals between breaths,” and claim 8 recites “the breathing patterns that are indicative of state (i) [a REM sleep state] comprise one or more patterns selected from the group consisting of (a) an

¹² We understand “the troubled wakeful state” recited in claim 5 refers to the “troubled wakefulness state” recited in independent claim 1, and Patent Owner does not argue that the “troubled wakeful state” is different from the “troubled wakefulness state.”

absence of large breaths, (b) a high respiratory rate, (c) a low flow rate, and (d) a cluster of small breaths.” *Id.* We agree with Petitioner that some of these particular breathing patterns do not require an analysis of amplitude and temporal structures. Pet. Reply 4 (citing Ex. 1001, claims 1, 5, 7, 8, 15; Ex. 1051 ¶¶ 9, 13–15; Ex. 1055, claim 24; Ex. 1057, claim 3; Ex. 1058, claim 4). With respect to the breathing patterns indicative of the troubled wakefulness state recited in claim 5, “pure mouth breathing” does not require an analysis of temporal structure. Similarly, with respect to the breathing patterns associated with REM sleep recited in claim 8, “an absence of large breaths,” “a high respiratory rate,” and “a low flow rate” do not require an analysis of temporal structure. Hence, according to the claims, neither an analysis of amplitude and temporal structures, nor a determination of sequence of parameters and the order in which they appear in time, is necessary to indicate whether the patient is in a troubled wakefulness state or a REM sleep state.

Patent Owner argues that some of the recited breathing patterns include temporal structures, and other recited breathing patterns include amplitude structures (Sur-reply 13), but Patent Owner does not refute that some of the recited breathing patterns may be determined without an analysis of both amplitude and temporal structures. Patent Owner also argues that claims 5 and 8 are not being asserted. Sur-reply 14. The court, however, in *Phillips*, makes clear that “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term.” *Phillips*, 415 F.3d at 1314 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Given that claims 5 and 8 recite breathing patterns

indicative of a troubled wakefulness state and a REM sleep state that do not require an analysis of both amplitude and temporal structures or a determination of a sequence of parameters and the order in which they appear in time, these claims show the claim term “analyze the breathing pattern” in independent claims 1 and 7 does not include the additional limitations set forth in Patent Owner’s proffered construction.

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F.3d at 1371 (citing *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004)). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech.*, 923 F.3d at 1044.

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

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

The Specification of the ’344 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to an analysis of amplitude and temporal structures, “a sequence of parameters,” “a series of breaths,” “examining the values of the parameters and the order

in which they appear in time,” or any of the other terms set forth in the proposed construction. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. *See* Pet. Reply 6 (Petitioner arguing “the terms ‘amplitude’ and ‘temporal’ do not appear anywhere”); Sur-reply 5 (Patent Owner asserting “Petitioner rightly observes that terms like ‘amplitude’ and ‘temporal’ are not named in the ’344 [p]atent”); *see also* Ex. 1051 ¶ 24 (Dr. Kirkness stating that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’344 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures”). Patent Owner directs us to a portion of the Specification for what Patent Owner characterizes as the process of analyzing breathing patterns. PO Resp. 19 (quoting Ex. 1001, 4:37–45). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” Ex. 1001, 4:37–45. The cited text does not describe an analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

The Specification describes how “processing arrangement 24 makes a determination as to the current state of the patient (e.g., whether the patient is asleep, awake and breathing regularly or awake and breathing irregularly due to distress or anxiousness).” Ex. 1001, 4:18–22. The Specification further describes that this “determination can be made based on a number of different measurements,” and provides “[f]or example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG

data, breathing patterns, etc. in determining the patient's state.” *Id.* at 4:22–26. There is no mention that analyzing breathing patterns requires analyzing a sequence of parameters and the order in which they appear in time or analyzing amplitude and temporal structures of the waveform. The Specification further describes, in an embodiment, “processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern.” Ex. 1001, 7:11–13. There is no mention that this embodiment requires any particular analysis of the waveform or the amplitude and temporal structures of the waveform.

Patent Owner relies on the descriptions Figures 7 and 8 to support its argument that an analysis of both the amplitude and temporal structures is required to distinguish between troubled wakefulness and REM sleep and fully enable the claimed invention. Sur-reply 4–6; *see also id.* at 8 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Even if we were to agree with Patent Owner that the descriptions of Figures 7 and 8 describe an analysis of amplitude and temporal structures of the depicted waveforms for troubled wakefulness and REM sleep, respectively, we fail to see how the analysis set forth in each description is something other than an example. The Specification explicitly describes that “[t]here are a number of characteristics of the patient's breathing patterns that may be taken into account in making a determination” as to the current state of the patient. Ex. 1001, 4:27–29. Moreover, with respect to the breathing pattern in Figure 8, the Specification describes:

This REM associated pattern of breathing may include e.g., the absence of larger breaths, especially after pauses, generally high respiratory rates and low flow rates, and a tendency for clustering of small breaths. These differences in the pattern of the respiratory airflow signal from those seen during troubled wakefulness allow the separation of these states and can be used to make a change in the applied pressure.

Id. at 5:26–34. We are persuaded that some of the breathing patterns indicative of REM sleep, namely “high respiratory rates” and “low flow rates,” do not require an analysis of temporal structures. *See* Pet. Reply 4 (citing Ex. 1001, claims 1, 5, 7, 8, 15; Ex. 1051 ¶¶ 9, 13–15; Ex. 1055, claim 24; Ex. 1057, claim 3; Ex. 1058, claim 4) (Petitioner arguing, *inter alia*, that “a low flow rate” and “a high respiratory rate” require no temporal structure). Given that an analysis of amplitude and temporal structures is simply one way to distinguish troubled wakefulness from REM sleep, Patent Owner’s proposed construction is unnecessary to “fully enable” the claimed invention and would improperly import limitations from the embodiments in the Specification into the claims.

Turning to the prosecution history, Patent Owner relies on an argument that the prior art failed to discern between regular wakefulness and troubled wakefulness to support its proposed construction. Specifically, during prosecution, Patent Owner argued the prior art does not disclose the recited processing arrangement configured to determine whether the detected breathing pattern is indicative of a REM sleep state, a non-troubled wake state, a non-REM sleep state, or a troubled wakefulness state because “the ‘micro-arousals’ cited by the Examiner refer[] to a light stage of sleep that is different from an awake or arousal state, and does not further identify whether the patient is anxious or uncomfortable.” Ex. 1002, 404. Instead of

distinguishing the prior art based on the particular analysis for differentiating the states, Patent Owner distinguished the claimed invention based on the type of states the processing identifies. Thus, the prosecution history does not support the additional limitations Patent Owner seeks to read into the claim term “analyze the breathing patterns.”

Having considered the intrinsic evidence, we review the extrinsic evidence, and specifically the testimony of Dr. Bates. Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 19–21 (citing Ex. 1001, 4:37–45, 4:53–60, 5:17–33, 6:33–39; Ex. 2006 ¶¶ 145–150). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. Ex. 2006 ¶¶ 145–150. Rather, Dr. Bates reads portions of the Specification and extrapolates, by taking several unsupported leaps, that the ’344 patent “implicitly demands certain parameter measurements.” Sur-reply 6 (citing Ex. 1052, 44:6–20).

Although expert testimony is legitimate to consider when construing claims, the court, in *Phillips*, has cautioned that, because it “is generated at the time of and for the purpose of litigation,” it “can suffer from bias that is not present in intrinsic evidence.” 415 F.3d at 1318. And, extrinsic evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* at 1317 (internal quotation marks and citations omitted). In the context presented here, Dr. Bates’s testimony is not supported sufficiently by the intrinsic record or

other extrinsic evidence, e.g., objective extrinsic evidence, and, therefore, even though we have considered it fully, we give it little weight.

For the reasons explained above, we determine Patent Owner did not implicitly define the claim term “analyze the breathing patterns,” as proposed, because Patent Owner has failed to show any sufficient evidence that the ’344 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner’s contentions in light of all the evidence of record, we do not adopt Patent Owner’s proposed construction; instead, we apply the plain and ordinary meaning of “analyze the breathing patterns” in our consideration of the issues before us.

C. Obviousness of Claims 1, 3, 7, 9, 11, and 13 over Sullivan995, Sullivan460, and Matthews

Petitioner challenges claims 1, 3, 7, 9, 11, and 13 under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Sullivan995, Sullivan460, and Matthews. Pet. 45–62; Pet. Reply 18–26. Patent Owner argues the references do not render the claimed subject matter obvious. PO Resp. 35–41; Sur-reply 20–24. Patent Owner contends there is no disclosure of all of the claim limitations, no motivation to combine the teachings of the references, and no reasonable expectation of success in combining the references, and Patent Owner further contends secondary considerations support non-obviousness. PO Resp. 35–41; Sur-reply 20–24.

We begin our analysis of this asserted ground of unpatentability with an overview of each of the references. We then discuss the Parties' contentions for each of the claims.

1. *Sullivan995 (Ex. 1005)*

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

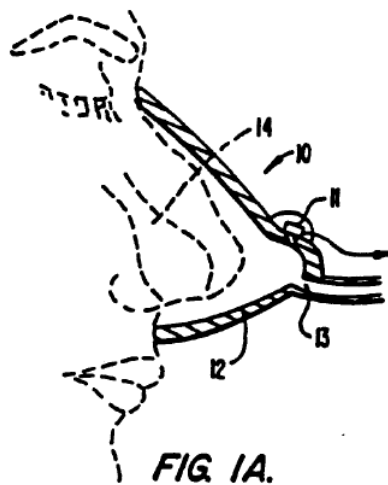


Figure 1A “is a schematic sectional view of one embodiment of a snoring detection apparatus.” *Id.* at 8:66–68. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a nose mask.” *Id.* at 8:47–49. Sullivan995 explains that “[a]ir, being inhaled by the patient, enters the nasal passageways 14 through the opening 13 in the nose mask 12 and is exhaled in the reverse direction” and that this

arrangement focuses and concentrates snoring and breathing sounds. *Id.* at 8:49–52, 8:57–59.

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

Figure 3 of Sullivan995 is reproduced below.

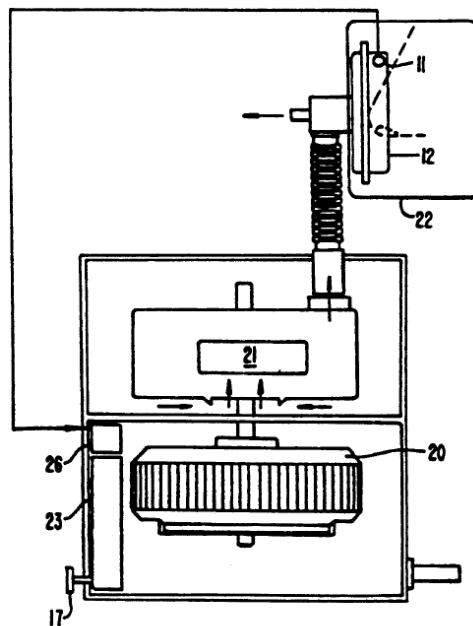


FIG. 3

Sullivan995’s Figure 3 shows a CPAP apparatus. *Id.* at 9:57–58. The CPAP apparatus includes motor 20 that drives blower 21. *Id.* at 9:58–59.

Sullivan995 explains “[t]he speed of the motor 20 is controlled by an electronic speed control unit 23.” *Id.* at 9:59–60. The CPAP apparatus further includes snoring detection means 22 that uses microphone 11 to

detect sounds. *Id.* at 9:64–66. Sullivan995 states that “snoring detection means 22 is conveniently in the form of the previously described device 10” and that “[i]n its most general form, the snoring detection means 22 is a pressure detection means and microphone 11 is a differential pressure sensor.” *Id.* at 9:66–10:1. Sullivan995 explains that:

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

Id. at 10:3–12.

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

Figure 12 of Sullivan995 is reproduced below.

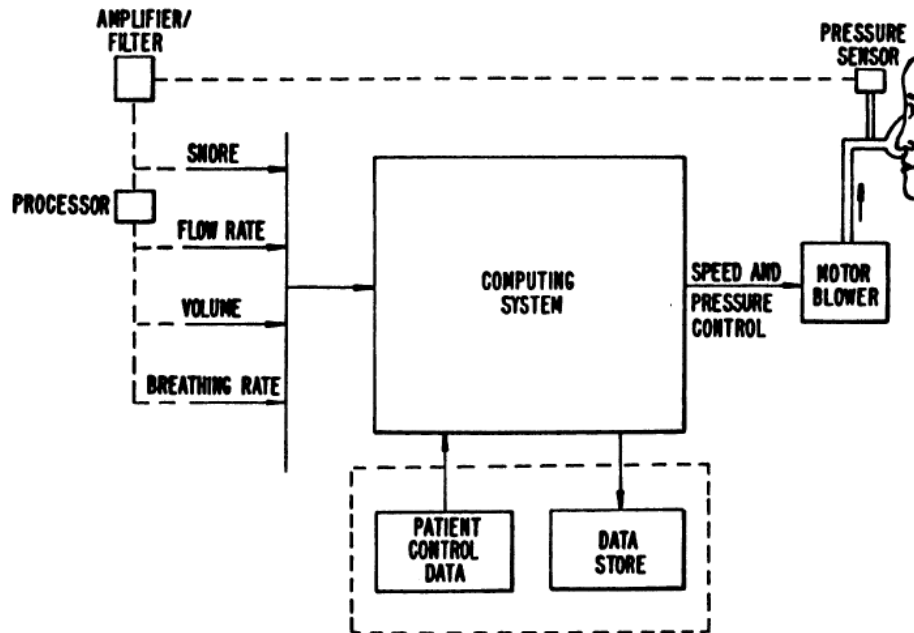


FIG. 12.

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

A pressure detection apparatus is provided either integral with or attached to the CPAP mask worn by the patient. The electrical signals from the pressure transducer are amplified and filtered to provide pressure waves of the desired frequencies indicative of snoring and breathing. The pressure wave indicative of breathing is further processed to generate signals indicative of flow rate, volume and breathing rate. Any or all signals are fed to a computing system which analyses the signals for deviation from predetermined values or patterns. The computing system may itself calculate control values or 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.” *Id.* at 1:5–8. Sullivan460 describes an embodiment in which a “treatment means is a device which applies Continuous Positive Airway Pressure (CPAP), more preferably nasal-Continuous Positive Airway Pressure (nCPAP), to the airway of the patient.” *Id.* at 6:17–20. Sullivan460 also describes an embodiment in which “the flow rate measurement means and the treatment means may be constructed together as part of one apparatus, such as the AutoSet product from ResMed described in [Sullivan995].” *Id.* at 6:22–24.

Figure 2 of Sullivan460 is reproduced below.

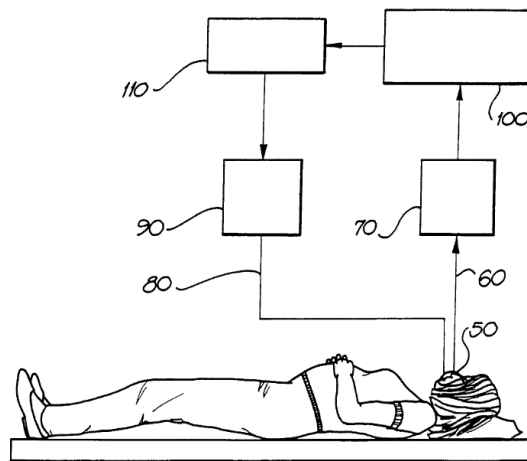


FIG. 2

“Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia.” *Id.* at 10:7–8. In Figure 2, patient 30 is lying on bed 40 and wears mask 50 over her nose. *Id.* at 10:8–9. Mask 50 is connected by 80 to nCPAP apparatus 90. *Id.* at 10:9–10. Sullivan460 states that “flow rate measurement means 70 detects the rate at which the patient breathes in air, and generates a signal which is sent to a central controller 100.” *Id.*

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

Sullivan460 explains:

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

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

3. *Matthews (Ex. 1007)*

Matthews is titled “Auto-Titration Pressure Support System and Method of Using Same.” Ex. 1007, code (54). Matthews is directed to “an auto-titration pressure support system and to a method of automatically

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

4. *Independent Claims 1 and 7*

a. *Identification of the Claim Limitations*

Petitioner provides a limitation-by-limitation analysis of independent claims 1 and 7 as a group, mapping the claim limitations to the references. Pet. 47–59. Petitioner generally relies on Sullivan995 to disclose the recited components of the claims. More specifically, Petitioner relies on Sullivan995’s microphone 11, amplifier/filter/processor unit 26, and blower 21 for disclosing the recited flow sensor, processing arrangement configured to analyze breathing patterns, and generator configured to supply airflow to an airway, respectively. Pet. 49–53 (citing Ex. 1003 ¶¶ 178–187; Ex. 1005, Abstract, 3:21–33, 8:47–61, 9:64–66, 10:1–3, 11:5–20, 15:56–64, 18:27–31, 18:50–53, Figs. 1A–B, 2A–B, 3, 7, 9), 53–54 (citing Ex. 1003

¶¶ 189, 193; Ex. 1005, 9:59–60, 10:3–6, 10:15, 10:37–66, 11:55–64, 14:40–41, 14:50–55, 15:1–3, 15:27–33, 15:59–63, Figs. 3, 4, 12), 57 (citing Ex. 1003 ¶ 202; Ex. 1005, 9:57–64).

For the recited function of the processing arrangement, namely the limitation of independent claim 1 reciting “to determine whether the breathing patterns are indicative of a troubled wakefulness state” and the similar limitation of independent claim 7 reciting “to determine to which of the following states the detected breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state,” Petitioner relies on the combined teachings of Sullivan460 and Matthews.¹³ Pet. 54. Petitioner argues Sullivan460 teaches using a sleep sensor to determine a sleep state and a wake state and two modes of air delivery, namely a first mode for the wake state and a second mode for the sleep state. *Id.* at 34–35 (citing Ex. 1003 ¶ 134; Ex. 1006, 7:3–7, 6:30–7:12, 7:17–19, claims 22–28, 43–46). Petitioner further argues that, for the specific types of wake and sleep states, Matthews teaches using the detection of erratic breathing. *Id.* at 35 (citing Ex. 1003 ¶ 135). According to Petitioner, “Matthews recognizes that ‘[w]hen a patient is awake, in *REM sleep*, or *in distress*, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable,’” and “[t]o address potential instability, Matthews discloses ‘a variable breathing

¹³ Petitioner’s arguments regarding the identification of these limitations are the same as its arguments for the identification of these limitations with respect to the asserted ground of unpatentability based on Rapoport502, Sullivan460, and Matthews. Pet. 54 (Petitioner referring to the arguments for these limitations with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews).

control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing.” *Id.* at 35–36 (first alteration in original) (citing Ex. 1007, 21:37–40, 40:25–30). Petitioner contends:

Matthews’s disclosure of monitoring and detecting erratic or irregular breathing, meets the *determine whether a breathing pattern is indicative of a non-troubled wake state, a troubled wakefulness state and a REM sleep*. Further, it follows where Matthews detects no erratic breathing in a sleep state (as taught by Rapoport⁵⁰² and also Sullivan⁴⁶⁰), Matthews determines *a non-REM sleep state*.

Id. at 36 (citing Ex. 1003 ¶ 137).

For the recited function of the generator, namely the limitation of independent claim 1 reciting “to reduce a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of a troubled wakefulness state, the second pressure being lower than the first pressure” and the similar limitation of independent claim 7 reciting “to adjust a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure as a function of a state determined by the processing arrangement,” Petitioner relies on the combined teachings of Sullivan⁹⁹⁵ and Matthews. Pet. 57–59. Petitioner argues “Sullivan⁹⁹⁵’s *generator* is configured to adjust a pressure of the airflow supplied to an airway of the patient as a function of a state determined by the processing arrangement.” *Id.* at 57 (citing Ex. 1003 ¶ 203). According to Petitioner, “Sullivan⁹⁹⁵ describes that . . . the CPAP should operate at a higher pressure immediately before, and during an apnea event or REM sleep, and at a lower pressure at other times.” *Id.* at 58 (citing Ex. 1003 ¶ 207; Ex. 1005, 11:23–25). Although Petitioner contends Sullivan⁹⁹⁵ discloses

adjusting the pressure as a function of patient state, Petitioner acknowledges Sullivan995 does not disclose a troubled wakefulness state. *Id.* at 58–59 (citing Ex. 1003 ¶ 208). Petitioner contends Matthews discloses a troubled wakefulness state.¹⁴ *Id.* at 59. Petitioner argues Matthews teaches interrupting the auto-CPAP controller and decreasing the pressure delivered to a patient when erratic breathing is detected. *Id.* at 39–40 (citing Ex. 1003 ¶ 153; Ex. 1007, 21:35–44, 21:57–61, 21:63–22:1, 23:67–24:2, claim 1). Petitioner further argues Matthews teaches using the values of previously applied pressures and patient breathing patterns to recognize the patient’s state and then optimize the applied pressure. *Id.* at 40–42 (citing Ex. 1003 ¶¶ 154–155; Ex. 1007, 21:37–39, 23:55–24:10, Fig. 13; Ex. 1016, 1; Ex. 1036, 3).

Patent Owner contends the combination of Sullivan995, Sullivan460, and Matthews does not disclose every claim limitation because the references do not distinguish between a troubled wakefulness state and a REM sleep state. PO Resp. 36–39. Regarding the specific claim limitations, Patent Owner contends the references do not disclose the processing arrangement and generator, particularly, the functions associated therewith, recited in independent claims 1 and 7.¹⁵ *Id.* at 38 (citing Ex. 2006

¹⁴ Petitioner’s arguments regarding the identification of the recited troubled wakefulness state are the same as its arguments for the identification of the recited troubled wakefulness state with respect to the asserted ground of unpatentability based on Rapoport502, Sullivan460, and Matthews. Pet. 59 (Petitioner referring to the arguments for the recited troubled wakefulness state with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews).

¹⁵ In its Response, Patent Owner reproduces independent claim 7, and argues “the missing claim limitations are highlighted in red.” PO Resp. 36.

¶¶ 209–212, 220–222). According to Patent Owner, “an analysis of both the amplitude structure and temporal structure of a breath-by-breath time series is required to distinguish between troubled wakefulness and REM sleep.” *Id.* at 37 (citing Ex. 2006 ¶ 214); *see also id.* at 39 (Patent Owner arguing “[a]s stated by Dr. Bates, the distinction between REM sleep and troubled wakefulness cannot be made purely on the basis of their respective degrees of variability in breath amplitude” (citing Ex. 2006 ¶¶ 226–231)). Patent Owner argues the references “only teach the identification of patient state based on mean flow and its standard deviation, which is an aspect of the *amplitude* structure of time series.” *Id.* (citing Ex. 2006 ¶ 213); *see also id.* at 39 (Patent Owner arguing “Sullivan460 and Matthews disclose only the analysis of the amplitude structure of the time series.” (citing Ex. 2006 ¶ 206)).

Petitioner replies that Patent Owner concedes that the references disclose “analyze the breathing pattern[s]” according to its plain meaning to determine asleep versus awake states, including troubled wakefulness and REM sleep. Pet. Reply 19. Petitioner also replies that, even if “analyze the breathing patterns” requires an analysis of both amplitude and temporal structures, the references disclose such an analysis. *Id.* at 19–20 (citing

However, there is no highlighting in Patent Owner’s reproduced version of independent claim 7. Patent Owner also argues “neither Sullivan460 nor Matthews teach the following claim limitations which are missing from Sullivan995” and quotes the processing arrangement recited in independent claim 1 and the generator recited in independent claims 1 and 7. *Id.* at 37–38. Given the similarities between independent claims 1 and 7, we understand Patent Owner is arguing that the combination of Sullivan995, Sullivan460, and Matthews does not disclose the processing arrangement and generator recited in independent claims 1 and 7.

Ex. 1051 ¶¶ 40–41. Petitioner argues Sullivan995 discloses patterns of normal breathing and snoring and increases the pressure in response. *Id.* at 20 (citing Ex. 1005, 9:15–27, 10:55–58, 14:65–15:17, Figs. 2A, 13; Ex. 1051 ¶ 46). Petitioner argues Sullivan460 teaches analyzing the temporal structure of a time series by: sensing an upper airway flow limitation characterized by at least one decrease in upper airway inspiratory flow rate followed by at least one increase in flow rate, determining the asleep state based on reduced average air flow in the patient’s upper airway, and distinguishing vibrations from breaths. *Id.* at 20–21 (citing Ex. 1006, 4:28, 5:22, 6:27–29, 7:17–19, 12:33, 15:22; Ex. 1051 ¶¶ 41–43; Ex. 1052, 49:19–50:2). Petitioner argues Matthews’s air flow time series shown in Figure 8, breath parameters obtained over time shown in Figures 23–24, and sequence of processed breath parameters shown in Figures 10A–B teach analyzing amplitude and temporal structures of a time series. *Id.* at 21 (citing Ex. 1051 ¶ 47).

In its Sur-reply, Patent Owner argues Sullivan995’s snoring sounds are not breathing patterns. Sur-reply 20 (citing Ex. 2006 ¶ 220). Patent Owner further argues that neither Sullivan460 nor Matthews teaches analyzing the amplitude and temporal structures of a breathing pattern because Dr. Kirkness mistakenly equates a temporal structure analysis with a time series. *Id.* at 21–23 (citing Ex. 1007, 4:27–29, 4:33–34, 5:4–8; Ex. 1051 ¶¶ 41–43; Ex. 1052, 46:15–18, 119:7–120:1; Ex. 1053, 247:5–19; Ex. 2006 ¶¶ 63, 72, 74, 77, 80, 93, 99, 220).

Patent Owner’s arguments alleging that the combination of Sullivan995, Sullivan460, and Matthews does not disclose the recited functions of the processing arrangement and generator are premised on its

proffered claim construction of “analyze the breathing patterns,” which we do not adopt for the reasons set forth above in Section II.B.3. As we discuss in this section, we disagree with Patent Owner that analysis of both amplitude and temporal structures is required to distinguish a troubled wakefulness state from REM sleep. Rather, the ’344 patent describes and claims breathing patterns indicative of a troubled wakefulness state and a REM sleep state that do not require an analysis of amplitude and temporal structures. *See* Ex. 1001, 4:27–29, 5:26–34, claims 5, 8.

Applying the Parties’ agreed-upon constructions and giving the remaining claim terms, including “analyze the breathing patterns,” their plain and ordinary meaning, Petitioner has persuasively identified in its proposed combination of Sullivan995, Sullivan460, and Matthews each limitation of independent claims 1 and 7, including the recited processing arrangement and generator. Regarding the recited processing arrangement, we are persuaded that Sullivan995’s amplifier/filter/processor unit 26, which generates a control signal indicative of a predetermined pattern, discloses a processing unit. Ex. 1003 ¶¶ 188–200, 193; Ex. 1005, 10:3–6, 10:37–66, 11:55–62, Fig. 4. We are also persuaded that Sullivan460 teaches determining whether a patient is awake or asleep (Ex. 1003 ¶ 134; Ex. 1006, 6:30–7:12, 7:17–19, claims 22–28, 43–46) and that Matthews teaches detecting erratic breathing during wakefulness and sleep (Ex. 1003 ¶¶ 135, 137; Ex. 1007, 21:37–40, 40:25–30). Combining the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes would result in a processing arrangement that determines whether the patient is awake or asleep and whether the patient is breathing erratically. By determining whether the patient is awake or asleep and whether the patient is breathing

erratically, the processing arrangement determines whether the patient's breathing pattern is indicative of the recited states, which include two sleep states that are distinguishable by erratic breathing and two awake states that are distinguishable by erratic breathing. We are persuaded Petitioner's proposed combination of the references would result in a processing arrangement that analyzes the patient's breathing pattern to determine whether a patient's breathing pattern is indicative of the following states: (i) a REM sleep state in which the patient is asleep and breathing erratically, (ii) a non-troubled wake state in which the patient is awake and not breathing erratically, (iii) a non-REM sleep state in which the patient is asleep and not breathing erratically, and (iv) a troubled wakefulness in which the patient is awake and breathing erratically. Accordingly, Petitioner has persuasively identified in its proposed combination of Sullivan995, Sullivan460, and Matthews the processing arrangement recited in independent claims 1 and 7.

Regarding the recited generator, we are persuaded that Sullivan995's motor 20 and blower 21, which are configured to deliver airflow at different pressures based on the patient's breathing patterns, disclose a generator configured to supply an airflow to an airway of the patient from a first pressure to a second pressure and to adjust the pressure of the airflow as a function of the breathing pattern and the state of the patient associated therewith. Ex. 1003 ¶¶ 202–203, 206–207; Ex. 1005, 9:57–64, 10:3–12, 11:23–35; 16:6–11, 16:35–50. We are also persuaded that Matthews teaches adjusting the air flow pressure depending on the patient breathing erratically and further teaches pressure decrease 332 after pressure increase 330 resulted in erratic breathing, as shown by case 2 in Figure 13. Ex. 1003

¶ 153; Ex. 1007, 21:57–61, 23:67–24:2. Petitioner has persuaded us that combining the teachings of the references as Petitioner proposes would result in a generator configured to adjust the airflow pressure based on the patient’s breathing patterns, which are indicative of the patient’s state, and to reduce the airflow pressure upon a detection of the patient being asleep and breathing erratically, which indicates troubled wakefulness. Accordingly, Petitioner has persuasively identified the generator recited in independent claims 1 and 7 in its proposed combination of the references.

b. Motivation to Combine

Petitioner argues it would have been obvious to modify Sullivan995’s system to determine whether the breathing patterns are indicative of certain states of the patient and to adjust the pressure of the airflow supplied to the patient based on the patient’s state, as Sullivan460 and Matthews teach. Pet. 45–46, 54–56, 59. Petitioner asserts that a person of ordinary skill in the art would have modified Sullivan995’s disclosure to detect different awake states because “[t]he modification to Sullivan995 CPAP system would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* at 46; *see also id.* at 55 (“This modification would have caused Sullivan995’s CPAP system to detect additional breathing states to better tailor the CPAP output to a patient’s needs.” (citing Ex. 1003 ¶ 197)). Petitioner further asserts that a person of ordinary skill in the art “would be motivated to configure the CPAP system of Sullivan995 to determine when a user’s breathing becomes so erratic that auto-CPAP controller is interrupted to alleviate the discomfort of the patient and facilitate compliance.” *Id.* at 56 (citing Ex. 1003 ¶ 198; Ex. 1007, 21:40–44).

Patent Owner contends there is no motivation to combine Sullivan995, Sullivan460, and Matthews as Petitioner proposes. PO Resp. 40–41; Sur-reply 17–20, 24 (Patent Owner referring to the arguments regarding motivation to combine with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews). Patent Owner argues there is no motivation to combine the teachings of the references because the systems of Sullivan460 and Matthews cannot distinguish between certain states. PO Resp. 40. According to Patent Owner:

It would not have been obvious to a [person of ordinary skill in the art] to modify the processing arrangement in Sullivan995 to determine breathing patterns *indicative of a REM sleep state and a troubled wakefulness state*, as Petitioner contends is taught by Sullivan460 and Matthews, because Sullivan460 and Matthews focus exclusively on the analysis of the amplitude structure of breath-by-breath parameter time series, which makes it impossible for them to distinguish between an awake and an asleep state such as REM sleep being distinct from troubled wakefulness.

Id. (citing Ex. 2006 ¶¶ 210, 220–221). Patent Owner further argues Petitioner erroneously equates “erratic breathing” and “troubled wakefulness,” which are not interchangeable because Matthews cannot differentiate between them. Sur-reply 18 (citing Ex. 1052, 175:1–5; Ex. 2006 ¶ 130(a)). Patent Owner also argues that Petitioner fails to explain how Matthews’s breathing pattern indicative of troubled wakefulness could be integrated into existing systems without accounting for both amplitude and temporal structures. *Id.* (citing Ex. 2006 ¶ 157).

Petitioner maintains that Patent Owner’s alleged lack of a motivation to combine the teachings of the references is a regurgitation of its argument

that the prior art does not disclose “analyze the breathing patterns” recited in independent claims 1 and 7. Pet. Reply 22. We agree with Petitioner.

Like its contentions that Sullivan995, Sullivan460, and Matthews fail to disclose all the claim limitations, Patent Owner’s arguments alleging a lack of a motivation to combine is premised on its proffered claim construction of “analyze the breathing patterns.” We do not adopt Patent Owner’s proffered claim constructions for the reasons set forth above in Section II.B.3. As we discuss in this section, we disagree with Patent Owner that analysis of both amplitude and temporal structures is required to distinguish a troubled wakefulness state from REM sleep.

Patent Owner also argues there is no motivation to combine the references because Dr. Kirkness did not know how to calculate Sullivan460’s preset level, which is a single value of flow rate. PO Resp. 40–41 (citing Ex. 2015, 48:6–20). Patent Owner further argues that Sullivan460 is not enabling because Sullivan460 fails to provide certain details to determine the preset flow rate. Sur-reply 18–19 (citing Ex. 2006 ¶ 99; Ex. 2015, 48:6–20).

At the outset, we agree with Petitioner that “enablement ‘is not a requirement to prove invalidity under § 103.’” Pet. Reply 23 (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003)). Moreover, we also agree with Petitioner that a person of ordinary skill in the art would have understood a preset level is established from previously-acquired data, such as an average level, as Sullivan995 discloses. *Id.* at 22 (citing Ex. 1005, 17:3–27, Fig. 12; Ex. 2015, 38:2–16). Sullivan995 discloses the computing system may “calculate control values of patterns for each patient based on moving average values or such values

or patterns will be pre-programmed into the computing system.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22.

Patent Owner additionally argues that “Petitioner simplifies Matthews’s teachings, claiming it advocates decreasing CPAP pressure when erratic breathing is detected” and that “[i]n reality, Matthews adjusts pressure based on the previous CPAP setting.” Sur-reply 17. According to Patent Owner, “Matthews’[s] adjustments to pressure do not differentiate between asleep and awake states, but employ[] an equation that calculates a variable breathing number to assess if the breathing becomes too erratic.” *Id.* at 17–18 (citing Ex. 1052, 173:12–22, 174:12–17). Petitioner, however, is not relying on Matthews for differentiating asleep and awake states, and Patent Owner focuses on Matthews without addressing Petitioner’s proposed combination of Sullivan995, Sullivan460, and Matthews. As we explain above in Section III.C.4.a, Sullivan460 teaches determining whether a patient is awake or asleep, and Matthews teaches detecting erratic breathing during wakefulness and sleep. Combining the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes would result in a processing arrangement that determines whether the patient is awake or asleep and whether the patient is breathing erratically. By determining whether the patient is awake or asleep and whether the patient is breathing erratically, the processing arrangement determines whether the patient’s breathing pattern is indicative of a REM sleep state, a non-troubled wake state, a non-REM sleep state, or a troubled wakefulness state. Furthermore,

in view of Sullivan995's disclosure of a generator configured to adjust the airflow pressure as a function of the breathing pattern and the associated patient state and Matthews's teaching of decreasing pressure after a pressure increase resulted in erratic breathing, Petitioner's proposed combination would result in a generator configured to adjust the airflow pressure based on the patient's state and reduce the airflow pressure upon a detection of the patient being asleep and breathing erratically, which is indicative of a troubled wakefulness state.

Patent Owner improperly argues for the first time in its Sur-reply that Petitioner's combination of Sullivan995, Sullivan460, and Matthews would have required "undue experimentation because analyzing both amplitude and temporal structures to determine asleep/asleep states was not known." Sur-reply 19–20. Patent Owner's alleged "undue experimentation" was not raised in Patent Owner's Response, and therefore Petitioner did not have an opportunity to respond to it. Accordingly, Patent Owner's argument is improper, and the issue is deemed waived. *See* Inst. Dec. 45 n.10 (stating that "Patent Owner is cautioned that any arguments not raised in the Patent Owner Response may be deemed waived"). Moreover, we disagree with Patent Owner's "undue experimentation" argument because it is premised on Patent Owner's proposed construction requiring analysis of "both amplitude and temporal structure," which we do not adopt.

After considering the Parties' arguments and evidence, we are persuaded a person of ordinary skill in the art would have combined the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes. Petitioner proposes to modify Sullivan995's system to determine whether the breathing patterns are indicative of certain states of the patient and to

adjust the pressure of the airflow supplied to the patient based on the patient's state, as Sullivan460 and Matthews teach. Pet. 45–46, 54–56, 59. Petitioner reasons that a person of ordinary skill in the art would have combined the teachings of Sullivan995, Sullivan460, and Matthews to “allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* at 46.

Petitioner's reason for combining the teachings of the references finds support in Sullivan995, which discloses using the lowest practicable airway pressure to promote the patient's comfort during CPAP therapy. Ex. 1005, 2:31–39; Ex. 1003 ¶ 171. Thus, Petitioner has provided persuasive reasoning for combining the teachings of Sullivan995, Sullivan460, and Matthews.

c. Reasonable Expectation of Success

Petitioner argues a person of ordinary skill in art in the art would have had a reasonable expectation of success in combining the teachings of Sullivan995, Sullivan460, and Matthews as Petitioner proposes. Pet. 46–47, 56, 59. Petitioner asserts that all of the references disclose CPAP systems with flow sensors and flow generators and that, like Sullivan995, Matthews teaches data from the flow sensor is monitored and used to control the pressure delivered to the patient. *Id.* at 46–47 (citing Ex. 1007, 8:54–9:10). According to Petitioner, Sullivan995 is already configured to monitor breathing patterns while a patient is asleep to determine the patient's pressure flow needs. *Id.* at 56 (citing Ex. 1005, 10:52–61). Petitioner asserts a person of ordinary skill in the art would have been able to incorporate Matthews's algorithm to interrupt Sullivan995's control in the same manner that Matthews teaches for interrupting an auto-CPAP

controller. *Id.* at 56 (citing Ex. 1003 ¶ 199; Ex. 1007, 15:13–28, 21:40–42, Figs. 4A–C, 6).

Patent Owner contends there is no reasonable expectation of success in combining the teachings of Sullivan995, Sullivan460, and Matthews to result in the claimed invention because “Sullivan995 does not teach how to distinguish awake state and an asleep state, let alone between the REM sleep and troubled wakefulness states, which have opposite implications for pressure and flow.” PO Resp. 41 (citing Ex. 2006 ¶¶ 218, 220). Patent Owner further argues that “the proposed modification to Sullivan995’s CPAP system would require methods of digital signal processing that go beyond a combination of known prior art elements” and that the proposed modification “would require the use of methods that analyze the temporal structure of a time series.” *Id.* (citing Ex. 2006 ¶¶ 206, 219, 226–227, 229).

Petitioner replies that claims do not require an analysis of temporal structures of a time series. Pet. Reply 3. We agree with Petitioner.

Patent Owner’s argument that there is no reasonable expectation of success in combining the teachings of the references to result in the claimed invention is premised on its proposed construction of the claim term “analyze the breathing patterns,” which, for the reasons set forth above in Section II.B.3, we do not adopt. Thus, Patent Owner’s arguments alleging there is no reasonable expectation of success are not commensurate with the scope of the claims.

Patent Owner also argues there is no reasonable expectation of success for the same reasons there is no motivation to combine the teachings of the references. Sur-reply 17–20; *see also id.* at 24 (Patent Owner referring to the arguments regarding reasonable expectation of success with

respect to the asserted ground based on Rapoport⁵⁰², Sullivan⁴⁶⁰, and Matthews). We address these arguments above in Section II.C.4.b.

After considering the Parties' arguments and evidence, we are persuaded a person of ordinary skill in the art would have combined the teachings of Sullivan⁹⁹⁵, Sullivan⁴⁶⁰, and Matthews with a reasonable expectation of success. Petitioner has persuaded us that Sullivan⁹⁹⁵ is configured to monitor breathing patterns to determine the patient's pressure flow needs and that a person of ordinary skill in the art would have been able to incorporate Matthews's algorithm to interrupt Sullivan⁹⁹⁵'s control in the same manner that Matthews teaches for interrupting an auto-CPAP controller. Ex. 1003 ¶ 199; Ex. 1005, 10:52–61; Ex. 1007, 15:13–28, 21:40–42, Figs. 4A–C, 6. Accordingly, Petitioner has shown a reasonable expectation of success in combining the teachings of the references to result in the claimed invention.

d. Secondary Considerations

We must consider—apart from what the prior art itself would have suggested—whether objective evidence of non-obviousness, i.e., secondary considerations, may lead to a conclusion that the challenged claims would not have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (instructing that evidence of secondary considerations, when present, must always be considered in determining obviousness). Objective evidence of non-obviousness may include evidence of commercial success, licensing, copying, praise by others, long felt but unresolved need, and failure or skepticism of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). But, secondary considerations are only a part of the “totality of the evidence”; their mere existence does not control

the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997).

Patent Owner argues the existence of a long-felt but unresolved need strongly supports the non-obviousness of the challenged claims. PO Resp. 33–35, 41 (Patent Owner referring to the arguments regarding secondary considerations with respect to the asserted ground based on Rapoport502, Sullivan460, and Matthews); Sur-reply 25–27. According to Patent Owner, since 1991 there has been “a need for patients to increase compliance with usage of their CPAP machines.” PO Resp. 34 (citing Ex. 1036, 5). Patent Owner further argues:

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients’ compliance with CPAP treatment by noting that “the conventional PAP therapy [had] not taken sleep/wake state into account” and “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” Further, before the development of the claimed invention in the ’994 [p]atent,^[16] self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. In fact, as of 2002, a [person of ordinary skill] was “not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters.” As such, the claimed invention solved a long felt but unresolved need – better compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 34–35 (first and second alterations in original) (citations omitted) (citing Ex. 1010, 2:33–37; Ex. 2002, 1:44–46, 1:64–65, 2:31–35).

¹⁶ The ’344 patent at issue in this proceeding claims priority to the ’944 patent. Ex. 1001, code (63).

Patent Owner further argues that “[c]onventional CPAP therapy had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control.” Sur-reply 25 (citing Ex. 1001, 2:11–13). According to Patent Owner, Dr. Bates’s testimony explained that “[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states.” *Id.* at 26 (citing Ex. 1052, 113:3–11, 115:22–116:10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by “the ’344 [p]atent’s ability to distinctly identify when a patient is awake or asleep,” because a person of ordinary skill in the art “prior to the [’]994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and awake.” *Id.* at 26–27 (third alteration in original) (citing Ex. 1052, 202:23–203:3, 203:15–204:5).

i. Nexus

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

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

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

Petitioner argues that Patent Owner does not meet its burden of proving nexus because: (1) Patent Owner did not identify any product tied to the objective evidence and thus did not establish a “presumption of nexus”; (2) Patent Owner did not “demonstrate a nexus by showing that long-felt

need was met as a ‘direct result of the unique characteristics of the claimed invention’”; and (3) Patent Owner did not identify “any failed efforts to solve the problem before the invention.” Pet. Reply 24–25.

Patent Owner has not argued that the presumption of nexus applies. We agree with Petitioner that Patent Owner is not entitled to a presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the challenged claims. We address Patent Owner’s evidence of long-felt, but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the ’344 patent, absent the presumption.

ii. Long-felt Need

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

Patent Owner suggests increasing the comfort of the CPAP system is a goal to improve patient compliance with CPAP therapy. Patent Owner does not explain, however, why Sullivan460’s system which “addresses . . . the comfort of CPAP,” and “is an improvement over the prior art” because of the two modes of air delivery where the pressure is lower in the awake state, does not meet the long-felt need identified by Patent Owner. Ex. 1006, 7:7–16. Thus, we agree with Petitioner that “[t]o the extent that any need existed, it was already satisfied.” Pet. Reply 25.

Additionally, Patent Owner does not identify any failed efforts to solve the problem before the invention, and Patent Owner does not provide sufficient evidence that the invention satisfies the alleged need. Dr. Bates's redirect testimony, which Patent Owner almost exclusively relies on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to "little or no weight." 37 C.F.R. § 42.65(a).

Patent Owner also supposes a need for better compliance with CPAP therapy by detecting troubled wakefulness. PO Resp. 35; Sur-reply 26. Patent Owner's argument suffers from the deficiencies identified above, particularly the failure by Patent Owner to show that the invention satisfies the alleged need.

In view of our discussion above, the record evidence shows minimal, if any, evidence of long-felt need. We, therefore, accord little weight to Patent Owner's evidence of non-obviousness.

e. Conclusion for Independent Claims 1 and 7

We have considered the scope and content of the prior art of record, any differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art. For the reasons discussed in Sections II.C.4.a–c, Petitioner provides persuasive evidence of obviousness for the subject matter of independent claims 1 and 7. As we explain above in Section II.C.4.d, Patent Owner's evidence of long-felt need is entitled to little, if any, weight. On balance, after weighing all of the evidence in the record, we determine that Petitioner has established by a preponderance of the evidence that Sullivan995, Sullivan460, and Matthews render obvious the subject matter of independent claims 1 and 7.

5. *Claims 3, 9, 11, and 13*

Claim 3 depends from independent claim 1, and claims 9, 11, and 13 depend from independent claim 7. Ex. 1001, 9:49–51, 10:25–27, 10:31–37, 10:40–45. Petitioner sets forth evidence and argument as to why Sullivan995, Sullivan460, and Matthews render these claims unpatentable. Pet. 43–45.

Patent Owner does not raise any arguments directed specifically to claims 3, 9, 11, and 13 aside from its arguments for independent claims 1 and 7. We address these arguments above in Section II.C.4.

Having reviewed the Parties’ arguments and evidence, we are persuaded that the claimed subject matter would have been obvious for the reasons provided by Petitioner. Petitioner has established by a preponderance of the evidence that Sullivan995, Sullivan460, and Matthews render obvious the subject matter of claims 3, 9, 11, and 13.

D. Obviousness Based on Rapoport502, Sullivan460, and Matthews and Anticipation Based on Sullivan460

As set forth above in Section II.C, we determine that Petitioner has shown that all of the claims challenged in the Petition—claims 1, 3, 7, 9, 11, and 13 of the ’344 patent—are unpatentable. In view of this determination, we do not reach Petitioner’s other challenges to the challenged claims. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”).

III. PATENT OWNER’S MOTION TO EXCLUDE EVIDENCE

Patent Owner seeks to exclude Exhibits 1018–1020, 1033–1034, 1038, 1049, 1051, 1054–1055, and 1057–1059, portions of Exhibits 1003, 1046, and 1052, and portions of the record relying on the disputed exhibits, e.g., the Petition and Reply. PO MTE 1–15; PO MTE Reply 1–5. Petitioner opposes the motion. PO MTE Opp. 1–15. For the following reasons, we deny Patent Owner’s Motion to Exclude Evidence.

A. Exhibits 1003 and 1046

Exhibit 1003 is the declaration of Petitioner’s original declarant, Dr. Behbehani. Exhibit 1046 is the declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s declaration. *See* Ex. 1046 ¶ 28 (Dr. Kirkness agreeing with and adopting paragraphs 20–28, 32–88, and 92–234 of Dr. Behbehani’s declaration). Patent Owner argues paragraphs 38–39, 42, 45, 81, and 219–232 of Exhibit 1003 and Dr. Kirkness’s adoption of those paragraphs in Exhibit 1046 should be excluded. PO MTE 3–6, 9–10. Because we do not rely on these paragraphs of Exhibit 1003 in rendering this Decision, we deny Patent Owner’s Motion to Exclude Evidence as to these paragraphs of Exhibit 1003 and the corresponding portions of Exhibit 1046 as moot.

B. Exhibits 1054–1055 and 1057–1058

Exhibit 1054 is the file history of U.S. Patent No. 9,108,009 B2, which is challenged in a related proceeding, IPR2022-00988, and Exhibit 1055 is this patent. Exhibit 1057 is U.S. Patent No. 9,427,539 B2, which is challenged in a related proceeding, IPR2022-00989. Exhibit 1058 is U.S. Patent No. 6,988,994 B2, which is related via priority to the ’344

patent (Ex. 1001, code (63)) and challenged in a related proceeding, IPR2022-00993.

Patent Owner asserts that Petitioner improperly relies on these exhibits in the Reply to support its claim construction arguments for the “analyze the breathing patterns.” PO MTE 6. According to Patent Owner, Petitioner does not propose a construction for this claim term in its Petition, and thus introduces new evidence with these exhibits in its Reply. *Id.*

Petitioner replies that these exhibits are proper evidence in the Reply because Petitioner uses the exhibits in response to claim construction arguments raised in Patent Owner’s Response. PO MTE Opp. 7–8. We agree with Petitioner.

In its Response, Patent Owner argues the claim term “analyze the breathing patterns” should be construed as “determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time.” PO Resp. 18–19. Petitioner’s first and only opportunity to respond to Patent Owner’s construction is in its Reply. *See* 37 C.F.R. 42.23(b) (“A reply may only respond to arguments raised in the corresponding . . . patent owner response.”). Petitioner properly relies on Exhibits 1054–1055 and 1057–1058 to respond to Patent Owner’s claim construction arguments in its Response. We, therefore, deny Patent Owner’s Motion to Exclude Evidence as to Exhibits 1054–1055 and 1057–1058.

C. Exhibits 1018, 1019, and 1033

Exhibit 1018 is a copy of Patent Owner’s complaint from a related district court action (*see supra* Section I.B). Exhibits 1019 and 1033 are exhibits to that complaint.

Patent Owner argues these exhibits should be excluded because “[a]ny discussion of infringement is irrelevant in [*inter partes* reviews].” PO MTE 7; PO MTE Reply 3. Petitioner argues that these exhibits are relied on in support of and are relevant to Petitioner’s anticipation contentions in this proceeding. PO MTE Opp. 9–10. We agree with Petitioner that these exhibits are relevant to Petitioner’s contentions in this proceeding. Furthermore, we do not rely on these exhibits in rendering this Decision. We, therefore, deny Patent Owner’s Motion to Exclude Evidence as to Exhibits 1018, 1019, and 1033 as moot.

D. Exhibits 1020 and 1034

Exhibit 1020 is European Patent No. 0 702 978 B1. Exhibit 1034 is International Publication No. WO 03/075991 A1.

Patent Owner argues that Petitioner does not discuss or cite to these exhibits in any paper in this proceeding. PO MTE 8. According to Patent Owner, these exhibits are “irrelevant,” and “the probative value of these exhibits is substantially outweighed by the unfair prejudice resulting from any use of these exhibits at this late stage of the proceedings.” *Id.*

Petitioner responds that “[t]he Board has already noted that these exhibits were not cited in the Petition” and “has already found the listing of these exhibits as ‘harmless.’” PO MTE Opp. 10 (citing Paper 11 at 4 n.1, 8). Patent Owner does not dispute that the Board has already determined the listing of these exhibits is harmless and instead argues “[i]f the exhibits are ‘harmless,’ Petitioner should not object to their exclusion.” PO MTE Reply 3–4.

There is no dispute that Petitioner does not cite to Exhibits 1020 and 1034, and we do not rely on these exhibits in rendering this Decision.

Accordingly, we deny Patent Owner's Motion to Exclude Evidence as to Exhibits 1020 and 1034 as moot.

E. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2, which lists Dr. Bates as an inventor. Patent Owner argues that the priority date of this patent is after the priority date of the '344 patent and that Exhibit 1049 should be excluded as irrelevant and "not prior art." PO MTE 9; PO MTE Reply 4. Patent Owner also argues the exhibit should have been introduced prior to Petitioner's Reply. PO MTE 9. Petitioner argues the exhibit is not being asserted as prior art, but rather for the credibility of Dr. Bates. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates's credibility, and we find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision. We therefore deny Patent Owner's Motion to Exclude Evidence as to Exhibit 1049 as moot.

F. Exhibit 1051

Exhibit 1051 is the declaration of Dr. Kirkness in support of Petitioner's Reply. Patent Owner argues that Exhibit 1051 "should be excluded for the same reasons as" Exhibits 1003 and 1046. PO MTE 7; PO MTE Reply 2. For the reasons discussed above in Section III.A regarding Exhibits 1003 and 1046, we do not find Patent Owner's arguments persuasive. Patent Owner also argues that Exhibit 1051 should be excluded because it raises "new issues" and "new evidence that could have been presented in a prior filing." PO MTE 10; PO MTE Reply 2–3. The only "example" Patent Owner provides in support of this argument is that Dr. Kirkness's reply declaration "uses Exhibits 1049, 1054–1055,

and 1057–1058 in the exact same manner” as they are used in Petitioner’s Reply. PO MTE 10. For the reasons discussed above in Section III.B regarding Exhibits 1054–1055 and 1057–1058 and Section III.E regarding Exhibit 1049, we deny Patent Owner’s Motion to Exclude Evidence as to Exhibit 1051.

G. Exhibit 1052

Exhibit 1052 is the transcript of Dr. Bates’s deposition testimony. Patent Owner argues that the portions of Exhibit 1052 including questions regarding patent-eligible subject matter and infringement should be excluded as irrelevant. PO MTE 11 (citing Ex. 1052, 62:7–23, 63:15–64:1–5, 117:9–118:11, 146:4–12); PO MTE Reply 4–5. Petitioner argues that these portions of Dr. Bates’s testimony are relevant to obviousness and anticipation issues in this proceeding, that there was “no discussion of ‘infringement’ or ‘patentable subject matter,’” and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 11–12. We agree with Petitioner and deny Patent Owner’s Motion to Exclude Evidence as to these portions of Exhibit 1052.

H. Exhibit 1059

Exhibit 1059 is an article titled “Control of breathing during sleep” and published in Clinical Science in 1984. Dr. Kirkness cites this article in his reply declaration (Exhibit 1051).

Patent Owner argues Dr. Kirkness relies on Exhibit 1059 to show that “a [person of ordinary skill in the art] knew ‘that a processor could be programmed to analyze breathing patterns that fall below or above certain preset levels of airflow rate to indicate awake or asleep states’ and that analysis of temporal structures was not necessary.” PO MTE 12 (citing

Ex. 1051 ¶¶ 11, 32). According to Patent Owner, “[a]ny use of [Exhibit 1059] is therefore an improper incorporation by reference through [Exhibit 1051], violating 37 C.F.R. § 42.6(a)(3), which prohibits incorporating arguments by reference from one document into another document.” *Id.* Patent Owner’s argument has no merit. As Petitioner correctly avers, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and Exhibit 1059 “is not an argument.” PO MTE Opp. 13.

Patent Owner also argues Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply 5. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his reply declaration are relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” Pet. MTE Opp. 13. We agree with Petitioner for the same reasons discussed above in Section III.B regarding Exhibits 1054–1055 and 1057–1058. Because Patent Owner shows no persuasive basis to exclude Exhibit 1059, Patent Owner’s Motion to Exclude Evidence as to Exhibit 1059 is denied.

I. Exhibit 1038

Exhibit 1038 as an article titled “Snoring and Sleep Architecture” and published in the American Review of Respiratory Disease in 1991. Dr. Behbehani cites this article in his declaration (Ex. 1003), which Dr. Kirkness adopts in his declaration.

Patent Owner asserts “[Dr. Kirkness] uses [Exhibit 1038] to argue that ‘[t]he well-known correlation between breathing patterns and sleep have

been used to indicate the sleep-wake state of a patient for decades. This is particularly true of the awake state, the non-REM sleep state (stable breathing), REM state (unstable breathing), and disordered sleep state.” PO MTE 13 (third alteration in original) (citing Ex. 1003 ¶ 53). According to Patent Owner, “[a]ny use of [Exhibit 1038] is therefore an improper incorporation by reference through [Exhibit 1003], violating 37 C.F.R. § 42.6(a)(3) in the same manner as [Exhibit 1059].” *Id.* For the reasons discussed above in Section III.H regarding Exhibit 1059, we do not find Patent Owner’s arguments persuasive, and we deny Patent Owner’s Motion to Exclude Evidence as to Exhibit 1038.

IV. PETITIONER’S MOTION TO EXCLUDE EVIDENCE

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

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

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

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

In opposition, Patent Owner argues Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner argues the Board’s

Consolidated Trial Practice Guide¹⁷ provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or *otherwise exceeds the proper scope* of reply or sur-reply, it may request authorization to file a motion to strike.” PO MTE Opp. 2 (quoting CTPG 80). Patent Owner contends that “Petitioner’s counsel reserved that right to strike Dr. Bates’[s] redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of [Patent Owner] submitting its Sur-[r]epley.” *Id.* at 2–3 (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact *inadmissible*,” only that “it should be excluded (not stricken) because it is beyond the scope of its cross examination.” *Id.* at 4. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–25).

In reply, Petitioner contends it “properly focused its [M]otion to [E]xclude on the portions of Dr. Bates’[s] inadmissible re-direct deposition testimony cited in [the] Sur-[r]epley,” and that Patent Owner “uses its Sur-[r]epley as no more than a ‘vehicle’ to enter new evidence into the record.” Pet. MTE Reply 1. Petitioner contends that it “timely objected at the

¹⁷ USPTO, Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019, <https://www.uspto.gov/TrialPracticeGuideConsolidated> (“CTPG”).

deposition” once Patent Owner began “improperly elicit[ing] new opinions by Dr. Bates.” *Id.* at 4–5 (citing Ex. 1053, 294:19–296:11). Petitioner further contends that it, in fact, argued that the testimony is inadmissible under Federal Rule of Evidence 611(b). *Id.* at 3 (citing Pet. MTE 7).

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

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

As noted in the Consolidated Trial Practice Guide, motions to strike are intended to address, *inter alia*, whether a brief raises new issues or exceeds the proper scope of a sur-reply. Here, Petitioner argues that the redirect testimony is inadmissible under Federal Rule of Evidence 611(b) and/or 37 C.F.R. § 42.53(d)(5)(ii) as exceeding the scope of cross-examination. But, Petitioner does not seek to exclude all redirect

testimony on secondary considerations, only the testimony relied on by Patent Owner in the Sur-reply. Pet. MTE 5 n.2.

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

strike those arguments. The best course of action would have been to object and pursue a motion to exclude as Petitioner has here and to also seek authorization to file a motion to strike after seeing the opposing party's brief and the arguments raised therein and evidence relied upon.

Although we agree with Petitioner that Federal Rule of Evidence 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination, just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony,¹⁸ Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of non-obviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the circumstances presented here and in light of the little weight to which Patent Owner's argument and Dr. Bates's redirect is entitled, we determine that the better course is to deny Petitioner's Motion to Exclude Evidence.

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

V. CONCLUSION

The outcome for claims 1, 3, 7, 9, 11, and 13 challenged in this proceeding is set forth in summary as follows:

Claims Challenged	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 3, 7, 9, 11, 13	103(a)	Sullivan995, Sullivan460, Matthews	1, 3, 7, 9, 11, 13	
1, 3, 7, 9, 11, 13	103(a)	Rapoport502 Sullivan460, Matthews ¹⁹		
1, 3, 7, 9, 11, 13	102(a), (b)	Sullivan995 ²⁰		
Overall Outcome			1, 3, 7, 9, 11, 13	

VI. ORDER²¹

In consideration of the foregoing, it is hereby:

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

¹⁹ We do not reach the merits of this ground because, as set forth above in Section II.C, we determine that Petitioner has shown claims 1, 3, 7, 9, 11, and 13 are unpatentable over Sullivan995, Sullivan460, and Matthews.

²⁰ We do not reach the merits of this ground because, as set forth above in Section II.C, we determine that Petitioner has shown claims 1, 3, 7, 9, 11, and 13 are unpatentable over Sullivan995, Sullivan460, and Matthews.

²¹ Should Patent Owner wish to pursue amendment of a challenged claim in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding, 84 Fed.

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

FURTHER ORDERED that claims 1, 3, 7, 9, 11, and 13 of U.S. Patent No. 9,168,344 B2 have been proven by a preponderance of the evidence to be unpatentable; and

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

Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

IPR2022-00994
Patent 9,168,344 B2

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