

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED, INC.,
Petitioner,

v.

NEW YORK UNIVERSITY,
Patent Owner.

IPR2022-00992
Patent 10,384,024 B2

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

GERSTENBLITH, *Administrative Patent Judge*.

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

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

I. INTRODUCTION

A. Background

ResMed, Inc. (“Petitioner”) filed a Petition (Paper 1) requesting institution of *inter partes* review of claims 1–14 (“the Challenged Claims”) of U.S. Patent No. 10,384,024 B2 (Ex. 1001, “the ’024 patent”). With our prior authorization (Paper 6), Petitioner filed a Motion to Correct the Petition (Paper 7), which New York University (“Patent Owner”) opposed (Paper 8). We granted Petitioner’s Motion to Correct the Petition (Paper 9), and Petitioner filed a Corrected Petition (Paper 10, “Pet.”).¹ Patent Owner filed a Preliminary Response (Paper 11). With our prior authorization, Petitioner filed a Reply to Patent Owner’s Preliminary Response (Paper 13), and Patent Owner filed a Sur-reply (Paper 14). Applying the standard set forth in 35 U.S.C. § 314(a), we instituted an *inter partes* review as to all claims and grounds set forth in the Petition. Paper 15 (“Inst. Dec.”).

After institution, Patent Owner filed a Patent Owner Response (Paper 32, “PO Resp.”), Petitioner filed a Reply (Paper 40, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 43, “Sur-reply”). Additionally, Patent Owner filed a Motion to Exclude (Paper 47, “PO MTE”), Petitioner filed an Opposition (Paper 51, “PO MTE Opp.”), and Patent Owner filed a Reply (Paper 52 “PO MTE Reply”). And Petitioner filed a Motion to Exclude (Paper 48, “Pet. MTE”), Patent Owner filed an Opposition (Paper 50, “Pet. MTE Opp.”), and Petitioner filed a Reply (Paper 53, “Pet. MTE Reply”). A consolidated oral hearing was held for this proceeding as well as six related proceedings, IPR2022-00988, IPR2022-00989,

¹ Further references to “Petition” are to the Corrected Petition (Paper 10), unless otherwise indicated.

IPR2022-00990, IPR2022-00991, IPR2022-00993, and IPR2022-00994, on October 2, 2023, and the transcript is of record.² Paper 62.

We have jurisdiction pursuant to 35 U.S.C. § 6. This Decision is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of the Challenged Claims. Petitioner bears the burden of proving unpatentability of the Challenged Claims. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2021). Having reviewed the arguments and the supporting evidence, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–14 of the '024 patent are unpatentable.

B. Related Proceedings

The Parties identify *New York University v. ResMed Inc.*, No. 1:21-cv-00813-JPM (D. Del.), as a related matter. Pet. 1; Paper 4 (Patent Owner's Mandatory Notices), 2. Petitioner also states that it filed petitions for *inter partes* review challenging claims of several patents related to the '024 patent in IPR2022-00988, IPR2022-00989, IPR2022-00990, IPR2022-00991, IPR2022-00993, and IPR2022-00994. *See* Pet. 2 (identifying the related patents).

² Each party filed objections to the other party's demonstrative exhibits and hearing arguments along with responses to those objections. *See* Papers 59, 60, 63–66. Demonstrative exhibits and hearing arguments are not evidence and are not relied on as a basis of this Decision. Accordingly, the objections are denied as moot.

C. Real Parties in Interest

Petitioner identifies only itself as the real party in interest. Pet. 1.
Patent Owner identifies only itself as the real party in interest. Paper 4, 2.

D. The Asserted Grounds of Unpatentability and Declaration Evidence

Petitioner challenges the patentability of claims 1–14 of the
'024 patent on the following grounds:

Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
1–5, 7–14	103(a)	Sullivan995, ⁴ Sullivan460 ⁵
6	103(a)	Sullivan995, Sullivan460, Matthews ⁶
1–5, 7–14	103(a)	Rapoport502, ⁷ Sullivan460
6	103(a)	Rapoport502, Sullivan460, Matthews

Pet. 3–4. Petitioner supports its challenge with a Declaration of
Dr. Khosrow Behbehani (Ex. 1003), a Substitute Declaration of Dr. Jason P.

³ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. The '024 patent was filed on October 15, 2019, but asserts priority to several patent applications filed before March 16, 2013. Ex. 1001, codes (22), (63). In this Decision, we assume the asserted priority (which has not been challenged) is correct, so we apply the pre-AIA version of § 103 here.

⁴ U.S. Patent No. 5,245,995, issued Sept. 21, 1993 (Ex. 1005, “Sullivan995”).

⁵ WO 01/05460 A1, published Jan. 25, 2001 (Ex. 1006, “Sullivan460”).

⁶ U.S. Patent No. 7,168,429 B2, filed Oct. 10, 2002, issued Jan. 30, 2007 (Ex. 1007, “Matthews”).

⁷ U.S. Patent No. 5,490,502, issued Feb. 13, 1996 (Ex. 1008, “Rapoport502”).

Kirkness in support of the Petition⁸ (Ex. 1046), and a Declaration of Dr. Jason P. Kirkness in support of Petitioner's Reply (Ex. 1051). Patent Owner supports its arguments with a Declaration of Dr. James Hamilton Tunstall Bates⁹ (Ex. 2006). Additionally, Petitioner cross-examined Dr. Bates and a two-part transcript of that deposition is of record. Exs. 1052, 1053. And, Patent Owner cross-examined Dr. Kirkness and a two-part transcript of that deposition also is of record. Exs. 2015, 2016.

E. The '024 Patent

The '024 patent is directed to a system and method for diagnosing and treating the breathing pattern of a patient. Ex. 1001, code (54). As background, the '024 patent explains that “[o]bstructive sleep apnea syndrome (OSAS) is a well[-]recognized disorder which may affect as much as 1-5% of the adult population.” *Id.* at 1:29–31. According to the '024 patent:

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

⁸ The Petition was originally supported by the Declaration of Dr. Khosrow Behbehani (Ex. 1003). After institution, Petitioner informed the Board that Dr. Behbehani was unable to continue to serve as an expert in this proceeding (Paper 28), and, with our authorization (Paper 31), Petitioner replaced Dr. Behbehani with Dr. Kirkness, who adopted substantially the entirety of Dr. Behbehani's prior opinions. *See* Ex. 1046 ¶¶ 1, 28 (adopting paragraphs 20–28, 32–86, and 90–283 of Dr. Behbehani's Declaration). For consistency with the citations in the Petition, in this Decision we cite to the Declaration of Dr. Behbehani (Ex. 1003) with the understanding that the paragraphs we cite (and opinions expressed therein) were adopted by and, therefore, are attributable to Dr. Kirkness.

⁹ Dr. Bates provided corrections to citations in his declaration via email to Petitioner, which Petitioner then filed as Exhibit 1048.

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

Id. at 1:35–42. The '024 patent further explains that positive airway pressure (PAP) therapy “has evolved as the most effective treatment for OSAS, and is now the standard of care.” *Id.* at 1:58–61. The '024 patent explains that PAP therapy is applied by a tight-fitting nasal mask worn during sleep (*id.* at 1:58–59), and that “PAP therapy is directed to maintaining pressure in the collapsible portion of the airway at or above the critical tissue pressure at all times” (*id.* at 2:11–13).

The '024 patent states that “[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy.” Ex. 1001, 1:65–67. Specifically, “conventional PAP therapy has not taken sleep/wake state into account, and conventional PAP systems apply pressure unnecessarily when the patient is awake.” *Id.* at 2:18–21. The '024 patent also states that “patients often report discomfort due to high pressure while being awake.” *Id.* at 2:32–33.

Figure 1 of the '024 patent is reproduced below.

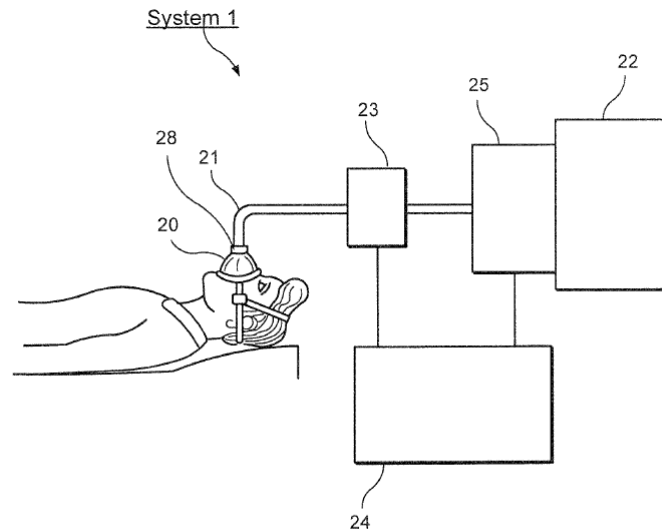


FIG. 1

Figure 1 “shows an exemplary embodiment of a system according to” the '024 patent. Ex. 1001, 3:22–23, 3:52–53. System 1, shown in Figure 1, includes mask 20, placed over the face of the patient, connected via tube 21 to receive airflow of a particular pressure from flow generator 22. *Id.* at 3:53–56. Conventional flow sensors 23 are coupled to tube 21 and detect the rate of airflow to/from the patient and/or a pressure supplied to the patient via generator 22. *Id.* at 3:61–63. The '024 patent states that “[s]ignals corresponding to the airflow and/or the pressure are provided to a processing arrangement 24 for processing” and “processing arrangement 24 outputs a signal to a conventional flow control device 25 to control a pressure applied to the flow tube 21 by the flow generator 22.” *Id.* at 3:65–4:2.

Figure 2 of the '024 patent is reproduced below.

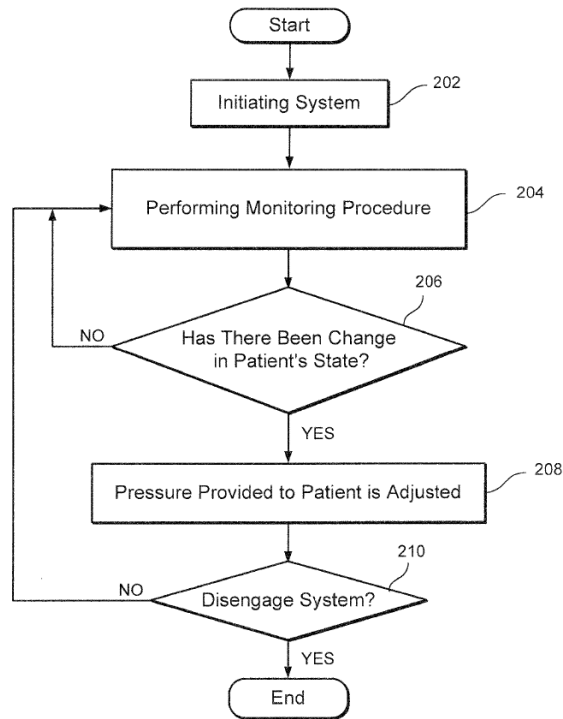


FIG. 2

Figure 2 of the '024 patent “shows an exemplary embodiment of a method . . . which utilizes the system shown in FIG. 1.” Ex. 1001, 3:24–26, 4:13–14. The '024 patent explains the following regarding the method shown in Figure 2. “In step 202, the patient initiates the system 1 by placing the mask 20 over his face and powering up the generator 22, the flow control device 25 and the processing arrangement 24.” *Id.* at 4:13–17. In step 204, “system 1 initiates a real-time monitoring procedure of the patient’s breathing patterns. The monitoring procedure is performed by the processing arrangement 24 which may utilize pre-stored patient data along with current data provided by the sensors 23 regarding the airflow to and from the patient and/or the applied pressure.” *Id.* at 4:18–23. The '024 patent teaches that “the processing arrangement 24 makes a

determination as to a current state of the patient (e.g., whether the patient is asleep, awake and breathing regularly or awake and breathing irregularly due to distress or anxiousness).” *Id.* at 4:24–28. As explained by the ’024 patent, “[s]uch determination can be made based on a number of different measurements. For example, the processing arrangement 24 may analyze the patient’s heart rate, blood pressure, EEG [electroencephalogram] data, breathing patterns, etc. in the determining the patient’s state.” *Id.* at 4:28–32.

The ’024 patent further explains that, “[i]n step 206, the processing arrangement 24 determines whether there has been a change in the patient’s state.” Ex. 1001, 5:53–54. “For example, the processing arrangement 24 may determine whether the patient was asleep and has been awakened; or the patient was awake and has fallen asleep. If there has been no change, the processing arrangement 24 continues with the monitoring procedures.” *Id.* at 5:54–59. The ’024 patent explains that, “[i]f there has been a change in the patient’s state, the processing arrangement 24 adjusts the pressure to correspond to the patient’s current state (step 208).” *Id.* at 5:60–62. “For example, if the patient has been awakened and the patient’s breathing patterns indicate a period of troubled wakefulness . . . , the processing arrangement 24 may reduce the applied pressure provided to the patient during such period.” *Id.* at 5:62–66. The ’024 patent explains that, “[o]n the other hand, if the patient has fallen asleep, the processing arrangement 24 may instruct the flow control device 25 to elevate the pressure to the level to be applied while the patient is asleep.” *Id.* at 6:9–12. In step 210, “the processing arrangement 24 determines whether instructions to disengage the system 1 have been given,” and, if so, “system 1 shuts down and ends all

monitoring and flow generating activities. Otherwise, the system 1 continues with the monitoring procedure of step 204.” *Id.* at 6:32–40.

Figure 10 of the '024 patent is reproduced below.

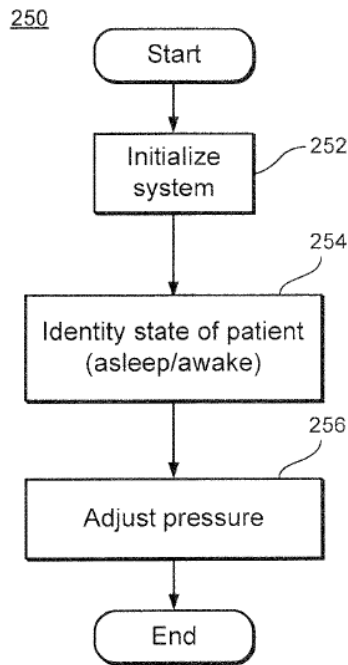


FIG. 10

Figure 10 shows a method identifying a sleep state and a wake state of a patient. Ex. 1001, 3:43–44. The '024 patent explains that, “[i]n a further embodiment . . . , the system 1 may be utilized to detect when the patient is asleep/awake and adjust the pressure based thereon” and method 250 illustrates this embodiment in Figure 10. *Id.* at 7:14–17. In step 252, “system 1 is initialized and coupled to the patient. In step 254, the processing arrangement 24 determines a first state of the patient based on data obtained from the sensors 23 regarding the breathing pattern of the patient.” *Id.* at 7:17–21. The '024 patent explains that, “[i]n this embodiment, the processing arrangement 24 may determine whether the patient is in a sleep state or a wake state based on the breathing pattern. That

is, the data may be indicative of a regular breathing state which is generally identified with the sleep state or the wake state.” *Id.* at 7:22–26.

The ’024 patent further explains:

In step 256, the processing arrangement applies supplies [sic] the air pressure as a function of the state. In one embodiment, the CPAP may be applied at a first level for the sleep state and a second level for the wake state. In another embodiment, an automatically adjusting CPAP (“auto-CPAP”) may be applied. In this embodiment, the processing arrangement 24 may adjust the pressure toward the first level when the sleep state is identified, and toward the second level when the wake state is identified. Those of skill in the art will understand that, using this embodiment, a total sleep time of the patient may be determined by the processing arrangement 24 based on identification of the sleep and wake states.

In another embodiment . . . , the system 1 may include a neural network coupled to the processing arrangement 24 and the sensors 23 for identifying the state of the patient. The neural network may obtain data from the sensors 23 and determine the state of the patient based on the data.

Ex. 1001, 7:36–54.

F. Illustrative Claim

Claim 1, the sole independent claim challenged in this proceeding, is illustrative of the claimed subject matter and is reproduced below with Petitioner’s bracketing added for reference (*see* Pet. 78 (Claims App.)):

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

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

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

[c] a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns, [d] the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, [e] wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state, wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.

Ex. 1001, 9:49–10:12.

G. Level of Ordinary Skill in the Art

Petitioner, supported by Dr. Kirkness's testimony, proposes that a person of ordinary skill in the art at the time of the invention would have had "at least a bachelor's degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience." Pet. 16 (citing Ex. 1003 ¶ 87). Petitioner asserts that "[a]dditional experience could substitute for less education, and additional education could likewise substitute for less experience." *Id.* (citing Ex. 1003 ¶ 87).

Patent Owner "does not object to Petitioner's definition of a [person of ordinary skill in the art]," which we adopted preliminarily in our Institution Decision. Inst. Dec. 10.

Based on the complete record before us, we find (as we did in the Institution Decision) that Petitioner’s uncontested level of ordinary skill in the art is consistent with the level of ordinary skill in the art reflected by the ’024 patent and the prior art of record. *See* Inst. Dec. 10 (citing *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978)). Therefore, we maintain and reaffirm our adoption of Petitioner’s uncontested level of ordinary skill in the art.

II. CLAIM CONSTRUCTION

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

If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during

prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thornerv. Sony Comput. Ent. Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

A. “troubled wakefulness”

Petitioner proposes that we construe “troubled wakefulness” to mean a “state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable.” Pet. 17 (citing Ex. 1003 ¶ 91). Petitioner contends that “[t]his term is not an industry standard term and was coined in the ’024 Patent.” *Id.* (citing Ex. 1003 ¶ 92). Petitioner explains that the construction of the term “is derived directly from the specification, which describes ‘troubled wakefulness’ as a state ‘in which the breathing pattern is characterized by irregularity [sic] variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient’s airflow tracing indicating that the patient is awake and either anxious or uncomfortable.’” *Id.* (quoting Ex. 1001, 4:59–64) (citing Ex. 1001, Fig. 7). Petitioner asserts that “[t]he specification further confirms that [a] ‘patient’s discomfort during wakefulness is often associated with changes from a regular breathing pattern . . . and frequently occur when the patient is distressed by the PAP system.’” *Id.* (quoting Ex. 1001, 2:40–47).

Patent Owner agrees with Petitioner's construction, noting that "this term is not in dispute." PO Resp. 29.

We adopt Petitioner's undisputed construction of "troubled wakefulness" because it is supported by and consistent with the Specification's description of the term. *See, e.g.*, Ex. 1001, 4:59–64.

B. "analyzes the data to determine the patient's breathing patterns"

Claim 1 recites, *inter alia*, "a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns." Ex. 1001, 9:63–10:2. In the Petition, Petitioner did not expressly construe this phrase, but did analyze and address the prior art to identify the teachings of the prior art that Petitioner contends teach this limitation of the claim. *See, e.g.*, Pet. 28–31 (discussing element 1[c]). Patent Owner first proposes this phrase for construction in its Patent Owner Response. PO Resp. 30–32.

In the Patent Owner Response, Patent Owner argues that "analyzes the data to determine the patient's breathing patterns" means "determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order which they appear in time." PO Resp. 30. As borne out through Patent Owner's arguments in response to Petitioner's challenges and as further elaborated in Patent Owner's Sur-reply, Patent Owner contends that "analyzes the data to determine the patient's breathing patterns" requires analysis of "both the amplitude structure and the temporal structure." PO Resp. 36–38; Sur-reply 4–5.

Petitioner disputes this proposed construction and contends that the plain and ordinary meaning applies. Pet. Reply 2; *see id.* at 2–11. For the reasons that follow, we agree with Petitioner.

I. The Parties' Contentions

To explain why the claim phrase should be construed as proposed, Patent Owner argues that “[t]he process of analyzing breathing patterns is specifically discussed in the [S]pecification” of the ’024 patent. PO Resp. 30 (citing Ex. 1001, 4:44–51; Ex. 2006 ¶ 136); *see also* Sur-reply 13 (citing Ex. 1052, 108:25–109:1–7) (arguing that according to Dr. Bates “‘breathing patterns’ has no ordinary meaning and ‘is an extremely general term’”). According to Patent Owner, the Specification “defines the different breathing patterns associated with both apnea and hypopnea in terms of a sequence of parameters of a single breath in a series of breaths from a flow waveform . . . and then sets forth the values of the parameters and the order in which they appear in time.” *Id.* at 30–31 (citing Ex. 2006 ¶ 137).

Patent Owner points to the description of Figures 7 and 8 of the ’024 patent in support of its construction. *Id.* at 31–32 (citing Ex. 1001, 4:59–66, 5:23–39; Ex. 2006 ¶¶ 138–140). Figure 7 shows a waveform for a period of troubled wakefulness, and the waveform is characterized by irregular variations in the size of breaths, frequency of breaths, and shape of the patient’s airflow, but no periodic irregularity in breath size. Ex. 1001, 4:59–66. Figure 8 shows a waveform for REM sleep, which differs from the waveform for troubled wakefulness and includes the absence of larger breaths, especially after pauses, high respiratory rates with low flow rates, and a tendency for clustering of small breaths. *Id.* at 5:23–39.

According to Patent Owner, “[t]his methodology of determining a patient state of awake and either anxious or uncomfortable rests on an analysis of breathing patterns” and focuses “on a determination of ‘the sequence of parameters of a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time.’” PO Resp. 31 (citing Ex. 2006 ¶ 139); *see also* Sur-reply 4 (citing Ex. 1001, 4:59–66; Ex. 2006 ¶ 136) (asserting that “[b]oth amplitude and temporal structures are likewise described when examining specific flow waveforms”). Patent Owner further argues that the description of Figure 8 in the Specification “differentiates the pattern of airflow signals seen during REM sleep from those seen in troubled wakefulness.” PO Resp. 31–32 (citing Ex. 1001, 5:23–39; Ex. 2006 ¶ 140); *see* Sur-reply 5–12.

Additionally, Patent Owner suggests the Specification’s discussion of an “advantage” of the system—lowering or eliminating the pressure supplied to a patient when the patient has an irregular breathing pattern suggesting the patient is awake and anxious, but maintaining or increasing the pressure when breathing is either regular or shows sleep disorder breathing events—further supports Patent Owner’s proposed construction. *Id.* at 32 (citing Ex. 1001, 6:41–48; Ex. 2006 ¶ 141).

Turning to the Sur-reply, Patent Owner contends its construction is supported by “intrinsic evidence and implied lexicography, and fully enables the ’024 Patent.” PO Sur-reply 3; *see also id.* at 9–14 (arguing that distinguishing troubled wakefulness from REM sleep requires assessing both amplitude and temporal structure). First, Patent Owner points to the description in the Specification of breathing patterns during periods of apnea

and hypopnea as exhibiting “periods of intermittent and cyclical change in the shape of the signal.” PO Sur-reply 3–4 (quoting Ex. 1001, 4:44–51) (citing Ex. 2006 ¶ 134). Patent Owner maintains that the descriptions of the waveforms shown in Figures 7 and 8 include analyzing both amplitude and temporal structures of waveforms. *Id.* at 4–7 (citing Ex. 1001, 4:59–66, 5:30–39, 6:41–48; Ex. 1052, 81:17–23, 180:1–15; Ex. 2006 ¶ 138). Patent Owner recognizes that “terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’024 Patent,” but contends that “these are not obligatory.” *Id.* at 5. Patent Owner asserts that enablement of the ’024 patent “hinges on its ability to distinguish between all awake and asleep states,” and “[i]f not achieved, incorrect pressure could be supplied, reinforcing the need for [Patent Owner’s] precise construction.” *Id.* at 6.

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

Third, Patent Owner argues that “a patentee does not need to rigidly define terms, but can imply their own meaning.” Sur-reply 7. Patent Owner relies on Dr. Bates’s testimony, contending that the Specification “implicitly demands certain parameter measurements, evidenced by Figure 7 – a flow waveform indicating troubled wakefulness.” *Id.* (citing Ex. 1052, 44:6–20). Patent Owner also points to Dr. Bates’s testimony that the Specification “provides special definitions of particular key types of breathing patterns,” and Patent Owner asserts that, “[s]ince ‘analyses the data’ is followed by ‘to

determine the patient's breathing patterns,' some of which occur in the asleep state and some of which occur in the awake state, this further implies that these states can be separated from one another." *Id.* (citing Ex. 1052, 108:20–24, 178:24–25, 179:1–22). Patent Owner contends that, "[g]iven the separation between awake and asleep states discussed in the '024 Patent, [Patent Owner's] construction is integral for discerning the difference and applying the correct pressure" because without doing so, it "could result in inappropriate pressure administration." *Id.* at 7–8 (citing Ex. 1052, 179:23–25; Ex. 2006 ¶ 139).

Patent Owner also argues that extrinsic evidence supports its proposed construction. Sur-reply 8–13. Based on Dr. Bates's testimony, Patent Owner asserts that "by assessing *only amplitude*" the waveforms of troubled wakefulness and REM sleep "appear indistinguishable," but "their temporal structure (order in time) . . . offers differentiation." *Id.* at 9–10 (citing Ex. 2006 ¶ 70). Patent Owner asserts that its argument is correct, alleging that if the "temporal structure" of the REM sleep waveform is "rearranged in time," the resulting "time series has a random appearance that *cannot be distinguished* from troubled wakefulness." *Id.* at 10 (citing Ex. 2006 ¶ 71). Patent Owner reasons that "amplitude structure and temporal structure convey independent information" and both must be considered in an analysis or "the awake state can be confused with an asleep state, leading to application of the wrong CPAP pressure." *Id.* at 11 (citing Ex. 2006 ¶ 64). According to Patent Owner, it is "Dr. Bates' illustrations [that] clearly present the problem solved by the '024 Patent." *Id.*

According to Patent Owner, construing "analyzing breathing patterns" to include "any type" of breathing pattern analysis, as suggested by

Dr. Kirkness, is “impractical, as it might even encompass using a mirror to check for breaths.” *Id.* at 13 (citing Ex. 1051 ¶ 16).¹⁰

Specifically, Patent Owner argues

Dr. Bates examined the specification to determine what characteristics of breathing were crucial to analyzing the breathing pattern with respect to the invention’s essence. [Ex. 1052], 24:20-25, 25:1-13. He determined that a [person of ordinary skill in the art], after reading the ’994¹¹ [sic] patent, would understand that analyzing breathing patterns, with respect to the ’024 Patent, needs to confer the ability to distinguish between troubled wakefulness and REM sleep. *Id.*, 111:22-25 – 112:1-21. In contrast to the broad construction proposed by Petitioner, [Patent Owner’s] construction evidences the understanding of a [person of ordinary skill in the art] – that analyzing breathing patter[n]s requires analysis of amplitude and temporal structures.

Sur-reply 13–14¹² (footnote added).

¹⁰ Patent Owner also states that “Dr. Kirkness argues that the ’024 Patent is indefinite, especially regarding the measurement of airflow waveforms and temporal/amplitude aspects” and that “Ppetitioner has never directly raised indefiniteness.” Sur-reply 12. We agree that indefiniteness is not an issue before us. Accordingly, we consider whether the prior art asserted by Petitioner renders the claims unpatentable, not whether the claims are so broad as to include, for example, using “a mirror to check for breaths.”

¹¹ U.S. Patent No. 6,988,994 B2 (“the ’994 patent”) is related to the ’024 patent (Ex. 1001, code (63)) and is challenged by Petitioner in related proceeding IPR2022-00993.

¹² In some instances where Patent Owner cites to testimony that carries over to a second page of a transcript, Patent Owner uses a format such as “111:22-25 – 112:1-21.” See Sur-reply 13–14 (block quote above). We understand Patent Owner to mean the entire range from 111:22–112:21. In the future, we suggest Patent Owner use the conventional citation form covering the full range to avoid potential confusion.

Petitioner proposes that we construe the phrase in accordance with its plain and ordinary meaning because “[n]othing in the intrinsic record limits the ‘analyzing the breathing patterns’ term to analysis of either or both amplitude and temporal structures—instead, the claims, specification, and prosecution history use this term in accordance with its plain meaning.” Pet. Reply 3–4 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Petitioner asserts “[c]laim terms are generally given their plain and ordinary meanings’ unless ‘the patentee disavows the full scope of the claim term either in the specification or during prosecution’ or ‘a patentee sets out a definition and acts as his own lexicographer.’” *Id.* at 6 (quoting *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014)). Petitioner contends Patent Owner “made no disavowal” and “did not act as his own lexicographer.” *Id.* Petitioner argues that, “[t]o insert the narrow limitations that [Patent Owner] now proposes, ‘the patentee must clearly express an intent to redefine the term.’” *Id.* at 6–7 (quoting *Bradium Techs LLC v. Iancu*, 923 F.3d 1032, 1044 (Fed. Cir. 2019)). Petitioner contends “[n]o such intent exists here” and Patent Owner’s “construction is found nowhere in the intrinsic record.” *Id.* at 7 (citing Ex. 1051 ¶ 24).

Petitioner further contends that, “[t]o the extent construction is necessary, [Patent Owner’s] proposal is improper.” Pet. Reply 3. Petitioner characterizes Patent Owner’s argument as “propos[ing] a lengthy construction and then constru[ing] its own construction to inject two requirements: that the processor must analyze (1) ‘the value[s] of the parameters’ (i.e., the waveform’s amplitude structure) and (2) ‘the order in which they appear in time’ (i.e., the waveform’s temporal structure).” *Id.*

(third alteration in original) (citing PO Resp. 9–11, 30–31; Ex. 1052, 181:4–25). Petitioner asserts that Patent Owner’s “construction is found nowhere in the intrinsic record, or even [Patent Owner’s] cited documents,” and instead consists of “subjective limitations that [Patent Owner’s] expert decided based on his personal experience, as opposed to that of a” person of ordinary skill in the art. *Id.* (citing Ex. 1053, 271:10–14).

Responding to Patent Owner’s citations to the Specification, Petitioner contends that the Specification “further confirms that the terms encompass any type of breathing pattern analysis” and “states that ‘[t]here are a number of characteristics of the patient’s breathing patterns that may be taken into account in making such a determination’ . . . and does not limit the analysis to any particular characteristic such as amplitude and temporal structures.” Pet. Reply 4–5 (first alteration in original) (citing Ex. 1001, 2:40–43, 4:18–32, 4:32–35, Figs. 3–8; Ex. 1051 ¶¶ 16–24; Ex. 1052, 28:4–30:21; Ex. 2006 ¶¶ 46–47). Petitioner also contends that “[t]he specification further states that the flow sensors ‘detect the rate of airflow’ to and from the patient, and provide ‘[s]ignals corresponding to the airflow’ to a processing arrangement for processing.” *Id.* at 5 (second alteration in original) (citing Ex. 1001, 3:60–66). Thus, Petitioner asserts the Specification “confirms that temporal analysis is not required.” *Id.*

Petitioner also addresses the prosecution history of patents related to the ’024 patent, contending that the terms are used consistently with their plain and ordinary meaning in that context as well. Pet. Reply 5. Petitioner asserts that, in responding to different office actions, the applicant did not seek to distinguish the prior art or characterize the invention in the manner argued by Patent Owner here. *Id.* (citing Ex. 1009, 404; Ex. 1054, 91, 128).

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

(1) Dr. Bates's analysis “is entirely hypothetical, and no [person of ordinary skill in the art] reviewing the '024 patent would have derived [Patent Owner's] construction.” *Id.* (citing Ex. 1051 ¶¶ 25–33). According to Petitioner, “Dr. Bates admitted that his analysis was ‘approximate’ and merely illustrative, not based on calculation of any unit values because the patent provided no such values.” *Id.* at 7–8 (citing Ex. 1052, 75:11–76:14; 78:16–79:19; 90:8–91:11).

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

(3) Dr. Bates's analysis contradicts the '024 patent and related patents, which expressly disclose how to distinguish troubled wakefulness and REM sleep without requiring temporal analysis. *Id.* at 8–9 (citing Ex. 1001, 4:52–59; 5:32–36; Ex. 1056, 9:55–10:3 (claim 5), 10:20–24 (claim 8); Ex. 1051 ¶¶ 25–33).

(4) “Dr. Bates admitted Figures 7–8 are merely exemplary.” *Id.* at 9 (citing Ex. 1052, 30:8–14). And Petitioner contends that these examples “do

not limit the broader claim terms of the patent.” *Id.* (citing *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004)).

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

2. Analysis

Our analysis starts with the claim language. *Phillips*, 415 F.3d at 1312–14. Claim 1 recites, *inter alia*, “a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and *analyzes the data to determine the patient’s breathing patterns.*” Ex. 1001, 9:63–10:2 (emphasis added). As reflected, claim 1 does not recite “a sequence of parameters” or “a series of breaths” or “examining the values of the parameters and the order in which they appear in time” or any analysis of amplitude or temporal structure. Rather, this portion of claim 1 recites that the processor analyzes the data, without specifically reciting how the analysis is performed. The claim phrase does, however, recite the purpose of the analysis—to determine the patient’s breathing patterns—but does not provide any further limitations as to specific requirements of said breathing patterns. Thus, it is clear on the complete record that Patent Owner’s construction seeks to import a

significant number of limitations neither expressly recited nor suggested by the specific language of the phrase.

Next, we turn to the Specification. “While we read claims in view of the specification . . . we do not read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs.*, 755 F. 3d at 1371 (citation omitted). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.” *Id.* In order for a patentee to act as its own lexicographer, the “patentee must ‘clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning’” and “must ‘clearly express an intent’ to redefine the terms.” *Bradium Tech. LLC v. Iancu*, 923 F. 3d 1032, 1044 (Fed. Cir. 2019).

In this case, Patent Owner does not argue that it disavowed the full scope of the plain and ordinary meaning of the disputed phrase, nor does Patent Owner argue that it explicitly defined the phrase in the Specification. PO Resp. 30–32. We agree that there is no disavowal nor any explicit lexicographic definition of “analyzes the data to determine the patient’s breathing patterns” in the Specification. Patent Owner instead relies on an “implied lexicography” theory as to why we should construe the phrase as Patent Owner proposes. PO Sur-reply 3, 7–8 (citing, *inter alia*, *AstraZeneca AB v. Mut. Pharm. Co., Inc.*, 384 F.3d 1333 (Fed. Cir. 2004)). We disagree.

In *AstraZeneca AB*, the United States Court of Appeals for the Federal Circuit reiterated the principle that “[a] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” 384 F.3d 1333,

1339–40 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)); see *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051–52 (Fed. Cir. 2010) (“[W]hen a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term ‘by implication.’” (quoting *Bell Atl.*, 262 F.3d at 1271)). In determining that the inventors “deliberately acted as their own lexicographers” to limit the claim term “solubilizer” to surfactants, the Federal Circuit explained that the “Description of the Invention” section stated, “[t]he solubilizers suitable according to the invention *are defined below*” and further stated “[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic *surface active agents*.” *AstraZeneca AB*, 384 F.3d at 1339. The Federal Circuit rejected AstraZeneca’s argument that these statements simply referred to preferred embodiments of suitable solubilizers, relying instead on a theory of implied lexicography, explaining that the use of the language quoted above “provides a strong signal of lexicography.” *Id.* at 1340.

The Specification of the ’024 patent is easily distinguishable from the specification at issue in *AstraZeneca AB*. Here, in contrast to Patent Owner’s proposed construction, the Specification makes no reference to “a sequence of parameters” (PO Resp. 30) or an analysis of “both the amplitude structure and the temporal structure of a breath-by-breath parameter time series” (*id.* at 37) or any of the other terms set forth in the proposed construction. See *id.* at 30–32. Further, it is undisputed that words like “amplitude” and “temporal” do not appear in the Specification. See Pet. Reply 7 (“[T]he terms ‘amplitude’ and ‘temporal’ do not appear

anywhere.”); Sur-reply 5 (“Petitioner rightly observes that terms like ‘amplitude’ and ‘temporal’ are not explicitly named in the ’024 Patent.”); *see also* Ex. 1051 ¶ 24 (Dr. Kirkness stating that “amplitude,” “temporal,” and “sequence” do not appear anywhere in the ’024 patent, which “describes several approaches to breathing pattern analysis that do not require analysis of amplitude and temporal structures”). Patent Owner directs us to a portion of the Specification that Patent Owner characterizes as the process of analyzing breathing patterns. PO Resp. 30 (quoting Ex. 1001, 4:44–51). The portion of the Specification Patent Owner relies upon describes “[i]ndices of sleep disordered breathing.” *Id.* (citing Ex. 1001, 4:44–51; Ex. 2006 ¶ 136). The cited text does not describe analysis of a sequence of parameters and the order in which they appear in time, much less the amplitude and temporal aspects of the waveform. Nevertheless, it is important to evaluate other related text for understanding the context of the cited description.

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

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

Patent Owner relies on Figures 7 and 8 to support its argument that analysis of “both the amplitude structure and the temporal structure of a breath-by-breath parameter time series” is required to distinguish between an awake state and a sleep state, including troubled wakefulness and REM sleep. PO Resp. 37; Sur-reply 8–9 (“analyzing the time series of a flow waveform reflecting troubled wakefulness for its temporal structure reveals that it is quite different from REM sleep”). Figures 7 and 8, however, depict one particular example of an awake state (i.e., troubled wakefulness) and one particular example of a sleep state (i.e., REM sleep), respectively. Ex. 1001, 3:37–41. But Patent Owner’s analysis does not address Figures 3–6 of the ’024 patent. PO Resp. 30–32; Sur-reply 3–16. Figures 3 and 4 show waveforms of a patient during “regular wakefulness” and “regular sleep,” respectively. *Id.* at 3:27–31. Figures 5 and 6 show waveforms from a sleeping patient indicative of “hypopnea” and “repetitive obstructive apnea,” respectively. *Id.* at 3:32–36. Patent Owner provides no evidence or explanation why amplitude and temporal aspects of a waveform are required to distinguish regular wakefulness from regular sleep or hypopnea or repetitive obstructive apnea.¹³

¹³ Patent Owner points to an argument during prosecution of a related patent contending it supports Patent Owner’s claim construction. Sur-reply 6–7. That argument stated that the prior art reference “does not teach or suggest a

Claim 1 also recites

the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state, wherein the delay lasts at least until the processor determines that the patient is in an asleep state.

Ex. 1001, 10:2–12. As reflected by the express claim language, claim 1 is *not* limited to distinguishing *solely* between troubled wakefulness and REM sleep, but rather encompasses other states, such as those shown in Figures 3–6. Thus, even if we were to agree with Patent Owner that an analysis of one or both of the amplitude and temporal structures of a waveform is required to distinguish between troubled wakefulness and REM sleep, that determination, alone, is insufficient to narrow the scope of claim 1, which by their own terms are broad enough to include specific types of awake or sleep states other than troubled wakefulness and REM sleep.

For the same reasons, we are not persuaded that the additional limitations Patent Owner seeks to read into the claims are necessary to “fully enable” the claims, as Patent Owner asserts.

processing arrangement that distinguishes between regular wakefulness and troubled wakefulness,” but it did not refer to anything even close to resembling the construction proposed by Patent Owner or the concepts of amplitude and temporal structures. Ex. 1009, 404. Thus, this portion of the prosecution history of a related patent does not support Patent Owner’s position here.

Having reviewed the intrinsic evidence, we next consider the extrinsic evidence, and specifically the testimony of Dr. Bates.¹⁴ Initially, we observe that Patent Owner’s construction relies nearly entirely on Dr. Bates’s interpretation of the Specification, as opposed to any specific statements in the Specification remotely similar to the statements in the specification in, for example, *AstraZeneca AB*. PO Resp. 30–32 (citing Ex. 1001, 4:44–51, 4:59–66, 5:23–39, 6:41–48; Ex. 2006 ¶¶ 136–141¹⁵). Dr. Bates’s analysis is not supported by other objective evidence, such as dictionary definitions or treatises. *See* Ex. 2006 ¶¶ 136–141.¹⁶ Rather, Dr. Bates reads portions of the Specification and extrapolates (by taking several unsupported leaps) that the ’024 patent “implicitly demands certain parameter measurements.” Sur-reply 7 (citing Ex. 1052, 44:6–20).

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

¹⁴ Although the Parties briefly address the prosecution history of patents related to the ’024 patent, we do not find the discussion thereof informative on this issue.

¹⁵ It appears that Patent Owner intended to cite paragraphs 133–139 of Dr. Bates’s declaration.

¹⁶ Again, it appears that Patent Owner intended to cite paragraphs 133–139 of Dr. Bates’s declaration.

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

For the reasons explained above, we determine that Patent Owner did not implicitly define the phrase “analyzes the data to determine the patient’s breathing patterns,” as proposed, because Patent Owner has failed to show any sufficient evidence that the ’024 patent clearly expresses an intent to redefine the phrase or define the phrase in terms other than its plain and ordinary meaning. In other words, implied lexicography does not apply here. Accordingly, after reviewing Patent Owner’s contentions in light of all the evidence of record, we do not adopt Patent Owner’s proposed construction; instead, we apply the plain and ordinary meaning of “analyzes the data to determine the patient’s breathing patterns” in our consideration of the issues before us.

C. Other Claim Terms

The Parties do not dispute the construction of any other claim terms, and we find that no other terms require express construction to resolve the controversy between the Parties. Accordingly, we do not construe any other claim terms expressly. *See Realtime Data*, 912 F.3d at 1375 (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs.*, 200 F.3d at 803)).

III. ANALYSIS

A. Legal Standards – Obviousness

The United States Supreme Court set forth the framework for applying the statutory language of 35 U.S.C. § 103 in *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966):

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

The Supreme Court explained in *KSR International Co. v. Teleflex Inc.* that

[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (alteration in original))).

“Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1327 (Fed. Cir. 2016) (citations omitted).

“[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan ‘would have had a reasonable expectation of success from doing so.’” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting

In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

B. Ground 1: Obviousness over Sullivan995 and Sullivan460

Petitioner asserts that the combination of Sullivan995 and Sullivan460 would have rendered the subject matter of claims 1–5 and 7–14 obvious to one of ordinary skill in the art at the time of the invention. Pet. 18–52. Patent Owner opposes. PO Resp. 34–45.

1. Scope and Content of the Prior Art

a. Sullivan995 (Ex. 1005)

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

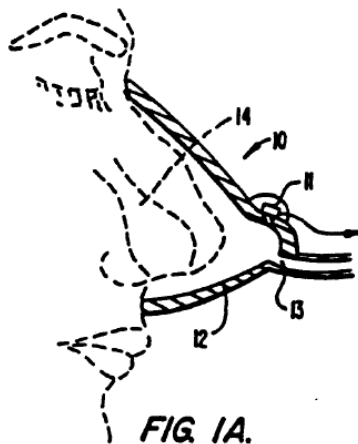


Figure 1A “is a schematic sectional view of one embodiment of a snoring detection apparatus.” *Id.* at 7:66–68. Snoring detection device 10 includes microphone 11 that is “in sound communication with the container 12 of a

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

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

Figure 3 of Sullivan995 is reproduced below.

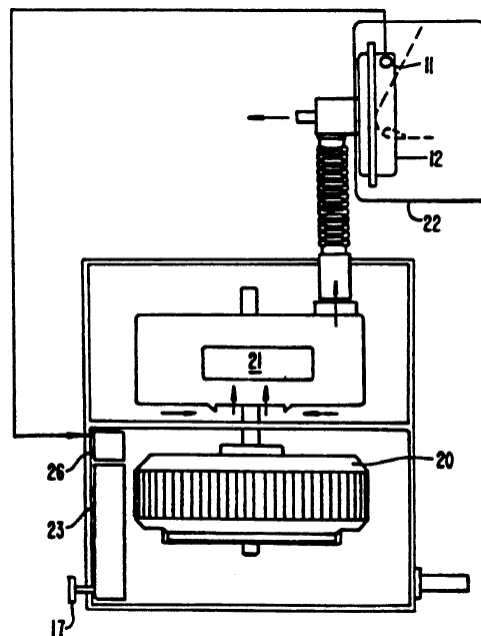


FIG. 3

Figure 3 shows a CPAP apparatus. Ex. 1005, 9:57–58. The CPAP apparatus includes motor 20 that drives blower 21. *Id.* at 9:58–59.

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

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

Id. at 10:3–12.

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

Figure 12 of Sullivan995 is reproduced below.

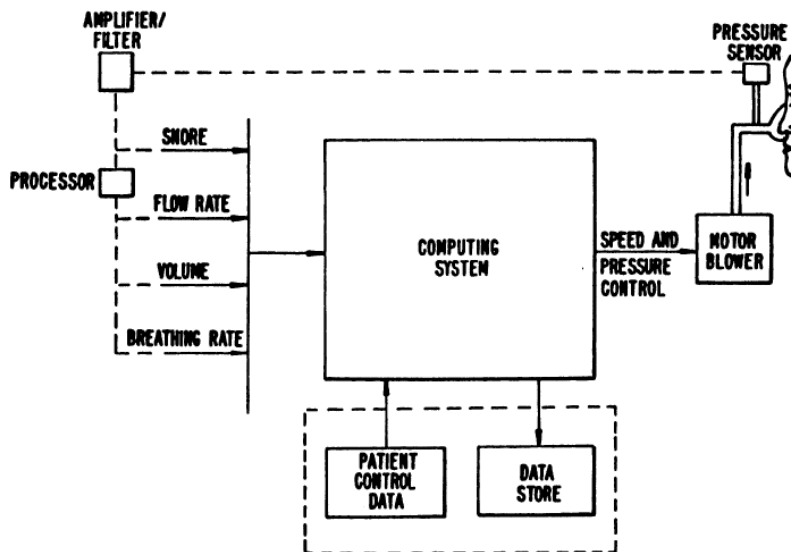


FIG. 12.

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

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

Id. at 17:4–18.

b. Sullivan460 (Ex. 1006)

Sullivan460 is directed to “an apparatus and method for the treatment of an upper airway flow limitation in a patient” and particularly “an

apparatus and method of treating hypertension caused by pre-eclampsia.”

Ex. 1006, 1:5–8.¹⁷ Sullivan460 describes an embodiment in which its “treatment means is a device which applies Continuous Positive Airway Pressure (CPAP), more preferably nasal-Continuous Positive Airway Pressure (nCPAP), to the airway of the patient.” *Id.* at 6:17–20.

Sullivan460 also describes an embodiment in which “the flow rate measurement means and the treatment means may be constructed together as part of one apparatus, such as the AutoSet product from ResMed described in [Sullivan995].”¹⁸ *Id.* at 6:22–24.

Sullivan460 describes two modes of delivery for the treatment means:

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

Ex. 1006, 6:30–7:2. Sullivan460 also describes an embodiment in which “the treatment means may additionally include a sleep sensor which senses whether or not the patient is asleep, and may also include a switching means which responds to the sleep sensor and automatically switches the treatment means between the two modes of air delivery.” *Id.* at 7:3–7. Sullivan460

¹⁷ For consistency with the citation style of the Parties, citations to Sullivan460 are to the native page numbers of the document, and not the page numbers added by Petitioner in the bottom, righthand corner of each page of Exhibit 1006.

¹⁸ Sullivan460 incorporates Sullivan995 by reference. Ex. 1006, 6:24–25.

explains that “[t]his feature is an improvement over the prior art because as soon as the patient goes to sleep (as determined by an appropriate sensing algorithm in the treatment means), the second treatment mode is activated.” *Id.* at 7:10–12.

Figure 2 of Sullivan460 is reproduced below.

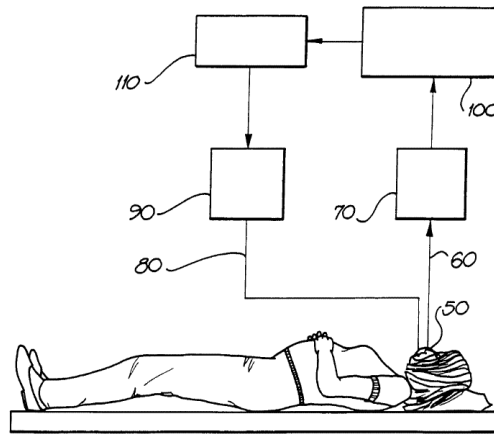


FIG. 2

“Figure 2 shows a patient 30 being treated for hypertension caused by pre-eclampsia.” Ex. 1006, 10:7–8. In Figure 2, patient 30 is lying on bed 40 and wears mask 50 over her nose. *Id.* at 10:8–9. Mask 50 is connected via 80 to nCPAP apparatus 90. *Id.* at 10:9–10. Sullivan460 states that “flow rate measurement means 70 detects the rate at which the patient breathes in air, and generates a signal which is sent to a central controller 100.” *Id.* at 10:10–12. Sullivan460 explains that “[w]hen the flow rate measurement means 70 detects the interruptions to inspiratory flow 10, the controller 100 activates a switch 110 which activates the nCPAP apparatus 90 to supply air to the patient 30 at a pressure which ameliorates or eliminates the upper airway flow limitation for that patient.” *Id.* at 10:12–16.

2. *Differences Between the Prior Art and the Claims*

Petitioner sets forth a detailed analysis showing how the combined teachings of the references meet the elements of claims 1–5 and 7–14. Pet. 21–52. In particular, regarding claim 1, Petitioner relies on Sullivan995 as teaching most of the elements of the claim, but relies, in part, on Sullivan460 for elements 1[e] and 1[f]. *See id.*; *see also id.* at 33–37 (addressing elements 1[e] and 1[f]). Additionally, Petitioner contends that it would have been obvious to one of ordinary skill in the art to combine the teachings of Sullivan995 and Sullivan460 with a reasonable expectation of success. *Id.* at 18–21. Patent Owner challenges Petitioner’s analysis of several limitations of the claims, as well as Petitioner’s arguments regarding motivation to combine and reasonable expectation of success.¹⁹ PO Resp. 34–43. Patent Owner also contends objective indicia of nonobviousness support its position that the claimed invention would not have been obvious. *Id.* at 43–45. We address each argument below.

a. *Claim 1*

i. *Preamble*

The preamble of claim 1 recites “[a] positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient’s airways in order to assist in treating a sleeping disorder in a patient, the positive airway pressure system comprising.” Ex. 1001, 9:49–54. Petitioner

¹⁹ Patent Owner contends “the missing claim limitations [for claim 1] are highlighted in red” (PO Resp. 35–36), but there is no highlighting in Patent Owner’s Response. Nonetheless, we address each of Patent Owner’s arguments below.

contends, “[t]o the extent the preamble is limiting, Sullivan995 discloses this limitation.” Pet. 21 (citing Ex. 1003 ¶¶ 104–106). Petitioner asserts “Sullivan995 discloses a CPAP system (*a positive airway pressure system*) which ‘deliver[s] appropriate airway pressure’ to the patient’s airway passages (*for delivery of a flow of breathable gas*).” *Id.* (alteration in original) (citing Ex. 1005, Fig. 3, code (57), 1:33–36, 2:15–19, 9:57–58). Petitioner contends one of ordinary skill in the art would have understood “CPAP delivers ‘positive’ airway pressure relative to atmospheric pressure (*a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure*).” *Id.* at 22 (citing Ex. 1003 ¶ 104).

Petitioner asserts Sullivan995’s CPAP system includes “nose mask 12” that is “‘fluidly sealable to the [patient’s] nasal air passages’ and is ‘for delivery of air to the patient’s nasal passages’ (*a flow of breathable gas . . . delivered to an entrance of a patient’s airways*).” Pet. 22 (alterations in original) (citing Ex. 1005, claim 6, 5:12–34, 10:67–11:4, 11:23–43). Petitioner contends “[t]his is *in order to assist in treating a sleeping disorder in a patient* by providing air pressure at a certain level to ‘prevent the onset of apnea’ (*sleeping disorder*) in the patient.” *Id.* (citing Ex. 1005, 1:20–31, 1:32–48, 10:31–35, 11:15–20; Ex. 1003 ¶ 106).

Patent Owner does not challenge Petitioner’s analysis and evidence showing that the preamble of claim 1 is met by Sullivan995. *See generally* PO Resp.

We find Petitioner’s arguments persuasive as to the preamble of claim 1 and supported on the complete record before us, and, therefore, we

adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that Sullivan995 teaches the preamble of claim 1.²⁰

ii. Element 1[a]

Element 1[a] recites “a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient.” Ex. 1001, 9:55–57. Petitioner contends Sullivan995 discloses element 1[a]. Pet. 22 (citing Ex. 1003 ¶¶ 107–108). Petitioner asserts “Sullivan995’s CPAP system includes a variable speed motor 20 that drives a blower 21 (*flow generator*).” *Id.* (citing Ex. 1005, 9:57–64). Petitioner contends “blower 21 *supplies a positive treatment pressure flow of breathable gases to be supplied to a patient* by providing pressurized air to the patient.” *Id.* (citing Ex. 1005, 9:60–64; Ex. 1003 ¶¶ 107–108).

Patent Owner does not challenge Petitioner’s analysis and evidence showing that element 1[a] is met by Sullivan995. *See generally* PO Resp.

We find Petitioner’s arguments persuasive as to element 1[a] of claim 1 and supported on the complete record before us, and, therefore, we adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that Sullivan995 teaches element 1[a].

iii. Element 1[b]

Element 1[b] recites “a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient’s breathing patterns.” Ex. 1001, 9:58–

²⁰ We need not determine whether the preamble of claim 1 is limiting because we find, on the present record, that Petitioner has shown it is taught by Sullivan995.

62. Petitioner contends Sullivan995 discloses element 1[b]. Pet. 23 (citing Ex. 1003 ¶¶ 109–120). Petitioner asserts “Sullivan995’s CPAP system includes a differential pressure sensor, e.g., microphone 11 (*flow sensor*),” and that “[t]he microphone ‘consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the *rate of breathing*, inhaled air flow or inhaled *air flow rate*.’” *Id.* (quoting Ex. 1005, 3:21–30, code (57)). Petitioner contends Sullivan995 teaches that detection means 22, including microphone 11, can be located in different places, including “*in a flow path of the positive treatment pressure flow of breathable gases*” (e.g., in a nose mask or located within or attached to a nasal prong device). *Id.* at 24–25 (citing Ex. 1005, Figs. 1A, 1B, 2A, 2B, 8:47–61, 10:1–3; Ex. 1003 ¶¶ 110, 111, 113, 114).

Petitioner asserts “microphone 11 (*flow sensor*) performs a ‘form of measurement’ (*measuring data*) by ‘detecting snoring sounds’ and ‘other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate’ (*indicative of the patient’s breathing patterns*).” Pet. 26 (citing Ex. 1005, 3:21–30, 11:5–20, 15:56–64; Ex. 1003 ¶ 114).

Patent Owner does not challenge Petitioner’s analysis and evidence showing that element 1[b] is met by Sullivan995. *See generally* PO Resp.

We find Petitioner’s arguments persuasive as to element 1[b] of claim 1 and supported on the complete record before us, and, therefore, we adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that Sullivan995 teaches element 1[b].

iv. Elements 1[c]–[f]

We address these elements together because Patent Owner’s arguments appear to touch on different aspects of these elements.

a) *The Petition*

Element 1[c] recites “a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient’s breathing patterns.” Ex. 1001, 9:63–10:2. Petitioner contends Sullivan995 discloses element 1[c]. Pet. 28 (citing Ex. 1003 ¶¶ 121–126). Petitioner asserts “[t]he combination of an amplifier/filter/processor unit 26 and speed control unit 23 (depicted in Figure 3 and described in part as the computing system in Figure 12) is *a processing arrangement*.” *Id.* Petitioner contends “microphone 11 (*flow sensor*) provides its *measured data* to processor unit 26.” *Id.* (citing Ex. 1005, 10:3–6, 10:37–66, 11:55–62). Thus, Petitioner argues “processor unit 26 is part of a *processing arrangement that receives the measured data corresponding to the flow of breathable gases from the flow sensor*.” *Id.* at 29.

Additionally, Petitioner asserts “Sullivan995 describes various *breathing patterns* for the patient.” Pet. 30. Pointing to Figure 4, Petitioner contends “Sullivan995’s *processing arrangement* includes the processor unit 26, ‘which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.’” *Id.* (citing Ex. 1005, 11:55–62). Thus, Petitioner argues that, “[i]n generating this control signal, the processor unit 26 (included in the *processing arrangement*) therefore *analyzes the data [from the flow sensor] to determine the patient’s breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.” *Id.*

Further, Petitioner points to Sullivan995’s computing system, which includes processing unit 26 and speed controller 23, contending the

computing system “‘analyzes and records signals from the pressure sensor,’ and analyzes ‘the sound and breathing patterns’ to record ‘indexes such as the number of apneic episodes, the number of hypopneas, their duration, etc.’” Pet. 30–31 (quoting Ex. 1005, 12:67–13:8 (referencing Fig. 12)). Thus, Petitioner asserts Sullivan995’s “computing system is part of the *processing arrangement* and *analyzes the data [from the flow sensor] to determine the patient’s breathing patterns.*” *Id.* at 31.

Element 1[d] recites “the processing arrangement also determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part on the determined breathing patterns of the patient.” Ex. 1001, 10:2–6. Petitioner contends Sullivan995 discloses element 1[d]. Pet. 31 (citing Ex. 1003 ¶ 127). Petitioner asserts that, as explained for elements 1[b] and 1[c], “Sullivan995 describes various *breathing patterns* for the patient.” *Id.* Petitioner points to Figure 4 contending “Sullivan995’s *processing arrangement* includes the processor unit 26, ‘which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.’” *Id.* (citing Ex. 1005, 11:55–62). Petitioner asserts that, “[i]n generating this control signal, the processor unit 26 (included in the *processing arrangement*) therefore *analyzes the data [from the flow sensor] to determine the patient’s breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.” *Id.*

Additionally, Petitioner points to Figure 12 contending “the computing system (including processing unit 26 and speed controller 23) ‘analyses and records signals from the pressure sensor,’ and analyzes ‘the sound and breathing patterns’ to record ‘indexes such as the number of

apneic episodes, the number of hypopneas, their duration, etc.” Pet. 31 (citing Ex. 1005, 12:67–13:8). Petitioner asserts that, “[i]n response to the electrical signal generated when snoring sounds occur, a motor speed control means ‘increases the speed of the electronic motor 20,’ which ‘increases the blower speed,’ thereby ‘increas[ing] the output air pressure of the blower 21’ (*flow generator*).” *Id.* at 32 (second alteration in original) (citing Ex. 1005, 9:58–64, 10:6–12, 10:40–46). Petitioner contends the “motor speed control means in Sullivan995 is the same as the speed control unit 23 because it controls the speed of the motor and is therefore part of the *processing arrangement*.” *Id.* (citing Ex. 1005, 9:58–64; Ex. 1003 ¶ 128). Petitioner argues “[s]imilarly, ‘in the absence of an electronic signal from the microphone 11,’ meaning the patient is not snoring, Sullivan995’s processor unit 26 ‘achieve[s]’ a decrease in CPAP pressure by ‘continuously gradually reducing the blower speed over a period of time.’” *Id.* (second alteration in original) (citing Ex. 1005, 10:37–46; Ex. 1003 ¶ 128). Petitioner asserts “[i]ncreasing or decreasing the blower speed results i[n] an *alter[ing] [of] the pressure supplied by the blower (flow generator) to the airway of the patient* and is based on ‘when snoring sounds occur.’” *Id.* (citing Ex. 1003 ¶¶ 128–129).

In sum, Petitioner asserts “[t]he determination to increase the output air pressure in Sullivan995 is made when ‘respond[ing] to a snore, or a snore *pattern*,’ and is therefore made *based, at least in part, on the determined breathing patterns of the patient*.” Pet. 32–33 (second alteration in original) (citing Ex. 1005, 10:55–58). Thus, Petitioner argues that

by describing the speed control unit using the signal from the processor unit 26 to determine whether to increase or decrease the pressure, Sullivan995 describes a *processing arrangement*

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

Id. at 33 (citing Pet. §§ VIII.C.3 (addressing element 1[b]), VIII.C.4 (addressing element 1[c])).

Element 1[e] recites “wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state.”

Ex. 1001, 10:6–10. Petitioner contends “Sullivan995 renders this limitation obvious either alone or in view of Sullivan460.” Pet. 33 (citing Ex. 1003

¶ 140). Petitioner asserts the following

Sullivan995 discloses *the processing arrangement automatically delays the onset of a pressure increase to the patient* until a snore is detected, meaning the patient has fallen asleep. Specifically, “the output pressure of the CPAP unit increases in response to detection of snoring.” EX1005, 10:10-12, Fig. 3; *see also* 14:17-20, Fig. 13. Also, the pressure is decreased “if an extended period of snore free breathing occurs” by “automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected.” *Id.*, 10:31-47; *see also* Fig. 13. Put simply, because the pressure is reduced automatically in the absence of snoring and is increased in response to snore detection, *the processing arrangement automatically delays the onset of a patient increase to the patient* until snoring is detected. *See also id.* 10:47-61 (it is only “some time after going to sleep [when] the patient’s body relaxes, [and] the airway start[s] to become unstable and the patient start[s] to snore,” and the CPAP pressure increases “via the processor 26,” in response to the “snore, or snore pattern.”).

Pet. 33–34 (alterations in original). Petitioner acknowledges that,

“[a]lthough the patient is awake when he ‘connects himself to the CPAP unit’ when ‘[t]he CPAP pressure is initially at a minimum operating value’ (*id.*, 10:47-58), Sullivan995 does not explicitly disclose that the delay occurs

when the processing arrangement determines that the patient is in an awake state.” *Id.* at 34 (citing Ex. 1003 ¶ 144). Nonetheless, Petitioner asserts “this limitation would have been obvious from Sullivan995 in view of Sullivan460.” *Id.* (citing Ex. 1003 ¶ 144).

Turning to Sullivan460, Petitioner explains “Sullivan460 incorporates Sullivan995 by reference and refers to Sullivan995 as describing a ‘flow rate measurement means and [a] treatment means [as being] constructed together as part of one apparatus.’” Pet. 34 (citing Ex. 1006, 6:22–29). Petitioner asserts that, “[l]ike Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep.” *Id.* (citing Ex. 1006, 6:17–29, 7:3–12, 10:9–33, 11:10–12, claims 22–28, 43–46, Figs. 2–4; Ex. 1003 ¶ 145).

Petitioner contends the following regarding Sullivan460:

Sullivan460 discloses *determin[ing] that the patient is in an awake state* by describing embodiments in which “a sleep sensor [] senses whether or not the patient is asleep” by determining “when there is a reduced average airflow in the patient’s upper airway.” EX1006, 7:3-7, 7:10-12, 7:17-19; [Ex. 1003] ¶146. According to Sullivan460, “a switching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery,” where “a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep,” where the pressure for the second mode is higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46. Because Sullivan460 only enters the higher-pressure second mode when the patient is asleep, Sullivan460 discloses *automatically delay[ing] the onset of a pressure increase to the*

patient upon a determin[ation] that the patient is in an awake state. [Ex. 1003] ¶146.

Pet. 34–35 (second and final alterations added)).²¹

Element 1[f] recites “wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.” Ex. 1001, 10:10–12. Petitioner contends “Sullivan995 alone or in view of Sullivan460 discloses this limitation.” Pet. 35 (citing Ex. 1003 ¶ 148). Pointing to Sullivan995, Petitioner asserts it “delays the onset of a pressure increase to the patient until after a snore is detected” and one of ordinary skill in the art “would have readily understood, because the patient only begins snoring after *the patient is in an asleep state*, this means that Sullivan995 ensures *the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.*” *Id.* at 35–36 (citing Ex. 1003 ¶ 148). Petitioner contends that, “[t]o the extent this limitation is not explicitly disclosed in Sullivan995, the modified CPAP system taught by Sullivan995 in view of Sullivan460 would have rendered this limitation obvious.” *Id.* at 36.

Turning to Sullivan460, Petitioner asserts it “discloses a sleep detection technique based on detection of ‘reduced average airflow,’ and it would have been obvious to use Sullivan460’s sleep detection technique with the modified CPAP system for detecting an asleep state. Pet. 36 (citing Pet. §§ VIII.A (addressing motivation to combine), VIII.B (addressing reasonable expectation of success)). Petitioner contends “Sullivan460’s

²¹ We address motivation to combine and reasonable expectation of success following our discussion of the claim elements and the Parties’ arguments directed thereto.

awake/asleep determination technique based on ‘reduced average airflow’ would have been easily used in Sullivan995’s CPAP system, especially given Sullivan995’s use of a flow sensor to sense and analyze air flow rate.” *Id.* (citing Ex. 1005, Figs. 10–12, 6:54–68; Ex. 1003 ¶ 150).

Petitioner asserts “[t]he modified CPAP system ‘is an improvement over the prior art because as soon as the patient goes to sleep . . . , the second treatment mode [increased pressure] is activated.’” Pet. 36 (second and third alterations in original) (quoting Ex. 1006, 7:10–12). Petitioner thus contends “the modified CPAP system changes from a low pressure to a higher pressure when an asleep state is detected, meaning that *the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.*” *Id.* (citing Ex. 1006, 6:30–7:22, 10:7–16, 14:7–36, claims 22–31).

b) Patent Owner’s Response

Patent Owner first asserts “Sullivan995 discloses none of the limitations identified by Petitioner.” PO Resp. 38 (citing Ex. 2006 ¶¶ 148–187²²). Specifically Patent Owner asserts that Sullivan995 “does not teach how to distinguish between asleep and awake states because”: (1) “it does not have the signal processing necessary to do so”; (2) “does not have complete waveforms”; and (3) “only considers breathing parameters related to averages, which are aspects of the amplitude structure only, which cannot

²² To the extent Patent Owner seeks to import arguments from *forty paragraphs* of Dr. Bates’s declaration that are not included in Patent Owner’s Response, that attempt is rejected because incorporation by reference is not permitted under our Rules. 37 C.F.R. § 42.6(a)(3). We address the arguments specifically raised in Patent Owner’s Response.

determine i[f] a patient is asleep.” *Id.* (citing Ex. 2006 ¶¶ 149–155). Patent Owner explains “Sullivan995 also does not disclose these limitations because a snoring pattern is not a breathing pattern as described in the ’024 Patent.” *Id.* (citing Ex. 2006 ¶ 156; Ex. 1001, Figs. 3–8; Ex. 2012, 73:20–22). Patent Owner contends “[b]reathing patterns are used to determine if a subject is awake or asleep, which is something that Sull[iv]an995 does not teach.” *Id.* (citing Ex. 2006 ¶ 155). Patent Owner asserts “snore,” “flow rate,” “breathing rate,” “time interval,” and “volume” data in Sullivan995 “are all single parameters which, by themselves, do not constitute a breathing pattern; these parameters are all aspects of the amplitude structure of a breath-by-breath parameter time series and cannot on their own provide the ability to determine an awake state versus an asleep state.” *Id.* at 39 (citing Ex. 2006 ¶ 156, 167–168).

Turning to Sullivan460, Patent Owner contends “Sullivan460 does not teach how to detect an awake state versus an asleep state, because the Sullivan460 sleep sensor cannot reliably sense that the patient is not asleep.” PO Resp. 39 (citing Ex. 2006 ¶ 169). Patent Owner asserts that Sullivan460’s sleep detection technique, “which is based on detection of ‘reduced average airflow[,]’ is flawed because detecting an awake state versus an asleep state as claimed requires analysis of both the amplitude and temporal structures of a time series composed of breath-by-breath parameters derived from the flow waveform.” *Id.* (citing Ex. 2006 ¶ 173). In contrast, Patent Owner contends “Sullivan460 discloses only the analysis of the amplitude structure of the time series, i.e., how to make decisions based on average flow.” *Id.* (citing Ex. 2006 ¶ 173; Ex. 1006, 7:18–19).

Referring again to Sullivan995, Patent Owner asserts it “cannot switch from a low pressure to a higher pressure upon detection of an asleep state because it only teaches the analysis of snoring sounds which are not breathing patterns, and the analysis of pressure oscillations during inspiration typical of eclampsia in terms of events taking place within a single breath.” PO Resp. 40 (citing Ex. 2006 ¶ 174). Thus, Patent Owner argues “[t]hese do not teach how to determine an awake state versus an asleep state as claimed.” *Id.* (citing Ex. 2006 ¶ 174).

c) Discussion

We find that Petitioner establishes that the combination of Sullivan995 and Sullivan460 satisfies elements 1[c]–1[f] of claim 1, including Petitioner’s reliance on Sullivan460 in the context of elements 1[e] and 1[f]. Petitioner sets forth a compelling and detailed analysis, as reflected above, which we agree with for the reasons explained by Petitioner. In this discussion, we focus on Patent Owner’s arguments and explain why they do not identify a deficiency in Petitioner’s analysis.

First, Patent Owner’s arguments are substantially based on its proposed construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt for the reasons expressed above. Thus, we disagree with Patent Owner’s arguments attacking Sullivan995 and Sullivan460 based on their alleged focus on amplitude structure. *See* PO Resp. 38–39; *see also* Pet. Reply 11 (noting that Patent Owner’s arguments are based on its proposed claim construction).

Second, we disagree with Patent Owner’s argument that a snoring pattern is not a breathing pattern. PO Resp. 38. Patent Owner’s argument in this regard, focuses not on what a breathing pattern is but rather what it

contends a “breathing pattern[] [is] used” for. *See id.* (asserting a snoring pattern is not a breathing pattern because “[b]reathing patterns are used to determine if a subject is awake or asleep, which is something that Sullivan995 does not teach”). Patent Owner’s argument is again based on its proposed construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt for the same reasons expressed above.

Third, Sullivan460 explicitly discloses “a sleep sensor which senses whether or not the patient is asleep.” Ex. 1006, 7:4. Thus, Patent Owner’s arguments regarding whether Sullivan460 teaches determining an awake state versus an asleep state are directly contrary to Sullivan460’s express teaching, and we do not agree with those arguments. Additionally, Sullivan460 teaches that its sleep sensor can “register that a patient is asleep when there is a reduced average airflow in the patient’s upper airway.” *Id.* at 7:17–19. We agree with Petitioner that the ’024 patent uses “low flow rate” as one indicator of REM sleep. *See* Pet. Reply 11.

Fourth, we agree with Petitioner that Patent Owner effectively “concedes (as it must) that Sullivan995 in view of Sullivan460 ‘analy[zes] the breathing pattern’ according to its plain meaning, to determine asleep versus awake states.” Pet. Reply 12. Specifically, as Petitioner explains, Patent Owner acknowledges that Sullivan460 teaches “analysis of the amplitude structure of the time series”—“mean values of flow . . . in determining sleep versus awake and reduces CPAP when mean airflow increases (i.e., when the patient is awake).” *Id.* (alteration in original) (citing PO Resp. 39, 50; Ex. 1051 ¶¶ 37–39). We further agree with Petitioner that Patent Owner “thus admits that the combination analyzes breathing patterns

to determine asleep versus awake state” based on Patent Owner’s statement that “Sullivan460 identifies awake versus sleep only on the basis of average flow, . . . which is an aspect of the amplitude structure of a time series.” *Id.* (quoting PO Resp. 42).

Fifth, Patent Owner’s arguments in its Sur-reply reiterate several of the arguments from the Patent Owner Response and are dependent upon Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing,” which we do not adopt. *See* Sur-reply 16–18 (discussing snoring sounds, temporal analysis, and the alleged requirement of analyzing amplitude structure and temporal structure). Thus, we disagree with those arguments raised by Patent Owner for the reasons explained above.

Accordingly, for the reasons explained above, we find Petitioner has shown that the combination of Sullivan995 and Sullivan460 satisfies elements 1[c]–1[f] of claim 1.

b. Claims 2–5 and 7–14

Claims 2–5 and 7–14 depend, directly or indirectly, from claim 1. Petitioner sets forth a detailed analysis showing how the combined teachings of the references meet the elements of claims 2–5 and 7–14. Pet. 37–52.

Patent Owner does not raise additional argument challenging Petitioner’s analysis and evidence directed to these claims, in its Patent Owner Response,²³ aside from the arguments raised regarding claim 1. *See generally* PO Resp.

²³ Patent Owner states “Petitioner further argues that dependent claims 2–5 and 7–14 are likewise obvious; Petitioner fails for the reasons stated above, and for the additional reasons explained by Dr. Bates. PO Resp. 44–45

We find Petitioner’s arguments persuasive as to claims 2–5 and 7–14 and supported on the complete record before us, and, therefore, we adopt them as our own findings. Accordingly, for the reasons explained by Petitioner, we find that the combination of Sullivan995 and Sullivan460 satisfies the subject matter of claims 2–5 and 7–14.

3. *Motivation to Combine and
Reasonable Expectation of Success*

Petitioner contends one of ordinary skill in the art would have been motivated to modify Sullivan995 “so that the *processing arrangement in Sullivan995 determines that the patient is in an awake state, and in response, automatically delays the onset of a pressure increase to the patient*, as taught in Sullivan460.” Pet. 18 (citing Ex. 1003 ¶¶ 94–103). Petitioner asserts the modification would “cause Sullivan995’s CPAP system to apply a lower pressure or higher pressure upon detecting the patient’s awake state or asleep state, respectively.” *Id.*

Petitioner asserts one of ordinary skill in the art “would have recognized the advantages of using the same CPAP system to treat sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught

(citing Ex. 2006 ¶¶ 178–204). Our Rules do not permit incorporating arguments by reference from one document into another. 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”). Additionally, Patent Owner was expressly informed that “**any arguments not raised in the response may be deemed waived.**” Paper 16 (Scheduling Order), 9. Thus, to the extent Dr. Bates raises additional arguments in response to Petitioner’s challenge to these dependent claims, we do not consider those arguments, and instead we find those arguments waived by virtue of Patent Owner not expressly stating them in its Patent Owner Response.

in Sullivan460.” Pet. 18 (citing Ex. 1006, 7:3–12; Ex. 1003 ¶ 96).

Petitioner contends “[t]he modification to Sullivan995’s CPAP system would allow for detection of inaudible low frequency vibrations, including those associated with pre-eclampsia, so that the patient may be treated with high pressure.” *Id.* at 18–19 (citing Ex. 1006, 2:19–22, 4:33–34, 6:3–7:2, 9:31–10:6). And Petitioner argues “Sullivan995 even suggests that such modifications would be desirable, as its CPAP system is not limited to treating apnea and snoring, but also appl[ies] to other upper airway disorders, including pre-eclampsia.” *Id.* at 19 (citing Ex. 1005, 1:14–31, 4:36–45).

Additionally, Petitioner contends one of ordinary skill in the art “would have recognized that the modification is advantageous” and would “improve[] patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks,” because “[t]he modified CPAP system would apply a low pressure upon wake-up, adding to patient comfort and decreasing the likelihood the patient will remove the mask.” Pet. 19. Petitioner asserts “Sullivan995 suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (e.g., including an awake period). *Id.* (citing Ex. 1005, 10:13–46, 14:45–64). Petitioner also contends Sullivan995 “partially solves the problem” of “therapy pressure . . . [being] delivered at levels higher than necessary for substantial periods, causing discomfort,” “by reducing the pressure at the beginning of therapy.” *Id.* (citing Ex. 1005, 4:21–25; Ex. 1003 ¶ 99).²⁴

²⁴ In the context of element 1[e], Petitioner also provides an additional advantage that it contends would have been recognized by one of ordinary

In its discussion of reasonable expectation of success, Petitioner critically recognizes that “Sullivan460 expressly states that Sullivan995 may be modified to include features of Sullivan460, such as ‘sens[ing] an upper airway flow limitation characteri[z]ed by at least one decrease in upper airway inspiratory flow rate followed by at least one increase in flow rate.’” Pet. 19–20 (quoting Ex. 1006, 6:26–29). Petitioner asserts one of ordinary skill in the art “would have had a reasonable expectation of success in performing this modification because Sullivan460 already describes Sullivan995 as being used to sense flow limitations, and Sullivan460 further explains that flow data may be used to determine an awake/sleep state.” *Id.* at 20 (citing Ex. 1003 ¶¶ 100, 102).

Additionally, in further support of reasonable expectation of success, Petitioner points to many similarities between Sullivan995 and Sullivan460, which we agree with although we do not repeat here. *See* Pet. 20–21 (citing Ex. 1006, 10:10–12, Figs. 1–2, 9:31–34, 10:3–16). Petitioner asserts that “[g]iven the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements

skill in the art and would have provided additional motivation for modifying Sullivan995 with Sullivan460. Specifically, Petitioner contends that “the modification would have resulted in higher therapeutic pressure being permitted as soon as the patient goes to sleep,” which is an advantage because without such sleep detection, the CPAP system may activate a higher pressure either “(1) too early, so that the higher pressure is activated when the patient is still awake and causes discomfort, or (2) too late, so that the higher pressure is activated well after the patient has fallen asleep and may have already experienced apneic episodes at the lower pressure.” Pet. 37 (citing Ex. 1003 ¶ 153). Petitioner asserts “Sullivan460 solved that problem, which would have been a significant benefit for a patient using Sullivan995’s CPAP system.” *Id.* (citing Ex. 1003 ¶ 154).

according to known methods and techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.” *Id.* at 21.

Patent Owner challenges Petitioner’s motivation to combine and reasonable expectation of success based entirely on its proposed construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt. *See* PO Resp. 41–43. For example, Patent Owner argues “[t]here is no motivation to combine the teachings of Sullivan995 and Sullivan460 because these references do not teach how to detect an awake state versus an asleep state *as claimed*.” *Id.* at 41 (emphasis added). Patent Owner then continues to describe its proposed claim construction and its alleged requirement to analyze “both the amplitude and temporal structures of a time series,” asserting Sullivan995 and Sullivan460 “disclose only the analysis of the amplitude structure of the time series.” *Id.* (citing Ex. 1005, 6:62, 6:65; Ex. 1006, 7:18–19). Patent Owner’s argument in opposition to Petitioner’s showing on reasonable expectation of success also is based on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns.” *See id.* at 42 (“Sullivan460 cannot distinguish between awake and asleep states in accordance with the *claimed analysis/determination* of breathing patterns *because Sullivan460 does not consider both the amplitude and temporal structures* of a time series composed of breath-by-breath parameters derived from the flow waveform.” (emphases added)).

We disagree with Patent Owner’s arguments for several reasons. First, as noted above, we do not adopt Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns.”

Second, the combination proposed by Petitioner presents the rare case where the combination is described explicitly in one of the references itself. In other words, at least part of the motivation to combine comes *directly* from Sullivan460. And, Sullivan460 *expressly incorporates Sullivan995 by reference*. Ex. 1006, 6:22–25 (“[T]he flow rate measurement means and the treatment means may be constructed together as part of one apparatus, such as the AutoSet product from ResMed described in US Patent No 5245995 [i.e., Sullivan995], the contents of which are incorporated herein by reference.”).

Third, contrary to Patent Owner’s argument regarding whether Sullivan460 can distinguish between awake and asleep states, Sullivan460 *expressly states* that it can and does: “In another embodiment, the treatment means may additionally *include a sleep sensor which senses whether or not the patient is asleep*, and may also include a switching means which responds to the sleep sensor and automatically switches the treatment means between the two modes of air delivery.” Ex. 1006, 7:3–7 (emphasis added). And, Sullivan460 also *expressly states* that when the patient “goes to sleep (as determined by an appropriate sensing algorithm in the treatment means), the second treatment mode is activated” (*id.* at 7:10–12), where the second treatment mode “provides a relatively greater air and pressure delivery to the patient than in the first mode, which is sufficient to treat an air flow limitation” (*id.* at 6:30–7:2). Thus, we disagree with Patent Owner’s argument that Sullivan460 cannot distinguish between an awake state and an asleep state because Sullivan460 expressly states that it can and does.

Fourth, we also find that Petitioner has established that one of ordinary skill in the art would have had a reasonable expectation of success

in achieving the combination proposed. As noted above, Sullivan460 expressly states how to combine Sullivan995. And we find Petitioner’s argument persuasive and supported on the record that “[g]iven the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements according to known methods and techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.”²⁵ Pet. 21.

In its Sur-reply, Patent Owner asserts “[t]here is no motivation to combine Sullivan460 with any reference because Sullivan460 is not enabling.” Sur-reply 19–20. Specifically, Patent Owner asserts that one of ordinary skill in the art would not understand how to determine the preset flow rate in Sullivan460.²⁶ *Id.*

We disagree. As Petitioner correctly explains, enablement “is not a requirement to prove invalidity under §103.” Pet. 15 (citing *Amgen*, 314 F.3d at 1313 (Under §103, “a reference need not be enabled; it qualifies as a

²⁵ We disagree with Patent Owner’s one sentence argument contesting Petitioner’s statement (*see* PO Resp. 42–43) because Petitioner’s analysis is supported on the complete record for the reasons explained by Petitioner.

²⁶ Patent Owner raises a new argument in its Sur-reply that combining the teachings of Sullivan995 and Sullivan460 would require “undue experimentation.” Sur-reply 20 (“Since these prior art references lack essential elements, combining them to result in the ’024 Patent’s invention requires undue experimentation, because analyzing both amplitude and temporal structures to determine asleep/awake states was simply not known.”). Aside from the issues pertaining to Patent Owner raising the argument for the first time in its Sur-reply, we disagree with Patent Owner’s argument because, again, it is based on its proposed claim construction for “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt for the reasons discussed above.

prior art, regardless, for whatever is disclosed therein.”)). Moreover, we agree with Petitioner that the Challenged Claims do not require any preset level for a flow rate, and a person of ordinary skill “would have understood that a preset level is established from previously-acquired data or data from a previous window of time, such as an average level, for example, as taught in Sullivan995.” Pet. Reply 15 (citing Ex. 1005, 17:3–27, Fig. 12; Ex. 2015, 38:2–16). Additionally, Sullivan995 discloses that the computing system may “calculate control values of patterns for each patient based on moving average values or such values or patterns will be pre-programmed into the computing system.” Ex. 1005, 17:14–18. According to Sullivan995, when “signals deviate from predetermined values or patterns the computer system generates a signal which is sent to the feedback speed controller on the blower motor.” *Id.* at 17:19–22. Based on this disclosure, and given that Sullivan460 incorporates Sullivan995 by reference, we agree with Petitioner that Sullivan460’s disclosure of “detect[ing] that the flow rate has fallen below a present²⁷ [sic] level,” would have informed a person of ordinary skill that this level was predetermined, so that “the controller 100 activates the nCPAP apparatus 90 to supply air to the patient 30 at a pressure which ameliorates or eliminates the upper airway flow limitation.” Ex. 1006, 11:10–13 (footnote added).

Inexplicably, Patent Owner also contends one of ordinary skill in the art “would not have readily recognized that Sullivan995 and Sullivan460 are

²⁷ Sullivan460 refers to a “present level,” which we understand in the full context of the paragraph was a typographical error intended to be “preset level.” *See, e.g.*, Ex. 1006, 10:21–24 (stating that “[w]hen the flow rate measurement means 70 detects that the flow rate increases above the preset level, the controller activates the switch”).

analogous art.” PO Resp. 42 (citing Ex. 2006 ¶ 147). Patent Owner’s reason for this alleged lack of recognition is because “Sullivan460 identifies awake versus asleep only on the basis of average flow . . . which is an aspect of the amplitude structure of a time series.” *Id.* (citing Ex. 2006 ¶ 147).

We disagree with Patent Owner’s argument. Two separate tests are used to define the scope of analogous art: “(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *Netflix, Inc. v. DivX, LLC*, 80 F.4th 1352, 1358 (Fed. Cir. 2023) (citations omitted). As Petitioner explains, Sullivan995 and Sullivan460 are analogous art. Pet. 20. At a minimum, Sullivan995 and Sullivan460 are each in the same field of endeavor as the ’024 patent as each is directed to “CPAP systems that include flow sensors and generators” as Petitioner contends. *Id.* Thus, we disagree with Patent Owner’s argument that Sullivan995 and Sullivan460 are not analogous art to the ’024 patent.

As reflected above, Petitioner’s analysis is persuasive and fully supported on the complete record before us, and we disagree with Patent Owner’s arguments for the reasons explained above. On the complete record, for the reasons discussed above as well as the reasons articulated by Petitioner, which we adopt as our own, we find that Petitioner has established that one of ordinary skill in the art would have had reasons with rational underpinning to combine the teachings of Sullivan995 and

Sullivan460 as proposed by Petitioner and would have had a reasonable expectation of success in so doing.²⁸

4. *Objective Indicia of Nonobviousness*

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

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

²⁸ To the extent Patent Owner’s briefing could be interpreted as raising additional arguments contesting these issues (especially based on Patent Owner’s citations to Dr. Bates’s declaration, which could be interpreted as seeking to incorporate additional arguments by reference although prohibited by our Rules), we find Petitioner’s arguments (in the Petition and Reply) persuasive for the reasons explained by Petitioner and adopt them as our own findings.

The claimed invention realized the importance of applying a lower CPAP pressure in order to improve patients' compliance with CPAP treatment by noting that "the conventional PAP therapy [had] not taken sleep/wake state into account" and "[i]ncreasing the comfort of the PAP system has been a major goal of research aimed at improving patient compliance with the PAP therapy." '994 Patent, 1:44-46, 1:64-65. Further, before the development of the claimed invention in the '024 Patent, self-adjusting CPAP machines could not self-adjust upon a determination that the patient was in the troubled wakefulness state. *Id.* at 2:31-35. In fact, as of 2002, a [person of ordinary skill in the art] was "not aware of any prior art device which is able to monitor and diagnose a comprehensive range of both sleep and respiratory parameters." *See* EX2015, at 2:33-37. As such, the claimed invention solved a long felt but unresolved need – better compliance with CPAP therapy – by allowing for CPAP machines to detect the troubled wakefulness state, and adjust the pressure as needed.

Id. at 44 (first two alterations in original).

Patent Owner further argues that conventional CPAP treatment "had not considered asleep/awake states, underscoring the long-felt need to optimize CPAP control." Sur-reply 25 (citing Ex. 1001, 2:18–21; Ex. 1053, 296:22–25, 297:1–15). According to Patent Owner, Dr. Bates's testimony explained that "[w]ithout recognizing the troubled wakefulness and REM breathing patterns, professionals risked confusing awake and asleep states." *Id.* at 25–26 (citing Ex. 1052, 113:3–11, 115:22–25, 116:1–10). Patent Owner contends that the long-felt need for improved CPAP therapy is addressed by the '024 patent's "ability to distinctly identify when a patient is awake or asleep," because a person of ordinary skill in the art "prior to the 994 series of patents, would have been unaware . . . that the sleep sensor was, in fact, unable to unambiguously discriminate between sleep and

awake.” *Id.* at 26 (alteration in original) (citing Ex. 1052, 202:23–25, 203:1–3).

a. Nexus

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

The Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 32–33 (PTAB Jan. 24, 2020) (precedential), *aff’d sub nom. Zaxcom, Inc. v. Lectrosonics, Inc.*, 2022 WL 499848 (Fed. Cir. Feb. 18, 2022). We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* at 32. If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is

the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 33 (quoting *Fox Factory*, 944 F.3d at 1373–75). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *Id.* (citing *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011)). There is no requirement that the objective evidence of non-obviousness be tied exclusively to claim elements that are not disclosed in the prior art, and the claimed combination as a whole may serve as a nexus for the objective evidence. *Id.* (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)).

Petitioner argues that “for secondary considerations to be accorded substantial weight, [Patent Owner] bears the burden of showing that a nexus exists between the claimed features of the invention and the evidence offered to show non-obviousness.” Pet. Reply 25 (citing *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). According to Petitioner, Patent Owner does not meet this burden because: 1) Patent Owner did not establish “a presumption of nexus” since Patent Owner did not identify any product tied to the objective evidence; 2) Patent Owner did not “demonstrate a nexus by showing that long-felt need was met as a ‘direct result of the unique characteristics of the claimed invention’”; 3) Patent Owner did not identify “any failed efforts to solve the problem before the invention”; and 4) Patent Owner does not point to disclosure in the ’024 patent that the “prior art recognized the need to analyze temporal and amplitude structures.” *Id.* at 25–27 (citations omitted).

First, Patent Owner has not argued that the presumption of nexus applies, and we agree with Petitioner that Patent Owner is not entitled to a

presumption of nexus because Patent Owner has not identified any product, let alone a product that is coextensive with any of the Challenged Claims. Second, we address Patent Owner's evidence of long-felt but unresolved need, with the assumption that Patent Owner has established some degree of nexus to the claimed system of the '024 patent, absent the presumption.

b. Long-felt but Unmet Need

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

Here, Patent Owner suggests increasing the comfort of the PAP system is a goal to improve patient compliance with PAP therapy. Patent Owner does not explain, however, why Sullivan⁴⁶⁰'s treatment means which "addresses ... the comfort of CPAP," and "is an improvement over the prior art" because of the two modes of air delivery, does not meet the long-felt need identified by Patent Owner. *See* Ex. 1007, 7:7–16; *see also* Pet. Reply 25–26. Thus, we agree with Petitioner that "[t]o the extent that any need existed, it was already satisfied," especially in light of the proper construction of "analyzes the data to determine the patient's breathing patterns." Pet. Reply 26 (citations omitted).

Additionally, Patent Owner's Response fails to identify any failed efforts to solve the problem before the invention and similarly fails to provide sufficient evidence that the '024 patent satisfied the alleged need.

Dr. Bates’s redirect testimony, which Patent Owner almost exclusively relies on for support in its Sur-reply, fails to provide the underlying facts or data on which his opinion is based and therefore is entitled to “little or no weight.” 37 C.F.R. § 42.65(a). Patent Owner’s additional arguments regarding a supposed need for better compliance with CPAP therapy by detecting troubled wakefulness (*see* PO Resp. 44; Sur-reply 25–26) are only commensurate in scope with dependent claim 6 (which is the only claim that expressly recites troubled wakefulness and is discussed in Ground 2 below). Nonetheless, even assuming Patent Owner’s argument is commensurate in scope with each of the Challenged Claims, Patent Owner’s argument still suffers from the other deficiencies identified above, particularly the failure by Patent Owner to show that the ’024 patent satisfied the alleged need.

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

c. Collective Considerations of the Graham Factors

“Once all relevant facts are found, the ultimate legal determination [of obviousness or nonobviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat*, 876 F.3d at 1361. Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 teaches each limitation of claims 1–5 and 7–14 of the ’024 patent, that a person of ordinary skill in the art would have had reasons with rational underpinning to combine features

of Sullivan995 and Sullivan460 and would have had a reasonable expectation of success in so doing, and that Petitioner’s evidence of unpatentability significantly outweighs the marginal evidence of long-felt but unmet need provided by Patent Owner.

On the whole and considering the *Graham* factors collectively, Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995 and Sullivan460 would have rendered the subject matter of claims 1–5 and 7–14 of the ’024 patent obvious to one of ordinary skill in the art at the time of the invention.

C. Ground 2: Obviousness over Sullivan995, Sullivan460, and Matthews

Petitioner asserts that the combination of Sullivan995, Sullivan460, and Matthews would have rendered the subject matter of claim 6 obvious to one of ordinary skill in the art at the time of the invention. Pet. 52–55. Patent Owner opposes. PO Resp. 45–48.

1. Scope and Content of the Prior Art

a. Matthews (Ex. 1007)

Matthews is titled “Auto-Titration Pressure Support System and Method of Using Same.” Ex. 1007, code (54). Matthews is directed to “an auto-titration pressure support system and to a method of automatically titrating a pressure support system to optimize the pressure delivered to the patient to treat the disordered breathing while otherwise minimizing the delivered pressure for patient comfort.” *Id.* at 1:18–22. Matthews describes an auto-CPAP control layer that has a general goal of inducing slow pressure ramps or to provide a pressure hold period (i.e., a therapy pressure). *Id.* at 25:26–29. Matthews explains that “[t]he patient’s response to these pressure

changes and to the therapy pressure is evaluated by monitoring certain parameters associated with the flow waveform to determine whether the patient flow waveform is improving, degrading, or showing no change.” Matthews further states that “[w]hen a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable” and “[i]t is, therefore, important to interrupt the auto-CPAP controller if the patient's breathing pattern becomes too variable.” *Id.* at 21:37–42.

2. *Differences Between the Prior Art and Claim 6*

Claim 6 depends from claim 1 and recites “wherein the awake state is a troubled wakefulness state.” Ex. 1001, 10:32–33. Petitioner contends that Matthews “discloses *determining whether a breathing pattern is indicative of a troubled wakefulness state.*” Pet. 54 (citing Ex. 1003 ¶ 215). Specifically, Petitioner contends “Matthews recognizes that ‘[w]hen a patient is awake . . . or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable.’” *Id.* at 55 (alterations in original) (quoting Ex. 1007, 21:37–40). To address potential instability, Petitioner asserts “Matthews discloses ‘a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing.’” *Id.* (quoting Ex. 1007, 40:25–30). Petitioner contends “[t]he breathing control layer ‘performs statistical analysis on the scatter of the trended weighted peak flow data to detect unstable breathing patterns or abrupt changes in patient response,’ similar to those found in Figure 7” of the ’024 patent. *Id.* Thus, Petitioner argues “Matthews’s disclosure of monitoring and detecting erratic or irregular breathing, meets the

determining whether a breathing pattern is indicative of a troubled wakefulness state claim limitation.” *Id.* (citing Ex. 1003 ¶¶ 217–218).

Patent Owner first challenges whether Sullivan995 and Sullivan460 teach the subject matter of claim 6. PO Resp. 45–46 (citations omitted). Turning to Matthews, Patent Owner asserts Matthews does not teach determining that a patient has transitioned to a troubled wakefulness state from an asleep state because Matthews (and Sullivan995 and Sullivan460) “disclose only the analysis of the amplitude structure of the time series, i.e., how to make decisions based on mean values derived from inspiratory flow within a single breath and the standard deviation of such quantities.” *Id.* at 46 (citing Ex. 2006 ¶ 215).

We disagree with Patent Owner’s argument directed to Matthews because it too is based on Patent Owner’s proposed construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not adopt for the reasons explained above. Patent Owner’s additional arguments in response to Ground 2 are directed to motivation to combine, reasonable expectation of success, and objective indicia of nonobviousness, which we address below. For the reasons discussed above, we find Petitioner’s arguments persuasive as to claim 6 and supported on the complete record before us. Accordingly, we find that the combination of Sullivan995, Sullivan460, and Matthews satisfies the subject matter of claim 6.

3. *Motivation to Combine and Reasonable Expectation of Success*

We address Petitioner’s arguments regarding the combination of Sullivan995 and Sullivan460 above. Petitioner provides further argument

regarding motivation to combine Sullivan995 and Sullivan460 with Matthews, which we now address. In particular, Petitioner contends it would have been obvious to one of ordinary skill in the art “to modify the system of Sullivan995 and Sullivan460 in view of Matthews so that the *awake state is a troubled wakefulness state.*” Pet. 52 (citing Ex. 1003 ¶¶ 209–213). Petitioner asserts one of ordinary skill in the art “would have been motivated to implemented this modification to cause Sullivan995’s modified CPAP system to *lower[] the pressure* upon detecting the patient’s *troubled wakefulness state.*” *Id.* (alteration in original) (citing Ex. 1003 ¶¶ 209–210).

Petitioner contends one of ordinary skill in the art “would have recognized the advantages of detecting different awake states, including a distressed state (*troubled wakefulness*) in which the patient has breathing that becomes ‘erratic,’ as taught in Matthews.” Pet. 52 (citing Ex. 1003 ¶ 210). Petitioner asserts the modification to the combined CPAP system of Sullivan995 and Sullivan460 “would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort.” *Id.* at 52–53 (also noting that “Sullivan995 is already concerned with the patient’s comfort, and already discloses it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible” (citing Ex. 1005, 2:31–39)).

Turning to reasonable expectation of success, Petitioner contends all three references are “analogous art and describe CPAP systems with flow sensors and generators.” Pet. 53. Petitioner asserts

[l]ike Sullivan995 and Sullivan460, Matthews discloses a “flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34.” Ex., 1007, 7:11-16. The data from

the flow sensor are monitored to control the pressure. *Id.*, 8:54-9:15. Sullivan⁴⁶⁰ discloses lowering the pressure upon detecting an awake state (EX1006, 6:30-7:19, cls. 22-28, 43-46), and the [person of ordinary skill in the art] would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient. [Ex. 1003] ¶¶211-212.

Id. Additionally, Petitioner argues “[t]he modification is a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.” *Id.* (citing Ex. 1003 ¶ 213).

Patent Owner’s arguments in response are again based on its proposed claim construction of “analyzes the data to determine the patient’s breathing patterns,” which we do not accept for the reasons discussed above. *See* PO Resp. 47–48 (asserting no motivation to combine because “these references only teach identification of patient state based on mean flow and its standard deviation,” which “is an aspect of the amplitude structure of a time series”; “an analysis of the amplitude and temporal structure of a breath-by-breath time series is required to distinguish between an awake state and a sleep state, including troubled wakefulness and REM sleep”; one of ordinary skill in the art “would not have been motivated to make this combination to specifically reduce pressure upon detection of the troubled wakefulness state, because [one of ordinary skill in the art] would not be able to distinguish between REM sleep and troubled wakefulness and therefore would not know whether to increase or decrease pressure”). Additionally, Patent Owner asserts “there is no reasonable expectation of success, because “[t]his modification requires methods of digital signal processing that go

beyond a combination of known prior art elements.” *Id.* at 48 (citing Ex. 1003 ¶ 209). As reflected above, Patent Owner’s arguments repeat the arguments raised in the context of Ground 1, which arguments we addressed therein and did not agree with for the reasons explained above and, further, for the reasons explained by Petitioner in its Reply (*see* Pet. Reply 17–19), which we adopt in full as though they were our own.

On the complete record and for the reasons discussed above, we find that Petitioner has established that one of ordinary skill in the art would have had reasons with rational underpinning to combine the teachings of Sullivan995, Sullivan460, and Matthews as proposed by Petitioner and would have had a reasonable expectation of success in so doing.²⁹

4. *Objective Indicia of Nonobviousness*

“Once all relevant facts are found, the ultimate legal determination [of obviousness or nonobviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat*, 876 F.3d at 1361. Patent Owner relies on the same arguments and evidence raised in response to Petitioner’s challenge in Ground 1. *See* PO Resp. 48 (“Patent Owner incorporates the arguments made in Section VI.C. as if fully stated herein.”).

²⁹ To the extent Patent Owner’s briefing could be interpreted as raising additional arguments contesting these issues (especially based on Patent Owner’s citations to Dr. Bates’s declaration, which could be interpreted as seeking to incorporate additional arguments by reference although prohibited by our Rules), we find Petitioner’s arguments (in the Petition and Reply) persuasive for the reasons explained by Petitioner and adopt them as our own findings.

We considered Patent Owner's arguments and evidence in the context of Ground 1, above. We also indicated that Patent Owner includes arguments on long-felt need specifically tied to detecting troubled wakefulness. In addition to the reasoning discussed in the context of Ground 1, which we incorporated herein, we add that Patent Owner's argument suffers from the same deficiencies identified above, particularly the failure to show that the invention satisfies the alleged need.

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews teaches each limitation of claim 6 of the '024 patent, that a person of ordinary skill in the art would have had reasons with rational underpinning to combine features of Sullivan995, Sullivan460, and Matthews as asserted with a reasonable expectation of success in so doing, and that Petitioner's evidence of unpatentability significantly outweighs the marginal evidence of long-felt but unmet need provided by Patent Owner.

On the whole and considering the *Graham* factors collectively, Petitioner has shown by a preponderance of the evidence that the combination of Sullivan995, Sullivan460, and Matthews would have rendered the subject matter of claim 6 of the '024 patent obvious to one of ordinary skill in the art at the time of the invention.

D. Ground 3: Obviousness over Rapoport502 and Sullivan460
Ground 4: Obviousness over Rapoport502, Sullivan460, and Matthews

Petitioner asserts the combination of Rapoport502 and Sullivan460 would have rendered the subject matter of claims 1–5 and 7–14 obvious and

the combination of Rapoport502, Sullivan460, and Matthews would have rendered the subject matter of claim 6 obvious to one of ordinary skill in the art at the time of the invention. Pet. 55–72 (Ground 3), 72–75 (Ground 4). Patent Owner contests Petitioner’s assertions. *See, e.g.*, PO Resp. 48–51 (Ground 3), 51–54 (Ground 4).

Because we have determined above that Petitioner has established the unpatentability of these same claims based on the combination of Sullivan995 and Sullivan460 (Ground 1) and the combination of Sullivan995, Sullivan460, and Matthews (Ground 2), we need not and do not reach these additional challenges by Petitioner based on the combinations of Rapoport502 and Sullivan460 (Ground 3) and Rapoport502, Sullivan460, and Matthews (Ground 4). *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged.”).

IV. PATENT OWNER’S MOTION TO EXCLUDE

Patent Owner seeks to exclude, either in whole or in part, Exhibits 1003, 1009, 1034, 1046, 1049, 1051, 1052, and 1054–1059 as well as portions of the Petition and Petitioner’s Reply that rely on the allegedly inadmissible exhibits. PO MTE 1; *see* PO MTE Reply. Petitioner opposes Patent Owner’s Motion. PO MTE Opp. For the following reasons, we deny Patent Owner’s Motion to Exclude.

A. *Exhibits 1003 and 1046*

Exhibit 1003 is the declaration of Petitioner’s original declarant, Dr. Behbehani, and Exhibit 1046 is the substitute declaration of Dr. Kirkness in which he adopts substantially the entirety of Dr. Behbehani’s Declaration. *See* Ex. 1046 ¶ 28. Patent Owner argues that certain portions of

Exhibit 1003 should be excluded and that those portions should also be excluded from Exhibit 1046. PO MTE 3–6; PO MTE Reply 1. More specifically, Patent Owner seeks to exclude paragraphs 38, 39, 42, 45, 77, and 224 of Exhibit 1003 on the premise that they are based upon inadmissible hearsay. Patent Owner asserts Dr. Kirkness did not perform any independent analysis and offers testimony for the truth of the matter asserted. PO MTE 3–5. Further, according to Patent Owner, hearsay may not be “a basis for an expert opinion when, in fact, the expert adds nothing to the out-of-court statements other than transmitting them to the factfinder.” *Id.* at 4–5.

In opposition, Petitioner argues, among other things, that “[a]n expert such as Dr. Kirkness may base an opinion on any facts or data that the expert ‘has been made aware of or personally observed,’” that “the facts or data ‘need not be admissible’ if an expert in the particular field would ‘reasonably rely’ on those kinds of facts or data” (PO MTE Opp. 3 (citing Fed. R. Evid. 703)), and that Dr. Kirkness “would certainly rely on peer-reviewed articles regarding the results of a study testing a CPAP machine [Ex. 1012] and manufacturer’s information regarding a commercial CPAP product [Ex. 1028].” PO MTE Opp. 3; *see also id.* at 4 (discussing Dr. Kirkness’s reliance on printed publications to establish the state of the prior art).

Because we do not rely on the challenged portions of Exhibit 1003 in rendering this Decision, we deny Patent Owner’s Motion to Exclude as to these portions of Exhibit 1003 and the corresponding portions of Exhibit 1046 as moot.

B. Exhibits 1009 and 1054–1058

Exhibit 1009 is the file history of related U.S. Patent No. 9,168,344 B2 (“the ’344 patent”), and Exhibit 1056 is the ’344 patent. Exhibit 1054 is the file history of related U.S. Patent No. 9,108,009 B2 (“the ’009 patent”), and Exhibit 1055 is the ’009 patent. Exhibit 1057 is related U.S. Patent No. 9,427,539 B2, and Exhibit 1058 is the related ’994 patent.

Patent Owner asserts that “Petitioner introduced new evidence in its Reply with these exhibits,” contrary to 37 C.F.R. § 42.61(a), which provides that “[e]vidence that is not taken, sought, or filed in accordance with this subpart is not admissible.” PO MTE 5; PO MTE Reply 2–3. According to Patent Owner, these exhibits are “subject to exclusion under” Federal Rule of Evidence 403. In opposition, Petitioner argues that these exhibits are proper evidence in support of its Reply because Patent Owner “proposed a construction for the ‘analyzing the breathing patterns’ claim terms for the first time in [Patent Owner’s] Response.” PO MTE Opp. 6. Patent Owner contends Petitioner could have used these exhibits in its Petition, but instead “supplemented previous claim construction arguments made in the Petition with these exhibits.” PO MTE Reply 2–3.

We disagree with Patent Owner’s argument. Petitioner proposed one term for construction in the Petition—“troubled wakefulness.” Pet. 17. Patent Owner first presented a construction for “analyzes the data to determine the patient’s breathing patterns” in its Patent Owner Response. PO Resp. 30. Petitioner’s first and only opportunity to respond to Patent Owner’s construction was in its Reply. *See Ancacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380 (Fed. Cir. 2018) (“[T]he petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the

evidence is a legitimate reply to evidence introduced by patent owner.”). And Petitioner’s Reply does not change the theory, prior art, or evidence relied on to challenge the subject claims as compared to that which was presented in the Petition. Thus, we disagree with Patent Owner’s arguments.

Therefore, Petitioner properly relies on Exhibits 1009 and 1054–1058 in support of its response to Patent Owner’s construction of “analyzes the data to determine the patient’s breathing patterns,” first raised in the Patent Owner Response. Therefore, we deny Patent Owner’s Motion to Exclude as to Exhibits 1009 and 1054–1058.

C. Exhibits 1034 and 1059

Exhibit 1034 is International Publication No. WO 03/075991 A1. Exhibit 1034 was cited by Dr. Kirkness in paragraph 174 of Exhibit 1003. Exhibit 1059 is an article titled “Control of breathing during sleep” published in Clinical Science in 1984 and was cited by Dr. Kirkness in his reply declaration (Exhibit 1051). Patent Owner argues that neither exhibit was cited expressly by Petitioner and therefore the use of each is an improper incorporation of arguments by reference. PO MTE 8–10 (citing 37 C.F.R. § 42.6(a)(3)).

Patent Owner’s argument has no merit. As Petitioner notes, 37 C.F.R. § 42.6(a)(3) provides that “arguments must not be incorporated by reference from one document into another document,” and neither Exhibit 1034 nor Exhibit 1059 is an argument. PO MTE Opp. 10–11; *see also id.* at 11 (addressing Exhibit 1034 by referencing the same arguments raised in opposition to Patent Owner’s attempt to exclude Exhibit 1059). Patent Owner also argues in its Reply that Exhibit 1059 should have been filed with the Petition or through a motion as supplemental evidence. PO MTE Reply

4. Petitioner, however, explains that the opinions of Dr. Kirkness supported by Exhibit 1059 in his reply declaration were relied on by Petitioner “in support of its argument that the ‘analyzing the breathing patterns’ terms have their plain and ordinary meaning, in response to [Patent Owner’s] proposed construction.” PO MTE Opp. 10–11. We agree with Petitioner for the same reasons discussed above regarding Exhibits 1009 and 1054–1058. Because Patent Owner shows no persuasive basis to exclude Exhibits 1034 and 1059, we deny Patent Owner’s Motion to Exclude as to Exhibits 1034 and 1059.

D. Exhibit 1049

Exhibit 1049 is U.S. Patent No. 7,945,303 B2. Patent Owner argues that the priority date of this patent is after the priority date of the ’024 patent and should be excluded as irrelevant and “not prior art.” PO MTE 6; PO MTE Reply 3. Patent Owner also argues that the exhibit should have been introduced prior to Petitioner’s Reply. PO MTE 6. Petitioner argues that this patent was issued to Dr. Bates, Patent Owner’s declarant, and was not relied on as prior art, but is relevant to the credibility of Dr. Bates. PO MTE Opp. 8–9. We agree with Petitioner that Exhibit 1049 is sufficiently relevant to Dr. Bates’s credibility, not as prior art, and find Patent Owner offers no persuasive reason for its exclusion. Moreover, we do not rely on Exhibit 1049 in rendering this Decision, and we deny Patent Owner’s Motion to Exclude as to Exhibit 1049 as moot.

E. Exhibit 1051

Exhibit 1051 is the Declaration of Dr. Kirkness in support of Petitioner’s Reply. Patent Owner argues that Exhibit 1051 should be excluded because it raises “new issues” and “new evidence that could have been presented in a prior filing.” PO MTE 7; PO MTE Reply 1–2. The only

“example” provided by Patent Owner in support of its argument for exclusion is that Dr. Kirkness “uses Exhibits 1049 and 1054–1058 in the exact same manner” as they are used in Petitioner’s Reply and should therefore be excluded for the same reasons. PO MTE 7. For the same reasons discussed above regarding Exhibits 1049 and 1054–1058, we deny the Motion to Exclude as to Exhibit 1051.

F. Exhibit 1052

Exhibit 1052 is the transcript of the first day of Dr. Bates’s deposition testimony. Patent Owner argues that the portions of Exhibit 1052 “focusing on patent eligible subject matter and whether certain products, such as processors, infringe by meeting the limitations of the ’024 Patent should be excluded as irrelevant.” PO MTE 8 (citing Ex. 1052, 62:7–23, 63:15–25, 64:1–5, 117:9–25, 118:1–11, 146:4–12); PO MTE Reply 3–4. Petitioner argues that the testimony of Dr. Bates is relevant to obviousness issues in this proceeding, that there was “no discussion of ‘infringement’ or ‘patentable subject matter,’” and that the testimony is relevant to the credibility of Dr. Bates. PO MTE Opp. 9–10. We agree with Petitioner for the same reasons provided by Petitioner and deny Patent Owner’s Motion to Exclude as to the challenged portions of Exhibit 1052.

V. PETITIONER’S MOTION TO EXCLUDE

Petitioner seeks to exclude portions of Exhibit 1053, the deposition testimony of Dr. Bates. Pet. MTE 1–9; Pet. MTE Reply 1–5. Specifically, Petitioner moves to exclude parts of the redirect deposition testimony of Dr. Bates concerning secondary considerations of nonobviousness. Pet. MTE 1–2. Petitioner argues that the redirect testimony of Dr. Bates “was outside the scope of Petitioner’s cross-examination in contravention of

Federal Rule of Evidence 611(b) and 37 C.F.R. § 42.53 (d)(5)(ii).” *Id.* at 1. Petitioner does not seek to exclude the entirety of Dr. Bates’s redirect testimony concerning secondary considerations but only the specific portions cited by Patent Owner in the Sur-reply. *Id.* at 5 n.2. Patent Owner opposes Petitioner’s Motion. Pet. MTE Opp. 1–10.

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

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

§ 42.53(d)(5)(ii) “similarly prevents a party from expanding the scope of redirect examination beyond that of cross-examination.” *Id.* at 9.

In opposition, Patent Owner argues Petitioner’s Motion to Exclude is improper for two reasons. First, Patent Owner asserts the Consolidated Trial Practice Guide provides that “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence or *otherwise exceeds the proper scope* of reply or sur-reply, it may request authorization to file a motion to strike.” Pet. MTE Opp. 2 (citing PTAB Consolidated Trial Practice Guide (“CTPG”) 80 (PTAB Nov. 2019)). Patent Owner contends that “Petitioner’s counsel reserved the right to strike Dr. Bates’ redirect testimony” but “failed to preserve this right because it failed to file a motion to strike within one week of [Patent Owner] submitting its Sur-Reply.” *Id.* at 2–3 (citing CTPG 80–81). Second, Patent Owner contends that Petitioner “never argues that this testimony is, in fact, ***inadmissible***,” only that it “should be excluded (not stricken) because it is beyond the scope of its cross-examination.” *Id.* at 4. According to Patent Owner, “Petitioner never states why this testimony is inadmissible (e.g., based on relevance or hearsay), never identifies the corresponding objection in the record, and never explains any objections.” *Id.* (citing 37 C.F.R. § 42.64(c)). Patent Owner also contends “Petitioner’s counsel specifically questioned Dr. Bates on secondary considerations and cannot argue at this point that [Patent Owner’s] redirect was beyond the scope.” *Id.* at 5–6 (citing Ex. 1053, 242:12–243:2).

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

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

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

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

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

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

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

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

Although we agree with Petitioner that Rule 611(b) and 37 C.F.R. § 42.53(d)(5)(ii) should be understood as limiting the scope of a redirect examination of a witness to the scope of that witness's cross-examination (just as each rule expressly limits the scope of cross-examination to the scope of the direct examination/testimony³⁰), Patent Owner makes a colorable argument that Petitioner opened the door ever so slightly on the issue of objective indicia of nonobviousness by questioning Dr. Bates about commercial success during his cross-examination. Pet. MTE Opp. 5–6 (citing Ex. 1053, 242:12–25). We recognize that commercial success and long-felt need are different objective indicia; however, under the circumstances presented here and in light of the little weight to which Patent Owner's argument and Dr. Bates's redirect is entitled, we determine that the better course at this stage is to deny Petitioner's Motion to Exclude.

VI. SUMMARY

For the reasons discussed above, Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–14 of the '024 patent are unpatentable.

³⁰ There are exceptions, e.g., questions pertaining to a witness's credibility. See Fed. R. Evid. 611(b).

Our conclusions regarding the Challenged Claims are summarized below:

Claims Challenged	35 U.S.C. §	Reference(s) /Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–5, 7–14	103(a)	Sullivan995, Sullivan460	1–5, 7–14	
6	103(a)	Sullivan995, Sullivan460, Matthews	6	
1–5, 7–14	103(a)	Rapoport502, Sullivan460 ³¹		
6	103(a)	Rapoport502, Sullivan460, Matthews ³²		
Overall Outcome			1–14	

VII. ORDER³³

In consideration of the foregoing, it is:

ORDERED that Patent Owner’s Motion to Exclude (Paper 47) is *denied*;

³¹ For the reasons explained above, we do not reach this alternative ground because we determine that claims 1–5 and 7–14 are unpatentable based on Petitioner’s first ground, relying on the combination of Sullivan995 and Sullivan460.

³² For the reasons explained above, we do not reach this alternative ground because we determine that claim 6 is unpatentable based on Petitioner’s second ground, relying on the combination of Sullivan995, Sullivan460, and Matthews.

³³ Should Patent Owner wish to pursue amendment of a challenged claim in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner’s attention to the Notice Regarding

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 48) is *denied*;

FURTHER ORDERED that claims 1–14 of U.S. Patent No. 10,384,024 B2 are determined to be unpatentable; and

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

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

IPR2022-00992
Patent 10,384,024 B2

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