

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

IPR2025-00247
Patent 11,872,029 B1

Before SHERIDAN K. SNEDDEN, NEIL T. POWELL, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claim Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–19 of U.S. Patent No. 11,872,029 B1 (“the ’029 patent,” Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e). Having reviewed the parties’ arguments and cited evidence, for the reasons discussed below, we find that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–19 are unpatentable.

A. Procedural History

Petitioner ResMed Corp. requested *inter partes* review of claims 1–19 of the ’029 patent. Paper 1 (“Pet.”). Patent Owner Cleveland Medical Devices, Inc. filed a Preliminary Response. Paper 8 (“Prelim. Resp.”).¹ We instituted trial. Paper 12 (“Inst. Dec.”).

After institution, Patent Owner filed a Response. Paper 22 (“PO Resp.”). Petitioner filed a Reply. Paper 24 (“Reply”). Patent Owner filed a Sur-reply. Paper 30 (“Sur-reply”).

Patent Owner filed an authorized Motion to Terminate, alleging that Petitioner failed to name its corporate parent, Resmed Inc., as a real party in interest. Paper 29. Petitioner filed an opposition. Paper 31. Patent Owner filed a reply. Paper 32. We denied the Motion to Terminate. Paper 40.

Patent Owner requested authorization to file a motion to terminate based on Petitioner’s failure to disclose allegedly contradictory claim

¹ The parties also filed briefs directed to discretionary denial issues. *See* Papers 6, 9. The Director denied Patent Owner’s request for discretionary denial of the Petition and referred the case to the Board. *See* Paper 10.

construction positions taken in parallel district court litigation. We denied that request. Paper 41.

On April 29, 2026, we held an oral hearing, the transcript of which is of record. Paper 43 (“Tr.”).

B. Real Parties in Interest

Petitioner and Patent Owner each identify only themselves as the real party in interest. Pet. 72; Paper 3 (Patent Owner Mandatory Notices), 1.

C. Related Matters

The parties identify *ResMed Corp. v. Cleveland Medical Devices, Inc.*, 1:23-cv-02221-BMB (N.D. Ohio) (the “Ohio case”) as a related matter involving the ’029 patent. Pet. 73; Paper 3, 1.

Petitioner identifies *inter partes* reviews for U.S. Patent No. 11,602,284 (IPR2025-00157), U.S. Patent No. 11,375,921 (IPR2025-00159), U.S. Patent No. 11,690,512 (IPR2025-00158), U.S. Patent No. 11,786,680 (IPR2025-00160), U.S. Patent No. 11,857,333 (IPR2025-00246), and U.S. Patent No. 10,076,269 (IPR2023-00565). Pet. 73.

D. The ’029 patent (Ex. 1001)

The ’029 patent, titled “Devices and Methods for Sleep Disorder Diagnosis and Treatment,” issued on January 16, 2024, from U.S. Application 18/105,277, filed on February 3, 2023, and claims priority as a continuation to several utility applications, the earliest of which was filed on November 4, 2005. Ex. 1001, codes (21), (22), (45), (54), (63). The ’029 patent “relates to an integrated sleep diagnosis and treatment device, and more particularly to an integrated apnea diagnosis and treatment device” and “to [a] method of sleep diagnosis and treatment.” *Id.* at 1:31–35.

One embodiment of a diagnostic device of a sleep disorder treatment system is depicted in Figure 1 of the '029 patent, reproduced below.

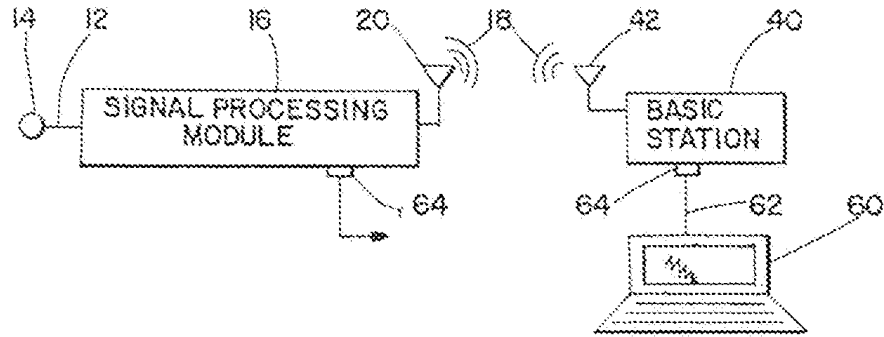


Fig. 1

Figure 1 of the '029 patent is a block diagram of a system in which external input 12 from sensor 14 is input to signal processing module 16. *Id.* at 9:6–9. The '029 patent describes signal processing module 16 as generating signal 18 that is “encoded with data corresponding to the external input 12” and transmitted “by wireless means to a base station 40.” *Id.* at 9:12–15.

Figure 7 of the '029 patent is reproduced below.

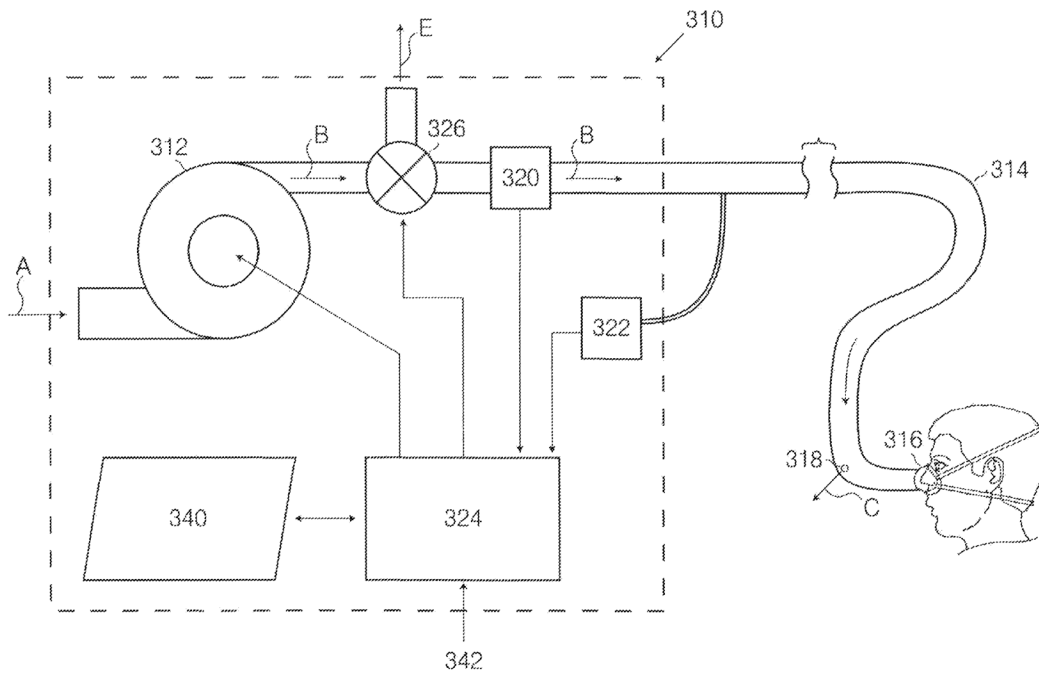


Fig. 7

Figure 7 depicts a continuous positive airway pressure (CPAP) device which “can be used to physically treat a subject’s sleep disorder, [and] which can be further adjusted using the output of the level of severity of the subject’s sleeping disorder.” *Id.* at 22:54–60. The '029 patent explains that

[t]his conventional pressure support system 310 shown in FIG. 7 includes a pressure generator 312, a blower, piston or bellows[] that receives a supply of gas from a gas source, such as ambient atmosphere, as indicated by arrow A, or pressurized gas tanks (not shown) and creates a flow of breathing gas, as indicated by arrows B, having a pressure greater than the ambient atmospheric pressure.

Id. at 22:60–67. Patient or subject circuit 314 “delivers the elevated pressure breathing gas to the airway of the subject” such as via patient interface device 316. *Id.* at 22:67–23:5.

Pressure support system 310 may further include flow sensor 320, pressure sensor 322, or both to “monitor the flow and/or pressure of gas passing in the subject circuit 314.” *Id.* at 23:20–23. According to the ’029 patent, “[t]he flow information can also be used to determine the volume of gas passing through the subject circuit 314” and “[t]he information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to control the pressure or flow of gas provided to the subject, monitor the condition of the subject, monitor the usage of the pressure support device, any combination thereof, or the like.” *Id.* at 23:23–30.

The ’029 patent states that “one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.” *Id.* at 19:19–22. In addition, the ’029 patent describes embodiments in which the “invention can be part of a remote communication station or base station.” *Id.* at 19:23–25. For instance, a remote communication system may be “a PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis.” *Id.* at 19:51–60.

E. The Challenged Claims

Petitioner challenges claims 1–19 of the '029 patent. Claim 1, the only independent challenged claim, is reproduced below with bracketed notations added:²

1. A positive airway pressure (PAP) sleep disorder treatment system comprising:

[1.a] a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone an index of treatment efficacy of the subject using a PAP device, the index based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, and a display;

[1.b] the PAP device with an enclosure further comprising:

[1.b.i] a blower having an air output within the enclosure,

[1.b.ii] an airflow sensor being any type of sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP device and outputting airflow sensor data,

[1.b.iii] a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating:

[1.b.iii.1] i) the data of a severity of the sleep disorder symptoms of the subject,

[1.b.iii.2] ii) the data of usage of the PAP device by the subject, and/or

² For ease of reference, we use the same bracketed notations Petitioner uses in the Petition. *See, e.g.*, Pet. 12–40. We note that Petitioner's recitation of claim 1 in the Claim Listing Appendix (*id.* at 76) is missing limitation [1.b.v].

[1.b.iii.3] iii) the index based in whole or in part on either i) or ii) or both i) and ii),

[1.b.iv] a mask or a nasal cannula connected to the enclosure, and

[1.b.v] at least one second radio frequency wireless transceiver within the enclosure, the at least one second radio frequency wireless transceiver adapted for transmitting i) and ii), and/or iii); and

[1.c] a remote internet site, the remote internet site adapted for receiving i) and ii), or i), ii), and iii), related to the subject's treatment and the treatment's efficacy in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.

Ex. 1001, 23:63–24:35.

F. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–19 are unpatentable on the following six grounds:

Ground	Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
1	1–11, 13–16, 18, 19	103(a)	Truitt, ⁴ Kumar ⁵

³ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Here, the parties apply “an effective filing date of no earlier than November 4, 2005.” Pet. 3; PO Resp. 11. Accordingly, we apply the pre-AIA version of § 103; however, our Decision would be no different under the AIA version of the statute.

⁴ Truitt et al., U.S. Patent 6,644,311 B1, issued November 11, 2003 (“Truitt,” Ex. 1007).

⁵ Kumar et al., U.S. Patent App. Pub. 2002/0198473 A1, published December 26, 2002 (“Kumar,” Ex. 1008).

Ground	Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
2	14, 15	103(a)	Truitt, Kumar, Dong ⁶
3	12, 17	103(a)	Truitt, Kumar, Wright ⁷
4	1–11, 13–16, 18, 19	103(a)	Truitt, Kumar, Mumford ⁸
5	10, 14–16	103(a)	Truitt, Kumar, Dong, Mumford
6	12, 17	103(a)	Truitt, Kumar, Wright, Mumford

Pet. 2–3. Grounds 4–6 present the same combinations of prior art presented for Grounds 1–3, but add Mumford for its disclosure of a sleep efficacy algorithm. *Id.* at 64. Petitioner states that it offers these grounds as an alternative to Grounds 1–3, in the event it is determined that Truitt does not disclose certain claim limitations. *Id.* at 66–67.

Petitioner supports its contentions with the Declarations of Jason Kirkness, Ph.D. (Ex. 1003; Ex. 1071) and Dr. Sandeep Chatterjee (Ex. 1005), among other evidence. Patent Owner supports its contentions with the Declaration of Dr. David A. Borkholder (Ex. 2019), among other evidence.

⁶ Dong et al., U.S. Patent 5,424,942, issued June 13, 1995 (“Dong,” Ex. 1014).

⁷ Wright et al., U.S. Patent App. Pub. 2002/0185130 A1, published December 12, 2002 (“Wright,” Ex. 1013).

⁸ Mumford et al., U.S. Patent 7,575,005 B2, issued August 18, 2009 (“Mumford,” Ex. 1009).

II. UNPATENTABILITY ARGUMENTS

A. Principles of Law

In an *inter partes* review, “the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). Petitioner ultimately bears the burden of persuasion to prove unpatentability of each challenged claim by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Under pre-AIA 35 U.S.C. § 103(a), a claim is unpatentable as obvious if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) any objective indicia of nonobviousness.⁹ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness determination requires finding a

⁹ Patent Owner does not assert any objective indicia of nonobviousness. *See generally* PO Resp.

reason to combine accompanied by a reasonable expectation of achieving what is claimed in the challenged patent. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). “[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR*, 550 U.S. at 419–20.

B. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time the invention was made.¹⁰ *See Graham*, 383 U.S. at 17–18. The parties agree that a person of ordinary skill in the art (sometimes referred to herein as “POSITA”) would have had:

at least a bachelor’s degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems, such as networked PAP machines. Additional experience could substitute for less education, and additional education could likewise substitute for less experience.

Pet. 4 (citing Ex. 1003 (Kirkness Decl.) ¶ 44); PO Resp. 11.

Because the proposed level of ordinary skill in the art is consistent with the cited prior art and is undisputed on this record, we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (indicating that the prior art itself may reflect an appropriate skill level).

¹⁰ For purposes of this Decision, we apply a priority date of November 4, 2005. *See supra* n.3.

C. Claim Construction

In AIA proceedings we interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

Petitioner states that it adopts Patent Owner’s interpretation of two claim terms¹¹ as described in Patent Owner’s opening claim construction brief in the Ohio case. Pet. 4–7 (citing Ex. 1054, 16–21). Petitioner, however, does not clearly indicate what Patent Owner’s alleged constructions for the identified terms are, and in the cited claim construction brief (Exhibit 1054, 16–21), Patent Owner appears to be addressing the alleged definiteness of the claim terms, rather than providing a proposed construction. *See id.*

Patent Owner addresses the meaning of the claim term “data of a severity of the symptoms of the subject.” *See* PO Resp. 14–17. We discuss this claim term below, and decide that no construction is necessary. *See infra* Section II.E.2.

We find it unnecessary to address the constructions of any other claim terms to resolve the issues in this case. *See Nidec Motor Corp. v. Zhongshan*

¹¹ The two claim terms are “calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i) and ii)” (recited in limitation [1.b.iii]) and “related to the subject’s treatment and the treatment’s efficacy” (recited in limitation [1.c]). *See* Pet. 5.

Broad Ocean Motor Co., 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that “we need only construe 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))).

D. Overview of Asserted Prior Art

1. *Truitt (Ex. 1007)*

Truitt, titled “Monitoring Fluid Flow in a Pressure Support System,” issued on November 11, 2003, from U.S. Application 10/027,487, which was filed on December 19, 2001. Ex. 1007, codes (45), (21), (22), (54), (57). Truitt “pertains to a pressure support system in which a flow or volume of gas is measured without using a dedicated flow element used in a conventional flow meter.” *Id.* at code (57).

Truitt's Figure 1 is reproduced below.

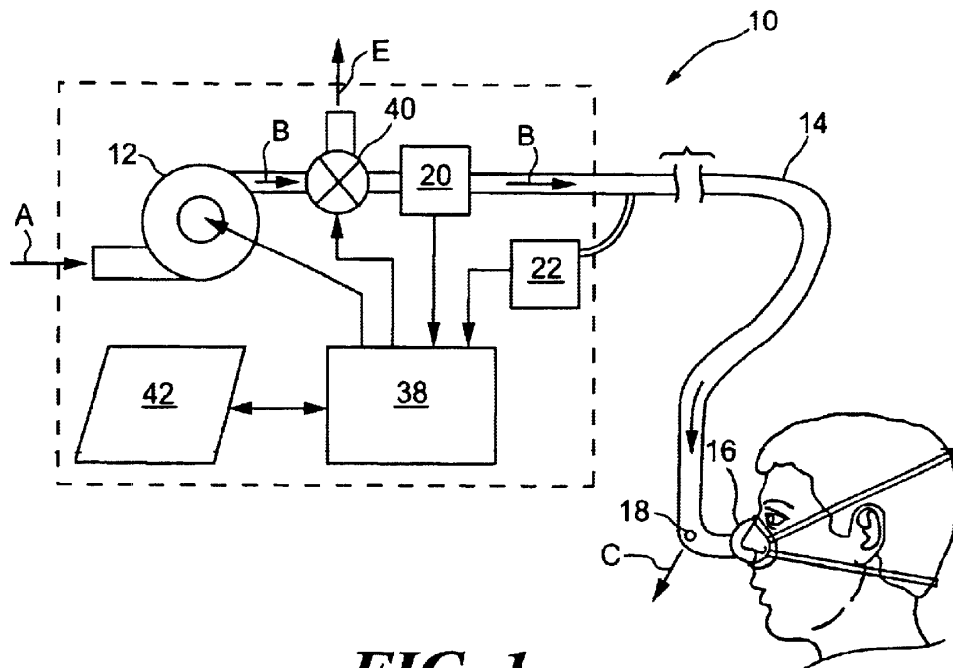


FIG. 1
(PRIOR ART)

Figure 1 depicts conventional pressure support system 10 that includes pressure generator 12 and patient circuit 14 to deliver elevated pressure breathing gas to a patient via patient interface device 16. *Id.* at 1:44–52, 1:56–58. Truitt explains that

[m]ore sophisticated pressure support devices include a flow sensor 20, pressure sensor 22 or both that monitor the flow and/or pressure of gas passing in patient circuit 14. The flow information can also be used to determine the volume of gas passing through patient circuit 14. The information from flow sensor 20 and/or pressure sensor 22 is used, for example, to control the pressure or flow of gas provided to the patient, monitor the condition of the patient, monitor the usage of the pressure support device (patient compliance), or any combination thereof.

Id. at 2:1–10.

Truitt discusses an auto-titration mode of pressure support, where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient, the[] pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc. The pressure and/or flow is then controlled to counteract or prevent these conditions.

Id. at 3:5–11.

Figure 3 of Truitt is reproduced below.

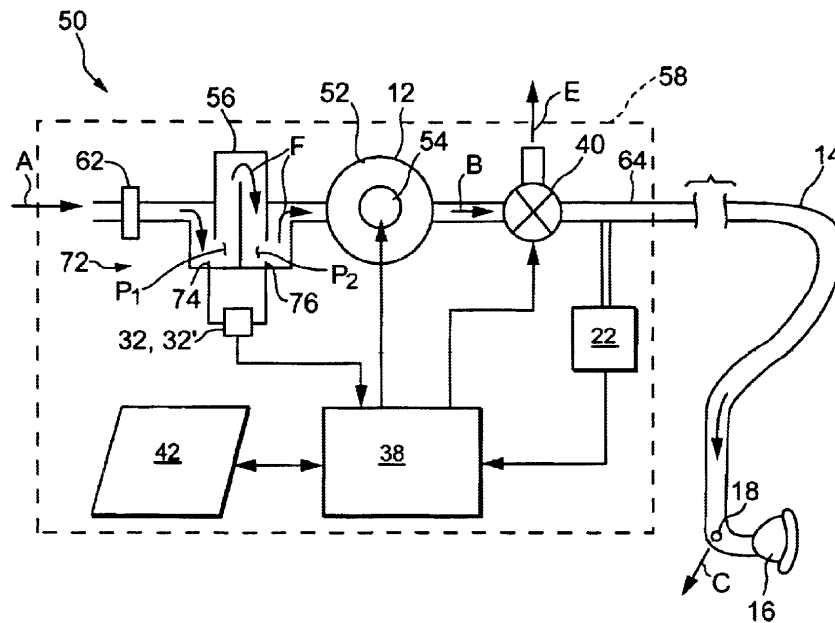


FIG. 3

Figure 3 shows pressure support system 50, which “includes a pressure generator 12 in the form of a blower assembly 52 driven by a motor 54.” *Id.* at 5:1–3. Truitt explains that “[a]n inlet of the blower is coupled to a first conduit 56 that communicates the inlet of the blower to a source of breathing gas for the pressure generator, such as ambient atmosphere.” *Id.* at 5:3–6. Truitt describes “[a] flow/volume sensing system, generally indicated at 72, and which includes the tortuous path defined by first conduit 56, provides a flow signal to controller 68.” *Id.* at 6:11–13. Truitt states that “[a] conventional pressure sensor 32 measures the pressure differential ΔP ($P_2 - P_1$) via ports 74 and 76, and provides a signal indicative of this pressure differential to controller 38 for calculating the flow and/or volume of gas passing through conduit 56.” *Id.* at 6:38–42. According to Truitt, “[t]he

output of flow sensor 32 is provided to controller 38 for calculating the flow and/or volume of gas passing through conduit 56.” *Id.* at 6:46–48.

Truitt explains that

in a bi-level mode of operation, controller 38 receives flow signals and pressure signals from flow/volume sensing assembly 72 and pressure sensor 22, respectively, to distinguish between the inspiratory and expiratory phase of the patient’s breathing cycle, as is known in the art, and delivers the appropriate IPAP and EPAP pressures by controlling valve 40, motor 54, or a combination thereof.

Id. at 6:53–60.

2. Kumar (Ex. 1008)

Kumar, titled “System and Method for Real-Time Monitoring, Assessment, Analysis, Retrieval, and Storage of Physiological Data Over a Wide Area Network,” is the December 26, 2002 publication of U.S. Application 10/109,958. Ex. 1008, codes (21), (43), (54).

Kumar relates to “remote monitoring of devices over a wide area network” and to “network-based transmission of data from a physiological collecting device.” *Id.* ¶ 2. We reproduce below Kumar’s Figure 1A.

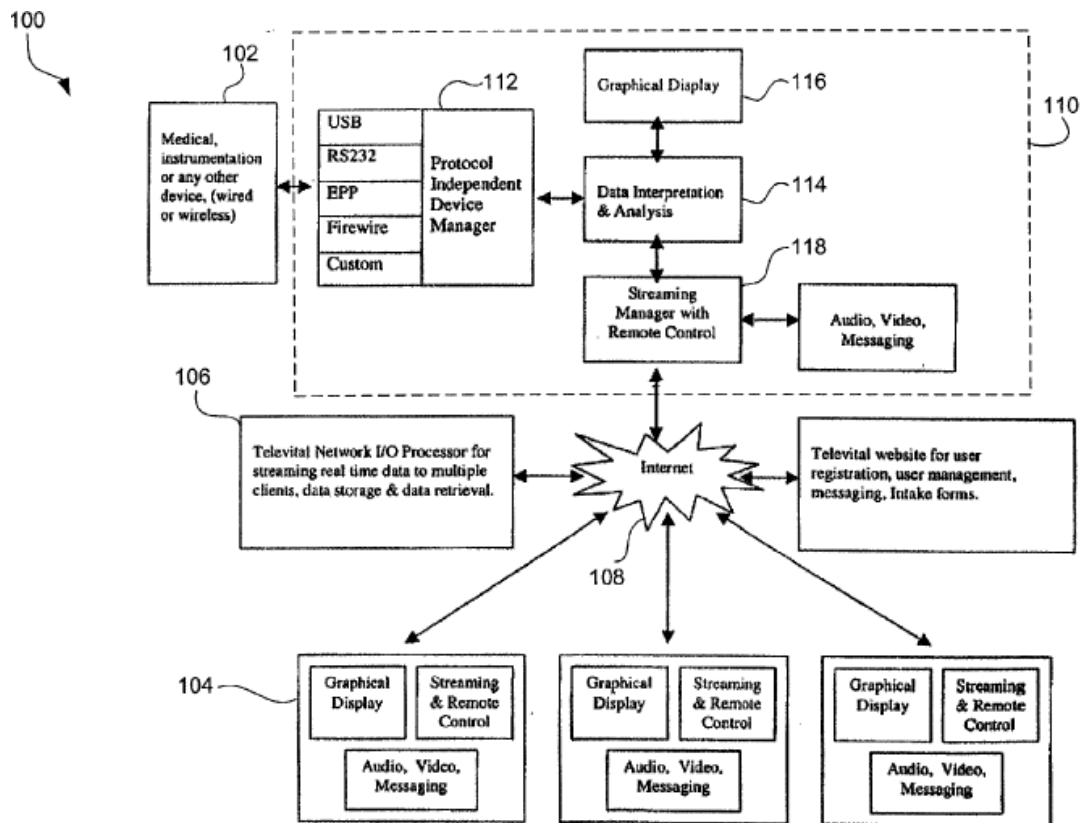


Fig. 1A

Figure 1A shows “an exemplary system architecture for network-based monitoring of data from a patient-side physiological collecting device.” *Id.* ¶ 22. Architecture 100 includes patient-side devices 102 for collecting data from a patient/client, provider-side devices 104, and central server 106 that implements an engine. *Id.* ¶ 67. “The devices and engine are connected to a wide area network (WAN) 108 such as the Internet, intranet, or extranet,” and “[t]he system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider.” *Id.*

Patient-side devices 102 may “be connected via a computing device 110, such as a computer, handheld devices such as personal digital assistants (PDAs) and pocket PCs such as IPAQ with Windows CE operating System and Palm devices based on Palm OS[], wireless telephone, or any other computing device, to the WAN.” *Id.* ¶ 72. “A protocol independent device manager 112 running on the computing device establishes a two-way communication with a vast array of client-side devices.” *Id.*

Kumar teaches “a modular architecture in which the patient-side device and/or the computing device coupled to the patient-side device can send a request to the engine with an identifier of the patient-side device, and the engine will send the appropriate plug-in which allows the computing device to communicate with the patient-side device.” *Id.* ¶ 74. Therefore, Kumar’s system “may support both plug-and-play web device drivers and customized graphical user interfaces (GUIs) for the various devices.” *Id.*

“The system may be implemented using Apache web server, MySQL on Linux, Oracle on Linux, Java servlets, Applets, HTML, JavaScript, Java, C#, Microsoft’s .NET etc.” and “the server may be implemented on the Internet, intranet, or an extranet.” *Id.* ¶ 87.

3. *Dong (Ex. 1014)*

Dong, titled “Extended Horizon Adaptive Block Predictive Controller with an Efficient Prediction System,” issued on June 13, 1995, from U.S. Application 08/104,882, which was filed on August 10, 1993. Ex. 1014, codes (45), (21), (22), (54). Dong “relates generally to the control and prediction of multivariable dynamic systems.” *Id.* at 1:7–8.

According to Dong, existing adaptive controllers have “two potentially crippling limitations: (1) computational complexity, which limits

their feasibility in multivariable applications; and (2) sensitivity to the choice of the input-output delays and model order selection.” *Id.* at 1:35–42. In view of this, Dong discloses “[a]n extended horizon adaptive block predictive controller [that] includes a block control system and an adaptive block prediction system.” *Id.* at code (57).

4. *Wright (Ex. 1013)*

Wright, titled “Methods and Apparatus for Stroke Patient Treatment,” is the December 12, 2002, publication of U.S. Application 10/014,684, which was filed on December 11, 2001. Ex. 1013, codes (43), (21), (22), (54). Wright “relates to methods and apparatus for diagnosing, managing and treating stroke patients both as in-patients and out-patients.” *Id.* ¶ 2.

According to Wright, CPAP systems provide advantages for stroke rehabilitation relative to oxygenation because “some CPAP devices can detect the presence of apneas, distinguish between central and obstructive apneas and provide an increased pressure if needed to stabilize an obstructed or partially obstructed airway.” *Id.* ¶ 27. Wright describes a CPAP system having “two treatment modes, a first mode for treating obstructive apneas and a second mode for treating central apneas.” *Id.* ¶ 31. According to Wright, “[i]n the first mode, the device provides a generally constant pressure throughout a breathing cycle, but may vary the pressure in accordance with indications of partial or complete obstruction of the airway.” *Id.* In the second mode, “the apparatus provides a higher pressure to the mask during the inspiratory portion of the breathing cycle, the so-called IPAP, and a lower pressure to the mask during the expiratory portion of the breathing cycle, the so-called EPAP.” *Id.* ¶ 32. Wright discloses that

“[t]his may be accomplished by monitoring the respiratory flow to the patient and defining a threshold level.” *Id.*

Wright states that “[t]he apparatus may be programmed with a particular protocol intended to identify between alternative forms of CPAP treatment appropriate for the patient based upon an assessment of the patient’s condition.” *Id.* at code (57).

5. Mumford (Ex. 1009)

Mumford, titled “Mask Assembly with Integrated Sensors,” issued on August 18, 2009, from U.S. Application 11/131,284, which was filed on May 18, 2005. Ex. 1009, codes (45), (21), (22), (54). Mumford “relates to a mask assembly with integrated sensors for sensing the efficacy of treatment of medical conditions.” *Id.* at 1:18–22.

Mumford explains that “Obstructive Sleep Apnea (OSA) is a life-threatening condition characterized by frequent episodes in which an individual stops breathing or breathes less efficiently during sleep” and “is caused by a blockage of the airway typically resulting from the collapse and closure of the soft tissue in the rear of the throat during sleep.” *Id.* at 1:26–31. According to Mumford, “[w]ith each apnea event, the brain arouses the individual in order for the individual to resume breathing, but consequently sleep is extremely fragmented and of poor quality.” *Id.* at 1:31–35.

Mumford discloses a CPAP system having a monitoring unit and a mask assembly including sensors, where physiological information provided by the sensors is processed “according to a sleep efficacy algorithm 36.” *Id.* at 6:63–66, 7:22–37. Mumford states that “[t]he sleep efficacy algorithm 36 monitors the quality of sleep for the wearer 18” which “can include determining how long the wearer 18 is in a given sleep state, how many

different sleep states the wearer 18 has experienced during sleep, the fragmentation of their sleep states and how many arousals the wearer 18 has experienced.” *Id.* at 7:37–46. “[T]he sleep efficacy control algorithm 36 can generate sleep profile information for the wearer 18 (the sleep profile information may include data, such as a test score, related to efficacy and compliance).” *Id.* According to Mumford, “[a]rousals are important for determining the quality of sleep and the efficacy of therapy.” *Id.* at 11:46–48.

Mumford further describes:

The sleep efficacy algorithm 36 further generates a control signal to control the operational parameters of the CPAP device 14 such as activating or deactivating the CPAP device 14 or altering the amount of pressure that is provided to the gas inlet 28 to improve the quality of sleep of the wearer 18.

Id. at 7:46–51.

E. Grounds 1–3 – Alleged Obviousness Over Truitt and Kumar (Ground 1), Truitt, Kumar, and Dong (Ground 2), and Truitt, Kumar, and Wright (Ground 3)

For Ground 1, Petitioner asserts that claims 1–11, 13–16, 18, and 19 are unpatentable as obvious over Truitt and Kumar. Pet. 17–59. For Ground 2, Petitioner asserts that claims 14 and 15 are unpatentable as obvious over Truitt, Kumar, and Dong. *Id.* at 58–61. For Ground 3, Petitioner asserts that claims 12 and 17 are unpatentable as obvious over Truitt, Kumar, and Wright. *Id.* at 62–64.

In brief, Petitioner asserts that Truitt discloses a PAP treatment system meeting many limitations of the challenged claims. *See, e.g.*, Pet. 12–40. Petitioner argues that a person of ordinary skill in the art would have been motivated with a reasonable expectation of success to improve Truitt’s PAP

device by networking it as taught by Kumar, including because doing so would have permitted the patient to use the PAP machine at home, thereby reducing the need for in-person appointments and allowing physicians to “obtain more representative data.” *See id.* at 7–10. Petitioner provides a claim-by-claim analysis as to how the asserted prior art combinations teach or suggest each and every limitation of the challenged claims. *See id.* at 12–64.

Patent Owner responds that Petitioner has not demonstrated that the combination of Truitt and Kumar teaches or suggests (1) “an airflow sensor . . . adapted for measuring or deriving the respiratory airflow of a subject” (claim limitation [1.b.ii]) or (2) “a second processor . . . adapted for receiving airflow sensor data and for calculating . . . the data of a severity of the sleep disorder symptoms of the subject” (claim limitation [1.b.iii]); or that a person of ordinary skill in the art would have been motivated to combine Truitt and Kumar. *See PO Resp.* 12–27. We evaluate the parties’ arguments below.

1. Whether Truitt Teaches or Suggests “an airflow sensor . . . adapted for measuring or deriving the respiratory airflow of a subject”

Claim 1 recites: “an ***airflow sensor*** . . . internal to the enclosure of the PAP device ***adapted for measuring or deriving the respiratory airflow of a subject*** while using the PAP device.” Pet. 76 (limitation [1.b.ii]) (emphasis added). For this limitation, Petitioner cites Truitt’s flow sensing system 72, which, among other things, operates “motor 54 and/or valve 40 that control air flow and pressure provided to the patient.” *Id.* at 28 (citing Ex. 1007 (Truitt) 6:11–62; Ex. 1003 (Kirkness Decl.) ¶ 219; Ex. 1005 (Chatterjee Decl. ¶ 106)).

Patent Owner disputes Petitioner’s showing, arguing that “[n]either Petitioner nor its experts explain how measuring the airflow provided to the

patient is either a measurement or derivation of the *patient's* respiratory airflow.” PO Resp. 12. According to Patent Owner, Truitt’s device measures “the airflow being provided *to the patient*,” but this “does not provide a measurement or derivation of the subject’s respiratory airflow without more processing of the airflow signal.” *Id.* at 13–14 (citing, e.g., Ex. 2019 (Borkholder Decl.) ¶¶ 49–50). Patent Owner further argues that Truitt does not disclose “how to derive the patient’s respiratory airflow from the measurements that its system does take.” *Id.* at 14.

Petitioner responds that Truitt’s flow sensing system meets the claim limitation because it uses flow and pressure signals to distinguish between the inspiratory and expiratory phase of the patient’s breathing cycle. Reply 1 (citing Pet. 28; Ex. 1003 (Kirkness Decl.) ¶ 219; Ex. 1005 (Chatterjee Decl.) ¶ 106).

We find that because Truitt’s flow sensing system uses flow and pressure signals to distinguish between the inspiratory and expiratory phase of the patient’s breathing cycle, Petitioner adequately demonstrates that Truitt teaches or suggests “an airflow sensor . . . adapted for measuring or deriving the respiratory airflow of a subject” as recited in limitation [1.b.ii]. Truitt explains that

controller 38 receives flow signals and pressure signals from flow/volume sensing assembly 72 and pressure sensor 22, respectively, to distinguish between the inspiratory and expiratory phase of the patient’s breathing cycle, as is known in the art, and delivers the appropriate IPAP and EPAP pressures by controlling valve 40, motor 54, or a combination thereof.

Ex. 1007 (Truitt) 6:53–62; Pet. 28. In other words, Truitt teaches or suggests that signals from the flow and pressure sensors are used to derive the subject’s respiratory airflow as claimed, because these signals are used to

distinguish at least the direction of the subject's airflow (inspiration vs. exhalation). *See* Ex. 1007 (Truitt) 2:64–3:11, 6:53–62; *see also* Pet. 14 (Truitt's "[c]ontroller 38 may also receive the signals from flow sensor 20 and pressure sensor 22, and 'uses this information to determine when the patient has transitioned from the inspiratory phase to the expiratory phase of the breathing cycle, or vice versa, to control the pressure accordingly.'") (quoting Ex. 1007 (Truitt) 2:64–3:4).

Consistent with Truitt's disclosure, the '029 patent confirms that airflow and pressure sensors can be used to measure or derive a subject's respirations. Specifically, the '029 patent Specification states:

The subject's respirations can be measured by measurement of airflow, respiratory effort, oxygenation and ventilation, and the like. Measurement of airflow is preferably measuring using sensors or devices such as . . . pressure sensors. . . . Airflow can be estimated by measuring nasal or oral airway pressure that decreases during inspiration and increases during expiration. Inspiration and expiration produce fluctuations on the pressure transducer's signal that is proportional to airflow.

Ex. 1001, 7:44–49, 8:18–22. Accordingly, the '029 patent Specification supports that the patient's respirations can be measured via pressure changes during inspiration and expiration, which is taught in Truitt. Indeed, Truitt explicitly discloses that its system can be "used to estimate the pressure at the patient" (i.e., "deriv[e] the respiratory airflow of a subject"). *See* Ex. 1007 (Truitt) 6:1–2; Ex. 1003 (Kirkness Decl.) ¶ 219; Ex. 1005 (Chatterjee Decl.) ¶ 106; Ex. 1071 (Kirkness Reply Decl.) ¶ 5;¹² Reply 1–2.

¹² Paragraph 5 of Dr. Kirkness's Reply Declaration additionally cites Truitt's disclosure of a "pick-off port" in the patient's mask and Truitt's claims 2 and 12 to demonstrate that Truitt measures or derives the respiratory airflow of a

Patent Owner’s argument that determining whether a patient is inhaling or exhaling “does not provide the necessary airflow sensor data of the subject needed to ‘derive the [subject’s] respiratory airflow’ and calculate ‘data of a severity of the [subject’s] sleep disorder systems [sic]’” is unavailing on this record because Patent Owner does not identify what additional data is allegedly needed. PO Resp. 13 (citing, e.g., Ex. 2019 (Borkholder Decl.) ¶ 48) (first two alterations in original).

For the above reasons, we find that Petitioner demonstrates by a preponderance of the evidence that Truitt teaches or suggests “an airflow sensor . . . adapted for measuring or deriving the respiratory airflow of a subject” as recited in limitation [1.b.ii].

2. Whether Truitt Teaches or Suggests a “processor . . . adapted for . . . calculating: i) the data of a severity of the sleep disorder symptoms of the subject, . . . and/or iii) the index”

Claim 1 recites:

a second ***processor*** within the enclosure ***adapted for*** receiving the airflow sensor data and for ***calculating***:

i) the data of a severity of the sleep disorder symptoms of the subject,

ii) the data of usage of the PAP device by the subject, and/or

iii) the *index* based in whole or in part on either i) or ii) or both i) and ii)

subject. Ex. 1071 (Kirkness Reply Decl.) ¶ 5. We do not credit these portions of Dr. Kirkness’s testimony. The Petition did not cite Truitt’s “pick-off port” or claims 2 and 12, and thus we agree with Patent Owner it is too late for Petitioner to rely on these new portions of Truitt for the first time in Reply. *See* Sur-reply 3–4; *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367–68 (Fed. Cir. 2015).

Pet. 76 (limitation [1.b.iii]) (emphasis added). Claim 1 also recites that the system includes software adapted to display on a cell phone “an index of treatment efficacy . . . based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device.” *See id.* (limitation [1.a]).

Petitioner argues that Truitt discloses the claimed “data of a severity” and “index.” *See* Pet. 28–29 (citing, e.g., Ex. 1003 (Kirkness Decl.) ¶¶ 220–224; Ex. 1005 (Chatterjee Decl.) ¶¶ 107, 110–113; Pet. 17–21). In brief, Petitioner asserts that “Truitt discloses calculating ‘i) the data of a severity of the sleep disorder symptoms of the subject’ because it discloses monitoring the patient’s condition, and specifically detecting snoring, apneas, and hypopneas,” and snoring, apneas, and hypopneas “are data of different levels of severity of sleep disorder symptoms.” *Id.* at 28, 18 (citing Ex. 1003 (Kirkness Decl.) ¶¶ 175–178); *see also* Ex. 1003 (Kirkness Decl.) ¶ 175; Ex. 1071 (Kirkness Reply Decl.) ¶ 12 (equating “snores, apneas, and hypopneas” with “data of severity”). Regarding the claimed index, Petitioner argues:

The “apnea hypopnea index” or “AHI” is a measured number of apnea and hypopnea events per unit time. EX1012, 8:8-17. Because AHI includes the detection of hypopnea events (in addition to apnea events), a POSITA would have known that AHI could be calculated based on the number of apneas and hypopneas detected by Truitt. EX1007, 3:4-11 (controlling “the flow of breathing gas and the pressure level thereof” based on the detection of “snoring, apneas, hypopneas, etc.”); Kirkness ¶¶ 181-183.

...

Given that Truitt discloses using data collected while using the PAP device relating to the severity of the patient’s symptoms

(e.g., the number of apnea and hypopnea events) to control the “pressure and/or flow” in order to “counteract or prevent these conditions” (EX1007, 3:4-11), including at least an auto-titration mode, Truitt discloses an “index [of treatment efficacy of the subject using a PAP device is] based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject.” Kirkness ¶¶185-186.

Id. at 19–21.

Patent Owner disputes Petitioner’s showing. PO Resp. 14–21. Patent Owner begins with claim construction, arguing that “‘data of a severity’ indicates ‘the degree of deviation from the baseline characteristics of a patient without sleep disorder symptoms.’” *Id.* at 14–15 (citing Ex. 2020 (Jafari Decl.¹³) ¶¶ 41–42, 46; Ex. 2019 (Borkholder Decl.) ¶ 53). Patent Owner further asserts that “data of a severity” and “sleep disorder symptoms” are “terms of art” that “have known algorithms.” *Id.* at 15 (citing Ex. 2020 (Jafari Decl.) ¶¶ 39–40, 46; Ex. 2019 (Borkholder Decl.) ¶ 53). Patent Owner then asserts that the Board previously found that “‘monitor[ing] the condition of the subject’ means to ‘quantitatively’ calculate ‘severity of sleep disorder symptoms’ not merely to detect symptoms.” *Id.* at 16 (citing PGR2024-00012, Paper 7 at 16) (alteration in original). Patent Owner then suggests that Truitt does not meet the claimed requirements because it merely identifies symptoms (like snores, apneas, and hypopneas), but does not quantitatively determine the severity of those symptoms. *Id.* (citing Ex. 2019 (Borkholder Decl.) ¶¶ 55–56). Patent

¹³ *Declaration of Dr. Roozbeh Jafari in Support of Defendant and Counterclaim Plaintiff Cleveland Medical Devices, Inc.’s Opening Claim Construction Brief*, submitted in the Ohio case.

Owner also disputes that Truitt calculates any index like AHI. *Id.* at 18–19. Stated differently, Patent Owner asserts that Petitioner wrongly “treats mere symptom detection (e.g., identification of individual snores, apneas, and hypopneas) as if it were the ‘calculating [of] the data of a severity’ required by Claim 1.” Sur-reply 4 (alteration in original). Patent Owner asserts that claim 1 requires the processor to “calculate” the data of severity, not just identify sleep disorder symptoms. *Id.* (citing Ex. 1001, claim 1, 3:4–20, 8:10–28).

Petitioner responds that “[a] POSITA would have understood that the patient’s conditions, such as snoring, apneas, and hypopneas, reflect the different levels of severity of sleep disorder symptoms.” Reply 4 (citing Pet. 18; Ex. 1003 (Kirkness Decl.) ¶¶ 174–175; Ex. 1007 (Truitt) 3:7–10; Ex. 1010, 27 (Patent Owner’s Preliminary Response (Paper 6) in PGR2024-00012, stating that “a skilled artisan would know that apnea and hypopnea events, which are indicated based on breathing metrics, represent data of severity of the patient’s sleep disorder symptoms”); Ex. 1071 (Kirkness Reply Decl.) ¶¶ 8–9).

Petitioner also disputes Patent Owner’s proposed claim construction, which requires that “calculating the data of a severity of the sleep disorder symptoms” “must be done ‘quantitatively.’” Reply 5. Petitioner argues that the Specification does not define this term, and Patent Owner is improperly attempting to import an optional embodiment from the Specification into the claims. *Id.* at 5–6 (citing Ex. 1001, 4:3–59, which Petitioner characterizes as “listing numerous embodiments where only one of seven include a quantitative assessment,” and 19:8–12). Petitioner also argues that the Jafari

Declaration and Board decision from PGR2024-00012¹⁴ do not support Patent Owner’s proposed construction. *Id.* at 6–8. Petitioner additionally argues that the Specification provides no basis for the portion of Patent Owner’s proposed construction reciting “the degree of deviation from the baseline characteristics of a patient without sleep disorder symptoms” or for Patent Owner’s suggestion that the claims require determining AHI. *Id.* at 9, 11.

Finally, Petitioner argues that “even if ‘calculating the data of a severity of the sleep disorder symptoms’ is limited to a ‘quantitative’ assessment, Truitt still discloses it because Truitt’s PAP device “calculate[s] the quantity (e.g., the number of) snores and apnea and hypopnea events in order to treat the patient over time.” *Id.* at 8–9 (citing Ex. 1003 (Kirkness Decl.) ¶¶ 181–183; Ex. 1071 (Kirkness Reply Decl.) ¶¶ 10–12); Ex. 1070, 9).

We begin by addressing claim construction, then turn to whether Petitioner has demonstrated that Truitt teaches or suggests the claimed subject matter.

a. Construction of “data of a severity”

Patent Owner proposes that the claim term “data of a severity” means “the degree of deviation from the baseline characteristics of a patient without sleep disorder symptoms.” PO Resp. 14–15. We decline to adopt this construction. Patent Owner identifies no intrinsic support for the portion of the construction reciting “the degree of deviation from the baseline

¹⁴ *ResMed Corp. v. Cleveland Med. Devices, Inc.*, PGR2024-00012, Paper 7 (PTAB June 24, 2024).

characteristics of a patient without sleep disorder symptoms.” *See* Reply 9. Instead, Patent Owner relies only on extrinsic evidence—namely, the declarations of Dr. Jafari and Dr. Borkholder—as supporting this portion of the construction. *See* PO Resp. 14–15.

First, as indicated by the Federal Circuit, extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). This is especially applicable to Dr. Jafari’s opinions. His declaration was not prepared for this proceeding and thus Dr. Jafari was not subject to cross examination in this proceeding. *See* Reply 6 n.3. Moreover, Dr. Jafari was not opining on claim construction; rather, he was addressing the alleged indefiniteness. *See* Ex. 2020 (Jafari Decl.) 12 (heading addressing definiteness), ¶¶ 41–42, 46. Additionally, paragraphs 41–42 of Dr. Jafari’s declaration discuss claim terms phrases in a different patent (US 11,375,921), which explicitly include the terms “quantified” and “quantitative.” *See* Reply 6–7; Ex. 2020 (Jafari Decl.) ¶ 34. For at least these reasons, Patent Owner has not persuaded us that Dr. Jafari’s testimony is applicable here.

Further, regarding the portion of Patent Owner’s proposed construction reciting “the degree of deviation from the baseline characteristics of a patient without sleep disorder symptoms,” Dr. Borkholder does not do his own analysis, but instead simply states that he “agree[s] with the litigation claim construction opinions of Dr. Jafari.” Ex. 2019 (Borkholder Decl.) ¶ 53. This is insufficient, and thus we do not credit Dr. Borkholder’s testimony regarding claim construction.

We instead credit Dr. Kirkness’s statement that “[s]everity data is frequently calculated as the deviation from baseline characteristics of the patient himself, not a generic person ‘without sleep disorder symptoms.’” Ex. 1071 (Kirkness Reply Decl.) ¶ 13; Reply 9. As Dr. Kirkness explains, and Patent Owner does not dispute (*see generally* Sur-reply), “[t]he ‘baseline characteristics of a [generic] patient without sleep disorder symptoms’ would be irrelevant to any particular patient with their own unique breathing patterns and sleep disorder symptoms.” Ex. 1071 (Kirkness Reply Decl.) ¶ 13 (second alteration in original). For at least these reasons, we reject Patent Owner’s proposed claim construction.

To the extent Patent Owner asserts that “data of a severity” and “sleep disorder symptoms” require a “quantitative” calculation or use of an algorithm, we also disagree. *See* PO Resp. 14–16. First, nothing in the language of the claims themselves describes or requires a “quantitative” calculation or an algorithm. *See generally* Ex. 1001, 23:6–26:59. To be sure, the ’029 patent discloses embodiments that use known algorithms to “quantify the level of severity of the subject’s sleeping disorder or symptoms.” *See, e.g., id.* at 20:16–19. But the Specification does not require an algorithm. The Specification also indicates that quantification is merely “preferable” (i.e., not required), and is merely one embodiment. *See, e.g., id.* at 19:8–12 (“The signals from the one or more sensors *used in various embodiments* of the present invention are *preferably analyzed using a processor and software that can quantitatively estimate or determine the severity* of the subject’s sleeping disorder or symptoms.”) (emphasis added), 4:51–59 (“Finally, in *still another embodiment*, the present invention includes a sleeping disorder treatment system comprising a device for

diagnosing and creating a quantitative output of a level of severity of a subject's sleeping disorder or symptoms") (emphasis added); *see also* Reply 5–6 (citing Ex. 1001, 4:3–59 and 19:8–12 and stating that the '029 patent lists "numerous embodiments where only one of seven include a quantitative assessment"). Elsewhere, the Specification more generally states that signals from sensors are "analyzed to determine the level of severity of the symptoms," without specifying that such analysis must be "quantitative" or performed by an algorithm. *See* Ex. 1001, 3:41–44. In view of these disclosures, Patent Owner does not persuade us to adopt its narrowing claim construction. Indeed, our reviewing court has "repeatedly warned against confining the claims" to specific embodiments disclosed in the Specification. *Phillips*, 415 F.3d at 1323.

Patent Owner's reliance on a prior Board decision in PGR2024-00012, which related to the parent of the '029 patent, is unavailing. *See* PO Resp. 15–16. We agree with Petitioner that in the cited case, "[t]he Board made no findings about the meaning of the term calculating 'the data of a severity of the sleep disorder symptoms of the subject' for claim construction." Reply 8. Indeed, neither party offered any claim construction, and the Board determined that no claim construction was necessary for purposes of that decision. *See ResMed Corp.*, PGR2024-00012, Paper 7 at 8. The page of the decision Patent Owner cites addresses written description support in the specification for the claims challenged in that PGR, not claim construction. *See id.* at 16. In any event, the cited decision is a decision on institution. The Board's statements there are, by nature, preliminary findings and conclusions based on a preliminary record, and are not binding here.

For at least the above reasons, Patent Owner does not persuade us to adopt its narrowing claim construction and we find that the term “data of a severity” does not need construction because the words of the term are clear on their face.

b. Whether Petitioner has Demonstrated that Truitt Teaches or Suggests a “processor . . . adapted for . . . calculating: i) the data of a severity of the sleep disorder symptoms of the subject, . . . and/or iii) the index”

Turning to whether Petitioner has demonstrated that Truitt teaches or suggests the “processor . . . adapted for . . . calculating: i) the data of a severity” or the claimed “index,” after considering the arguments and cited evidence of record, we find that Petitioner has not demonstrated by a preponderance of the evidence that Truitt teaches or suggests these claim limitations. As will be discussed, we agree with Patent Owner that Petitioner is “conflating symptom *detection* (e.g., snore/apnea/hypopnea detection) with *calculating* a level of severity of the subject’s symptoms.” Sur-reply 1 (emphasis added).

Truitt discloses that in a PAP device operating “[i]n the auto-titration mode,” “the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient.” Ex. 1007 (Truitt) 3:4–11; *see also id.* at 2:57–60. The condition of the patient is determined, in turn, based on signals from sensors “used to detect snoring, apneas, hypopneas, etc.,” and “[t]he pressure and/or flow is then controlled to counteract or prevent these conditions.” *Id.* at 3:4–11. Dr. Kirkness opines that the patient’s condition and symptoms themselves “reflect the different levels of severity of sleep disorder symptoms.” Ex. 1003 (Kirkness Decl.) ¶ 175 (“A POSITA would have understood that the patient’s conditions, such as snoring, apneas, and

hypopneas, reflect the different levels of severity of sleep disorder symptoms.”); *see also* Ex. 1071 (Kirkness Reply Decl.) ¶ 12 (equating “snores, apneas, and hypopneas” with “data of severity”). Petitioner asserts that “Truitt discloses calculating ‘i) the data of a severity of the sleep disorder symptoms of the subject’ because it discloses *monitoring* the patient’s condition, and specifically *detecting* snoring, apneas, and hypopneas.” Pet. 28 (emphasis added) (citing Ex. 1003 (Kirkness Decl.) ¶ 221; Ex. 1005 (Chatterjee Decl.) ¶ 110).

We are not persuaded that Truitt’s detection or monitoring of snores, apneas, and hypopneas with teaches or suggests “calculating: i) the data of a severity of the symptoms of the subject.” We agree with Patent Owner that snores, apneas, and hypopneas are themselves “the symptoms of the subject,” and merely monitoring or detecting them does not “calculate” anything relating to the severity of those symptoms. *See, e.g.*, PO Resp. 16 (“[M]erely identifying symptoms, like snores, apneas, and hypopneas not tantamount to calculating ‘data of a *severity* of the symptoms of the subject.’”). Petitioner’s effort to equate the *detection* and *monitoring* of snores, apneas, and hypopneas with “*calculating* i) the data of a severity” reads the term “calculating” out of the claim. *See id.* at 20 (“the ‘data of a severity of the sleep disorder symptoms of the subject’ is a required calculation that must be performed by the processor of the PAP device”); Sur-reply 4–5 (“[T]he claim requires a calculation of the severity of the subject’s symptoms, not mere detection of those symptoms.”). Thus, even if the snoring, apneas, and hypopneas detected by Truitt’s sensors “reflect the different levels of severity of sleep disorder symptoms” as Petitioner and Dr. Kirkness allege, Petitioner does not adequately explain how this meets

the claim language which requires that the PAP system have a processor adapted for “*calculating i) the data of a severity.*” *See* Ex. 1003 (Kirkness Decl.) ¶ 174; Pet. 18; Reply 4; *see also* Ex. 1007, 3:7–10 (“[T]hese pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc.”).

Further, claim 1 recites that the processor is adapted for calculating “the index [of treatment efficacy of the subject],” where “the index [is] based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject.” *See* Pet. 76 (limitations [1.a], [1.b.iii]). Petitioner asserts that “[a] POSITA would have understood that determining whether to increase/decrease pressure/flow based on patient conditions requires calculating the effectiveness of the PAP treatment system (i.e., an index of treatment efficacy) to meet the desired prescription pressure level and/or ‘counteract or prevent these conditions.’” *Id.* at 19 (citing Ex. 1003 (Kirkness Decl.) ¶¶ 179–180). Petitioner further asserts that “a POSITA would have known that AHI could be calculated based on the number of apneas and hypopneas detected by Truitt.” *Id.* (citing Ex. 1007 (Truitt) 3:4–11; Ex. 1003 (Kirkness Decl.) ¶¶ 181–183). Petitioner states:

Given that Truitt discloses using data collected while using the PAP device relating to the severity of the patient’s symptoms (e.g., the number of apnea and hypopnea events) to control the “pressure and/or flow” in order to “counteract or prevent these conditions” (EX1007, 3:4-11), including at least an auto-titration mode, Truitt discloses an “index [of treatment efficacy of the subject using a PAP device is] based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject.”

Id. at 21 (citing Ex. 1003 (Kirkness Decl.) ¶¶ 185–186).

Petitioner's arguments are not persuasive. Its arguments regarding Truitt disclosing the claimed "index" depends on the same flawed argument that detecting apneas and hypopneas equates to a data of severity of sleep disorder symptoms that we already rejected above.

Additionally, we agree with Patent Owner that "Petitioner does not claim that Truitt expressly discloses calculating an index, like AHI." PO Resp. 18; *see also* Tr. 14:7–15 (confirming that Petitioner does not contend that Truitt expressly discloses calculation of AHI). Petitioner instead argues that because Truitt's system "determin[es] whether to increase/decrease pressure/flow based on patient conditions" (such as "the number of apnea and hypopnea events"), it "calculat[es] the effectiveness of the PAP treatment system (i.e., an index of treatment efficacy)." Pet. 19. Petitioner, however, does not demonstrate that Truitt calculates any *index* over time. Instead we agree with Patent Owner that "Truitt discloses using 'auto-titration' or a bi-level mode, which respond[s] *immediately* to changes in pressure detected at the CPAP machine." PO Resp. 19 (emphasis added); Ex. 1007 (Truitt) 1:30–43, 3:4–11, 6:49–60; Ex. 2019 (Borkholder Decl.) ¶ 59.

Finally, Petitioner's suggestion that "[b]ecause AHI includes the detection of hypopnea events (in addition to apnea events), a POSITA **would have known** that AHI could be calculated based on the number of apneas and hypopneas detected by Truitt," is unavailing. Pet. 19 (emphasis added). The Petition lacks the necessary "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" because in connection with Grounds 1–3 it fails to provide any reason *why* a person of ordinary skill in the art would have been motivated to modify Truitt to

calculate AHI. *KSR*, 550 U.S. at 418; *see also* PO Resp. 19 (“Petitioner’s assertion that a POSITA *could have* calculated the patient’s AHI using data generated at Truitt’s CPAP machine does not establish that a POSITA *would have* been motivated to do so.”).

For the above reasons, we find that Petitioner has not carried its burden of demonstrating by a preponderance of the evidence that Truitt teaches or suggests the claimed “processor . . . adapted for . . . calculating: i) the data of a severity of the sleep disorder symptoms of the subject, . . . and/or iii) the index.” This finding is sufficient to resolve Grounds 1–3, and thus we do not reach Patent Owner’s arguments concerning motivation to combine Truitt and Kumar.

3. Conclusion – Grounds 1–3

On this record, we find that Petitioner has not demonstrated by a preponderance of the evidence that claim 1 is unpatentable as obvious over Truitt and Kumar. Additionally, because dependent claims are nonobvious under § 103 if the independent claims from which they depend are nonobvious (*see In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988)), we find that Petitioner also has not demonstrated by a preponderance of the evidence that (1) dependent claims 2–11, 13–16, 18, and 19 are unpatentable as obvious over Truitt and Kumar; (2) dependent claims 14 and 15 are unpatentable as obvious over Truitt, Kumar, and Dong; and (3) dependent claims 12 and 17 are unpatentable as obvious over Truitt, Kumar, and Wright.

F. Grounds 4–6 – Alleged Obviousness Over Truitt, Kumar, and Mumford (Ground 4), Truitt, Kumar, Dong, and Mumford (Ground 5), and Truitt, Kumar, Wright, and Mumford (Ground 6)

Grounds 4–6 present the same combinations of prior art presented for Grounds 1–3, but add Mumford for its disclosure of a sleep efficacy algorithm. Pet. 64. In brief, Petitioner argues that “[a] POSITA would have been motivated to modify the Truitt PAP device to incorporate the sleep efficacy algorithm of Mumford” to improve the PAP’s performance, improve compliance, and increase the effectiveness of treatment. *Id.* at 65–66 (citing Ex. 1003 (Kirkness Decl.) ¶¶ 310–313).

Patent Owner responds that “[i]mplementing Mumford’s sleep efficacy algorithm on Truitt’s device requires sensor inputs” from Mumford’s mask, but the Petition does not allege that these sensors are part of the proposed combination. PO Resp. 34–35 (citing Ex. 2019 (Borkholder Decl.) ¶ 92); *id.* at 39 (citing Ex. 2019 (Borkholder Decl.) ¶ 100). Patent Owner asserts that “[a] POSITA would not have had a reasonable expectation of success combining Mumford’s sleep efficacy algorithm with a PAP device like Truitt’s, where its only input to the algorithm would be from its flow sensing assembly.” *Id.* at 35 (citing Ex. 2019 (Borkholder Decl.) ¶ 93).

After considering the arguments and cited evidence of record, we find that Petitioner has not carried its burden of demonstrating that the challenged claims would have been obvious over the combination of Truitt, Mumford, and the other cited references. We agree with Patent Owner that “Petitioner identifies no disclosure in Mumford where its sleep efficacy algorithm is reliant [only] upon an internal airflow signal, nor does the Petition describe

incorporating any additional sensors, from Mumford or any other reference.”
Sur-reply 9.

More specifically, we agree with Patent Owner that “[t]here is no embodiment taught or suggested in Mumford, where the pressure transducer of an internal or external airflow assembly is the sole provider of information for its sleep efficacy algorithm.” PO Resp. 36; Ex. 2019 (Borkholder Decl.) ¶ 94. Instead, “[t]o implement Mumford’s sleep efficacy algorithm, one of ordinary skill would have to include a combination of electrodes and pressure transducers integrated into the mask.” PO Resp. 38; Ex. 2019 (Borkholder Decl.) ¶ 98; Ex. 1009 (Mumford) 4:24–35 (pressure transducer in combination with an oximeter or position sensor), 12:42–44 (“pressure transducer 316 is used to detect the pressure within the cavity of the nasal mask 20”), 12:62–13:22 (pressure transducer is optionally used in combination with the electrodes and other sensors), claims 10, 13 (pressure transducer used in combination with electrodes and other sensors).

Despite this, Petitioner only argues that “[a] POSITA would have been motivated to modify the Truitt PAP device to incorporate *the sleep efficacy algorithm of Mumford*.” Pet. 64 (emphasis added). In other words, the Petition does not assert that a person of ordinary skill in the art would have incorporated the required sensors from Mumford’s mask into the proposed combination of Truitt and Mumford. Neither Petitioner nor its expert show how Mumford’s algorithm would operate within Truitt’s device without the use of Mumford’s electrode signals. *See* PO Resp. 40; Ex. 1009 (Mumford) 15:39–16:3; Ex. 2019 (Borkholder Decl.) ¶ 101.

Petitioner responds that “Mumford’s algorithm does not require the use of electrode sensors” because the electrodes are used “to measure EEG

and EMG to determine sleep stage, not for the detection of sleep disordered events,” and determination of sleep stage “is not required.” Reply 21 (citing Ex. 1071 (Kirkness Reply Decl.) ¶¶ 27–28; Ex. 1009 (Mumford) 15:39–47). Petitioner also asserts that “Truitt’s PAP system included the use of electrode sensing elements,” e.g., “ports 74 and 76 incorporated electric sensing elements that could be ‘mounted on a circuit board’; these would have functioned similar to Mumford’s electrodes.” *Id.* (citing Ex. 1071 (Kirkness Reply Decl.) ¶ 28).

These arguments are unavailing. First, Petitioner’s contention that a skilled artisan would have incorporated only portions of Mumford’s algorithm into Truitt’s PAP (i.e., only those portions related to “the detection of sleep disordered events” and not the portions of the algorithm related to “determin[ing] sleep stage”) comes too late because this argument was not in the Petition. *See, e.g., Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1286–87 (Fed. Cir. 2017) (rejecting petitioner’s “attempts to cure the petition’s deficiencies in its subsequent briefing to the Board”). The Petition does not discuss modifying Mumford’s sleep efficacy algorithm before incorporating it into Truitt’s PAP device or incorporating only certain features of the algorithm. Indeed, the Petition and Dr. Kirkness rely on Mumford’s ability to detect sleep arousals when mapping Mumford to the claimed “data of a severity” and “index.” *See* Pet. 69–70; Ex. 1003 (Kirkness Decl.) ¶¶ 323–325. Mumford discloses that the mask electrodes detect arousals. *See* Ex. 1009 (Mumford) 2:4–10, 11:39–48.

The same lack of disclosure plagues Petitioner’s belated Reply argument that Truitt’s ports 74 and 76 can incorporate electric sensing elements that would have functioned similar to Mumford’s electrodes. *See*

Reply 22. The Petition did not mention ports 74 and 76 or otherwise suggest that a skilled artisan would have added functionality similar to Mumford's electrodes to Truitt's PAP, and we find that it is too late on Reply for Petitioner to posit this modification.

For the above reasons, we find that Petitioner has not demonstrated by a preponderance of the evidence that (1) claims 1–11, 13–16, 18, and 19 are unpatentable as obvious over Truitt, Kumar, and Mumford; (2) claims 10 and 14–16 are unpatentable as obvious over Truitt, Kumar, Dong, and Mumford; and (3) claims 12 and 17 are unpatentable as obvious over Truitt, Kumar, Wright, and Mumford.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–19 of the '029 patent are unpatentable.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–11, 13–16, 18, 19	103(a)	Truitt, Kumar		1–11, 13–16, 18, 19
14, 15	103(a)	Truitt, Kumar, Dong		14, 15
12, 17	103(a)	Truitt, Kumar, Wright		12, 17
1–11, 13–16, 18, 19	103(a)	Truitt, Kumar, Mumford		1–11, 13–16, 18, 19
10, 14–16	103(a)	Truitt, Kumar, Dong, Mumford		10, 14–16
12, 17	103(a)	Truitt, Kumar, Wright, Mumford		12, 17
Overall				1–19

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
Outcome				

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–19 of U.S. Patent No. 11,872,029 B1 are unpatentable; and

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

IPR2025-00247
Patent 11,872,029 B1

For PETITIONER:

Lisa Nguyen
David Tennant
Grace Wang
PAUL HASTINGS LLP
lisanguyen@paulhastings.com
davidtennant@paulhastings.com
gracewang@paulhastings.com

For PATENT OWNER:

James Hannah
Jeffrey Price
Jenna Fuller
Jeffrey Eng
KRAMER LEVIN NAFTALIS & FRANKEL LLP
jhannah@kramerlevin.com
jprice@kramerlevin.com
jfuller@kramerlevin.com
jeng@kramerlevin.com