

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

Case IPR2025-00247
U.S. Patent No. 11,872,029

PATENT OWNER'S RESPONSE

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PATENT OWNER'S EXHIBIT LIST

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2001	Response to Non-Final Rejection from File History of U.S. Patent No. 12,213,775, filed August 28, 2024
2002	Non-Final Rejection from File History of U.S. Patent No. 12,213,775, filed May 30, 2024
2003	Notice of Allowance from File History of U.S. Patent No. 12,213,775, filed September 24, 2024
2004	Excerpts of Plaintiff and Counterclaim Defendant ResMed Corp.'s Initial Invalidity and Unenforceability Contentions cover pleading, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB (N.D. Ohio), served on July 15, 2024
2005	Intentionally Omitted
2006	Excerpts of Plaintiff ResMed Corp.'s Response and Affirmative Defenses to Defendant's Second Amended Counterclaims for Patent Infringement, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 75 (N.D. Ohio), filed on April 25, 2024
2007	Excerpts of Declaration of James Hannah in Support of Defendant CleveMed's Opposition to Plaintiff ResMed's Motion for Temporary Stay Pending Mediation, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 87-1 (N.D. Ohio), filed on August 21, 2024
2008	Excerpts of Declaration of Lisa Kobialka in Support of Defendant CleveMed's Opposition to Plaintiff ResMed's Motion to Stay, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 100-1 (N.D. Ohio), filed on January 24, 2025
2009	Excerpts of ResMed Corp.'s Reply in Support of its Motion to Stay, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 101 (N.D. Ohio), filed on January 31, 2025

Exhibit	Description
2010	Excerpts of Defendant Cleveland Medical Devices, Inc.'s Memorandum in Support of its Motion to Dismiss Plaintiff's Complaint for Declaratory Judgment of Noninfringement, or to the Extent Not Granted, to Transfer, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-00500-TWR-JLB, Dkt. No. 10-1 (S.D. Cal.), filed on June 5, 2023
2011	<i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 87-5, Declaration of Hani Kayyali in Support of Patent Owner's Opposition to Motion to Stay Pending Mediation (N.D. Ohio), filed on August 21, 2024
2012	Excerpts of Petitioner's parent company's (ResMed) Q4 FY2024 Earnings call, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 87-6 (N.D. Ohio), filed on August 21, 2024
2013	Excerpts of Defendants' Initial Validity and Enforceability Contentions Pursuant to L.P.R. 3.7, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB (N.D. Ohio), served on August 5, 2024
2014	Case Management Order, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 54 (N.D. Ohio), filed on January 10, 2024
2015	Excerpts of Defendant ResMed Inc.'s Third Amended Initial Invalidity Contentions cover pleading from <i>Cleveland Med. Devices, Inc. v. ResMed, Inc.</i> , No. 22-cv-00794-GBW-CJB (D. Del.), served on November 10, 2023
2016	Excerpts of Non-Final Office Action from the File History of U.S. Patent 11,602,284 filed on September 13, 2022
2017	National Library of Medicine, National Center for Biotechnology Information webpage –Physiological Feedback, printed on May 8, 2025
2018	Declaration of Jeffrey H. Price

Exhibit	Description
2019	Declaration of Dr. David A. Borkholder in Support of Patent Owner's Response
2020	Declaration of Dr. Roozbeh Jafari in Support of Defendant and Counterclaim Plaintiff Cleveland Medical Devices, Inc.'s Opening Claim Construction Brief, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 94-2 (N.D. Ohio Nov. 25, 2024)
2021	"A Nasal Cannula Can Be Used to Treat Obstructive Sleep Apnea," by B.M. McGinley, et al., <i>Am. J. Respir. Crit. Care Med.</i> , Vol. 176, pp. 194-200 (2007)
2022	Resmed Press Release – "Resmed Acquires VirtuOx," available at https://investor.resmed.com/news-events/press-releases/detail/402/resmed-acquires-virtuox , dated May 1, 2025
2023	"NCA – Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)," available at https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=110 , dated October 21, 2025
2024	"Introduction to the practice of telemedicine," by J. Craig and V. Patterson, <i>Journal of Telemedicine and Telecare</i> , Vol. 11, pp. 3-9 (2005)
2025	"Automatic detection of sleep-disordered breathing from a single-channel airflow record," by H. Nakano, et al., <i>Eur Respir. J.</i> Vol. 29, pp. 728-736 (2007)
2026	"Envelope Analysis of the Airflow Signal To Improve Polysomnographic Assessment of Sleep Disordered Breathing," by J. Diaz, et al., <i>SLEEP</i> , Vol. 37, No. 1 (2014)

I. INTRODUCTION

The '029 Patent is patentable because the prior art of record fails to disclose the measuring respiratory airflow and calculating data of severity limitations of the claimed invention and the Petition fails to show the necessary motivation to combine the prior art. In particular, Petitioner relies upon generic and irrelevant motivations to combine Truitt and Kumar that provide no reason to combine the teachings of Truitt and Kumar to achieve the claimed invention.

Regarding Grounds 1-3, the Petition fails to show that Truitt's internal airflow sensor measures a patient's respiratory airflow or calculates data reflective of the severity of the patient's symptoms. Instead, Truitt discloses an "auto-titration" based CPAP system, which was known in the art to be "expensive and largely ineffective." These systems reacted in real time to changes in the pressure being delivered to the patient in an attempt to counteract a breathing event, like a snore, hypopnea, or apnea. Unlike the invention claimed in the '029 Patent, they were not reactive to data representing the *severity* of the patient's symptoms. Nor does Truitt disclose transmitting severity level data to a "remote internet site," and Petitioner's argument that it would have been obvious to modify Truitt with Kumar to reach the claimed invention is grounded in impermissible hindsight.

Recognizing that Truitt is deficient in calculating symptom severity data, Petitioner proposes modifying Truitt to perform Mumford's sleep efficacy algorithm

in Grounds 4-6. However, a POSITA would not use Mumford's unmodified algorithm in Truitt's system because Mumford makes clear that its algorithm is reliant upon multiple sensors found in the mask assembly, but which are not alleged as part of the combination. Petitioner's oversimplified reading of Mumford's algorithm fails to demonstrate that a POSITA would have had a reasonable expectation of success when only receiving information from a single airflow sensor.

Finally, Petitioner fails to demonstrate that Truitt and Kumar disclose a remote internet site that retransmits the patient's severity, usage, and/or index data to the patient's cell phone as claimed in Claims 9-13. The data received by Kumar's remote site would not be retransmitted back to the cell phone because in Kumar's system, patient data is always routed through its computing device that it likens to the claimed cell phone. Petitioner makes no showing that a POSITA would be motivated to send redundant data back to the cell phone.

For these reasons, and those discussed in detail below, Patent Owner respectfully requests that the Board find the Challenged Claims patentable.

II. OVERVIEW OF THE '029 PATENT AND THE ASSERTED ART

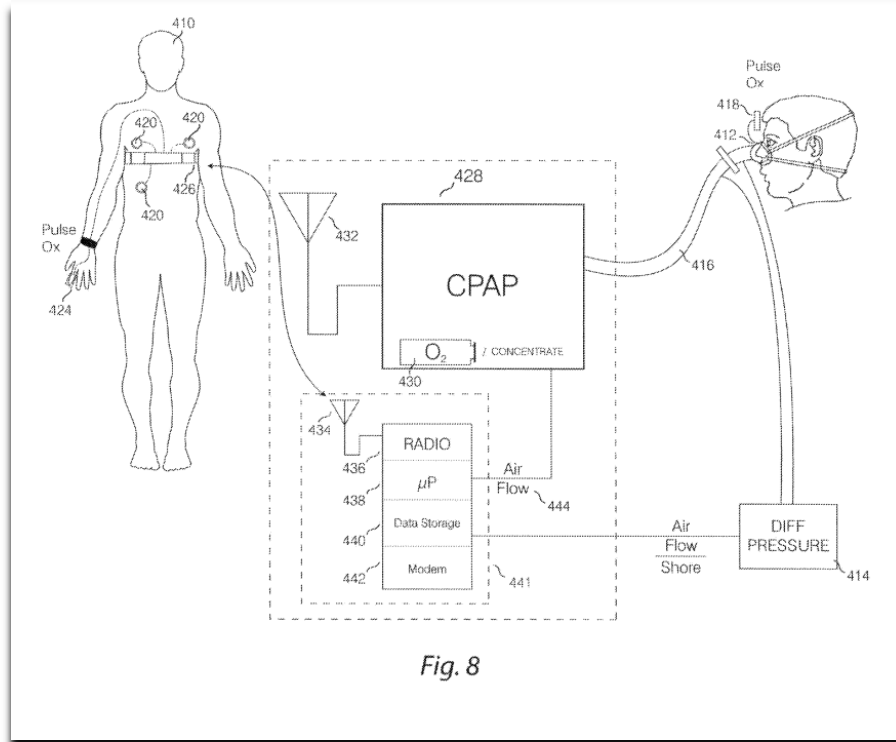
A. The '029 Patent (Ex. 1001)

The '029 Patent relates to a novel integrated sleep diagnosis and treatment device for patients suffering from sleep apnea. '029 Patent at Abstract, 1:31-35. The device (1) analyzes the patient's breathing metrics, including parameters related to

a patient's breath, such as respiratory airflow and effort, and blood oxygenation levels, and (2) adjusts the treatment based, at least in part, on this analysis. *Id.* at 2:49-56, 3:21-56.

The claimed invention uses a positive airway pressure ("PAP") device with internal airflow sensors that detect the patient's respiratory airflow data. *Id.* at 7:36-8:41. The readings from airflow sensors are collected and processed by the PAP's device processor(s) to indicate the data of severity of a patient's sleep disorder symptoms that is used along with the usage of the PAP device to generate an index (*e.g.*, respiratory disturbance index (RDI), apnea-hypopnea-index (AHI)), related to the patient's treatment and the treatment's efficacy, which are transferred to a remote internet site and a cell phone for display. *See id.* at Claim 1. The PAP device may distinguish between, and calculate the severity of, obstructive and central apneas and then be adjusted remotely based on the data sent to the remote internet site. *See id.* at Claims 12, 18.

An exemplary embodiment of the PAP device, shown below, includes a pressure generator, a blower with an air output, a mask or nasal cannula, a flow sensor, and a pressure sensor, with a microprocessor 438 for processing the data or signals from the flow sensor to determine the data of severity of the patient's sleep disorder symptoms and/or index related to the treatment's efficacy:



'029 Patent at FIG. 8, 23:31-54. The calculated information is used to control the pressure or flow of gas provided to the subject, initiate a medicinal intervention, monitor the condition of the subject, and/or monitor the usage of the pressure support device. *Id.* at 23:20-30, Claims 6, 12, 14, 18.

B. Truitt (Ex. 1007)

Truitt discloses a conventional PAP device with no disclosed ability to integrate the PAP device with other devices. The Truitt invention “pertains to a technique for measuring gas flow and/or volume in a pressure support system” so that its signal “can be used in the same manner” as those sensors used in conventional PAP devices. Truitt at 1:12-22, 3:41-46, 3:66-4:1.

The claims of the '029 Patent require a PAP device that measures a subject's respiratory airflow and calculates symptom severity data. '029 Patent at Claim 1. On the other hand, Truitt's invention seeks to measure the airflow provided to the patient, like conventional PAP devices, but without the flow sensors found on those conventional PAP devices. Truitt at 3:66-4:3, 5:35-38, 6:38-60. Thus, rather than disclose any new functionalities, Truitt discloses conventional functions, such as monitoring the pressure of gas delivered to the patient, adjusting the pressure or flow in a feedback fashion to meet the desired prescription pressure level, and adjusting pressure based on the breathing cycle. *Id.* at 2:60-3:4. Measurements of the airflow delivered to the patient do not represent the patient's respiratory airflow; they represent the airflow provided to the patient.

Further Truitt describes the conventional CPAP auto-titration mode distinguished in the '029 Patent, "where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient, these pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc." Truitt at 3:4-9; *id.* at 1:35-43 (describing the same known CPAP therapy, which changes pressure based on the detection of snoring or upper airway resistance); '029 Patent at 2:32-37 ("More advanced, but still very basic devices have been developed that adjust this continuous positive gas pressure through sensors built into the device for creating the positive gas pressure, which

measure gas flow through the device. These basic adjustable devices have been found to be expensive and largely ineffective.”). However, the feedback loop is not based on physiological data or symptom severity data but rather just whether an abnormal pressure or flow level is detected within the device. ’029 Patent at 2:38-40 (“None of the devices on the market can be used to adjust a patient's treatment, whether physical or chemical, based on the patient's current physiological state.”). That this event may be assigned as an apnea does not show that the subject’s symptom severity is quantified and used to adjust the PAP device.

As was known at the time, the determinations made by Truitt were highly inaccurate and not suitable for patient monitoring because conventional PAP devices (1) were not controlled by physiological feedback and (2) supplied air at different periods that were not always beneficial to the patient. Truitt at 3:21-36; *see also* Ex. 1002 at 160 (quoting Geva ¶ [0299]: “[c]onventional CPAP systems . . . have several drawbacks: (1) apnea events may return whenever the CPAP is used improperly, which is normally the case because conventional CPAP systems are poorly controlled, or not controlled at all, by physiological feedback. Therefore, these systems output a constant continuous pressure, or vary the pressure to coincide with the person’s breathing pattern, or start with low pressure, after which the pressure is gradually increased From technical point of view conventional CPAP systems are inefficient, because they supply, at different periods, air that is not beneficial to

the patient.”). As shown by the National Library of Medicine, “[p]hysiological feedback is mediated through extensive feedback mechanisms that use physiological cues as feedback loop signals to control other systems.” Ex. 2017 at 1.

C. Kumar (Ex. 1008)

Kumar discloses a system and method for network-based monitoring of physiological data. Kumar at Abstract. Kumar’s patient-side device 102 transmits signal data to computing device 110, which forwards that data to central server 106, from which it is sent to a medical provider. *Id.* at FIG. 1A. The signal data transmitted from the patient-side device is received and analyzed using computing device 110’s data interpretation and analysis module 114. *Id.* at ¶ [0075] (“data interpretation and analysis module 114 is used to interpret the data stream from the client-side device, perform mathematical analysis on the data using FFT, DFT, etc., and generate statistics”).

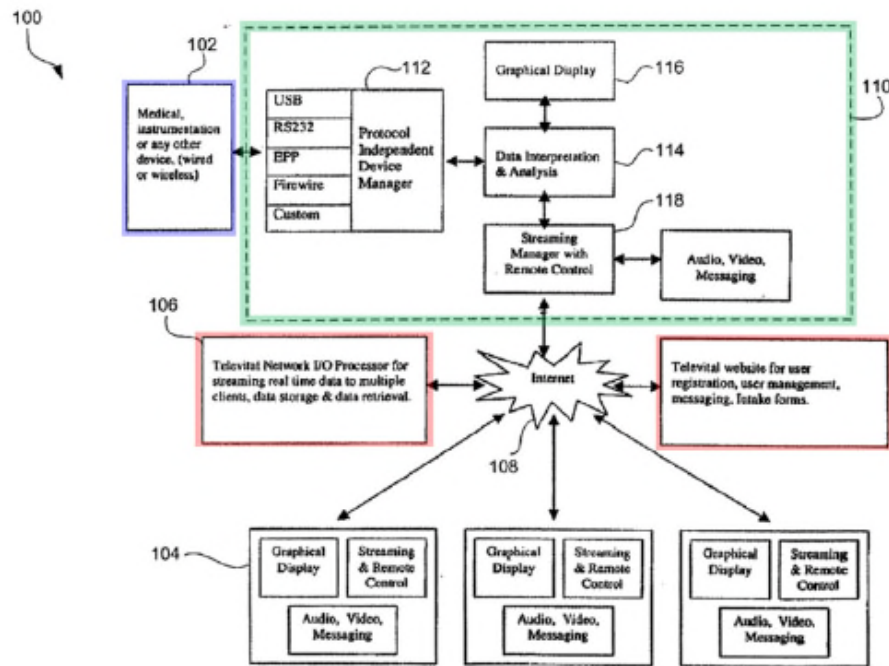


Fig. 1A

Pet. at 23 (citing Kumar, Fig. 1A) (annotated); *see also* Kumar at [0067] (“[T]he system includes one or more patient-side devices 102 for collecting data from a patient/client, one or more provider-side devices 104, and an engine implemented on a central server 106.”); Kumar at Fig. 5, [0078]-[0083], [0091]-[0092].

A POSITA would understand, that based on the type of sensors and devices described in Kumar, its implementation regarding its use for sleep apnea, its intended purpose is to replace attended, in-laboratory testing with “on-line live monitoring.” Kumar at [0240]-[0241] (disclosing that its system is intended for monitoring devices used in traditional in-home sleep testing, using polysomnography and oximetry, and in standard in-laboratory polysomnography and breathing monitoring,

using thermocouples or thermistors, thoracic EMG or inductive plethysmography, and oximetry); *id.* at [0179] (“Data collected by the unit is processed by the system to provide real-time medical monitoring, summary reports, statistical calculations, and visual displays, which can further be tailored for the healthcare provider’s particular needs, and can each be tailored for a particular protocol.”).

D. Mumford (Ex. 1009)

Mumford’s sleep efficacy algorithm requires signals from a combination of electrodes integrated into its mask, as the primary inputs for its sleep efficacy algorithm. Mumford at 15:39-16:3 (the sleep efficacy algorithm uses “a frontal staging algorithm, ***based on at least the electrode signals***, to determine which stage of sleep the wearer 18 is in”) (emphasis added); *id.* at 15:42-46. Without at least a combination of electrodes being used, Mumford’s sleep efficacy algorithm would be useless. *See id.* at Claims 1, 17-19, 24 (Mumford independent claims all claiming multiple sensors and electrodes used within the mask assembly); Ex. 2019 (“Borkholder Decl.”), ¶¶42-45.

Mumford discloses “a mask assembly with integrated sensors for sensing the efficacy of treatment of medical conditions.” Mumford at 1:20-22. “The mask assembly 12 further includes sensors (e.g., electrodes E1, E2, E3, E4 and E5 of FIGS. 2a and 2b) positioned on the nasal mask 12, the straps 24 and 26” *Id.* at FIGS. 2a-2b, 7:22-25, 9:40-10:24. The mask sensors are connected to the monitoring unit

and include electrodes for detecting EEG, EMG, EOG, and sensors for detecting blood oximetry, body position, and pressure. *Id.* at 7:25-33. The sensors are integrated directly into the inner surface of the mask so that the electrodes rest against the skin of the wearer. *Id.* at 7:58-60, 8:24-27, 8:40-45 (providing examples of the sensors that are preferable because they require minimal preparation of the skin of the CPAP wearer), 8:46-67 (discussing metal, saline, disk, and peel and stick electrodes that may directly integrated into the mask and require additional preparation prior to use), 9:2-6 (discussing how it is beneficial for the wearer to prepare their skin in the locations where the electrodes are used).

The locations of the various electrodes are chosen to be “on the face and head of the wearer 18 in order to obtain good signal quality and different types of physiological data with a minimal number of electrodes.” Mumford at 9:17-39 (discussing the physiological data collected from the electrodes providing data related to the CPAP wearer’s brainwaves, facial muscle tone and eye movements). Mumford also discloses the electrodes can be used in different combinations but in each instance, Mumford discloses using multiple sensors for gathering physiological information, never just a single sensor. *Id.* at 10:51-11:48. Thus, Mumford discloses that multiple sensor electrodes are necessary to supply the multiple channels of physiological information necessary for its algorithm to function as intended. *Id.* at 10:66-11:16.

Mumford has an alternative mask assembly embodiment with an integrated oximeter, pressure transducer, and position sensors. *Id.* at 11:66-12:21. In that embodiment, the pressure transducer is disposed within the nasal cavity of the mask so that it is near the gas inlet. *Id.* The pressure transducer is used to detect the pressure within the mask for deriving the breathing rate of the wearer to provide an indication of apnea and hypopnea events. *Id.* at 12:42-46. The electrodes and sensors are connected to a monitoring unit 16 with mask interface 602. *Id.* at 7:27-33, 14:65-66. The physiological information provided by the various sensors is processed by the monitoring unit according to a sleep efficacy algorithm that determines the sleep stage of the wearer and how many arousals they experienced. *Id.* at 7:34-42. Mumford also discloses using these parameters to control the CPAP. *Id.* at 7:46-51.

III. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) in 2005, is someone who “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.” Pet. at 4. “Additional experience could substitute for less education, and additional education could likewise substitute for less experience.” *Id.*

IV. THE CHALLENGED CLAIMS ARE PATENTABLE

A. Grounds 1-3: The Challenged Claims are Patentable Over Truitt and Kumar

1. Truitt Does Not Disclose Measuring or Deriving the Respiratory Airflow of a Subject While Using the PAP or Outputting Airflow Sensor Data

The Petition fails to demonstrate that Truitt discloses “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.” ’029 Patent, Claim 1; Pet. at 27-29; Borkholder Decl., ¶¶ 46-51. Neither 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. Pet. at 28; Ex. 1003 (Kirkness Decl.) at ¶ 219 (opining that the airflow “signal that controller 38 uses to calculate gas flow and/or volume passing through conduit 56” is used to control “the operations of blower assembly 52 . . . and/or the operation of valve 40 that controls air flow and pressure provided to the patient”); Ex. 1005 (Chatterjee Decl.) at ¶ 106 (“flow sensing assembly 72 . . . measures the pressure differential that can be used for calculating the flow of gas”).

Truitt discloses that its conventional PAP device merely receives flow and/or pressure signals and adjusts the internal flow or pressure “in a feedback fashion,” but that does not disclose or imply that the system derives respiratory airflow:

Controller 38 receives the signals output from sensors 20 and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof in a feedback fashion based on these received signals. For example, in a simple CPAP device, controller 38 monitors the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.

Truitt at 2:57-64; Borkholder Decl., ¶ 47. Using this feedback technique, conventional PAP devices measured the airflow being provided **to the patient** within the device and (1) provide bi-level pressure support, “where the pressure is greater during inspiration than during expiration,” or (2) auto-titrate pressure to counteract or prevent “snoring, apneas, hypopneas, etc.” Truitt at 2:64-3:11.

Determining whether a patient may be inhaling or exhaling so that a bi-level system can change its programmed pressure level, 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” in Claim 1. Paper 12 (Institution Decision) at 24-26; Truitt at 6:49-60; Borkholder Decl., ¶ 48. The ’029 Patent describes that a subject’s respiratory airflow can be derived using a “pneumotachograph . . . connected to a pressure transducer,” or through “nasal or oral airway pressure” fluctuations. ’029 Patent at 8:12-22. Using either method, a POSITA would recognize that just providing for the “flow and/or volume passing through the conduit” to the patient does not provide a measurement

or derivation of the subject's respiratory airflow without more processing of the airflow signal. Ex. 1003 (Kirkness Decl.), ¶ 219; Borkholder Decl., ¶¶ 49-50.

Although Truitt's system may detect certain symptoms, like snores, apneas, and hypopneas, it does not disclose detecting these symptoms as a function of the patient's respiratory airflow *or* how to derive the patient's respiratory airflow from the measurements that its system does take. Truitt at 2:57-60, 3:4-11, 6:39-48. Also, explained further below, Truitt does not disclose how its airflow sensor data can be used in calculating the data of a severity of the sleep disorder symptoms.

For at least the foregoing reasons, Patent Owner respectfully submits that Truitt does not disclose “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.”

2. Truitt and Kumar Do Not Disclose a Processor Within the PAP Device that Receives Airflow Sensor Data and Calculates Data Indicative of the Severity of the Patient's Symptoms

Truitt does not disclose a PAP device with a processor that receives airflow sensor data and calculates data indicative of the severity of the patient's symptoms, and Petitioner does not suggest that Kumar cures Truitt's deficiencies. Pet. at 17-21, 28-29.

Consistent with the positions taken in litigation, a POSITA would readily understand that “data of a severity” for the subject's symptoms indicates “the degree

of deviation from the baseline characteristics of a patient without sleep disorder symptoms.” Ex. 2020 (Jafari Decl.) at ¶¶ 41-42, 46; Borkholder Decl., ¶53. In the context of the ’029 Patent, the terms “data of a severity” and “sleep disorder symptoms” are terms of art that are readily understood by POSITAs. They have known algorithms to identify different categories of respiratory events (such as central or obstructive apneas, hypopneas, Cheyne-stokes breathing) and determine the level of severity of the patient’s sleep breathing disorder symptoms associated with those events. Borkholder Decl., ¶53; *see also* Ex. 2020 at ¶¶ 39-40, 46.

Petitioner’s suggestion that Truitt discloses this limitation “because it discloses monitoring the patient’s condition, and specifically detecting snoring, apneas, and hypopneas,” relies on an unsupported and overly broad (and unsupported) interpretation of the term “data of severity of sleep disorder symptoms of the subject.” Pet. at 17-18; Paper 12 (Institution Decision) at 27-28; 37 C.F.R § 42.104(b)(4). As the Board previously determined for a parent of the ’029 Patent:

Based on the above disclosures in the specification, we agree with Patent Owner that the specification discloses that the gathered information is processed to monitor the condition of the subject (i.e., the system quantitatively estimates or determines the “severity of sleep disorder symptoms”) and how much pressure / flow of gas is to be provided to the subject (i.e., the system calculates the “usage of the PAP device by the subject”).

ResMed Corp. v. Cleveland Med. Devices, Inc., No. PGR2024-00012, Paper 7 at 16 (P.T.A.B. June 24, 2024) (finding written description support for the term, “data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device”). The Board’s findings were supported from the specification’s discussion of the processor’s analytical functionality upon the received sensor signals. *See id.* at 14-16 (citing ’284 Patent¹ at 3:21-23, 8:37-41, 19:3-17, 23:20-25). This interpretation by the Board of what constitutes usage and severity data is fatal to Petitioner’s reliance upon Truitt. Borkholder Decl., ¶ 54.

First, the Board’s determination that “monitor[ing] the condition of the subject” means to “quantitatively” calculate “severity of sleep disorder symptoms” not merely to detect symptoms. *ResMed Corp.*, No. PGR2024-00012, Paper 7 at 16; ’029 Patent, Claim 1. Accordingly, merely identifying symptoms, like snores, apneas, and hypopneas not tantamount to calculating “data of a *severity* of the symptoms of the subject.” Borkholder Decl., ¶ 55; Pet. at 17-18. Indeed, Truitt gives no guidance as to how one would quantitatively determine the severity of the subject’s symptoms once they were detected. Borkholder Decl., ¶¶ 55-56.

¹ The same disclosures are found in the ’029 Patent at 3:25-27, 8:43-46, 19:8-22, 23:23-30.

Truitt represents the type of “more advanced” CPAP machines distinguished in the '029 Patent, which could “adjust this continuous positive gas pressure through sensors built into the device,” but which were unable “to adjust a patient’s treatment, whether physical or chemical, based on the patient’s current physiological state.” '029 Patent at 2:32-42. These systems, which “measure[ed] gas flow through the device,” were found to be “expensive and largely ineffective.” *Id.* Notably, Petitioner does not attempt to distinguish Truitt’s machine from the “basic adjustable devices” distinguished in the '029 Patent.

This is further confirmation that the basic adjustable CPAP machines, like Truitt’s were unable to monitor the physiological condition of the patient through the generic identification of snores apneas, and hypopneas via “measure[ing] gas flow through the device.” '029 Patent at 2:28-48. At the time of the invention, it was known that attempting to register events based on abnormal sensor readings from internal flow sensors was prone to inaccuracies caused, for example, by patient misuse or system leaks. These inaccuracies made such measures non-representative of the subject’s physiological condition. Borkholder Decl., ¶ 57. As discussed in detail below, Mumford attempts to solve this problem with the very proliferation of **additional** sensors that Truitt sought to avoid. *See infra* § B.2; Truitt at 3:39-46 (explaining that an object of the invention is to perform “an accurate flow or volume measurement of the gas passing . . . without the need for a dedicated flow element”).

Petitioner's reasoning on this point is also wrong because it assumes that all ways of monitoring a patient's condition involve "calculating 'data of severity of sleep disorder symptoms.'" Pet. at 17; *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) ("It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus."). While calculating severity data is one way to monitor a patient's condition, the opposite is not true: there are boundless ways to monitor a patient's condition (taking the patient's temperature, pulse, blood pressure, etc.) that are entirely unrelated to calculating the severity of a patient's symptoms. See Truitt at 3:4-9 (disclosing that in auto-titration mode, "other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc." in addition to pressure and flow sensors). Accordingly, there is no basis for Petitioner's conclusion that Truitt teaches calculating severity data from airflow sensor data merely because it discloses monitoring the patient's condition. Borkholder Decl., ¶ 58.

Second, although Truitt discloses detecting individual disordered breathing events, it does not disclose calculating indices like AHI, which represent the severity of the patient's symptoms. Pet. at 18-21. Petitioner does not claim that Truitt expressly discloses calculating an index, like AHI, it argues that Truitt's use of "data collected while using the PAP device" to "counteract or prevent" apneas and hypopneas satisfies the claimed "index." *Id.* at 21. That is not correct: Like the

PAP machines distinguished in the background of the '029 Patent, Truitt discloses using “auto-titration” or a bi-level mode, which respond immediately to changes in pressure detected at the CPAP machine. Truitt at 1:30-43, 6:49-60. These interventions are made in real-time as the breathing event occurs and are not based on any *index* calculated over time. Borkholder Decl., ¶ 59.

Additionally, 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. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (obviousness requires that Petitioner “explain why a person of ordinary skill in the art would have combined elements from specific references *in the way the claimed invention does*”). Petitioner does not explain how calculating AHI at Truitt's CPAP machine would provide any known benefit or how or why a POSITA would use that value in the context of Truitt's real-time treatment device. *See* Pet. at 18-21. Petitioner has not, therefore, established that a POSITA would have found it obvious to calculate the subject's AHI at the CPAP device. Borkholder Decl., ¶ 60. Petitioner's lack of explanation is particularly problematic here because the proposed modification would change Truitt's principle of operation such that it would no longer react in real-time to changes in the detected conditions of the patient. *See In re Ratti*, 270

F.2d 810, 813 (C.C.P.A. 1959) (a combination that changes the prior art's "basic principles" of operation is indicative of non-obviousness).

Furthermore, the PAP device is responsible for transmitting more than just an index to the remote internet site. '029 Patent at Claim 1 ("a remote internet site, the remote internet site adapted for receiving i) and ii), or i), ii), and iii)").² In either data transmission scenario, 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 and sent to the remote internet site. Borkholder Decl., ¶ 61. Rather than explain how simply noting an apnea or hypopnea event took place equates to the severity level of a subject's symptoms, the Petition conflates the Board's previous findings regarding an "index of treatment efficacy." Pet. at 18-20 (citing Ex. 1010 at 27 which is addressing the *Wands* factors for enablement of the "index of treatment efficacy"). However, the determination of an index of treatment efficacy is based upon the calculation of the severity of the patient's symptoms or usage. Borkholder Decl., ¶ 61.

² In Claim 1, "i)" is the "data of severity of the sleep disorder symptoms of the subject;" ii) is the "data of usage of the PAP device by the subject;" and iii) is "the index based in whole or in part on either i) or ii) or both i) and ii)."

The Petition attempts to draw support for its reading of Truitt by asserting that the '029 Patent equates “conditions” and “symptoms,” ignores that the cited discussion concerns how the subject’s physiological conditions or symptoms are determined as critical or not using an Auto-Regressive Moving Average (ARMA) model by the PAP processor on the airflow sensor signal. *Compare* Pet. at 18 (citing '029 Patent at 21:11-13) *with* '029 Patent at 20:56-21:29 (describing an embodiment of the invention using the ARMA model for determining a quantified level of severity of the subject’s symptoms). Notably, the ARMA model is used to determine the physiological change occurring in the patient at the onset of a symptom “allowing precisely controlled treatments to be delivered to the subject or patient.” '029 Patent at 21:1-15. No such disclosure is found anywhere in Truitt. Borkholder Decl., ¶62.

For at least the foregoing reasons, Truitt does not disclose a “processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms of the subject and/or the index.” And as discussed below, it would not have been obvious to modify Truitt with Mumford to reach this limitation because Mumford’s algorithm is incompatible with the design and intended purpose of Truitt.

3. There is no Motivation to Combine Truitt and Kumar to Reach the Claimed Invention

A POSITA would not have been motivated to combine implement Truitt into “a networked PAP treatment system” as taught by Kumar. Pet. at 7; Borkholder

Decl., ¶¶64-75. Petitioner's contention that a POSITA would need to "improve the PAP device of Truitt" in order to incorporate it into the "telemedicine system as taught by Kumar" (*id.*) simply creates a "problem to be solved" as the "reason to combine the prior art." *Purdue Pharma L.P. v. Depomed, Inc.*, 643 F. App'x 960, 966 (Fed. Cir. 2016). As discussed below, the motivations provided in the Petition are based on hindsight because they fail to demonstrate that "the problem was known in the art or that [CleveMed's] formulation of the problem was derived directly from the prior art, rather than the challenged claims." *Id.* (citing *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859 (Fed. Cir. 2015) ("Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.")).

First, the Petitioner and its expert allege that motivation is found in the need to obtain more representative data from monitoring a subject at their home. Pet. at 7-8 (citing Ex. 1003, Kirkness Decl. at ¶¶144-145). But this motivation is untethered to the record facts because conventional CPAPs, like those described in Truitt, were already being used by patients in their home. A POSITA would obtain the Petitioner's "representative data" simply by using a conventional CPAP, like in Truitt. Borkholder Decl., ¶ 65. Further, Petitioner's expert appears to suggest that a medical professional would need this "representative data" so they can observe the subject in different situation such as after drinking alcohol or after being sick. Ex. 1003

(Kirkness Decl.) at ¶ 145. As was known, conventional CPAPs included memory that could store and upload data through USB connection or SD Card and neither the Petition or any reference suggests that i) a physician would use at-home CPAP therapy in situations where the patient requires live monitoring and ii) that the Truitt-Kumar combination allows for the recording of background experiences such as whether a patient has been drinking all day or feeling ill. Borkholder Decl., ¶ 66. Thus, a POSITA would not be motivated to make the Truitt-Kumar combination to “obtain more representative data.”

Second, a POSITA would not seek to implement Kumar's “real-time monitoring” in at-home CPAP systems taught by Truitt, for physician convenience because at-home CPAP therapy is prescribed in situations where the patient does not require live monitoring. Pet. at 8-9; Kumar at Title; Borkholder Decl. at ¶¶ 67-69. Indeed, neither Petitioner nor its experts identify any issue with the monitoring methods known at the time. If anything, Kumar identifies an issue with the “standard in-laboratory” sleep apnea diagnostic testing methods which required real-time monitoring by a medical professional, a standard not applicable to at-home CPAP therapy use. Borkholder Decl., ¶ 67; '029 Patent at 1:63-66 (“The second [sleep apnea diagnosis method] is via physiological based evaluations such as all night polysomnography to evaluate the patients sleep architecture (e.g., obtaining respiratory disturbance index to diagnose sleep apnea)”); *Motorola Mobility*

LLC v. Largan Precision Co., No. 2024-1414, 2025 WL 2642194, at *2 (Fed. Cir. Sept. 15, 2025) (finding no legal error in the Board determining whether the differences between the prior art teachings rendered the references “inapplicable” to one another).

While Kumar is directed to telemedicine applications, its application regarding sleep apnea is focused upon replacing the in-lab monitoring of sleep apnea diagnostic tests, not sleep apnea therapies. Kumar seeks to replace sleep apnea tests that were “collected in the lab by attended monitoring” with “on-line live monitoring” of “polysomnogr[a]phy and oximetry with newer portable and/or disposable devices.” Kumar at [0240]-[0241]. As Petitioner’s expert has written, the “standard polysomnographic recording techniques” include capturing signals such as “electroencephalograms (C3-A2, A2-O1), left and right electrooculograms, submental electromyogram, tibial electromyogram, electrocardiogram, oxyhemoglobin saturation, body position via infrared video camera, nasal cannula for measuring airflow (Nights 2 and 3), and thoracic and abdominal belts for measuring respiratory effort.” Ex. 2021 (McGinley et al., “A Nasal Cannula Can Be Used to Treat Obstructive Sleep Apnea,” *Am. J. of Respiratory and Critical Care Med.*, 176:194-200 (2007)) at 195. At-home CPAP would not be used in situations where a patient needs “live monitoring” by a medical practitioner on a nightly basis. Borkholder Decl., ¶ 68; *Motorola Mobility*, 2025 WL 2642194, at *3 (“The mere

fact that a combination is possible does not establish that a skilled artisan would be motivated to pursue it.”).

The Petition does not argue that the inclusion of polysomnography and oximetry is necessary to complete their combination because inclusion of such capabilities in CPAPs requires the integration of sleep diagnosis and treatment functionalities as first taught in the '029 Patent. See '029 Patent at 2:66-3:1 (“The present invention relates to an *integrated sleep diagnosis and treatment device*, and more particularly to an *integrated apnea diagnosis and treatment device*.”) (emphasis added). Indeed, additional data calculations of symptom severity required by polysomnography utilize sensors not taught in Truitt’s CPAPs and the real-time monitoring of Kumar requires wireless data communication techniques between CPAPs and a distributed computing system not disclosed in Truitt or Kumar. Borkholder Decl., ¶ 69.

Third, configuring a CPAP to operate on a network has no effect on increasing the “health access to more people” to CPAP therapy because the only way to increase the access to CPAP therapy is by making home sleep testing more available and getting more patients diagnosed with sleep apnea and prescribed a CPAP. Pet. at 9; Borkholder Decl., ¶¶ 70-72. While the PAP devices of the '029 Patent are capable of providing diagnostic metrics, a CPAP would not be used in the diagnosis of patents for sleep apnea. Borkholder Decl., ¶ 71.

Even today, the only way to increase access to CPAP therapy is by way of a home sleep test, which is why ResMed recently acquired VirtuOx, an independent diagnostic facility, to “accelerate the time between evaluation and treatment, reduce drop-off, and help more people access the life-changing benefits of therapy for sleep apnea.” Ex. 2022 at 1. Thus, a POSITA is unable to increase the accessibility of CPAP treatment by placing it within a network, without first having diagnostic tests made more readily available. Furthermore, there is no reason a physician required networking a CPAP to have a telemedicine conference. Borkholder Decl., ¶ 72. The ability to collect therapy data through conventional means, USB or SD Card transfer, still allowed for physicians to obtain the data and then set a teleconference with the patient. *Id.*

Lastly, neither “advances in mobile computing and wireless communications” nor the “general [IoT] market trend” show that a POSITA would be motivated to combine Truitt with Kumar. Pet. at 9-10; Borkholder Decl., ¶¶ 73-75. The Petition contends that Truitt’s pressure and flow sensors would be “ideal to improve” with the “advantages of [] wireless, as opposed to wired, sensors.” Pet. at 9. But that is not motivation to arrive at the claimed invention of the ’029 Patent, which requires an “airflow sensor . . . internal to the enclosure of the PAP device,” i.e. wired sensors. ’029 Patent, Claim 1.

A POSITA would not draw a general motivation from the general market trend of connecting consumer devices to the internet. Pet. at 10; Borkholder Decl., ¶ 74. Indeed, sending restricted health information over the internet is not the same as sending refrigerator data. Pet. at 10. Further, the Petition holds Kumar out as a simple “plug-and-play” solution for Truitt, but that is not the case. *Id.* As discussed above, Kumar is directed to replacing in-lab polysomnography and oximetry, not CPAP therapy. Further, Truitt does not disclose calculation of sleep apnea diagnostic metrics and requires wireless data communication functionalities not disclosed in Truitt, before it could be considered for a networked system.

Therefore, the Petition's attempt to gin up reasons to combine Truitt and Kumar fail to address with “sufficient detail how or why a skilled artisan would have been motivated to combine” and are rooted in hindsight. *Purdue Pharma*, 643 F. App'x at 966. Thus, a finding of the claims patentable is warranted.

4. Truitt and Kumar Do Not Disclose “wherein the airflow sensor data is processed by the second processor, at least in part using one or more of the signal processing techniques from the group . . .” (Claims 8 and 11)

Challenged Claims 8 and 11 further limit the how the signal processing techniques used upon the airflow sensor signal of Claim 1, that are necessary for measuring or deriving the respiratory airflow of the subject such that data indicative of the severity of the subject's symptoms can be calculated. Borkholder Decl., ¶¶ 76-84. A POSITA recognizes that these signal processing techniques would be used

on the airflow sensor signal to derive the respiratory airflow of the subject and determine the severity of each sleep apnea symptom experienced by the subject. Borkholder Decl., ¶¶ 76-77.

The '029 Patent discloses various techniques for calculating symptom data from respiratory airflow data. *See, e.g.*, '029 Patent at 19:61-64 (“The quantitative method for estimating or determining the severity of the subject’s sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein.”). Indeed, a POSITA would recognize from the '029 Patent that different “sleeping disorders have symptoms that can be predicted based on various combinations of physiological signals or data” and algorithms are used to “quantify the level of severity of the subject’s sleeping disorder or symptoms.” *Id.* at 20:16-55; Borkholder Decl., 78.

The '029 Patent further teaches that the present invention identifies the sleep disorder symptoms at their “onset by identifying various characteristic shifts in the power spectrum of the sensors” used to monitor the subject’s physiological condition. *Id.* at 20:26-30. To accomplish this method of monitoring, the '029 Patent discloses specific algorithms used to identify the symptoms severity through the use of signal processing techniques upon the airflow sensor signal. *Id.* at 20:33-46; *see also id.* at 20:47-22:13 (describing the application of the signal processing techniques).

While Truitt is devoid of any teachings for the algorithms used to process the airflow sensor data to measure or derive a subject's respiratory airflow such that the severity of their symptoms can be derived, the '029 Patent discloses and claims the use of specific signal processing techniques, such as, "a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, [or] a wavelet analysis." See '029 Patent, Claims 8 and 11; *id.* at 20:24-22:13 (disclosing signal processing methods to quantitatively determine the severity of the subject's symptoms).

Through use of these signal processing techniques, a POSITA can utilize the airflow sensor data to derive the quantitative severity of each individual symptom. See, e.g., '029 Patent at 19:61-64 ("The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein."); Borkholder Decl., ¶¶ 76-77, 81. Thus, a POSITA would understand that determining the "data of a severity" for the subject's symptoms indicates "the degree of deviation from the baseline characteristics of a patient without sleep disorder symptoms." Ex. 2020 (Jafari Decl.) at ¶¶ 41-42, 46.

Further, Truitt's measurement of airflow to the patient is not a measurement of the patient's respiratory airflow, and Truitt does not teach or suggest deriving the patient's respiratory airflow for calculating symptom severity from this data. Borkholder Decl., ¶ 81. Under Petitioner's theory of how treatment is adjusted, a change in pressure or flow is based upon the frequency of events regardless of whether the severity of the current symptom is greater or less than those before it. Pet. at 19 (asserting that the changes in therapy are determined by AHI). Truitt's feedback loop is used to adjust the blower pressure and is based upon its airflow system readings of the system without any consideration of the patient's present respiratory airflow or the severity of the symptom. See Truitt at 5:35-6:10 (describing pressure and motor control), 6:39-53 (describing the controller for calculating the flow and/or volume of gas passing through the conduit for control of the motor), 6:60-62 (describing that "other sensors" are needed "to provide additional information to the controller"). This is because Truitt does not teach or suggest using the patient's respiratory airflow for calculating symptom severity. Borkholder Decl., ¶ 82.

Under Petitioner's view of Truitt's auto-titration, there can be no "precisely controlled treatment" because just relying upon the presence of a respiratory event does not provide the necessary information to "enable adaptive model selection for the subject's physiological condition" that alters the pressure and flow of the

patient's treatment. Borkholder Decl., ¶ 83. Indeed, a POSITA recognizes that the claimed signal processing techniques provide the system with the ability to identify the severity of each symptom, allowing for a precise pressure change in response to the severity of each symptom. *Id.*

Because Truitt does not disclose how its airflow sensor data relates to the patient's respiratory airflow and fails to disclose calculation of a level of severity for the subject's symptoms, Challenged Claims 8 and 11 are patentable.

5. Truitt in View of Kumar Does Not Disclose the system
“wherein the remote internet site is adapted to retransmit to the first radio frequency wireless transceiver on the cell phone . . .”
(Claims 9 and 13)

Challenged Claims 9 and 13 are patentable because Kumar does not disclose transmitting data from the PAP device to a remote internet which is then retransmitted to the patient's cell phone, as claimed. Borkholder Decl., ¶¶ 85-89. Petitioner does not rely on Truitt for these limitations. Pet. at 50-51.

There is no disclosure in Kumar of separately sending the data of severity of the subject's symptoms and/or an index based in whole or in part on the subject's symptom severity data generated and transmitted by the PAP device to a remote internet site and then to a cell phone, as claimed. See '029 Patent, Claims 9 and 13. Petitioner's allegation that the remote internet site is hosted at Kumar's central server 106, and is accessible to patient-side device 102 (Pet. at 34-40), means that the data

pathway from the patient-side device 102 always traverses computing device 110 (which is alleged to be the claimed “cell phone”) (*id.* at 41):

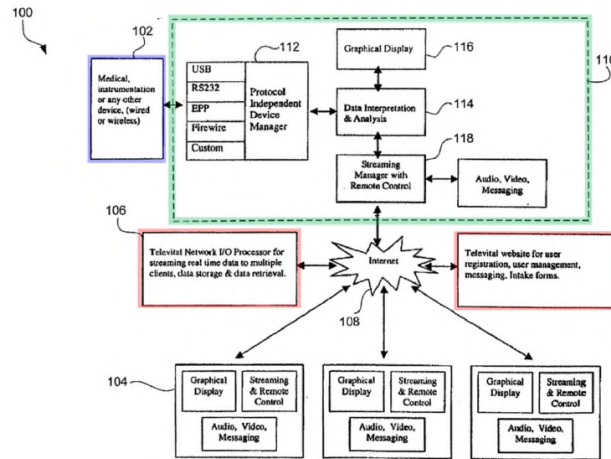


Fig. 1A

EX1008, FIG. 1A

Pet. at 35 (Kumar, Fig. 1A annotated by Petitioner).

Accordingly, Petitioner does not identify where Kumar teaches “the remote internet site is adapted to retransmit to the first radio frequency wireless transceiver on the cell phone the data, in whole or in part, the data of i) and ii), or i), ii), and iii) or a second index related to the data of the subject’s treatment and the treatment’s efficacy calculated and transmitted by the PAP device.” ’029 Patent, Claim 9, 13. A POSITA would not design a system to send redundant data back to the device in which originally received and transmitted the data in the first instance, and Petitioner does not attempt to explain why a POSITA would design the remote internet site to retransmit information back to its original source. Borkholder Decl., ¶¶87-88. According to the combination proposed in the Petition, the subject would already

have the data from the PAP device to review so retransmission back to the subject's device is unnecessary and nonsensical. Furthermore, the Petition does not argue that a "second index" would be sent back to the patient's cell phone indicating that there are no new calculations performed by the remote internet site or retransmission of the data back to the cell phone. Pet. at 50-51.

For at least the foregoing reasons, Patent Owner respectfully requests that the Board find Claims 9 and 13 patentable.

B. Grounds 4-6: The Challenged Claims are Patentable Over Truitt in View of Kumar and in Further View of Mumford

Petitioner recognizes Truitt's inability to calculate the claimed symptom severity data and seeks to fill the gap using the sleep efficacy algorithm of Mumford. Pet. at 64-71. However, Mumford's sleep efficacy algorithm relies on sensor inputs not present in Truitt, and Mumford's algorithm detection of apneas provides the same functionality already present in Kumar's external computing device. *Id.* at 64-66; Borkholder Decl., ¶¶ 90-102. Thus, POSITA would not be motivated to modify Truitt's PAP device with Mumford's sleep efficacy algorithm absent of hindsight. *Purdue Pharma*, 643 F. App'x at 966 (affirming that the Board's did not err in concluding that Purdue failed to establish a reason to combine the prior art).

1. Petitioner And Its Experts Fail To Show A POSITA Would Find Motivation Or Success In Combining Mumford And Truitt

Petitioner presents only generic reasons for combining Mumford with Truitt. Pet. at 64-66 (citing Ex. 1003 (Kirkness Decl.) at ¶¶ 311-312). In the two paragraphs devoted to this issue, Petitioner discusses some interrelated teachings of each reference without explaining why or how a POSITA would have combined Mumford's sleep efficacy algorithm (which is reliant upon multiple sensor inputs) with Truitt's device (which is only equipped with an internal airflow sensor). *Id.*; see also Pet. at 70-71 (citing Ex. 1003 at ¶¶ 328-331); *Purdue Pharma*, 643 F. App'x at 966; *Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 888 (Fed. Cir. 2024) (finding legal error in the Board's obviousness determination because motivation requires more than a showing that two similar systems "known" in the prior art).

Implementing Mumford's sleep efficacy algorithm on Truitt's device requires sensor inputs that are outside the scope of the claims. Borkholder Decl., ¶ 92. At institution, the Board interpreted the Petition as accounting for data produced from Truitt's "other sensors, such as a microphone" as rationale for utilizing Mumford's electrodes and sleep efficacy algorithm. Paper 12 (Institution Decision) at 35. This is incorrect, as neither the Petition nor the Challenged Claims utilize any other sensor data to perform its calculations of severity data or an index, other than the internal airflow sensor. See '029 Patent, Claim 1; Pet. at 64-71 (alleging that only

Mumford's sleep efficacy algorithm would be incorporated into Truitt, not the entire mask assembly with its integrated sensors and its algorithm). While the '029 Patent discloses several different embodiments of its integrated diagnostic and treatment PAP device, the claims are limited to determining its diagnostic level of severity based only on the internal airflow sensor. '029 Patent, Claim 1. And while a POSITA would recognize that additional sensors could be added to Truitt's system, those sensors would be external to the PAP device and go beyond the scope of the Challenged Claims. Borkholder Decl., ¶ 92.

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. Borkholder Decl., ¶ 93. Indeed, Petitioner and its expert's assertion that an expectation of success exists because "Truitt and Mumford are analogous art" and the "proposed modification involves a simple change" is inaccurate and legally insufficient. Pet. at 66; *Juniper Networks, Inc. v. Correct Transmission, LLC*, No. 2023-1046, 2024 WL 3517862, at *4-6 (Fed. Cir. July 24, 2024) (determining that an expert opinion concluding that "the prior art combinations were simple and would have led to predictable results" was insufficient to show a reasonable expectation of success).

The Petition only points to Truitt's CPAP with an internal flow sensing assembly that sends signals to its controller used in determining the flow or volume

of gas in the system, not external sensors. *See* Pet. at 17 (“The output of the flow sensor is provided to controller 38 ‘for calculating the flow and/or volume of gas passing through conduit 56.’”). There 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. Borkholder Decl., ¶ 94; Mumford at 4:24-35 (pressure transducer in combination with an oximeter or position sensor), 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). Moreover, Mumford’s pressure transducer is found integrated within the mask worn by the patient, not within the CPAP device like Truitt. Mumford at 11:66-12:17.

Thus, Mumford suggests to a POSITA that its sleep efficacy algorithm is not compatible with data from only one sensor. Borkholder Decl., ¶ 95; Mumford at 10:66-11:16 (discussing why “[i]t is preferable, and more robust, although not necessary, to use a subset of electrodes that contains ***at least three electrodes***. However, in some cases ***it may be possible to use only two electrodes***.”) (emphasis added). Therefore, a POSITA would not be motivated to use Mumford’s algorithm with Truitt’s device that only utilizes a flow/pressure sensor within the device and not the mask. Borkholder Decl., ¶ 95.

2. Mumford's Sleep Efficacy Algorithm Relies On Electrodes Not Present in Truitt

Petitioner's argument that Mumford furthers the objective and purpose of Truitt, ignores that Mumford defeats Truitt's purpose of providing an "accurate flow or volume measurement of the gas passing therethrough, without the need for a dedicated flow element." Borkholder Decl., ¶96; Truitt at 3:42-47; *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (finding nonobviousness where proposed combination "destroy[s] the basic objective" of the primary reference); *see also Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1376 (Fed. Cir. 2021) (reversing the Board's obviousness determination because the Board failed to explain why a POSITA would have "alter[ed] the inventive concept").

The entire premise of Truitt's invention is to eliminate the extra sensors and achieve the same functionality as standard CPAP machines with only an internal airflow sensor. Truitt at 3:42-47 ("In particular, it is an object of the present invention to provide a pressure support system that allows for a relatively accurate flow or volume measurement of the gas passing therethrough, without the need for a dedicated flow element."); *id.* at 3:66-4:7 (describing the object of the invention to "be used in the same manner as the signal from a conventional flow sensor") The idea of adding only mask-based sensors back into Truitt's device is antithetical to Truitt's purpose. Borkholder Decl., ¶ 97.

To 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. Pet. at 64-66; Borkholder Decl., ¶ 98; Mumford at 12:14-16 ("The **pressure transducer 316 is disposed within the nasal mask 20** preferably in close proximity to the gas inlet 28."); *id.* at 12:42-44 ("The pressure transducer 316 is used to **detect the pressure within the cavity of the nasal mask 20**") (emphases added). Thus, a POSITA would not look to Mumford's algorithm when attempting to interpret Truitt's internal flow or volume reading sent from its flow-sensing assembly found within the PAP device to determine "data of severity of sleep disorder symptoms" or an "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." Pet. at 68-70.

Both the Federal Circuit and the Board have repeatedly held that the Petitioner's obviousness case must provide a reasoned analysis explaining how the references are combined and how the proposed combination works to meet the claim limitation. *Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017) ("Indeed, [] nowhere [was it] clearly explained, or [was there] cited evidence showing, *how* the combination of the two references was supposed to work."); *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1368 (Fed. Cir. 2012) (must be an "explanation as to how . . . the references would be combined to

produce the claimed invention”); *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1351-52 (Fed. Cir. 2010) (obviousness requires some teaching of how the references could be combined to work together); *LG Elecs., Inc. v. Constellation Designs, LLC*, No. IPR2023-00228, Paper 10 at 15 (P.T.A.B. July 11, 2023) (“lacks sufficient reasoning that would inform how [the proposed combination] would have resulted in the claim limitation”) (quoting *Pers. Web Techs.*, 848 F.3d at 994); *Roku, Inc. v. Universal Elecs., Inc.*, No. IPR2019-01595, Paper 15 at 15 (P.T.A.B. May 13, 2021) (the Board “nowhere clearly explained, or cited evidence showing, *how the combination of the two references was supposed to work*”) (quoting *Pers. Web Techs.*, 848 F.3d at 994). Here, neither Petitioner nor their experts demonstrate how Mumford’s algorithms would need to be modified to be successfully operational with Truitt’s PAP device and the data it measures. Pet. at 66-71.

The integration of Mumford’s sleep efficacy algorithm requires “at least the electrode signals” received from the sensors and electrodes integrated into its mask assembly and not alleged as part of the Mumford combinations. Borkholder Decl., ¶¶ 100; Pet. at 64 (“A POSITA would have been motivated to modify the Truitt PAP device to incorporate the sleep efficacy algorithm of Mumford.”). Mumford’s sleep efficacy algorithm determines two things: (1) the present sleep stage of the wearer and (2) how many arousals they experienced. Mumford at 7:34-42. Mumford teaches that determination of these data points each require multiple streams of data

as inputs because the “information is weak” and the “signals are more difficult to detect because they do not originate in the frontal lobes of the brain.” *Id.* at 10:66-11:16. Thus, a POSITA considering Mumford’s sleep efficacy algorithm must use it in conjunction with the electrodes integrated into Mumford’s mask assembly, contrary to the configuration of Truitt and the Challenged Claims. Borkholder Decl., ¶ 100.

Neither Petitioner nor its expert show how Mumford’s “frontal staging algorithm, based on at least the electrode signals, to determine which stage of sleep the wearer 18 is in,” would operate within Truitt’s device without the use of Mumford’s “electrode signals.” Mumford at 15:39-16:3; Borkholder Decl., ¶ 101. Indeed, the primary inputs used in Mumford’s algorithm come from multiple electrode signals such that it would not be a “simple change in a programming algorithm” because the very inputs upon which Mumford’s algorithm is built must change significantly to operate with Truitt’s lone flow sensor. Pet. at 66; Borkholder Decl., ¶ 101; Mumford at 15:42-45 (“The information provided by the electrodes is important since it is well known that some sleep apnea events occur more frequently in some of the sleep stages rather than others.”).

For at least the foregoing reasons, Patent Owner respectfully requests that the Board find Challenged Claims patentable over the Mumford combinations.

V. CONCLUSION

For all of these reasons, Patent Owner accordingly requests that the Board find the Challenged Claims of the '029 Patent patentable.

Respectfully submitted,

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(Case No. IPR2025-00247)

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CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

The undersigned hereby certifies that the portions of the above-captioned **PATENT OWNER'S RESPONSE** specified in 37 C.F.R. § 42.24 has 9,143 words in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(b)(2). This word count was prepared using the Microsoft Word word-processing system used to prepare this paper.

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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), and pursuant to agreement by the parties that filing with the Board through the P-TACTS constitutes electronic service if Patent Owner provides the foregoing document (excluding exhibits), that service was made on the Petitioner as detailed below.

<i>Date of service</i>	October 22, 2025
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S RESPONSE
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