

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.
Patent Owner.

Case IPR2023-00565
U.S. Patent No. 10,076,296

PATENT OWNER'S RESPONSE

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PATENT OWNER'S EXHIBIT LIST

Exhibit	Description
2001	Scheduling Order, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 40 (D. Del. Nov. 3, 2022)
2002	Excerpts from ResMed Inc.'s Amended Initial Invalidity Contentions, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW (D. Del. Apr. 5, 2023)
2003	Cleveland Medical Devices, Inc.'s Initial Infringement Contentions and Initial Election of Asserted Claims, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW (D. Del. Jan. 9, 2023)
2004	Oral Order Denying Stipulation to Modify Scheduling Order, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 56 (D. Del. Mar. 9, 2023)
2005	ResMed Inc.'s Motion for Reconsideration, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 61 (D. Del. Mar. 20, 2023)
2006	Email correspondence between counsel for CleveMed and counsel for ResMed, dated Feb. 15., 2023 - Exhibit 2 to ResMed Inc.'s Motion for Reconsideration, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 61-3 (D. Del. Mar. 20, 2023)
2007	Declaration of Benu Wells in Support of Patent Owner's Preliminary Response
2008	Joint Claim Construction Brief, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 96 (D. Del. June 21, 2023)
2009	Excerpts from Defendant ResMed Inc.'s Initial Invalidity Contentions, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW (D. Del. Feb. 21, 2023)
2010	LaFrenz, C., "How the pandemic changed ResMed boss Mick Farrell" (May 21, 2021) https://www.afr.com/companies/healthcare-and-fitness/how-the-pandemic-changed-resmed-boss-mick-farrell-20210514-p57s49

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2011	Thompson, H., “ResMed is disrupting connected health: Here’s how” (Apr. 3, 2018) https://www.medicaldesignandoutsourcing.com/resmed-is-disrupting-connected-health-heres-how/
2012	Email from Kramer Levin to counsel for Petitioner regarding Service of Patent Owner’s Preliminary Response and Exhibits (June 28, 2023)
2013	Memorandum Opinion, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 181 (D. Del. Oct. 30, 2023)
2014	Transcript of Telephonic Conference Hearing with Board (P.T.A.B. Dec. 8, 2023)
2015	U.S. Patent No. 5,704,345 (“Berthon-Jones”)
2016	Transcript of Deposition of Jacob Sharony, Ph.D., <i>ResMed Corp. v. Cleveland Medical Devices, Inc.</i> , IPR2023-00565, taken on July 10, 2024
2017	Declaration of Dr. David A. Borkholder in Support of Patent Owner’s Response
2018	Declaration of Dr. Susheel Patil in Support of Patent Owner’s Response
2019	Excerpts from Microsoft Computer Dictionary (5th Ed. 2002)
2020	Cleveland Clinic webpage – “CPAP Machine: What It Is, How It Works & Side Effects,” available at https://my.clevelandclinic.org/health/treatments/22043-cpap-machine , dated July 28, 2024
2021	Drugs webpage – “What is a CPAP Machine, Benefits, Usage Tips,” available at https://www.drugs.com/cg/cpap.html , dated July 7, 2024
2022	G. White, et al., “Right-Sizing Cable Modem Buffers for Maximum Application Performance”

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2023	“Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research,” Sleep, Vol. 22, No. 5 (1999)
2024	P. J. Strollo, Jr., et al., “Positive Pressure Therapy,” Clinics in Chest Medicine, Vol. 19, No. 1 (1998)
2025	A. Guerrero, et al., “Sleep Breathing Flow Characteristics as a Sign for the Detection of Wakefulness in Patients with Sleep Apnea,” Respiration 2010, 80:495-499 (2009)
2026	U.S. Dept. of Health and Human Services, Food and Drug Admin., “Deciding When to Submit a 510(k) for a Change to an Existing Device,” (Oct. 25, 2017)
2027	U.S. Dept. of Health and Human Services, Food and Drug Admin., “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],” (July 28, 2014)
2028	T. Young, et al., “The Occurrence of Sleep-Disordered Breathing Among Middle-Aged Adults,” The New England Journal of Medicine (April 29, 1993)
2029	The AASM Manual for the Scoring of Sleep and Associated Events, Version 3 (2023), https://aasm.org/clinical-resources/scoring-manual/

I. INTRODUCTION

Patent Owner respectfully requests that the Board confirm the patentability of the Challenged Claims of U.S. Patent No. 10,076,269 (Ex. 1001, the "'269 Patent") because the prior art of record admittedly does not disclose key aspects of the claimed invention, and the conclusory testimony of Dr. Sharony relied on to fill those gaps is inadmissible and not credible.

The '269 Patent discloses and recites a novel positive air pressure ("PAP") device for diagnosing and treating a subject's sleep disorder and symptoms. '269 Patent at 2:63-3:8. These systems were designed to supplement and eventually replace expensive and invasive polysomnography tests with a home-based integrated diagnostic and treatment system that can diagnose a patient's sleep disorder and adjust the patient's treatment with or without the intervention of a remotely-located medical professional.

One key feature of this inventive system is its base station, which not only relays the level of severity of the patient's symptoms during PAP treatment to a remote website for monitoring, but also displays the data to the user at home. Dr. Sharony's conclusory testimony that this feature, undisclosed in any art of record, was nevertheless obvious at the time of the invention is not credible given ResMed's own admissions of the unexpected results stemming from this very feature of its infringing systems. Nor is Dr. Sharony's testimony on this subject admissible

because he does not meet his own definition of a POSITA and does not have any other special experience or knowledge that would help the Board understand this issue.

Another key advance of the '269 Patent was its internal respiratory airflow sensor. Traditional CPAP machines mounted respiratory airflow sensors, otherwise known as pneumotachographs, at or near the mask. The relevant prior art references, Ex. 1005 ("Genger") and Ex. 1008 ("Farrell") all disclose this standard arrangement. Dr. Sharony, who admittedly has never operated a CPAP machine, nevertheless testifies that by the time of the claimed invention, ***internal*** respiratory airflow sensors were "common." The only evidence he cites in support of this contention, an airflow sensor disclosed in Berthon-Jones, U.S. Patent No. 5,704,345 (Ex. 2015), is not internal to the PAP device, and Petitioner provides no motivation to replace Genger's pneumotachograph with an internal airflow sensor that can only measure the patient's respiration indirectly

Claims 8-14 are patentable for the same reason that the Examiner withdrew his rejection of these claims during prosecution of the '269 Patent: Ex. 1010 ("Stahmann") does not disclose a controller that adjusts a pharmaceutical agent that treats a sleep disorder or symptoms based on the level of severity of the patient's symptoms. Petitioner admits this and again attempts to rely on conclusory, inadmissible testimony from Dr. Sharony to fill the gap. These claims are

patentable, therefore, because Ex. 1011 (“Edgar”) is not alleged to disclose adjusting treatment based on the level of severity of the patient’s systems and because administering a sleeping medication to a CPAP patient does not treat the patient’s sleep disorder or symptoms, it only serves to ensure that the patient does not remove the mask during CPAP treatment.

Finally, Petitioner acknowledges that Genger does not disclose storing level of severity data in a nonvolatile memory before transmitting it to a remote location. Ex. 1007 (“Westbrook”), cited in an attempt to cure this deficiency also does not disclose storing such data in a nonvolatile memory and does not, therefore, cure Genger’s acknowledged deficiencies.

II. FACTUAL OVERVIEW

Founded in 1990, CleveMed is a small medical device company headquartered in Cleveland, Ohio. Over the years, CleveMed has pioneered advanced research and development in therapy systems, including PAP devices, which monitor, diagnose, and treat breathing-related sleep disorders, including sleep apnea. As a result of CleveMed’s research and development efforts, it was awarded a number of patents relating to PAP devices., including the ’269 Patent. Today CleveMed offers devices and associated web-based services that meet clinical guidelines for home sleep tests (“HST”). In recognition of its innovation and expertise in the field, the United States Patent and Trademark Office (the “PTO”)

awarded CleveMed numerous patents, including the '269 Patent, which claims various aspects of CleveMed's HST products and services.

A. Background of the Technical Field

Sleep apnea refers to the cessation of breathing during sleep. A chronic sleep disorder, sleep apnea presents in three forms: obstructive sleep apnea, central sleep apnea, and mixed sleep apnea. '269 Patent at 5:43-50. These apneas disrupt normal sleep patterns and can lead to serious health consequences, including sleep deprivation, coronary artery disease, heart attack, heart failure, stroke, and an increased risk of type 2 diabetes. *See Id.* at 1:27-39. Sleep deprivation can severely degrade a person's quality of life and is responsible for an estimated \$150 billion dollars per year in excess medical and social costs. *Id.*

Doctors traditionally diagnosed sleep apnea using two methods. The first method required patients to answer questions concerning their symptoms. *Id.* at 1:40-50. Subjective diagnostic methods like these are problematic, however, because patients often underestimate their symptoms or give false responses (*e.g.*, to avoid negative consequences or obtain restricted medication). *Id.* The second traditional method for diagnosing sleep apnea involved an all-night polysomnography, commonly known as a sleep study, conducted in a lab. *Id.* at 1:51-2:10. A polysomnography is typically followed by an all-day test, where the patient has to spend the day in a specialized sleep clinic for monitoring. *Id.* Neither

of these methods effectively determined how patients were responding to their prescribed sleep therapy because they did not collect quantifiable data from patients while they were sleeping in their home environments. *Id.*

The most common treatment method for sleep apnea at the time of filing involved applying constant positive pressure to a patient's airway with a continuous positive airway pressure treatment device (CPAP), which forces the patient to breathe. *Id.* at 2:17-26. While some CPAP machines could be tuned to provide a prescribed pressure, none were adjustable on the fly based on sleep disorder symptom data, which reflects the patient's current physiological state. *Id.* at 2:27-37.

B. The '269 Patent

The '269 Patent discloses a novel integrated diagnosis and treatment device for patients suffering from sleep apnea. The device analyzes the patient's physiological symptoms, determines a level of severity for the symptoms, and adjusts the patient's treatment accordingly. '269 Patent at 1:19-23, 2:38-51. The claimed invention uses a CPAP with sensors that detect the patient's physiological condition, including parameters related to a patient's breath, such as respiratory airflow and effort, and blood oxygenation levels. *Id.* at 6:10-8:25.

The diagnostic readings from pulse oximeters and/or airflow sensors are combined to determine sleep disorder symptom data, which is transferred to a

medical professional, displayed to the user, and/or used to adjust the patient's treatment. *Id.* at Claims 1-7 (using pulse oximetry and respiratory airflow data in combination with a CPAP); *id.* at Claims 8-14 (using the level of severity of a patient's symptoms to adjust a chemical treatment applied to a patient while also providing CPAP therapy); *id.* at Claims 15-20 (using respiratory airflow data and a CPAP to analyze and wirelessly send the patient's data allowing for remote adjustment of the patient's treatment).

An exemplary embodiment of the CPAP device, shown below, includes pressure generator 312, hose 314, mask or nasal cannula 316, flow sensor 320, and pressure sensor 322:

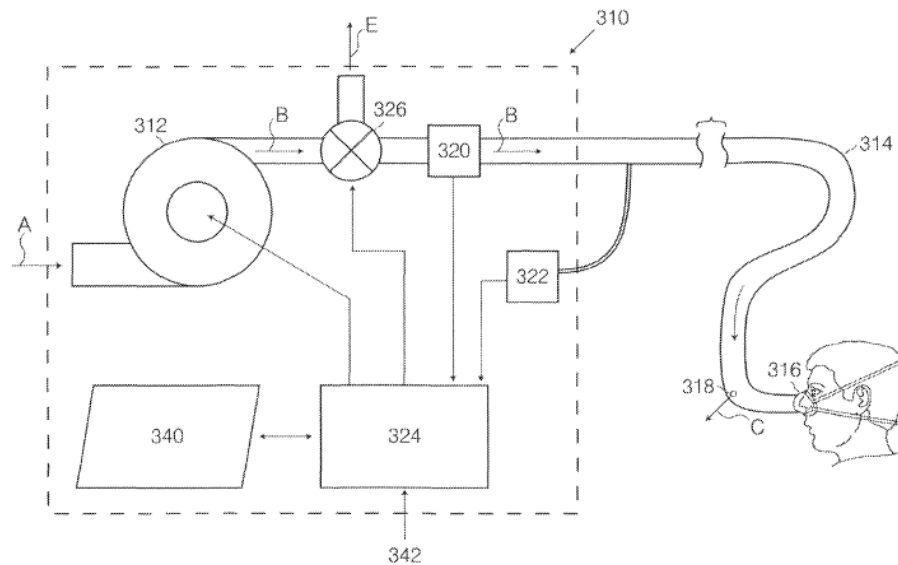


Fig. 7

Id. at FIG. 7. The information from flow sensor 320 and/or pressure sensor 322 is used to control the pressure or flow of gas provided to the subject, monitor the

condition of the subject, and/or monitor the usage of the pressure support device. *Id.* at 23:7-17.

In some claimed embodiments, the CPAP machine measures a patient's respiratory airflow using a respiratory airflow sensor located within the device. *Id.* at 7:27-43. Data from flow sensor 320 and pressure sensor 322 are used to monitor the condition of the subject, monitor the usage of the pressure support device, and control the blower. *Id.* at 23:7-17. The device is capable of analyzing fluctuations on the pressure transducer in a breath-by-breath manner. *Id.* at 8:2-6. The system may also include a pulse oximeter that measures the oxygenation of the subject's blood to help determine the severity of the patient's symptoms. *Id.* at 8:13-25.

Signals from the sensors are sent to a processor, which analyzes the data and calculates the level of severity of the patient's symptoms. *Id.* at 8:26-30. A data acquisition system or signal processing module receives inputs from external sensors (e.g., a pulse oximeter), conditions the data signal, and relays the conditioned data signal to a processor, where it is combined with internally derived signals (e.g., respiratory airflow signals). *Id.* at 8:26-42, 8:50-56. Quantitative methods for estimating the severity of a patient's sleeping disorder or symptoms based upon the physiological signals include a standard deviation technique, a recursively fit ARMA system identification model, a short-time Fourier transform technique, a

time-frequency signal analysis with a variety of different kernels, and a wavelet analysis. *Id.* at 19:46-21:67.

Data indicating the severity of a patient's sleeping disorder is then transferred wirelessly to a wireless communications module, which sends it to a remote location, such as a doctor's office. *Id.* at 8:63-9:45.

III. LEVEL OF ORDINARY SKILL IN THE ART

A. Person of Ordinary Skill in the Art

For purposes of this proceeding, CleveMed adopts Petitioner's definition of a person of ordinary skill in the art ("POSITA"), as one having "a bachelor's degree in mechanical engineering, electrical engineering, computer science, or an equivalent field and two years of industry experience working with diagnostic sensor systems and networked data systems. An increase in experience could compensate for less education, and vice-versa." Pet. at 24.

B. Dr. Sharony is Not a POSITA and Provides Testimony on Subjects in Which He Has no Relevant Knowledge or Experience

The Board should disregard the opinions of Dr. Sharony because he does not qualify as a person of ordinary skill in the art under his own definition. *Kyocera Senco Indus. Tools, Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022) ("To offer expert testimony from the perspective of a skilled artisan in a patent case . . . a witness must at least have ordinary skill in the art").

Dr. Sharony's education and experience do not include any industry experience in diagnostic sensor systems in general or CPAP machines in particular. Dr. Sharony states only that he has "experience working with and analyzing physiological sensors" (Ex. 1004 at ¶ 10) and with "bar code imagers" (*id.* at ¶ 16), which are not diagnostic sensor systems. Nor does this statement establish the requisite two years of industry experience in such systems.

There is a major difference between understanding, from a physics or engineering perspective, how particular sensors detect and transfer signals and understanding *diagnostic sensor systems*, like the PAP devices disclosed and claimed in the '269 Patent. Designing and operating diagnostic sensor systems requires far more than mere knowledge about some subset of the components of the system, and Dr. Sharony's conclusory and incorrect testimony about what a POSITA would have known or modified about such systems at the time of the invention illustrates the need for a purported expert to have the background necessary to help the Board understand the lay of the land at the time of the invention.

For example, Dr. Sharony testified regarding the "obviousness" of relocating a respiratory airflow sensor of a CPAP machine. Ex. 1004 at ¶¶ 86-88. However, because he has no experience with diagnostic sensor systems like CPAP machines, he is unqualified to testify about system-level design questions, including whether a POSITA would have found it "obvious" to relocate a mask-based respiratory airflow

sensor to a location within the PAP device.¹ *Kyocera Senco*, 22 F.4th at 1377 (“[A]dmitting testimony from a person . . . with no skill in the pertinent art serves only to cause mischief and confuse the factfinder” because “[t]hat testimony would ‘amount[] to nothing more than advocacy from the witness stand.’”) (citation omitted).

The Board should not, therefore, rely on any of Dr. Sharony's testimony given from the point of view of a POSITA. *Avail Medsystems, Inc., v. Teladoc Health, Inc.*, No. IPR2022-00444, Paper 10 at 24-26 (P.T.A.B. Jul. 21, 2022) (declining to consider expert testimony because of the expert's lack of knowledge and experience); *Incyte Corp. v. Concert Pharm., Inc.*, No. PGR2021-00006, Paper 68 at 6-9 (P.T.A.B. May 11, 2022).

Many of Dr. Sharony's opinions are also inadmissible under Rule 702 of the Federal Rules of Evidence because he does not have “scientific, technical, or other specialized knowledge [that] will assist the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702. For example, Dr. Sharony

¹ This is to say nothing of Dr. Sharony's reliance on a reference, Berthon-Jones (Ex. 2015), which he did not ever “recall seeing,” and which provided the only basis for his opinion that internal respiratory airflow sensors were “common” at the time of the invention. See Section IV.A.1.c, *infra*; Ex. 2016 (Sharony Tr. at 50:3-22).

testified regarding how and under what circumstances it would be obvious to administer pharmaceutical treatments in conjunction with CPAP treatment to patients, despite admitting on cross-examination that he is “not a medical doctor,” has never diagnosed a sleeping disorder, has never treated a sleeping disorder, has no experience operating or designing a CPAP machine:

Q. Are you a medical doctor?

A. I'm not a medical doctor.

Q. Have you ever diagnosed a patient for any disease?

A. I'm not a medical doctor, doctor. I'm not allowed to deal with patients.

Q. Have you ever treated a patient for any disease?

A. No. I'm not a medical practitioner. But this patent is about the system. It's – there is nothing about medical here

. . . .

Q. Do you have any experience diagnosing sleep disorders?

A. I'm not a medical professional.

Q. Do you have any experience treating sleep disorders?

THE WITNESS: Same answer. I'm not a medical professional.

Q. Do you have any experience operating a CPAP machine?

THE WITNESS: I'm not a medical practitioner; so...

Q. Do you have any experience designing a CPAP machine?

A. I haven't designed CPAP machine

Ex. 2016 at 24:9-25:22. As became clear, however, his testimony on this issue, including his statement that “it would make sense to tailor the administering of the drug delivery based on the condition” did not derive from any “scientific, technical, or other specialized knowledge” but from his own “common sense.” *Id.* at 65:13-67:3; Fed. R. Evid. 702.

Petitioner's arguments in this case rely on bridging acknowledged differences between the prior art of record and the Challenged Claims using the conclusory, and often demonstrably wrong, testimony of a person who was not qualified to testify from the point of view of a POSITA or as someone with “scientific, technical, or other specialized knowledge” under the Federal Rules of Evidence. Patent Owner requests, therefore, that the Board disregard or appropriately weight Dr. Sharony's “advocacy from the witness stand.” *Kyocera Senco*, 22 F.4th at 1377 (citation omitted).

IV. THE CHALLENGED CLAIMS ARE PATENTABLE

A. GROUND 1: Claims 1-3, 5 and 7 are Patentable Over the Genger Combinations

1. Genger in View of Farrell Does not Disclose nor Render Obvious an “Airflow Sensor Internal to the PAP Device For Measuring the Respiratory Airflow Data of a Subject” (Claims 1-3)

The combination of Genger and Farrell does not disclose a respiratory airflow sensor internal to a CPAP machine because—as Petitioner admits and a POSITA would recognize—Genger and Farrell both teach mask-located respiratory sensors,

which are not internal to the CPAP. In view of these acknowledged deficiencies, Petitioner turns to Dr. Sharony, who testified that a POSITA would have found it obvious to relocate Genger's airflow sensor internally because internal airflow sensors were "common." See Pet. at 34 ("Genger shows the airflow sensor outside the CPAP device"); Ex. 1004 at ¶¶ 86-87; Ex. 2017 ("Borkholder Decl.") at ¶¶ 33-34.

The Board should reject Petitioner's argument because Dr. Sharony is not qualified to testify as an expert on this issue, and the sole piece of evidence he cites in support of his position, Berthon-Jones (Ex. 2015) does not disclose an internal airflow sensor, does not establish a "common" location for the type of pneumotachograph of Genger, and he does not argue that a POSITA would have been motivated to replace Genger's pneumotachograph with a sensor that indirectly measures airflow. Notably, while Dr. Sharony purports to rely on Berthon-Jones in his declaration, neither he nor Petitioner cited the reference as an exhibit, and Petitioner improperly relies on arguments and evidence incorporated by reference. The Board should find Claims 1-4 patentable, therefore, because Petitioner's argument attempting to bridge the gap between the prior art and the claimed invention relies entirely on inadmissible testimony that is inconsistent with the allegedly supporting evidence.

a) Genger Does Not Disclose an Airflow Sensor Internal to the CPAP Machine

Petitioner admits that Genger's respiratory airflow sensor, which is located at the patient's mask, is located outside of the CPAP machine. Pet. at 34 ("Genger shows the airflow sensor outside the CPAP device . . ."); *see also* Borkholder Decl. at ¶ 33. And to the extent that Dr. Sharony's testimony is entitled to any weight, he re-confirmed this opinion during cross-examination, stating plainly that a POSITA would not consider airflow sensor attached to a CPAP mask or hose to be "internal" to the PAP machine with an "enclosure," as recited in the Challenged Claims. Ex. 2016 at 44:16-45:25.

CleveMed agrees with Petitioner that an airflow sensor located at the patient's mask is external to the CPAP machine because that is the only conclusion that is consistent with the plain meaning of the claim language and the intrinsic record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." (citation omitted)); *see also* Borkholder Decl. at ¶¶ 33-34. The '269 Patent discloses a PAP device that "includes a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit" where 320 and 322 are sensors that reside inside the enclosure of the PAP device. '269 Patent at 23:7-10; Borkholder Decl. at ¶ 35.

Unlike Farrell's design, which discloses a pneumotachograph that measures exhalation at or near an exhaust port on the mask, the '269 Patent discloses an embodiment where the patient's respiratory airflow is measured with an airflow sensor internal to the CPAP machine:

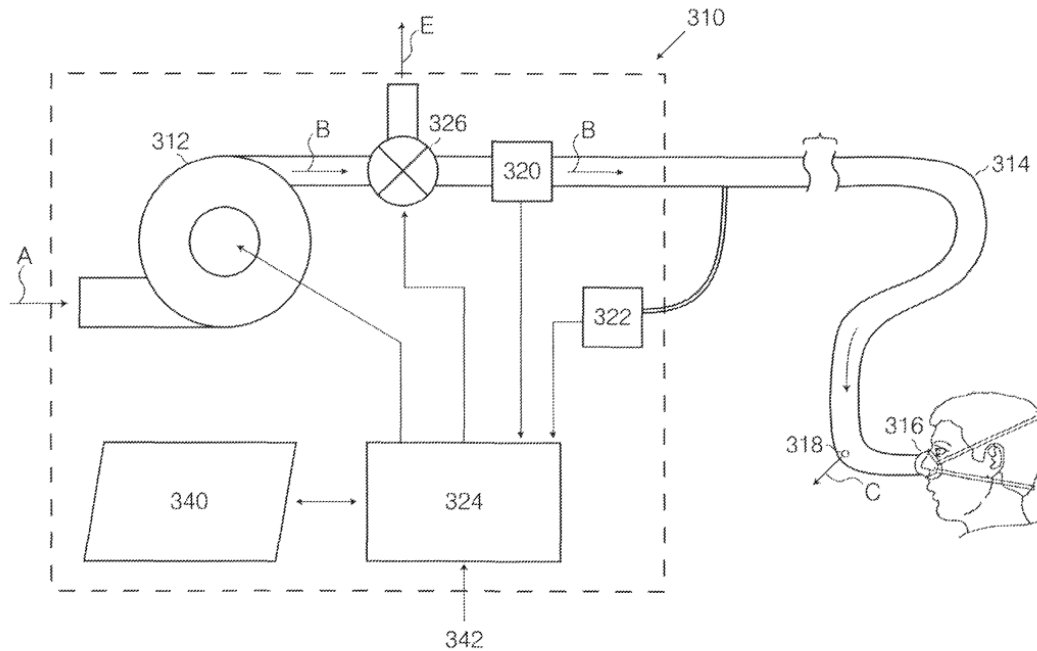


Fig. 7

'269 Patent at FIG. 7. The novel construction of the '269 Patent involves both the structure and functionality of the invention, whereby the airflow sensor (320) and the pressure sensor (322), located in the PAP device, can measure the respiratory airflow, before the processor generates the level of severity of the sleep disorder symptom and/or associated index and transfers that data to a remote location. See Borkholder Decl. at ¶ 36.

Thus, the specification supports the parties' shared understanding that an "internal" airflow sensor must be within the physical enclosure of the PAP device, not outside the enclosure on the hose or the mask. *See id.* at ¶ 37. In view of this agreement over the scope of the claims, the Board should determine that Genger's mask-located airflow sensor is not internal to the CPAP machine. *Cf.* Institution Decision, Paper 23 ("DI") at 31 (determining that Petitioner raised a reasonable likelihood of success on the merits solely because a mask-located airflow sensor could be considered "internal"); *see* Borkholder Decl. at ¶ 37.

The Board should, therefore, confirm the patentability of the Challenged Claims because Farrell and Berthon-Jones, which is incorporated by reference in Farrell, teaches an airflow sensor mounted on the hose, not internal to the CPAP, let alone provide evidence that it was "common" to locate the type of sensor taught in Genger and Ferrell internal to a PAP device at the time of the invention. Pet. at 34; Ex. 1004 at ¶ 86; *see* Borkholder Decl. at ¶ 38.

b) Farrell's Sensors Incorporated in the Mask Are Not Internal to the CPAP Machine

In the Institution Decision, the Board determined that Farrell's suggestion of "incorporating sensors into the mask" was sufficient to teach an internal respiratory airflow sensor. DI at 30-31. However, for the reasons discussed above, a mask-located sensor is not internal to the PAP device. *See* § IV.A.1.a; *see* Borkholder Decl. at ¶ 39.

Farrell discloses a pneumotachograph for measuring a patient's respiratory function. See DI at 27, n.7 ("A pneumotachograph is a device or apparatus for measuring the rate of the respiratory function"); see also *id.* at 49 (relying on Farrell's pneumotachograph to conclude that the art teaches a device for measuring a subject's respiratory airflow); Borkholder Decl. at ¶ 40. As the Board correctly recognized, Farrell's pneumotachograph and pressure sensor are located at or near the mask. See DI at 30-31 ("Farrell reasonably teaches that a sensor can be included in the mask of the CPAP device."), 44-45; see also Ex. 1008 at 5:4-9 ("[M]ask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{\text{mask}}(t)$," where the pressure trap is located at the exhaust vent); Borkholder Decl. at ¶¶ 40-41. Thus, Farrell's mask-located airflow sensor is not internal to the CPAP machine.

For at least these reasons, Farrell does not cure Genger's admitted deficiencies because it does not disclose or suggest an internal respiratory airflow sensor. See Borkholder Decl. at ¶ 42. Dr. Sharony's further obviousness arguments are wrong and should be disregarded because he is not a POSITA, and his conclusions contradict the record evidence. *Id.*

c) Dr. Sharony's Testimony Does Not Cure Genger's and Farrell's Deficiencies

The Board should reject Petitioner's attempts to substantiate its claim that it was "common" to locate the types of sensors taught in Genger and Farrell internal

to a PAP with testimony from Dr. Sharony because (1) Dr. Sharony does not qualify as a POSITA, (2) Berthon-Jones does not disclose an internal airflow sensor, and (3) Dr. Sharony has not established any motivation for replacing Genger's pneumotachograph with a different type of airflow sensor. *See* Borkholder Decl. at ¶ 43.

First, the Board should disregard Dr. Sharony's testimony on this issue because he was not a POSITA at the time of the claimed invention. *See* § III.B, *infra*. Yet even if the Board deems some of Dr. Sharony's declaration testimony admissible, he admittedly did not have "knowledge, training, or experience that would be helpful to the factfinder" to testify reliably about what was and was not "common" in CPAP machines at the time of the invention. *Kyocera Senco*, 22 F.4th at 1376-77 ("To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art. Without that skill, the witness' opinions are neither relevant nor reliable."). As Dr. Sharony readily admitted during cross-examination, he has no personal experience designing or operating CPAP machines. Ex. 2016 at 25:14-22.

Indeed, the Board should disregard Dr. Sharony's testimony on this issue because he did not recall ever reviewing Berthon-Jones. *Id.* at 50:3-22 (discussing Ex. 2015, Berthon-Jones); *see also* Borkholder Decl. at ¶¶ 43-44. As became evident

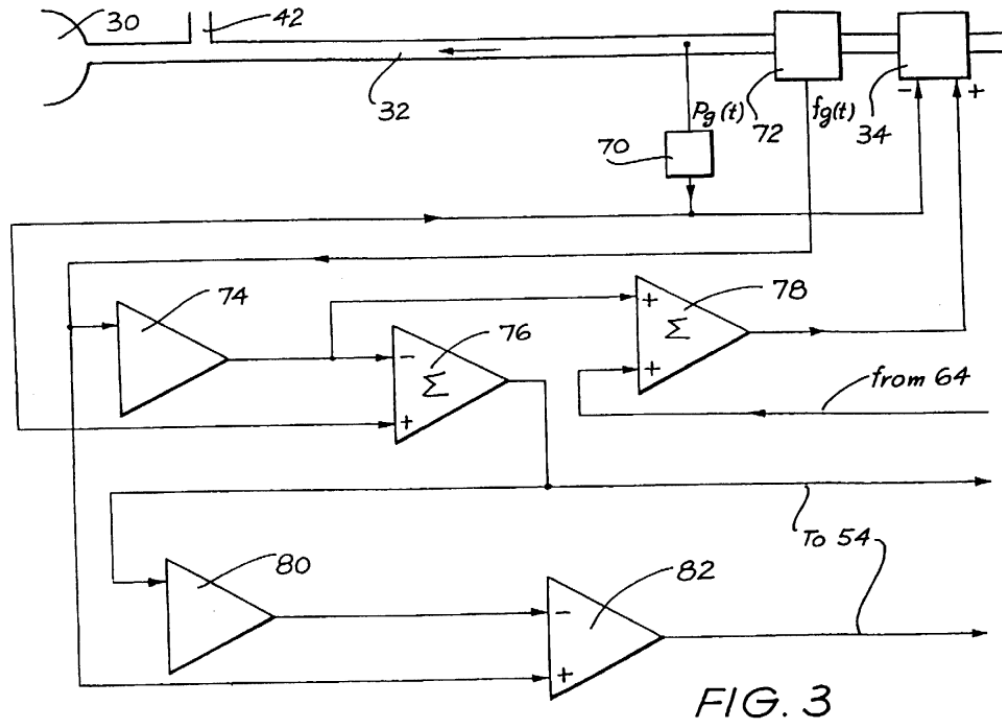
during his deposition, Dr. Sharony had not previously seen the sole piece of evidence cited in his Declaration to support the notion that it was “common” to locate pneumotachographs within a PAP device at the time of the invention. *Id.*; *see also id.* at 56:21-57:7.

Second, Petitioner's assertion that internal respiratory airflow sensors were “common” is not substantiated in Berthon-Jones. Pet. at 34 (citing Ex. 1004, ¶ 86 (citing Ex. 2015 at 7:17-24)); *see also* Borkholder Decl. at ¶ 44. The relevant portion of Berthon-Jones, states that an airflow sensor may measure airflow at or near the output of the turbine, not that the airflow sensor is internal to the CPAP machine:

Further, **it may not be convenient to mount the flow transducer 44 at or near the mask 30**, nor to measure the mask pressure at or near the mask. An alternative arrangement, where the **flow and pressure transducers are mounted at or near the air pressure generator** (in the embodiment being the turbine 34) is shown in FIG. 3. The pressure $p_g(t)$ occurring at the pressure generator 34 outlet is measured by a pressure transducer 70. The flow $f_g(t)$ through tubing 32 is measured with flow sensor 72 provided at the output of the turbine 34.

Ex. 2015 at 8:31-40 (emphasis added). Indeed, Dr. Sharony acknowledged during his deposition that the relevant figure does not illustrate where the enclosure would be relative to the flow and pressure sensors. Ex. 2016 at 55:11-19; *see also* Borkholder Decl. at ¶ 44.

As illustrated in FIG. 3 of Berthon-Jones, the flow sensor is mounted to the tubing that connects the CPAP machine's turbine output to the mask:



Ex. 2015 at FIG. 3; see Borkholder Decl. at ¶ 45. As someone with familiarity with CPAP machines would recognize, this hose extends between the CPAP machine and the mask rather than being internal to the machine. Borkholder Decl. at ¶¶ 44-46; see also Ex. 2020, Ex. 2021.

Third, Petitioner has not established that it would have been obvious to relocate Genger's pneumotachograph based on the teachings of Berthon-Jones because Berthon-Jones' airflow sensor is not a pneumotachograph. See Borkholder Decl. at ¶ 46. A POSITA would recognize that pneumotachographs directly sense a patient's respiratory airflow, whereas the airflow sensor disclosed in Berthon-Jones

measures respiratory airflow indirectly. *See id.* at ¶ 46 (citing Ex. 2015 at 8:31-62). Accordingly, Berthon-Jones does not establish that “POSITA would have found it obvious to locate [Genger’s] airflow sensor internally because that location was common,” as Dr. Sharony states, because that location was not common or possible for pneumotachographs. *See* Borkholder Decl. at ¶¶ 46-47; Ex. 1004 at ¶ 86.

Nor has Petitioner attempted to show motivation to replace Genger’s pneumotachograph with the non-pneumotachograph disclosed in Berthon-Jones. *In re: Stepan Co.*, 868 F.3d 1342, 1345-46, n.1 (Fed. Cir. 2017) (“Whether a rejection is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination.”).

POSITA and medical professionals recognize that substantial changes to medical devices can have significant costs that weigh against modifying an existing device without strong motivations. Ex. 2018 (“Patil Decl.”) ¶¶ 23-25 (discussing the FDCA approval process for changes to medical devices). In this case, Petitioner has not presented any motivation for modifying Genger’s pneumotachograph-based system with one that does not use a pneumotachograph, let alone a motivation that would overcome the possibility of requiring a new premarket approval. *Id.*; *see also*

Borkholder Decl. at ¶¶ 43-47. Indeed, the only reason Dr. Sharony gives for this redesign, that relocating Genger's sensor "puts the airflow data where Genger wants it, and avoids the need to transmit airflow data from an external sensor or change external sensor batteries," is conclusory and unsupported. Ex. 1004 at ¶ 88. It is also a solution in search of a problem given that external sensors were commonplace and worked for their purpose. Borkholder Decl. at ¶¶ 43-47. This hindsight reasoning is insufficient to have motivated the proposed modification.

Moreover, instead of filing the evidence Petitioner's expert relied on, or even providing a bare citation to the reference in the Petition, Petitioner's argument and evidence were incorporated by reference, which is prohibited under 37 C.F.R. § 42.6(a)(3). Accordingly, Petitioner has not provided "a detailed explanation of the significance of the evidence including material facts" pursuant to 37 C.F.R. § 42.22(a)(2). *See Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1371 (Fed. Cir. 2023).

This incorporation by reference issue is not merely a technical fault. Dr. Sharony intimates that Farrell cites Berthon-Jones for details about where a POSITA would re-locate Farrell's pneumotachograph, but Farrell does not reference Berthon-Jones when discussing the location of the airflow sensor. *Compare* Ex. 1004 at ¶ 86 *with* Ex. 1008 at 5:13-19 (citing three *different* patents disclosing alternative solutions for estimating or calculating flow and pressure signals "in relation to the

blower motor by monitoring current supplied to the motor and/or the speed of the motor”); *see also* Borkholder Decl. at ¶ 46.

Patent Owner respectfully requests, therefore, that the Board confirm the patentability of Claim 1 and each of the claims depending therefrom, including Claims 2-4, because Genger in view of Farrell does not teach or suggest the internal respiratory airflow sensor recited in Claim 1. As shown below, Claims 15-20 are also patentable because Farrell does not cure the admitted deficiencies of Ex. 1012 (“Kocinski”) for the same reasons that it does not cure the deficiencies of Genger. *See* § IV.C, *infra*.

2. Genger Does Not Teach or Suggest a “Nonvolatile Memory” Being Provided “Sleep Disorder Symptom Data and/or the Index of the Level of Severity of the Subject’s symptoms” (Claim 5)

Genger does not disclose a “the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject’s symptoms to a *nonvolatile memory* to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject’s symptoms to a remote location.” ’269 Patent at Claim 5 (emphasis added).

Petitioner admits that Genger does not disclose sending this data to nonvolatile memory. Pet. at 46. This is because Genger discloses a modem that “relay[s]” information output from the controller. *See* Ex. 1005 at 6:13-22. In these

circumstances, a POSITA would recognize that this data would be, at best, stored in volatile buffer memory for immediate transmission because memory buffer is only meant to store data long enough to ensure no transmission failure has occurred. *See* Borkholder Decl. at ¶¶ 49-51; Ex. 2019 at 344, 367, 558 (definitions from Microsoft 2002 Computer Dictionary for “modem” is “[a]ny communications device that acts as an interface between a computer or terminal and a communications channel”; for “non-volatile memory” is “[a] storage system that does not lose data when power is removed from it”; and for “volatile memory” as “[m]emory, such as RAM, that loses its data when the power is shut off”). Petitioner again relies on the testimony of Dr. Sharony in an attempt to fill the gap with the benefit of hindsight. Pet. at 46.

Volatile memory and non-volatile memory are used for different purposes. Borkholder Decl. at ¶ 52; *see also* Ex. 2019 (definitions from Microsoft 2002 Computer Dictionary for “modem” is “[a]ny communications device that acts as an interface between a computer or terminal and a communications channel”). Not only was nonvolatile memory not used for this storing data being transmitted by a modem at the time, there are factors that would lead a POSITA to avoid using non-volatile memory to store data intended for immediate transmission, which would not only make the system more expensive, but would also have the potential to impact speed of data transmission. *See* Borkholder Decl. at ¶¶ 50-54. A POSITA would

understand these constraints and would not have been motivated to change the memory in the modem to non-volatile memory. *See* Borkholder Decl. at ¶¶ 52-54.

Further, a POSITA would not have been motivated to provide or add non-volatile memory in order to address communication errors. *Pet.* at 46. Volatile memory retains all sufficient data for re-transmission in the case of there are communication errors. *See* Borkholder Decl. at ¶¶ 53-54. Non-volatile memory was neither required nor well-suited, given its expense and relative lethargy, to fulfill this function. *See id.* Thus, I do not believe it would have been obvious to modify Genger's volatile memory with a nonvolatile memory. '269 Patent Claim 5.

Nor would a POSITA have had motivation to add additional non-volatile memory to the system of Genger given the teachings of Westbrook, given the stated intent to immediately relay data to the remote location. *See* Borkholder Decl. at ¶54. A POSITA would not add additional cost and complexity to a system without a strong motivating factor, which is absent from Dr. Sharony's analysis.

In fact, the non-volatile memory disclosed in Westbrook is used to store different data for a different reason. *See* Borkholder Decl. at ¶¶ 55-56. Westbrook discloses a physiological monitoring system including a micro-controller 42, which transmits digitized sensor signals to an associated flash memory. *Ex. 1007* at [0058], [0075] ("Flash memory chips 44 provide a low cost method to store the signals acquired during use of the physiological monitor 12."). This raw "sleep data" is then

transferred to a host computer system by removing the flash card from the machine and placing it in a card reader for computer 20, which analyzes the data. *Id.* at [0054], [0077]-[0078]. Accordingly, while Westbrook suggests storing large amounts of raw sleep data in non-volatile memory, it does not provide any motivation to store Genger's *alarms and trend data* in a non-volatile memory, particularly given that Genger's goal is to relay that data to a server immediately. Ex. 1005 at 12:18-25; see Borkholder Decl. at ¶¶ 55-56.

As discussed above, Westbrook's inclusion of flash memory into the modem would make the modem more expensive and negatively impact data transmission rates. Moreover, Westbrook's disclosure of storing up to 40 hours of data before transferring it to the computer for analysis would plainly frustrate Genger's key objective, which is to allow for fast reactions and response times for severely disabled patients. Ex. 1005 at 6:20-22, 18:30; see also Ex. 1007 at FIG. 2, [0058], [0078]; Borkholder Decl. at ¶¶ 55-56. If the intent of the Genger system is to monitor patients in hospitals, and provide alarms that can initiate dispatch of an ambulance when monitoring patients in the home, the Genger system would not be designed to accommodate capture of data over long periods prior to transmitting that data. See Borkholder Decl. at ¶ 56. Nor would it be designed to incorporate the claimed nonvolatile memory.

For at least these reasons, Claim 5 is patentable over Genger because the combination does not teach or suggest a CPAP that had nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location. *See* Borkholder Decl. at ¶ 57.

B. GROUND 3: Claims 8-11 and 13 are Patentable Over Stahmann in View of Edgar

Petitioner's Stahmann-Edgar combination does not disclose a "[PAP] apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, *using the output of the level of severity of the subject's sleep disorder.*" '269 Patent at Claim 8 (emphasis added); *see* Borkholder Decl. at ¶¶ 60-62. Petitioner admits that Stahmann does not disclose adjusting drug therapy in response to the level of severity of the subject's sleep disorder. *See* Pet. at 53-57 (acknowledging that Stahmann does not disclose this aspect of the claimed invention); *see* Borkholder Decl. at ¶¶ 59-62. Its arguments that it would nevertheless have been obvious to do so rely on nothing more than the testimony of Dr. Sharony, who cites no evidence in support of this position, who is not a POSITA, and who does not have any knowledge or experience related to treating patients generally or sleep disorders specifically. Pet. at 57 (citing Ex. 1004 at ¶124); Ex. 2016 at 25:1-12; *see* Borkholder Decl. at ¶ 63. Petitioner also does not suggest that Edgar, which discloses treating a patient with a sleep-promoting medication to

discourage the patient from removing the CPAP mask during treatment, cures this deficiency.

1. Stahmann Does Not Disclose Adjusting a Pharmaceutical Agent Based on the Level of Severity of the Subject's Sleep Disorder

Stahmann does not disclose “a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system,” and Petitioner does not suggest that it does. *See* Pet. at 53-57 (acknowledging that Stahmann does not disclose this aspect of the claimed invention); Ex. 2016 at 31:17-19 (“Let me be specific. One of the references, the Stahmann, doesn't mention the agent or the pharmaceutical delivery.”). Petitioner's argument that it would be obvious to modify Stahmann to reach this feature of the claimed invention must be rejected because it is supported by nothing more than the conclusory opinion of Dr. Sharony, who is not qualified to testify as an expert on this topic.

The integrated diagnostic and treatment device disclosed in the '269 Patent includes a number of sensors, including respiratory airflow and pulse oximetry sensors, which collect data reflecting the patient's physiological state while receiving treatment for a sleeping disorder. '269 Patent at 19:46-67. This data is provided to a microprocessor that determines “a level of severity of the subject's sleeping disorder or symptoms.” *Id.* at 23:27-33. This severity level is then used to

adjust different aspects of the patient's treatment, including the air pressure provided by the CPAP machine, oxygen from a connected O₂ tank, and/or medication from a connected nebulizer. *Id.* at 23:33-41; *see also id.* at 22:9-12 ("Various embodiments of the present invention include a device for physically or chemically treating a subject's sleeping disorder, which can be adjusted using the output of the level of severity of the subject's sleeping disorder."). Accordingly, the integrated diagnosis and treatment system disclosed and claimed in the '269 Patent does not merely administer a pharmaceutical agent upon detection of a sleep disorder system, it uses a controller to adjust the pharmaceutical agent based on the level of severity of the patient's sleep disorder. *See* Borkholder Decl. at ¶ 60; Patil Decl. at ¶ 26.

Rather than disclosing a controller that adjusts a pharmaceutical agent based on the level of severity of a patient's sleep disorder systems, Stahmann discloses releasing carbon dioxide each and every time a central apnea is detected. Ex. 1010 at 22:29-31, 309:25-27; Patil Decl. at ¶ 27. However, single apnea events are not a level of severity of the subject's sleep disorder, and Petitioner does not suggest that they are. As Dr. Borkholder explains, the level of severity of a patient's sleep disorder symptoms may be based on the detection of a certain number of sleep disorder symptoms events over a period of time. *See* Borkholder Decl. at ¶ 61. For example, a single apnea event over the course of an entire night's sleep could represent a very low level of severity, potentially resulting in a downward

adjustment of the pharmaceutical agent whereas each and every apnea event in Stahmann's system is treated exactly the same way. *See id.*

Accordingly, the Board's factual determination that "Stahmann reasonably suggests detecting sleep events including arousals from sleep" does not facially read on the language of the claims, which requires *adjusting* a pharmaceutical agent based on a *level of severity* of a patient's sleep disorder rather than administering a therapy whenever a central apnea is detected. DI at 39-41; *see* Borkholder Decl. at ¶ 62; Patil Decl. at ¶¶ 27-29. Indeed, the Examiner noted this very deficiency during original prosecution of the '269 Patent. Ex. 1002 at 283 ("Stahmann[] nor the prior art of record teaches the device of [claim 8], including . . . a pharmaceutical agent . . . which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder . . .").

Petitioner also recognizes this deficiency in the Stahmann reference. *See* Pet. at 53-57 (acknowledging that Stahmann does not disclose this aspect of the claimed invention). In attempting to fill this missing limitation, Petitioner alleges, with no analysis or evidentiary support, that a POSITA would have been motivated to adjust drug therapy based on AHI. Indeed, the only support for Petitioner's argument comes from the conclusory testimony of Dr. Sharony, who is not qualified to testify as an expert on such matters. *Id.* at 57. But medical professionals understand that treatments for one disorder are not fungible, so there is no medical basis

undergirding Dr. Sharony's attempt to derive an "obvious" treatment for a sleep disorder based on the level of severity of the patient's sleep disorder symptoms from the disclosure of providing drug therapy to a patient suffering from a cardiopulmonary disorder. *See* Borkholder Decl. at ¶ 63; Patil Decl. at ¶¶ 27-29.

Because Edgar also does not disclose a controller for adjusting a pharmaceutical agent based on the level of severity of the patient's symptoms, the Board should confirm the patentability of Claim 8 and Claims 9-11 and 13, which depend therefrom.

2. Stahmann in View of Edgar Does Not Teach Treating Sleeping Disorders or Symptoms with a Pharmaceutical Agent

Stahmann's system provides for the treatment of sleeping disorders using a positive airway pressure device and the treatment of other respiratory issues, such as asthma, using a pharmaceutical agent. *See* Ex. 1010 at 224:15-17 ("Asthma may be treated with a nebulizer."); *see* Borkholder Decl. at ¶ 65. Asthma is not (and Petitioner has not alleged that it is) a sleep disorder. Borkholder Decl. at ¶ 65. In view of Stahmann's acknowledged deficiencies, Petitioner cites Edgar, but Edgar discloses providing a sleep-promoting agent in order to increase the chance that the patient leaves the CPAP mask on during the night, not to treat a sleep disorder or its symptoms.

Edgar discloses using a CPAP machine to treat a patient with a pharmaceutical compound to promote sleep. However, like Stahmann, Edgar's treatment is unrelated to "the output of the level of severity of the subject's sleep disorder." '269 Patent at Claim 8. Instead, Edgar discloses supplementing normal CPAP treatment with a sleeping agent to prevent the patient from removing the mask during the night:

[M]any patients cannot tolerate the [CPAP] apparatus or pressure and refuse treatment. Moreover, recent covert monitoring studies demonstrated that long-term compliance with CPAP treatment is very poor. It is known that patients remove their mask while sleeping.

Ex. 1011 at [0406]; see Borkholder Decl. at ¶66.

Edgar discloses a compound "to promote sleep" in order to ensure that the subject does not remove the mask, not treating the subject's sleep disorder through the pharmaceutical agent. See Borkholder Decl. at ¶ 67; Patil Decl. at ¶¶ 30-31; Edgar at [0406-0408]. Accordingly, Edgar teaches the use of a pharmaceutical agent to ensure that a *different* therapy, *i.e.* continuous positive air pressure, is effective. See Borkholder Decl. at ¶ 67; Patil Decl. at ¶¶ 30-31.

For at least these reasons, Claim 8 is patentable over Stahmann in view of Edgar because the combination does not teach or suggest a CPAP for providing a pharmaceutical agent based on the level of severity of the subject's sleep disorder symptoms.

3. The Examiner Determined that Stahmann Does Not Teach this Limitation

At institution, the Board determined that the Office materially erred by not “reinstating the rejection based on Miles, Hedner and the ’690 Stahmann in the next office action.” DI at 18-20. However, the Board overlooked the fact that the Examiner found that Stahmann (with Miles and Hedner) failed to disclose *both* the treatment with “additional CO₂” *and* “a pharmaceutical agent:

[N]either Miles, Hedner, Stahmann, nor the prior art of record teaches the device of claim 34, including the following in combination with all other limitations of the claim: an [sic] positive airway pressure apparatus for providing pressurized air and **chemically treating a subject's sleep disorder or symptoms with additional CO₂** resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, **or a pharmaceutical agent**, either which can be adjusted at least in part using the output of the level of severity of the subject's sleep disorder from the data acquisition system.

Ex. 1002 at 283 (emphasis added); DI at 18. In other words, the Examiner found that Stahmann did not disclose *either* of these treatments. Accordingly, when the applicant amended the claim to remove the reference to CO₂, there was no basis for the Examiner to reinstate the rejection over Stahmann, which was already found not to disclose the pharmaceutical agent limitation.

C. GROUND 6: Claims 15-16 and 18-19 are Patentable Over Kocinski in View of Farrell and Bluetooth

Independent Claim 15 is patentable at least because the combination of Kocinski, Farrell, and Bluetooth does not disclose “an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject.” ’269 Patent at Claim 15. Rather than measure the respiratory airflow of a subject, both Kocinski and Farrell disclose pressure sensors that measure the pressure that the CPAP machine provides to the patient. The combination of references asserted as part of Ground 6 also does not disclose or suggest the display or transmission of the subject’s sleep disorder symptom data and/or an associated index.

1. Kocinski alone or in combination with Farrell fails to teach or suggest an internal PAP airflow sensor is “adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data.”

Kocinski, alone or in combination with Farrell, fails to teach or suggest an internal airflow sensor adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data. *See* Borkholder Decl. at ¶ 70. Petitioner does not suggest that Kocinski discloses the claimed airflow sensor, relying instead on Dr. Sharony’s testimony regarding Farrell to fill the gap. Pet. at 64-65. However, it would not have been obvious to modify Kocinski with Farrell to reach the claimed internal airflow sensor for at the same reasons discussed above with respect to

Petitioner's proposed combination of Genger and Farrell. See Borkholder Decl. at ¶ 70; see Section IV.A.1, *supra*.

In view of the foregoing reasons, Kocinski taken alone or in combination with Farrell does not teach or suggest an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data.

2. Kocinski does not teach or suggest transmitting symptom data and/or index of symptom data from the CPAP device via the base station to a remote internet site

Kocinski fails to teach or suggest “transmitting the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device” or “retransmit[ting] the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.” '269 Patent Claim 15; see Borkholder Decl. at ¶ 72.

Petitioner relies on Kocinski, paragraphs 28 and 31, for the transmission of the symptom data and/or index of symptom data both from the CPAP device to the base station and from the base station to a remote internet site. Pet. at 71. However, Kocinski does not transmit symptom data (which Petitioner alleges is Apnea events, Hypopnea events, or counts) or an index of symptom data (which Petitioner alleges is AI, HI, AHI). Borkholder Decl. at ¶ 73. Rather, Kocinski simply provides an

email notification to the medical professional if the number of apnea events or hypoapnea per hour exceeds a programmed threshold. Ex. 1012 at [0028]. Specifically, the email only informs the recipient that the threshold has been exceeded and does not provide symptom data, such as the apnea event count or its associated index, to the medical professional. See Borkholder Decl. at ¶ 73. Similarly, in paragraph 31, Kocinski's CPAP apparatus discloses the ability to trigger the unexpected transmission of the email notification if the subject is experiencing too many abnormal sleep events to alert the medical professional.

Petitioner relies on Farrell in an attempt to cure Kocinski's deficiency. See Pet. at 66-67. However, Farrell also does not disclose the transmission of any symptom data, either to its hand-held device for display or to a remote location. See Borkholder Decl. at ¶ 74. The citation that Petitioner points to only provides that, "[t]he apparatus preferably also includes a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12." Ex. 1008 at 5:28-31, Fig. 1. As evidenced by the full recitation of the referenced citation, however, Farrell does not disclose the transmission of symptom data nor its related indexes to the hand-held device. See Borkholder Decl. at ¶ 74. Rather, Farrell discloses that this data is merely "recorded for analysis." Ex. 1008 at 7:35-8:3.

Petitioner also asserts, with no underlying evidentiary support, that the Farrell and Kocinski combination would not only allow for the viewing of the information but also the transmission of data to a remote location. These assertions are not supported by either the Kocinski or Farrell reference. See Borkholder Decl. at ¶¶ 73-74. To cure this lack of supporting evidence, Petitioner cites Declarant, Dr. Jacob Sharony. However, Dr. Sharony's expert opinion is nothing more than a perfect verbatim recitation of the unsupported position asserted in the Petition. Dr. Sharony's testimony on this combination should be given little to no weight as it does not disclose any underlying facts or data on which the opinion is based. 37 C.F.R. § 42.65(a); see also *Xerox Corp. v. Bytemark, Inc.*, No. IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (precedential) (concluding when the expert simply repeated verbatim the conclusory allegations provided in the opinion, the expert's opinion should be given little to no weight).

For at least this reason, Kocinski does not meet independent claim 15.f nor 15.g.2 because of its lack of transmission of the subject's symptom data and/or the index of the subject's symptom data.

3. Kocinski does not teach or suggest a base station, cellular phone or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms

As established above, Kocinski fails to teach or suggest an internal airflow sensor adapted for measuring the respiratory airflow of a subject and outputting

airflow sensor data. Kocinski's Figure 10 does not display either the subject's sleep disorder symptom data or the index of the subject's symptoms.

Petitioner's argument that it would have been obvious to display symptom data (which is not transmitted in Kocinski system and which is not displayed in FIG. 10), to "the patient, patient's family, and visiting medical professionals to see the patient's data on-site" is entirely conclusory. Pet. at 74. Prior to the '269 Patent, it was not known to display this type of data to such parties, and Petitioner cites no evidence that it was. See Borkholder Decl. at ¶¶ 77-78; *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1360 (Fed. Cir. 2019) (reliance on "a conclusory statement is 'not sufficient and is fraught with hindsight bias.'" (citation omitted)).

Indeed, ResMed's CEO credited this feature with an unexpectedly large increase in compliance rates over prior systems (like Kocinski), which only displayed the patient's compliance data. Ex. 2010 at 5 (Patients' visibility into their own sleep data "significantly improve[d] their adherence to sleep therapy"); Ex. 2011 at 3-4 (crediting the AirView and myAir platforms for improving compliance to more than 87% adherence). These "surprising and unexpected" results related to displaying the patient's symptom data belie Petitioner's conclusory assertion that it would have been obvious to display this data. See Borkholder Decl. at ¶¶ 77-78; *Forest Lab's, LLC v. Sigmapharm Lab's LLC*, 918 F.3d 928, 937 (Fed. Cir. 2019).

For at least this reason, Kocinski does not meet independent claim 15.g.2 because of its lack of transmission of the subject's symptom data and/or the index of the subject's symptom data which results in the inability to display the data on the base station, cellular phone or PDA.

D. GROUND 2: Claims 4 and 6 are Patentable Over Genger in View of Schmidt, Westbrook, Farrell, and Paradiso

As established above, Petitioner fails to demonstrate by a preponderance of the evidence that Claims 1 and 5 are obvious over Genger, Schmidt, Westbrook, Farrell, and Paradiso to cure any of the deficiencies as set forth above. See Borkholder Decl. at ¶¶ 80-81; see § IV.A, *supra*.

Therefore, Petitioner also fails to show by a preponderance of the evidence that the cited combination renders obvious Claims 4 and 6, which depend on independent Claims 1 and 5.

E. GROUND 4: Claim 12 is Patentable Over Stahmann, Edgar, and Schmidt

As established above, Petitioner fails to demonstrate by a preponderance of the evidence that Claim 8 is obvious over Stahmann and Edgar, and Schmidt to cure any of the deficiencies as set forth above. See Borkholder Decl. at ¶¶ 82-83; See § IV.B, *supra*.

Therefore, Petitioner also fails to show by a preponderance of the evidence that the combination renders obvious Claim 12, which depends on independent Claim 8.

F. GROUND 5: Claim 14 is Patentable Over Stahmann, Edgar, and Paradiso

As established above, Petitioner fails to demonstrate by a preponderance of the evidence that Claims 8-11 and 13 are obvious over Stahmann, Edgar, and Paradiso to cure any of the deficiencies as set forth above. *See Borkholder Decl. at ¶¶ 84-85; see § IV.B, supra.*

Therefore, Petitioner also fails to show by a preponderance of the evidence that the combination renders obvious Claim 14, which depends on independent Claim 8.

G. GROUND 7: Claim 17 is Patentable Over Kocinski, Farrell, Bluetooth, Guillemineault-2004, and Westbrook

As established above, Petitioner fails to demonstrate by a preponderance of the evidence that Claim 15 is obvious over Kocinski, Farrell, Bluetooth, Guillemineault-2004, and Westbrook to cure any of the deficiencies as set forth above. *See Borkholder Decl. at ¶¶ 86-87; see § IV.C, supra.*

Therefore, Petitioner also fails to show by a preponderance of the evidence that the combination renders obvious Claim 17, which depends on independent Claim 15.

H. GROUND 8: Claim 20 is Patentable Over Kocinski, Farrell, Bluetooth, and Paradiso

As established above, Petitioner fails to demonstrate by a preponderance of the evidence that Claim 15 is obvious over Kocinski, Farrell, Bluetooth, and Paradiso to cure any of the deficiencies as set forth above. *See Borkholder Decl. at ¶¶ 88-89; see § IV.C, supra.*

Therefore, Petitioner also fails to show by a preponderance of the evidence that the combination renders obvious Claim 20, which depends on independent Claim 15.

V. CONCLUSION

For all of these reasons, CleveMed respectfully requests the board hold patentable the Challenged Claims.

Dated: July 29, 2024

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

The undersigned hereby certifies that the portions of the foregoing **PATENT OWNER'S RESPONSE** specified in 37 C.F.R. § 42.24 has 9,139 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), that
service was made on the Petitioner as detailed below.

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