

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. 10,076,269

PATENT OWNER'S SUR-REPLY

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I. INTRODUCTION

Patent Owner Cleveland Medical Devices, Inc. (“CleveMed”) respectfully submits this Sur-Reply to Petitioner ResMed Corp.’s (“ResMed”) Reply in Support of its Petition for Inter Partes Review of U.S. Patent No. 10,076,269 (Ex. 1001, “the ’269 Patent”). The ’269 Patent, covering devices and methods for sleep disorder diagnosis and treatment, is patentable over the prior art of record because ResMed’s Reply attacks strawmen and relies almost entirely on the inadmissible and conclusory testimony of its expert witness, Dr. Jacob Sharony, to fill the gaps between the prior art and the Challenged Claims. The Board should disregard Dr. Sharony’s testimony in its entirety because he does not qualify as a person of ordinary skill in the art (“POSITA”), but even if the Board considers Dr. Sharony’s testimony, it does not cure the deficiencies of the prior art relied upon in the Petition.

In the POR, CleveMed (1) argued that Petitioner had not substantiated its claim that it was “common” to locate Genger’s mask-based pneumotachograph, which measures the patient’s airflow directly, internal to a CPAP machine, and (2) that “Petitioner provides no motivation to replace Genger’s pneumotachograph with an internal airflow sensor that can only measure the patient’s respiration indirectly.” PO Response (“POR”) at 2, 16-21. Rather than responding to these arguments, Petitioner called them “irrelevant” (Reply at 14) and, instead, introduced several new references (without any expert testimony discussing their significance)

arguing that internal airflow sensors capable of indirectly measuring a patient's respiration were known in the art. This new evidence does not address CleveMed's arguments or cure the Petition's failure to demonstrate a motivation to modify Genger or a reasonable expectation of success.

Nor does Petitioner show why a POSITA would have placed nonvolatile memory in Genger's modem where the purpose of the modem is to immediately transmit data. *See id.* at 16-18 (Ground 1 relying on Ex. 1005 ("Genger")). Although Petitioner argues that placing nonvolatile memory into a modem would allow it to store data for later transmission, it does not address the fact that modems immediately transmit the data they receive and use volatile memory to do so. Thus, Petitioner resorts to misstating Genger's plain disclosure. *Compare* Reply at 18 (claiming that "Genger suggests transmitting 'trend data' every two to three hours") with Genger at 6:20-22 (relaying trend data and alarms can reduce "the care of the severely disabled . . . from 24 hours to as little as 2 to 3 hours per day").

Petitioner has also failed to demonstrate that a POSITA would have found it obvious to combine Stahmann's breathing therapy feedback process to "adjust drug therapy . . . based on AHI." Reply at 20 (Ground 3 relying on Ex. 1010 ("Stahmann")) in view of Ex. 1011 ("Edgar")); *see also id.* at 18-20 (relying on AHI for adjustments). Indeed, Petitioner has not sought to establish that Stahmann's nebulizer and Edgar's Doxepin are used to treat sleep disorders while the patient is

sleeping, or that it would have been appropriate to adjust those treatments based on AHI, which measures the severity of an entirely different disorder, *i.e.* sleep apnea.

Furthermore, Petitioner's Kocinski-Farrell combination is missing a device that displays and retransmits symptom data and/or index, as required in Claim 15. (Ground 6 relying on Ex. 1012 ("Kocinski") in view of Ex. 1008 ("Farrell")). Instead, Kocinski displays compliance data on a medical professional's device, which does not retransmit any data to a remote internet site. The Board recognized this deficiency at institution (Paper 23 at 47-48), and Farrell does not resolve it because it also teaches the display of data on a medical professional's device without retransmitting data from that device to a remote internet site.

II. DR. SHARONY IS NOT A POSITA

Dr. Sharony does not hold the requisite work experience in "diagnostic sensor systems" to testify as a POSITA in this matter. See POR at 8-10 (arguing that "Dr. Sharony's education and experience do not include any industry experience in diagnostic sensor systems"); *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—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art.").

Petitioner's Reply does not demonstrate that Dr. Sharony has the requisite qualifications to testify in this matter. Although Dr. Sharony has experience with

“data capture devices,” this experience facially does not encompass diagnostic sensor systems. See Reply at 4-6; Ex. 1004 at ¶ 16 (explaining that “data capture devices” include digital imagers (bar code readers) and wireless communications devices); Reply at 5 (admitting that Dr. Sharony’s experience is in “communication technology”).

And though Petitioner attempts to denigrate Dr. Borkholder (Reply at 7-8), Dr. Borkholder has over 25-years of experience working with medical diagnostic systems. Ex. 2017 (Borkholder Decl.) at ¶ 7 (“engineered a full-featured medical diagnostic imaging system”), ¶ 15 (explaining that “[a]ll of my research has been biomedical Cepheid, Zonare, and Casana are all medical device companies: Cepheid is DNA diagnostics”), Appendix A (CV) at 2 (listing his work experience at “ZONARE Medical Systems, Inc.” where he “[s]uccessfully engineered a full featured medical diagnostic imaging system”); *see also id.* at 1-3 (showing work experience at various medical device companies, including Cepheid dating back to 1998). Accordingly, Dr. Borkholder has extensive work experience with diagnostic sensor systems, while Dr. Sharony has none. See Ex. 1004, Appendix A at 100-02 (CV) (showing only work experience in “data networks and mobile and wireless technologies”) at ¶¶ 8-16.

And while Petitioner argues that Dr. Sharony qualifies as a POSITA because “[a]n increase in experience could compensate for less education, and vice versa,”

Dr. Sharony does not only have “less” than two years’ experience working with diagnostic sensor systems, he has none. Reply at 6-7. Nor is this case similar to *Medtronic, Inc. v. Teleflex Life Scis. Ltd.*, which Petitioner cites in its Reply. In that case, the level of skill in the art allowed “[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience.” *Medtronic, Inc. v. Teleflex Life Scis. Ltd.*, No. IPR2020-01343, Paper 85 at 17-19 (P.T.A.B. Feb. 23, 2022) (emphasis added).

Accordingly, the Board should disregard Dr. Sharony’s testimony that purports to be given from the point of view of a POSITA having expertise with diagnostic sensor systems.

III. GROUND 1: CLAIMS 1-3, 5 AND 7 ARE PATENTABLE OVER THE GENDER COMBINATIONS

A. It Would Not Have Been Obvious to Replace Genger’s External Direct Respiratory Airflow Sensor with an Indirect Internal Airflow Sensor

Claims 1-3, 5, and 7 are patentable because (1) Petitioner has not substantiated its claim that it was “common” to locate mask-based pneumotachographs, which directly measure a patient’s airflow, inside a CPAP machine, and (2) that “Petitioner provides no motivation to replace Genger’s pneumotachograph with an internal airflow sensor that can only measure the patient’s respiration indirectly.” POR at 2, 16-21. Instead of addressing CleveMed’s arguments, Petitioner called them

“irrelevant” and proceeded to focus the majority of its Reply discussing new, unresponsive evidence and reinventing the disclosure of Farrell.

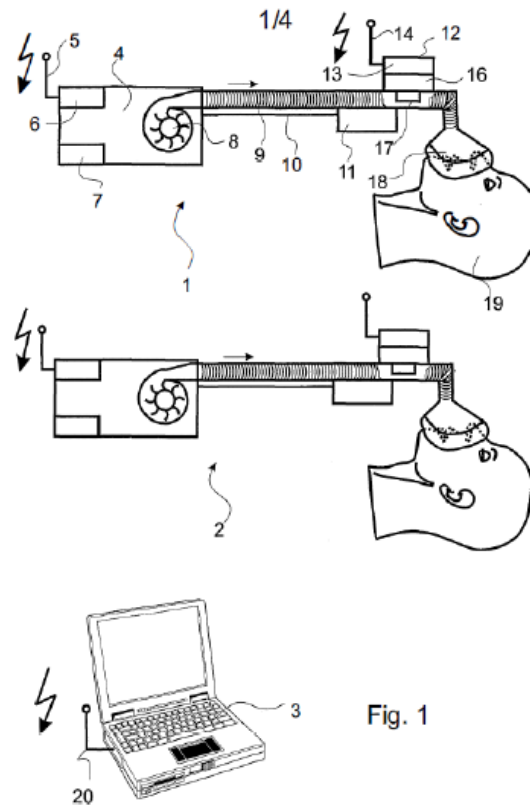
A pneumotachograph is a sensor that “quantitatively and directly” measures a patient’s nasal or oral airflow. ’269 Patent at 7:63-8:2. Consistent with this description, Genger and Farrell both disclose *directly* measuring a patient’s respiratory airflow with mask-based pneumotachographs. The evidence cited in the Petition did not establish, however, that “a POSITA would have found it obvious to locate Genger’s airflow sensor internally because such a location was common,” as Petitioner maintains. Reply at 8-9; Pet. at 34. Instead, Petitioner’s evidence (which was not filed with the Board and which Dr. Sharony did not recall reviewing) attempted to establish that it was known to place airflow sensors capable of *indirectly* measuring a patient’s respirations near the output of the CPAP machine’s blower. POR at 2, 13, 20-21.

Given that Petitioner’s evidence did not establish that it was “common” to locate the type of airflow sensors used in Genger and Ferrell anywhere but near the mask, Petitioner required to show (1) a motivation to modify Genger’s pneumotachograph with an internally-based airflow sensor that could only measure the patient’s respirations indirectly and (2) that a POSITA would have had a reasonable expectation of success in carrying out the claimed invention, which requires the use of such measurements to accurately calculate “a level of severity

and/or an index of a level of severity of the subject's sleep disorder symptoms.” *Id.* at 21. Petitioner did not attempt to make this showing in the Petition and it doubled down on that strategy in its Reply, calling this argument “irrelevant.” Reply at 14.

The fact that Petitioner has not legally established a motivation to combine and a reasonable expectation of success is not “irrelevant,” it means that it has not carried its burden to demonstrate that the Challenged Claims are obvious. Regardless of whether a POSITA was aware of “type[s] of airflow sensor[s] located internally,” there still must be a reason why a POSITA would have modified Genger to use such sensors in place of its mask-based pneumotachograph. *Intercont'l Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1343 (Fed. Cir. 2017).

Genger's pneumotachograph (flow sensor unit 12) directly measures respiratory airflow at the mask region neither meets the claimed structure or functionality. Reply at 8 (acknowledging that “Genger's airflow sensor is outside the PAP device”); POR at 14.



Genger at Fig. 1; *id.* at 10:27-11:5, Fig. 7 (depicting similar external airflow sensor configuration). According to Genger, this approach is advantageous because the sensor “can be flexibly added or omitted, depending on the clinical condition of patient.” *Id.* at 15:15-20; *see also id.* at 10:27-30, 11:7-9. Thus, Genger stresses the convenience of locating the sensor at the mask region, and Petitioner acknowledges that when “convenient” the sensor is mounted at or near the mask, not elsewhere. *See Reply* at 12 (alleging that when “it may not be convenient to mount . . . at or near the mask” the sensor is located elsewhere).

Farrell also uses a pneumotachograph that “incorporate[s] sensors into the mask,” as the Board recognized at institution. Paper 23 at 30-31 (“Farrell reasonably

teaches that a sensor can be included in the mask of the CPAP device.”); POR at 17 (asserting that “Farrell’s pneumotachograph and pressure sensor are located at or near the mask”). Petitioner ignores this evidence and claims, for the first time in Reply that Farrell’s flow sensor 4f is an internal airflow sensor. Reply at 9. This new argument is inconsistent with the record evidence and its previous recognition that 4f is only shown “symbolically” in the figure. See Farrell at 5:9-11; Pet. at 35; POR at 17.

Even if it was “well known in the art” (Reply at 10) to locate a pneumotachograph internally, that fact does not address why such a relocation would have been an improvement to Genger’s system when Genger touts the advantages of external positioning and its sensor already calculates respiratory airflow. *Id.* at 8 (asserting that Genger’s sensor measures the respiratory airflow); *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1380 (Fed. Cir. 2008) (affirming nonobviousness holding where the challenger failed to provide evidence of a need for the proposed modification); *Sony Corp. v. Fujifilm Corp.*, No. IPR2018-01751, Paper 14 at 11 (P.T.A.B. Apr. 12, 2019) (“Petitioner does not explain adequately why modifying Ejiri . . . would have been an improvement Ejiri already addresses the problem.”); *Microsoft Corp. v. Koninklijke Philips N.V.*, No. IPR2018-00026, Paper 7 at 14-15 (P.T.A.B. Apr. 27, 2018) (concluding that the petitioner failed to explain

why the modification would be an improvement on what the primary system already provides).

Indeed, Petitioner's proposed relocation presents a substantial change to Genger that would "have significant costs that weigh against modifying an existing device"—such as removing the ability to manipulate the pneumotachograph as needed and retaining the sensor's accurate measurement of respiratory airflow. POR at 21 (citing Ex. 2018 at ¶¶ 23-25); Genger at 15:15-17.

B. A POSITA Would Not Have Placed Nonvolatile Memory In Genger's Modem (Element [5.f.2])

A POSITA would not have found it obvious to put nonvolatile memory in Genger's modem 7 for the later transmission of "trend data" to arrive as the claim element because Genger's modem uses volatile memory for immediate transmission. *See* Pet. at 46 (alleging that the "'second output' **goes to modem 7**"), *id.* (alleging to "put data/AHI/alarm(s) into nonvolatile memory **prior to transmission by modem 7**"), *id.* (alleging that it would have been obvious to put nonvolatile memory "**to permit retransmission**") (emphases added). Petitioner's obviousness contentions are either contradicted by the purpose of a modem and Genger's disclosure or advance a strawman attack. *See* Reply at 16-18.

The purpose of a modem is to convert data from one form to another to instantly pass the converted data through a network, a task that does not require relatively slow and expensive nonvolatile memory. *See, e.g.,* Ex. 2019 at 344

(“Modem:” “A communications device that converts between digital data from a computer or terminal and analog audio signals that can pass through a standard telephone line.”). Data is only temporarily stored in buffers (volatile memory) while the conversion takes place and then is immediately transmitted. See POR at 24 (“[T]his 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.”) (emphasis added) (citing Ex. 2017 at ¶¶ 49-51). Accordingly, Genger’s modem converts “trend data” (stored in volatile memory) for the immediate transmission through the “public switched telephone network (PSTN)” to a server. Genger at 10:23-25, 12:22-25, 13:8-10; see also POR at 24.

Petitioner’s contention that Genger does not have “an intent to ‘immediately’ transmit collected data” is not only contradicted by the purpose of the modem but also by Genger’s express disclosure. Reply at 17-18; POR at 26 (Genger discloses continuously sending trend data and alarms, which result in an ambulance being sent to the patient). Thus, while Petitioner claims that “Genger suggests transmitting ‘trend data’ every two to three hours a day,” (Reply at 18), that is not what Genger says. Genger at 6:20-22 (“Through the modem, the respirator can relay trend data or alarms to a medical and health care supplier or hospital. In this way, the care of the severely disabled can be reduced from 24 hours to as little as 2 to 3 hours per

day.”); *id.* at 18:27-30 (“Trend data - transmitted from the domestic environment 97 or 99 to the hospital server 94, the national server 96, or the medical and health care supplier - can be further analyzed in the respective facilities, either automatically or with the assistance of a physician, nurse, or care 30 worker. The result of this analysis may be an alarm, **so that an ambulance is sent to the patient.**”) (emphasis added).

To actively monitor a patient, a medical provider receives ***newly collected*** trend data from the CPAP, not old trend data that would be unhelpful in monitoring treatment. *See id.* at 8:13-15 (“The advantage of equipping a CPAP treatment device with a modem is ***increased patient safety*** through the ability to automatically send alarms and the ability to ***perform remote monitoring of the treatment, by forwarding trend data.***”) (emphasis added). Even if there was a need for old trend data, that data would be stored on a server for retrieval by a hospital, health insurance company, or health care supplier. *See id.* at 8:13-15, 9:7-19, 12:18-25 (disclosing that the collected trend data is sent to the modem for transmission to a server so the medical provider can monitor the health and safety of the patient); *see also id.* at 17:11-18:16. And because trend data is collected and sent to the modem for immediate transmission (per the modem’s purpose), there is no concern of losing “multiple hours of data” if the CPAP were to lose power. Reply at 17. Indeed, the “multiple hours of data” is stored at the server. *Id.*

Petitioner also advances a strawman attack on cost. *See id.* at 16-17. In the POR, CleveMed addressed the “additional cost” of placing nonvolatile memory in modem 7 to store trend data for longer durations. *See* POR at 25-26. Here, Petitioner touts the “low cost” of nonvolatile memory in general (Reply at 16-17), while not actually confronting the added cost of nonvolatile memory in Genger’s modem which does not require such memory given its use of volatile memory for immediate data transfer, as discussed above.

In view of the above, Petitioner fails to show that Genger renders obvious placing “nonvolatile memory” in modem 7 (or elsewhere) “for the latter transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject’s symptoms.”

IV. GROUND 3: CLAIMS 8-11 AND 13 ARE PATENTABLE OVER THE STAHMANN COMBINATIONS

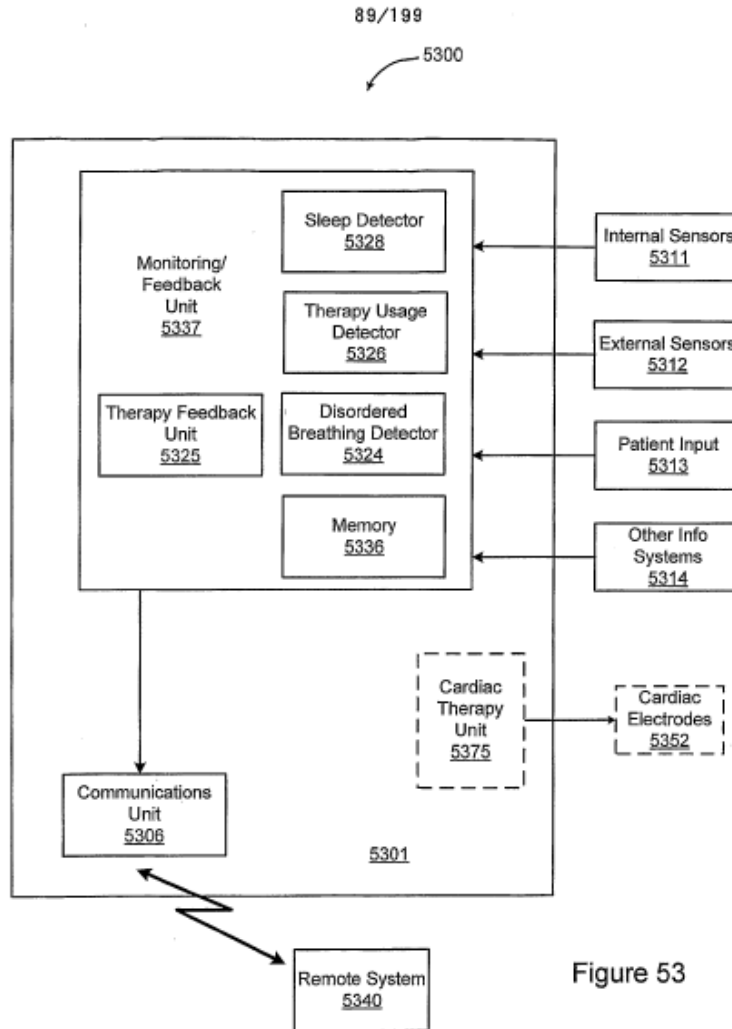
A. Stahmann Does Not Disclose a Positive Airway Apparatus For Adjusting Drug Therapy Based on the Feedback Processes’ AHI, and Petitioner Does Not Show Why Such a Device Would Have Been Obvious (Element [8.b])

Independent Claim 8 requires a positive airway apparatus that is “adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject’s sleep.” ’269 Patent at Claim 8.

Petitioner does not contend that Stahmann expressly discloses a device performing such action. Instead, Petitioner alleges that because drug therapy and a

feedback process are both disclosed in Stahmann, a POSITA would have been motivated to have a device “to adjust drug therapy . . . based on AHI.” Reply at 20 (based on “a POSITA viewing Stahmann’s disclosure on feedback adjustments and drug therapy”); *see also id.* at 18-20. This, however, is a conclusion without the requisite rationale for why a POSITA would have combined separately disclosed features to arrive at drug therapy adjustment in combination with use of AHI .

As shown in Fig. 53 (reproduced below), Stahmann discloses a device including a ***therapy feedback unit*** used for collecting feedback information (AHI) and making sleep therapy adjustments (*i.e.* using a CPAP to adjust the “breathing therapy pressure”). *See* Stahmann at 244:4-11 (“For example, if the AHI is high, the breathing therapy pressure may be adjusted upward . . .”).



Stahmann at Fig. 53; *see also id.* at Figs. 54A-54F (depicting the feedback mechanism of figure 53); Pet. at 53 (relying on Stahmann's Fig. 53). In this embodiment, there is no drug delivery therapy used, let alone one combined with AHI. *See* Reply at 19-20 (Petitioner equates AHI to the "level of severity"); Pet. at 55-56 (same).

Although Stahmann discloses that "drug therapy may also be used" alongside breathing therapy, it does not disclose adjusting drug therapy based on the Patient's

AHI, and Petitioner does not explain *any* drug therapy would be adjusted based on AHI. *See* Reply at 18-20 (identifying the drug therapy disclosure): *see also* Pet. at 53-55 (same). Just because drug therapy is disclosed does not suggest that its application should be adjusted based on the patient's AHI, let alone adjusting pharmaceutical agents identified by Petitioner for the treatment of sleep-related disorders.¹

In Stahmann, the only therapy adjusted using AHI is “breathing therapy pressure,” not drug therapy. *See* Stahmann at 244:4-11; *see also* POR at 29 (describing breathing therapy pressure adjustment of releasing carbon dioxide). Further, the embodiment where Stahmann discusses drug therapy in detail does not include a therapy feedback unit (providing AHI), let alone disclose the device's use of AHI to adjust drug therapy. *See* Stahmann at Fig. 79 (disclosing a medical device with a drug delivery control unit/drug therapy device with no feedback therapy unit); Paper 23 at 40 (referencing figure 79's device embodiment).

Therefore, the only rationale for Petitioner's conclusion that a POSITA would have been motivated to have Stahmann's device to adjust drug therapy based on AHI

¹ Petitioner's identified pharmaceutical agents are a nebulizer agent and Doxepin, which Dr. Patil opines would not be used to treat a sleeping disorder as claimed. *See* § IV.B, *infra*.

is one of impermissible hindsight. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

B. Neither Stahmann or Edgar Treats a “Subject’s Sleep Disorder or Symptoms” by “Adjust[ing] the Pharmaceutical Agent . . . Using the Output of the Level of Severity of the Subject’s Sleep Disorder” (Element [8.b])

Neither of Petitioner’s identified pharmaceutical agents treat sleep-related breathing disorders in connection with AHI. Reply at 19-20 (relying on AHI as “a level of severity”), 20-22 (identifying Stahmann’s nebulizer agent and Edgar’s Doxepin as pharmaceutical agents); POR at 31-32.

Stahmann’s nebulizer does not treat a sleeping disorder, and Petitioner does not suggest that it does. Pet. at 55 (Stahmann discloses drug therapy for “disordered breathing,” not a sleeping disorder). For example, a nebulizer may be used to treat asthma, which is not a sleep disorder and is not treated based on AHI. *See* POR at 31; Stahmann at 222:15-17; Ex. 2017 at ¶ 65. That Stahmann discloses nebulizers being used alongside a CPAP device does not change the conclusion. *See* Reply at 21 (citing Genger at 222:21-23). And whether or not a nebulizer may be used to treat other breathing disorders, Petitioner has not even alleged that any would be adjusted based on the patient’s AHI, let alone provided evidence to support such a conclusion.

Edgar does not resolve Stahmann’s shortcomings because its agent treats insomnia, and Petitioner fails to provide any evidence that it would or should be

adjusted based on AHI. Reply at 21-22 (identifying Doxepin for treating insomnia which promotes sleep); *see also* Pet. at 56 (identifying Doxepin for “promot[ing] sleep,” *i.e.* treating insomnia). In reply, Petitioner’s entire focus is on Edgar’s Doxepin treatment of insomnia for the claim language “[the] subject’s sleep disorder or symptoms.” Reply at 21-22. Given this myopic focus, Petitioner omits the remaining claim language of “adjust the pharmaceutical agent . . . using the output of the level of severity.” *Id.* at 18-20 (equating AHI to the claimed “level of severity.”). Through this omission, Petitioner fails to identify why or how Edgar’s Doxepin (treatment for insomnia) would be adjusted based on AHI.

Where insomnia is a ***patient’s inability to sleep***, AHI tracks apnea events that ***occur during sleep***. Compare *id.* at 22 (insomnia is “trouble with sleeping”) with *id.* at 20 (equating AHI with sleep apnea events). Although sleep apnea events may cause the patient to wake, as the Board recognized at institution, this arousal is due to “oxygen levels in the brain decreas[ing], while the carbon dioxide (CO₂) levels rise”—not insomnia. Ex. 1007 at ¶ [0005]; Paper 23 at 42. Accordingly, insomnia (inability to sleep) is not indicated by AHI (measured during sleep) for which Doxepin would be adjusted. See Ex. 2018 at ¶ 28 (explaining that medical professionals would recognize that the treatment for different conditions are not interchangeable); POR at 30-31. Thus, Edgar’s Doxepin, like Stahmann’s nebulizer agent, is not adjusted “using the output of the level of severity.”

The uncontested testimony of Dr. Patil, a medical doctor, further confirms that Edgar's Doxepin would not be used in the treatment of sleep-related breathing disorders as claimed:

A medical professional would understand that Edgar primarily addresses a different problem than the one solved by the claimed invention—namely, that patients would often remove the CPAP device while sleeping due to discomfort. As Edgar teaches, doxepin could be administered to improve the likelihood that the patient kept the mask on all night. *See* Edgar at Paragraphs 0406-0408. In this case, the treatment for the patient's sleep disorder or symptoms was the positive pressure provided by the CPAP, not the doxepin.

Ex. 2018 at ¶ 31; *see also id.* at ¶ 28 (“A medical professional would understand that treatments for different conditions are not interchangeable”). Thus, while Doxepin can be used alongside CPAP treatment to reduce the likelihood that a patient would remove their mask (Edgar ¶¶ [0407]-[0409]), it would not be used in the treatment of the sleep-related breathing based on AHI.

Petitioner's expert, Dr. Sharony, does not show otherwise because he lacks the specialized knowledge to opine on medical treatments. *See* POR at 10-12 (arguing that because Dr. Sharony lacks the requisite knowledge and experience, his testimony is inadmissible (citing Fed. R. Evid. 702)); Ex. 1004 at ¶¶ 123-24 (alleging that Edgar's treatment for promoting sleep would be used in the treatment of sleep-

related breathing disorder). Indeed, during cross-examination, Dr. Sharony admitted that he has no knowledge or experience in diagnosing or treating sleep-related breathing disorders. See POR at 11-12; Ex. 2016 at 25:1-12. In fact, in PGR2024-00012—a post-grant review petition challenging a related patent—Dr. Sharony abstained from opining on sleep-related diagnostics because it called for testimony from a medical professional. See *ResMed Corp. v. Cleveland Medical Devices, Inc.*, No. PGR2024-00012, Ex. 1003 at ¶¶ 57, 63 (relying on the testimony of a medical professional for an “index of treatment efficacy” where it is used in sleep-related breathing disorder diagnostics). Here too, medical professional testimony is called for on whether Petitioner’s identified pharmaceutical agents would be used to treat sleep-related breathing disorders based on a patient’s AHI, and that evidence does not exist.

V. GROUND 6: CLAIMS 15-16 AND 18-19 ARE PATENTABLE OVER THE KOCINSKI COMBINATIONS

A. Kocinski in View of Farrell Does Not Disclose Nor Render Obvious a “Base Station, Cellular Phone, or PDA Adapted to Display the Symptom Data . . . and/or the Index . . . and to Retransmit . . . to a Remote Internet Site” (Element [15.g.2])

Independent Claim 15 requires a “base station, cellular phone, or PDA adapted to display the symptom data . . . and/or the index . . . and to retransmit . . . to a remote internet site.” For this limitation, Petitioner identifies Kocinski’s figure 10 to allege that the figure is displayed on a base station (or PDA) for a “patient,

patient's family, and visiting medical professionals to see the patient's data on-site." See Reply at 26-27; Pet. at 74-75 (citing figure 10's display of "patient-specific data."). The data illustrated in Kocinski FIG. 10 (1) is not displayed on a device that receives and retransmits symptom or index data and (2) is compliance data not symptom data. See POR at 35-39.

Kocinski discloses transmitting data to a server where it is accessed and displayed on a medical professional's device. See Kocinski at ¶¶ [0028], [0031], [0045], Fig. 10 (depicting a medical professional choosing to review "Sample, Patient#3"). The medical procession's device is not a "base station" that receives, displays, and retransmits symptom and/or index data, it is a device that receives an email from the CPAP apparatus. POR at 35-36. At institution, the Board recognized that Kocinski's system transmits data to a server for medical professional access, with no on-site base station display:

Kocinski teaches "[t]wo-way communication between the CPAP apparatus 11 and the central database server 15 is accomplished via an internet processing system (IPS). The IPS collects compliance data and other parametric data from the CPAP apparatus 11 in the patient's home 14, ***transmits the data to a central database server 15, . . . and makes the data available to the medical professional 17.***" *Id.* ¶ 35.

Paper 23 at 47-48 (emphasis added) (agreeing with CleveMed that in Kocinski there is no "on-site" display at the base station).

While the Board relied on Farrell's hand-held device to fill the gap, Farrell shares Kocinski's deficiencies. In particular, Farrell discloses that data is made available to the medical professional (via a hand-held device) to "remotely monitor, analyze or record the status or data history of a patient." Farrell at 6:20-32. Like Kocinski, Farrell's display is on a medical professional's device—not a base station device that retransmits symptom and/or index data to a remote internet site. POR at 35-38. Farrell, therefore, does not cure Kocinski's deficiency.

Accordingly, because both references only display data on a medical professional's device after transmission, there is no on-site display by a base station (or PDA) having also done the transmission. Pet. at 74 (wrongly alleging that "patient-specific data" is displayed "on-site"); Reply at 26-27. Nor would a POSITA have found it obvious for patient-specific data to be displayed on-site for a patient to see because Kocinski expressly teaches that such data is "made available **only** to the medical professional." Kocinski at ¶ [0028] (emphasis added); *see also id.* ¶¶ [0039], [0045] (disclosing that only authorized viewers, medical professionals, can login and review reports "by selecting a patient from the 'Patient' window"), Fig.10 (depicting the "Patient" window and a list of patients a medical professional can choose from to receive their report).

Objective indicia of nonobviousness supports the conclusion that it would not have been obvious to display symptom and/or index data on a base station that

retransmits it to a remote internet site. POR at 38-39. And although Petitioner attempts to downplay this evidence, the fact remains that ResMed expressly credited its myAir software, which scores sleep apnea patients and presents the data to the patient, with an increase from 50% compliance to 87% compliance. Ex. 2011 at 1-3. If that result was not “surprising or unexpected,” it begs the question why ResMed did not implement this feature until long after CleveMed’s invention. *In re: Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (unexpected results based on a significant increase in performance).

Given the foregoing, Kocinski in view of Farrell does not disclose a device “adapted to display the symptom data . . . and/or index . . . and to retransmit . . . to a remote internet site.” Therefore, whether it would have been obvious to add symptom data to Kocinski’s figure 10 is of no moment, because the data would “*only*” be displayed on a medical professional’s device, not the on-site device having transmitted the data. See Reply at 26-27 (contending that it would have been obvious to add calculated symptom data to Kocinski’s figure 10); Pet. at 74-75 (relying on figure 10’s display of “patient-specific data”).

B. Kocinski in View of Farrell Does Not Render Obvious An “Airflow Sensor Internal to the PAP Device Adapted For Measuring the Respiratory Airflow of a Subject” (Element [15.a.2])

Petitioner’s obviousness theory here fails for two reasons: (1) Kocinski does not disclose an internal airflow sensor for measuring a subject’s respiratory airflow;

and (2) Petitioner's motivation rationale does not show why a POSITA would have combined the two elements in a way to arrive at the claimed invention. See Reply at 23-24; Pet. at 64-65.

First, Kocinski's pressure transducer is not the claimed "airflow sensor" because it does not "measure[e] the respiratory airflow of a subject." '269 Patent at Claim 15.² Instead, Kocinski's pressure transducer monitors and adjusts the pressure applied to the patient. See POR at 34; Kocinski at ¶ [0046] ("CPAP . . . uses an internal pressure transducer . . . that allows a range of pressure to be used and will adjust to give the patient more or less pressure"), ¶ [0010] (monitoring "the level of pressures applied to the patient"). Petitioner does not dispute this. In fact, Petitioner essentially concedes that Kocinski's pressure transducer does "not [] constitute an airflow sensor." Reply at 23.

Second, Petitioner's alternative argument that a POSITA would have "found it obvious to add such a sensor, like Farrell's . . . to **better monitor airflow to the**

² Petitioner compares Kocinski's pressure transducer to the "pressure sensor 322" of the '269 Patent. See Reply at 23. Petitioner, however, omits that the '269 Patent also includes a "flow sensor 320" that measures the respiratory airflow of the subject. See '269 Patent at 23:7-10, Figs. 7-8

patient” does not fare any better. *Id.* (emphasis added). To start, this argument fails for the same reasons as discussed in Section III, *supra*.

This argument also fails because Petitioner does not show why a POSITA would have added a sensor “adapted for **measuring the respiratory airflow** of a subject.” ’269 Patent at Claim 15 (emphasis added); *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1360 (Fed. Cir. 2019). Indeed, a sensor monitoring airflow pressure provided **to** the patient by the CPAP device is not one monitoring airflow **of** the patient, as required by the Challenged Claim. Therefore, Kocinski’s added sensor that measures airflow to the patient does not even facially arrive at the claim’s airflow sensor that measures the “respiratory airflow of a subject.” ’269 Patent at Claim 15.

Moreover, the claim requires that the “airflow sensor” is “adapted for” (or “made”/“designed” for) measuring the respiratory airflow from the patient, as opposed to merely “having the capacity to.” *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012) (equating “adapted to” with “made to” or “designed to”); *Sta-Rite Indus., LLC v. ITT Corp.*, 682 F. Supp. 2d 738, 753 (E.D. Tex. 2010) (construing “adapted to” as meaning “designed or configured to,” not “having the capacity to.”). Thus, Petitioner does not show why it would have been obvious to have the sensor “adapted to” (or made/designed to) perform the function. *In re Giannelli*, 739 F.3d 1375, 1379-80 (Fed. Cir. 2014) (finding that

the Board's conclusion that a function could be performed using the prior art was insufficient; the correct inquiry was whether it would have been obvious to modify the prior art to contain structure "adapted to" or configured to perform the function).

VI. CONCLUSION

In view of the foregoing, the Board should confirm patentability of the Challenged Claims.

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

This paper complies with the type-volume limitation of 37 C.F.R. § 42.24. The paper includes 5,596 words, excluding the parts of the paper exempted by § 42.24(a).

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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), that
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