

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 B1

**PETITIONER'S REPLY TO PATENT OWNER'S
RESPONSE**

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PETITIONER'S EXHIBIT LIST

Exhibit No.	Description
EX1001	U.S. Patent No. 10,076,269 (Kayyali et al.)
EX1002	U.S. Patent No. 10,076,269 Prosecution History
EX1003	U.S. SN 11/266,899 ('269 parent) Prosecution History
EX1004	Declaration of Jacob Sharony, Ph.D.
EX1005	WO 02/078775A2 (Genger et al.) including certified English translation
EX1006	U.S. Patent No. 6,167,258 (Schmidt et al.)
EX1007	U.S. Patent Application Publication 2002/0165462A1 (Westbrook et al.)
EX1008	WO 2005/096737A2 (Farrell et al.)
EX1009	Paradiso, et al., <i>Wearable Health Care System for Vital Signs Monitoring</i> , 4 th Annual IEEE Conf. on Information Technology Applications in Biomedicine, 2003, at 283 ("Paradiso")
EX1010	WO 2005/028029A2 (Stahmann et al.)
EX1011	U.S. Patent Application Publication 2005/0171160A1 (Edgar et al.)
EX1012	U.S. Patent Application Publication 2003/0236450A1 (Kocinski)
EX1013	Guilleminault, et al., <i>Obstructive sleep apnea syndromes</i> , Med. Clin. N.Am. Vol. 88, No. 3 (May 1, 2004), pp.611-630. ("Guilleminault-2004").
EX1014	Guilleminault, et al., <i>Clinical Overview of the Sleep Apnea Syndromes</i> , Sleep Apnea Syndromes (1978), pp.1-12. ("Guilleminault-1978").

EX1015	“Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research: The Report of an American Academy of Sleep Medicine Task Force,” SLEEP Vol. 22, No. 5 (1999), pp.667-689 (“Chicago Criteria”)
EX1016	Morón, et al., <i>A wireless monitoring system for pulse-oximetry sensors</i> , 2005 Systems Communications (ICW'05, ICHSN'05, ICMCS'05, SENET'05), Montreal, Quebec, August 14-17, 2005, pp.79-84.
EX1017	Bluetooth Ver.1.0B (Parts A and B) (November 1999)
EX1018	Roux et al., <i>Continuous positive airway pressure: new generations</i> , Clinics in Chest Medicine, Vol. 24 (2003), pp.315-342.
EX1019	U.S. Patent Application Publication 2005/0115561A1 (Stahmann et al.) (“Stahmann-EX1019”)
EX1020	U.S. Patent No. 7,757,690 (Stahmann et al.) (“Stahmann-EX1020”)
EX1021	USPTO's June 2022 Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation.
EX1022	Nieto et al., <i>Association of Sleep-Disordered Breathing, Sleep Apnea, and Hypertension in a Large Community-Based Study</i> , JAMA Vol. 284, No. 14 (April 12, 2000), pp.1829-1985.
EX1023	Transcript of Conference Call with Board on November 28, 2023.
EX1024	Defendant ResMed Inc.'s Final Invalidity Contentions and Exhibit G05 thereto, <i>Cleveland Medical Devices, Inc., v. ResMed Inc.</i> , case no. 1:22-cv-00794-GBW (served 11/20/2023) (redacted)
EX1025	Expert Report of Dr. Morten O. Jensen Regarding Invalidity Issues, <i>Cleveland Medical Devices, Inc., v. ResMed Inc.</i> , case no. 1:22-cv-00794-GBW (served December 4, 2023) (redacted)
EX1026	U.S. Patent No. 6,644,311 (“Truitt”)

EX1027	Cleveland Clinic, <i>Sleep Disorders</i> , available at https://my.clevelandclinic.org/health/diseases/11429-sleep-disorders
EX1028	Mayo Clinic, <i>Drugs and Supplements Doxepin (Oral Route)</i> , available at https://www.mayoclinic.org/drugs-supplements/doxepin-oral-route/side-effects/drg-20072083?p=1#:~:text=Doxepin%20is%20used%20to%20treat,certain%20chemicals%20in%20the%20brain
EX1029	IPR2023-00565 Deposition Transcript of David Borkholder, Ph.D
EX1030	AU Patent App. Pub. 2005/200987 (“Berthon-Jones 987”)
EX1031	CA Patent App. Pub. 2 520 745 (“Berthon-Jones 745”)
EX1032	Excerpted C.A. 1:22-cv-00794-JLH January 5, 2024 Rebuttal Expert Report of David Borkholder, Ph.D
EX1033	U.S. Patent No. 6,142,952 (“Behbehani”)

I. INTRODUCTION

CleveMed's Patent Owner's Response ("POR") mischaracterizes the Petition and record evidence, levies an unwarranted attack against ResMed's expert, and includes irrelevant arguments, such as disputing the Board's Section 325(d) discretionary denial decision and attacking a combination with Berthon-Jones the Petition does not assert. POR, 33.

CleveMed attempts to identify "key features" that make the patent inventive, ignoring that each independent claim recites different components. *E.g.*, POR, 1 (alleging a "key feature of [the '269 patent's] inventive system is its base station"—ignoring that a base station is only recited in claim 15). CleveMed's "key features" are also components the '269 patent admits are conventional. For example, far from a novel feature, CleveMed argued in the district court proceeding that the '269 patent describes a base station as "a computer, which is not limited in any manner and can be a personal computer." EX2008, 9.

CleveMed also argues "[a]nother key advance of the '269 Patent was its internal respiratory airflow sensor." POR, 2; *see also* POR, 15 (claiming that Fig. 7 of the '269 patent discloses a "novel construction" where "the airflow sensor (320) and the pressure sensor (322)" are located internally). But the '269 patent states that Fig. 7, showing an internal airflow sensor, is conventional. EX1001, 22:47-48 ("conventional pressure support system 310 shown in FIG. 7"). Dr.

Borkholder agreed in his district court rebuttal report that Fig. 7 is conventional, directly contradicting his testimony in this IPR that Fig. 7 is a “novel construction.” Compare EX2017, ¶¶36 (describing Fig. 7 as a “novel construction”), 46 (stating that internal airflow sensors are not common or possible), with EX1032, ¶1789 (the ’269 patent specification...***makes clear that Figure 7 shows ‘a conventional pressure support system.’***”).

Not only were internal airflow sensors disclosed by the prior art (*e.g.*, EX1008, Fig. 1), CleveMed copied Fig. 7 from the prior art Truitt patent (EX1026):

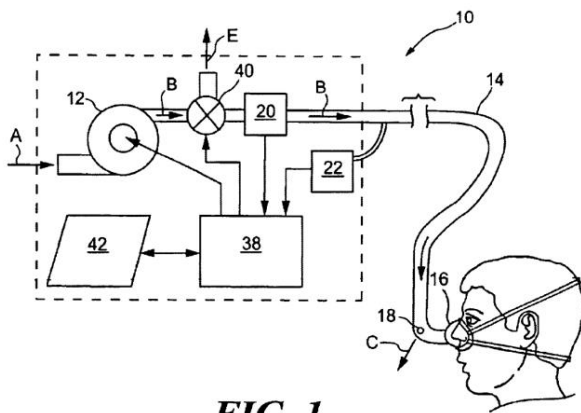


FIG. 1
(PRIOR ART)

Truitt Fig. 1

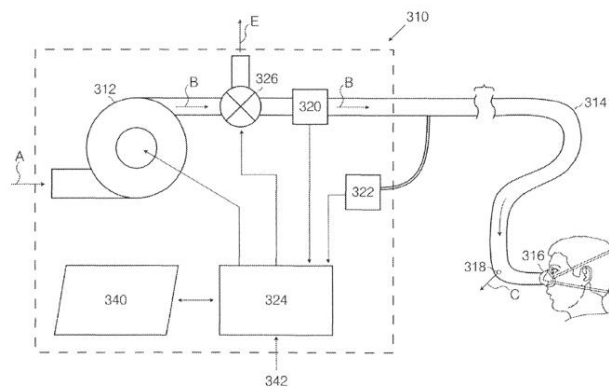


Fig. 7

'269 Patent, Fig. 7

Dr. Borkholder confirmed that Fig. 1 of Truitt has a “striking resemblance” to the ’269 patent’s Fig. 7. EX1029, 54:14-24. As shown, the ’269 patent’s Fig. 7 and Truitt’s Fig. 1 (itself labeled “PRIOR ART”) disclose internal airflow and pressure sensors. EX1026, 1:44-3:36 (“FIG. 1 [is] a **conventional** pressure support

system”); 2:5-7 (“information from flow sensor 20 and/or pressure sensor 22 is used, for example, to control the pressure or flow of gas”).¹ Indeed, Dr. Borkholder agreed that, like the ’269 patent Fig. 7, Truitt’s Fig. 1 illustrates air flow and pressure sensors within the CPAP housing. EX1029, 55:9-56:12. Thus, CleveMed’s purported “key advance” of the ’269 patent (POR, 2) was copied from a “prior art” figure of a prior art patent filed by a third-party CPAP manufacturer (Respironics, Inc.) in 2001, *years before the ’269 patent’s alleged priority date*.

CleveMed’s mischaracterizations of the evidence do not end there. For claims 8-14, CleveMed incorrectly argues that Petitioner “admits” 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.” Notably, CleveMed cites to *five pages* of text in the Petition leaving it to the Board to discover the alleged “admission.” POR, 27-28, 30 (citing Pet., 53-57). For claim 15, CleveMed asserts an unsupported theory of unexpected results by

¹ CleveMed also copied Truitt’s background section. *Compare* EX1026, 1:45-2:10, *with* EX1001, 22:45-23:17. The ’269 patent added “present invention.” *Compare* EX1026, 2:1-2, *with* EX1001, 23:7-10 (“A more sophisticated pressure support device **of the present invention** includes a flow sensor 20.”). Truitt was not cited during prosecution of the challenged patent or its parent.

misrepresenting the contents of two ResMed articles (EX2010; EX2011). POR, 38.

ResMed respectfully requests that the Board confirm the Challenged Claims of the '269 patent are unpatentable.

II. DR. SHARONY IS A POSITA

Dr. Sharony's extensive education and 35+ years of professional experience meets the undisputed definition of a POSITA (proposed by ResMed and adopted by CleveMed) 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." Pet., 24; POR, 8. CleveMed does not dispute that Dr. Sharony meets the educational portion of this definition. EX1004, ¶11 (listing Dr. Sharony's Bachelor's Degree, Master's Degree, M.Phil., and Ph.D. in Electrical Engineering). Nor does CleveMed dispute that Dr. Sharony possesses "two years of industry experience working with ... networked data systems." *See also id.*, ¶12-14 (describing "substantial experience" in "wireless networking and architecture solutions.").

CleveMed only disputes that Dr. Sharony has "experience working with diagnostic sensor systems." POR, 9. This is simply incorrect. Dr. Sharony plainly has "several years" of experience with data capture devices, including "sensors

[that] could be used as physiological sensors to sense changes in blood oxygen saturation or blood vessels volume and detect various vital signs” as well as “human activity sensors, heart rate and pulse sensors, and environmental sensors (*e.g.*, proximity, temperature).” EX1004, ¶¶10, 14, 16. This experience is directly relevant to the claims of the '269 patent that recite electronics, processors, and transceivers adapted for measuring, filtering, processing, and transmitting signals from “a pulse oximeter” and other sensors, as well as the electronic connections between those sensors, processors, electronics, transceivers, and a PAP device. *See e.g.*, EX1001, 23:53-57 (“a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data.”).

Moreover, CleveMed cites *zero* evidence for its conclusory attorney argument that there is a “major difference” between understanding sensors from an engineering perspective and understanding diagnostic sensors for the purposes of the claims of the '269 patent. To the contrary, the claims are directed to a PAP device with data acquisition components and sensors “known to those skilled in the art” (EX1001, 6:10-11), and transmission of acquired data—issues that are well within the purview of an electrical engineer with 35+ years of experience in communication technology. For example, the location of a sensor on or within the

PAP device is well within the purview of an engineer. *See* POR, 9-10; EX2016, 59:3-15 (testifying that the location of the airflow sensor is “a matter of engineering.”); *id.*, 51:16-21 (“it’s a matter of implementation. That[’s] what we engineers really do.”).² Notably, despite CleveMed’s critique that Dr. Sharony is not a medical doctor, a medical degree is **not** a requirement of the undisputed definition of a POSITA.

Further, the undisputed definition of a POSITA recites that “[a]n increase in experience could compensate for less education, and vice-versa.” Pet., 24; POR, 8. Thus, even if Dr. Sharony lacked experience with diagnostic sensors (he does not), his Master’s Degree, M.Phil., and Ph.D. in Electrical Engineering compensates for this. *Medtronic, Inc. v. Teleflex Life Scis. Ltd.*, No. IPR2020-01343, 2022 WL 557277, at *8 (P.T.A.B. Feb. 23, 2022) (rejecting argument that Petitioner’s expert

² CleveMed criticizes Dr. Sharony for not immediately recalling the Berthon-Jones reference, but he testified in detail about its disclosure. EX2016, 52:11-59:15.

Moreover, a deposition is not a memory test—Dr. Sharony was deposed over a year after submitting his declaration due to the unique nature of this IPR’s history. *Id.*, 48:17-23 (“It has been more than a year, so I had to refresh my memory, yeah”), 57:3-7. Additionally, the Petition did not rely on Berthon-Jones for motivation.

did not meet the definition POSITA where “it is undisputed that ‘[e]xtensive experience and technical training might substitute for education.’”).

Notably, CleveMed fails to address this portion of the POSITA definition. Indeed, this built-in flexibility in the definition firmly distinguishes the present IPR from the cases CleveMed relies on. Unlike this IPR, the POSITA definitions in *Kyocera*, *Avail Medical*, and *Incyte* did not allow for experience to compensate for education and vice-versa. *See Kyocera Senco Indus. Tools, Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022); *Avail Medsystems, Inc., v. Teladoc Health, Inc.*, No. IPR2022-00444, 2022 WL 2903454, at *9 (P.T.A.B. Jul. 21, 2022); *Incyte Corp. v. Concert Pharm., Inc.*, No. PGR2021-00006, 2022 WL 1613509, at *3 (P.T.A.B. May 11, 2022).

Moreover, CleveMed relies almost exclusively on the opinions of Dr. Borkholder—an engineer who has no experience designing or developing PAP devices. *See* EX2017, ¶¶2-15; EX1029, 15:25-22:5. Indeed, like Dr. Sharony, Dr. Borkholder has experience with pulse oximeter sensors in other systems. EX1029, 22:6-23:1. Dr. Borkholder alone testifies on the same topics for which CleveMed alleges Dr. Sharony is unqualified. For example, despite arguing that Dr. Sharony is not qualified to testify on the location of airflow sensors in PAP devices (POR, 9-10), Dr. Borkholder testifies on the same topic. EX2017, ¶46 (“that location was neither common or (without major system modifications) even possible for

pneumotachographs.”).

Although the POR cites to a declaration from Dr. Patil, a medical doctor, his background does not fit the POSITA definition because he does not have an engineering degree. Dr. Patil does not opine on the location of airflow sensors for PAP devices, leaving only Dr. Borkholder (an engineer) to support CleveMed's arguments. Dr. Borkholder also does not cite to Dr. Patil or claim to have reviewed his opinions. EX1029, 11:10-12:15. Thus, applying CleveMed's logic, both of its experts are unqualified to testify about what was common about the location of airflow sensors.

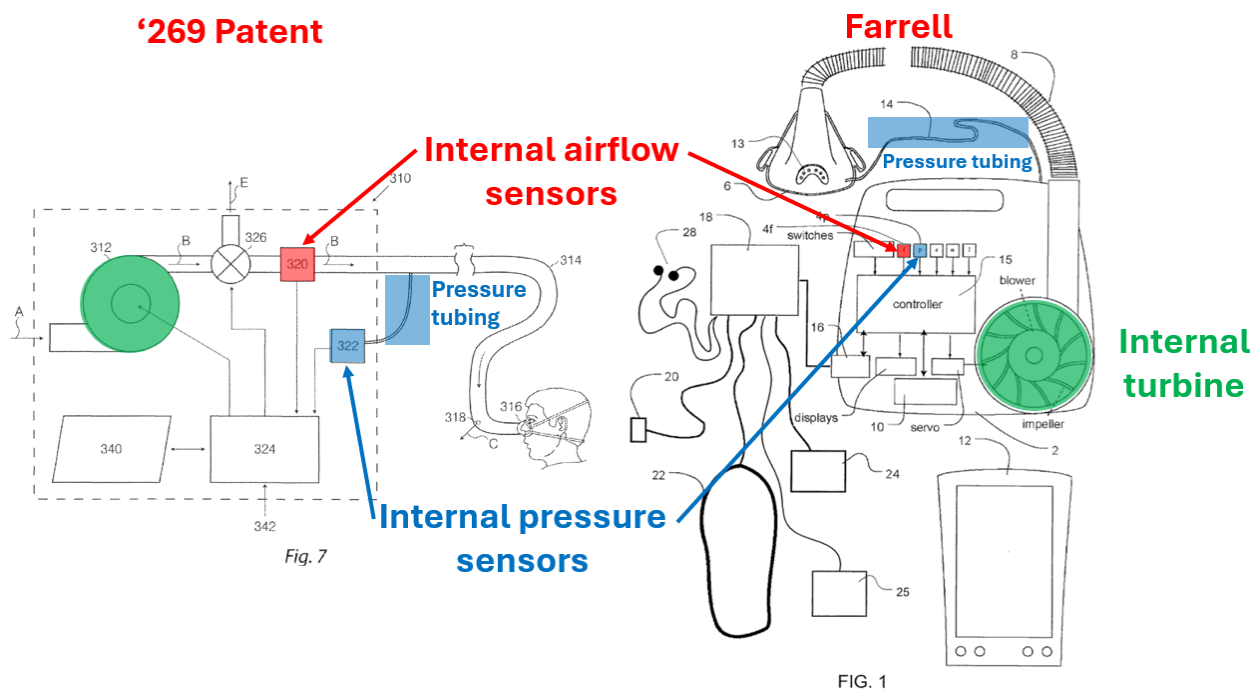
III. GROUND 1: CLAIMS 1-3, 5, 7

A. Genger in View of Farrell Teaches an Internal Airflow Sensor (Claims 1-3)

CleveMed does not dispute that Genger discloses an airflow sensor, nor does CleveMed dispute that the airflow sensor is “adapted for measuring the respiratory airflow data of a subject using the PAP device,” as required by limitation [1.b.3]. *See* Pet., 34; EX1005,10:26-27 (“treatment devices are supplemented by a wireless flow sensor unit as an example”). Rather, CleveMed disputes that a POSITA would have found it obvious to place Genger's airflow sensor “internal to the PAP device.” POR, 12-23.

The Petition acknowledges that Genger's airflow sensor is outside the PAP device, but establishes a POSITA would have found it obvious to locate Genger's

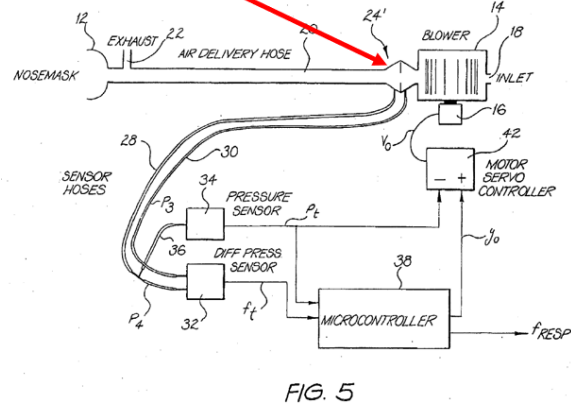
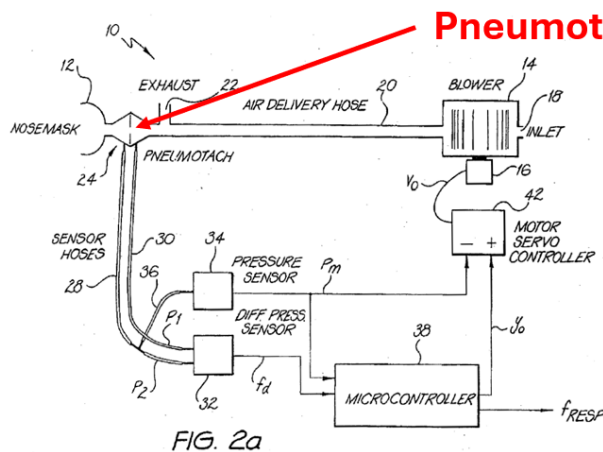
airflow sensor internally because such a location was common and the location is immaterial as long as measurements are accurate, relying on Farrell and Genger for motivation. Pet., 34-36. As shown in the Petition, Farrell discloses, referring to Fig. 1, “a flow sensor 4f and/or pressure sensor 4p may also be utilized in which case mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal $F(t)$” EX1008, 5:5-7, Fig. 1. This is similar (if not identical) to what is disclosed by the '269 patent. See POR, 15. Below are Fig. 7 of the '269 patent and Fig. 1 of Farrell—both showing internal flow and pressure sensors:



As shown, Farrell's “flow sensor 4f” and “pressure sensor 4p” are located internal to the PAP enclosure.

Instead of directly addressing this disclosure, CleveMed mischaracterizes Farrell by arguing Farrell's flow sensor may only be located at the mask, which is contrary to Farrell as shown above. POR, 16-17. Moreover, contrary to CleveMed's argument, a POSITA would understand that Farrell's pneumotachograph "or similar device to derive a [mask] flow signal $F(t)$ " is located anywhere in the closed air path from "blower 2" through "conduit 8" to the "mask 6." EX1008, 5:5-7, Fig. 1. And because Figure 1 shows the flow sensor 4f inside the boundary of the device housing, it teaches an embodiment where the flow sensor is at or near the air path where it is at/near the output of the blower within the housing.

Moreover, contrary to CleveMed's argument, it was well known in the art that pneumotachographs were located within the housing of a pressure device and are not only located at the mask (as CleveMed argues). For example, EX1030 discloses that a "pneumotachograph" may be "placed in the gas delivery path between the mask and the ventilator" (1:25-26, Fig. 2a) or "interposed between the turbine 14 and the delivery hose 20" at the output of the turbine (8:11-13, Fig. 5):



see also *id.*, 8:15-16 (“This arrangement removes the pressure sensing hoses and pneumotachograph from the region of the mask 12.”); EX1031, 9:17-20, Figs. 2a, 5 (showing same); EX1033, 4:27:30, Figs. 2 (showing a “pneumotachograph” provided “between source of pressurized air 117 and hose 115”—i.e., not at the mask); EX1004, ¶86 (“the location of the sensor is immaterial as long as its measurements are accurate.”). And again, Farrell discloses a pneumotachograph as one *example* of measuring flow signal $F(t)$ —a POSITA would understand that any type of internal flow sensor could be used in Farrell’s system. EX1008, 5:5-9 (disclosing a pneumotachograph “or similar device to derive a flow signal $F(t)$.”). CleveMed also argues that Farrell’s “pressure sensor [is] located at or near the mask,” but Dr. Borkholder confirmed that Farrell’s pressure sensor is located within the housing. EX1029, 72:18-74:13. Thus, a POSITA viewing Farrell, particularly Figure 1, would understand that Farrell’s pressure sensor and flow sensor (whether a pneumotachograph or other type of flow sensor) are within the

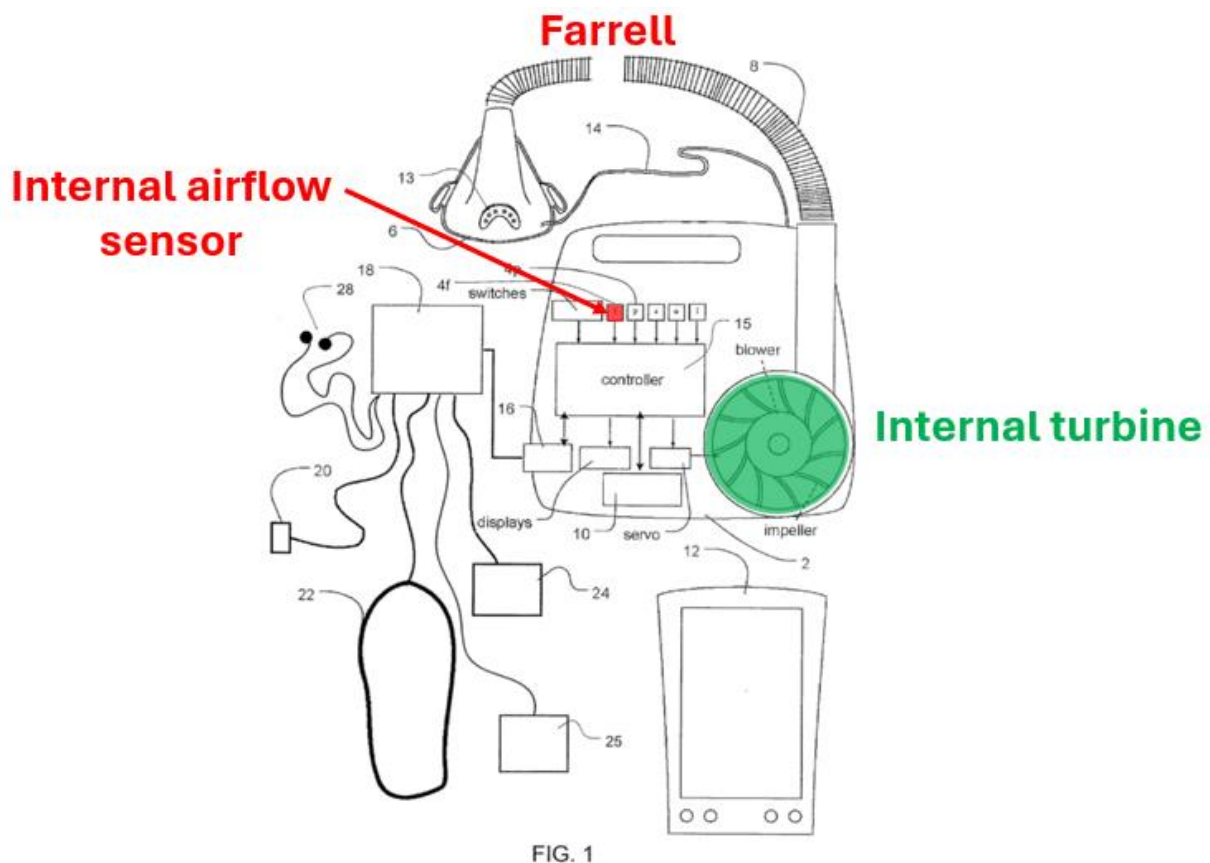
housing. *See also* EX1029, 33:20-35:18 (acknowledging that typical, prior art CPAPs had an “attachment point” on the exterior wall of the device connecting the breathing tube).

CleveMed also mischaracterizes the Petition and Dr. Sharony's declaration by arguing that Berthon-Jones is the “sole piece of evidence” relied upon for motivation, but, as addressed above, the Petition relies on Farrell, Genger, and the knowledge of a POSITA for motivation. POR, 13 (“the sole piece of evidence [Dr. Sharony] cites in support of his position, Berthon-Jones (Ex. 2015)...”); *see also* Pet., 34-36.

Moreover, Dr. Sharony is correct that Berthon-Jones supports the Petition's position. Berthon-Jones discloses a flow sensor “at or near the air pressure generator,” which is internal to the PAP device. EX2015, 8:31-40, Fig. 3; EX1008, 2:5-6 (incorporating Berthon-Jones by reference). Dr. Sharony testified consistently at his deposition that there are only two possible places to put that sensor: in the mask or internally in the PAP device housing. EX2016, 58:16-22. A POSITA would not, for example, put a sensor in the flexible tubing due to possible tube breakage or replacement. *Id.*, 58:23-59:15. Thus, in light of Berthon-Jones's disclosure that “it may not be convenient to mount the flow transducer 44 at or near the mask” (EX2015, 8:31-35), a POSITA would understand that Berthon-Jones's disclosure of an airflow sensor “at or near the air pressure generator”

teaches an airflow sensor internal to the PAP device. *Id.*; EX2016, 58:16-59:15; see also EX2015, Fig. 16 (block 164 “CPAP Machine With Flow Sensor (Figs. 2 or 3)”); see also EX1030, 8:11-13, Fig. 5; EX1031, 9:18-20, Fig. 5.

Berthon-Jones's disclosure of an airflow sensor “at” the air pressure generator also plainly discloses an internal airflow sensor. Even CleveMed would agree that air pressure generators (*i.e.*, turbines) are located internal to the PAP device. Indeed, Farrell shows an internal pressure generator shown below alongside the internal airflow sensor:



EX1008, Fig. 1. The exhibits CleveMed cites (POR, 20) also describe air pressure generators internal to the PAP device. *E.g.*, EX2020, 1-3 (“A CPAP machine

includes: ... A motor that blows air into the tube.”); EX1029, 31:4-32:7 (noting that every exhibit in this case shows an air pressure generator within the housing).

In addition, the Petition never argued combining Genger with Berthon-Jones or that a POSITA would be motivated by Berthon-Jones to make any modifications. As such, CleveMed's arguments at POR, 20-23 that 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” and that Petitioner has not “attempted to show motivation to replace Genger's pneumotachograph with the non-pneumotachograph disclosed in Berthon-Jones” are irrelevant. Moreover, a POSITA has ordinary creativity and would be motivated by any type of airflow sensor located internally to relocate Genger's airflow sensor internally. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (the obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claims, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”).

For the same reasons, CleveMed's argument that combining Genger and Berthon-Jones could trigger a new FDA premarket approval is likewise irrelevant and also inconsistent with the record. POR, 21-22. Farrell discloses an internal airflow sensor. And Berthon-Jones teaches that the location of the airflow sensor

is a simple alternative due to convenience (EX2015, 8:31-36), not a substantial change that would trigger a new premarket approval. Indeed, Dr. Sharony testified that, from an engineering standpoint, “the location of the sensor is immaterial as long as its measurements are accurate.” EX1004, ¶86; *see also Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1292 (Fed. Cir. 2013) (finding motivation to combine where the combination “was common at the time of the invention” and rejecting arguments to the contrary regarding the difficulty of obtaining FDA approval due to the FDA not considering the proposed motivation for FDA approval purposes); *id.* (“There is no requirement in patent law that the person of ordinary skill be motivated to develop the claimed invention based on a rationale that forms the basis for FDA approval.”).

Thus, having knowledge of Farrell or Genger, a POSITA would have been motivated to locate Genger's airflow sensor internally, and Berthon-Jones further supports this position. Pet., 34-35. Significantly, as discussed above, the '269 patent explicitly states that Fig. 7 showing an internal airflow sensor is **conventional**. EX1001, 22:47-48. Fig. 7 was copied from the prior art Truitt's Fig. 1 (EX1026):

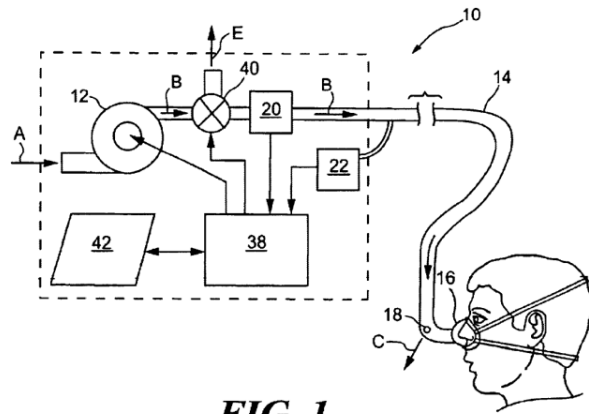


FIG. 1
(PRIOR ART)

Truitt Fig. 1

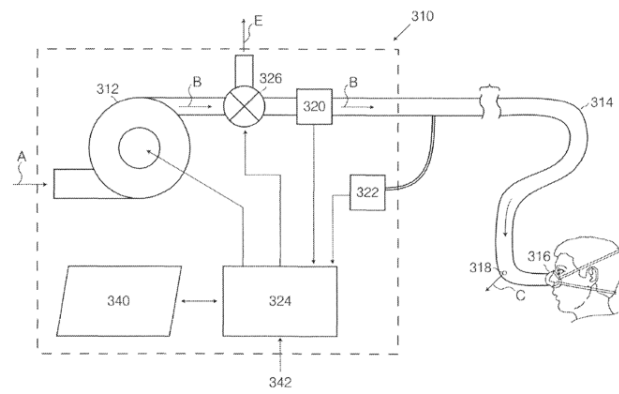


Fig. 7

'269 Patent, Fig. 7

See also EX1032, ¶¶1787 (acknowledging that Fig. 7 is conventional), 1789 (same).

B. Genger Discloses a Nonvolatile Memory (Claim 5)

CleveMed's argument that modifying Genger's PAP device to include a nonvolatile memory would lead to increased costs is contrary to the record. POR, 23-27. Westbrook states "[f]lash memory chips 44 provide a **low cost method** to store the signals acquired during use of the physiological monitor 12." EX1007, [0075]; Pet., 46.

Even if a nonvolatile memory could lead to trivially increased costs and slightly slower transmission speeds, a POSITA would have weighed these disadvantages with the principal advantage of using nonvolatile memory as storage "that does not lose data when power is removed from it." *Winner Intern. Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the

motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.”); *Medichem, SA v. Rolabo, SL*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“Likewise, a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”).

For example, with a nonvolatile memory, data collected from Genger’s PAP is not lost if the PAP loses power, and the data may still be transmitted once power is restored. This ensures that data or alarms are transmitted and that patients are treated and diagnosed in a timely manner. EX2016, 46:11-47:15 (“all the data would be erased once we switch off the device.”). Absent a nonvolatile memory, multiple hours of data could be lost—significantly delaying diagnosis and treatment. *See id.*

Moreover, as Dr. Sharony testified, a nonvolatile memory is advantageous for more than data transfer, such as maintaining device and operational settings. EX2016, 46:11-47:15 (“there are certain things that you would like to keep, like, for example, program, applications, sometime parameters of device operation.”).

CleveMed’s argument also severely mischaracterizes Genger. For example, Genger does not state an intent to “immediately” transmit collected data or restrict its application “to monitor patients in hospitals,” as CleveMed argues. POR, 23-

24, 26. Rather, Genger suggests transmitting “trend data” every two to three hours a day, also to health insurance company, and such a system would benefit from nonvolatile memory. EX1005, 6:19-22, 12:18-25 (transmission of data from a domestic environment). Without a nonvolatile memory, alarms and trend data recorded prior to transmission would be lost if the PAP device were to lose power.

IV. GROUND 3: CLAIMS 8-11, 13

A. Stahmann Discloses Adjusting a Pharmaceutical Agent

Stahmann discloses “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 the Petition never suggested otherwise. Pet., 53-57; POR, 27-28 (incorrectly asserting “Petitioner admits that Stahmann does not disclose adjusting drug therapy in response to the level of severity of the subject’s sleep disorder.”).³

As the Petition established, Stahmann discloses “feedback information may be used to ... automatically adjust the sleep disordered breathing therapy.” EX1010, 241:19-25, 237:24-26; Pet., 54. Stahmann’s feedback process (Figures 54A-54F) adjusts therapy based on “apnea/hypopnea index (AHI) ... among other

³ Dr. Sharony noted Stahmann does not disclose *a specific drug*—as the Petition acknowledged. EX2016, 31:17-21; Pet., 56.

indices.” EX1010, 241:31-242:9, Fig. 54B (“Use the Feedback Information to Adjust the Sleep Disordered Breathing Therapy”), 54C, 54E (“Adjust Therapy Using the Feedback Information”). Feedback adjustments can also use sleep disorder events (5436) or other “severity, frequency, and/or duration” characteristics of such events. *Id.*

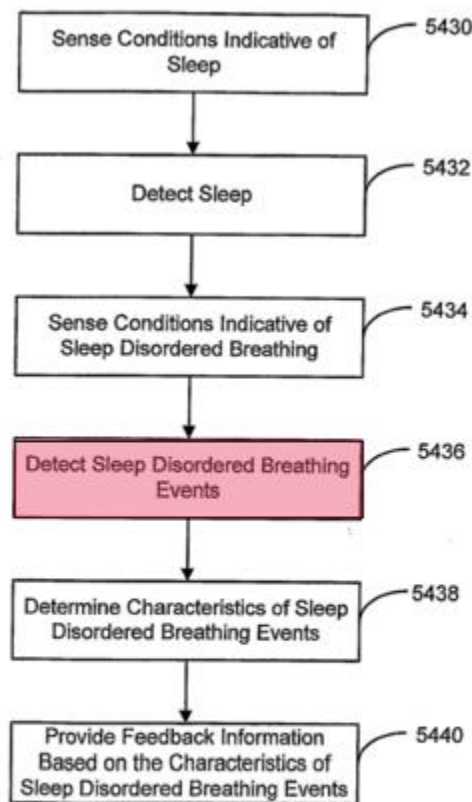


Figure 54C

CleveMed’s argument that Stahmann only “discloses releasing carbon dioxide each and every time a central apnea is detected” (POR, 29) cherry picks from Stahmann, which discloses, to the contrary, feedback adjustments based on

the “severity, frequency, and/or duration” of events (*e.g.*, apnea events) or AHI. EX1010, 241:31-242:9, Fig. 54C. The parties do not dispute for the purposes of this IPR that AHI is a level of severity, and CleveMed’s medical expert, Dr. Patil, disagrees with CleveMed’s POR, stating: “Stahmann discloses adjusting breathing therapy based on AHI.” EX2018, ¶28.

Stahmann further explains that “[d]rug therapy may also be used to treat disordered breathing. Drugs may be delivered to the patient through one or more automatically controllable drug delivery devices, *e.g.*, ... a controllable nebulizer....” *Id.*, 236:12-15; *see also* 273:3-6; 302:31-34. Thus, a POSITA viewing Stahmann’s disclosure on feedback adjustments and drug therapy would have been motivated to adjust drug therapy using Figure 53 and 54’s embodiments and based on AHI. Pet., 55-56.⁴

B. Stahmann in View of Edgar Teaches Treating Sleeping Disorders or Symptoms With a Pharmaceutical Agent

CleveMed does not dispute that Stahmann and Edgar disclose pharmaceutical agents. POR, 31-32 (“Edgar teaches the use of a pharmaceutical

⁴ CleveMed argues the ’269 patent discloses an “integrated diagnostic” feature, but this is not claimed (POR, 28-29), and the patent’s Figure 8 description does not disclose *adjusting* a pharmaceutical agent based on level of severity. *Id.*; EX1001, 23:18-41.

agent”). Rather, CleveMed only disputes that the specific pharmaceutical agents disclosed in Stahmann and Edgar are used in “treating a subject’s sleep disorder or symptoms.” But CleveMed mischaracterizes Stahmann’s disclosure, which states that “one or both of the medical devices 210, 220 may be used to control a drug therapy device, such as a drug pump, a controllable nebulizer, and/or electrically activated drug patch.” EX1010, 47:17-19. Thus, Stahmann discloses use of a pharmaceutical agent, *e.g.*, via a nebulizer. CleveMed incredibly (*i.e.*, not credibly) argues that nebulizers are only used to treat asthma—but Stahmann explicitly discloses that nebulizers can be used to treat sleep disordered breathing alone or in combination with PAP devices. EX1010, 222:21-23 (“**External breathing therapy may be delivered by various types of patient-external respiratory therapy devices, including, for example, nebulizers, ... and/or positive airway pressure devices.**”), 236:12-15; Pet., 55, 59.

The Petition also cited Edgar as a system for providing a pharmaceutical compound with a CPAP device. Pet., 56. CleveMed argues that Edgar only discloses using the medication Doxepin with improving treatment compliance (POR, 32), but Edgar discloses much more, including administering Doxepin to promote and improve sleep:

In one aspect, the compound of the invention is administered in conjunction with a CPAP device to promote sleep. In another aspect,

the compound of the invention is administered in conjunction with a CPAP device to improve sleep. In another aspect, the compound of the invention is administered in conjunction with a CPAP device to improve compliance regarding with CPAP treatment.

EX1011, [0407]-[0409]. This teaches “treating a subject’s sleep disorder or symptoms” because lack of sleep is a symptom of sleep disorders. Moreover, Doxepin is FDA-approved to treat insomnia, which is a sleeping disorder. EX1027 (listing insomnia as a sleep disorder); EX1028 (Doxepin is “used to treat insomnia (trouble with sleeping)”).⁵

C. The Board’s Section 325(d) Decision

CleveMed disputes a portion of the Board’s decision declining to exercise its discretion to deny institution, arguing “the Board overlooked the fact that the Examiner found that [’690] Stahmann ... failed to disclose ... ‘a pharmaceutical agent.’” POR, 33 (citing Institution Decision, 18-20). But the Board found that the Examiner did not appreciate the material teachings of ’029 Stahmann as applied to claim 8, regardless of whether the Examiner found ’690 Stahmann disclosed a pharmaceutical agent. Institution Decision, 19-20 (“The Examiner,

⁵ The ’269 patent does not limit or identify any exemplary “symptom” or “pharmaceutical agent.”

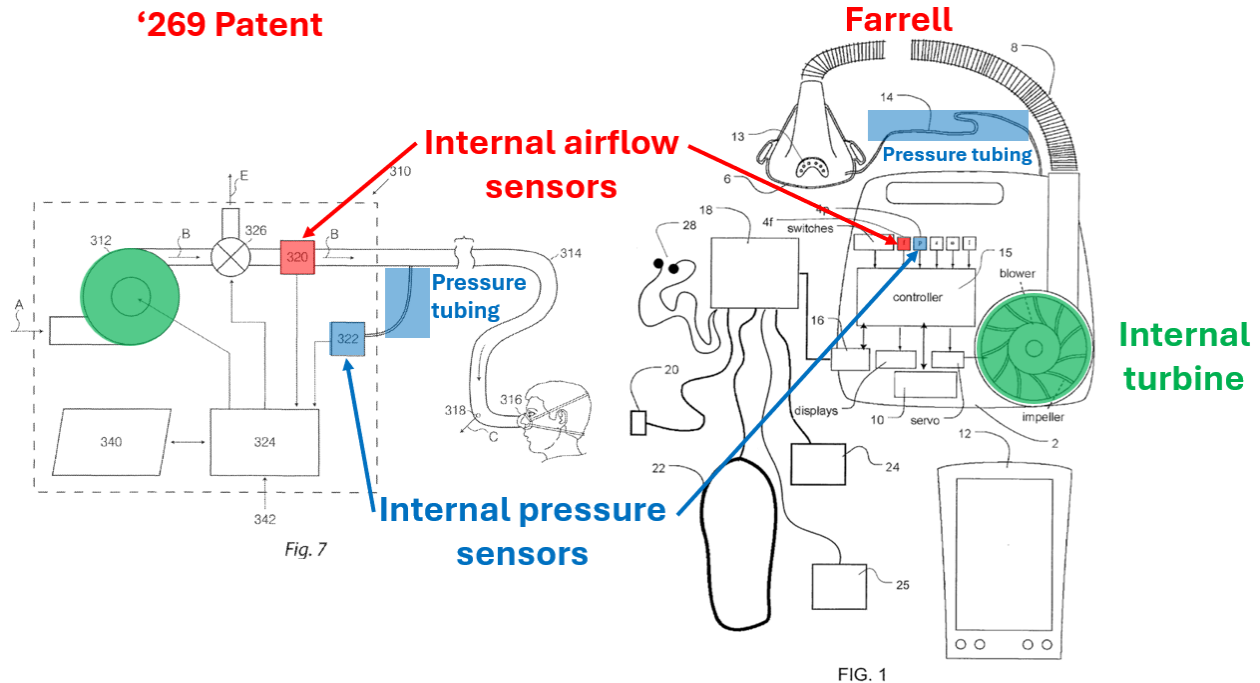
therefore, did not appreciate that the controller as taught in the '029 Stahmann reference could be used to administer *both CPAP treatment and a pharmaceutical agent.*”).

V. GROUND 6: CLAIMS 15-16, 18-19

A. Kocinski and Farrell Disclose an Internal Airflow Sensor

CleveMed incorrectly argues “Petitioner does not suggest that Kocinski discloses the claimed airflow sensor.” POR, 34. The Petition established Kocinski discloses “an internal pressure transducer,” similar to the '269 patent's description of a “pressure sensor 322” (EX1001, 23:8-10), that satisfies limitation [15.a.2]. EX1012, [0046]; Pet., 64.

But, as the Petition states, “[t]o the extent the pressure transducer is deemed not to constitute an airflow sensor, POSITA would have found it obvious to add such a sensor, like Farrell's, to Kocinski's CPAP enclosure to better monitor airflow to the patient.” Pet., 64. CleveMed argues it would not have been obvious to modify Kocinski with Farrell to teach the claimed internal airflow sensor for “the same reasons discussed [for the] combination of Genger and Farrell.” POR, 34-35. But this is incorrect. As established above, Farrell discloses an internal airflow sensor the same way the '269 patent does:



See Section III.A; Pet., 64-65.

B. Kocinski Alone or in View of Farrell Teaches Transmitting Symptom Data and/or Index of Symptom Data

CleveMed does not dispute that Kocinski and Farrell disclose symptom data (e.g., the number of apnea or hypopnea events) or an index of symptom data (e.g., AI, HI, AHI). POR, 35-36. Nor could it—Kocinski indisputably collects and stores “the frequency and nature of events detected while the patient sleeps, such as apnea events.” EX1012, [0028]. Rather, CleveMed only disputes that Kocinski and Farrell transmit such data and ignores the disclosures relied on in the Petition.

Although CleveMed incorrectly focuses on the notifications described at Kocinski’s paragraphs 28 and 31 (POR, 35), Kocinski explicitly discloses there notifying a medical professional “if the number of apnea events exceed a

programmed threshold.” EX1012, [0028]. CleveMed contends this notification “only informs the recipient that the threshold has been exceeded,” but that transmission still informs the recipient of the number of apnea events (undisputed “symptom data”). *Id.*; POR, 35-36. For example, if the programmed threshold is five apnea events, the medical professional receiving a notification is informed there have been at least five apnea events.

CleveMed ignores Kocinski’s further disclosure that the CPAP is “programmed to transfer data to the central database server 15 at intervals set by the medical professional”—CleveMed does not dispute this refers to transmission of symptom data. EX1012, [0031]; *see also* Pet., 65-66, 71-75; EX1004, ¶136. CleveMed also ignores that transferred data would include the frequency and nature of events like apneas to be included in reports. EX1012, [0028] (“sleep events may be made available only to the medical professional”), [0045], claim 3 (“the communication remotely monitors ... CPAP apparatus”), FIG. 10 (showing “Daily Summary,” “Pressure” tabs), [0010] (“medical professional can access the database server over the internet to obtain information ... such as a patient’s response to CPAP treatments”); Pet., 71-75.

Farrell also discloses this limitation: “[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.” EX1008, 5:28-31; Pet., 71. CleveMed fails to explain its argument that the “full recitation” of this citation shows that “Farrell does not disclose the transmission of symptom data nor its related indexes to the hand-held device” (POR, 36-37 (emphasized)) and points to another part of Farrell to incorrectly argue that Farrell’s symptom data is merely “recorded for analysis.” *Id.* (citing EX1008, 7:35-8:3). But the recorded data must be transmitted before it is analyzed, and Farrell explicitly discloses wireless transmission for analysis, as shown above. EX1008, 5:28-31, *see also* 6:23-31 (“apparatus can interface with a variety of hand-held devices” with which “a physician may ... remotely monitor, analyze or record the status or data history of a patient. ...[R]emote devices may send to or retrieve from the apparatus any desired cardiovascular or other information. Such information may even be transmitted from the apparatus to a database of one or more patients.”).

Last, contrary to CleveMed’s argument (POR, 37), Kocinski and Farrell disclose transmission to a remote location. EX1012, [0028] (“CPAP apparatus 11 may be programmed ... to send a message **to the central database** server 15 which is relayed to the medical professional”), FIG. 1 (showing “INTERNET CONNECTION” to elements 17, 18, 19); EX1008, 5:28-31; 6:27-31.

C. Kocinski Discloses Displaying Symptom Data

CleveMed does not dispute that Kocinski displays usage data (*e.g.*, Kocinski

Fig. 10), and only disputes that Kocinski displays symptom data or that it would be obvious to do so. CleveMed is incorrect that it was not known prior to the '269 patent to display symptom data to “the patient, patient’s family, and visiting medical professionals.” Petitioner argued that displaying symptom data *would have been an obvious modification of Kocinski*, which already discloses displaying patient usage data:

POSITA would have found it obvious to do so, and likewise to display such information on the base station (or PDA). Motivation would have been to allow the patient, patient’s family, and visiting medical professionals to see the patient’s data on-site, and because ‘two-way’ Internet Processing Software (and its displays in Figures 3-8, 10-12) is necessarily present on the home-located base station in order to exchange data with the IPS software at third parties 17-19. See Kocinski, [0035]-[0039], [0049], Figure 12. EX1004, ¶149.

Pet., 74.

CleveMed’s unexpected results argument also fails. CleveMed cites two articles (EX2010 and EX2011), but neither say anything about increased compliance being surprising or unexpected. CleveMed also misleadingly includes the words “surprising and unexpected” in quotation marks as if those words came from EX2010 or EX2011—they do not. POR, 38. These words come from the

Forest Lab's case that CleveMed cites only as a string cite (after first citing Dr. Borkholder's expert declaration).⁶ CleveMed also fails to establish a nexus between the claims and the alleged unexpected results. CleveMed is incorrect that ResMed's CEO credited displaying symptom data to patients as increasing compliance "over prior systems (like Kocinski), which only displayed the patient's compliance data." POR, 38. EX2010 and EX2011 say nothing about "prior systems" that "only displayed the patient's compliance data." CleveMed also inserts the phrase "'Patients' visibility into their own sleep data" into a parenthetical for EX2010—but the article says nothing about this as opposed to viewing merely usage data as a reason for improved patient compliance. These articles simply credit the myAir app and AirView generally without mentioning which specific features increased compliance.

VI. GROUNDS 2, 4-5, 7-8

For Grounds 2, 4-5, 7-8, CleveMed relies on the arguments addressed above.

VII. CONCLUSION

Petitioner has shown the claims of the Challenged Patent are unpatentable.

⁶ Dr. Borkholder's declaration says "surprising and unexpected" in quotes without citing *Forest Lab*'s. EX2017, ¶78.

Respectfully submitted,

Dated: October 21, 2024

/s/ Tiffany C. Miller

Tiffany C. Miller

Reg. No. 52,032

Attorney for Petitioner

CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(c) and (d), Petitioner certifies that the word count of Petitioner's Reply in Support of its Petition for *Inter Partes* Review (exclusive of any table of contents, table of authorities, certificates of service and word count, and list of exhibits or claim listing) as measured by Microsoft Word is 5,531 words, which is less than the 5,600 allowed under 37 C.F.R. § 42.24.

By: /s/ Tiffany C. Miller
Tiffany C. Miller

CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner by **Electronic Mail** of this Petitioner's Reply to Patent Owner Supplemental Response.

James Hannah, Esq.
(PTO Reg. 56,369)
c/o KRAMER LEVIN NAFTALIS & FRANKEL, LLP
333 Twin Dolphin Drive
Suite 700
Redwood Shores, CA 94065
(650) 752-1700
jhannah@kramerlevin.com

Jeffrey H. Price, Esq.
(PTO Reg. 69,141)
c/o KRAMER LEVIN NAFTALIS & FRANKEL, LLP
333 Twin Dolphin Drive
Suite 700
Redwood Shores, CA 94065
(650) 752-1700
jprice@kramerlevin.com

Jenna Fuller, Esq.
(PTO Reg. 74,212)
c/o KRAMER LEVIN NAFTALIS & FRANKEL, LLP
333 Twin Dolphin Drive
Suite 700
Redwood Shores, CA 94065
(650) 752-1700
jfuller@kramerlevin.com

Petitioner's Reply

Jeffery Eng, Esq.
(PTO Reg. 63,189)
c/o KRAMER LEVIN NAFTALIS & FRANKEL, LLP
333 Twin Dolphin Drive
Suite 700
Redwood Shores, CA 94065
(650) 752-1700
jeng@kramerlevin.com

Dated: October 21, 2024 /s/ Tiffany C. Miller
Tiffany C. Miller
Reg. No. 52,032
Attorney for Petitioner