

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.
Petitioner,

v.

CLEVELAND MEDICAL DEVICES INC.
Patent Owner.

IPR2023–00565
Patent 10,076,269 B1

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

I. INTRODUCTION

In this *inter partes* review, ResMed Corp. (“Petitioner”) challenges claims 1–20 of U.S. Patent No. 10,076,269 B1 (Ex. 1001, “the ’269 patent”) assigned to Cleveland Medical Devices Inc. (“Patent Owner”). Paper 1 (“Pet.”).

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision, issued pursuant to 35 U.S.C. § 318(a), addresses issues and arguments raised during the trial in this *inter partes* review. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–20 of the ’269 patent are unpatentable (*see* 35 U.S.C. § 316(e) (2018) (“In an *inter partes* review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.”)).

A. *Procedural Background*

On March 22, 2023, Petitioner filed a Petition seeking *inter partes* review of claims 1–20 of the ’269 patent. On June 29, 2023, Patent Owner filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). With our authorization (Paper 10), Petitioner filed a Reply to Patent Owner’s Preliminary Response (Paper 11) and Patent Owner filed a Sur-reply (Paper 12). We denied institution. Paper 13.

Petitioner filed a request for rehearing by the Director, seeking Director Review of the Board’s decision denying institution. Paper 14. The Director vacated our decision and remanded the case back to the Board. Paper 15. The Director granted Petitioner’s request to file a supplemental brief and for Patent Owner to file a supplemental response. *See* Papers 15, 16, 18, 21.

Pursuant to 35 U.S.C. § 314, we instituted *inter partes* review of challenged claims 1–20 of the ’269 patent on May 6, 2023. Paper 23 (“Decision” or “Dec.”). After institution of trial, Patent Owner filed a request for Director review. Paper 26. The request for director review was denied. Paper 28. Patent Owner filed a Response (Paper 29, “PO Resp.”), to which Petitioner filed a Reply (Paper 31, “Reply”), and Patent Owner, in turn, filed a Sur-Reply (Paper 32, “Sur-Reply”).

Patent Owner also filed a Motion to Exclude certain evidence submitted by Petitioner (Paper 35, “Mot.”) to which Petitioner filed an Opposition (Paper 37, “Pet. Opp.”) and Patent Owner filed a Reply to the Opposition (Paper 38, “PO Reply Opp.”).

Oral argument was held on February 4, 2025. A transcript of the oral argument is included in the record. Paper 41 (“Tr.”).

B. *Real Parties in Interest*

Petitioner identifies itself (ResMed Corp.) and ResMed Inc., as real parties-in-interest. Pet. 1.¹ Patent Owner, Cleveland Medical Devices Inc., identifies itself as the real party-in-interest. Paper 4, 1.

C. *Related Matters*

The ’269 patent is at issue in *Cleveland Medical Devices, Inc. v. ResMed Inc.*, Case No. 1:22-cv-00794-UNA (D. Del. filed June 16, 2022). Paper 1, 1; Paper 4, 1.

D. *The ’269 Patent (Ex. 1001)*

The ’269 patent issued on Sept. 18, 2018, from U.S. Application No. 13/440,116, filed April 5, 2012, which is a continuation of U.S. Application

¹ Petitioner asserts that ResMed Inc. is a separate entity. Pet. 5, n.1.

No. 11/266,899, filed Nov. 4, 2005, now U.S. Patent No. 8,172,766.
Ex. 1001, codes (10), (12), (22), (45), (63) (“the ’766 patent”).

a) Overview

The ’269 patent is titled “Devices And Methods For Sleep Disorder Diagnosis And Treatment.” *Id.* at code (54). The ’269 patent relates to devices and methods for sleep apnea diagnosis and treatment. *Id.* at code (57). According to the Specification, nearly one in seven people in the United States suffers from some type of chronic sleep disorder, which can deteriorate the quality of life and is a major cause of morbidity and mortality in industrial and transportation accidents. *Id.* at 1:27–36.

The ’269 patent explains that certain sleep disorders such as sleep apnea can be treated by applying a continuous positive gas pressure to the patient’s airway, but the devices for this treatment are expensive and largely ineffective. *Id.* at 2:11–26. The claimed invention analyzes the patient’s physiological symptoms and adjusts the treatment based, at least in part, on this analysis. *Id.* at 1:19–23; 2:38–52. According to the Specification, the claimed invention combines a continuous positive airway pressure (CPAP) device with sensors that detect the patient’s physiological condition, including parameters related to a patient’s breath, such as respiratory airflow and effort, blood oxygenation levels, and breathing parameters, and automatically adjusts the airflow rate for the benefit of the patient. *Id.* at 3:65–4:4, 5:35–40, 6:10–7:30.

According to disclosed embodiments, diagnostic readings from pulse oximeters and/or airflow sensors are combined to determine sleep disorder symptom data (*id.* at 4:37–42), which is transferred to a medical professional, displayed to the user, and/or used to adjust the patient’s

treatment. *See id.* at 9:3–37, 19:15–26 (using pulse oximetry and airflow data in combination with a CPAP); *id.* at 3:9–27, 7:27–43 (using a combination of airflow data, pulse oximetry, and respiratory effort with a CPAP to adjust the treatment of a patient requiring chemical treatment in addition to traditional CPAP therapy); *id.* at 2:63–3:8, 4:10–19, 4:28–36, 18:60–19:7, 20:9–18 (using airflow data and a CPAP to analyze and wirelessly send the patient’s data and allowing for remote adjustment to the patient’s treatment); *id.* at 22:29–59.

Figure 1 is reproduced below.

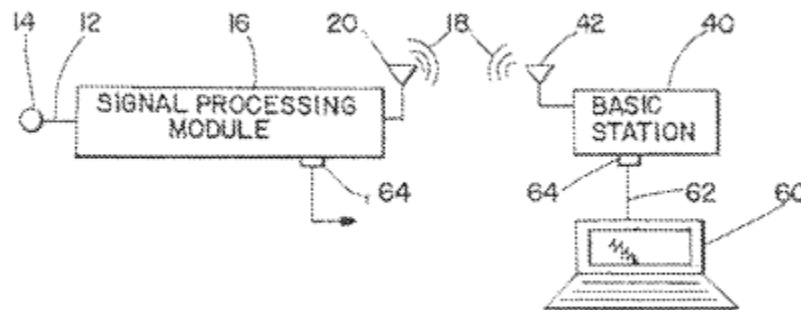


Fig. 1

Figure 1 shows a part of the claimed diagnostic device of a sleeping disorder treatment system of the present invention depicting wireless transfer of patient data. *See id.* at 5:65–67. In particular, Figure 1 shows external input 12 received from sensor 14. Although one sensor is shown, signal processing module 16 is capable of using multiple sensors. *Id.* at 8:60–64. The signal processing module 16 generates and wirelessly transmits the signal 18 to a base station, where it is demodulated. *Id.* at 8:63–9:10.

Figure 8 is reproduced below.

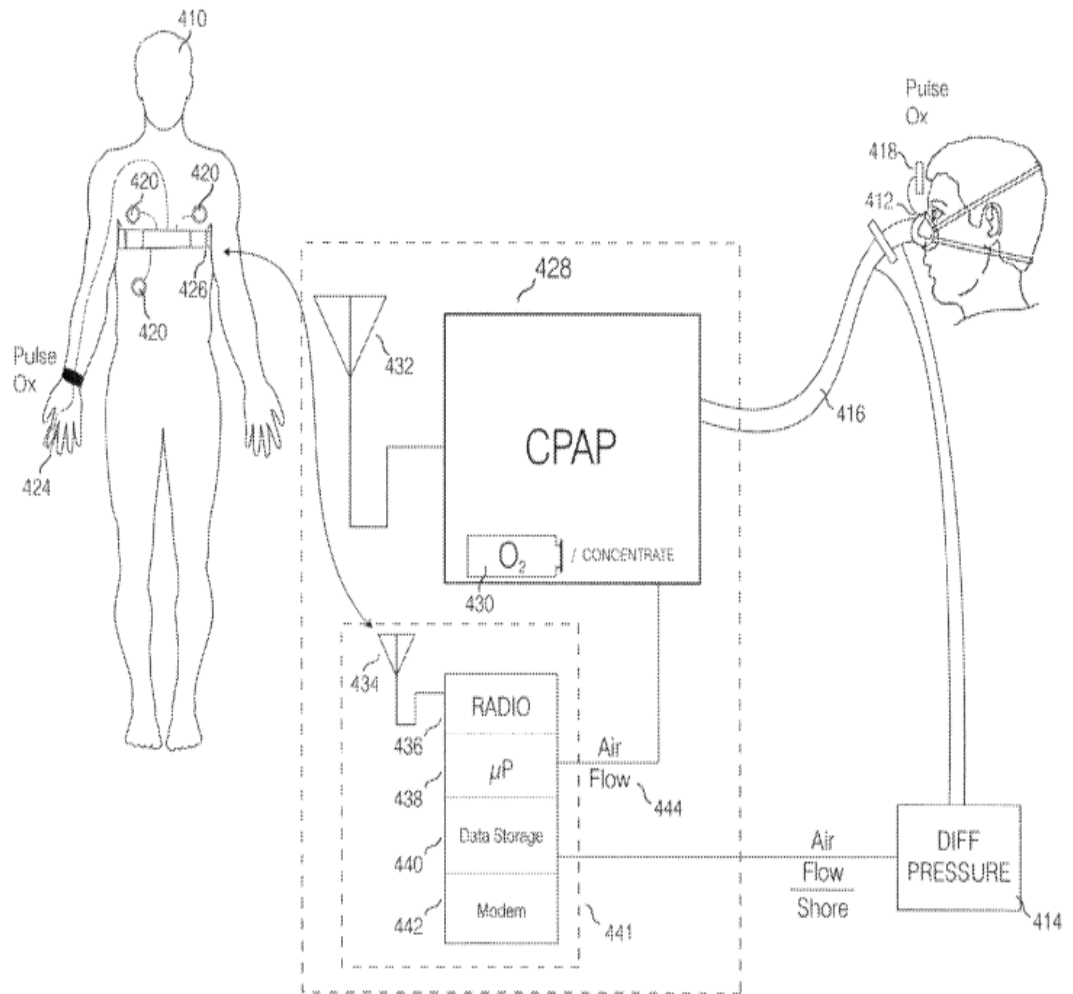


Fig. 8

Figure 8 shows a schematic view of an embodiment of the claimed sleep disorder treatment system. *Id.* at 5:20–21. In Figure 8, subject 410 is attached to sensors 420, 424, 418, and 426. *Id.* at 23:20–21. The subject is wearing respiratory mask 412 which is connected to positive air pressure device 428. *Id.* at 23:21–24. Diagnostic device 441 receives the data from the sensors and based on the data, the flow of air to the subject is adjusted. *See id.* at 23:18–41.

b) Illustrative Claims

Claims 1, 5, 8, and 15 are independent. These claims are illustrative of the claimed subject matter of the '269 patent and are reproduced below (with emphasis added):

1. Claim 1

[Claim 1.pre] A positive airway pressure (PAP) sleep disorder treatment system comprising:

[1.a] 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;

[1.b] a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module further comprising:

[1.b.1] a blower having an air output,

[1.b.2] a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,

[1.b.3] an *airflow sensor internal to the PAP device* adapted for measuring the respiratory airflow data of a subject using the PAP device, and

[1.b.4] a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device;

[1.c] a mask or a nasal cannula; and

[1.d] a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of

severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location.

Id. at 23:51–24:13 (bracketing and formatting maintained from Petition for convenience) (emphasis added).

2. *Claim 5*

[Claim 5.pre] A sleep disorder treatment system comprising:

[5.a] a data acquisition system;

[5.b] a positive airway pressure (PAP) device; and

[5.c] a processor;

[5.d] the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device;

[5.e] the PAP device comprising:

[5.e.1] a hose,

[5.e.2] a blower,

[5.e.3] an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject,

[5.e.4] a second input for receiving pulse oximetry sensor data from the data acquisition device; and

[5.e.5] a mask or nasal cannula for treating a subject's sleep disorder symptoms; and

[5.f.1] the processor adapted for receiving pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor, the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or

index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device,

[5.f.2] 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.

Id. at 24:32–25:3 (bracketing and formatting maintained from Petition for convenience).

3. *Claim 8*

[Claim 8.pre] A sleep disorder treatment system comprising:

[8.a] a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and

[8.b] a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure 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 from the data acquisition system.

Id. at 25:16–31 (bracketing and formatting maintained from Petition for convenience).

4. *Claim 15*

[Claim 15.pre] A positive airway pressure (PAP) sleep disorder treatment system comprising:

[15.a] a PAP device with an enclosure further comprising:

[15.a.1] a blower having an air output,

[15.a.2] 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;

[15.b] a processor adapted for receiving the airflow sensor data, and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device;

[15.c] a mask or a nasal cannula;

[15.d] a first radio frequency wireless module transceiver and

[15.e] a base station, cellular phone, or PDA;

[15.f] the first radio frequency wireless module transceiver adapted for receiving and 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 and the data of usage to the base station, cellular phone or PDA;

[15.g.1] the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display,

[15.g.2] the 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, and

to retransmit 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.

Id. at 26:3–33 (bracketing and formatting maintained from Petition for convenience).

E. *Prior Art*

Petitioner relies upon the following prior art references (Pet. 29–45).

Reference	Date	Exhibit No.
Genger et al., WO 02/078775A2 (“Genger”)	Oct. 10, 2002	1005
Schmidt et al., U.S. Patent No. 6,167,258 (“Schmidt”)	Dec. 26, 2000	1006
Westbrook et al., U.S. 2002/0165462 A1 (“Westbrook”)	Nov. 7, 2002	1007
Farrell et al., WO 2005/096737A2 (“Farrell ’737”)	Oct. 20, 2005	1008
Paradiso et al., <i>Wearable Health Care System for Vital Signs Monitoring</i> , 4th Annual IEEE Conf. on Information Technology Applications in Biomedicine, (2003). (“Paradiso”)	April 24, 2003	1009
Stahmann et al., WO 2005/028029 A2 (“Stahmann ’029”)	March 31, 2005	1010
Edgar et al., U.S. 2005/0171160A1 (“Edgar”)	Aug. 4, 2005	1011
Kocinski, U.S. 2003/0236450A1 (“Kocinski”)	Dec. 25, 2003	1012
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”)	May 1, 2004	1013
Bluetooth Ver.1.0B (Parts A and B) (November 1999) (“Bluetooth”)	Nov. 1999	1017

F. *Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 1–20 of the '269 patent on following grounds (Pet. 3–4):

Claim(s) Challenged	35 U.S.C. §²	Reference(s)/Basis
1–3, 5, 7	103	Genger, Schmidt, Westbrook,
4, 6	103	Genger, Schmidt, Westbrook, Farrell '737, Paradiso
8–11, 13	103	Stahmann '029, Edgar
12	103	Stahmann '029, Edgar, Schmidt
14	103	Stahmann '029, Edgar, Paradiso
15, 16, 18, 19	103	Kocinski, Farrell '737, Bluetooth
17	103	Kocinski, Farrell '737, Bluetooth, Guilleminault-2004, Westbrook
20	103	Kocinski, Farrell '737, Bluetooth, Paradiso

In support of its patentability challenge, Petitioner relies on the Declaration of Jacob Sharony, Ph.D. (Ex. 1004). Patent Owner relies on the Declarations of Dr. Borkholder (Ex. 2017) and Dr. Patil (Ex. 2018). Deposition testimony of Dr. Sharony (Ex. 2016) and Dr. Borkholder (Ex. 1029) are also submitted.

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

a) *Petitioner's Contentions*

According to Petitioner, a person of ordinary skill in the art ("POSITA")

² The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because the '269 patent issued from an application filed before March 16, 2013, we apply the pre-AIA versions of the statutory basis for unpatentability.

as of the priority date of the Challenged Patent (November 4, 2005) would have had 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. 24 (emphasis added).

b) Patent Owner's Contentions

Patent Owner adopts Petitioner's definition of a POSITA. PO Resp. 8. Patent Owner, however, contends that Dr. Sharony does not meet Petitioner's definition of a POSITA because "Dr. Sharony's education and experience do not include any industry experience in diagnostic sensor systems in general or CPAP machines." *Id.* at 9. Patent Owner contends that "[d]esigning and operating diagnostic sensor systems requires far more than mere knowledge about some subset of the components of the system." *Id.* Patent Owner contends that because Dr. Sharony "has no experience with diagnostic sensor systems like CPAP machines," he is unqualified to testify about "relocating a respiratory airflow sensor of a CPAP machine." *Id.*

c) Petitioner's Reply

Petitioner argues that "Dr. Sharony's extensive education and 35+ years of professional experience meets the undisputed definition of a POSITA." Reply 4. Petitioner asserts that

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).”

Reply 4–5 (alteration in original)(quoting Ex. 1004 ¶¶ 10, 14, 16). Petitioner contends that experience with these sensors is directly relevant to the claims of the ’269 patent. *Id.* at 5.

Petitioner contends that Patent Owner “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.” Reply 5. Petitioner argues that even if “Dr. Sharony lacked experience with diagnostic sensors (he does not), his Master’s Degree, M.Phil., and Ph.D. in Electrical Engineering compensate[] for this.” *Id.* at 6.

Petitioner also contends that applying Patent Owner’s logic with respect to the definition of a POSITA, both of Patent Owner’s experts do not qualify if design “experience with diagnostic sensor systems like CPAP machines” is read into the definition of one of ordinary skill in the art. PO Resp. 9. Specifically, Petitioner argues that “Dr. Borkholder—an engineer who has no experience designing or developing PAP devices” would also not meet the definition of one of ordinary skill in the art if a requirement of developing CPAP machines is read into the definition. Reply 7 (citing Ex. 2017, ¶¶ 2-15; Ex. 1029, 15:25-22:5). Additionally, Petitioner argues that Patent Owner’s second expert “Dr. Patil, a medical doctor, . . . does not fit the POSITA definition because he does not have an engineering degree.” *Id.* at 8.

d) Patent Owner’s Sur-reply

Patent Owner contends that “Dr. Sharony does not hold the requisite work experience in ‘diagnostic sensor[s].’” Sur-reply 3. “Nor is this case

similar to *Medtronic, Inc. v. Teleflex Life Scis. Ltd.* [No. IPR2020-01343, Paper 85 at 17–19 (P.T.A.B. Feb. 23, 2022)], which Petitioner cites in its Reply. In that case, the level of skill in the art allowed [that] “[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience.” *Id.* at 5 (emphasis removed).

Patent Owner asserts that “Dr. Borkholder has over 25-years of experience working with medical diagnostic systems.” Sur-reply 4 (citing Ex. 2017 ¶ 7).

e) Analysis

We adopt the undisputed definition of a POSITA set forth in the Petition. Pet. 24. We now turn to the parties’ arguments regarding whether the declarants in this proceeding meet this definition of a POSITA.

1. Dr. Sharony

Dr. Sharony testifies that he has “over 35 years of experience working in data networks and mobile and wireless technologies.” Ex. 1004 ¶ 9. Dr. Sharony testifies that he “received a Bachelor’s Degree (1979) and Master’s Degree (1984) in Electrical Engineering from Tel Aviv University,” and “M.Phil. (1991) and Ph.D. (1993) Degrees in Electrical Engineering from Columbia University.” *Id.* ¶ 11. Dr. Sharony also testifies that he has “experience working with and analyzing physiological sensors, including but not limited to human activity sensors, heart rate and pulse sensors, and environmental sensors (e.g., proximity, temperature).” *Id.* ¶ 10. Dr. Sharony testifies that “[w]hile working at Motorola/Symbol [for seven years] I gained substantial experience in application-specific and data-capture mobile devices, and wireless networking and architecture solutions

in several vertical applications, e.g., transportation and logistics, healthcare, warehousing, retail, and education, among others.” *Id.* ¶ 14. At “Symbol Technologies, [Dr. Sharony was] conducting research and development in data capture devices such as bar code imagers. Many of those devices used solid state image sensors, such as CMOS or CCD, which are particularly useful in capturing two-dimensional images in which machine readable code might be found.” *Id.* ¶ 16. Dr. Sharony further explains that “[s]uch image sensors could be used as physiological sensors to sense changes in blood oxygen saturation or blood vessels volume and detect various vital signs.” *Id.*

The definition of the POSITA, as put forth by Petitioner and accepted by Patent Owner, states that the POSITA would have at least a bachelor degree in electrical engineering. Pet. 24; PO Resp. 8. Here, Dr. Sharony demonstrates that he has a PhD in Electrical Engineering from Columbia University. Ex. 1004 ¶ 11. Therefore, Dr. Sharony meets the education requirement of the POSITA as accepted by the parties.

The agreed-upon definition of the POSITA states that the artisan has two years of industry experience working with sensors and networked data systems. Pet. 24; PO Resp. 8. Dr. Sharony testifies that he has 7 years’ experience working in industry with sensors and networked data systems at Motorola/Symbol. Ex. 1004 ¶ 14. Therefore, Dr. Sharony meets the working experience definition of the POSITA as accepted by the parties.

The agreed-upon definition of the POSITA also states that “[a]n increase in experience could compensate for less education, and vice-versa.” Pet. 24 (citing Ex. 1004 ¶ 70). What is not included in the definition of a POSITA, as agreed upon by the parties, is having medical degree or specific experience with sensors in CPAP machines. *See* Pet. 24; *see also* Reply 6

(“[D]espite [Patent Owner’s] critique that Dr. Sharony is not a medical doctor, a medical degree is not a requirement of the undisputed definition of a POSITA”).

We are not persuaded by Patent Owner’s contention that we should disregard Dr. Sharony’s testimony because “has no experience with diagnostic sensor systems like CPAP machines,” and therefore, is unqualified to testify about the location of sensors in a CPAP machine. PO Resp. 9; Tr. 25:1–2 (Dr. Sharony “does not have any experience in diagnostic sensor devices.”). Contrary to Patent Owner’s contention, Dr. Sharony testified that he has “experience working with and analyzing physiological sensors, including but not limited to human activity sensors, heart rate and pulse sensors, and environmental sensors (e.g., proximity, temperature).” Ex. 1004 ¶ 10. Therefore, Dr. Sharony meets the requirements of a POSITA.

Because we find that Dr. Sharony meets the definition of a POSITA as set out in the Petition, and that definition is accepted by Patent Owner, we do not find that Patent Owner has established a sufficient basis for disregarding Dr. Sharony’s testimony. *See* Pet. 24; PO Resp. 8–9; *see below II.F* (Motion to Exclude).

2. Dr. Borkholder

Dr. Borkholder testifies that he has “over 30 years of professional engineering experience in industry and academia.” Ex. 2017 ¶ 3. Dr. Borkholder testifies that he “hold[s] a Ph.D and M.S. in Electrical Engineering from Stanford University, Stanford, California, and a B.S. in Microelectronic Engineering from the Rochester Institute of Technology (RIT), Rochester, New York.” *Id.*

Dr. Borkholder testifies that he has experience with “proprietary algorithms to detect changes in heart rate and blood oxygenation to help care teams monitor patients’ health trends” (*id.* ¶ 5), “sensor technology that instantly assesses forces that can cause traumatic brain injury” (*id.* ¶ 6), “development of a portable ultrasound system utilizing non-traditional imaging techniques” (*id.* ¶ 7), “programs for DNA analysis” (*id.* ¶ 8), and “the manufacture and characterization of charge-coupled device (CCD) image sensors” (*id.* ¶ 9). Notably absent, however, from the list of industrial work experience by Dr. Borkholder is any experience in developing a CPAP system, an element argued by Patent Owner as being necessary to provide reliable testimony about CPAP machines. *See* Reply 7–8; PO Resp. 9.

The definition of a POSITA as set out in the Petition and accepted by both parties does not require experience in designing a CPAP machine. *See* Pet. 24. Therefore, we are not persuaded by Petitioner’s contention that we should disregard Dr. Borkholder testimony because he is “unqualified to testify about what was common about the location of airflow sensors” since he has no experience in designing CPAP machines. Reply 8. Here, Dr. Borkholder’s testimony establishes that he has sufficient educational and work experience to qualify as a POSITA as defined in the Petition. Because we find that Dr. Borkholder meets the definition of a POSITA as set out in the Petition we do not find that Petitioner has established a sufficient basis for disregarding Dr. Borkholder’s testimony. *See id.* at 7.

3. *Dr. Patil*

Dr. Patil testifies that he has “practiced sleep and respiratory medicine over the past 20 years.” Ex. 2018 ¶ 7. Dr. Patil testifies that he “hold[s] a Ph.D. in Clinical Investigation from John Hopkins Bloomberg School of

Public Health, Baltimore, Maryland, an M.D. from Jefferson Medical College, Philadelphia, Pennsylvania, and a B.S. in General Science from Pennsylvania State University State College, Pennsylvania.” *Id.* ¶ 2.

Dr. Patil’s bachelor degree in general science does not meet the requirements of a POSITA as set out in the Petition. *See* Pet. 24 (noting that a POSITA has “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”). Dr. Patil’s Ph.D. in clinical investigation and medical degree also do not substitute for the absence of any education in mechanical engineering, electrical engineering, or computer science. Ex. 2018 ¶ 2.

Dr. Patil testifies that he is “familiar with many of the technologies used for the diagnosis and treatment of sleep disordered breathing, including in-lab and at home PAP treatments.” Ex. 2018 ¶ 7. Dr. Patil explains that “Positive airway pressure (PAP) devices such as continuous PAP (CPAP) or auto-adjusting PAP (APAP) are typically used to treat sleep apnea, particularly OSA [obstructive sleep apnea].” *Id.* ¶ 14. Dr. Patil testifies that in the November 2005 timeframe “CPAP did not offer significant data tracking capabilities, and the data that was reported mainly concerned measures of CPAP usage (e.g. hours of CPAP use per day).” *Id.* ¶ 18.

Here, Dr. Patil’s testimony does not establish that he has sufficient educational and work experience to qualify as a POSITA as defined in the Petition. Tr. 54:12–12 (Patent Owner’s counsel agreeing that “Dr. Patil does not have the engineering requirements, but that’s why we have both experts in there. And also, again, it comes down to weighing the evidence, so.”). The claims in the ’269 patent are directed to a device/system for treating sleep disorder. *See* Ex. 1001, 23:50–26:56). Because we find that Dr. Patil does

not meet the definition of a POSITA as set out in the Petition we will not rely on Dr. Patil's testimony with respect to making design choices in a CPAP machine. *See* Reply 7.

We do, however, consider Dr. Patil's testimony within the limited scope of using a CPAP machine with respect to treating a patient for sleep disorder as well as chemically treating a patient for sleep disorder.

f) Summary

In sum, we determine that Petitioner has demonstrated that Dr. Sharony meets the definition of a POSITA as set out in the Petition. Likewise, we determine that Dr. Borkholder meets the definition of a POSITA as set out in the Petition.

With respect to Dr. Patil's testimony, we do not find that Dr. Patil meets the definition of POSITA as set out in the Petition.

B. Claim Construction

According to Petitioner no "claim term needs formal construction." Pet. 24. Patent Owner does not contest Petitioner's position and agrees that no formal construction is required. *See generally* PO Resp.

Based on the record before us, we conclude that no claim term requires express interpretation. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) ("The Board is required to construe 'only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

C. *Grounds Based on Genger (Ex. 1005), Schmidt (Ex. 1006), Westbrook (Ex. 1007), and Farrell '737 (Ex. 1008)*

a) Prior Art

We begin with a review of the relevant references and then summarize the parties' contentions.

1. Overview of Genger (Ex. 1005)

Genger discloses a CPAP device that applies positive airway pressure in the patient's airways. Ex. 1005, 1:27–30. Genger further discloses measuring methods for determining several parameters of a patient's body, including electroencephalography (EEG), electrocardiogram (ECG), electromyography (EMG), electrooculography (EOG), respiration volume, or blood oxygen content. *Id.* at 2:10–26, 10:16–30, 15:15–20. Genger explains that transmitting data by radio from the sensor modules to the respirator makes the system more flexible because the sensor units can be adjusted based on patient need. *Id.* at 15:15–20.

Genger teaches a CPAP treatment device in a domestic environment. The device determines trend data from the sensor signals and transmits them to a network server. *Id.* at 12:18–25. “Trend data refer to data obtained from the measurement data by the sensors, but the amount of data is significantly reduced, for example, by averaging.” *Id.* at 12:17–28.

2. Overview of Schmidt (Ex. 1006)

Schmidt discloses a programmable wireless physiological data acquisition system for remotely receiving physiological input signals (i.e., EEG, EKG, EOG, etc.) and wirelessly transmitting output signals encoded with the specific physiological data in response to remotely received instructions. Ex. 1006, 4:6–37. Figure 1 of Schmidt is reproduced below.

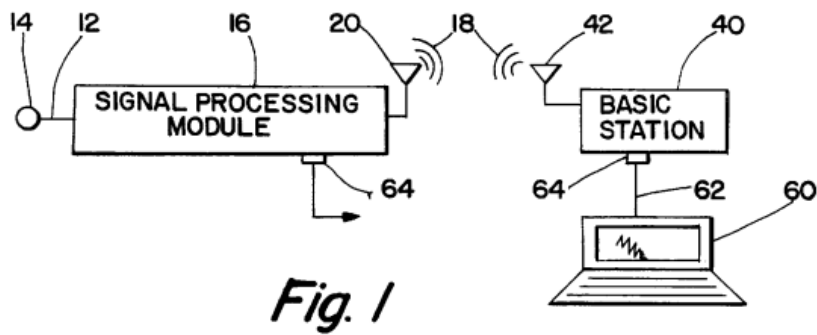


Figure 1 shows a block diagram of Schmidt's invention. Ex. 1006, 4:46. In particular, Figure 1 shows example external input 12 from sensor 14 as an input into the signal processing module 16. *Id.* at 4:63–67. The signal processing module then transmits, by wireless means, output signal 18 encoded with data corresponding to input 12. Signal 18 is then transmitted wirelessly to base station 40, where the signal is demodulated and the data decoded. Ex. 1006, 5:1–12.

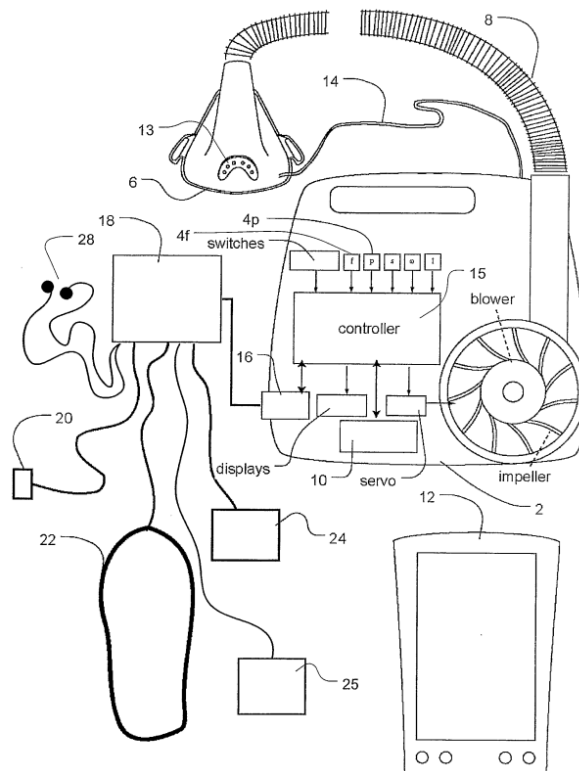
3. Overview of Westbrook (Ex. 1007)

Westbrook describes a technique for collecting and analyzing physiological signals to detect sleep apnea by a small light-weight physiological monitoring system, affixed to a patient's forehead, which detects and records the pulse, oximetry, snoring sounds, and head position of a patient to detect a respiratory event, such as sleep apnea. Ex. 1007, (57), ¶ 33. Westbrook teaches that “[a]n airflow signal could be added to the physiological monitor with minimal intrusiveness.” *Id.* ¶ 161, *see also id.* ¶¶ 59, 139 (“[T]he measurement of airflow or nasal pressure can confirm that the desaturation is due to inspiratory flow limitation or a decrease in airflow as well as identify increases in airflow corresponding with arousals.”). Westbrook teaches that the monitoring system is used in conjunction with “software which classifies types of respiratory events” to

assess the overall risk for sleep apnea. Ex. 1007 ¶¶ 155–156, *see also* ¶ 166 (“[R]espiratory events would be monitored in real-time using a digital signal processing chip or micro-controller capable of processing the data (or signals).”).

4. Overview of Farrell ’737 (Ex. 1008)

Farrell ’737 discloses monitoring and treating sleep disordered breathing in patients with cardiovascular disease or otherwise monitoring the cardiovascular condition of such patients. Ex. 1008, 1:7–9. Figure 1 of Farrell ’737 is reproduced below:



Farrell’s figure 1 reproduced above shows a CPAP system having: a pressure delivery device that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6. Exhaust gas is vented via exhaust 13. Optionally, a flow sensor 4f and/or pressure sensor 4p may also be utilized in which case mask

flow may be measured using a pneumotachograph³ and differential pressure transducer or similar device to derive a flow signal $F(t)$, and mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{\text{mask}}(t)$. Ex. 1008, 5:2–9. The device includes “[a] controller 15 or processor . . . configured and adapted to implement the methodology . . . and may include integrated chips, a memory and/or other instruction or data storage medium.” *Id.* at 5:25–27. The device may “optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band, EEG & ECG 24, EOG 25 and/or electrodes 28 for 35 detecting cardiac rhythm.” *Id.* at 5:33–35.

Farrell ’737 teaches “monitoring sleep disordered breathing (SDB) by tracking and recording or scoring SDB events or related information or indices over time, for example, by tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring.” *Id.* at 7:35–8:2. Farrell ’737 further discloses that the apparatus incorporates various pressure treatment protocols that may be used to treat the condition of the patient, “the therapeutic pressure levels of the . . . protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc.” *Id.* at 7:17–20.

³ A pneumotachograph is a device or apparatus for measuring the rate of the respiratory function. *See* <https://www.merriam-webster.com/medical/pneumotachograph> (last visited Sept. 15, 2023). *See* Dec. 27.

b) Petitioner's Contentions

1. Claim 1

Petitioner contends that the combination of Genger, Schmidt, Westbrook, and Farrell '737 renders the positive airway pressure system of claim 1 of the '269 patent obvious. *See* Pet. 25–40; Ex. 1004 ¶¶ 72–96. Petitioner contends that Genger discloses a signal processing module. Pet. 28–29. To the extent that Genger's electronics or radio modules do not meet the requisite filtering and signal processing function as claimed, Petitioner contends that a person of ordinary skill in the art would have used "Schmidt's signal processing module 16, which has the same electronics disclosed in the Challenged Patent's module 16 and was designed to process the same blood oxygen signal (SpO₂, 4:17) as Genger, in biomedical environments (EX1006 (Schmidt), 8:32-33)." Pet. 29 (citing Ex. 1004 ¶ 76).

Petitioner contends that it would have been "obvious to use a pulse oximeter like Westbrook's as Genger's blood oxygen level sensor." Pet. 30. Westbrook teaches the use of pulse oximeters in sleep apnea systems. *Id.* (citing Ex. 1007 ¶¶ 21, 22, 64–67, 137–139).

Petitioner acknowledges that the airflow sensor of Genger is outside the CPAP device but argues that Farrell '737 provides motivation to move the sensor into the device. Pet. 35 (citing Ex. 1008, 5:5–7; Ex. 1004 ¶ 87).

Petitioner contends that the "[m]otivation to use Genger's airflow data and pulse oximetry data together to calculate the claimed level and/or index would have come from Westbrook, whose methods 'improve the accuracy and resolution of the detection of oxyhemoglobin desaturation events caused by sleep apnea or hypopneas.'" Pet. 37 (quoting Ex. 1007 ¶ 32). Petitioner argues that Farrell '737 also would have motivated a person of ordinary skill in the art to combine respiratory airflow and blood oxygen saturation to

calculate an apnea hypopnea index (AHI). *See* Pet. 38–39 (Ex. 1008, 5:20–22, 7:35–8:24).

2. Claim 5

Petitioner contends that the combination of Genger, Schmidt, Westbrook, and Farrell ’737 renders the positive airway pressure system of claim 5 of the ’269 patent obvious. *See* Pet. 43–46; Ex. 1004 ¶¶ 99–112.

Claim element 5.f.2 describes a processor that is either part of the PAP device or is external to the PAP device and saves information about the subject’s symptoms to a nonvolatile memory for later transmission to a remote location. Ex. 1001, 24:54–25:3. Petitioner acknowledges that Genger’s CPAP does not contain nonvolatile memory but asserts that a “POSITA would have found it obvious for Genger’s CPAP to put data/AHI/alarm(s) into nonvolatile memory prior to transmission by modem 7.” Pet. 46. Petitioner relies on “Westbrook’s use of flash memory 44 to assist transmitting up to forty hours of sleep data from physiological monitoring system 12 to remote host 20” to assert that putting data into nonvolatile memory prior to transmitting the information would have been obvious at the time the invention was made. *Id.* (citing Ex. 1007 ¶¶ 58, 78, Figure 2; Ex. 1004 ¶ 111).

c) Patent Owner’s Contentions

1. Claim 1

Patent Owner opposes. Specifically, Patent Owner argues that the combination of references as articulated by Petitioner does not teach or suggest claim element 1.b.3, which recites in relevant part “an airflow sensor internal to the PAP device.” PO Resp. 12–23. With respect to claim element 1.b.3, Patent Owner argues that “Genger and Farrell both teach mask-located

respiratory sensors, which are not internal to the CPAP.” PO Resp. 12–13. According to Patent Owner, Petitioner admits that Genger’s respiratory airflow sensor is located outside of the CPAP machine. PO Resp. 14. Patent Owner argues that “Farrell and Berthon-Jones⁴, which is incorporated by reference in Farrell, teach[] an airflow sensor mounted on the hose, not internal to the CPAP,” and neither reference “provide[s] 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.” *Id.* at 16. “Farrell does not cure Genger’s admitted deficiencies because it does not disclose or suggest an internal respiratory airflow sensor.” *Id.* at 17 (citing Ex. 2017 ¶ 42).

Patent Owner contends that “Petitioner’s assertion that internal respiratory airflow sensors were ‘common’ is not substantiated in Berthon-Jones.” PO Resp. 19. Patent Owner contends that Petitioner has not shown “motivation to replace Genger’s pneumotachograph with the non-pneumotachograph disclosed in Berthon-Jones.” PO Resp. 21.

2. Claim 5

Patent Owner contends that the combination of references does not teach or suggest the nonvolatile memory of claim element 5.f.2. PO Resp. 23–27. Patent Owner asserts that “Petitioner again relies on the testimony of

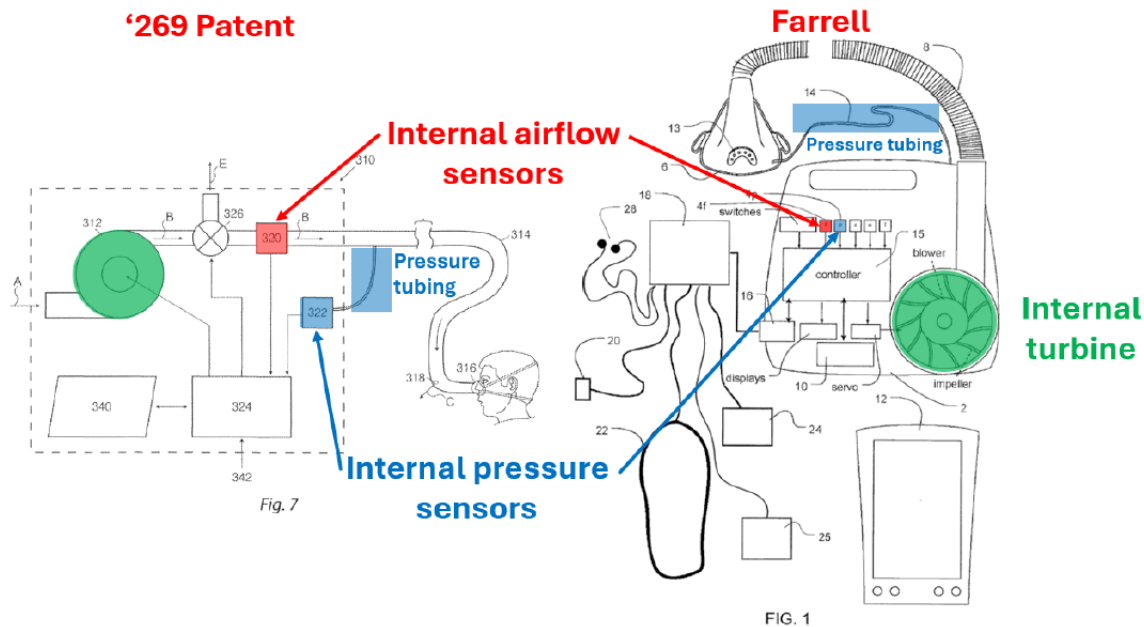
⁴ Berthon-Jones, U.S. Patent No. 5,704,345 (“Berthon-Jones,” Ex. 2015). Farrell ’737 incorporates two Berthon-Jones patents into the disclosure. *See* Ex. 1008, 2:5–6 (“The entire disclosure of U.S. Patent 5,704,345 [Berthon-Jones] is incorporated herein by reference.”), *see also id.* at 7:28–29 (“U.S. Patent 6,152,129 (Berthon-Jones), the entire disclosure of which is incorporated herein by reference”). Petitioner additionally cites two different Berthon-Jones references in response to Patent Owner’s arguments. *See* Reply 12–13 (citing AU 2005200987 A1 (Berthon-Jones) (Ex. 1030) and CA 2 520 745 A1 (Berthon-Jones) (Ex. 1031)).

Dr. Sharony in an attempt to fill the gap with the benefit of hindsight.” PO Resp. 24. Patent Owner asserts that “a POSITA would not have been motivated to provide or add nonvolatile memory in order to address communication errors” because “[n]on-volatile memory was neither required nor well-suited, given its expense and relative lethargy, to fulfill this function.” *Id.* at 24–25 (citing Ex. 2017 ¶¶ 53–54). Patent Owner contends that “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.” *Id.* at 26 (citing Ex. 1005, 12:18–25; Ex. 2017 ¶¶ 55–56).

d) Petitioner’s Reply

1. Claim 1

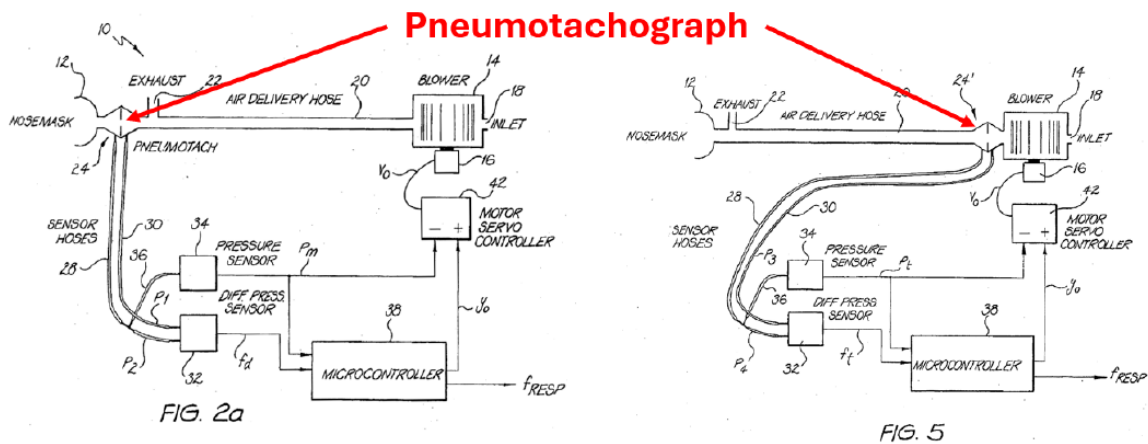
Petitioner responds that Farrell ’737 discloses internal flow and pressure sensors. Reply 9. Petitioner’s annotated figure showing a side-by-side comparison of Figure 7 of the ’269 patent next to Figure 1 of Farrell ’737 is reproduced below:



The figure above shows a CPAP system depicted in Figure 7 of the '269 patent on the left and the CPAP system depicted in Figure 1 of Farrell on the right. *See* Reply 9. The annotations show the internal turbine in green, the pressure sensor and pressure tubing in blue, and the internal airflow sensor in red in each system. Petitioner contends that “Farrell’s ‘flow sensor 4f’ and ‘pressure sensor 4p’ are located internal to the PAP enclosure.” Reply 9. “[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.’” *Id.* at 10 (citing Ex. 1008, 5:5–7 (“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 $F(t)$ ”), Fig. 1).

Petitioner contends that it was known “that pneumotachographs were located within the housing of a pressure device and are not only located at the mask.” Reply 10 (citing Ex. 1030, 1:25–26 (“Respiratory airflow is commonly measured with a pneumotachograph placed in the gas delivery

path between the mask and the ventilator.”), 8:11–13 (“[T]he pneumotachograph 24' is interposed between the turbine 14 and the delivery hose 20.”); 8:15–16 (“This arrangement removes the pressure sensing hoses and pneumotachograph from the region of the mask 12.”)). Reproduced below are Petitioner’s annotated figures from Berthon-Jones highlighting alternative locations for a pneumotachograph.



The figure above shows a side-by-side comparison of a CPAP system depicted in Berthon-Jones’ Figure 2a (on the left) and a CPAP system depicted in Figure 5 (on the right), with the location of the pneumotachograph in each system highlighted. Reply 11 (citing Ex. 1030, Figures 2a and 5).

Petitioner contends that “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.”

Reply 11. Petitioner contends that Farrell’s pressure sensor is located within the housing. *Id.* (citing Ex. 1029, 72:18–74:13). In the deposition, Patent Owner’s expert Dr. Borkholder acknowledges that the pressure sensor is located at least at the housing of the blower:

Q. And it's fair to say that the pressure sensor used by Ferral is within the housing of the CPAP device, right?

A. So my recollection is that Ferral actually isn't explicit on that, but in that drawing it appears that it is going at least -- the pressure sensor is at least at the main housing of the blower.

Q. When you say at the housing of the blower what do you mean?

A. So it says there's a sense tube 14 connected to the main housing of the blower and so presumably the pressure sensor is located at the main housing of the blower.

Ex. 1029, 73:23–74:13.

Petitioner's annotated Figure 1 of Farrell '737 is reproduced below:

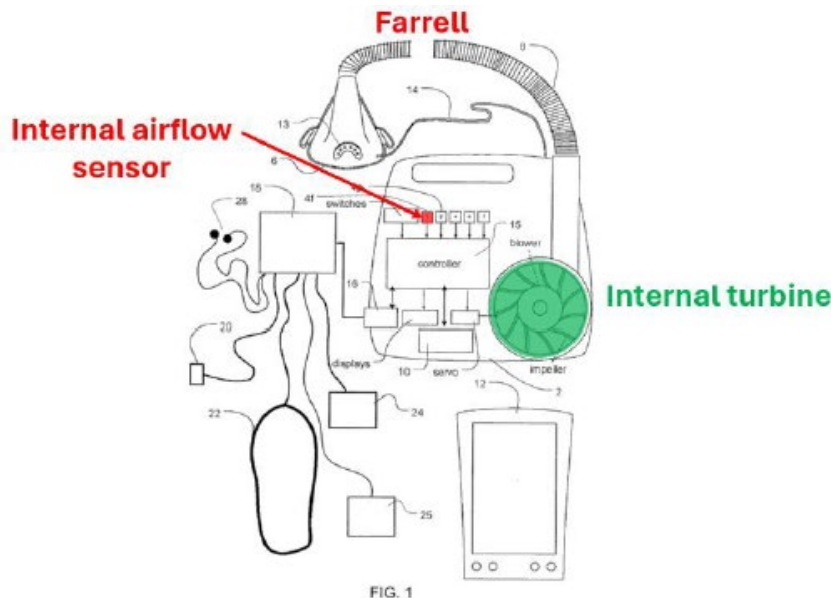


Figure 1 of Farrell '737 reproduced above shows a CPAP system with the internal turbine highlighted in green and flow sensor highlighted in red. Reply 13. Petitioner contends that “Farrell discloses an internal airflow sensor. And Berthon-Jones [incorporated by reference into Farrell '737] teaches that the location of the airflow sensor is a simple alternative due to convenience.” Reply 14–15 (citing Ex. 2015, 8:31–36).

2. *Claim 5*

Petitioner explains that “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.” Reply 17. “Without a nonvolatile memory, alarms and trend data recorded prior to transmission would be lost if the PAP device were to lose power.” *Id.* at 18. Furthermore, “Westbrook states ‘[f]lash memory chips 44 provide a low cost method to store the signals acquired during use of the physiological monitor 12.’” Reply 16 (quoting Ex. 1007, ¶ 75; Pet. 46).

e) *Patent Owner’s Sur-reply*

1. *Claim 1*

Patent Owner contends that “Genger and Farrell both disclose directly measuring a patient’s respiratory airflow with mask-based pneumotachographs.” Sur-reply 6. Patent Owner contends that Petitioner has not articulated why a POSITA would have relocated the external sensor from Genger when “Genger touts the advantages of external positioning and its sensor already calculates respiratory airflow.” Sur-reply 9. Patent Owner contends that “Petitioner ignores this evidence and claims, for the first time in Reply that Farrell’s flow sensor 4f is an internal airflow sensor.” *Id.* (citing Reply 9).

2. *Claim 5*

Patent Owner contends that “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 a[t] the claim element because Genger’s modem uses volatile memory for immediate transmission.” Sur-

reply 10. “Data [in Genger] is only temporarily stored in buffers (volatile memory) while the conversion takes place and then is immediately transmitted.” *Id.* 11. Patent Owner contends that “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” because the server stores the data. *Id.* at 12.

f) Analysis

Patent Owner challenges Petitioner’s assertions only as to certain claim elements, specifically claim element 1.b.3 and claim element 5.f.2. *See* PO Resp. 12–23. The unchallenged elements will not be discussed, nor will claims that have not been separately argued by Patent Owner. *See* PO Resp. 12–27. With respect to the unchallenged elements and claims, we adopt Petitioner’s reasoning as our own. *See* Pet. 41–43, 46–49. Based upon our review of the arguments and evidence, we find that Petitioner has shown by a preponderance of the evidence that the combination of Genger, Schimdt, Westbrook, and Farrell ’737 teaches the positive pressure airway (PAP) device as recited in claims 1 and 5. Pet. 25–40, 43–46; Ex. 1004 ¶¶ 72–96.

1. Claim 1 – element 1.b.3

Claim 1 differs from claim 5 in that the mask is not part of the PAP device in claim 1. *Compare* element 1.c (Ex. 1001, 24:9), *with* element 5.e.5. (Ex. 1001, 24:52–53); *see* Tr. 14:21–25 (claim 5 encompasses the mask as part of the PAP device). In the Decision, we made the error of interpreting claim 1 to include the mask as part of the CPAP machine. *See* Dec. 30. In that Decision, we determined that the teaching of a sense tube 14 in Farrell ’737 reasonably supports “incorporating sensors into the mask.” Dec. 30.

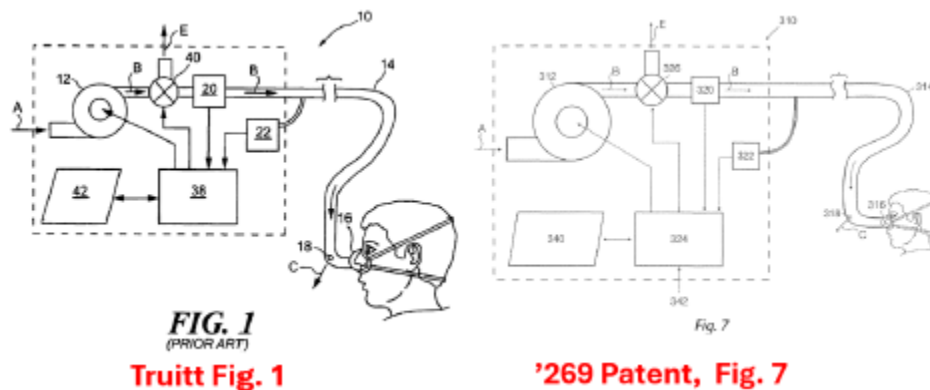
In the Reply, Petitioner clarified that the sense tube 14 in Farrell '737 is just a tube and that the actual air pressure sensor is found in the body of the PAP device housing holding the blower. *See* Reply 8–16; Tr. 11:6–25. Petitioner further argues that at the time the invention was made this type of configuration was conventional. Reply 15.

After considering the full record before us, we determine that the preponderance of evidence of record supports Petitioner's contention that the combination of Genger, Schimdt, Westbrook, and Farrell '737 teaches the location of the air flow sensor as set out in claim element 1.b.3 ("air flow sensor internal to the PAP device"). Petitioner's articulated combination does not rely on Genger as disclosing a respiratory airflow sensor located internal to the PAP device as recited in claim element 1.b.3. Instead, Petitioner demonstrates by a preponderance of the evidence that Farrell '737 suggests the sensors can be included in the PAP device that houses the blower assembly. *See* Pet. 34–36; Ex. 1004 ¶¶ 85–88; Reply 8–16. Farrell '737 teaches that the device can include "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 $F(t)$* , and mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{\text{mask}}(t)$." Ex. 1008, 5:5–9 (emphasis added). Farrell '737 teaches that "[t]here is a sense tube 14 connected to the main housing of the blower to the mask that allows the apparatus to sense oxygen concentration and pressure levels in the mask 6." *Id.* at 5:36–6:2.

Petitioner explains that "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.’” Reply 10 (citing Ex. 1008, 5:5–7). The record supports Petitioner’s contention that it was also known “that pneumotachographs were located within the housing of a pressure device and are not only located at the mask.” *Id.* (citing Ex. 1030, 1:25–26 (“Respiratory airflow is commonly measured with a pneumotachograph placed in the gas delivery path between the mask and the ventilator.”), 8:11–13 (“[T]he pneumotachograph 24’ is interposed between the turbine 14 and the delivery hose 20.”)); 8:15–16 (“This arrangement removes the pressure sensing hoses and pneumotachograph from the region of the mask 12.”)).

Petitioner additionally demonstrates that the ’269 patent’s Fig. 7 and Fig. 1 of a prior art patent to Truitt⁵ are strikingly similar, and both depict airflow and pressure sensors internal to the PAP device. Reply 2. Petitioner’s annotated figure showing a side-by-side comparison of Truitt Figure 1 and Figure 7 of the ’269 patent is reproduced below:



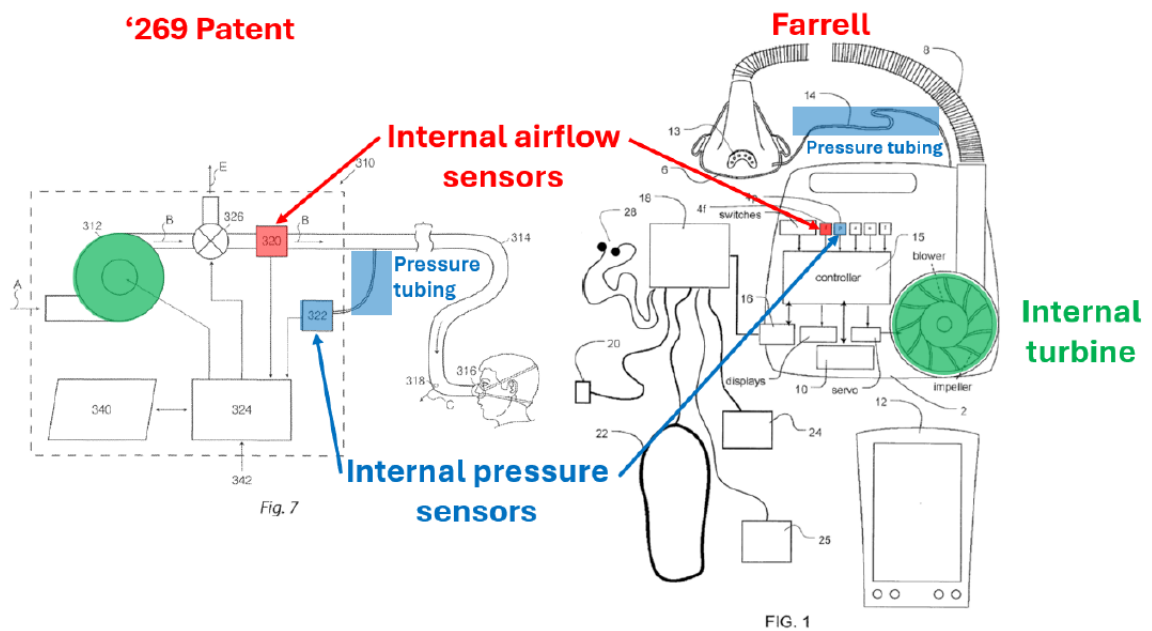
Reply 15–16 (citing Ex. 1026, Figure 1; Ex. 1032,⁶ ¶¶ 1787 (Dr. Borkholder acknowledging that Fig. 7 of the ’269 patent describes a “conventional” pressure support system), 1789 (same)). Truitt describes its Figure 1 (shown

⁵ Truitt et al., U.S. 6,644,311 B1 (“Truitt”).

⁶ Excerpts from the rebuttal report of Dr. Borkholder in the related District Court Litigation. *See above* I.C.

above left) as a conventional pressure support system. Ex. 1026, 1:44–45. Truitt further explains that “the information from flow sensor 20 and/or pressure sensor 22 is used, for example, to control the pressure or flow of gas provided to the patient.” *Id.* at 2:5–8. The ’269 patent describes Figure 7 (shown above right) as “a particular type of physical treatment device known as continuous positive airway pressure (CPAP) device. This conventional pressure support system 310 shown in FIG. 7 includes a pressure generator 312, a blower, piston or bellows.” Ex. 1001, 22:47–49. The ’269 patent further describes “a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit 314.” *Id.* 23:8–10. Both Truitt Figure 1 and Figure 7 of the ’269 patent, reproduced above, show a conventional prior art CPAP configuration in which the pressure sensor is located inside the device holding the blower.

Petitioner’s annotated figure showing a side-by-side comparison of Figure 7 of the ’269 patent next to Figure 1 of Farrell ’737 is reproduced below:



Petitioner contends that “Farrell’s ‘flow sensor 4f’ and ‘pressure sensor 4p’ are located internal to the PAP enclosure.” Reply 9.

Patent figures are routinely relied upon for relative information regarding the placement of components. *See, e.g., In re Skvorecz*, 580 F.3d 1262, 1270 (Fed. Cir. 2009) (“A person skilled in the mechanical arts would understand the specification including the drawings as showing the offsets and the lateral displacement of each wire leg.”). Here, in Figure 1 of Farrell ’737 the flow sensor 4f and pressure sensor 4p are shown as located within the PAP housing. Even though Farrell ’737 describes that “[t]he pressure sensor 4f and flow sensor 4p have only been shown symbolically,” the figure reasonably depicts them as being internal to the CPAP device. Ex. 1008, 5:9–10. Petitioner further demonstrates that the placement of the sensor as shown in Figure 1 of Farrell 737 is consistent with known prior art PAP devices, e.g., Truitt’s device discussed above. *See* Reply 15–16; Ex. 1026, 1:44–45, 2:5–8, Figure 1; Ex. 1032 ¶¶ 1797, 1789; Ex. 1004 ¶ 86 (“the location of the sensor is immaterial as long as its measurements are accurate”); Ex. 1029, 74:1–6 (“So my recollection is that [Farrell] actually isn’t explicit on that, but in that drawing it appears that it is going at least -- the pressure sensor is at least at the main housing of the blower.”). Here, the pressure sensor shown in the CPAP device in Figure 1 of Farrell ’737 is reasonably understood to be located inside the CPAP housing just like in another prior art PAP device (e.g., Truitt (Ex. 1026)). *See Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) (“Art can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness.”).

For the reasons discussed above, we find that Petitioner has shown by a preponderance of the evidence of record that the location of an air pressure sensor being internal to the PAP device was taught or suggested by the prior art of record. Accordingly, we conclude that Petitioner has shown by a preponderance of the evidence of record that claim 1 is unpatentable as obvious over the combination of Genger, Schmidt, Westbrook, and Farrell '737.

2. Claim 5 – element 5.f.2

Patent Owner challenges Petitioner's assertions only as to the obviousness of using nonvolatile memory as set out in claim element 5.f.2. PO Resp. 23. The unchallenged elements will not be discussed. *See* PO Resp. 23–27. We adopt Petitioner's assertions with respect to the unchallenged elements. *See* Pet. 43–46.

As to claim element 5.f.2, Petitioner demonstrates that a person of ordinary skill in the art would have understood

Genger's controller to be implemented by a processor, and the "trend data," such as "the number of apneas in a predetermined period" (13:3-6)[,] to constitute the claimed "sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device."

Pet. 37. Genger teaches a CPAP treatment device used in a domestic environment. The device determines trend data from the sensor signals and transmits them to a network server. Ex. 1005, 12:18–25; Pet. 37. "Trend data refer to data obtained from the measurement data by the sensors, but the amount of data is significantly reduced, for example, by averaging." *Id.* at 12:17–28.

Here, the record supports that a processor/controller in Genger is used to collect and generate trend data before the data transmitted via a network. *See* Ex. 1005, 12:22–27 (“[T]he controller determines trend data from the sensor signals. . . . Trend data refer to data obtained from the measurement data by the sensors, but the amount of data is significantly reduced, for example, by averaging.”).

The record also supports that Genger transmits information including trend data via a modem.

[T]he controller in the compressor is able to determine alarms if, for example, the number of apneas increases sharply. The alarms can also be forwarded via the modem 7 and the public switched telephone network (PSTN), to a relevant unit. The modem may be designed for an analog telephone connection, an ISDN connection or a DSL connection. Furthermore, the modem may be a cell phone unit, so that the trend data and/or alarms are transmitted via D or E network to the appropriate server.

Ex. 1005, 13:8–14.

Contrary to Patent Owner’s suggestion (*see* PO Resp. 23–27), Petitioner does not rely on Genger alone in arriving at the conclusion that it would have been obvious to include nonvolatile memory into Genger’s device. Petitioner also demonstrates that Westbrook teaches the use of flash memory – a nonvolatile memory. Pet. 46; Ex. 1007 ¶¶ 58, 78; Ex. 1004 ¶ 111; Ex. 2016, 46:23–47–15. Westbrook teaches that flash memory can save hours of data collected:

The micro-controller has an associated flash memory 44, such as a multi-media flash memory card, capable of storing forty hours of sleep data, and a high-speed data transfer connection 46 to a multimedia flash card reader or an RS-232 serial interface for uploading and downloading data to and from the physiological monitoring system 12.

Ex. 1007 ¶ 58. Petitioner demonstrates that Westbrook teaches a “desire to permit retransmission in the event of communication errors with the remote location,” while Genger teaches a “desire to make sure remote parties such as insurance, etc., are informed about a patient’s situation.” Pet. 46. Thus, we find that Petitioner has demonstrated that there would have been motivation and a reasonable expectation of success that incorporating flash memory into Genger would prevent data loss in the event of a power outage. *Id.*

Ordinary creativity is presumed on the part of one of ordinary skill in the art. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417, 421 (2007) (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”). Petitioner explains that incorporating nonvolatile memory into Genger would have been obvious because “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.” Reply 17 (citing Ex. 2016, 46:11–47:15); Pet. 46 (citing Ex. 1004 ¶ 110).

Dr. Sharony explains that there are two general types of memory: volatile memory and nonvolatile memory. Volatile memory is temporary and “when you shut off the machine, all what stores in memory, you know, will disappear, would be erased,” whereas nonvolatile memory is used for “certain things that you would like to keep, like, for example, program, applications, sometime parameters of device operation. So you want the next time you switch on the device, that you will use the same apps, same programs. So you put it in a nonvolatile memory. Like in a flash memory.” Ex. 2016, 46:11–24; Reply 17; Ex. 2019, 4, 5; Ex. 2017 ¶ 52.

Petitioner argues that by including nonvolatile memory / flash memory into Genger any information stored in the device before it is transmitted via modem is not lost should the device lose power before the transmission is complete. Reply 17 (“Absent a nonvolatile memory, multiple hours of data could be lost—significantly delaying diagnosis and treatment.”).

Patent Owner argues that “[v]olatile memory retains all sufficient data for re-transmission in the case [] there are communication errors” during the modem transmission and, therefore, that there is no motivation to include nonvolatile memory. PO Resp. 25 (citing Ex. 2017 ¶¶ 53–54). But as Petitioner explains, a power outage before the information is transmitted via the modem would result in the loss of information from volatile memory, thereby significantly delaying diagnosis and treatment. Reply 17; Ex. 2019, 5; Ex. 2017 ¶ 52 (Dr. Borkholder acknowledging “volatile memory” as “[m]emory, such as RAM, that loses its data when the power is shut off”).

We are not persuaded by Patent Owner’s argument that “[n]on-volatile memory was neither required nor well-suited, given its expense and relative lethargy, to fulfill this function.” PO Resp. 25. Making something cheaper may provide a motivation to follow a certain path but the opposite – making something more expensive – does not require a conclusion of non-obviousness. *See In re Farrenkopf*, 713 F.2d 714, 718 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983)) (“[A]dditional expense associated with the addition of inhibitors would not discourage one of ordinary skill in the art from seeking the convenience expected therefrom. That a given combination would not be made by businessmen for economic reasons does not mean that persons skilled in the art would not make the combination because of some

technological incompatibility. Only the latter fact would be relevant.”). Here, the benefit of not losing data from a power outage in a PAP machine that is intended for home use is reasonably balanced against any potential of increased expense with the addition of nonvolatile memory.

We are also not persuaded by Patent Owner’s contention that Petitioner seeks to add the nonvolatile memory to the modem. Tr. 32:15–19; PO Resp. 23–24. Here, Petitioner suggests adding the nonvolatile memory before reaching the modem for transmission of the information. Pet. 46 (“POSITA would have found it obvious for Genger’s CPAP to put data/AHI/alarm(s) into nonvolatile memory prior to transmission by modem 7.”).

For the reasons discussed above, we find that Petitioner has shown by a preponderance of the evidence of record that a person of ordinary skill in the art would have added nonvolatile memory to Genger’s PAP device in order to prevent data loss during a power outage. Accordingly, we conclude that Petitioner has shown by a preponderance of the evidence of record that claim is 5 is unpatentable as obvious over the combination of Genger, Schmidt, Westbrook, and Farrell ’737.

3. *Summary*

In sum, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 5 would have been obvious over the combination of Genger, Schmidt, Westbrook, and Farrell ’737.

We adopt Petitioner’s reasoning with respect to claims 2–4, 6, and 7 as our own. *See* Pet. 25–49; Reply 8–18. Specifically, Petitioner relies on the combination of Genger, Schmidt, Westbrook, and Farrell ’737 to also challenge claims 2, 3, 5, and 7. Pet. 3. Petitioner challenges claims 4 and 6,

depending from independent claims 1 and 5, and relies on the same references in conjunction with *Paradiso*. *Id.* Based on the undisputed arguments and evidence presented in the Petition, Petitioner has demonstrated by a preponderance of the evidence that claims 2–4, 6, and 7 are unpatentable as obvious.

D. *Grounds Based on Kocinski (Ex. 1012), Farrell '737 (Ex. 1008), and Bluetooth (Ex. 1017)*

a) *Prior Art*

We begin with a review of the relevant references and then address the parties' contentions.

1. *Overview of Kocinski (Ex. 1012)*

Kocinski discloses a CPAP device that can be remotely programmed and that collects and stores patient data. Ex. 1012 ¶ 9. Kocinski discloses that the CPAP device periodically transfers the data to a central database server. *Id.* Medical professionals can remotely operate the settings for the CPAP device. *Id.* Figure 1 is shown below.

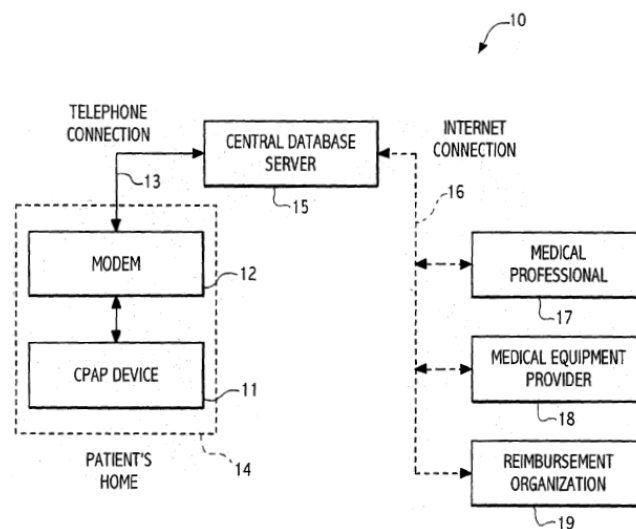


FIG. 1

Figure 1 above is a diagrammatic view of a system for providing information from a CPAP user's home environment to remote locations to allow for remote programming of the operational settings of the CPAP device. Ex. 1012 ¶ 24. CPAP device 11 is used with a modem that sends the patient's data to a medical professional for monitoring. *Id.* ¶¶ 24–28.

2. Overview of Farrell '737 (Ex. 1008)

Farrell '737 is discussed above in section II.C.a.4. Farrell '737 teaches that, in its CPAP device “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 $F(t)$, and mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{\text{mask}}(t)$.” Ex. 1008, 5:5–9. Farrell '737 also teaches that “[t]here is a sense tube 14 connected to the main housing of the blower to the mask that allows the apparatus to sense oxygen concentration and pressure levels in the mask 6.” *Id.* at 5:36–6:2.

3. Overview of Bluetooth (Ex. 1017)

The Bluetooth reference provides general descriptions of the Bluetooth system including radio, baseband, protocol specifications and compliance requirements. *See generally* Ex. 1017.

a) Petitioner's Contentions

Petitioner contends that the combination of Kocinski, Farrell '737, and Bluetooth teaches all the limitations of claim 15. Pet. 61–75. Petitioner contends that “Kocinski discloses a PAP sleep disorder treatment system.” Pet. 62, 61–75. According to Petitioner, “Kocinski's CPAP preferably has

‘auto-adjust capabilities, which uses an internal pressure transducer ... and will adjust to give the patient more or less pressure.’ *Id.* at 64 (citing Ex. 1012 ¶ 46). Petitioner asserts that, if Kocinski’s pressure transducer is deemed not to constitute an airflow sensor, then it would have been obvious to add such a sensor based on the teachings of Farrell ’737. *Id.* at 64. Petitioner concludes that “[m]otivation would have come from Farrell (EX1008) whose CPAP 2 includes ‘a flow sensor 4f[so] mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal F(t).’” *Id.* (citing Ex. 1008, 5:5–7). Petitioner contends that “Kocinski advocates any method of communication to/from the CPAP 11, including wired or wireless” and Bluetooth’s radio frequency architecture allows for bidirectional communication with the device. *Id.* 68–69 (citing Ex. 1012 ¶ 26; Ex. 1017). Based on the combined teachings of Kocinski, Farrell ’737, and Bluetooth, Petitioner concludes that all the elements of claims 15 are taught by the references. *Id.* at 61–75.

b) Patent Owner’s Contentions

Patent Owner opposes. PO Resp. 34–39. Specifically, Patent Owner argues that the combination of references as articulated by Petitioner does not teach or suggest claim elements 15.a.2, 15.f and 15.g.2. PO Resp. 37. Patent Owner contends that “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.” PO Resp. 34. Patent Owner also contends that

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). . . . 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.

PO Resp. 35–36. According to Patent Owner, “Farrell also does not disclose the transmission of any symptom data, either to its hand-held device for display or to a remote location.” *Id.* at 36. Patent Owner contends that “Farrell discloses that this data is merely ‘recorded for analysis.’” *Id.*

Patent Owner contends that “Kocinski’s Figure 10 does not display either the subject’s sleep disorder symptom data or the index of the subject’s symptoms.” PO Resp. 38. Patent Owner argues that Petitioner’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).

PO Resp. 38. In other words, according to Patent Owner, providing a patient with feedback about the quality of their sleep and showing improvements with the use of the device unexpectedly increased patient compliance in continuing their treatment.

c) Petitioner’s Reply

Petitioner argues that “Kocinski indisputably collects and stores ‘the frequency and nature of events detected while the patient sleeps, such as apnea events.’” Reply 24; Ex. 1012 ¶ 28 (“Information may be collected and stored regarding the output pressure, startup delays and pressures in which a lower pressure is initially applied to the patient, and the frequency and nature of events detected while the patient sleeps, such as apnea events, maintenance warnings.”).

In response to Patent Owner’s unexpected results arguments, Petitioner contends that neither reference (Ex. 2010 and Ex. 2011) cited by Patent Owner supports the position that increased compliance is surprising or unexpected. Reply 27. Petitioner contends that Patent Owner has not shown a nexus between the claims and any alleged unexpected results. *Id.* at 28.

d) Patent Owner’s Sur-reply

Patent Owner contends that “Kocinski’s system transmits data to a server for medical professional access, with no on-site base station display.” Sur-reply 21. And Farrell similarly “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.’” *Id.* at 22. “[B]ecause 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 [personal digital assistant]) having also done the transmission” and there is no patient specific data displayed on-site. *Id.*

e) Analysis

Patent Owner challenges Petitioner’s assertions only as to certain claim elements. Specifically, claim elements 15.a.2, 15.f, and 15.g.2. PO Resp. 34–39. The disputed elements of claim 15 read as follows:

[15.a.2] “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” Ex. 1001, 26:7–9;

[15.f] “the first radio frequency wireless module transceiver adapted for receiving and 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 and the data of usage to the base station, cellular phone or PDA” Ex. 1001, 26:18–23; and

[15.g.2] “the 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, and to retransmit 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.” Ex. 1001, 26:24–31.

The unchallenged elements will not be discussed, nor will claims that have not been separately argued by Patent Owner. *See* PO Resp. 34–39, 40–41. With respect to the unchallenged elements and claims, we adopt Petitioner’s reasoning. *See* Pet. 61–79. Based upon our review of the arguments and evidence, we find that Petitioner has shown by a preponderance of the evidence that the combination of Kocinski, Farrell ’737, and Bluetooth teaches the positive pressure airway (PAP) device as recited in claim 15. Pet. 61–79; Ex. 1004 ¶¶ 132–156.

1. Element 15.a.2 – internal air flow sensor

We find that Kocinski teaches an “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” Ex. 1001, 26:7–9. In particular, Kocinski teaches

a CPAP apparatus 11 that has auto-adjust capabilities, which uses *an internal pressure transducer* and has internal memory that allows a range of pressure to be used and will adjust to give the patient more or less pressure, depending on their needs through the night. Such a CPAP apparatus 11 will react to the patient’s sleep and breathing patterns for maximum comfort.

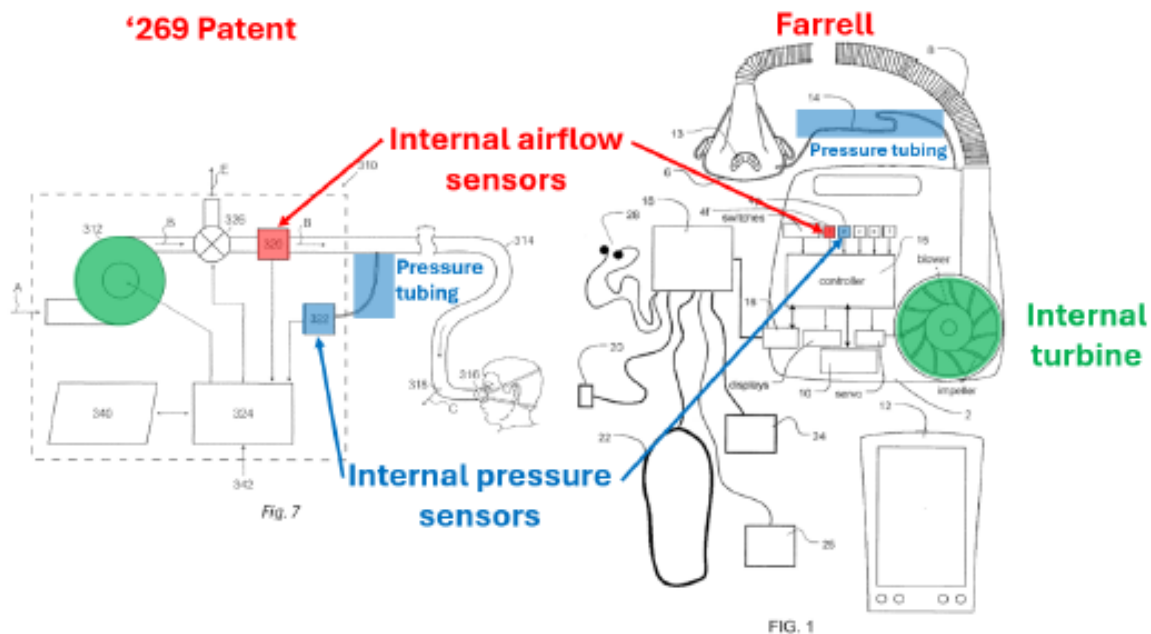
Ex. 1012 ¶ 46 (emphasis added); Pet. 64–65 (citing Ex. 1004 ¶ 153); Reply 23.

Patent Owner contends that the internal pressure transducer only controls the blower pressure provided to the subject but does not measure the subject's respiratory airflow. PO Resp. 34–35 (citing Ex. 2017 ¶ 70). Here, Kocinski teaches that the apparatus reacts to the patient's sleep and breathing patterns for maximum comfort, thereby reasonably suggesting that the patient's airflow is monitored at least to assess comfort in Kocinski. See Ex. 1012 ¶ 46.

Petitioner, however, does not solely rely on Kocinski to teach an airflow sensor or the location of the airflow sensor. Pet. 64 (“To the extent the pressure transducer is deemed not to constitute an airflow sensor, [a] 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.”); PO Resp. 34 (citing Ex. 2017 ¶ 70 (Kocinski's pressure sensor does not measure air flow)). Petitioner explains that flow and pressure sensors are common in CPAP machines and that “[m]otivation [to add a flow sensor] would have come from Farrell (EX1008) whose CPAP 2 includes ‘a flow sensor 4f [so] mask flow may be measured using a pneumotachograph and differential pressure transducer *or similar device to derive a flow signal $F(t)$* .’” Pet. 64 (citing Ex. 1008, 5:5–7 (emphasis added)). In other words, Petitioner contends that a separate flow sensor provides for better monitoring of airflow to the patient and respiratory airflow of the patient (i.e. greater accuracy).

Patent Owner contends that Farrell's sensors are not internal to the CPAP machine. PO Resp. 16–17 (citing Ex. 2017 ¶¶ 40–41). Farrell's Figure 1 (reproduced below) shows an internal pressure sensor alongside the

internal airflow sensor. *See* Reply 9; Pet. 35. Patent figures are routinely relied upon for relative information regarding the placement of components. *See, e.g., In re Skvorecz*, 580 F.3d at 1270. We agree with Petitioner that Farrell '737's Figure 1 depicts an air flow sensor internal to the PAP device. *See* Ex. 1008, 5:1–19, Figure 1; Pet. 35; Reply 13; Ex. 1004 ¶¶ 85–88. Petitioner's annotated figure, reproduced below, shows the location of the sensors in Figure 1 of the '269 patent compared with the location of the pressure and airflow sensors in Farrell '737.



The annotated figure above compares the PAP system depicted in Figure 7 of the '269 patent (left) with the PAP system depicted in Figure 1 of Farrell (right). The figure highlights the location of the blower (green), internal air flow sensor (red), and internal pressure sensor (blue). *See* Reply 9; Pet. 35. Here, we agree with Petitioner that Farrell '737 shows the flow and pressure sensors are depicted as being internal to the CPAP device that houses the blower.

Farrell '737 describes the CPAP as containing:

a pressure delivery device that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6. Exhaust gas is vented via exhaust 13. Optionally, 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 $F(t)$, and mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{\text{mask}}(t)$. The pressure sensor 4f and flow sensor 4p have only been shown symbolically in FIG. 1 since it is understood that those skilled in the art would understand how to measure flow and pressure. Flow $F(t)$ and pressure $P_{\text{mask}}(t)$ signals are sent to a controller or microprocessor 15 to derive a pressure request signal $P_{\text{request}}(t)$.

Ex. 1008, 5:1–13. Farrell '737 further teaches that “[t]here is a sense tube 14 connected to the main housing of the blower to the mask that allows the apparatus to sense oxygen concentration and pressure levels in the mask 6.”

Ex. 1008, 5:36–6:2; Tr. 30:3–11 (“[A] sense tube 14 connected to the main housing of the blower to the mask that allows the apparatus to sense oxygen concentration and pressure levels in the mask 6 . . . the airflow sensor needs to be within the flow of the air from the patient’s mouth. And that little tube that goes down in Farrell is not it that [it] measures the pressure.”). Because the sense tube 14 in Farrell '737 is connected to the main body of the CPAP machine we find that pressure information is processed in the main housing. Patent Owner’s expert, Dr. Borkholder, acknowledges that the pressure sensor in Farrell '737 is at the main housing. Ex. 1029, 74:1–13 (“So it says there’s a sense tube 14 connected to the main housing of the blower and so presumably the pressure sensor is located at the main housing of the blower.”).

Petitioner's expert, Dr. Sharony further explains that "the location of the sensor is immaterial as long as the measurement is accurate." Ex. 1004 ¶ 86 (citing Ex. 2015 (Berthon-Jones), 8:31–36 ("[I]t 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)."); Ex. 2016, 59:10–15 ("It's a matter of engineering. You don't put the sensor in a tubing that is flexible and it can crack, can break. It's replaceable. It is more secure to put it inside the mask, inside the device or inside the generator.").

Additionally, we agree with Petitioner that Farrell '737 is not limited to the flow sensor being a pneumotachograph. Farrell '737 describes that "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 $F(t)$* , and mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{\text{mask}}(t)$." Ex. 1008, 5–9 (emphasis added); Reply 9, 12–13.

We are not persuaded by Patent Owner's contention that the risk of additional FDA consideration upon moving a sensor in a PAP device would render the combinations as articulated by Petitioner unobvious and weigh against making changes. PO Resp. (citing Ex. 2018 ¶¶ 23–25) (discussing the FDCA approval process for changes to medical devices); Reply 15. Our reviewing court has "noted that FDA approval may be relevant to the obviousness inquiry." *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291 (Fed. Cir. 2013) (citing *Knoll Pharm. Co. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004)). Nevertheless, the court stated that 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. Motivation to combine may be found in many different places and forms; it cannot be limited to those reasons the FDA sees fit to consider in approving drug applications.” *Id.* at 1292.

Based on the combination of disclosures in Kocinski and Farrell ’737 in conjunction with Dr. Sharony’s testimony, Petitioner has demonstrated by a preponderance of the evidence that it would have been obvious to include a pressure sensor and airflow sensor internal to the PAP device.

2. Element 15.f – transmission of symptom data

Petitioner explains that “Kocinski’s CPAP includes a processor that receives airflow sensor data, e.g. Farrell’s, to detect apnea and/or hypopnea events.” Pet. 66. Petitioner explains that “Kocinski counts apnea and hypopnea events” and, therefore, that it would have been obvious to “calculate AHI and/or RDI [respiratory disturbance index]” to assess sleep disorders just like Farrell ’373. Pet. 66.

Kocinski teaches that “different amounts of data may be collected and transferred to the central database server 15.” Ex. 1012 ¶ 28. “CPAP apparatus 11 is programmed to transfer data to the central database server 15 at intervals set by the medical professional 17. . . [A] call may be made if there is a service problem or if the patient is experiencing too many abnormal sleep events.” *Id.* ¶ 31. Transmitting an observation that there are too many abnormal sleep events would be transmitting symptom data. This disclosure, therefore, supports Petitioner’s position. Pet. 71.

Kocinski’s Figure 1 reproduced above in section II.D.a.1 shows that information from the CPAP device is communicated to the central sever and is accessible by internet connection with the medical professional, medical

equipment provider, and the reimbursement organization. Ex. 1012 ¶ 24, Figure 1. Kocinski teaches “a system for providing communications between a CPAP apparatus located in a patient’s home or premises and a medical professional, and/or a medical equipment provider and, optionally, a medical insurance or other reimbursing organization.” Ex. 1012 ¶ 24. Kocinski, therefore, establishes that the collected CPAP information can be communicated to a variety of persons. Kocinski teaches that communication between a patient’s home and central servers is primarily via telephone because of general availability of the telephone line but suggests other modes of communication for data transfer can also apply, such as a cable modem and the internet or via a satellite communications system. *Id.* ¶¶ 26, 35 (“Two-way communication between the CPAP apparatus 11 and the central database server 15 is accomplished via an internet processing system (IPS).”).

Depending on the sophistication of the CPAP apparatus 11, different amounts of data may be collected and transferred to the central database server 15. . . . The CPAP apparatus 11 may be programmed, for example, to send a message to the central database server 15 which is relayed to the medical professional 17 if the number of apnea events per hour exceed a programmed threshold, or if the number of hypoapnea events per hour exceed a programmed threshold, or if the blood desaturation exceeds a programmed threshold. . . . The medical professional 17 may program multiple thresholds for the patient in the CPAP apparatus 11. The maintenance warnings may be made available only to the medical equipment provider 18 and the pressures and sleep events may be made available only to the medical professional 17, since others do not need this information. The CPAP apparatus 11 may be programmed to automatically send a warning to the central database server 15 anytime an operating problem is detected. For example, if the CPAP apparatus 11 ceases operation or if it cannot provide an adequate pressure, a warning message can be sent.

Ex. 1012 ¶ 28. “The IPS collects compliance data and other parametric data from the CPAP apparatus 11 in the patient’s home 14, [and] transmits the data to a central database server 15.” *Id.* ¶ 35.

CPAP apparatus 11 . . . has auto-adjust capabilities, which uses an internal pressure transducer and has internal memory that allows a range of pressure to be used and will adjust to give the patient more or less pressure, depending on their needs through the night. Such a CPAP apparatus 11 will react to the patient’s sleep and breathing patterns for maximum comfort.

Ex. 1012 ¶ 46.

Farrell ’737 teaches that “the device provides efficacy tracking by detecting and recording or scoring SDB [sleep disordered breathing] events or related information or indices over time . . . [T]he device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. In one embodiment of the invention an AHI scoring scheme may be implemented.” Ex. 1008, 7:35–8:10. Farrell ’737 also teaches that “[t]hese events may be recorded with the time they occur or added to a total for a particular time period.” *Id.* at 8:21–22. Farrell ’737 explains that

the cardiovascular and SDB information may be periodically remotely transferred to the physician or it may be accessed directly through displays on the device. In this way, a physician may keep up with and observe the changing cardiovascular condition of the patient with minimal direct oversight or intervention. Optionally, the device can be programmed with thresholds for comparison to the recorded cardiovascular information to trigger an alarm or send a message or generate a warning for the user, clinician or physician either directly on the device, or remotely, for example, over a secure electronic network to a database.

Ex. 1008, 10:18–25 (emphasis added). The device in Farrell ’737 records SDB and scores AHI events in conjunction with cardiovascular information

that is then periodically remotely transferred to the physician or alternatively can be directly accessed on the device.

Based on these disclosures in Kocinski and Farrell '737, Petitioner has demonstrated by a preponderance of the evidence that AHI is a measure of symptom data and that the combination of references supports the transmission/communication of symptom data to a remote site. We are not persuaded by Patent Owner's contention that the combination does not teach or suggest transmitting symptom data to a remote internet site. PO Resp. 35–37.

3. Element 15.g.2 – display of symptom data

Petitioner asserts that Kocinski's "base station (or PDA's cell connection) retransmits symptom data, index, and usage data to the third parties . . . [And t]hose third parties are accessed over an 'Internet Connection 16' (Figure 1) and therefore are understood to be remote internet sites." Pet. 74 (citing Ex. 1008 ¶¶ 28, 31, 45, 49); *see above* II.D.a.1 (Kocinski's Figure 1). Petitioner contends that

Kocinski displays patient-specific data (e.g., Figure 10), and to the extent Figure 10 does not explicitly display the calculated symptom data and/or index (or 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. Pet. 74 (citing Ex. 1008 ¶¶ 35–39, 49, Figure 12; Ex. 1004 ¶ 149).

Kocinski's Figure 10 is reproduced below:

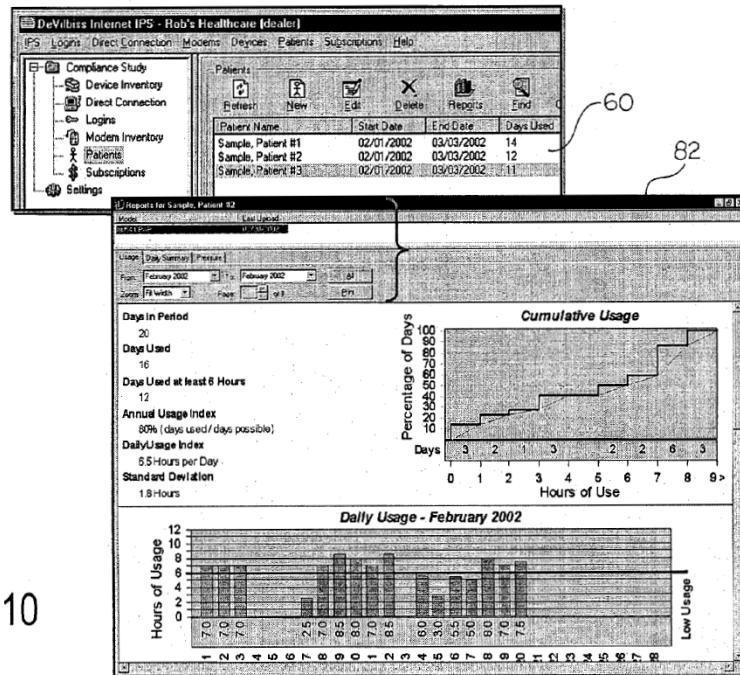


FIG. 10

Figure 10, shown above, "is an image of the 'Patient' window of the internet processing system and a report accessible by authorized users by clicking a 'Report' button in the 'Patient' window." Ex. 1010 ¶ 21.

Kocinski teaches that "[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." Ex. 1012 ¶ 35.

After the initial call to the central database server 15, the modem 12 can automatically call in data to the center database server 15 at certain time intervals, as indicated in function step 42. During the call, data will be immediately transferred from the CPAP apparatus 11 to the central database server 15, which stores and analyzes usage compliance data. . . . Authorized users will get reports, such as the report 82 as illustrated in FIG. 10. Reports can be viewed by selecting a patient from the "Patient" window 60. This is accomplished by highlighting the patient and

then clicking the “Reports” button. To view the patient's compliance data, the viewer can scroll through and select a period, such as a month, or select all and print a graph. Reports will vary depending on the model of the CPAP apparatus 11. The patient's name will appear in the title bar of the window. Tabs can be used to move between reports.

Ex. 1012 ¶ 45. “Authorized users and viewers can be entered, as indicated in function step 26, through a ‘Login’ window 52, . . . A user who is authorized to view reports has read only access. Such a user can only view and print patient, device, modem, and compliance information. . . . Linking to patients will occur during patient set up. Existing user rights can be opened and edited as desired.” Ex. 1012 ¶ 39. Here, Kocinski provides that information is collected and transmitted from the CPAP machine found in the patient's home. The collected data includes information about compliance and other parametric data that can be displayed on a monitor for an authorized user to view. Thus, Kocinski teaches displaying parametric data (i.e. symptom data) to users that are accessing the information from a central database.

Contrary to Patent Owner's suggestion (*see* PO Resp. 34–39), Petitioner does not rely solely on Kocinski for arriving at the conclusion that it would have been obvious to display symptom data or the index of symptom data to a display accessible to “the patient, patient's family, and visiting medical professionals to see the patient's data on-site.” Pet. 74. Petitioner explains that Farrell '737 shows a hand-held display and control device that “would have given Kocinski's patient the advantage of viewing information without leaving bed, and allowed family and visiting medical professionals to see, more conveniently, the patient's data on-site.” Pet. 71 (citing Ex. 1008, Figure 1, 5:28–31 (“The 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. 1012 ¶ 39); Ex. 1008, 6:23–25 (“[T]he apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication or it may interface with a network for transmission between the devices.”). Because Farrell ’737 can transmit the information via a network to a hand-held device and even allows for communication between devices, we conclude that multiple devices may have access to the same information so that not only the doctor can access the information remotely but the patient can view the same results at home.

Based on these disclosures in Kocinski and Farrell ’737, Petitioner has demonstrated by a preponderance of the evidence that the combination of references teaches the display of symptom data, including making this data available to the patient. We are not persuaded by Patent Owner’s contention that references do not teach or suggest displaying symptom data to a patient.

4. Unexpected results

Patent Owner contends that displaying symptom data to the patient has the unexpected effect of increasing patient compliance:

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.

PO Resp. 38 (citing Ex. 2017 ¶¶ 77–78; *Forest Labs., LLC v. Sigmapharm Labs. LLC*, 918 F.3d 928, 937 (Fed. Cir. 2019)). Patent Owner in its Sur-reply reiterated that ResMed’s CEO “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.” Sur-reply 23.

Petitioner’s response is that neither reference (Ex. 2010; 2011) cited in Patent Owner’s response says anything about increased compliance being surprising and unexpected. Reply 27. Petitioner additionally argues that Patent Owner fails to establish a nexus between the claims and the alleged unexpected results. The cited articles “simply credit the myAir app and AirView generally without mentioning which specific features increased compliance.” *Id.* at 28.

To begin, we observe that objective indicia of nonobviousness, such as unexpected results, are “only relevant to the obviousness inquiry ‘if there is a nexus between the claimed invention and the [objective indicia].’” *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). In a similar vein, “[i]t is well established that the objective evidence of nonobviousness must be commensurate in scope with the claims.” *In re Lindner*, 457 F.2d 506, 508 (CCPA 1972); *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (explaining that an applicant must provide an evidentiary basis to support the conclusion that other embodiments within the scope of the claims will behave the same and produce unexpected results). For objective indicia of non-obviousness to be accorded substantial weight, their proponent must establish a nexus between the evidence and the merits of the claimed invention. *ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016).

We have reviewed the references submitted by Patent Owner in support of their assertion of unexpected results. According to the references, “[c]ontinuous positive airway pressure has been shown in numerous studies to be effective in improving sleep apnea and preventing a host of co-morbidities such as obesity. . . . But the buy-in from patients is notoriously lacking.” Ex. 2011, 1.

According to designers specializing in patient behavior, the key to user adoption of connected devices is really not to give them an option. . . . Every Air Solutions device is cloud-connected out of the box. Data from the cloud can be seen the next morning by the patient or (with the patient’s permission) a doctor, enabling the monitoring and support of patients without an office visit. Ex. 2011, 3; Ex. 2010, 5 (“Patients using the myAir software platform significantly improve their adherence to sleep therapy”).

[D]evice developers often talk about three-legged stools when discussing what makes a product successful: Cost, outcomes and loyalty. The decisions ResMed made on how to best collect, store and share data with patients and caregivers led to better outcomes. And patients get immediate feedback from their device, including prompts to order new supplies or replace parts and assessments of sleep improvement. All that helps build loyalty. Ex. 2011, 3–4.

After carefully reviewing the references proffered by Patent Owner, we agree with Petitioner that Patent Owner has not established a nexus between the claims and the alleged unexpected results. Patent Owner asserts that the references credit the AirView and myAir platforms with improving compliance. *See* PO Resp. 38. What is missing from Patent Owner’s assertion, however, is a showing that the AirView and myAir platforms practice the challenged claims, including the relevant limitation of “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."

5. *Additionally, we agree with Petitioner that Patent Owner "is incorrect that ResMed's CEO credited displaying symptom data to patients as increasing compliance" over prior systems. Reply 28. Instead, "these articles simply credit the myAir app and AirView generally without mentioning which specific features increased compliance." Id. The references support the position that it is not a single thing that is responsible for the increased compliance with the device but instead it is a combination of factors that result in the products' success in this regard. Therefore, after considering all the evidence before us, we conclude that Patent Owner has not provided sufficient evidence to demonstrate unexpected results.*
Summary

In sum, we determine that Petitioner has demonstrated by a preponderance of evidence that claim 15 would have been obvious at the time the invention was made over Kocinski, Farrell '737, and Bluetooth.

We adopt Petitioner's reasoning with respect to claims 16–20 as our own. Specifically, Petitioner relies on the combination of Kocinski, Farrell '737, and Bluetooth to challenge claims 16, 18, and 19. Pet. 4, 75–77. Petitioner relies on the same references in conjunction with Guillemineault-2004 and Westbrook to challenge claim 17. *Id.* at 4, 78. Petitioner relies on the same references in conjunction with Paradiso to challenge claim 20. *Id.* at 4, 79. Based on the undisputed arguments and evidence presented in the Petition, Petitioner has demonstrated by a preponderance of the evidence that claims 16–20 are unpatentable as obvious.

E. *Grounds Based on Stahmann '029 (Ex. 1010) and Edgar (Ex. 1011)*

a) *Prior Art*

We begin with a review of the relevant references and then address the parties' contentions.

1. *Overview of Stahmann '029 (Ex. 1010)*

Stahmann '029 discloses methods and systems for patient monitoring, diagnosis and therapy. Ex. 1010⁷, 1:6–7. Stahmann '029 discloses embodiments that include a disordered breathing discrimination system comprising a disordered breathing detector configured to detect a disordered breathing event, a motion sensor configured to sense motion associated with respiratory effort of a patient during the disordered breathing event, and a disordered breathing classification processor coupled to the motion sensor and the disordered breathing detector. *Id.* at 4:5–10.

Stahmann '029 discloses embodiments that include an implantable device and a patient-external respiratory therapy device configured to operate cooperatively to adapt a therapy for disordered breathing. *Id.* at 4:29–31. Stahmann '029 also discloses embodiments that are directed to sensing, detection, and treatment of snoring using an at least partially implantable device. *Id.* at 17:3–6. Snoring information is useful in disordered breathing detection, verification, and/or prediction, such as for detecting or predicting apnea events. *Id.*

Stahmann '029 discloses a sensor may be configured to detect disordered breathing, and in response to detecting disordered breathing, gas

⁷ In this decision we reference the native page numbers of Stahmann '029 and not the Bates numbers of the exhibit.

therapy may be modified (e.g., initiated, modified, terminated) to suppress the disordered breathing. *Id.* at 22:25–31. In addition, the type of disordered breathing may be discerned, such as discerning central apnea from obstructive apnea. *Id.* If, for example, central apnea is detected, small amounts of carbon dioxide may be applied to the patient’s air supply (e.g., via a positive airway pressure device) to mitigate the carbon dioxide instability that is leading to central apnea. *Id.*

2. Overview of Edgar (Ex. 1011)

Edgar discloses administering doxepin analogs compounds to modulate sleep. Ex. 1011 ¶ 7. Edgar discloses in one embodiment the doxepin analogs are used to treat a *sleep apnea disorder*. *Id.* ¶¶ 32, 36.

a) Petitioner’s Contentions

Petitioner contends that the combination of Stahmann ’029 and Edgar teaches all the limitations of claim 8. Pet. 49–59. Petitioner contends that Stahmann ’029 teaches a sleep disorder treatment system including a CPAP device that contains all the elements of claim 8 including applying drug therapy. Pet. 50–57. More specifically, Petitioner contends that Stahmann ’029 Figure 53 teaches a “device 5340 [that] is generically described as a ‘sleep disordered breathing therapy device.’” *Id.* at 50, 52. Petitioner contends that Stahmann ’029 “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.* at 55. Petitioner acknowledges that “Stahmann does not limit the type of drug therapy [as claimed], but Edgar teaches a system for providing a pharmaceutical compound, e.g., ‘doxepin analog compounds ... or a pharmaceutically

effective salt thereof” (Abstract), to a patient via their CPAP device.”
Pet. 56.

b) Patent Owner’s Contentions

Patent Owner opposes. PO Resp. 27–32. According to Patent Owner, “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.***” *Id.* at 27 (quoting claim 8).

Patent Owner contends that “[r]ather 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.” *Id.* at 29 (citing Ex. 1010, 22:29–31, 309:25–27; Ex. 2018 ¶ 27). Patent Owner contends that “single apnea events are not a level of severity of the subject’s sleep disorder.” *Id.* Patent Owner explains that “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.” *Id.* at 29–30. “Edgar also does not disclose a controller for adjusting a pharmaceutical agent based on the level of severity of the patient’s symptoms.” *Id.* at 30. “Edgar’s treatment is unrelated to ‘the output of the level of severity of the subject’s sleep disorder.’” *Id.* at 32. “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.” *Id.* (citing Ex. 2017 ¶ 67; Ex. 2018 ¶¶ 30–31).

Patent Owner contends that claim 8 “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.” PO Resp. 30 (citing Ex. 2017 ¶ 62; Ex. 2018 ¶¶ 27–29). Patent Owner contends that neither Stahmann ’029 nor Edgar teaches adjusting a pharmaceutical agent based on the level of severity, therefore, the combination does not render the claims obvious.

c) Petitioner’s Reply

Petitioner disagrees and finds that Stahmann ’029 adjusts therapy based on “apnea/hypopnea index (AHI) . . . among other indices.” Reply 18–19 (citing Ex. 1010, Figures 54A–54F). Petitioner contends that the parties do not dispute that AHI is a level of severity, and Patent Owner’s medical expert, Dr. Patil, agrees that “Stahmann discloses adjusting breathing therapy based on AHI.” Reply 20 (quoting Ex. 2018 ¶ 28, which in turn cites Ex. 1010 at 232). “Stahmann discloses use of a pharmaceutical agent, e.g., via a nebulizer. . . . Stahmann explicitly discloses that nebulizers can be used to treat sleep disordered breathing alone or in combination with PAP devices.” Reply 21 (citing Ex. 1010, 222:21–23 (“External breathing therapy may be delivered by various types of patient-external respiratory therapy devices, including, for example, nebulizers, respirators, ventilators, external gas therapy devices and/or positive airway pressure devices.”)).

Petitioner contends that “Edgar discloses much more, including administering Doxepin to promote and improve sleep. . . . [And] lack of sleep is a symptom of sleep disorders. Moreover, Doxepin is FDA-approved to treat insomnia, which is a sleeping disorder.” Reply 21–22.

d) Patent Owner's Sur-reply

Patent Owner contends that in the system depicted in Figure 53 of Stahmann '029 “there is no drug delivery therapy used, let alone one combined with AHI.” Sur-reply 15. “[T]he only therapy adjusted [in Stahmann '029] using AHI is ‘breathing therapy pressure,’ not drug therapy.” *Id.* at 16. “[T]he 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.” *Id.* “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.” *Id.* at 19.

e) Analysis

Patent Owner challenges Petitioner’s assertions only as to claim element 8b. *See* PO Resp. 27–33, 39–40. Claim element 8b reads as follows: “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.” Ex. 1001, 25:27–31.

The unchallenged elements will not be discussed, nor will claims that have not been separately argued by Patent Owner. *See* PO Resp. 27–33, 39–40. With respect to the unchallenged elements and claims, we adopt Petitioner’s reasoning. *See* Pet. 49–57; Reply 18–23. Based upon our review of the arguments and evidence, we find that Petitioner has shown by a preponderance of the evidence that the combination of Stahmann '029 and Edgar teaches a sleep disorder treatment system as recited in claim 8. Pet. 49–57.

1. *Element 8b – adjusting the pharmaceutical agent*

Figure 53 of Stahmann '029, reproduced below, teaches a monitoring device that can also apply therapy.

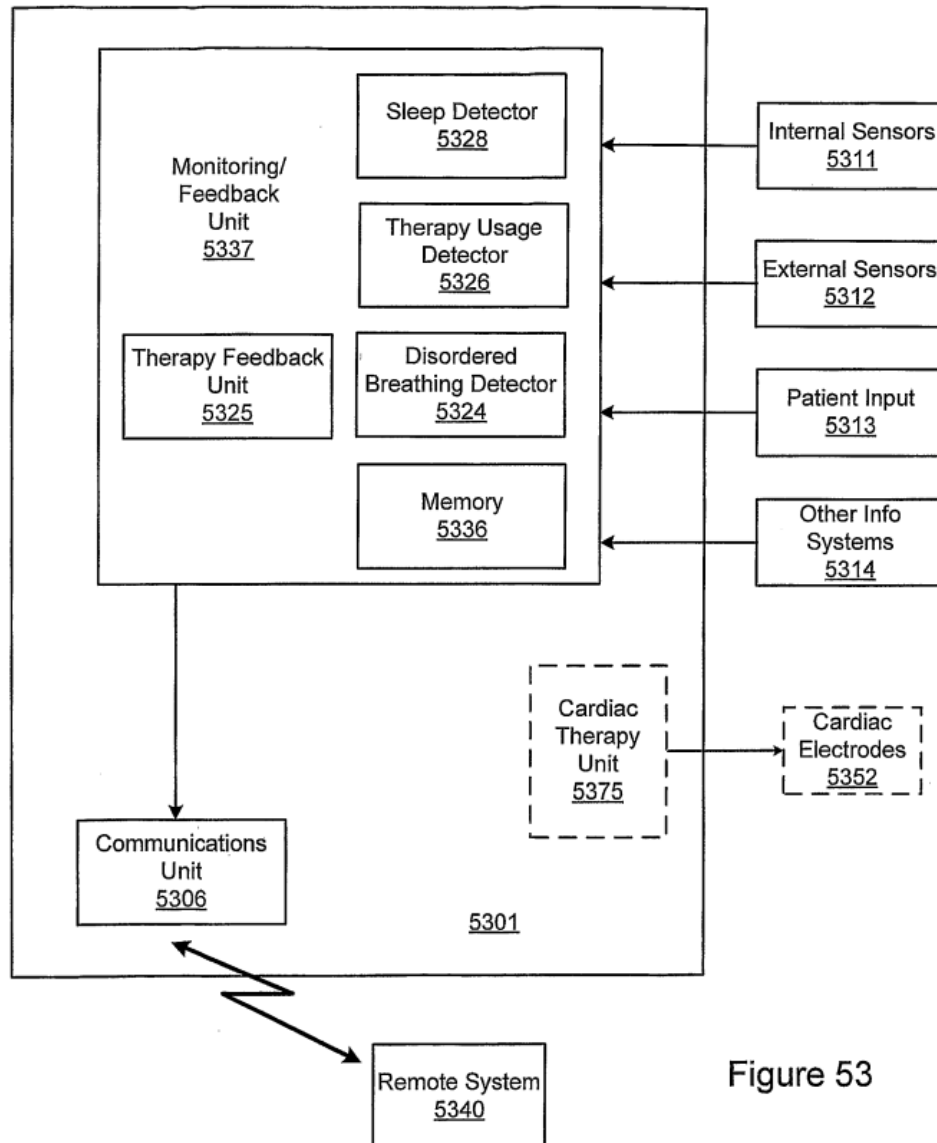


Figure 53

Figure 53 above shows “a block diagram of an implantable medical device including a cardiac therapy pulse generator that may be used to monitor patient conditions.” Ex. 1010, 32:9–10; Pet. 50–51. The device “may be used to monitor patient conditions and to develop feedback information *for a device delivering sleep disordered breathing therapy.*” Ex. 1010, 236:16–19

(emphasis added). “Drug 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 drug pump, a *controllable nebulizer*, or an electrically activated drug patch, for example.” Ex. 1010, 236:12–15 (emphasis added). “The monitoring circuitry 53[3]7 communicates with a therapy feedback unit 5325 that develops feedback information based on the monitored conditions, the detected events, and/or the calculated indices.” *Id.* at 237:5–8.

The therapy feedback unit in Stahmann ’029 applies sequential steps as shown in flow charts of Figures 54A–54F. Pet. 54 (“adjusts therapy based on ‘apnea/hypopnea index (AHI) ... among other indices’”) (quoting Ex. 1010, 241:31–242:9). The flow charts show the steps of assessing sleep disordered breathing events and adjusting therapy in accordance with the gathered information.

Figure 54C of Stahmann '029 is reproduced below:

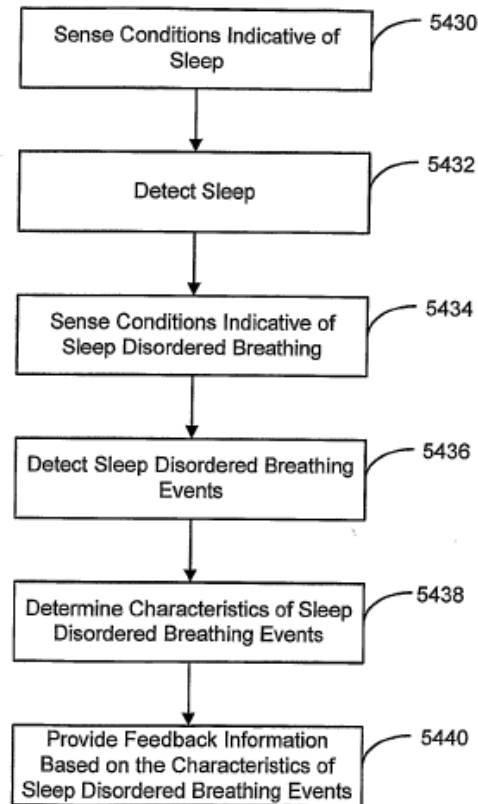


Figure 54C, reproduced above, shows a flow chart for detecting sleep disordered breathing events and providing feedback. Ex. 1010, 32:15–17, 238:12–15; Pet. 55. Specifically,

[t]he monitoring device senses 5430 one or more patient conditions associated with sleep. Sleep is detected 5432 based on the sleep-related conditions. The monitoring device senses 5434 one or more conditions associated with disordered breathing during sleep. One or more disordered breathing events occurring during sleep are detected 5436. Characteristics of the sleep disordered breathing events, such as, severity, frequency, and/or duration, may be determined 5438. Determination of the one or more characteristics of the sleep disordered breathing events may involve calculation of one or more indices characterizing the disordered breathing events. *The indices may include, for example, an apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB), among other indices.* Feedback

information is provided 5440 to a device delivering therapy for sleep disordered breathing based on the one or more characteristics of the sleep disordered breathing events.

Ex. 1010, 241:32–242:9 (emphasis added). According to Stahmann '029, “[e]pisodes of disordered breathing are associated with acute and chronic physiological effects. Acute responses to disordered breathing may include, for example, negative intrathoracic pressure, hypoxia, *arousal from sleep*, and increases in blood pressure and heart rate.” Ex. 1010, 67:2–5 (emphasis added). Thus, Stahmann '029 reasonably suggests detecting sleep events including apnea and arousal from sleep. *See* Pet. 51–52, 60 (“[S]leep threshold identifies arousals and waking”).

According to Stahmann '029, a gas therapy device may “provide a variety of respiration therapies, including, for example, *providing vasodilating or bronchodilator agents*, continuous positive airway pressure (CPAP), bi-level positive airway pressure (bi-level PAP), proportional positive airway pressure (PPAP), auto-titrating positive airway pressure, ventilation, oxygen, *carbon dioxide or other gas therapies*.” *Id.* at 310:14–18 (emphasis added). Stahmann '029 explains that if a “central apnea is detected, small amounts of carbon dioxide may be applied to the patient’s air supply (e.g., via a positive airway pressure device) to mitigate the carbon dioxide instability that is leading to central apnea.” *Id.* at 22:29–31, 309:25–27. Thus, Stahmann '029 reasonably suggests applying and adjusting therapy in response to the detection of a sleep disorder based on collecting feedback information that includes a combination of AHI and sleep arousal information to determine therapy effectiveness.

Figure 54F of Stahmann '029 is reproduced below:

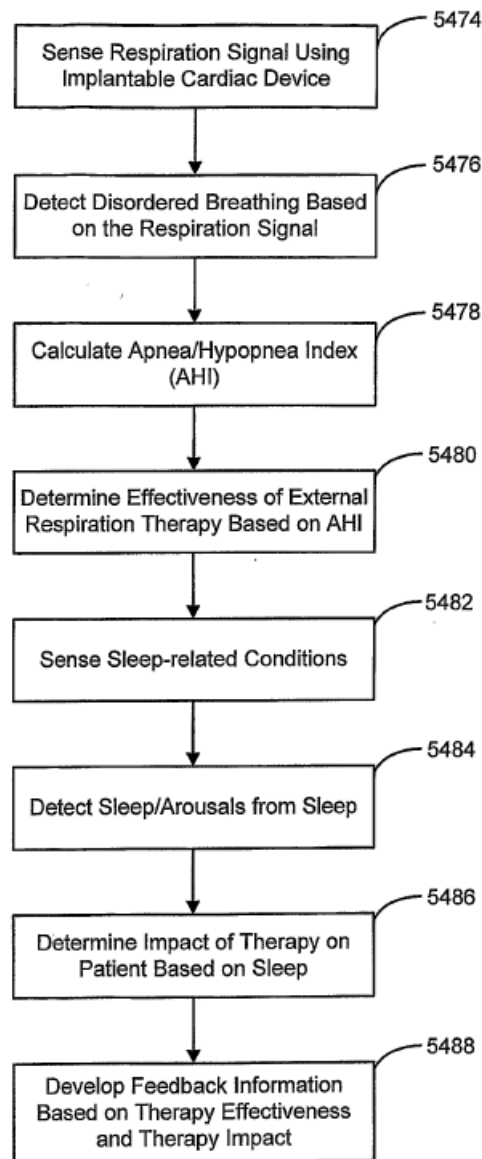


Figure 54F, reproduced above, illustrates a flow chart of a method for monitoring therapy delivered by a breathing therapy device. Ex. 1010, 243:31–33. Stahmann '029 in step 5480 of Figure 54F teaches “determin[ing] effectiveness of external respiration therapy based on AHI” and takes this measure into consideration in step 5488 to “develop feedback information based on therapy effectiveness and therapy impact.” Ex. 1010, Figure 54F. Stahmann '029 also suggests vasodilating or bronchodilator

agents can be applied in response to the detection of a sleep disorder; thus, Stahmann '029 teaches administering pharmaceutical agents. *Id.* at 310:14–18.

Figure 79 of Stahmann '029, reproduced below, teaches another monitoring device that can also apply therapy.

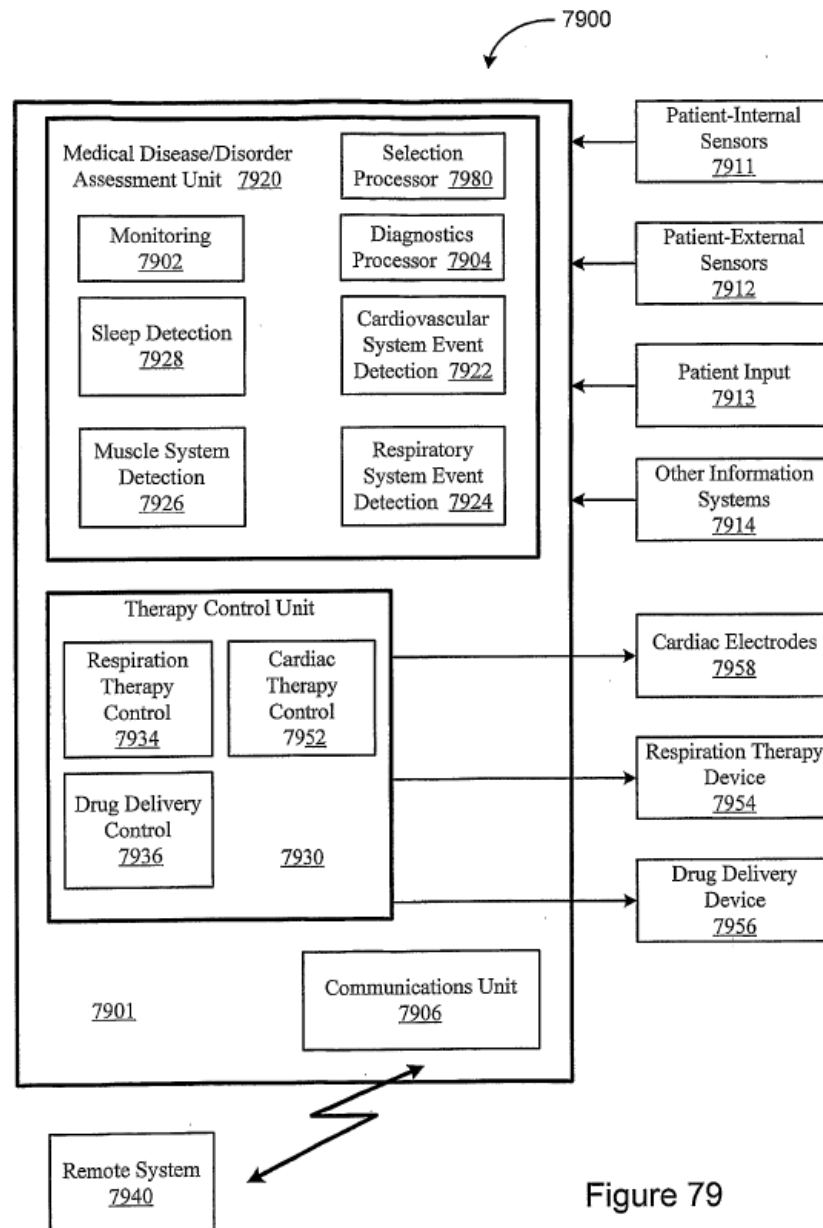


Figure 79

Figure 79, reproduced above, shows a “block diagram of an implantable medical device that may be utilized in connection with a medical

disease/disorder detection and/or monitoring system.” Ex. 1010, 34:24–25.
“Figure 79 provides an example of a coordinated monitoring, diagnosis and/or therapeutic system.” Ex. 1010, 318:4–5.

The medical device 7901 of Figure 79 includes a medical disease/disorder assessment unit 7920 that processes data collected from one or more of the patient-internal sensors 7911, patient-external sensors 7912, patient input devices 7913, information systems 7914, and/or data collected from the remote system 7940 to assess the presence of various medical diseases and/or disorders. . . . The event/condition detectors 7922, 7924, 7926, 7928 may be used to detect normal and/or abnormal physiological system events or conditions. . . . The respiratory system event detector 7924 may be used to detect events or conditions associated with various respiratory system disorders, such as a disordered breathing event or a pulmonary congestion condition. The respiratory system event/condition detector 7924 may also be used to detect the inspiratory and expiratory phases of normal respiration cycles, for example.

Ex. 1010, 318:15– 319:2. The medical device shown above in Figure 79 includes a therapy control unit. “The therapy control unit 7930 may also include respiration therapy control unit 7934 that provides control signals to a respiratory therapy device 7954 and a drug control unit 7936 that provides control signals to a drug delivery device 7956.” Ex. 1010, 320:10–13. The medical device shown in Figure 79 includes a sleep stage detector that can “detect sleep-related events, including, for example, sleep onset, sleep offset, sleep stages, and *arousals from sleep*.” Ex. 1010, 319:13–14 (emphasis added). Thus, Stahmann ’029 reasonably suggests detecting sleep events including arousal from sleep and supplying medicines.

Edgar teaches “doxepin analogs compounds and their use to modulate sleep.” Ex. 1011 ¶ 7. Specifically, Edgar’s list of potential uses of the doxepin analogs including using the drug to treat a *sleep apnea disorder*. See

id. ¶¶ 32–38. Edgar teaches that the doxepin analog compounds, which are sleep-inducing compounds, can also be administered via pulmonary administration and would allow patients to sleep more soundly. *See* Pet. 56–57 (citing Ex. 1011 ¶¶ 392–393, 407–409). Edgar discloses that doxepin analogs can be administered prior to the CPAP treatment, or the compound can be “administered at substantially the same time as the CPAP treatment. In one embodiment, parallel administration of an effective amount of the compound is accomplished by adding an additional aerosol channel to the air pressure treatment portion of the CPAP device.” Ex. 1011 ¶ 408.

Based on the disclosures in Stahmann ’029 and Edgar, we find that Petitioner has shown by a preponderance of evidence that this combination of references suggests applying therapy in response to detecting the level of severity of a subject’s sleep disorder as manifested by detecting apnea resulting in the arousal or awakening of the patient from their sleep. *See* Pet. 49–59. *Awakening* is a symptom of apnea or hypopnea, which are sleep disorders. *See* Ex. 1004 ¶¶ 34–36. As stated in Westbrook:

Apnea is typically defined as a complete cessation of airflow. Hypopnea is typically defined as a reduction in airflow disproportionate to the amount of respiratory effort expended and/or insufficient to meet the individual’s metabolic needs. During an *apnea or hypopnea*, commonly referred to as a respiratory event, oxygen levels in the brain decrease, while the carbon dioxide (CO₂) levels rise, *causing the sleeper to awaken*.

Ex. 1007 ¶ 5 (emphasis added).

Treating a *symptom* of a sleep disorder, such as *arousal from sleep* due to apnea, meets the claim limitation of element 8b. Here, providing a chemical – doxepin – to reduce awakenings as taught in Edgar would reasonably result in the patient staying asleep, thereby treating a sleep

disorder symptom. Reply 22 (“[L]ack of sleep is a symptom of sleep disorders.”); Ex. 1011 ¶¶ 233, 407–409.

We are not persuaded by Patent Owner’s contention that Stahmann ’029 does not use a measure of a level of severity of the subject’s sleep disorder to treat a subject. Here, the parties agree that an apnea/hypopnea index (AHI) is a measure of the level of severity. Reply 20 (citing Ex. 2018 ¶ 28 (“Stahmann discloses adjusting breathing therapy based on AHI (Ex. 1010 at 232).”); Tr. 20:21–26 (Patent Owner “conceded that AHI is a level of severity”); Ex. 1003, 39 (“AHI is indeed an indicator of the level of severity of a patient’s sleep disordered breathing.”). Stahmann ’029 explains that the

[d]etermination of the one or more characteristics of the sleep disordered breathing events may involve calculation of one or more indices characterizing the disordered breathing events. The indices may include, for example, an apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB), among other indices. Feedback information is provided 5440 to a device delivering therapy for sleep disordered breathing based on the one or more characteristics of the sleep disordered breathing events.

Ex. 1010, 142:4–9. Thus, Stahmann ’029 explicitly states that the AHI is one of the calculated indices that can be used to determine whether sleep disordered breathing events are happening and that information in conjunction with other information such as arousal can be combined to adjust therapy. *See* Ex. 1010, Figure 54E. Claim element 8b recites that the pharmaceutical agent is adjusted “at least in part” using the severity of a subject’s sleep disorder (AHI). The claim, therefore, does not require that the therapy is adjusted solely based on AHI. Here, Stahmann ’029 teaches

collecting and processing information from multiple inputs, including AHI, to make adjustments to the therapy.

We are also not persuaded by Patent Owner's contention that "[i]n Stahmann, the only therapy adjusted using AHI is 'breathing therapy pressure,' not drug therapy." Sur-reply 16. Petitioner's asserted unpatentability ground is based on obviousness over the combination of Stahmann '029 and Edgar, not anticipation. Petitioner demonstrates by a preponderance of the evidence that the combination of these references teaches or suggests adjusting drug therapy. More specifically, Stahmann '029 teaches a device that "may be used to monitor patient conditions and to develop feedback information for a device delivering sleep disordered breathing therapy." Ex. 1010, 236:16–19. Stahmann '029 teaches that an apnea/hypopnea index (AHI) can be used determine sleep disordered breathing events. *Id.* at 241:32–242:9. Stahmann '029 teaches that disordered breathing events "are associated with acute and chronic physiological effects. Acute responses to disordered breathing may include . . . arousal from sleep, and increases in blood pressure and heart rate." *Id.* at 67:2–5; 319:13–14 ("The medical device shown in Figure 79 . . . includes a sleep stage detector that can 'detect sleep-related events, including, for example, sleep onset, sleep offset, sleep stages, and arousals from sleep.'"). Thus, Stahmann '029 reasonably suggests detecting sleep disordered breathing events including arousal from sleep.

Stahmann '029 also teaches that "[d]rug therapy may . . . be used to treat disordered breathing," and that the therapy can be administered via various routes. Ex. 1010, 236:12–15. In addition, Stahmann '029 also teaches that "[t]he feedback information may be used to adjust 5420 (Figure 54B) the sleep disordered breathing therapy." *Id.* at 242:18–19.

We agree with Petitioner that Stahmann '029 reasonably teaches a system that administers drugs and treats a breathing disorder with a drug (the claimed “pharmaceutical agent”). Pet. 55–57. Petitioner acknowledges that “Stahmann does not limit the type of drug therapy” and looks to Edgar for reciting a sleep-promoting compound. Pet. 56. Petitioner demonstrates by a preponderance of the evidence that a “POSITA would have found it obvious, and expected success, by using Edgar’s pharmaceutical delivery in Stahmann’s adjustable-therapy PAP device. The motivation would have been to let patients ‘sleep better and more soundly’ . . . to accomplish Stahmann’s goal of improving patient’s sleep through therapy feedback.” Pet. 57 (citing Ex. 1011 ¶ 364).

Patent Owner contends that Examiner during prosecution of the '269 patent found that Stahmann did not disclose adjusting a pharmaceutical agent using the output of the level of severity. PO Resp. 30. This argument is not persuasive. The Examiner cited three different Stahmann references during prosecution (Stahmann references: U.S. Patent No. 7,757,690 B2 (Ex. 1020 (“Stahmann '690”)); U.S. Patent Publication No. 2005/0085738 A1 (“Stahmann '738”)); and U.S. Patent Publication No. 2005/0115561 A1 (Ex. 1019 (“Stahmann '561”)) *See* Ex. 1001, (56); Dec. 16. The Examiner applied only two of the Stahmann references in any rejection during prosecution – the '690 and '561 Stahmann references. The Stahmann '690 reference does not have the same disclosure as Stahmann '029. *Compare* Ex. 1010, *with* Ex. 1002, 283 (citing Stahmann U.S. Patent No. 7,757,690 B2 (Ex. 1020)). The Stahmann '561 reference was considered by Examiner only in the context of an anticipation rejection and did not address the issues presented in the context of this obviousness ground. Ex. 1003, 174, 117 (citing Stahmann U.S. Patent Application No. 2005/0115561 (Ex. 1019)).

The Examiner's analysis, therefore, says nothing about the applicability of Stahmann '029 in the context of an obviousness ground. The Stahmann '738 reference was cited by the Examiner on a form but was not otherwise discussed during prosecution. *See* Ex. 1003, 180, *see also id.* at 178 ("The other patents cited in the PTO-892 teach subject matter related to Applicant's claims" but were not otherwise discussed during prosecution).

We are also not persuaded by Patent Owner's contention "that neither Stahmann '029 nor Edgar teach adjusting a pharmaceutical agent based on the level of severity." PO Resp. 30. Patent Owner argues that Dr. Patil's testimony "further confirms that Edgar's Doxepin would not be used in the treatment of sleep-related breathing disorders as claimed." Sur-reply 17. As addressed above in section II.A.e.3, we agree with Petitioner that Dr. Patil, a medical doctor, "does not fit the POSITA definition because he does not have an engineering degree." Reply 8.

Here, Patent Owner relies on the testimony of Dr. Patil to support the position that Edgar's doxepin "would not be used in the treatment of the sleep-related breathing based on AHI." Sur-reply 19. According to Dr. Patil, Edgar teaches that "doxepin could be administered to improve the likelihood that the patient kept the mask on all night. . . . 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 ¶ 31 (citing Ex. 1011 ¶¶ 406–408); Sur-reply 19. We are not persuaded by Dr. Patil's position that "the treatment [in Stahmann '029 or Edgar] for the patient's sleep disorder or symptoms was [only] the positive pressure provided by the CPAP, not the doxepin." Ex. 2018 ¶ 31.

Edgar explains that "by administering an effective amount of a sleep promoting compound of the invention [doxepin] to a patient in conjunction

with CPAP treatment, the patient will sleep better and more soundly and therefore, not be as likely to remove the mask.” Ex. 1011 ¶¶ 407, 437 (“Sleep quality can be associated with sleep continuity or sleep maintenance. For example, a subject with sleep apnea wakes up numerous times during a sleep period, e.g., the subject has difficulty maintaining continuous sleep.”). By not removing the mask, Edgar’s patient will derive greater benefit from the CPAP treatment, but it is the combination of both drug and CPAP treatment that improves the quality of the patient’s sleep in Edgar.

We disagree with Patent Owner’s position that detecting arousal from sleep as suggested by Stahmann ’029 and giving a sleep medication as suggested by Edgar so that the patient does not wake up would not reasonably support the claimed limitation of chemically treating a subject’s “sleep disorder *or symptoms* with a pharmaceutical agent” as recited in claim 8b. Ex. 1011 ¶ 407 (“[B]y administering an effective amount of a sleep promoting compound of the invention to a patient in conjunction with CPAP treatment, the patient will sleep better and more soundly and therefore, not be as likely to remove the mask.”).

Stahmann ’029 explains that awakening is a symptom of a sleep disorder that can be detected based on disordered breathing events which are determined using various indices including apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB). Ex. 1010, 241:32–242:9; *see* Ex. 1011 ¶ 437. In Stahmann ’029, “[f]eedback information is provided 5440 to a device delivering therapy for sleep disordered breathing based on the one or more characteristics of the sleep disordered breathing events.” Ex. 1010, 241:32–242:9.

Stahmann ’029 teaches 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 drug pump, a controllable nebulizer, or an electrically activated drug patch, for example.” Ex. 1010, 236:12–15. Thus, Stahmann ’029 clearly suggests applying drug therapy for the treatment of disordered breathing. Stahmann ’029 also recognizes that arousal from sleep is a symptom of a disordered breathing event. *See* Ex. 1010, 67:2–5, 241:32–242:9; Ex. 1011 ¶ 437. We, therefore, are not persuaded by Patent Owner’s contention that including a pharmaceutical agent that can promote sleep would not also reasonably treat a symptom of sleep disorder – *awakening* – due to a detected disordered breathing event.

We recognize but are not persuaded by Patent Owner’s contention that “doxepin could be administered to improve the likelihood that the patient kept the mask on all night” but “it would not be used in the treatment of the sleep-related breathing based on AHI.” Sur-reply 19 (citing Ex. 1011 ¶¶ 407–409; Ex. 2018 ¶ 31); Tr. 23:1–18 (“If you gave doxepin to a patient that had a breathing irregularity, and you gave that every time during the middle of the night as they’re having trouble breathing, you may kill the patient with doxepin.”).

Stahmann ’029 does not suggest that therapy is applied with every single detected disordered breathing event. Stahmann ’029 describes monitoring sleep disordered breathing by using *one or more indices*, such as apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB) in order to determine whether there is disordered breathing, and to calculate an index requires observation of breathing episodes over time. Ex. 1010, 241:32–242:9, 231:24–26 (“the monitoring device may calculate 5256 an apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB) indicative of the frequency of disordered breathing

episodes.”). Stahmann ’029 also teaches that “disordered breathing may include . . . arousal from sleep, and increases in blood pressure and heart rate.” Ex. 1010, 67:2–5. Stahmann ’029 describes that

[t]he therapy effectiveness and impact information may be transmitted 5268 to the CPAP device and/or an APM server. The information may be used to automatically or manually adjust the therapy delivered to the patient. For example, if the AHI is high, the breathing therapy pressure may be adjusted upward to provide a more effective therapy. If the patient experiences an arousal rate, e.g., A/h [arousal experienced by patient per hour], greater than a threshold without experiencing sleep disordered breathing episodes, the therapy may be determined to be too aggressive. The breathing therapy pressure may be adjusted downward to provide a disordered breathing therapy that is more comfortable to the patient and allows the patient to sleep with fewer interruptions.

Ex. 1010, 232:12–20. Thus, Stahmann ’029 reasonably suggests evaluating the effectiveness of therapy and making adjustments to therapy based on a combination of factors including detecting arousal from sleep in conjunction with AHI or other indices. Ex. 1010, 67:2–5; 319:13–14, Figure 54F.

Stahmann ’029 teaches a device that includes a therapy control unit. “The therapy control unit 7930 may also include respiration therapy control unit 7934 that provides control signals to a respiratory therapy device 7954 and a drug control unit 7936 that provides control signals to a drug delivery device 7956.” Ex. 1010, 320:10–13. The medical device of Stahmann ’029 includes a sleep stage detector that can “detect sleep-related events, including, for example, sleep onset, sleep offset, sleep stages, and *arousals from sleep*.” Ex. 1010, 319:13–14 (emphasis added), Figure 79. Thus, Stahmann ’029 reasonably suggests detecting sleep events including arousal from sleep and supplying medicines, indicating that the device disclosed in Stahmann ’029 can perform the function as recited in element 8b.

2. *Summary*

We determine that Petitioner has demonstrated by a preponderance of the evidence that claim 8 would have been obvious over Stahmann '029 and Edgar.

We adopt Petitioner's reasoning with respect to claims 9–14 as our own. Specifically, Petitioner relies on the combination of Stahmann '029 and Edgar to challenge claims 9–11, and 13. Pet. 3, 58–59. Petitioner relies on the same references in conjunction with Schmidt to challenge claim 12. *Id.* at 3, 60–61. Petitioner relies on the same references in conjunction with Paradiso to challenge claim 14. *Id.* at 4, 61. Based on the undisputed arguments and evidence presented in the Petition, Petitioner has demonstrated by a preponderance of the evidence that claims 9–14 are unpatentable as obvious.

F. *Motion to Exclude*

The party moving to exclude evidence bears the burden of proof to establish that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence (“FRE”). *See* 37 C.F.R. §§ 42.20(c), 42.62(a). Here, Patent Owner moves to exclude the testimony of Petitioner's expert Dr. Sharony (Exhibit 1004). Mot. 1. Patent Owner contends that under FRE 702 a witness must be “qualified in the pertinent art” to testify as an expert concerning an obviousness challenge. Mot. 1 (quoting *HVLPO2, LLC v. Oxygen Frog, LLC*, 949 F.3d 685, 689 (Fed. Cir. 2020)). Patent Owner contends that “Dr. Sharony does not qualify as a person of ordinary skill in the art (“POSITA”) or a medical expert in this matter.” Mot. 1. Patent Owner contends that the Board should exclude Dr. Sharony's entire Declaration, or at the very least

should exclude paragraphs 120–128 of Dr. Sharony’s Declaration. Mot. 4. Patent Owner contends that Dr. Sharony does not meet the standard of a POSITA because he has no experience working with diagnostic sensors. Mot. 2; PO Reply Opp. 2.

Petitioner contends that the Motion should be denied as untimely because Patent Owner did not file an objection on this basis in compliance with the Board’s procedures. *See* Opp. 2–3. Patent Owner opposes and contends that it timely filed the objections to certain evidence within the requisite time frame. PO Reply Opp. 2; Paper 25, 1–2 (objecting to Dr. Sharony’s testimony). Our rules provide that “[a]ny objection to evidence submitted during a preliminary proceeding must be filed within ten business days of the institution of the trial.” 37 C.F.R. § 42.64(b)(1); CTPG⁸ 78–79. The Institution Decision mailed May 6, 2024 and Patent Owner filed its objections on May 17, 2024. *See* Paper 23, 25. Here, the objection was filed within 9 business days from the institution of the trial. Therefore, we agree with Patent Owner that the objections were timely filed.

In its Opposition, Petitioner reiterates that Dr. Sharony has “extensive education and 35+ years of professional experience including ‘experience working with diagnostic sensor systems.’” Opp. 3 (citing Ex. 1004 ¶¶ 11–14). The definition of a POSITA as agreed upon by both parties recites that “[a]n increase in experience could compensate for less education, and vice-versa.” Opp. 5 (citing Pet. 24; PO Resp. 8); *see above* II.A.e. Petitioner contends that “Dr. Sharony’s experience with physiological sensors used in diagnostic sensor systems for sensing blood oxygen

⁸ Consolidated Trial Practice Guide (Nov. 2019), available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf> (“CTPG”).

saturation, blood vessels volume, vital signs, human activity, heart rate, and pulse is directly relevant to the claims of the '269 patent.” Opp. 4 (citing Ex. 1004 ¶¶ 10, 14, 16).

As discussed above in section II.A.e, the agreed upon definition by the parties of a POSITA does not include a requirement that the POSITA have specific experience with CPAP machines. For the reasons discussed above in section II.A.e.1, we find that Dr. Sharony is qualified as a POSITA in the pertinent art to provide reliable testimony with respect to the technology at issue in the present IPR. Accordingly, Patent Owner’s motion to exclude is denied.

Patent Owner additionally requested that we at least exclude paragraphs 120–128 of Dr. Sharony’s Declaration (Ex. 1004). Mot. 4. Because our Final Written Decision does not rely on paragraphs 120–128 of Exhibit 1004, Patent Owner’s motion to exclude those paragraphs is moot.

III. CONCLUSION

Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–20 of the '269 patent are unpatentable on the bases set forth in the following table.

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–3, 5, 7	103	Genger, Schmidt, Westbrook Farrell '737	1–3, 5, 7	
4, 6	103	Genger, Schmidt, Westbrook, Farrell '737, Paradiso	4, 6	
8–11, 13	103	Stahmann '029, Edgar	8–11, 13	
12	103	Stahmann '029, Edgar, Schmidt	12	
14	103	Stahmann '029, Edgar, Paradiso	14	
15, 16, 18, 19	103	Kocinski, Farrell '737, Bluetooth	15, 16, 18, 19	
17	103	Kocinski, Farrell '737, Bluetooth, Guilleminault- 2004, Westbrook	17	
20	103	Kocinski, Farrell '737, Bluetooth, Paradiso	20	
Overall Outcome			1–20	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–20 of the '269 patent are determined to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is denied; and

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

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FOR PETITIONER:

Tiffany Miller
Edward Sikorski
James Heintz
DLA PIPER LLP (US)
tiffany.miller@dlapiper.com
ed.sikorski@dlapiper.com
jim.heintz@dlapiper.com

FOR PATENT OWNER:

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