

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*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

ResMed Corp. (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–20 (“the challenged claims”) of U.S. Patent No. 10,076,269 B1 (Ex. 1001, “the ’269 patent”). Paper 1 (“Pet.”). Cleveland Medical Devices Inc. (“Patent Owner”) filed a Patent Owner Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”). Petitioner filed an authorized Reply to the Preliminary Response (Paper 11, “Reply”), and Patent Owner filed a corresponding Sur-reply (Paper 12, “Sur-reply”). On September 25, 2023, we issued a decision denying institution. Paper 13.

Our discretionary denial of the Petition under *Apple Inc. v. Fintiv Inc.*, IPR2020-00019, Paper 11 at 5–6, 8 (PTAB March 20, 2020) (precedential) (“*Fintiv*”) was vacated by the Director, who also authorized Petitioner to file a supplemental brief and Patent Owner to file a supplemental response, and remanded to the Board for reevaluation of the institution decision in light of all pre-institution papers. Paper 15; Ex. 3100; Paper 18 (Supplemental Brief); Paper 21 (Supplemental Response). In our order dated December 18, 2023, we authorized the parties to file additional exhibits and authorized Petitioner to file a response to Patent Owner’s supplemental response. Paper 20 at 4; Paper 22.

Considering the totality of the arguments and evidence of record anew, we determine that the Petition demonstrates “a reasonable likelihood that [P]etitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Accordingly, we institute an *inter partes* review.

A. *Real Parties in Interest*

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

B. *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). Pet. 1; Paper 4 at 1.

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

The '269 patent is titled “Devices and Methods for Sleep Disorder Diagnosis and Treatment.” *Id.* at (54). The '269 patent relates to devices and methods for sleep apnea diagnosis and treatment. *Id.* at (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.

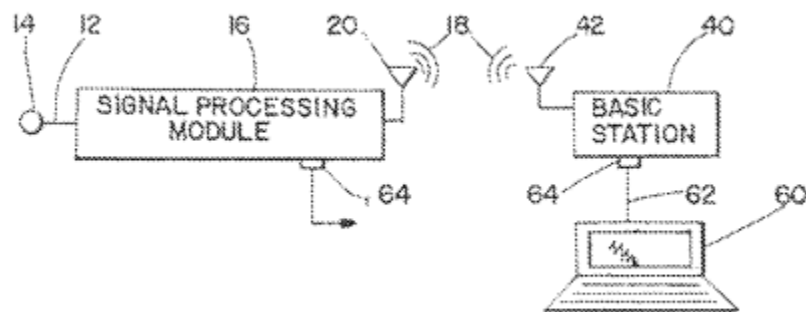


Fig. 1

Figure 1 shows a part of the diagnostic device of a sleeping disorder treatment system of the present invention depicting wireless transfer of patient data. *See id.* 4:65–67. 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 8:63–9:6.

Figure 8 is reproduced below.

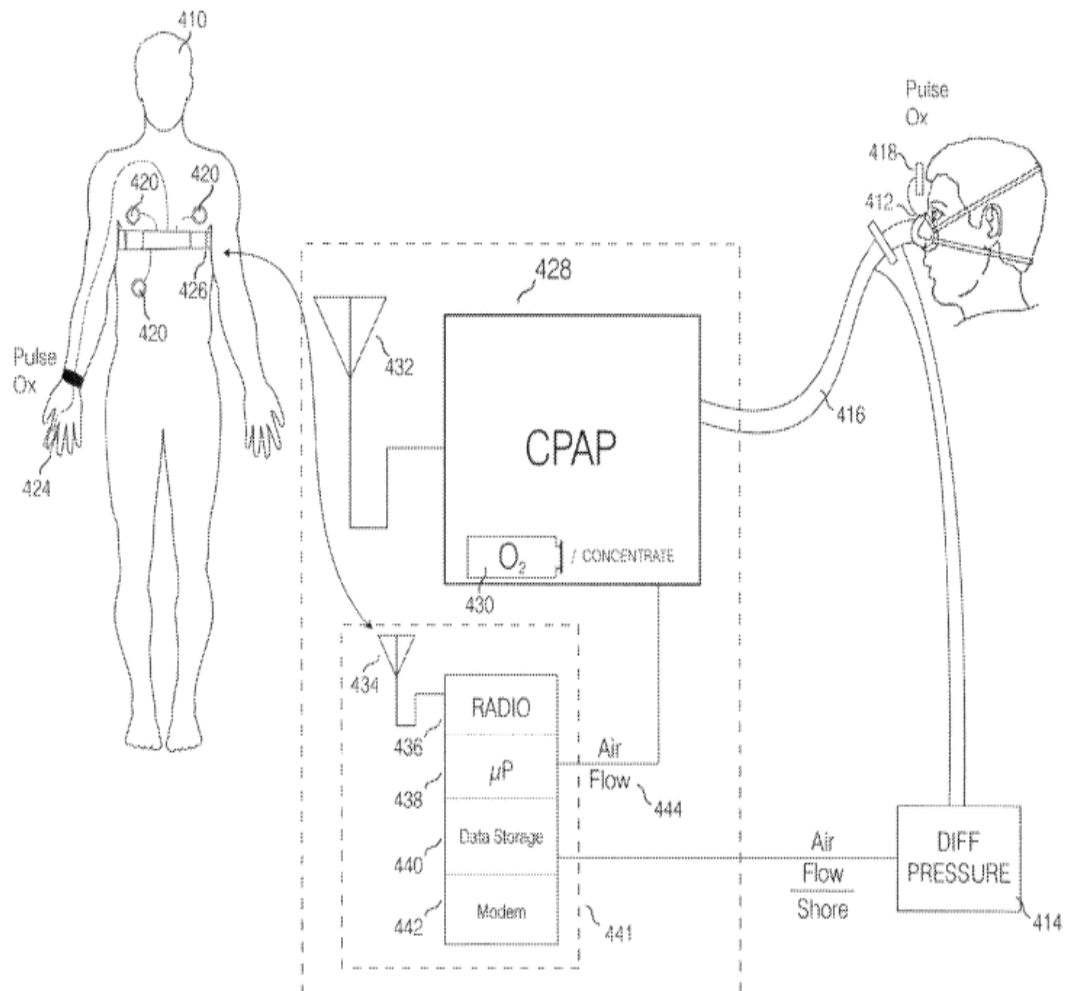


Fig. 8

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.

a) Illustrative Claims

Claims 1, 5, 8, and 15 are independent. Claims 1, 8, and 15 are illustrative of the claimed subject matter of the '269 patent and are reproduced below:

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.

Ex. 1001, 23:51–24:13 (bracketing and formatting added for reference convenience).

2. *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 added for reference convenience).

3. *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 added for reference convenience).

D. *Prior Art*

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

Reference	Date	Exhibit No.
Genger et al., WO 02/078775 A2 (“Genger”)	Oct. 10, 2002	1005
Schmidt et al., US Patent No. 6,167,258 (“Schmidt”)	Dec. 26, 2000	1006
Westbrook et al., US 2002/0165462 A1 (“Westbrook”)	Nov. 7, 2002	1007
Farrell et al., WO 2005/096737 A2 (“the ’737 Farrell”)	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”)	Apr. 24, 2003	1009
Stahmann et al., WO 2005/028029 A2 (“the ’029 Stahmann”)	Mar. 31, 2005	1010
Edgar et al., US 2005/0171160 A1 (“Edgar”)	Aug. 4, 2005	1011
Kocinski, US 2003/0236450 A1 (“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

E. *Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 1–20 of the ’269 patent on following grounds:

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

Pet. 3–4. In support of its patentability challenge, Petitioner relies on the Declaration of Jacob Sharony, Ph.D. (Ex. 1004).

II. ANALYSIS

A. *Discretionary Denial Under § 314(a)*

Patent Owner asks that we exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition based on the state of the related litigation. Prelim. Resp. 9–20; Sur-reply 4–9.

Petitioner now argues that it “no longer asserts in the district court invalidity of the '269 patent based on the challenges in this IPR.” Paper 18 at 1. Specifically, Petitioner states:

¹ 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.

Petitioner hereby provides a *Sotera* stipulation: if the Board institutes this IPR, Petitioner will not assert invalidity of the '269 patent in the parallel district court proceeding between the parties based on any ground that was raised or that reasonably could have been raised in this IPR. Providing this stipulation on remand after vacatur of the previous institution decision is proper as found by the Board upon remand of the *Vector Flow* decision vacated by Director Vidal. *Vector Flow, Inc. v. HID Global Corp.*, IPR2023-00353, Paper 15, at 8-9 (P.T.A.B. October 17, 2023). Petitioner respectfully submits that this stipulation disposes of the need for a *Fintiv* analysis because “the PTAB will not discretionarily deny institution of an IPR or PGR in view of parallel district court litigation” when a petitioner provides such a *Sotera* stipulation.

Paper 18 at 1–2. Petitioner contends “[t]hat *Sotera* stipulation streamlines these proceedings on remand and avoids the need for the Board to conduct a full analysis of the changed facts under *Fintiv*.” Paper 22, 4 (citing *BMW of No. Am., LLC v. Northstar Sys. LLC*, IPR2023-01017, Paper 12 at 10 (PTAB Dec. 8, 2023)).

Patent Owner contends that we should reject Petitioner’s “belated *Sotera* stipulation because it violates the Director’s order in *NXP*.” Paper 21 at 3 (citing *NXP USA v. Impinj, Inc.*, IPR2021-01556, Paper 13, 4 (PTAB Sept. 7, 2022) (precedential)). Patent Owner contends that “[t]he stipulation filed in this case was even later than the untimely stipulation filed in *NXP* and, therefore fails to comport with the precedential holding of that case.” *Id.* at 5.

Petitioner’s stipulation disposes of the *Fintiv* issue. The Director’s Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation² (“Interim Procedure”) directs that

² *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation*, available at

“the PTAB will not discretionarily deny institution of an IPR or PGR in view of parallel district court litigation where a petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition.” Interim Procedure 7.

Patent Owner’s reliance on *NXP* is misplaced. Paper 21 at 4. According to Patent Owner, “[t]he plain language of the Director’s holding in *NXP* requires that any stipulation should be filed before the Board’s *initial* Institution Decision.” *Id.* With the Director’s vacatur of our earlier Decision Denying Institution, i.e., setting aside our prior decision, that is the posture now before us. Paper 15 at 6 (“Decision Denying Institution (Paper 13) is vacated.”). We accordingly follow the Interim Procedure’s directive and decline to deny the Petition under *Fintiv*.

B. *Discretionary Denial Under § 325(d)*

a) *Petitioner’s Contentions*

Petitioner admits that the ’737 Farrell (Ex. 1008) and the ’029 Stahmann (Ex. 1010) disclosures relied on in the present Petition share similarities with the disclosures of the Farrell (U.S. Patent No. 7,878,198 B2 (“the ’198 Farrell”)) and Stahmann (U.S. Patent No. 7,757,690 B2 (Ex. 1020; “the ’690 Stahmann”) and U.S. Patent Publication No. 2005/0115561 A1 (Ex. 1019; “the ’561 Stahmann”)) references presented during prosecution. Pet. 6–7. Petitioner contends, however, that Genger, Schmidt, and Kocinski were not previously considered by the Office and therefore the combination with Farrell was not considered. *Id.*

www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf

Petitioner contends that the '029 Stahmann (Ex. 1010) reference applied in the Petition is more comprehensive than the '561 Stahmann reference (Ex. 1019) relied on during prosecution. Pet. 6. Petitioner also contends that “the then-pending claims recited materially different limitations than now-patented claim 8 against which [the '029 Stahmann] is used.” *Id.* at 6–7. “[T]o the extent there is overlap in disclosure among Stahmann’s references, Petitioner respectfully submits the Office materially erred by not fully appreciating the entirety of Stahmann’s disclosures and the obvious combination (expressed herein) of [the '029 Stahmann] and secondary art.” *Id.* at 7.

b) Patent Owner’s Contentions

Patent Owner disagrees and argues that Petitioner is relying on the same or substantially the same prior art or arguments previously presented to the Office during prosecution for each of the asserted grounds. “Farrell and Stahmann—both critical to at least one ground raised in the Petition—were traversed during the prosecution of the application that led to the '269 Patent as well as its parent U.S. Patent No. 8,172,766.” Prelim. Resp. 21. Patent Owner argues:

[T]he same art and arguments relied on in the Petition were presented to and considered by the Office. The '269 Patent lists among its References Cited U.S. Patent No. 7,878,198 titled Methods And Apparatus For Monitoring The Cardiovascular Condition Of Patients With Sleep Disordered Breathing. Ex. 1008 (“[’198] Farrell”). This reference cited by the Examiner has the same title, inventors, and disclosures as the [’737] Farrell reference cited in the Petition because they stem from the same provisional application No. 60/557,846, filed on March 31, 2004. In fact, the Petition admits that this is just the WIPO publication of the U.S. patent reviewed and cited in the prosecution of the '269 Patent.

Prelim. Resp. 22.

Finally, Patent Owner argues that “Petitioner alleges no error by the Office, let alone material error,” and therefore, we should defer to the Examiner’s evaluation and deny institution. *Id.* at 24–25.

c) Analysis

1. Legal Standard

Section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the Office. The statute states, in pertinent part, “[i]n determining whether to institute . . . , the Director may take into account whether, and reject the petition . . . because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d).

The question of whether a petition presents art or arguments that are “the same or substantially the same” as art or arguments previously presented to the Office is a factual inquiry. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”).

The precedential section of *Becton, Dickinson* sets forth the following non-exclusive factors for consideration:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson, 17–18.

Advanced Bionics sets out a two-part framework for analyzing these factors. In the first part, we consider factors (a), (b), and (d) to determine whether the art and arguments presented in the petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics, LLC v. MED-EL Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8–10 (Feb. 13, 2020) (precedential) (“*Advanced Bionics*”). “If, after review of factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office,” then we move on to the second part of the analysis to determine “whether the petitioner has demonstrated a material error by the Office” in view of factors (c), (e), and (f). *Id.*

2. *Advanced Bionics Part One*

Patent Owner argues that the disclosures in the ’737 Farrell and the ’029 Stahmann were considered by the Examiner and “traversed during the prosecution of the application that led to the ’269 Patent as well as its parent U.S. Patent No. 8,172,766.” Prelim. Resp. 21. We agree.

The ’269 patent lists two Farrell references under the references cited on the front of the patent: the ’198 Farrell and U.S. Patent Publication No. 2007/0161913 (“the ’913 Farrell”). *See* Ex. 1001, (56). Petitioner’s grounds of unpatentability rely on a third Farrell reference, the ’737 Farrell. Pet. 6.

Petitioner admits that the '737 Farrell reference applied in the Petition has similarities with the '198 Farrell reference cited during prosecution. Pet. 6; *compare* the '737 Farrell (Ex. 1008), *with* the '198 Farrell.

During prosecution of the '269 patent, the Examiner cited three Stahmann references: U.S. Patent No. 7,757,690 B2 (Ex. 1020 (“the '690 Stahmann”)); U.S. Patent Publication No. 2005/0085738 A1 (“the '738 Stahmann”)); and U.S. Patent Publication No. 2005/0115561 A1 (Ex. 1019 (“the '561 Stahmann”). *See* Ex. 1001, (56). Petitioner’s grounds of unpatentability rely on a fourth Stahmann reference, the '029 Stahmann. Pet. 6.

Petitioner contends that the '029 Stahmann reference (Ex. 1010) applied in the Petition is more comprehensive than the '561 Stahmann reference (Ex. 1019) relied on during prosecution. Pet. 6. We have reviewed and compared the references, and are not persuaded that there are material differences between these two Stahmann references. *Compare* Ex. 1010, *with* Ex. 1019. At best, the '029 Stahmann lists priority data that is not part of the '561 Stahmann reference.

The Examiner asserted the '561 Stahmann, the '690 Stahmann, or the '198 Farrell reference in either anticipation or obviousness rejections during prosecution of the '269 patent or the '766 patent. *See* Pet. 6; Prelim. Resp. 21–23; Ex. 1002, 346–48 (citing the '690 Stahmann), 372, 389–402 (citing the '198 Farrell); Ex. 1003, 64 (citing the '198 Farrell), 174 (citing the '561 Stahmann). There is no dispute that the same disclosures the Petition relies upon in the '737 Farrell reference and the '029 Stahmann reference were before the Examiner during prosecution.

For these reasons, we determine that the Petition presents art that was the same or substantially the same as that previously presented to the Office and proceed to the second part of the *Advanced Bionics* framework.

3. *Advanced Bionics Part Two*

During prosecution of the '766 patent (the parent to the '269 patent), the Examiner rejected the then-pending claims as anticipated by the '561 Stahmann reference. Ex. 1003, 174–177. Patent Owner responded by amending the claims and asserting that the '561 Stahmann “does not teach a single data acquisition device having inputs for receiving signals from sensors including a respiration belt sensor and a pulse oximeter sensor as claimed.” *Id.* at 155 (emphasis omitted). In the next office action, the Examiner withdrew the rejection based on the '561 Stahmann and presented a new ground of rejection applying another set of references. *Id.* at 117. The Examiner never relied on the '561 Stahmann reference again during prosecution leading to the '766 patent, nor was the '561 Stahmann reference discussed during prosecution leading to the '269 patent.

During prosecution of the '269 patent, the Examiner relied on the '690 Stahmann reference (Ex. 1020) for teaching bidirectional wireless communication. Ex. 1002, 282, *see also id.* at 213 (“Stahmann’s teaching is solely to modify Miles in view of Wright to incorporate the teaching of bidirectional radio frequency communication between two devices.”). Patent Owner responded by amending claims, and the Examiner then determined that none of the references taught the claimed apparatus of claim 34³ as amended. *See* Ex. 1002, 313 (claim 34 was amended to recite treating a subject with “additional CO₂ resulting in a concentration higher than

³ Claim 34 has been renumbered to claim 8 in the '269 patent.

atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent” (emphasis omitted)). The Examiner concluded that

neither Miles [U.S. Patent No. 5,252,788 A], Hedner U.S. Patent No. 6,832,609 B2], [the ’690] Stahmann, nor the prior art of record teaches the device of claim 34, including the following in combination with all other limitations of the claim: an [sic] positive airway pressure apparatus for providing pressurized air and chemically treating a subject’s sleep disorder or symptoms with additional CO₂ resulting in a concentration higher than atmospheric concentration of carbon dioxide in air, or a pharmaceutical agent, either which can be adjusted at least in part using the output of the level of severity of the subject’s sleep disorder from the data acquisition system.

Ex. 1002, 283. In the same office action, however, the Examiner asserted that claim 34 did not have written description support in the specification for treating sleep disorder symptoms with additional CO₂ as claimed. Ex. 1002, 267. In order to overcome the written description rejection, Patent Owner amended claim 34 to remove any reference to administering additional CO₂. Ex. 1002, 259. In other words, by removing the “additional CO₂” language, Patent Owner reverted to the prior claim 34 language. Rather than reinstating the rejection based on Miles, Hedner, and the ’690 Stahmann in the next office action, the Examiner entered another new ground of rejection of claim 34 in view of Wright. *See* Ex. 1002, 142–145.

Patent Owner argues that “Petitioner alleges no error by the Office, let alone material error.” Prelim Resp. 24; Sur-reply 10. We are not persuaded by Patent Owner’s assertion that Petitioner did not allege material error, but agree that Petitioner could have provided a more thorough explanation with respect to articulating the Examiner’s error in their section 325(d) discussion. *See* Pet. 7 (“[T]o the extent there is overlap in disclosure among Stahmann’s references, Petitioner respectfully submits the Office materially

erred by not fully appreciating the entirety of Stahmann's disclosures and the obvious combination (expressed herein) of Stahmann-EX1010 and secondary art.")

Nevertheless, based on its showing with the combination of the '029 Stahmann and Edgar as applied to claim 8, we determine that Petitioner has sufficiently demonstrated a material error during the examination. Other Board panels have instituted an *inter partes* review after inferring material error based on the strength of the petitioner's grounds. *See, e.g., STMicroelecs., Inc. v. Trustees of Purdue Univ.*, IPR2022-00309, Paper 14 at 12–13 (PTAB July 6, 2022) (finding that petitioner demonstrated examiner erred by not appreciating that reference on IDS disclosed features recited in the challenged claims, as demonstrated by petitioner's unpatentability grounds); *Apple Inc. v. Telefonaktiebolaget LM Ericsson*, IPR2022-00457, Paper 7 at 8 (PTAB Sept. 21, 2022) (same); *Sci. Design Co. v. Shell Oil Co.*, IPR2021-01537, Paper 7 at 24–25 (PTAB Mar. 18, 2022) (same). Furthermore, *Advanced Bionics* specifically provides that we consider "whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims," not whether Petitioner has expressly stated that the Office erred in a manner material to patentability. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8 (emphasis added). Consistent with these cases, here we find that Petitioner sufficiently shows material error by pointing to material teachings in the '029 Stahmann reference that were not raised during prosecution.

Claim 8 and its dependent claims were allowed after Patent Owner amended the claim to recite "the positive airway pressure apparatus comprising a controller adapted to adjust the pharmaceutical agent." Ex. 1002, 29. This suggests the Examiner determined that the art did not

teach an apparatus that has a controller that can adjust a pharmaceutical agent. The Examiner, therefore, did not appreciate that the controller as taught in the '029 Stahmann reference could be used to administer *both CPAP treatment and a pharmaceutical agent*. See Ex. 1010, 237–238 (“Positive airway pressure devices, e.g., continuous positive airway pressure (CPAP) devices are among the most frequently used mechanical respiration therapy devices employed for treating sleep disordered breathing. . . . Drugs may [also] be delivered to the patient through one or more automatically controllable drug delivery devices. . . [such as a] nebulizer.”), *see also* 322 (“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.”). Moreover, the Petition presents additional evidence regarding element 8.b (*see* Ex. 1004 ¶¶ 120–124) that warrants reconsideration of the '029 Stahmann reference in this proceeding.

For these reasons, we find that Petitioner has demonstrated a material error, and therefore, will not exercise discretion to deny institution of *inter partes* review under 35 U.S.C. § 325(d).

C. *Claim Construction*

The issue is whether the Petition contains sufficient detail to meet the requirements under 37 C.F.R. § 42.104(b)(3), which requires that a petition set forth how the challenged claims are to be construed.

a) *Patent Owner's Contentions*

Patent Owner states that in the co-pending district court litigation, real party-in-interest ResMed Inc. asserted that three claim limitations in the '269 patent should be construed as means-plus-function terms pursuant to

35 U.S.C. § 112(6). Patent Owner argues that we should deny the Petition because Petitioner should have provided either reasons why these limitations are not governed by 35 U.S.C. § 112(6), or an explicit claim construction as required by the rules. Prelim. Resp. 7–8. According to Patent Owner, it is “Petitioner’s burden to construe means-plus-function limitations [and this] extends to all terms that ‘may’ be construed according to 35 U.S.C.

§ 112(6).” *Id.* at 7 (citing *Samsung Elecs. Co. v. Power2B Inc.*, IPR2022-01378, Paper 12 at 11–14 (PTAB Mar. 15, 2023); *see also* Consolidated Trial Practice Guide (“CTPG”)⁴ at 45). Patent Owner argues that Petitioner is gaming the system by presenting inconsistent claim constructions at the Board and the district court. Prelim. Resp. 20 (“Petitioner’s gamesmanship regarding the proper construction of the claims is another reason to deny its Petition under the *Fintiv* factors.”).

b) Petitioner’s Contentions

In the Petition, Petitioner asserts that it does “not believe any claim term needs formal construction . . . but reserves the right to propose formal constructions in other forums where disputed issues may differ.” Pet. 24. Petitioner additionally asserts that (1) the claim limitations do not recite “means” and thus are presumptively not subject to mean-plus-function construction; (2) in its briefs here, Patent Owner asserts the limitations are not subject to mean-plus-function construction; and (3) no tribunal has yet determined the limitations are subject to mean-plus-function construction. *See* Reply 2 (citing Prelim. Resp. 8–9).

⁴ Consolidated Trial Practice Guide (2019), available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

According to Petitioner, the CTPG allows a petitioner to “include a statement that the claim terms require no express construction.” Reply 1 (citing CTPG at 44). Petitioner contends that it did exactly that by stating that it does “not believe any claim term needs formal construction.” Pet. 24. Petitioner asserts that § 42.104(b)(3) also includes no requirement to advance the same claim construction argument in an IPR and district court. Reply 3 (citing *Abbott Diabetes Care Inc. v. Dexcom, Inc.*, IPR2022-00913, Paper 14 at 14 (PTAB Nov. 3, 2022)). Additionally, Petitioner asserts that neither the CTPG nor § 42.104(b)(3) requires that a petition propose a means-plus-function construction for any term that *might* be subject to means-plus-function construction. Reply 1.

c) Analysis

Patent Owner argues that Petitioner fails to comply with 37 C.F.R. § 42.104(b)(3), which states that a petition must set forth:

(b) Identification of challenge. Provide a statement of the precise relief requested for each claim challenged. The statement must identify the following:

* * *

(3) How the challenged claim is to be construed. Where the claim to be construed contains a means-plus-function or step-plus-function limitation as permitted under 35 U.S.C. 112(f), the construction of the claim must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function.

37 C.F.R. § 42.104.

We decline Patent Owner’s request to deny the Petition under § 42.104(b)(3). In this case, it is not readily apparent on the current record from the claim or the intrinsic evidence whether the “processor adapted for”

limitation invokes § 112(6) under 37 C.F.R. § 42.104(b)(3). It is well understood that if a claim limitation lacks the word “means,” then there is a rebuttable presumption that the limitation is not subject to § 112(6) as a means-plus-function limitation. *MTD Prods. Inc. v. Iancu*, 933 F.3d 1336, 1341 (Fed. Cir. 2019). None of the challenged claims expressly recites “means,” and are thereby presumed not to contain terms that are subject to interpretation under § 112(6). *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc).

Petitioner in its Reply asserts that it has met its burden by including a statement in the Petition that no construction is necessary. Reply 1 (citing Pet. 24–25). By indicating “no construction is necessary” in the Petition, we agree with Petitioner that on the facts of this case, the Petition has described “how the challenged claim is to be construed” under section 37 C.F.R. § 42.104(b)(3). *See* Pet. 24. Accordingly, on the current record,⁵ we decline Patent Owner’s request to deny the Petition under 37 C.F.R. § 42.104(b)(3).

D. *Alleged Obviousness over Genger (Ex. 1005), Schmidt (Ex. 1006), Westbrook (Ex. 1007), and the ’737 Farrell (Ex. 1008)*

a) Prior Art

We have reviewed the parties’ arguments and supporting evidence with respect to claim 1. We determine that Petitioner has shown a reasonable likelihood of demonstrating where each of the recited elements is supported in the record. *See* Pet. 25–40. We begin with a review of the relevant references, and then address the parties’ contentions.

⁵ The district court’s claim construction order, as well as the parties’ final infringement contentions and final invalidity contentions in the co-pending district court proceeding, have now been filed as exhibits here. Ex. 2013; Ex. 1024.

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, and 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 12:22–28.

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,⁶ 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.

⁶ Electrocardiogram (EKG). Ex. 1006, 2:8–9

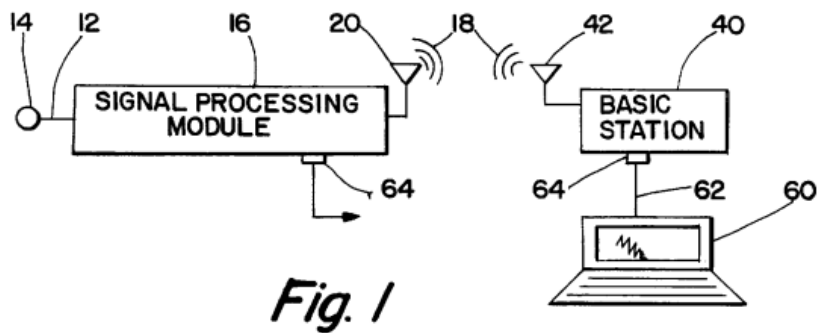


Figure 1 shows a block diagram of Schmidt's invention. Ex. 1006, 4:46. In particular, Figure 1 shows external input 12 from sensor 14 as an input into the signal processing module 16. *Id.* at 4:63–67. The signal processing module then wirelessly transmits output signal 18 encoded with data corresponding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

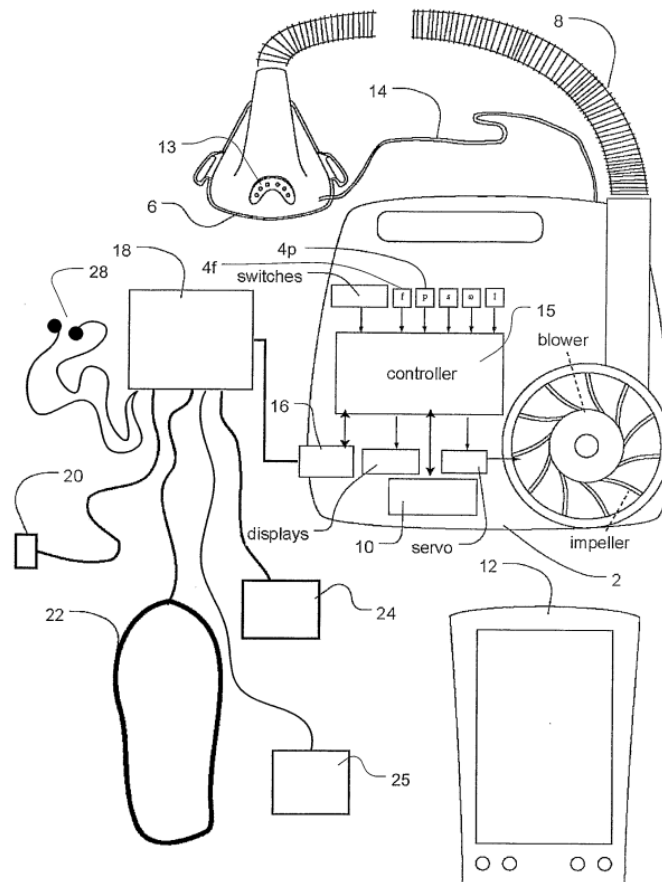
3. Overview of Westbrook (Ex. 1007)

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 the '737 Farrell (Ex. 1008)

The '737 Farrell 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 the '737 Farrell is reproduced below:



Farrell’s figure 1 reproduced above shows: 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. *Id.* at 5:2–4.

Exhaust gas is vented via exhaust 13. Ex. 1008, 5: 4–5. Optionally, a flow sensor 4f and/or pressure sensor 4p may also be utilized in which case mask flow may be measured using a pneumotachograph⁷ 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 $P_{\text{mask}}(t)$. *Id.* at 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 5:20–22. 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 detecting cardiac rhythm.” *Id.* at 5:33–35. Farrell 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 further discloses that the apparatus incorporates various pressure treatment protocols that may be used to treat the condition of the patient, where “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.

⁷ 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).

b) Petitioner's Contentions

Petitioner contends that the combination of Genger, Schmidt, Westbrook, and the '737 Farrell renders the positive airway pressure system of claim 1 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 it would have been obvious to use "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 the '737 Farrell provides motivation to move the sensor into the device. Pet. 34–35 (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 (emphasis omitted) (citing Ex. 1007 ¶ 32). In addition, Petitioner argues that the '737 Farrell 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 (citing Ex. 1008, 5:20–22, 7:35–8:24).

c) Patent Owner’s Contentions

Patent Owner opposes. Specifically, Patent Owner argues that the combination of references as articulated by Petitioner does not satisfy claim elements 1.b.3 and 1.b.4. Prelim. Resp. 27–32. With respect to claim element 1.b.3, Patent Owner argues that “Genger’s respiratory airflow sensor is admittedly located outside of the CPAP machine. . . [and] neither Farrell nor Berthon-Jones [incorporated by reference into Farrell] expressly discloses locating a respiratory airflow sensor within a CPAP machine, let alone state that such a location was ‘common.’” *Id.* at 30.

With respect to claim element 1.b.4, Patent Owner argues that Genger and Westbrook do not calculate sleep disorder data from both respiratory and pulse oximetry sensors. Prelim. Resp. 28–29. Patent Owner argues “Farrell also does not cure Genger’s deficiencies because Farrell’s pressure sensor measures the output of the CPAP machine’s blower rather than the respiratory airflow of the subject.” *Id.* at 31.

d) Analysis

Based upon our review of the arguments and evidence, we find that Petitioner has shown a reasonable likelihood that the combination of Genger, Schmidt, Westbrook, and the ’737 Farrell teaches the positive pressure airway (PAP) system as recited in claim 1. Pet. 25–40; Ex. 1004 ¶¶ 72–96.

We are not persuaded by Patent Owner’s argument that element 1.b.3 is missing from the combination of Genger, Schmidt, Westbrook, and the ’737 Farrell. *See* Prelim Resp. 30–32. With respect to the location of the respiratory sensor in claim element 1.b.3, Petitioner’s articulated

combination does not rely on Genger as disclosing a respiratory airflow sensor. Instead, Petitioner is relying on the teaching in the '737 Farrell that suggests the sensors *can be* included in the mask, which is part of the CPAP machine. *See* Pet. 34–36; Ex. 1004 ¶¶ 85–88. The '737 Farrell teaches 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, 5:5–9. The '737 Farrell 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. Based on these teachings, Petitioner shows a reasonable likelihood that this disclosure in the '737 Farrell suggests incorporating sensors into the mask.

Genger explains that generally ventilators and respirators have “[a] spirometer [that] is built into the expiration segment of these devices, which measures the patient’s respiratory volume.” Ex. 1005, 1:15–17. Genger explains that “wireless sensor units may be provided for recording the respiration volume, the air pressure with which the patient is ventilated, or the patient’s blood oxygen content.” Ex. 1005, 10: 28–30, Figure 1. According to Petitioner, “[m]otivation for modifying Genger’s CPAP would also have come from the fact that Genger wants the CPAP device 4/5/6/7/8 to have the airflow data.” Pet. 36.

“[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (citing *United States v.*

Adams, 383 U.S. 39, 50–51 (1966)). We have reviewed the record in light of Patent Owner’s arguments but find the arguments unavailing. We find that Petitioner has directed us to sufficient evidence in the record to demonstrate a reasonable likelihood that Genger includes a sensor for measuring respiratory airflow in the device and that Farrell reasonably teaches that a sensor can be included in the mask of the CPAP device.

We are also not persuaded by Patent Owner’s argument that element 1.b.4 is missing from the combination of Genger, Schmidt, Westbrook, and the ’737 Farrell. *See* Prelim Resp. 28–29. We find that Petitioner has directed us to sufficient evidence to demonstrate a reasonable likelihood that the combination of references teaches the element of calculating sleep disorder symptom data using both respiratory airflow *and* pulse oximetry sensor data as recited in claim element 1.b.4. Here, Petitioner identifies that Westbrook teaches this limitation. *See* Pet. 37.

Petitioner contends 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 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 12:22–28.

The record supports a reasonable likelihood that a processor/controller in Genger is used to collect and generate trend data before the data is

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.”).

Westbrook teaches a physiological monitor that “detects and records the pulse rate, oximetry, snoring sounds, and head position of a patient” and suggests that “[a]n airflow signal could be added to the physiological monitor with minimal intrusiveness.” Ex. 1007 ¶¶ 161, 33, 52, 147, Figure 16; *see* Pet. 37. “[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.” Ex. 1007 ¶ 139. The algorithms “that quantify the type of the desaturation and detect arousals can be combined to classify the type of respiratory event.” *Id.* ¶ 147.

According to Petitioner, “[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. Based on the disclosures in Genger and Westbrook as identified by Petitioner, we are not persuaded by Patent Owner’s contention that the references do not calculate sleep disorder data from both respiratory and pulse oximetry data. Here, Westbrook specifically suggests using both pulse oximetry data and respiration data. Westbrook uses the respiration data to verify desaturation events as measured by the pulse oximeter. Ex. 1007 ¶¶ 139, 147.

e) Summary

In sum, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claim 1 would have been obvious over the combination of Genger, Schmidt, Westbrook, and the '737 Farrell.

Petitioner relies on the combination of Genger, Schmidt, Westbrook, and the '737 Farrell to also challenge claims 2, 3, 5, and 7. Pet. 3. Petitioner challenges claims 4 and 6, which depend from independent claims 1 and 5, and relies on the same underlying references in conjunction with Paradiso. *Id.* Patent Owner did not make any additional arguments directed to the limitations of claims 2–7. Based on the current record, we determine Petitioner has made a sufficient showing regarding claims 2–7 as well. *See* Pet. 41–49.

E. Alleged Obviousness over the '029 Stahmann and Edgar

a) Prior Art

We have reviewed the parties' arguments and supporting evidence with respect to claim 8. We determine that Petitioner has shown a reasonable likelihood of demonstrating where each of the recited elements is supported in the record. *See* Pet. 49–57. We begin with a review of the relevant references and then address the parties' contentions.

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

The '029 Stahmann discloses methods and systems for patient monitoring, diagnosis and therapy. Ex. 1010, 1:6–7. The '029 Stahmann discloses embodiments of the invention 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.

The '029 Stahmann discloses embodiments of the invention 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.

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

b) Petitioner's Contentions

Petitioner contends that the combination of the '029 Stahmann and Edgar teaches all the limitations of claim 8. Pet. 49–59; Ex. 1004 ¶¶ 117–124. Petitioner contends that the '029 Stahmann 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. Petitioner acknowledges that “[the '029] 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. Petitioner contends that a person of ordinary skill in the art “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’ (Edgar, [0364]) to accomplish Stahmann’s goal of improving patient’s sleep through therapy feedback.” Pet. 57 (citing Ex. 1004 ¶ 124)

c) Patent Owner's Contentions

Patent Owner opposes. Prelim. Resp. 32–35. Patent Owner contends that “[the '029] Stahmann fails to teach or suggest a CPAP for providing a pharmaceutical agent based on the level of severity of the subject’s sleep disorder symptoms.” Prelim. Resp. 33. Patent Owner contends that Edgar does not cure the deficiency of the '029 Stahmann. Specifically, Patent Owner contends that Edgar discloses administering sleep promoting agents but does not teach “treating the subject’s sleep disorder through the pharmaceutical agent. . . . Edgar discloses ensuring that the subject stays

asleep using a pharmaceutical agent rather than treating the subject's sleep disorder as referenced in the claim language.” Prelim. Resp. 34–35.

d) Analysis

Based upon our review of the arguments and evidence, we find that Petitioner has shown a reasonable likelihood of demonstrating that the combination of the '029 Stahmann and Edgar teaches the sleep disorder treatment system as recited in claim 8. Pet. 49–57; Ex. 1004 ¶¶ 117–124.

The disputed element of claim 8 reads: “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.

Figure 51 of the '029 Stahmann, reproduced below, teaches a monitoring device that can also apply therapy.

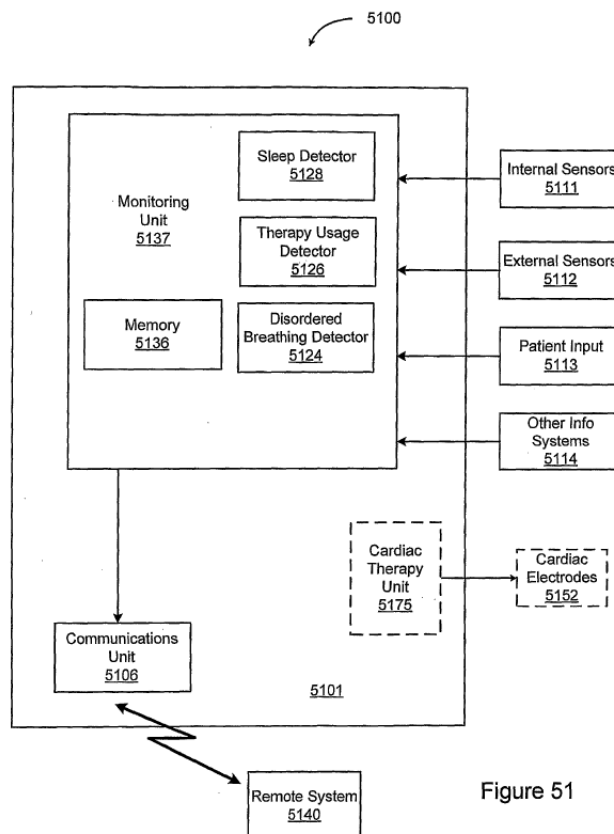


Figure 51

Figure 51, shown above, shows “a block diagram of a patient-external respiratory therapy device that may be used to provide breathing therapy monitored by an implantable device.” Ex. 1010, 32:1–3. “The system 5100 employs a medical device 5101 that may be coupled to an array of data acquisition devices, including patient-internal sensors 5111, patient-external sensors 5112, patient input devices 5113, and/or other information systems 5114.” Ex. 1010, 224:2–4. “The sleep detector 5128 may analyze various inputs from the patient-internal sensors 5111, patient-external sensors 5112, patient input devices 5113, and/ or other information systems 5114 to detect sleep related events, including, for example, sleep onset, sleep offset, sleep stages, *and arousals from sleep.*” *Id.* at 224:26–30 (emphasis added). “The medical device 5101 may optionally include a therapy unit.” *Id.* at 225:14.

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

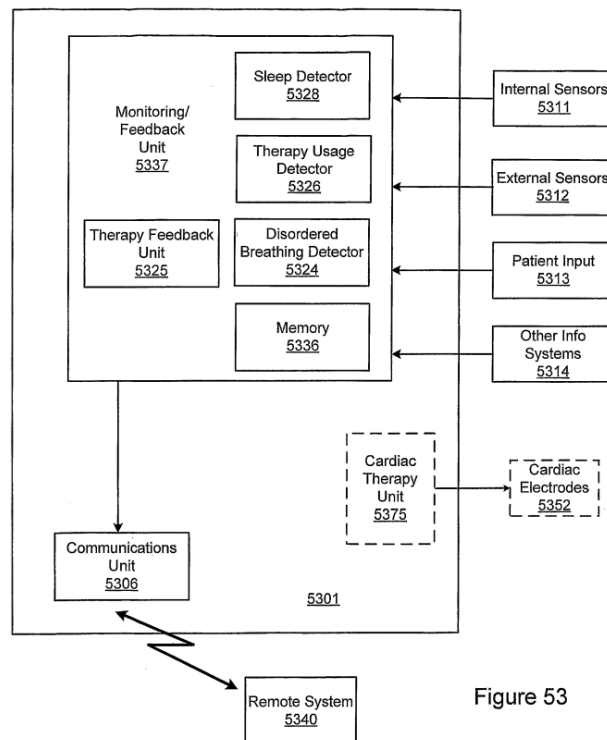


Figure 53

Figure 53, shown 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. The device “may be used to monitor patient conditions and to develop feedback information *for a device delivering sleep disordered breathing therapy.*” *Id.* at 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.” *Id.* at 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 the '029 Stahmann applies sequential steps as shown in the following flow chart to assess sleep disordered breathing events.

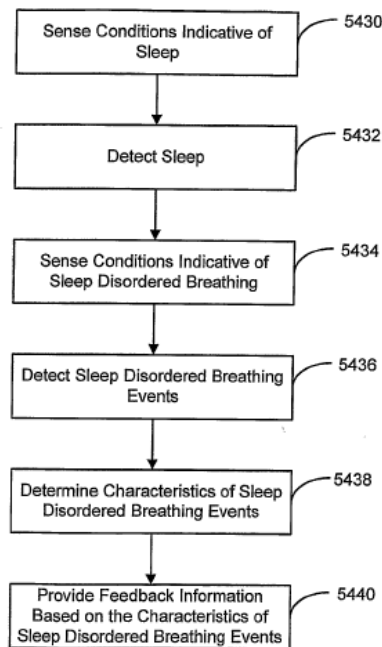


Figure 54C, reproduced above, shows a flow chart for detecting sleep disordered breathing events and providing feedback. Ex. 1010, 32:12–14, 238:12–15. Specifically,

[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; Ex. 1004 ¶ 122. According to the '029 Stahmann, “[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).

According to the '029 Stahmann, 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. The '029 Stahmann 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, the '029 Stahmann reasonably suggests applying therapy in response to the detection of a sleep disorder.

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

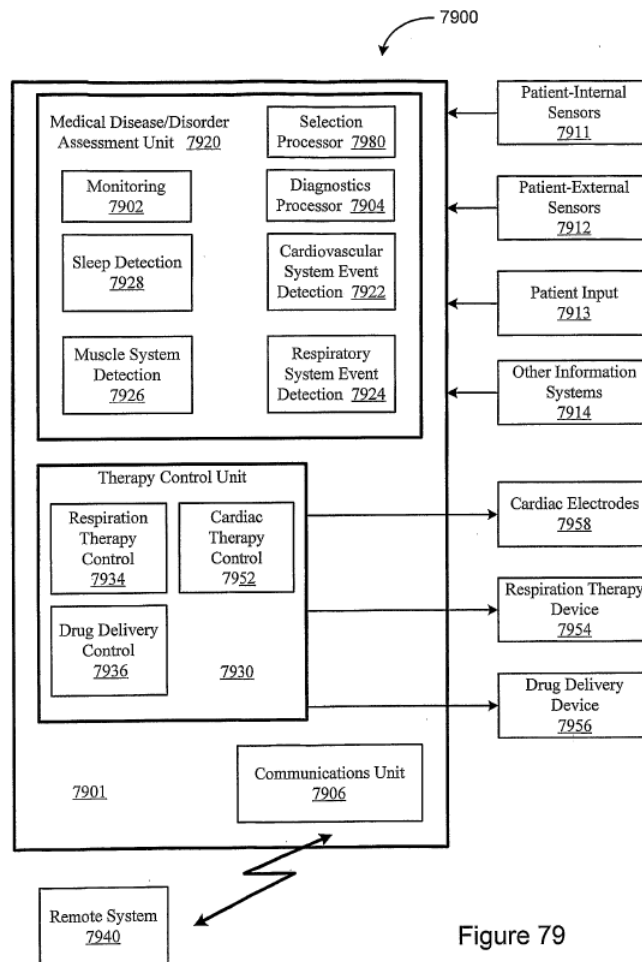


Figure 79

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.” *Id.* at 318:4–5. The ’029 Stahmann teaches

[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*.” *Id.* at 319:13–14 (emphasis added). Thus, the ’029 Stahmann reasonably suggests detecting sleep events including arousal from sleep.

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 includes 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); Ex. 1004 ¶¶ 123, 124 (Administering doxepin analogs would “let patients ‘sleep better and more soundly’ (Edgar, [0407]) to accomplish Stahmann’s goal of improving patient’s sleep through therapy feedback.”). 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.

Claim limitation 8b recites “providing pressurized air and dosing and chemically treating a subjects’ sleep disorder or symptom 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.” Ex. 1001, 25:24–31. Awakening is a symptom of apnea or hypopnea, which are sleep disorders. *See* Ex. 1004 ¶¶ 34–36; Ex. 1007 ¶ 5. As Westbrook explains:

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. Treating a symptom of a sleep disorder, such as arousal from sleep, therefore, meets the claim limitation. Accordingly, we are not persuaded by Patent Owner’s argument that providing treatment for a

subject to stay asleep would not achieve the stated goal of treating a subject's sleep disorder.

Based on these disclosures, Petitioner has shown a reasonable likelihood of demonstrating that the combination of the '029 Stahmann and Edgar suggests applying therapy in response to detecting a sleep disorder.

e) Summary

In sum, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claim 8 would have been obvious over the '029 Stahmann and Edgar.

Petitioner relies on the combination of the '029 Stahmann and Edgar to also challenge claims 9–11 and 13. Pet. 3. Petitioner challenges claim 12, which depends from independent claim 8, by relying on the same underlying references in conjunction with Schmidt. *Id.* Petitioner challenges claim 14, which depends from independent claim 8, by relying on the same underlying references in conjunction with Paradiso. *Id.* at 4. Patent Owner did not make any additional arguments directed to the limitations of claims 9–14. Based on the current record, we determine Petitioner has made a sufficient showing regarding claims 9–14 as well. *See* Pet. 57–61.

F. *Alleged Obviousness over Kocinski, the '737 Farrell, and Bluetooth*

a) Prior Art

We have reviewed the parties' arguments and supporting evidence with respect to claim 15. We determine that Petitioner has shown a reasonable likelihood of demonstrating where each of the recited elements is supported in the record. *See* Pet. 61–75. 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 machine 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.

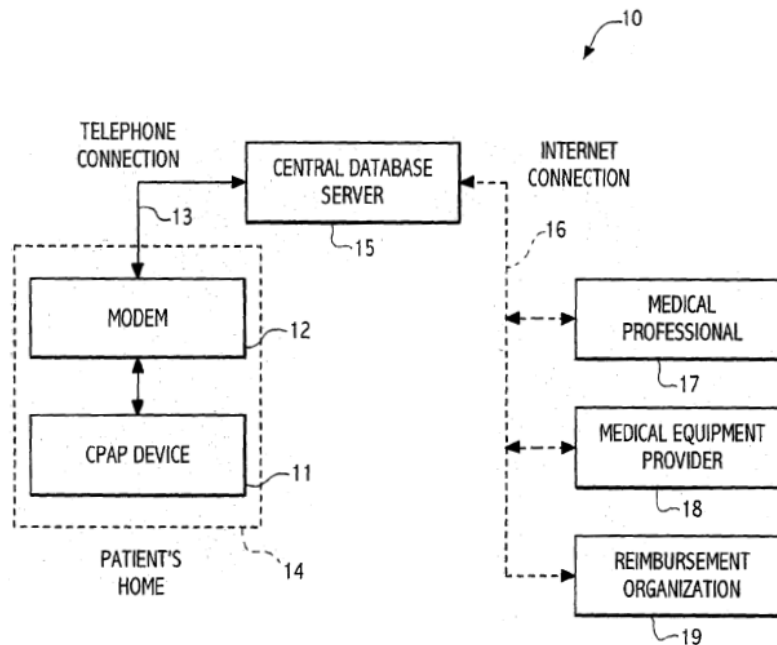


FIG. 1

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 apparatus 11 is used with a modem that sends the patient's data to a medical professional for monitoring. *Id.* ¶¶ 24–28.

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

The '737 Farrell is discussed above. *See* II.D.c.4. The '737 Farrell teaches 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, 5:5–9. The ’737 Farrell 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.

b) Petitioner’s Contentions

Petitioner contends that the combination of Kocinski, the ’737 Farrell, 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 the ’737 Farrell. *Id.* 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 that Bluetooth’s radio frequency architecture allows for bidirectional communication with the device. *Id.* at 68–69 (citing Ex. 1012 ¶ 26; Ex. 1017). Petitioner contends that Kocinski displays patient specific data using an external network. *Id.* at 72 (citing Ex. 1012, Figures 10–12; Ex. 1004 ¶ 147). Petitioner concludes that it would have been obvious to one of ordinary skill in the art to also “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.” *Id.* at 74 (citing Ex. 1012 ¶¶ 35–39, Figure 12; Ex. 1004 ¶ 149).

c) Patent Owner’s Contentions

Patent Owner opposes. Prelim. Resp. 35–41. Patent Owner contends that

Kocinski, alone or in combination with [the ’737] Farrell, fails to teach or suggest an internal airflow sensor adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data. Both references disclose pressure sensors, but they measure the pressure output by the CPAP machine, not the patient’s respiratory airflow.

Prelim. Resp. 36. Patent Owner contends that Kocinski does not teach or suggest transmitting symptom or index data to a remote internet site. *Id.* at 37. “Kocinski does not display this data because ‘the pressures and sleep events may be made available only to the medical professional since others do not need this information,’ and in Kocinski’s system, the medical professional is remote.” *Id.* at 40.

d) Analysis

Based upon our review of the arguments and evidence, we find that Petitioner has shown a reasonable likelihood of demonstrating that the combination of Kocinski, the '737 Farrell, and Bluetooth teaches the positive airway pressure (PAP) treatment system as recited in claim 15. Pet. 61–75; Ex. 1004 ¶¶ 132–149.

Kocinski teaches “a data collection and processing system that provides user and apparatus information from a CPAP apparatus in a patient’s home to a medical professional and to a medical equipment provider at remote locations.” Ex. 1012 ¶ 9. The data is stored in the CPAP device and is periodically transferred to a remote location. “The CPAP apparatus is programmed to periodically transfer data via a modem and a telephone connection to a central database server.” *Id.* “The central database server 15 [in Figure 1] also can be connected to the internet, which is represented by a dashed line 16.” *Id.* ¶ 27. Kocinski teaches “[t]wo-way communication between the CPAP apparatus 11 and the central database server 15 is accomplished via an internet processing system (IPS). The IPS collects compliance data and other parametric data from the CPAP apparatus 11 in the patient’s home 14, transmits the data to a central database server 15, . . . and makes the data available to the medical professional 17.” *Id.* ¶ 35. Kocinski teaches that the information can be displayed. “The IPS can be a software-driven system. The software can be in the form of a windows-based application having point-and-click menu options that can easily be selected by the user.” *Id.* ¶ 37. “Authorized users and viewers can be entered, as indicated in function step 26, through a ‘Login’ window 52, as shown in FIG. 5, that can be opened by selecting ‘Login’ from a menu selection.” *Id.* ¶ 39.

We agree with Patent Owner that Kocinski does not appear to include a display on the CPAP base station. Prelim. Resp. 40. Petitioner, however, does not solely rely on Kocinski for teaching this element. Pet. 71, 74–75; Ex. 1004 ¶ 149. The '737 Farrell suggests that “the 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.” Ex. 1008, 6: 23–25. The '737 Farrell also does not place a display on the device. Petitioner’s expert explains, and on this preliminary record we agree, that displaying information on the base station (or PDA) would “allow the patient, patient’s family, and visiting medical professionals to see the patient’s data on-site.” Ex. 1004 ¶ 149; Pet. 74–75. Accordingly, Patent Owner’s contention that adding a display to the base station (or PDA) would not have been obvious is unavailing.

Patent Owner’s contention that Kocinski does not teach or suggest transmitting symptom or index data to a remote internet site is also unavailing. Prelim. Resp. 37–39. As Petitioner explains, “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,” therefore, it would have been obvious to “calculate AHI and /or RDI” to assess sleep disorders just like Farrell. 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, reasonably supports the Petitioner's position. Pet. 71.

Patent Owner's contention that Kocinski and the '737 Farrell fail to suggest measuring the respiratory airflow of a subject is also unavailing. Prelim. Resp. 36–37. The '737 Farrell teaches that the device can include a pneumotachograph, which is a device for measuring airflow. Ex. 1008, 5:5–9; Ex. 1004 ¶ 135; Pet. 64.

e) Summary

In sum, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claim 15 would have been obvious over Kocinski, the '737 Farrell, and Bluetooth.

Petitioner relies on the combination of Kocinski, the '737 Farrell, and Bluetooth to also challenge claims 16, 18, and 19. Pet. 4. Petitioner challenges claim 17, which depends from independent claim 15, by relying on the same underlying references in conjunction with Guillemineault-2004 and Westbrook. *Id.* Petitioner challenges claim 20, which depends from independent claim 15, by relying on the same underlying references in conjunction with Paradiso. *Id.* Patent Owner did not make any additional arguments directed to the limitations of claims 16–20. Based on the current record, we determine Petitioner has made a sufficient showing regarding claims 16–20 as well. *See* Pet. 75–79.

III. CONCLUSION

Based on the current record, we determine Petitioner has shown a reasonable likelihood that it will prevail in establishing that at least one claim of the '269 patent is unpatentable. Accordingly, we institute review of all claims challenged on all of the grounds in the Petition. *See* CTPG 64;

PGS Geophysical AS v. Iancu, 891 F.3d 1354, 1359–60 (Fed. Cir. 2018) (interpreting the relevant statutory provisions, in light of *SAS*, to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”).

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim. Our view with regard to any conclusion reached in the foregoing analysis could change upon completion of the record.

IV. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to claims 1–20 of the ’269 patent based on the unpatentability challenges presented in the Petition;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

IPR2023-00565
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