

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.
Patent Owner

CASE PGR: Unassigned
U.S. Patent No. 11,602,284
Issue Date: March 14, 2023
Title: Devices and Methods for Sleep Disorder Diagnosis and Treatment

**PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 11,602,284
UNDER 35 U.S.C. §§ 321-329 AND 37 C.F.R. §§ 42.200 *ET SEQ.***

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EXHIBIT LIST

Exhibit No.	Description
EX1001	U.S. Patent No. 11,602,284
EX1002	File History of U.S. Patent No. 11,602,284
EX1003	Declaration of Jacob Sharony, Ph.D.
EX1004	File History of U.S. Patent No. 8,172,766
EX1005	File History of U.S. Patent No. 10,076,269
EX1006	File History of U.S. Patent No. 11,375,921
EX1007	U.S. Patent No. 6,167,258 (“Schmidt”)
EX1008	U.S. Patent No. 8,172,766
EX1009	U.S. Patent Application Publication 2016/0193437 (“Bao”)
EX1010	U.S. Patent Application Publication 2018/0199882 (“Klee”)
EX1011	WO 2021/152526 (“Shouldice”)
EX1012	U.S. Patent Application Publication 2007/0161913 (“Farrell”)
EX1013	U.S. Patent Application Publication 2007/0155208 (“Pirzada”)
EX1014	USPTO’s June 2022 Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation.
EX1015	U.S. Patent No. 5,424,942 (“Dong”)
EX1016	Roux et al., <i>Continuous positive airway pressure: new generations</i> , Clinics in Chest Medicine, Vol. 24 (2003), pp.315-342
EX1017	US 5,704,345 (“Berthon-Jones”)
EX1018	US 6,644,311 (“Truitt”)
EX1019	U.S. 2004/0129838 (“Lisy”)
EX1020	Declaration of Dr. Alan R. Schwartz

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EX1021	Memorandum Opinion re: Claim Construction, <i>Cleveland Med. Devices, Inc., v. ResMed Inc.</i> , C.A. No. 22-794-GBW, D.I. 181 (October 30, 2023 D. Del.)
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Petitioner ResMed Corp. (“ResMed”) petitions for Post Grant Review (“PGR”) of Claims 1-20 (“challenged claims”) of U.S. Patent No. 11,602,284 (“’284 patent,” EX1001).

I. REQUIREMENTS FOR PGR

A. Grounds for Standing (37 CFR § 42.204(a))

Petitioner certifies that the ’284 patent is available for PGR because the present Petition is being filed less than 9 months after the issue date of the ’284 patent (March 14, 2023).

Petitioner further certifies that the ’284 patent is available for post-grant review as set forth below and that Petitioner is not barred or estopped from requesting a post-grant review challenging the patent claims on the grounds identified in the petition.

B. The ’284 Patent is an AIA Patent and Eligible for PGR

To be eligible for PGR, the ’284 patent must be subject to the first-inventor-to-file provisions of the AIA. *Leahy-Smith America Invents Act*, Pub. L. No. 112–29, 125 Stat. 284 (September 16, 2011) (“AIA”), §6(f)(2)(A); *Tricam v. Little Giant Ladder*, PGR2021-00044, Paper 10, p. 14 (PTAB August 3, 2021) (“*Tricam*”). To be subject to the first-inventor-to-file provisions of the AIA, Petitioner must show that the ’284 patent contains or contained at any time “a claim that lacks written description and enabling support in a priority application

filed before March 16, 2013.” *Tricam*, 15. As discussed below in Sections IV.C, VII.A and VII.B, many limitations of independent Claim 1 lack such support. The ’284 patent is thus subject to the first-inventor-to-file provisions of the AIA and eligible for PGR. *See id.*

The ’284 patent was filed as U.S. App. No. 17/825,166 (“’166 application”) and claims priority, through a string of continuations, to U.S. App. No. 11/266,899 (“’899 application”), filed on November 4, 2005. EX1001, INID. (63). Other applications in the chain include U.S. App. No. 13/440,116 (“’116 application”), filed April 5, 2012, and U.S. App. No. 16/057,963 (“’963 application”), filed August 8, 2018. *Id.* But the ’899 and other applications in the chain do not disclose or otherwise reasonably convey at least the following claim limitations of the ’284 patent’s lone independent claim. EX1003, ¶¶57-59; EX1020, ¶¶42-49:

- “an index of treatment efficacy of the subject using a PAP device, ... the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone;” and
- “a first software, the first software executable by a first processor and configured to be used with a cell phone to display to a subject for

viewing on the cell phone on to which the first software is
downloaded an index of treatment efficacy of the subject using a PAP
device.”

As discussed below in more detail in Sections IV.C, VII.A and VII.B, the
alleged priority applications do not disclose or otherwise reasonably convey “an
index of treatment efficacy of the subject using a PAP device.” EX1003, ¶¶57-59,
62-75; EX1020, ¶¶42-49. The term simply does not appear anywhere in any of the
priority applications or their prosecution histories. Moreover, the claim specifically
requires that the index be “based in part on data of severity of sleep disorder
symptoms of the subject and data of usage of the PAP device by the subject,” and
the alleged priority applications do not disclose or otherwise reasonably convey
any determination, let alone an “index of treatment efficacy,” based on these
parameters. EX1003, ¶¶57-59, 62-75; EX1020, ¶¶42-49.

Furthermore, the priority applications are completely silent with respect to
“software ... configured to be used with a cell phone to display to a subject for
viewing on the cell phone ... an index of treatment efficacy of the subject using a
PAP device, the first software used for displaying the index on the cell phone.”
Although the Applicant introduced the concepts of software for a cell phone and
software for displaying certain parameters on a cell phone during the prosecution
of some of the priority applications, such disclosure did not support the display of

“an index of treatment efficacy” as recited by Claim 1 and was introduced well after March 16, 2013. EX1003, ¶¶57-59, 62-75.

The ’899 and ’116 applications, filed before March 16, 2013, do not provide support for at least Claim 1 of the ’284 patent. No other application in the priority chain of the ’284 patent was filed prior to March 16, 2013. Accordingly, at least independent Claim 1 “lacks written description and enabling support in a priority application filed before March 16, 2013.” *Tricam*, 15; EX1003, ¶¶57-59, 62-75; EX1020, ¶¶42-56. The ’284 patent is subject to the first-inventor-to-file provisions of the AIA and eligible for PGR.

II. COMPLIANCE WITH FORMAL REQUIREMENTS

A. Mandatory Notices Under 37 C.F.R. §§ 42.8(b)(1)-(4)

1. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

ResMed Corp. (“Petitioner”) identifies ResMed Inc. as a real party in interest without conceding that it is, in fact, a real party in interest.

2. Related Matters (37 C.F.R. § 42.8(b)(2))

The ’284 patent is asserted in the following lawsuit that may affect or be affected by a decision in this proceeding: *ResMed Corp., v. Cleveland Medical Devices, Inc.*, case no. 23-cv-02221 in the U.S. District Court for the Northern District of Ohio.

The '284 patent is related to U.S. Patent No. 10,076,269 (the "'269 patent") asserted in the following lawsuit that may affect or be affected by a decision in this proceeding: *Cleveland Medical Devices, Inc., v. ResMed Inc.*, case no. 1:22-cv-00794-GBW, filed June 16, 2022, in the U.S. District Court for the District of Delaware. The lawsuit also involves unrelated U.S. Patents 10,028,698; 10,426,399; 10,925,535; 11,064,937; 11,202,603; 11,234,637.

The related '269 patent has also been challenged in IPR2023-00565, filed March 22, 2023.

Petitioner is not aware of any other proceeding that would affect, or be affected by, this proceeding.

3. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3))

Petitioner designates the following counsel. Power of attorney pursuant to 37 C.F.R. § 42.10(b) accompanies this Petition.

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4. Service Information (37 C.F.R. § 42.8(b)(4))

Please address all correspondence to counsel at the address above.

Petitioner also consents to electronic service by email at:

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B. Payment of Fees

Authorization is given to charge any fees due in connection with this
Petition, to Deposit Account No. **50-3266**.

III. IDENTIFICATION OF CHALLENGED CLAIMS AND STATEMENT OF PRECISE RELIEF REQUESTED

Post-grant review of claims 1-20 of the '284 Patent be instituted because it is more likely than not that at least one of these claims is unpatentable under post-AIA 35 U.S.C. §§ 112 and/or 103.¹

Ground	Claims	Statutory Basis	Prior Art References
1	1-20	35 U.S.C. § 112(a) Written Description	n/a
2	1-20	35 U.S.C. § 112(a) Enablement	n/a
3	1-8, 14, 19	35 U.S.C. § 103 Obviousness	Bao, Klee
4	9-13, 20	35 U.S.C. § 103	Bao, Klee, Shouldice
5	15, 16, 18	35 U.S.C. § 103	Bao, Klee, Dong
6	17	35 U.S.C. § 103	Bao, Klee, Dong, Shouldice
7	1-3, 6, 19-20	35 U.S.C. § 103	Farrell, Pirzada
8	4, 5, 7, 8, 14	35 U.S.C. § 103	Farrell, Pirzada, Bao
9	9-13	35 U.S.C. § 103	Farrell, Pirzada, Bao, Shouldice
10	15-18	35 U.S.C. § 103	Farrell, Pirzada, Bao, Dong

Each prior art reference is analogous art to each other and to the '284 patent because they describe the collection and communication of data among components of sleep disorder diagnosis and treatment systems and face problems similar to those alleged in the '284 patent. EX1003, ¶¶138-39, 153, 176, 183, 187, 190.

¹ Unless otherwise noted herein, all references to sections of 35 U.S.C. are made with respect to post-AIA sections.

IV. THE '284 PATENT

A. Summary of the '284 Patent

The '284 patent claims a positive airway pressure (PAP) sleep disorder treatment system that determines the “severity” of a patient’s sleep disorder and transmits certain data amongst a PAP device, a cell phone, and a remote internet site.

Despite PO’s acknowledgement that prior art CPAP devices already used feedback sensors to adjust their operation (EX1001, 2:25-34 (the sensor “measure[s] gas flow through the device.”)), the '284 patent purports to provide an invention that merely, without more, adjusts a treatment device based on sensor feedback. *Id.*, 2:46-49; EX1003, ¶¶38-40.

1. '284 Patent Copies a Previous Patent’s Description of Prior Art Sensors and a Wireless Signal Processing Unit

Ten columns of the '284 patent’s specification—from 9:1 to 18:60, as well as Figs. 1-6—copy the entire Detailed Description of AIA §102(a)/pre-AIA §102(b) prior art U.S. 6,167,258 (Schmidt) (EX1007).²

Like the '284 patent, Schmidt discloses sensors, including an “air flow” sensor, that supply data to signal processing module 16 for conditioning and

² Schmidt was not identified to the '284 patent’s Examiner. It shares an inventor (Schmidt) with the '284 patent, who is a Patent Practitioner identified in the PTO’s Correspondence Address records for the '284 patent and the Schmidt reference.

processing. EX1007, 4:7-22; 14:40-54; EX1001, 18:46-60. The processing module 16 wirelessly transmits data to base station 40 via bidirectional transceivers (*id.*, 5:32-38; Fig. 1), as in the '284 patent (9:37-45). EX1003, ¶¶41-43.

2. '284 Patent Copies a Previous Patent's Description of a "Prior Art" "Conventional" PAP System

The '284 patent's Figure 7 and corresponding description (22:49-23:25) are copied from U.S. 6,644,311 (Truitt) at Figure 1 (labeled "Prior Art") and "Background of the Invention" at 1:45-2:10. EX1018.³ Despite the '284 patent's assertion that Figure 7 is a "device of the present invention," the description of a flow sensor internal to a PAP device and using information from a flow sensor to control or monitor usage were copied, without citation, from Truitt's description of *prior art*. Compare EX1001, 23:15-25 with EX1018, 1:45-2:10. EX1003, ¶48.

3. The Purported Invention Uses Known Treatment Devices, Sensors and Data Analysis Algorithms

The '284 patent does not disclose a new sleep disorder treatment device. Instead, "[t]he treatment device can be any device known to those skilled in the art." EX1001, 3:56-61; 4:6-12; 2:25-29.

The '284 patent also did not invent a new type of sensor. "Sensors which can be used are known to those skilled in the art." EX1001, 6:21-22. "The

³ Figure 7 of the '284 patent depicts a "conventional pressure support system" (22:53-62) leaving only Figure 8 to depict purportedly new subject matter.

diagnostic part of the system of device can use various sensors for measuring the subject's brain wave signals, respirations and the like. ... Sensors for measuring the subject's respirations or oxygen levels include sensors to measure airflow, respiratory effort, oxygenation and ventilation, and the like." *Id.*, 3:17-23.

The '284 patent also relies on known data analysis algorithms. "Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms." EX1001, 20:11-14. The purported invention "would also include other on-line signal processing algorithms known to those skill in the art, such as wavelet analysis...." *Id.*, 20:36-41. The "signal-processing techniques" disclosed at 20:21-22:8 are copied, without citation, from paragraphs 40-45 of U.S. 2004/0129838. EX1019 (AIA §102(a)/pre-AIA §102(b) prior art); EX1003, ¶¶44-47.

B. '284 Patent's Prosecution History

The '284 patent was filed as the '266 application on May 26, 2022, as a continuation of the '963 application, now U.S. 11,375,921. EX1001, INID. (63). The '963 application is a continuation of the '116 application, now U.S. 10,076,269, which is a continuation of the '899 application, now U.S. 8,172,766. *Id.*

Claim 1 initially broadly recited a “sleeping disorder treatment system”

comprising:

- “a first device for diagnosing and creating a quantitative output of a level of severity of a subject's sleeping disorder or symptoms;” and
- “a second device for physically or chemically treating a subject’s sleeping disorder or symptoms, which can be adjusted using in part the output of the level of severity of the subject’s sleeping disorder.”

EX1004, 295; EX1002, 235.

Eventually, Claim 1 became a “positive airway pressure (PAP) sleep disorder treatment system” comprising, among other things:

- “first software executable by a first processor and configured to be used with a cell phone to display . . . an index of treatment efficacy of the subject using a PAP device . . . on the cell phone,”
- “an index of treatment efficacy . . . based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject,”
- a PAP device calculating “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject,”

- a PAP device comprising “a second processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device;” and
- a “remote internet site adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject.”

EX1001, Claim 1.

At no point, however, did the Applicant indicate support for any claim amendment, particularly during the prosecution of the '266 application, which issued as the '284 patent. *See, e.g.*, EX1002, 67, 107, 172; EX1004, 35, 95, 155, 202; EX1005, 105, 186, 247, 300, 370, 478; EX1006, 181, 229. This is significant because many limitations of independent Claim 1 lack written description support and are not enabled. *See* Sections IV.C, VII.A and VII.B; EX1003, ¶¶49-53; EX1020, ¶¶42-56.

In addition, the Applicant overcame an obviousness rejection of most of the pending claims, including the claim that issued as Claim 1, over the combination of Farrell (EX1012) and Pirzada (EX1013) by alleging that Pirzada was not prior art. EX1002, 67. But this argument was made with respect to the alleged priority date of November 4, 2005. *Id.* As noted below, the '284 patent is not entitled to this

priority date. Section IV.C. Thus, the Examiner erred by disqualifying Pirzada as prior art and allowing the '284 patent over the combination of Farrell and Pirzada. EX1003, ¶¶49-53.

C. The Challenged Claims Have a Priority Date No Earlier Than May 26, 2022

It is well settled that “a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112.” *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995); IPR2020-00832, paper 17, 30-31.

The challenged claims are not entitled to the 2005 priority date alleged by PO during the prosecution of the '266 application. Specifically, the challenged claims include several limitations that were first introduced during the prosecution of the '266 application, 17 years after the filing of the initial '899 priority application. Some of these limitations include:

- “an index of treatment efficacy of the subject using a PAP device, ... the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject;”
- “the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject’s treatment and the treatment's efficacy;”

- “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone;” and
- “software ... configured to be used with a cell phone to display to a subject for viewing on the cell phone ... an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the index on the cell phone” as required by Claim 1.

EX1003, ¶¶54-57; EX1020, ¶¶57-60. The Applicant did not make a statement or provide any evidence of how the specification of the '266 application or any of the priority applications supported this new claim language. *E.g.*, EX1002, 67, 107, 172.

None of the above limitations appear in the '284 patent's specification or in any of the priority applications, whose specifications are almost identical to the '284 patent's specification. EX1003, ¶¶57-58; EX1020, ¶59. A POSITA, reading each priority application, would not have understood that the inventor had invented or had actual possession of the newly claimed subject matter. EX1003, ¶58; EX1020, ¶59. Instead, a POSITA, reading the written description of each priority application, would have understood that the inventor had not invented nor had actual possession of the newly claimed subject matter. EX1003, ¶58; EX1020, ¶59. As such, each priority application fails to provide proper 112 written description

support for at least the above limitations of the challenged claims. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

Because each of the priority applications lack “written description support for the challenged claims,” there cannot be a “continuous chain of copending applications each of which satisfies the requirements of § 112 with respect to the subject matter presently claimed.” *Hollmer*, 681 F.3d 1351 at 1355. As such, the challenged claims are not entitled to a priority date of any of the prior applications in the chain. *Id.* The correct priority date of the challenged claims can be no earlier than the date in which the ’266 application was filed—May 26, 2022. EX1001, INID. (22); EX1003, ¶59.

V. POSITA

A POSITA 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, where an increase in experience could compensate for less education, and vice-versa. A POSITA would have worked with professionals having specialized training in related disciplines such as clinical use and operation of sleep disordered breathing treatment devices. EX1003, ¶60.

VI. CLAIM CONSTRUCTION

No claim term needs formal construction for purposes of evaluating the prior art in this Petition. Petitioner reserves the right to propose formal constructions in other forums where disputed issues may differ, or in response to PO's arguments in this proceeding. EX1003, ¶61.⁴

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1-20 are not Supported by the Written Description

Section 112(a) requires that a patent's written description "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm.*, 598 F.3d at 1351. Moreover, §112(a) requires that the specification teach a POSITA how to make and use the full scope of the claimed invention without "undue experimentation." *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

To satisfy §112(a), a patent's written description must demonstrate to those skilled in the art that the inventor had actual "possession" of the claimed subject matter. *Ariad*, 598 F.3d at 1351. The test for adequate written description support "requires an objective inquiry into the four corners of the specification from the

⁴ Petitioner took claim construction positions on claim terms recited in related '269 patent in the identified Delaware proceeding, but here follows the guidance in the claim construction order from that proceeding. See EX1021.

perspective of a [POSITA]. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Ariad*, 598 F.3d at 1351.

1. “index of treatment efficacy”

Claim 1 recites an “index of treatment efficacy of the subject using a PAP device” where “the index [is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” The applicant added these limitations in its September 20, 2022 Amendment, shown below.

software is downloaded an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the[[an]] index on the cell phone, the index based in part on a data of severity of sleep disorder symptoms of the subject-data and a data of usage related to a subject’s treatment efficacy withof the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received from a PAP device on aby

EX1002, 102-103 (highlighting added) (amendment to Claim 21, renumbered to Claim 1 when the ’266 application was allowed). The amendment added that the “symptoms” are specifically “sleep disorder symptoms,” and specified that the index itself is an “index of treatment efficacy” rather than merely an index “related to a subject’s treatment efficacy.” The Applicant added Claim 21 to the ’266 application via a June 10, 2022 Preliminary Amendment, which recited the limitation as “an index based in part on a data of severity of symptom data and data

of usage related to a subject's treatment efficacy with the PAP device." EX1002, 168. The Applicant when submitting the new claim and subsequent amendments did not inform the Patent Office where support for these new claim limitations could be found in the '266 application or its priority applications. Nor could it because the limitations are not supported. EX1020, ¶¶43-49.

The term "efficacy" does not appear in the '284 patent's specification, let alone an "index of treatment efficacy." EX1003, ¶¶62-53; EX1020, ¶43. Moreover, the term "index" is used in reference to the prior art's "respiratory disturbance index."⁵ EX1001, 1:59-64; EX1020, ¶43. The patent specification only mentions RDI as a parameter obtained via all night polysymnography to diagnose sleep apnea. EX1001, 1:59-64. The independent claim does not mention diagnosis and instead is directed to a "treatment system." The patent specification does not describe or link RDI to a parameter calculated by a PAP sleep disorder treatment device, or "based in part on data of severity of sleep disorder symptoms of the subject" as claimed. EX1020, ¶43.

Moreover, there is no disclosure of any other parameter, whether or not referred to as an index, that is "based in part on data of severity of sleep disorder

⁵ Petitioner notes that "index" is also used in the '284 patent to refer to a patient's index finger, EX1001, 8:35-36, and when referring to an index for opcodes used by a microcontroller. EX1001, 17:54-57.

symptoms of the subject *and* data of usage of the PAP device by the subject.”

EX1020, ¶44. That correlation is simply not disclosed or contemplated by the ’284 patent’s specification. EX1020, ¶44.

Thus, a POSITA would not have understood from the specification that the applicant actually invented, or “possessed,” any claim limitation reciting an “index of treatment efficacy” where “the index [is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” EX1020, ¶¶43-49.

Accordingly, Claim 1 and its dependent claims are invalid at least because the “index of treatment efficacy” limitations are not supported by the written description of the ’284 patent. *Ariad*, 598 F.3d at 1351.

2. “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device,”

The Applicant added this limitation to Claim 21 in the September 20, 2022 Amendment. EX1002, 102-103. Prior to this amendment, Claim 21 merely recited “an index based in part on a data of severity of symptom data and data of usage related to a subject’s treatment efficacy with the PAP device calculated by and received from a PAP device on a cell phone.” EX1002, 168. The Applicant when submitting the amendments did not inform the Patent Office where support for

these new claim limitations could be found. Nor could it because the limitations are not supported.

The term “data of usage” does not appear in the ’284 patent’s specification, nor is there a disclosure of a PAP device calculating the data of usage. EX1003, ¶¶64-65. Instead, the lone reference to “usage” appears in a catch-all statement on how “information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to control the pressure or flow of gas provided to the subject, monitor the condition of the subject, *monitor the usage of the pressure support device*, any combination thereof, or the like.” EX1001, 23:20-25. This single statement provides no suggestion that this usage be displayed, used in any calculation, or otherwise be combined with any other data collected from the PAP device. EX1003, ¶65. Indeed, there is simply no disclosure or suggestion of “calculating” “data of usage” by the PAP device or any device for that matter. EX1003, ¶65. That correlation is simply not disclosed or contemplated by the ’284 patent’s specification. EX1003, ¶65.

Thus, a POSITA would not have understood from the specification that the applicant actually invented, or “possessed,” any claim limitation reciting that “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device.” EX1003, ¶¶66-67.

Claim 1 and its dependent claims are invalid for this additional reason.

3. **“non-transitory computer readable medium comprising a first software executable by a first processor and configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using a PAP device....”**

The Applicant added this limitation to Claim 21 in the September 20, 2022 Amendment. EX1002, 102-103. Prior to this amendment, Claim 21 merely recited “software configured to be used with and to display to the subject for viewing an index based in part on a data of severity of symptom data and data of usage related to a subject’s treatment efficacy with the PAP device calculated by and received from a PAP device on a cell phone.” EX1002, 168. The Applicant when submitting the amendment did not inform the Patent Office where support for these new claim limitations could be found. Nor could it because the limitations are not supported.

The ’284 patent simply does not identify, describe or refer to any software “configured to be used with” or “downloaded” on a cell phone, let alone any software “to display to a subject for viewing on the cell phone ... an index of treatment efficacy....” EX1003, ¶¶68-69. The instances where software is described in the ’284 patent relate to software on the signal processing module 16 or the computer used to program the signal processing module 16 or base station 40. *E.g.*, EX1001, 9:23-26; 12:22-25; 19:5; EX1003, ¶69.

Similarly, references to a cell phone are not made with respect to software. EX1003, ¶70. Even if one presumes that a cell phone includes software, the '284 patent does not describe or even suggest displaying on the cell phone “an index of treatment efficacy.” EX1003, ¶70. Functions attributed to the cell phone by the '284 patent's specification, are listed as “receiv[ing] the physiological data transmission, optionally re-process[ing] the information, and re-transmit[ting] the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis.” EX1001, 19:45-51; EX1003, ¶70. Display of “data or records” is only mentioned with respect to an “example where the remote communication system is a computer or processor,” not a cell phone, “which receives the data transmission and displays the data or records it on some recording medium.” EX1001, 19:51-55; EX1003, ¶70.

As such, a POSITA would not have understood from the specification that the applicant actually invented, or “possessed,” any claim limitation reciting software “configured to be used with” or “downloaded” on a cell phone, or software on the cell phone “to display to a subject for viewing on the cell phone ... an index of treatment efficacy of the subject using a PAP device.” EX1003, ¶¶71-72.

Claim 1 and its dependent claims are invalid for this additional reason.

4. **“the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone**

the data of the severity of the symptoms of the subject, the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, calculated by the PAP device” (Claims 10, 14)

A majority of these dependent claims were added to the '266 application via the 6/10/2022 Preliminary Amendment. EX1022, 170-171. One amendment (related to amendments to the independent claim) revised this language to its current form. EX1002, 105. The specification only describes the “remote internet site” as *receiving* data “for analysis,” including in one example from a “cell phone.” EX1001, 19:43-51. However, the specification does not disclose that the remote internet site is (1) configured to retransmit anything to a radio frequency wireless transceiver on a cell phone, and (2) is configured to re-transmit “a second index.”

A POSITA would not have understood from the specification that the applicant actually invented, or “possessed,” any claim limitation reciting a “remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index.” EX1003, ¶¶73-74. Accordingly, Claims 10 and 14 are invalid for the additional reason that their limitations are not supported by

the written description of the '284 patent. Dependent Claims 15-17 are invalid for at least the same reasons.⁶

B. Ground 2: Claims 1-20 are not Enabled

Claims 1-20 are not enabled because the specification would not have taught a POSITA how to make and use the full scope of the claimed invention without undue experimentation. This lack of enablement arises from the same written description issues noted above. EX1003, ¶75; EX1020, ¶¶50-56.

First, the challenged claims are not enabled regarding the “index of treatment efficacy” claim elements. Outside of the claim language, there is no mention in the '284 patent or any of its priority applications of such an “index of treatment efficacy,” let alone an index “based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” See Sections VII.A.1, VII.A.2; EX1020, ¶¶51, 42-49. There is also no support for displaying such an index on a cell phone. See Section VII.A.3.

The specification provides absolutely *no* direction or guidance on how to actually determine or use the “index of treatment efficacy.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (Factor 2); EX1020, ¶52. There are no working examples in the '284 patent or its priority applications for determining the “index of

⁶ Petitioner reserves the right to allege additional claim limitations lack written description and enablement support, and are indefinite.

treatment efficacy,” let alone determining it “based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” *In re Wands*, 858 F.2d at 737 (Factor 3); EX1020, ¶52. While the claim requires “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject” to be “both calculated by the PAP device,” there is no teaching in the ’284 patent or its priority applications to support these calculations either. EX1020, ¶52. Likewise, there is also no disclosure of displaying the index of treatment efficacy on a cell phone or transmitting it to a remote internet site, which are additional requirements of all of the challenged claims.

Because the ’284 patent and its priority applications are completely silent with respect to these requirements for, and use of, the “index of treatment efficacy,” a POSITA would have recognized and continue to recognize that the unpredictable nature of sleep disorder treatment and the patient’s adherence to the treatment means that, absent specific guidance, a significant amount of experimentation would be needed to determine a treatment efficacy, and an index for quantifying that efficacy so that it could be displayed and used in the claimed sleep disorder treatment system. *Wands*, 858 F.2d at 737 (Factors 1, 4, 7); EX1020, ¶¶50-56.

The lack of any enabling disclosure is even more evident in view of the claim terms themselves, which broadly claim the determination, display, transmission, and receipt of the “index of treatment efficacy,” but there is no guidance in the specification to enable these claimed elements. *In re Wands*, 858 F.2d at 737 (Wands Factor 8); EX1020, ¶¶50-56. Thus, at least six Wands factors support that the “index of treatment efficacy” claim elements are not enabled. EX1020, ¶¶50-56.

C. Ground 3: Claims 1-8, 14, and 19 are Rendered Obvious by Bao in view of Klee

As discussed in Section IV.C, the earliest possible priority date of the challenged claims is May 26, 2022.

Bao (EX1009) published July 7, 2016 and is prior art under 35 U.S.C. §§102(a)(1), (2).

Klee (EX1010) published July 19, 2018 and is prior art under 35 U.S.C. §§102(a)(1), (2).

1. Claim 1

It is more likely than not that claim 1 is rendered obvious by Bao in view of Klee for the reasons set forth below.

a. 1pre. “A positive airway pressure (PAP) sleep disorder treatment system comprising:”

To the extent the preamble is limiting, Bao discloses this limitation.

EX1003, ¶¶76-80.

Bao discloses “a CPAP device/apparatus 200 incorporating certain features, aspects and advantages of an embodiment of the present invention. The CPAP apparatus 200 comprises a blower 202 that propels a stream of pressurized air through a breathing conduit 106 (see FIG. 1) to an interface 107 wearable by a patient.” EX1009, ¶124; FIGS. 1, 2.

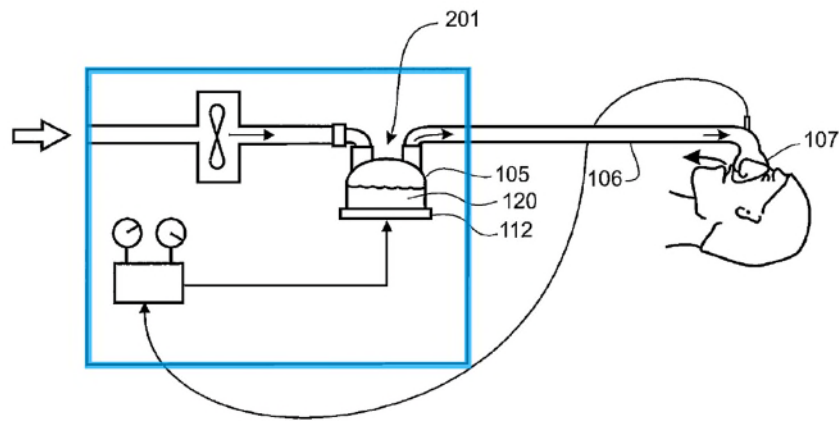


FIGURE 1

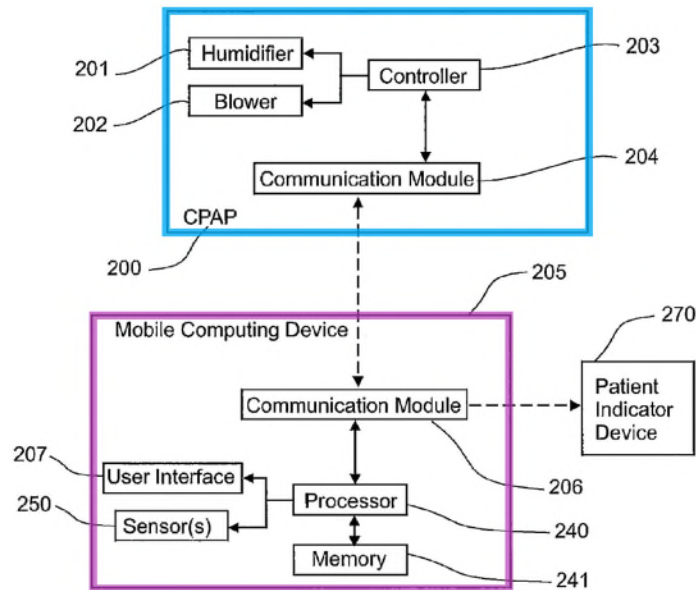


FIGURE 2

The Bao system also comprises a “mobile computing device 205,” EX1009, ¶¶125, 126, that “may be configured to transmit (e.g. through use of the internet) data such as, but without limitation, patient and compliance data to a website that also hosts details of other patients and/or support groups.” *Id.*, ¶156; EX1003, ¶¶80-81.

- b. 1a. “a non-transitory computer readable medium, the non-transitory computer readable medium comprising a first software, the first software executable by a first processor and configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the index on the cell phone, the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data

of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display;”

Bao in view of Klee disclose the subparts of this limitation directed to the components, configuration and use of the cell phone. EX1003, ¶82.

(i) non-transitory computer readable medium comprising first software executable by a first processor and configured to be used with a cell phone, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display:

The Bao mobile computing device 205 is “a cellular phone comprising a display screen 207 comprising a graphical user interface 208.” EX1009, ¶132. As such, it discloses the “cell phone” and “display” portions of this limitation. EX1003, ¶83.

“The mobile communication device 205 comprises a processor 240 with associated memory 241 configured to execute computer-executable instructions.” EX1009, ¶¶126, 95, FIG. 2. The processor 240 is the claimed “first processor” and executes the “first software” to perform the functions discussed below because it can “connect to the internet ... and download a software update and/or modification for the mobile computing device 205.” *Id.*, ¶170. A POSITA would have understood that to “download a software update,” the mobile device 205

would necessarily comprise software needing to be updated. EX1003, ¶84.

Likewise, a POSITA would have understood that the software was stored in a computer readable medium in at least the memory 241 of the mobile device 205 so that it would be downloaded and executed by the processor 240. EX1003, ¶¶83-84.

Mobile computing device 205 further includes a communication module 206 that can be a “radiofrequency (RF) module[] capable of communication.” EX1009, ¶125. Communication module 206 can receive and transmit data and other signals from/to a communication module 204 in the CPAP device 200 “through one or more types of wireless networks and associated protocols, including but not limited to WiFi, Bluetooth, and 2G/3G/4G.” EX1009, ¶125. A POSITA would have understood that because the communication module 206 can transmit and receive data wirelessly, it would necessarily comprise a transceiver and therefore disclose “at least one first radio frequency wireless transceiver.” EX1003, ¶85.

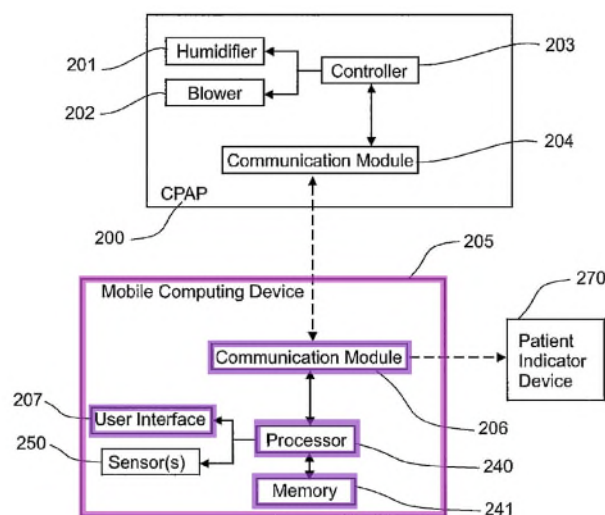


FIGURE 2

(ii) displaying, on the cell phone, an index of treatment efficacy of the subject:

Bao discloses “display[ing] to a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the index on the cell phone.” EX1003, ¶86. Bao discloses that “the mobile computing device 205 is shown in the form of a cellular phone comprising a display screen 207 comprising a graphical user interface 208” and the “first software” as discussed above. EX1009, ¶¶126, 131-132, 170. Regarding the claimed “index of treatment efficacy of the subject using a PAP device,” Bao discloses:

The graphical user interface 208... may display, though (sp.)
the use of one or more pop-up window(s) or some other display
configuration, one or more value(s) conveying information to
the patient. This information may convey at least one or more
of the following: compliance data, ***therapy efficacy data***,
trending data representing compliance and/or ***therapy efficacy***
for a patient over time, AHI data, number of hours used...

Id., ¶132 (emphasis added). The '284 patent contains no written description support or enabling disclosure for the claimed “index of treatment efficacy.”

See Sections VII.A.1, VII.B. A POSITA would have understood that at least

one of the “**therapy efficacy data**” or “**therapy efficacy for a patient over time**” would comprise an index, which, as known in the art, is merely one way of a limited number of options to quantify the “therapy efficacy” disclosed by Bao. EX1003, ¶86. Bao discloses “AHI data,” and a POSITA would have understood that “AHI” means “Apnea-Hypopnea-Index,” and that Bao contemplated indices for its patient therapy information. EX1010, ¶41; EX1003, ¶86. For example, it is known that AHI averages apneas and hypopneas over time and is an index. *Id.* In the same way, Bao’s therapy efficacy “over time” would also have been recognized as an index (i.e., an index of treatment efficacy). *Id.*

(iii) the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject:

To the extent understood, Bao in view of Klee discloses “the index [of treatment efficacy of the subject being] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” EX1003, ¶87. Bao discloses that its mobile computing device 205 and graphical user interface 208 can display, among other things, “**therapy efficacy data, ..., therapy efficacy for a patient over time, ..., number of hours used.**” EX1009, ¶132 (emphasis added). As such Bao discloses at least one component

(i.e., data of usage of the PAP device by the subject) for determining the claimed, but not disclosed or enabled, “index of treatment efficacy.” EX1003, ¶87.

Bao also discloses AHI data, which a POSITA would have understood to be “an index used to indicate the ***severity of sleep apnea***.” EX1010, ¶41 (emphasis added); EX1003, ¶88. Accordingly, Bao discloses a form of “data of severity of sleep disorder symptoms of the subject,” as best understood. EX1003, ¶88. Bao, however, does not appear to disclose use of different forms of data (e.g., severity and usage) to produce the claimed “index of treatment efficacy.” *Id.*

Klee, however, discloses an analogous system that uses a broad range of therapy data and ways to *combine* the data to determine, e.g., “an overall sleep apnea severity score.” EX1010, ¶41. Specifically, and as shown below, Klee discloses both the sleep severity data and the time of usage data that determine the “index of treatment efficacy.” EX1003, ¶89.

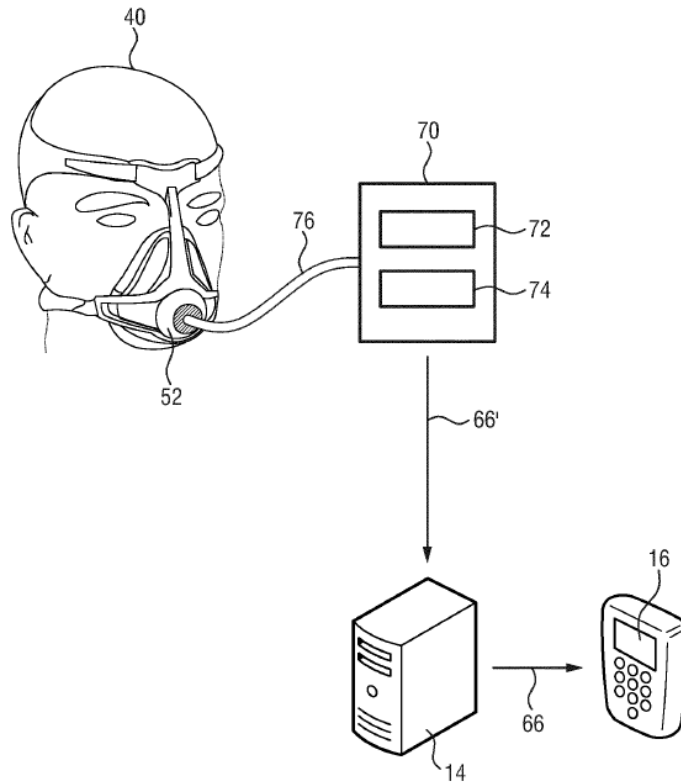


FIG.2b

Specifically, Klee discloses that:

“Therapy data” include all data which may be measured and/or determined along therapy and data relating to controlling the device used for therapy. Preferred therapy data include one or more of the *Apnea-Hypopnea-Index (AHI)*, *overall sleep apnea severity score*, number of apneas and/or apopneas per time unit, e.g. by night, and *time of usage of a therapy device for providing said therapy*, fit of mask but any other parameters might be also included. *The AHI is an index used to indicate*

the severity of sleep apnea. It is represented by the number of apnea and hypopnea events per hour of sleep. The apneas (pauses in breathing) must last for at least 10 seconds and are associated with a decrease in blood oxygenation. ***Combining AHI and oxygen desaturation gives an overall sleep apnea severity score that evaluates both number sleep disruptions and degree of oxygen desaturation (low blood level).***

EX1010, ¶41.

As mentioned above, there is no disclosure of how the '284 patent determines the “index of treatment efficacy.” However, seeing as how Bao and Klee disclose therapy efficacy data, therapy efficacy for a patient over time, usage of the PAP device (i.e., number of hours used), an index (i.e., AHI), and combining data to achieve an overall sleep apnea severity score, a POSITA would have understood that the combined teachings of Bao and Klee would be used to determine, as best understood, an “index of treatment efficacy” “based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” EX1003, ¶¶90-91.

To the extent that Bao does not expressly disclose the details of all of the different types of therapy data required by the Claim, a POSITA would have looked to disclosures like Klee for details on what types of therapy data would be

used for the recited “treatment efficacy.” A POSITA, with knowledge of Bao and Klee, would have considered it obvious to combine their respective teachings.

EX1003, ¶92. Bao and Klee share commonalities in terms of their general subject matter (e.g., using CPAP and other devices to treat sleeping/breathing disorders) and technique used (e.g., evaluating patient, treatment and other data) to improve operation of CPAP treatment devices to better treat the patient and its disorder. *Id.* Moreover, Bao and Klee are within the same technical field as each other and the ’284 Patent. *Id.*

A POSITA would have been further motivated to combine the teachings of Bao and Klee to arrive at the claimed treatment system because it would amount to merely applying a known technique (i.e., determining treatment efficacy based on multiple factors) to a known device ready for improvement (e.g., CPAP treatment system comprising multiple devices) to yield predictable results (i.e., improve operation of CPAP treatment to better treat the patient and its disorder). *KSR Int’l Co. v. Teleflex, Inc.* (“KSR”), 550 U.S. 398, 416 (2007); EX1003, ¶93.

It was well known and disclosed in both Bao and Klee that a number of useful parameters could be calculated at the PAP processor. *E.g.*, EX1009, ¶¶129-131; EX1010, ¶¶41, 122, 128. It was also known that compliance and efficacy were important, and could be used to motivate a patient to comply with their prescribed treatment. *E.g.*, Bao at ¶102 (“several ways in which such mobile

computing device may be used to help the patient comply with a CPAP therapy regime ...”); Klee at ¶44 (“Feedback information preferably encompasses information regarding the progress and effort of the therapy.”); *see also* ¶52. Accordingly, a POSITA would have been motivated to make the claimed combination, and had a reasonable expectation of success in doing so. *Id.*; EX1003, ¶¶94-95.

Moreover, there is simply nothing in the ’284 patent to contradict such a combination of Bao and Klee.

(iv) the data of severity and the data of usage both calculated by the PAP device and received by the cell phone:

Bao in view of Klee discloses that “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone.” EX1003, ¶96.

Bao discloses that “the mobile computing device 205 may be configured to interrogate the CPAP apparatus 200 for compliance data.” EX1009, ¶¶150, 159 (receiving information from the CPAP), 163 (“CPAP apparatus 200 could sense the wakefulness of the patient through conditions sensed at the CPAP apparatus 200”), 132 (listing examples of relevant information, including compliance data, number of hours used). A POSITA would have understood that compliance data

from the CPAP apparatus 200 would include data of usage of the PAP device by the subject. EX1003, ¶¶96-97.

Moreover, Klee discloses that “PAP system 70 also generates therapy data 22 derived from system settings and one or more sensors of the system 70 for measuring system related parameters.” EX1010, ¶122. The “therapy data include[s] one or more of the Apnea-Hypopnea-Index (AHI),” and “overall sleep apnea severity score,” and “time of usage of a therapy device.” EX1010, ¶41.

Moreover, Klee discloses that “a remote device, such as a smartphone or tablet, [is] provided for instant or later displaying the feedback information 30 based on the data 20, 22, 24, 26 and 28.” EX1010, ¶¶119, 128 (“CPAP data 22' encompass data about AHI 80, ... mask usage 84”), 130 (“CPAP usage data 22 (therapy data) can be downloaded by the patient 40 via an app from his/her mobile phone”). A POSITA would have understood that the Bao and Klee data comprising “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject” are therefore “both calculated by the PAP device and received by the cell phone.” EX1003, ¶98.

c. 1b. “the PAP device with an enclosure further comprising: a blower having an air output,”

Bao discloses this limitation. EX1003, ¶99. Bao discloses that “FIG. 2 is a block diagram illustrating an embodiment of a CPAP device/apparatus 200 incorporating certain features, aspects and advantages of an embodiment of the

present invention.” EX1009, ¶124. The “CPAP apparatus 200 comprises a blower 202 that propels a stream of pressurized air through a breathing conduit.” EX1009, ¶124.

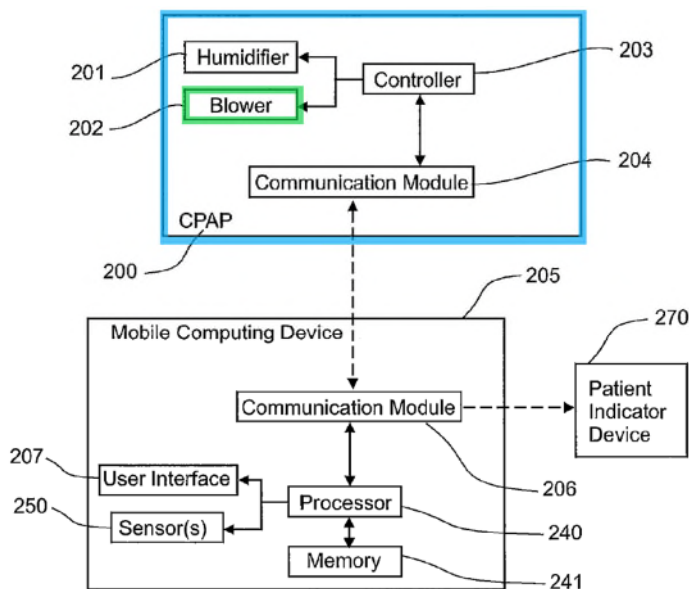


FIGURE 2

Although the blower 202 is not specifically disclosed in the text of Bao as being within the CPAP apparatus’ housing/enclosure, the humidifier 201 and other components are. *E.g.*, EX1009, ¶¶124, 141-143, 160. FIG. 1 also shows a representation that a POSITA would understand as a blower within the same PAP apparatus as the humidifier 201. A POSITA would have understood that the blower 202 is within the apparatus’ enclosure. EX1003, ¶¶99-100.

- d. **1c. “an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data,”**

Bao discloses this limitation. EX1003, ¶¶101-103. Bao discloses that “[t]he operation parameters of the CPAP apparatus 200 that are capable of being adjusted may include, but are not limited to, ... **flow**.... Additionally, such parameters along with other data, including data obtained by **sensors** on, **within** or connected to the CPAP apparatus 200 can be displayed on the display screen of the mobile computing device 205.” EX1009, ¶131, 132 (“current flow”), 99 (“sensors” as “hardware modules on a typical CPAP device”), 172 (“sensor data (e.g., pressure and/or flow data, etc.) obtained at the CPAP apparatus”). A POSITA would have understood the reference to “flow” as meaning airflow and that the corresponding sensor would be an “airflow sensor” internal to the CPAP apparatus as explicitly disclosed by Bao (i.e., “sensors ... within ... the CPAP apparatus 200”). EX1003, ¶101. A POSITA would have also recognized that there were two typical locations for placement of a “flow” sensor, which were (1) at the flow generator (blower), or (2) at or near the mask. *See, e.g.*, EX1017, 8:31-36; EX1003, ¶101. Accordingly, a POSITA would have recognized a flow sensor is the type of sensor that would be “within” the CPAP apparatus. EX1003, ¶101. Accordingly, a POSITA would have recognized a flow sensor is the type of sensor that would be “within” the CPAP apparatus. Alternatively, based on these two location options known to a POSITA, it would have at least been obvious to locate the flow sensor within the CPAP apparatus enclosure as known to those skilled in the art. EX1003, ¶101.

Bao further discloses that its sensors output “sensor data.” EX1003, ¶102.

For example, “one or more of the CPAP apparatus 200, the mobile computing device 205, and ***associated sensor(s)*** are configured to transmit ... ***sensor data generated by the sensors and/or information corresponding to the sensor data*** to another computing device.” EX1009, ¶149.

The phrase “respiratory airflow of a subject” could be understood to be airflow at the mask. A POSITA would have recognized that Bao’s flow sensor within the apparatus would be used to derive “mask flow” as known in the art by accounting for pressure loss along the tubing and exhaust and/or leak at the mask. EX1017, 8:31-62, FIG. 3; EX1009, ¶132 (“severity of mask leak, ... current flow”); EX1018, 2:1-10 (copied into the ’284 at 23:15-25) (using flow information from an internal flow sensor to “determine the volume of gas passing through patient circuit,” and to “monitor the condition of the patient”);⁷ EX1003, ¶103. A POSITA would have recognized the “mask flow” calculation is used as part of Bao’s disclosed “sleep algorithm” as feedback for “controlling the blower” of the CPAP apparatus, and that it would have at least been obvious to calculate “mask flow” at the CPAP apparatus’s controller as disclosed by Bao, rendering this

⁷ PO argued in IPR2023-00565 that this description of conventional devices, copied into the ’284 patent from EX1018, describes the claimed airflow sensor. IPR2023-00565, Paper 6, 5-6.

limitation at least obvious. EX1009, ¶¶127, 171 (“mobile computing device 205 may be configured to process at least one sleep algorithm for the control of the CPAP apparatus 200, rather than the controller 203”); EX1003, ¶103.

- e. **1d. “a second processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device,”**

Bao in view of Klee discloses this limitation. EX1003, ¶104. Bao discloses “a controller 203, which preferably comprises a microprocessor with associated memory.” EX1009, ¶125; FIG. 2.

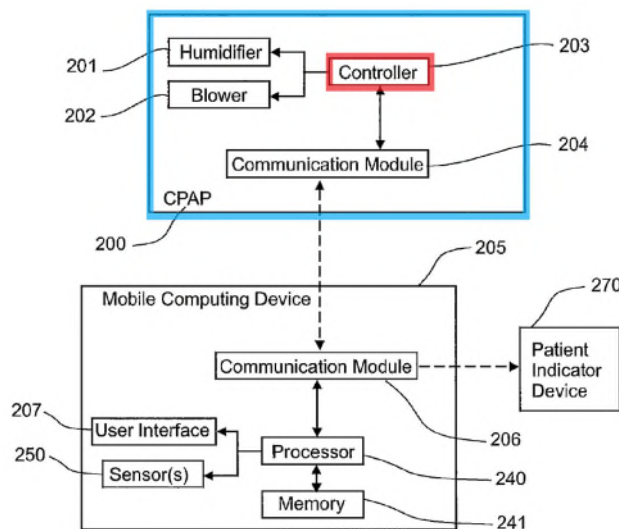


FIGURE 2

The Bao and Klee combination discloses “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone.” Section VII.C.1.b; EX1003, ¶105. A POSITA would have understood that the controller

203 is the claimed “second processor” because it controls the operation of the CPAP apparatus 200. EX1009, ¶¶125, 127; EX1003, ¶105.

A POSITA would have understood that the Bao controller 203 “is adapted to” receive the airflow sensor data because the CPAP apparatus 200 is configured to “transmit ... sensor data generated by the sensors and/or information corresponding to the sensor data to another computing device,” meaning that the airflow sensor data must be received by the controller 203, which interacts with the communication module 204 that transmits such information off of the CPAP apparatus. EX1009, ¶¶125, 149; EX1003, ¶106.

Petitioner notes that while the claimed second processor is adapted to receive the airflow sensor data, the claim does not require it to be used in any of the claimed calculations. EX1003, ¶107.

f. 1e. “a mask or a nasal cannula, and”

Bao discloses this limitation. EX1003, ¶108. Bao discloses that the “CPAP apparatus 200 comprises a blower 202 that propels a stream of pressurized air through a breathing conduit 106 (see FIG. 1) to an interface 107 wearable by a patient.” EX1009, ¶124. The “patient interface 107” is shown and described as a “mask.” *Id.*, 135.

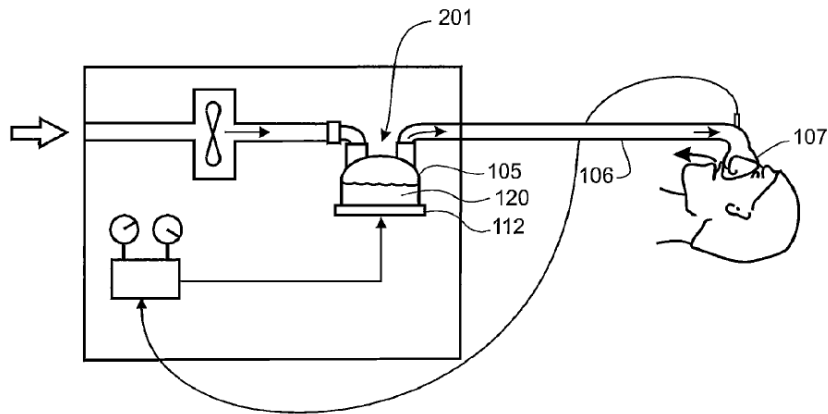


FIGURE 1

- g. 1f. “at least one second radio frequency wireless transceiver, the at least one second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor; and”**

Bao in view of Klee discloses this limitation. EX1003, ¶109. Bao discloses “a communication module 204, which may transmit and/or receive control signals and/or other data to and/or from a corresponding communication module 206 in a mobile computing device 205 through at least one communication or data link, such as at least one communications network.” EX1009, ¶124.

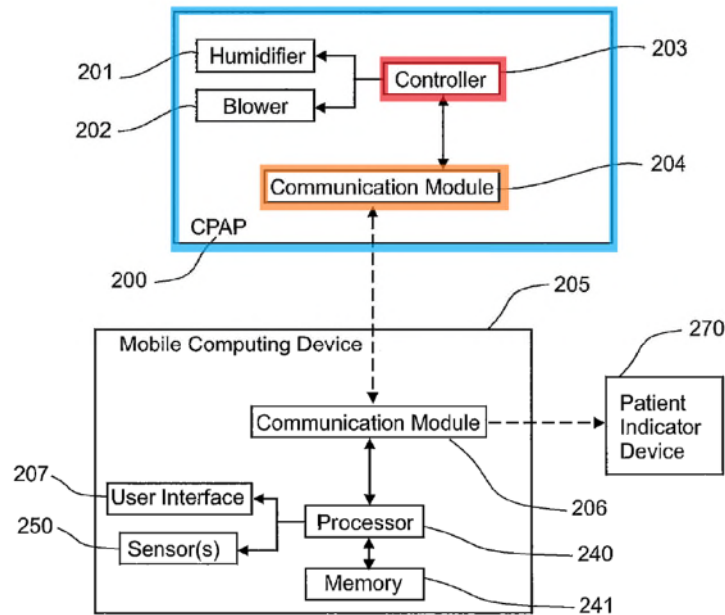


FIGURE 2

The communication module 204 can be a “radiofrequency (RF) module[] capable of communication” that can receive and transmit data and other signals from/to a communication module 206 “through one or more types of wireless networks and associated protocols, including but not limited to WiFi, Bluetooth, and 2G/3G/4G.” EX1009, ¶125. A POSITA would have understood that because the communication module 204 can transmit and receive data wirelessly, it would necessarily comprise a transceiver and therefore disclose “at least one second radio frequency wireless transceiver.” EX1003, ¶110.

The Bao and Klee combination discloses “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone.” Section VII.C.1.b; EX1003, ¶111. A POSITA would have understood that the controller

203 is the claimed “second processor.” Section VII.C.1.e; EX1003, ¶111.

Accordingly, the communication module’s 204 ability to “transmit and/or receive control signals and/or other data,” means that the communication module 204 “is adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor.” EX1003, ¶111.

- h. 1g. “a remote internet site, the remote internet site adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.”**

Bao in view of Klee discloses this limitation. EX1003, ¶112. Bao discloses that “one or more of the CPAP apparatus 200, the mobile computing device 205, and associated sensor(s) are configured to transmit compliance data, therapy efficacy data, sensor data generated by the sensors and/or information corresponding to the sensor data to another computing device. The other computing device may be located remotely from the CPAP apparatus 200 and the mobile computing device 205, for example, and may be accessible by a clinician overseeing operation of the CPAP apparatus ...” EX1009, ¶¶149, 159 (“a data connection may be established in which information can be transferred from the CPAP apparatus 200 to the mobile computing device 205 ..., and then from the

mobile computing device 205 ... to **the internet** or another mobile computing device ...”). Moreover, BAO discloses that “the CPAP apparatus 200 ... [is] configured to communicate with the other computing device ... through one or more communication or data links including WiFi, Bluetooth, 2G/3G/4G, the internet. EX1009, ¶149.

Bao further discloses “a remote cloud based service” where “data such as, but not limited to, sensor data, patient settings, compliance data, and/or therapy efficacy data” can be accessed in real-time, shared and analyzed. EX1009, ¶151. The “CPAP apparatus 200 or one or more sensor modules (e.g. sensor modules 310, 312) may be configured to transmit sensor data through a wireless or wireless data connection directly (not through the mobile computing device 205) to the remote cloud based service.” *Id.*; EX1003, ¶113.

Bao also discloses that “the mobile computing device 205 may be configured to transmit (e.g. through use of the internet) data such as, but without limitation, patient and compliance data to a **website** that also hosts details of other patients and/or support groups. In some configurations, the **website** may be configured so patients can participate in challenges and/or compare compliance with other patients.” *Id.*, ¶156; EX1003, ¶114.

A POSITA would have understood that the CPAP apparatus, and specifically its “radio frequency wireless transceiver,” would be adapted to

transmit the “the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject’s treatment and the treatment’s efficacy” disclosed by Bao in view of Klee (see Section VII.C.1.g) “in whole or part” to a website (such as the one disclosed for use by the patient) or cloud based service (storing “sensor data, patient settings, compliance data, and/or therapy efficacy data” so they can be accessed in real-time, shared and analyzed) through the mobile computing device 205. EX1003, ¶114.

Doing so would have merely involved combining prior art elements (i.e., transmission of patient, sensor, therapy data and treatment efficacy from devices in a CPAP system to a website) according to known methods (e.g., wireless transmissions over the internet) to yield predictable results (a remote website reachable over the internet for receiving, storing and analyzing the patient, sensor, therapy data and treatment efficacy information). *KSR*, 550 U.S. at 416; EX1003, ¶115. Doing so would have, among other things, improved the clinician’s ability to access the data in real time and analyze it. EX1003, ¶115. In addition, the website allows patients to participate in challenges and/or compare compliance with other patients, which would entice the patients to adhere to their therapy because “patients feel their goals are attainable.” *Id.*; EX1009, ¶156. A POSITA would

have had a reasonable expectation of success in implementing such a remote internet site based on the combined teachings of Bao and Klee. *Id.*

2. Claim 2

- a. **“The system of claim 1, wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol.”**

Bao discloses this limitation. EX1003, ¶116. Bao discloses that “the modules 204, 205 can communicate through one or more types of wireless networks and associated protocols, including but not limited to WiFi, *Bluetooth*, and 2G/3G/4G.” EX1009, ¶125.

3. Claim 3

- a. **“The system of claim 1, wherein the at least one second radio frequency wireless transceiver is configured to transmit the data to the remote internet site and/or the cell phone of the data of the severity of the symptoms of the subject and/or the index, and the data of usage via in part by cell towers.”**

Bao discloses this limitation. EX1003, ¶117. Bao discloses that “the modules 204 [of the CPAP apparatus], 205 [of the mobile computing device] can communicate through one or more types of wireless networks and associated protocols, including but not limited to WiFi, Bluetooth, and **2G/3G/4G**.” EX1009, ¶125. A POSITA would have recognized the reference to “2G/3G/4G” to disclose cellular communication protocols that use cell towers. EX1003, ¶117.

4. Claim 4

- a. “The system of claim 3, the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is configured for calculating the data of severity of the symptoms of the subject, wherein the PAP is further adapted to be reprogram or modify the at least one second software from the remote internet site or a second remote internet site.”**

Bao in view of Klee discloses this limitation. EX1003, ¶118. Bao in view of Klee discloses that the CPAP apparatus 200 comprises the “second processor ... for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device.” Section VII.C.1.e; EX1003, ¶118. Bao discloses a memory associated with the second processor. EX1009, ¶125 (“a controller 203, which preferably comprises a microprocessor with associated memory.”), FIG. 2. Bao further discloses downloading “a software update and/or modification for the ... the CPAP apparatus 200.” EX1009, ¶170. A POSITA would have understood that to “download a software update,” the CPAP apparatus 200 would necessarily comprise software needing to be updated. EX1003, ¶118. This software is the claimed “second software stored on a memory and executed by the second processor.” *Id.*

Bao further discloses that the software update and/or modification is received over the internet. EX1009, ¶170. A POSITA would have understood that

the software update and/or modification, received over the internet, would have been from an internet site remote from the CPAP apparatus; meaning that Bao discloses that “the PAP is further adapted to be reprogram or modify the at least one second software from the remote internet site or a second remote internet site.” EX1003, ¶119.

5. Claim 5

- a. “The system of claim 4, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the data measured, calculated and then transmitted to the remote internet site.”**

Bao in view of Klee discloses this limitation. EX1003, ¶120. Bao in view of Klee discloses that the CPAP apparatus 200 comprises the “second processor ... for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device.” Section VII.C.1.e; EX1003, ¶120. Bao in view of Klee further disclose “the remote internet site adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject ... generated by the PAP device.” Section VII.C.1.h; EX1003, ¶120.

Bao discloses that a “mobile computing device... may be linked to a CPAP apparatus in such a way that the CPAP apparatus may be remotely controlled

through use of a user interface located on the mobile computing device.

Additionally, using the communication link, data obtained from sensors on or connected to the mobile computing device may be used to adjust various operating parameters of the CPAP device.” EX1009, ¶100. Bao further discloses “the clinician’s computing device may be a mobile computing device. In some configurations, the clinician’s computing device may be remotely located from the patient and/or CPAP apparatus 200, such as in a sleep laboratory. The clinician may analyze and use the data to adjust the pressure and/or flow settings, for example, of the CPAP apparatus 200.” EX1009, ¶145. Bao further discloses “[t]he operation parameters of the CPAP apparatus 200 that are capable of being adjusted may include, but are not limited to, treatment pressure, flow, motor speed, heater plate power/temperature, heated breathing tube power, level of humidification,...” EX1009, ¶131. Thus, the CPAP apparatus 200 comprises more than one “electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the data measured, calculated and then transmitted to the remote internet site.” EX1003, ¶121.

6. Claim 6

- a. “The system of claim 1, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the**

symptoms of the subject and/or the index, based in part on the data measured, calculated and then transmitted to the remote internet site.”

Bao discloses this limitation for at least the same reasons discussed for Claim 5. EX1003, ¶122; Section VII.C.5.a.

7. Claim 7

- a. “The system of claim 1, wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely.”**

Bao discloses this limitation. EX1003, ¶123. Bao discloses “first software” stored a computer readable medium on the cell phone (i.e., mobile computing device 205) and executed by the cell phone adapted to “connect to the internet ... and download a software update and/or modification for the mobile computing device 205.” EX1009, ¶170; Section VII.C.1.b.

A POSITA would have understood the download of the software update and/or modification in the Bao system would have been initiated remotely. EX1003, ¶124. Bao discloses that a remote clinician’s computing device can adjust the CPAP apparatus 200 via communications with the mobile computing device 205. EX1009, ¶145. Thus, the capability of remotely updating components of the Bao system from a device external to the CPAP apparatus 200 and mobile computing device 205 already exists in the Bao system. EX1003, ¶124. Indeed, the “mobile computing device 205 may notify the patient if such an update and/or

modification can be made and request permission to install the update and/or modification.” EX1009, ¶170. A POSITA would have understood that by seeking “permission to install the update and/or modification” from the patient, the mobile computing device 205 is “adapted to be reprogrammed or modified remotely.” EX1003, ¶124.

Should PO dispute that Bao discloses the mobile computing device 205’s software being “adapted to” be reprogrammed or modified remotely, such a limitation would have been obvious to try as merely choosing from a finite number of identified, predictable solutions (i.e., remote reprogramming/modification v. local reprogramming/modification), with a reasonable expectation of success (updated/modified software on the device). *KSR*, 550 U.S. at 416; EX1003, ¶125.

8. Claim 8

- a. “The system of claim 7, wherein the first software is configured to be stored on and executed by the cell phone and is further adapted to be reprogrammed or modified remotely.”**

Bao discloses this limitation for at least the same reasons discussed for Claim 7. EX1003, ¶126; Section VII.C.7.a.

9. Claim 14

- a. “The system of claim 1, wherein the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index and/or the data of usage**

related to the subject's treatment and the treatment's efficacy, in whole or part, calculated by the PAP device.”

Bao in view of Klee discloses this limitation. EX1003, ¶127. Bao in view of Klee discloses the remote internet site “adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject.” Section VII.C.1.h; EX1003, ¶127. Bao discloses an external computing device communicating to the mobile communication device 205 and the CPAP apparatus 200 via the internet, and a clinician’s computer that can set and transmit goals or challenges to the user via the mobile communication device 205. EX1009, ¶¶149, 151, 156, 159 (transferring “from the internet or another mobile computing device to the mobile computing device associated with the CPAP apparatus”). Bao discloses that “the mobile computing device 205 may be configured so challenges and/or goals can be issued, such as by a remote cloud based service for example, to a patient through the user interface 207 of the mobile computing device 205. In some configurations, the website and/or remote cloud-based service may be configured to host and/or issue challenges and/or goals that are specific to an individual patient and/or group of patients.” EX1009, ¶156.

Bao may not explicitly disclose the remote internet site being configured to “retransmit” the claimed data to the cell phone. Bao, however, discloses that the CPAP can communicate directly (via cellular) with the remote website or

indirectly (via the mobile computing device 205). EX1009, ¶¶149, 151, 156, 159.

A POSITA would have found it obvious that the remote website retransmits the AHI and usage hours (received directly from the CPAP) to the mobile computing device 205 so it can correlate it with the corresponding challenges or goals set and transmitted by the remote website. EX1003, ¶128.

A POSITA would have understood that issued challenges and or goals, for example, sent to the mobile communication device 205, whether in relation to the patient or group of patients, would include one or more of “retransmit[ting] to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index *and/or* the data of usage related to the subject's treatment and the treatment's efficacy, *in whole or part*, calculated by the PAP device” as broadly claimed by the '284 patent. EX1003, ¶129. For example, a POSITA would have recognized, or at least found it obvious, that a challenge or goal related to usage hours or AHI transmitted to the mobile communication device would include retransmission of the patient's actual usage hours and AHI information (e.g., a second index) calculated by their CPAP device so as to indicate whether the patient has met the challenge or goal. *Id.*

10. Claim 19

- a. **“The system of claim 1, wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency**

wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.”

Bao in view of Klee discloses this limitation. EX1003, ¶¶130-132. Bao in view of Klee discloses a remote internet site adapted to receive data from the first or second radio frequency wireless transceiver. *See, e.g.*, Section VII.C.1.h. Bao in view of Klee also discloses that “remote internet site is hosted on a remote communication system with a third processor.”

Bao discloses that “the clinician's computing device may be remotely located from the patient and/or CPAP apparatus 200, such as in a sleep laboratory. The clinician may analyze and use the data to adjust the pressure and/or flow settings, for example, of the CPAP apparatus 200.” EX1009, ¶145. By having the capability for the clinician to analyze the data received on his/her computing device and determined adjustments need to the CPAP apparatus, a POSITA would have understood that Bao discloses that “the remote internet site ***is configured to output ... to a second display*** the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.” EX1003, ¶132.

D. Ground 4: Claims 9-13, and 20 are Rendered Obvious by Bao in view of Klee and Shouldice

Shouldice (EX1011) published August 5, 2021, and is prior art under 35 U.S.C. §§102(a)(1), (2).

1. Claim 9

- a. “The system of claim 8, wherein the airflow sensor data is processed by the second processor, in part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.”**

Bao in view of Klee and Shouldice discloses this limitation. EX1003, ¶¶133-135. Bao discloses “an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data.” Section VII.C.1.d. Bao in view of Klee discloses “a second processor adapted for receiving the airflow sensor data.” Section VII.C.1.e.

While Bao in view of Klee disclose use of airflow sensor data, the combination does not specifically disclose “using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis” to process “in part” the data. EX1003, ¶135. Shouldice, however does. *Id.*

Shouldice discloses that “airflow data associated with the user of the respiratory device (e.g., the respiratory device 122 of the system 100 shown in FIG. 1) is received” and at “step 720, the airflow data associated with the user is analyzed.” EX1011, ¶191. The “airflow data further includes flow rate data.” *Id.*, 192. According to Shouldice, “airflow data can include pressure data.” *Id.*, ¶192. Shouldice specifically discloses that “the airflow data is processed.” *Id.*, ¶194.

Specific signal processing of the airflow data disclosed by Shouldice includes, among other things, “derivative of the flow signal,” “standard deviation of the flow signal,” a “fast Fourier transform (FFT) with a sliding window, a spectrogram, a neural network, a short time Fourier transform (STFT), a wavelet-based analysis, or any combination thereof.” *Id.*, ¶¶203, 245, 250 (“The method of any one of Alternative Implementations 1 to 9, further comprising: receiving, from a flow sensor, airflow data associated with the user of the respiratory device during the sleep session; analyzing the airflow data associated with the user; and determining the mouth leak status based, at least in part, on both the analysis of the first acoustic data and the analysis of the airflow data of the user.”). Thus, Bao in view of Klee and Shouldice discloses this limitation EX1003, ¶¶136-137.

A POSITA would have found it obvious, and had reasonable expectations of success, to incorporate one or more of the claimed signal processing techniques, all of which were well-known to POSITA, into the Bao-Klee CPAP system. EX1003,

¶138. A POSITA, with knowledge of Bao, Klee and Shouldice, would have considered it obvious to combine their respective teachings. EX1003, ¶¶137-139. Bao, Klee and Shouldice share commonalities in terms of their general subject matter (e.g., using CPAP and other devices to treat sleeping/breathing disorders) and technique used (e.g., evaluating data from a CPAP device and other devices) to improve operation of CPAP treatment devices to ensure treatment. *Id.* Moreover, Bao, Klee and Shouldice are within the same technical field as each other and the '284 Patent. *Id.*

Notably, the '284 patent relies on the knowledge of a POSITA to implement this well-known feature: “***The present invention would also include other on-line signal processing algorithms known to those skilled in the art, such as wavelet analysis,....***” EX1001, 20:36-41; *see also* EX1019, ¶¶40-45 (copied into '284). For at least the same reasons, a POSITA would have found it obvious, and known how, to successfully implement these techniques in the Bao-Klee CPAP system to arrive at the claimed system, particularly where a POSITA having the Bao-Klee combination would have looked to a disclosure like Shouldice that provided details on how to implement the controller. EX1003, ¶¶138-139.

2. Claim 10

- a. “**The system of claim 9, wherein the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject,**

the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, calculated by the PAP device.”

Bao in view of Klee and Shouldice discloses this limitation for at least the same reasons discussed for Claim 14. EX1003, ¶140; Section VII.C.9.a.

3. Claim 11

- a. “The system in claim 9, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.”**

Bao in view of Klee and Shouldice discloses this limitation for at least the same reasons discussed for Claim 9. EX1003, ¶141; Section VII.D.1.a.

4. Claim 12

- a. “The system of claim 1, wherein the airflow sensor data is processed by the second processor, in part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.”**

Bao in view of Klee and Shouldice discloses this limitation for at least the same reasons discussed for Claim 9. EX1003, ¶142; Section VII.D.1.a.

5. Claim 13

- a. “The system in claim 12, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.”**

Bao in view of Klee and Shouldice discloses this limitation for at least the same reasons discussed for Claim 11. EX1003, ¶143; Section VII.D.3.a.

6. Claim 20

- a. “The system in claim 1, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.”**

Bao in view of Klee and Shouldice discloses this limitation. EX1003, ¶144. Bao in view of Klee discloses the second processor calculating, among other things, “the data of a severity of the symptoms of the subject and/or the index.” Section VII.C.1.e.; EX1003, ¶144. The combination, however, does not appear to explicitly disclose that the second processor is “configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.” Shouldice, however, does. EX1003, ¶144.

Shouldice discloses determining “a number of events per hour, a pattern of events, ... during the sleep session.” EX1011, ¶80. “The event(s) can include snoring, apneas, central apneas, obstructive apneas, mixed apneas, hypopneas, a mask leak (e.g., from the user interface 124), a restless leg, a sleeping disorder...” *Id.*; *see also* ¶81. Shouldice discloses that the “data from the one or more sensors 130 can be analyzed to determine one or more sleep-related parameters ... The one

or more events can include snoring, apneas, central apneas, obstructive apneas, mixed apneas, hypopneas, a mask leak, a cough, a restless leg, a sleeping disorder.” *Id.*, ¶105; EX1003, ¶145.

Accordingly, a POSITA would have understood that the combination of Bao, Klee and Shouldice discloses that “the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.” EX1003, ¶146. Motivation for the combination is provided above in the discussion of Claim 9. *Id.*

E. Ground 5: Claims 15, 16, and 18 are Rendered Obvious by Bao in view of Klee and Dong

1. Claim 15

- a. “The system of claim 14, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.”**

Bao in view of Klee and Dong discloses this limitation. EX1003, ¶147. Bao in view of Klee discloses “data of the severity of the symptoms of the subject calculated by the second processor.” Section VII.C.1.e.

Bao also discloses a controller that adjusts the flow of the blower that the “blower 202 and/or the humidifier 201 may be controlled by a controller 203,

which preferably comprises a microprocessor with associated memory or some other suitable control configuration.” EX1009, ¶125. A POSITA would have understood that the controller 203, which calculates the claimed “data of the severity of the symptoms of the subject” and also controls the blower 202, would have performed the control of the blower 202 “based *in part* on the data of the severity of the symptoms of the subject.” EX1003, ¶148.

Dong discloses an extended horizon adaptive, predictive controller. EX1015, 7:60-62 (“FIG. 1 illustrates the overall structure of extended horizon adaptive block predictive controller with an efficient prediction system.”). A POSITA would have a motivation and reasonable expectation of success in combining Bao’s controller that adjusts the flow of the blower based in part on the data of the severity of the symptoms of the subject and Dong’s extended horizon adaptive, predictive controller. EX1003, ¶149. For example, Bao and Dong are in related fields i.e., Dong concerns a class of adaptive controllers using predictive techniques in dynamic systems and Bao concerns controlling respiratory devices which are dynamic systems. Moreover, a POSITA would have been aware that using such a controller “reduces run time and memory requirements” in comparison to other controllers. *Id.*; EX1015, 6:44-46, 2:1-41 (describing known controllers). The ’284 patent further acknowledges that an “extended horizon, adaptive, predictive controller” for use with a PAP device was available off-the-

shelf by the time of the November 2005 filing of the 11/266,899 application, and known over ten years before the filing of any of the priority applications. EX1001, 20:55-59 (referencing Dong, which issued June 13, 1995). Thus, a POSITA having knowledge of the well-known “extended horizon, adaptive, predictive controller” would have found it suitable for use with the Bao CPAP apparatus 200, and specifically its controller 203. EX1003, ¶149. Indeed, it would have been obvious to try as merely choosing from a finite number of identified, predictable solutions (i.e., adaptive, predictive controller v. a controller that was not adaptive and predictive), with a reasonable expectation of success (suitable control of a CPAP blower based in part of the patient’s “data of the severity of the symptoms of the subject” with reduced run time and memory requirements). *KSR*, 550 U.S. at 416; EX1003, ¶149.

2. Claim 16

- a. **“The system of claim 15, wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.”**

Bao in view of Klee discloses this limitation for at least the same reasons discussed for claim 19. EX1003, ¶150; Section VII.C.10.

3. Claim 18

- a. “The system of claim 1, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.”**

Bao in view of Klee and Dong discloses this limitation for at least the same reasons discussed for Claim 15. EX1003, ¶151; Section VII.E.1.a.

F. Ground 6: Claim 17 is Rendered Obvious by Bao in view of Klee, Dong and Shouldice

1. Claim 17

- a. “The system in claim 16, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.”**

Bao in view of Klee, Dong and Shouldice discloses this limitation. EX1003, ¶152; Section VII.D.6. Motivation for the combination of Bao, Klee, and Shouldice is provided above in the discussion of Claim 9. *Id.* A POSITA would further have been motivated to combine Bao, Klee, and Shouldice with Dong. A POSITA would have found it obvious, and had reasonable expectations of success, to incorporate one or more of the claimed signal processing techniques, all of which were well-known to POSITA, into the Bao-Klee CPAP system. EX1003, ¶153. A POSITA, with knowledge of Bao, Klee, Shouldice and Dong would have

considered it obvious to combine their respective teachings. EX1003, ¶153. Bao, Klee, Shouldice and Dong share commonalities in terms of their general subject matter (e.g., using CPAP and other devices to treat sleeping/breathing disorders) and technique used (e.g., evaluating data from a CPAP device and other devices) to improve operation of CPAP treatment devices to ensure treatment and techniques to process and control signals and dynamic systems. *Id.*; EX1015, 2:1-43.

Moreover, Bao, Klee, Shouldice and Dong are within the same technical field as each other and the '284 Patent. Section VII.E.6; *e.g.*, EX1015, 1:7-15, 2:1-43.

G. Ground 7: Claims 1-3, 6 and 19-20 are Rendered Obvious by Farrell in view of Pirzada

Farrell (EX1012) published July 12, 2007 and is prior art under 35 U.S.C. §§102(a)(1), (2).

Pirzada (EX1013) published July 5, 2007 and is prior art under 35 U.S.C. §§102(a)(1), (2).

1. Claim 1

It is more likely than not that claim 1 is rendered obvious by Farrell in view of Pirzada for the reasons set forth below and in the October 21, 2022 Final Rejection (EX1002), 85-93.

a. 1pre.

To the extent it is a limitation, Farrell discloses the Claim 1 preamble. EX1003, ¶¶154-157.

Farrell discloses an “apparatus for treating and monitoring sleep disordered breathing (“SDB) in patients with cardiovascular disease...” EX1012, ¶2; FIG. 1. The apparatus itself is not labeled, but its components are. The Farrell system also comprises a hand-held display and control device 12. *Id.*, ¶2; EX1003, ¶158.

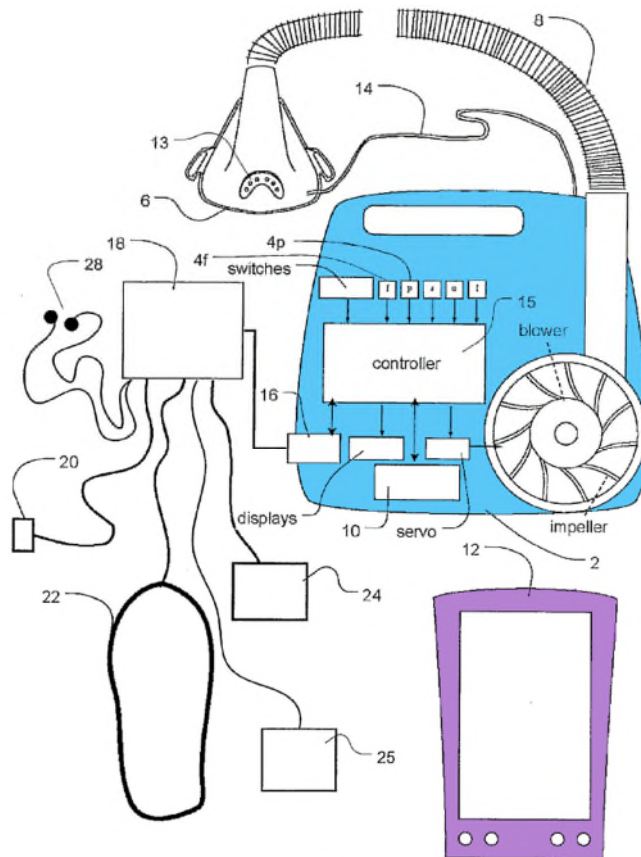


FIG. 1

b. Limitation 1a.

Farrell in view of Pirzada discloses Limitation 1a. EX1003, ¶159.

(i) cell phone components:

Farrell discloses that the apparatus contains “a communication port or module 10,” which is 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.” EX1012, ¶26. One example hand-held device 12 is a “Palm Pilot.” *Id.*, ¶28. Using the hand-held device 12, “a physician may, for example, remotely monitor, analyze or record the status or data history of a patient. For example, remote devices may send to or retrieve from the apparatus any desired cardiovascular or other information.” *Id.* A POSITA would have understood that to wirelessly exchange data/information with the apparatus, the hand-held device 12 necessarily requires the claimed “first radio frequency wireless transceiver.” EX1003, ¶160. Likewise, to “remotely monitor, analyze or record the status or data history of a patient,” a POSITA would have understood that the hand-held device 12 comprises a display, a non-transitory computer readable medium for storing first software executed by a processor so that the device can perform its functions and for storing data/information processed by the device 12. *Id.*

Farrell does not explicitly disclose that the hand-held device 12 is a cell phone as required by Claim 1. A POSITA, however, would have understood that a cell phone could also have been used as the hand-held device 12 in the Farrell system. Specifically, cell phones with a display and wireless data transmissions in PAP systems were well known as evidenced by Pirzada. EX1013, ¶83; EX1003, ¶161. A POSITA would have found it obvious to try implementing a cell phone as

a hand-held device 12 as merely choosing from a finite number of identified, predictable solutions (i.e., cell phone v. PDA), with a reasonable expectation of success (allowing doctors to remotely monitor their patients and patients to monitor their therapy from cell phone). *KSR*, 550 U.S. at 416; EX1003, ¶161.

(ii) cell phone displaying an index of treatment efficacy:

Farrell discloses that its PAP “device provides ***efficacy tracking*** by detecting and recording or scoring ***SDB events or related information or indices over time***,....” EX1012, ¶36. One such index is the “AHI (apnea hypopnea index).” *Id.*, ¶37. Moreover, Farrell discloses that the PAP “device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting.” *Id.* “Preferably, the cardiovascular and SDB information may be periodically ***remotely transferred to the physician***.” *Id.*, ¶47. One remote destination for the index is Farrell’s hand held device (or cell phone). EX1003, ¶162.

The ’284 patent contains no written description support or enabling disclosure for the claimed “index of treatment efficacy.” See Sections VII.A.1, VII.B. A POSITA would have understood that Farrell’s disclosure of “efficacy tracking” and scoring “indices over time” would comprise an “index of treatment efficacy,” as best understood. EX1003, ¶163.

(iii) the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject:

To the extent understood, Farrell discloses “the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” EX1003, ¶164. A POSITA would have understood that Farrell’s disclosure of “efficacy tracking” and scoring “indices over time” would comprise an “index of treatment efficacy” as best understood. EX1003, ¶164. A POSITA would have also understood that Farrell’s “detecting and recording or scoring SDB events or related information or indices over time” would be the claimed, but undefined, “data of severity of sleep disorder symptoms.” *Id.*

Moreover, Farrell discloses “compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting.” EX1012, ¶36. A POSITA would have understood this to be the “data of usage of the PAP device by the subject.” EX1003, ¶164.

There is no disclosure of how the ’284 patent determines the “index of treatment efficacy.” However, a POSITA would have understood that the Farrell determines, as best understood, an “index of treatment efficacy” “based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject” because Farrell discloses tracking efficacy, SDB and

other events, determining indices, tracking usage of the PAP device over time, and combining data to calculate scores. EX1003, ¶¶164-165.

(iv) data of severity and data of usage calculated by the PAP device:

Farrell discloses that the PAP apparatus' controller 15 is "configured and adapted to implement" Farrell's methodology. EX1012, ¶25. As such, Farrell discloses that the claimed "data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject," as best understood, are "both calculated by the PAP device." EX1003, ¶166. The same data is received by the Farrell hand held device (or cell phone) as discussed above. *Id.*

c. Limitation 1b.

Farrell discloses Limitation 1b. EX1003, ¶167. Farrell FIG. 1 illustrates a blower within an enclosure of the PAP apparatus. EX1012, ¶24.

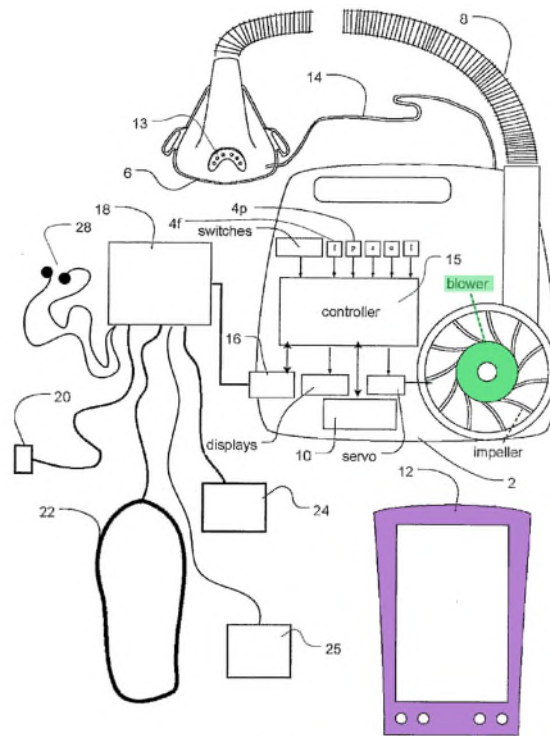


FIG. 1

d. Limitation 1c.

Farrell discloses Limitation 1c. EX1003, ¶168. Farrell discloses “a flow sensor 4f ... may also be utilized in which case mask flow may be measured ... to derive a flow signal $F(t)$.” EX1012, ¶24, FIG. 1 (showing flow sensor 4f within the CPAP enclosure). The flow signal $F(t)$ is sent to the PAP apparatus’ controller 15 for processing. *Id.* A POSITA would have understood that the flow sensor 4f outputs airflow sensor data in the form of the flow signal $F(t)$. EX1003, ¶¶168-169. PO is expected to argue that the PTO Examiner agreed that “Farrell makes clear that flow and pressure measurements of the delivered [sic] are used to adjust the PAP device –not [the subject’s] respiratory effort.” IPR2023-00565, paper 6, 31 (citing to an alleged agreement in the prosecution of the related ’269 patent). But

PO would be wrong as the patent examiner subsequently determined that Farrell discloses limitation 1c. EX1002, 122 (Farrell discloses “an airflow sensor (‘flow sensor’) 4f internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data (see para. [0024])”).

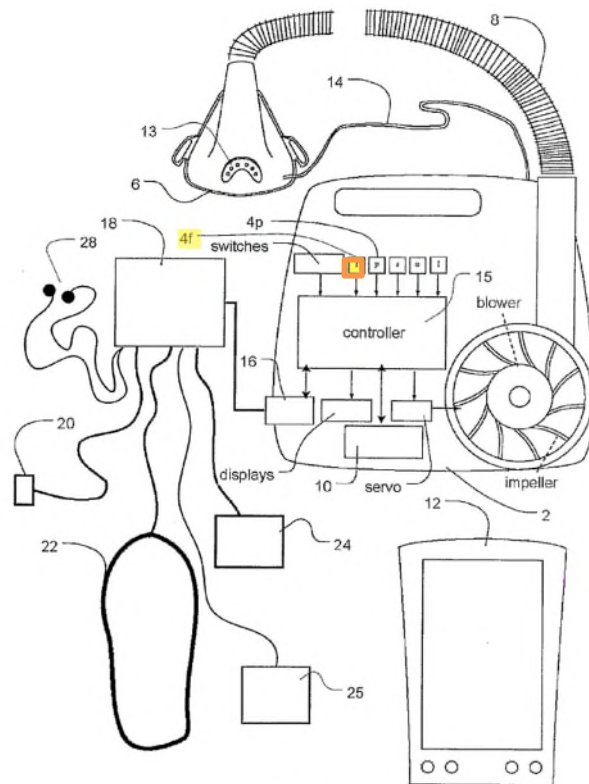


FIG. 1

Farrell also discloses that “accurate determination of respiratory airflow is important,” and, as was known in the art, “the determined flow rate of air to the patient may be adjusted to account for the effect of leak.” EX1012, ¶33, ¶44 (“respiratory flow signal”), ¶30 (“patient respiratory airflow”). A POSITA would

have recognized, or at least found it obvious, that the respiratory airflow is derived using the flow sensor 4f. EX1003, ¶169.

e. Limitation 1d.

Farrell discloses Limitation 1d. EX1003, ¶¶170-171. Farrell discloses that the PAP apparatus comprises “a controller or microprocessor 15.” EX1012, ¶¶24, 25; FIG. 1. Farrell discloses “data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone.” Section VII.G.1.b; EX1003, ¶¶171-172. Farrell also discloses the controller 15 receiving the flow signal $F(t)$. Section VII.G.1.c.

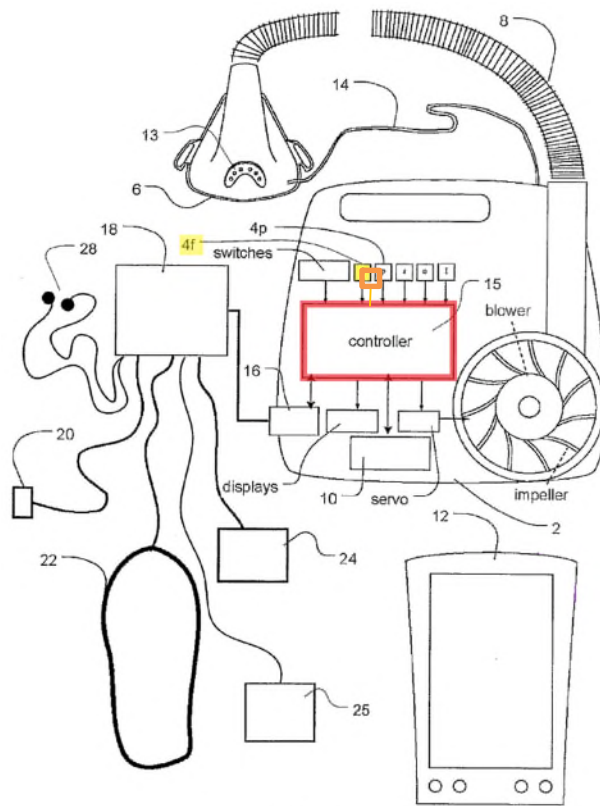


FIG. 1

A POSITA would have understood that the controller 15 is the claimed “second processor” because it is a microprocessor “configured and adapted to implement” Farrell’s methodology. EX1012, ¶25; EX1003, ¶¶171-172.

f. Limitation 1e.

Farrell discloses Limitation 1e. EX1003, ¶172. Farrell discloses “mask 6.” EX1012, ¶24; FIG. 1.

g. Limitation 1f.

Farrell discloses Limitation 1f. EX1003, ¶173. Farrell discloses that the PAP apparatus “preferably also includes a communication port or module 10, for example, a wireless communication transceiver ... for communication with other devices or computers such as hand-held display and control devices 12.” EX1012, ¶26. “Preferably, the cardiovascular and SDB information may be periodically remotely transferred to the physician...” *Id.*, ¶47.

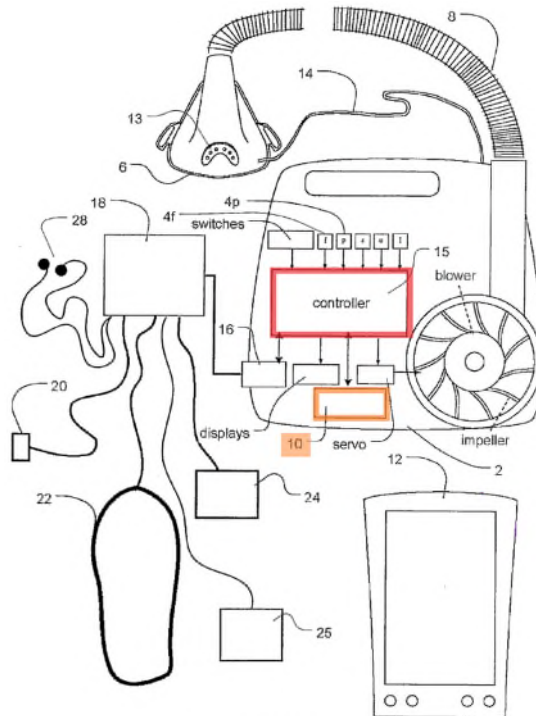


FIG. 1

Farrell disclose “the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone.” Section VII.G.1.b; EX1003, ¶174. Moreover, a POSITA would have understood that the controller 15 is the claimed “second processor.” Section VII.G.1.e; EX1003, ¶174. Accordingly, a POSITA would have understood that Farrell discloses “at least one second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor.” EX1003, ¶174.

h. Limitation 1g.

Farrell alone or Farrell in view of Pirzada discloses Limitation 1g. EX1003, ¶175. Farrell discloses “the cardiovascular and SDB information may be periodically remotely transferred to the physician” from the PAP apparatus. EX1012, ¶47. Farrell further discloses that the apparatus can transmit the information “remotely, for example, over a secure electronic network to a database.” *Id.* A POSITA would have understood that the “information may be periodically remotely transferred to the physician [website or portal].” EX1003, ¶175. During prosecution, the Examiner indicated that this read on the claimed “remote internet site.” EX1002, 89-90. The PO disagreed. *Id.*, 72. To the extent that PO maintains its position that Farrell does not disclose Limitation 1g because the Internet would not be considered “a secure electronic network,” a POSITA would have found it obvious because transmitting treatment and other information from a PAP apparatus to a remote internet site was well known at the time as evidenced by Pirzada. EX1003, ¶175. Pirzada discloses that the prior art already included “a method and apparatus for health and disease management combining patient data monitoring with wireless internet connectivity.” EX1013, ¶2. Pirzada discloses that its “device 10 can communicate ... via WiFi communication 152, through GSM network or any cellular based telephone communication 154, or through broadband communication network 156” and that its “SIM card can interact with the Internet 160 to communicate with an off-site database 170.”

EX1013, ¶60. Pirzada also discloses that “[d]atabase 170 can be stored on a server 162 or any other type personal computer,” *id.*, and that “web applications are also in communication with the database 170.” *Id.*, 68. Pirzada also discloses a “web page” accessible to control its device 10. *Id.*, 83. A POSITA would have understood that “web applications” and or a “web page” would be implemented by a remote internet site. EX1003, ¶175.

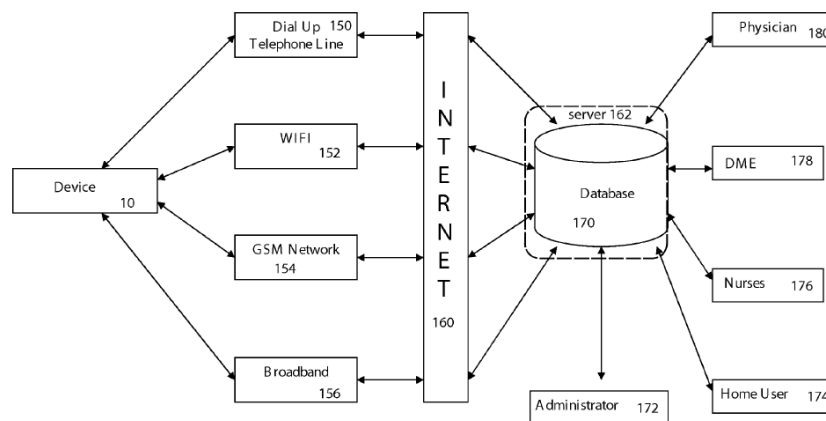


FIG. 4

A POSITA would have understood that the CPAP apparatus, and specifically its “radio frequency wireless transceiver,” would be adapted to transmit the “the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject’s treatment and the treatment’s efficacy” (see Section VII.G.1.g) “in whole or part” to the database 170 where it is accessible by a web application or internet site, remote to the PAP system. *Id.*; EX1003, ¶176.

2. Claim 2

Farrell in view of Pirzada discloses Claim 2. EX1003, ¶177. Farrell discloses the claimed “first radio frequency wireless transceiver” and “second radio frequency wireless transceiver.” Sections VII.G.1.b, VII.G.1.g. Farrell does not explicitly disclose these transceivers as implementing the Bluetooth protocol. But a POSITA would have understood that a PAP system comprising wireless transceivers that implement the Bluetooth protocol was well known at the time as evidenced by Pirzada. EX1013, ¶¶37, 64, 70; EX1003, ¶177. A POSITA would have understood that implementing the Bluetooth protocol in both the first and second radio frequency wireless transceivers disclosed by Farrell would have been obvious to try as merely choosing from a finite number of identified, predictable solutions (i.e., cellular or wireless WiFi communications v. Bluetooth wireless communications), with a reasonable expectation of success (exchanging information throughout the PAP system wirelessly). *KSR*, 550 U.S. at 416; EX1003, ¶177.

3. Claim 3

Farrell in view of Pirzada discloses Claim 3. EX1003, ¶178. Farrell discloses the claimed “second radio frequency wireless transceiver.” Section VII.G.1.g. Farrell does not explicitly disclose the transceiver transmitting the claimed data using cell towers. But a POSITA would have understood that a PAP apparatus

comprising a wireless transceiver that transmits data using cell towers was well known at the time as evidenced by Pirzada. EX1013, ¶¶54, 60; EX1003, ¶178. A POSITA would have understood that transmitting the data via cell towers would have been obvious to try as merely choosing from a finite number of identified, predictable solutions (i.e., wireless WiFi or Bluetooth communications v. cellular communications), with a reasonable expectation of success (exchanging information throughout the PAP system wirelessly). *KSR*, 550 U.S. at 416; EX1003, ¶178.

4. Claim 6

Farrell discloses Claim 6. EX1003, ¶179. Farrell discloses “automated changes to the control of the device may be made such as a change in treatment protocol” based on information calculated by the PAP apparatus and transmitted to the remote internet site. EX1012, ¶47; *see also* ¶28; Section VII.G.1.h. One example is the changing of pressure via “controlling an opening of a servo-valve that may variably divert/vent or deliver airflow to the mask.” *Id.*, 24.

5. Claim 19

Farrell alone or Farrell in view of Pirzada discloses Claim 19. EX1003, ¶180. Farrell alone or Farrell in view of Pirzada discloses the remote internet site. Section VII.G.1.h. Moreover, Farrell discloses that “[v]arious appropriate input and output devices such as keypads and display screens and other alternatives are

known in the art.” EX1012, ¶27. Farrell further discloses that “the treatment program that is being run on the patient can be monitored and changed remotely.” *Id.*, 28. A POSITA would have understood that, at a minimum, the computer implementing the remote internet site disclosed by Farrell alone or Farrell and Pirzada would be configured to output to a second, remote display for review by a clinician to determine treatment efficacy. EX1003, ¶180.

6. Claim 20

Farrell discloses Claim 20. EX1003, ¶181. Farrell discloses “the device provides efficacy tracking by ... tracking or detecting central apneas, obstructive apneas, ...” EX1012, ¶36.

H. Ground 8: Claims 4, 5, 7, 8, and 14 are Rendered Obvious by Farrell in view of Pirzada and Bao

1. Claim 4

Farrell in view of Pirzada and Bao discloses Claim 4. EX1003, ¶182. Farrell discloses the claimed second processor. Section VII.G.1.g. While a POSITA would have understood that Farrell’s second processor would execute the claimed second software from the corresponding memory, Farrell does not explicitly disclose reprogramming or modifying the software from a remote internet site. Bao, however, does. *See* Section VII.C.4.a; EX1003, ¶182.

A POSITA would have been motivated to modify Farrell’s system with Bao’s remote software reprogramming. EX1003, ¶183. Doing so would have

merely involved combining prior art elements (i.e., known remote software updating) according to known methods (e.g., wireless transmissions over the internet) to yield predictable results (an enhanced device with current updates and/or modifications). *KSR*, 550 U.S. at 416; EX1003, ¶183. A POSITA would have had a reasonable expectation of success in remotely updating/modifying Farrell’s PAP apparatus software based on the combined teachings of Farrell and Bao. *Id.*

2. Claim 5

Farrell in view of Pirzada and Bao discloses Claim 5 for at least the reasons discussed for Claim 6. Section VII.G.4; EX1003, ¶184.

3. Claim 7

Farrell in view of Pirzada and Bao discloses Claim 7. EX1003, ¶185. Farrell in view of Pirzada discloses the claimed “first software” stored a computer readable medium on the cell phone and executed by the cell phone. Section VII.H.1.b. The combination does not explicitly disclose being adapted to be reprogrammed or modified remotely.

Bao, however, does disclose the first software being adapted to be reprogrammed or modified remotely. *See* Section VII.C.7.a; EX1003, ¶186.

A POSITA would have been motivated to modify Farrell’s system with Bao’s remote software reprogramming. EX1003, ¶187. Doing so would have

merely involved combining prior art elements (i.e., known remote software updating) according to known methods (e.g., wireless transmissions over the internet) to yield predictable results (an enhanced device with current updates and/or modifications). *KSR*, 550 U.S. at 416; EX1003, ¶187. A POSITA would have had a reasonable expectation of success in remotely updating/modifying Farrell's hand-held device software based on the combined teachings of Farrell and Bao. *Id.*

4. Claim 8

Farrell in view of Pirzada and Bao discloses Claim 8 for at least the same reasons discussed for Claim 7. Section VII.H.3; EX1003, ¶188.

5. Claim 14

Farrell in view of Pirzada and Bao discloses Claim 14. EX1003, ¶189. Farrell alone or Farrell in view of Pirzada discloses the remote internet site receiving the claimed data from the PAP device. Section VII.G.1.h; EX1003, ¶189. The combination, however, does not explicitly disclose the remote internet site retransmitting the data to the cell phone. Bao does. EX1003, ¶189.

A POSITA would have been motivated to update the Farrell/Pirzada system such that the cell phone received retransmitted data from the remote internet site as known and disclosed by Bao. EX1003, ¶190. Such capability, for example, would have provided hand-held device users to participate in challenges and/or achieve

“goals that are specific to an individual patient and/or group of patients.” EX1009, ¶156. A POSITA would have found doing so obvious to try as merely choosing from a finite number of identified, predictable solutions (i.e., retransmitting certain data and information to a patient’s handheld device v. keeping the data and information accessible only to the clinician), with a reasonable expectation of success (patients’ enhanced use of the therapy to meet the challenge or achieve the goals). *KSR*, 550 U.S. at 416; EX1003, ¶190.

I. Ground 9: Claims 9-13 are Rendered Obvious by Farrell in view of Pirzada, Bao and Shouldice

1. Claim 9

Farrell in view of Pirzada, Bao and Shouldice discloses Claim 9. EX1003, ¶191. Farrell discloses airflow sensor data received by the second processor. Section VII.G.1.d.

Neither Farrell, Pirzada nor Bao specifically, disclose, using one or more of the Claim 9 signal processing techniques to process the data. Shouldice does. Section VII.D.1.a; EX1003, ¶192.

A POSITA would have found it obvious to incorporate one or more of the claimed signal processing techniques, all of which were well-known to POSITA, into the Farrell-Pirzada-Bao CPAP system, and had reasonable expectations of success. EX1003, ¶193. A POSITA, with knowledge of Farrell, Pirzada, Bao and Shouldice, would have considered it obvious to combine their respective teachings.

EX1003, ¶193. Farrell, Pirzada, Bao and Shouldice share commonalities in terms of their general subject matter (e.g., using CPAP and other devices to treat sleeping/breathing disorders) and technique used (e.g., evaluating data from a CPAP device and other devices) to improve operation of CPAP treatment devices to ensure treatment. *Id.* Moreover, Farrell, Pirzada, Bao and Shouldice are within the same technical field as each other and the '284 Patent. *Id.*

Notably, the '284 patent relies on the knowledge of a POSITA to implement this well-known feature: “***The present invention would also include other on-line signal processing algorithms known to those skilled in the art, such as wavelet analysis,....***” EX1001, 20:36-41 (emphasis added). For at least the same reasons, a POSITA would have found it obvious, and known how, to successfully implement these techniques in the Farrell-Pirzada-Bao CPAP system to arrive at the claimed system. EX1003, ¶194.

2. Claim 10

Farrell in view of Pirzada, Bao and Shouldice discloses this limitation for at least the same reasons discussed for Claim 14. Section VII.H.5; EX1003, ¶195.

3. Claim 11

Farrell in view of Pirzada, Bao and Shouldice discloses this limitation for at least the same reasons discussed for Claim 9. EX1003, ¶196; Section VII.I.1.

4. Claim 12

Farrell in view of Pirzada, Bao and Shouldice discloses Claim 12 for at least the same reasons discussed for Claim 9. Section VII.I.1; EX1003, ¶197.

5. Claim 13

Farrell in view of Pirzada, Bao and Shouldice discloses Claim 13 for at least the same reasons discussed for Claim 11. Section VII.I.3; EX1003, ¶198.

J. Ground 10: Claims 15-18 are Rendered Obvious by Farrell in view of Pirzada, Bao and Dong

1. Claim 15

Farrell in view of Pirzada, Bao and Dong discloses Claim 15. EX1003, ¶200. Farrell discloses adjusting the flow of a blower unit. EX1012, ¶25. A POSITA based on the teachings of Farrell, Pirzada and/or Bao would have understood that the controller, which calculates the claimed discloses “data of the severity of the symptoms of the subject” and also controls the blower, would have performed the control of the blower “based *in part* on the data of the severity of the symptoms of the subject.” EX1003, ¶199.

In addition, extended horizon adaptive, predictive controllers were well known to the POSITA as evidenced by Dong. EX1015, 7:60-62. A POSITA would have also been aware that using such a controller “reduces run time and memory requirements” in comparison to other controllers. *Id.*, 6:44-46; EX1003, ¶200. The ’284 patent acknowledges that an “extended horizon, adaptive, predictive

controller” for use with a PAP device was well known years before the filing of any of the priority applications. EX1001, 20:55-59. Thus, a POSITA having knowledge of Dong’s well-known “extended horizon, adaptive, predictive controller” would have found it suitable for use with the Farrell-Pirzada-Bao apparatus and its controller. EX1003, ¶200. Indeed, it would have been obvious to try as merely choosing from a finite number of identified, predictable solutions (i.e., adaptive, predictive controller v. a controller that was not adaptive and predictive), with a reasonable expectation of success (suitable control of a CPAP blower based in part of the patient’s “data of the severity of the symptoms of the subject” with reduced run time and memory requirements). *KSR*, 550 U.S. at 416; EX1003, ¶200.

2. Claim 16

Farrell in view of Pirzada, Bao and Dong disclose Claim 16 for at least the reasons discussed for Claim 19. Section VII.G.5; EX1003, ¶201.

3. Claim 17

Farrell in view of Pirzada, Bao and Dong discloses Claim 17 for at least the reasons discussed for Claim 20. Section VII.G.6; EX1003, ¶202.

4. Claim 18

Farrell in view of Pirzada, Bao and Dong discloses Claim 18 for at least the reasons discussed for Claim 15. Section VII.J.1; EX1003, ¶203.

VIII. 35 U.S.C. §§ 314(a) AND 325(d) – Institution is Appropriate

A. § 314(a) – Institution is Appropriate under *Fintiv*

The *Fintiv* factors weigh against discretionary denial. *Fintiv*, IPR2020-00019, Paper 11, 5-6.

This Petition provides compelling, meritorious evidence of the challenged claims’ unpatentability. Accordingly, under PTAB guidance, the PTAB “will not rely on the *Fintiv* factors to discretionarily deny institution in view of parallel district court litigation” EX1014 (June 2022 Interim Procedure for Discretionary Denials), 2, 4. No scheduling order has been entered in the related District of Ohio proceeding. Should the Board prefer to consider *Fintiv* factors individually, Petitioner reserves the right to request/provide additional briefing.

B. § 325(d) – Institution is Appropriate under *Becton-Dickinson*

Discretionary denial is guided by *Advanced Bionics*, IPR2019-01469, Paper 6 at 7. Bao, Klee and Shouldice were not before the Office during prosecution. So, the Grounds identified herein could not have been considered by the Office.

Moreover, the Office erred in overlooking Bao, Klee and Shouldice. As discussed in Section IV.C, the earliest priority date to which the challenged claims are entitled is May 26, 2022. Thus, the Examiner erred by: (1) disqualifying Pirzada as prior art and then allowing the ’284 patent over the combination of Farrell and Pirzada; see Section IV.B; and (2) not considering any prior art filed

after the alleged November 4, 2005 priority date. The Office also erred in overlooking Berthon-Jones, and, for example, its disclosure of the claimed airflow sensor as discussed in Section VII.C.

Finally, the Office did not have the benefit of the accompanying expert declarations (EX1003; EX1020) and should institute for at least the above reasons.

IX. CONCLUSION

Petitioner requests that post-grant review be instituted because it is more likely than not that claims 1-20 of the '284 Patent are unpatentable under one or more of 35 U.S.C. §§ 103, 112.

Respectfully submitted,

Dated: December 13, 2023

/Gianni Minutoli/
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Attorney for Petitioner

CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(c) and (d), Petitioner certifies that the word count of the foregoing Petition for *Inter Partes* Review (exclusive of any table of contents, table of authorities, mandatory notices under § 42.8, certificates of service and word count, and list of exhibits or claim listing) as measured by Microsoft Word totals 17,808 words, which is less than the 18,700 allowed under 37 CFR § 42.24.

Respectfully submitted,

Dated: December 13, 2023

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Gianni Minutoli
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Attorney for Petitioner

**CERTIFICATE OF SERVICE
UNDER 37 C.F.R. § 42.105**

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner by **UPS Overnight** of this Petition for Post-Grant Review and supporting material at the following correspondence address of record for the '284 patent:

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