

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

PGR2024-00012
Patent 11,602,284 B1

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

JENKS, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

ResMed Corp. (“Petitioner”) filed a Petition requesting a post-grant review of claims 1–20 (“the challenged claims”) of U.S. Patent No. 11,602,284 B1 (Ex. 1001, “the ’284 patent”). Paper 2 (“Pet.”). Cleveland Medical Devices, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

Institution of a post-grant review is authorized by statute when “the information presented in the petition filed under [35 U.S.C. §] 321 . . . demonstrates that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a). For the reasons set forth below, we determine that Petitioner has not demonstrated that the ’284 patent is eligible for post-grant review. Accordingly, we decline to institute a post-grant review of claims 1–20 based on the grounds set forth in the Petition.

A. Real Parties-in-Interest

Petitioner identifies itself as a real party-in-interest and states that it “identifies ResMed Inc. as a real party in interest without conceding that it is, in fact, a real party in interest.” Pet. 4. Patent Owner identifies itself as the real party-in-interest for Patent Owner. Paper 4, 1.

B. Related Matters

The parties identify as a related matter *ResMed Corp. v. Cleveland Medical Devices, Inc.*, Case No. 1:23-cv-02221-BMB (N.D. Ohio). Pet. 4; Paper 4, 1. Petitioner also states that “[t]he ’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 [(D. Del.)], filed June 16, 2022.” Pet. 5. According to Petitioner, the

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

C. The '284 Patent (Ex. 1001)

The '284 patent is titled “Devices and Methods for Sleep Disorder Diagnosis and Treatment.” Ex. 1001, code (54). The '284 patent was filed as Application No. 17/825,266 (“the '266 application”) on May 26, 2022, and is a continuation of Application No. 16/057,963 (“the '963 application”), filed on August 8, 2018, which is a continuation of Application No. 13/440,116 (“the '116 application”), filed on April 5, 2012, which is a continuation of Application No. 11/266,899 (“the '899 application”), filed on November 4, 2005. *Id.*, codes (21), (22), (63).

The '284 patent discloses “an integrated sleep diagnosis and treatment device, and more particularly [] an integrated apnea diagnosis and treatment device.” Ex. 1001, 1:27–29. The '284 patent seeks “to provide a system and method of treatment, which analyzes a subject’s sleeping disorder or symptoms and adjusts a treatment device based, in part, on this analysis.” *Id.* at 2:46–49. According to the '284 patent, the sleep disorder treatment device can also function as “a diagnosis device to perform various forms of analysis to determine or diagnose a subject’s sleeping disorder or symptoms of a subject’s sleep disorder” and can use this analysis or diagnosis to treat the subject to improve symptoms of the sleeping disorder with or without human intervention. *Id.* at 3:4–11. The diagnostic device “can use many different types of sensors and methods for diagnosing the severity of the symptoms of or the sleep disorder itself” including sensors for measuring the subject’s brain wave signals, respirations, and the like. *Id.* at 3:11–18. One embodiment of the invention described in the '284 patent diagnoses the level of severity of a subject’s sleep apnea and adjusts an apparatus for providing

positive airway pressure to the subject with or without human intervention.
Id. at 3:40–44.

Figure 8, reproduced below, depicts a schematic view of one embodiment of the sleep disorder treatment system of the '284 patent.

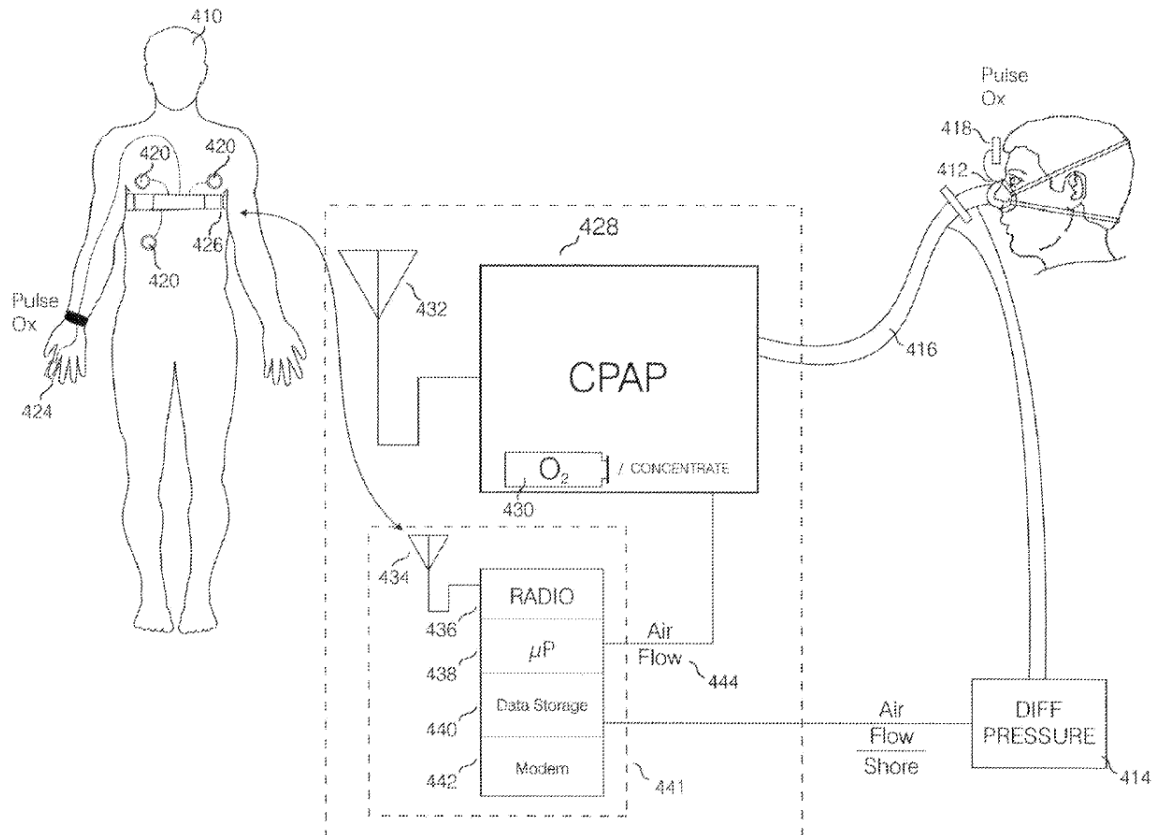


Fig. 8

In the schematic shown in Figure 8, a subject 410 with a respiratory mask 412 “is hooked up with a number of sensors 420, 424, 418, and 426.” Ex. 1001, 23:27–32. The respiratory mask 412 is connected by an air hose or subject circuit 416 to a continuous positive air pressure device (“CPAP”) 428. *Id.* A diagnostic device 441 comprises a radio 436, antenna 434, and microprocessor 438 for picking up signals or data from one or more of the sensors 420, 424, 418, and 426. *Id.* at 23:32–37. The microprocessor 438 processes the data or signals to determine a level of

severity of the subject's sleeping disorder or symptoms, and the diagnostic device 441 transmits a signal based on the level of severity by either a tether 444 or radio signal (not shown) to an actuator (not shown) in the CPAP device 428, which controls the flow of air or gas to the subject. *Id.* at 23:35–41. The CPAP device 428 may have “a sensor in the air hose 416, which can measure the differential pressure 414 and thereby accurately measure air flow provided to the patient.” *Id.* at 23:44–47.

D. Illustrative Claim

Independent claim 1 of the '284 patent is illustrative and reproduced below.

1. A positive airway pressure (PAP) sleep disorder treatment system comprising:

- 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;

the PAP device with an enclosure further comprising:

- a blower having an air output,
- 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,

- 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,
- a mask or a nasal cannula, and
- 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
- 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.

Ex. 1001, 23:58–24:35.

E. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–20 of the '284 patent on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–20	112(a)	Written Description
1–20	112(a)	Enablement
1–8, 14, 19	103	Bao ¹ , Klee ²
9–13, 20	103	Bao, Klee, Shouldice ³
15, 16, 18	103	Bao, Klee, Dong ⁴
17	103	Bao, Klee, Dong, Shouldice

¹ Bao et al., US 2016/0193437 A1, published Jul. 7, 2016 (Ex. 1009).

² Klee et al., US 2018/0199882 A1, published Jul. 19, 2018 (Ex. 1010).

³ Shouldice et al., WO 2021/152526 A1, published Aug. 5, 2021 (Ex. 1011).

⁴ Dong et al., US 5,424,942, issued Jun. 13, 1995 (Ex. 1015).

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 6, 19, 20	103	Farrell ⁵ , Pirzada ⁶
4, 5, 7, 8, 14	103	Farrell, Pirzada, Bao
9–13	103	Farrell, Pirzada, Bao, Shouldice
15–18	103	Farrell, Pirzada, Bao, Dong

Pet. 7. Petitioner also relies on the Declarations of Jacob Sharony, Ph.D. (Ex. 1003) and Alan R. Schwartz, M.D. (Ex. 1020) to support its assertions. Patent Owner relies on the Declaration of Carolyn M. D’Ambrosio, M.S., M.D. (Ex. 2004).

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art “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.” Pet. 15 (citing Ex. 1003 ¶ 60). Petitioner also states that a person of ordinary skill in the art “would have worked with professionals having specialized training in related disciplines such as clinical use and operation of sleep disordered breathing treatment devices.” *Id.*

Patent Owner states that it applies Petitioner’s definition of a person of ordinary skill in the art “[f]or the purpose of this preliminary proceeding only” and “reserves the right to propose its own definition of a [person of ordinary skill in the art] if the Board institutes review.” Prelim. Resp. 6–7.

⁵ Farrell et al., US 2007/0161913 A1, published Jul. 12, 2007 (Ex. 1012).

⁶ Pirzada, US 2007 /0155208 A1, published Jul. 5, 2007 (Ex. 1013).

Petitioner’s unopposed proposed definition is consistent with the cited prior art and the disclosure of the ’284 patent, and we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that the prior art itself may “reflect[] an appropriate level” of ordinary skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Claim Construction

In this post-grant review, we construe the claims of the ’284 patent “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b).” 37 C.F.R. § 42.200(b) (2019). Under that standard, the words of a claim are generally given their “ordinary and customary meaning,” which is the meaning the term would have to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner contends that “[n]o claim term needs formal construction for purposes of evaluating the prior art in this Petition.” Pet. 16. Patent Owner also does not construe any claim terms. *See generally* Prelim. Resp. For purposes of this Decision, and based on the record before us, we determine that none of the claim terms requires an explicit construction to determine whether to institute post-grant review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

C. Post-Grant Review Eligibility

As a threshold issue, we must determine whether the '284 patent is eligible for post-grant review. There are two requirements that must be met for post-grant review to be available. First, post-grant review is only available if the petition is filed within nine months of the issuance of the challenged patent. 35 U.S.C. § 321(c). Here, the Petition was filed on December 13, 2023, which is within nine months of the '284 patent's March 14, 2023, issue date. Pet. 1; Ex. 1001, code (45).

Second, post-grant review is available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013, or later. *See Leahy-Smith America Invents Act*, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA") §§ 3(n)(1), 6(f)(2)(A). The "effective filing date" for a claim is either the application's actual filing date or the filing date of the earliest application that supports the claim. 35 U.S.C. § 100(i) (2018). A patent claiming the benefit of priority of an application filed before March 16, 2013, must have written description support for the claimed invention in the earlier-filed application in order to avoid PGR-eligibility.⁷ *Id.*

Petitioner has the burden of establishing eligibility for post-grant review. *See Mylan Pharms. Inc. v. Yeda Res. & Dev. Co.*, PGR2016-00010, Paper 9 at 10 (PTAB Aug. 15, 2016). To show that the '284 patent is eligible for post-grant review, Petitioner bears the burden of proving that the challenged claims lack the priority benefit of the filing date of an earlier

⁷ The '284 patent issued from a transition application. A "transition application" is a patent application filed on or after March 16, 2013 (the effective date of the AIA), but which claims priority to an application that was filed prior to the effective date of the AIA. *See, e.g.*, MPEP § 2159.04.

application. In particular, Petitioner must show that at least one of the challenged claims, or a claim pending during examination of the '266 application, “was not disclosed in compliance with the written description and enablement requirements of § 112(a) in the earlier application for which the benefit of an earlier filing date prior to March 16, 2013 was sought.” *Inguran, LLC v. Premium Genetics (UK) Ltd.*, PGR2015-00017, Paper 8 at 11 (PTAB Dec. 22, 2015).

Petitioner contends that the '284 patent is eligible for post-grant review because “at least independent Claim 1 ‘lacks written description and enabling support in a priority application filed before March 16, 2013.’” Pet. 4. Notably, the '284 patent claims priority to two pre-AIA applications, the '899 application filed on November 4, 2005 and the '116 application filed on April 5, 2012. Ex. 1001, code (63).

Patent Owner contends that the claims of the '284 patent have an effective filing date of November 4, 2005, and therefore, the patent is not available for post-grant review. *See* Prelim. Resp. 7–8.

1. Written Description

To satisfy the written description requirement under 35 U.S.C. § 112(a), the specification must “reasonably convey[] to those skilled in the art that the inventor had possession” of the claimed invention as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). An adequate description does not require any particular form of disclosure or that the specification recite the claimed invention *in haec verba*, but must do more than render the claimed invention obvious. *Id.* at 1352. In evaluating the adequacy of the written description, a court may consider “the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the

predictability of the aspect at issue.” *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) (cited with approval in *Ariad*, 598 F.3d at 1352); *see also Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) (holding that because the assessment for written description is made from the perspective of a person of ordinary skill in the art, in some instances, a patentee can rely on information that is “well-known in the art” to satisfy written description).

Petitioner contends that claims 1–20 do not have written description support in the ’899 and ’166 application⁸ for the following limitations: (a) “index of treatment efficacy” in claim 1 (from which all other claims depend) (Pet. 17–19); (b) “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” in claim 1 (*id.* at 19–21); (c) “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” in claim 1 (*id.* at 21–22); and (d) “the remote internet site is configured to retransmit to

⁸ For expediency, going forward in the remainder of the Decision we cite only disclosures in the ’284 patent specification and the ’899 application. All the applications are related as continuation applications, and the parties appear to agree that the specifications of the continuation ’963 (Ex. 1006), ’116 (Ex. 1005), and ’899 (Ex. 1004) applications, and of the ’266 (Ex. 1002) application as filed, are substantively identical to the ’284 patent specification (Ex. 1001). *See* Pet. 14 (acknowledging that “any of the priority applications [have] specifications [that] are almost identical to the ’284 patent’s specification.”); Prelim. Resp. 7 (“Petitioner identifies no defects in the priority claims aside from the alleged lack of written description and enablement”).

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" in claims 10 and 14 (*id.* at 22–24).

We find that Petitioner has failed to show that it is more likely than not that the pre-AIA priority applications⁹ lack written description support for the claims in the '284 patent. *See* Prelim. Resp. 8–25. We address Petitioner's contentions below:

a) "an 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." Ex. 1001, 23:65–24:3.

Petitioner contends that this limitation was added in an amendment of September 20, 2022. Pet. 17. According to Petitioner, this limitation is not supported in the specification or priority applications. *Id.* at 18 (citing Ex. 1020 ¶¶ 43–49).

We are not persuaded by Petitioner's contention. "[I]t is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005).

⁹ Exhibit 1004 is the file history of the '899 application filed on November 4, 2005.

Here, the '284 patent specification explains that the treatment system allows for “diagnosing sleep apnea comprising EEG [(electroencephalogram)] sensors, and creating an output of a level of severity of a subject’s sleep apnea; and a CPAP device for treating the subject’s sleep apnea, which can be automatically adjusted using the output.” Ex. 1001, 4:15–18; Ex. 1002, 198; Ex. 1004, 259 (disclosing identical language in the '899 application).

Signals from these sensors are then analyzed to determine the level of severity of the symptoms of the subject’s sleep disorder and in some cases to diagnose the sleep disorder itself. One particular embodiment of the present invention involves diagnosing the level of severity of a subject’s sleep apnea and *with or without human intervention adjusting an apparatus for providing positive airway pressure to the subject*. The treatment device can be adjusted by either by a closed loop control system which uses, in part, *the data or signals from the diagnosis device to actuate a physical or chemical treatment system for the subject*, or an open loop control system which can alert a human who then adjusts the treatment device based in part on the data or signals from the diagnosis device. Alternatively, signals from the sensors can be saved on a medium in order to be retrieved and analyzed at a later date. Media on which data can be saved include, but are not limited to chart recorders, hard drive, floppy disks, computer networks, optical storage, solid-state memory, magnetic tape, punch cards, etc.

Ex. 1001, 3:37–55 (emphasis added); *see also id.* at 23:15–49; Ex. 1004, 258.

Thus, the '284 patent specification explains that the system can adjust the positive airway pressure supplied to the subject without human intervention. The system gathers information from the sensors and uses it to “monitor the condition of the subject” and “determine a level of severity of the subject’s sleeping disorder.” Ex. 1001, 23:20–41. Based on this

information, the system can “regulate the physical or chemical treatment of the subject,” for example by adjusting the positive airway pressure provided to the subject. *See id.* at 19:3–17, 3:37–55. In this way, the ’284 patent specification discloses generating “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,” because the system uses data collected from the sensors to evaluate the severity of the subject’s sleeping disorder and efficacy of the current treatment, and can adjust the treatment without human intervention as needed.

Accordingly, Petitioner has not demonstrated that it is more likely than not that the ’284 patent claims lack written description support in the pre-AIA priority applications for “an index of treatment efficacy” claim term.

b) *“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”*

Claim 1 recites “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.” Ex. 1001, 24:3–6.

Petitioner contends that this limitation was added in an amendment of September 20, 2022. Pet. 19. According to Petitioner, “[t]he 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.” Pet. 20 (citing Ex. 1020 ¶¶ 64–65).

Patent Owner disagrees and argues that “a skilled artisan would immediately discern that to monitor the usage of the PAP device, the usage

data is calculated by the PAP device.” Prelim. Resp. 17–18 (citing Ex. 1001, 23:20–25); Ex. 1004, 294.

Here, the ’284 patent specification explains that the pressure support device contains sensors that measure the flow and pressure of gas passing to the subject. “[T]he signals from one or more of the [] sensors are fed into some form of device with a processor or relayed to a processor for analyzing the one or more signals from these sensors through either a wireless system, a tethered system or some combination thereof.” Ex. 1001, 8:37–41; Ex. 1004, 267.

The signals from the one or more sensors used in various embodiments of the present invention are preferably *analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject’s sleeping disorder or symptoms*. Using either the microcontroller 26 of a data acquisition system, a separate computer, base station or processor, a PDA, a processor on a device for treating the subject’s sleeping disorder or a combination of these processors, the severity of the *subject’s sleeping disorder and/or symptoms is determined and is used at least in part to regulate the physical or chemical treatment of the subject*. Also optionally, the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.

Ex. 1001, 19:3–17 (emphasis added); Ex. 1004, 286.

“Sensors for measuring the subject’s respirations or oxygen levels include sensors to measure airflow, respiratory effort, oxygenation and ventilation, and the like.” Ex. 1001, 3:21–23; Ex. 1004, 257. “Signals from these sensors are then analyzed to determine the level of severity of the symptoms of the subject’s sleep disorder and in some cases to diagnose the sleep disorder itself.” Ex. 1001, 3:21–23; Ex. 1004, 258.

The flow information can also be used to determine the volume of gas passing through the subject circuit 314. The 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.*

Ex. 1001, 23:18–25 (emphasis added); Ex. 1004, 293–294.

Based on the above disclosures in the specification, we agree with Patent Owner that the specification discloses that the gathered information is processed to monitor the condition of the subject (i.e., the system quantitatively estimates or determines the “severity of sleep disorder symptoms”) and how much pressure / flow of gas is to be provided to the subject (i.e., the system calculates the “usage of the PAP device by the subject”). In addition, the device monitors how often it has to supply support to the subject.

Accordingly, Petitioner has not demonstrated that it is more likely than not that the ’284 patent claims lack written description support in the pre-AIA priority applications for 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” claim term.

- c) *“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 . . .”*

Claim 1 recites a “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.” Ex. 1001, 23:60–66.

Petitioner contends that this limitation was added in an amendment of September 20, 2022. Pet. 21. Petitioner contends that the ’284 patent “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.’” Pet. 21 (citing Ex. 1003 ¶¶ 68–69).

We are not persuaded by Petitioner’s contention and agree with Patent Owner, that software downloadable on a cell phone for displaying data, such as an index of treatment efficacy is sufficiently supported in the specification. Prelim. Resp. 21.

In the context of the claims, “software” is a generic term that describes programs or operating information used by computer or computing device. Our reviewing court has stated that, “[f]or generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including ‘the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.’” *Ariad*, 598 F.3d at 1351 (quoting *Capon*, 418 F.3d at 1359).

Accordingly:

A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention

in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (quoting *LizardTech*, 424 F.3d at 1345); *see also Capon*, 418 F.3d at 1359 (“It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention.”).

The '284 patent explains that data is analyzed and displayed. “[T]he data interface cable 62 also can be used to convey data from the base station 40 to the external programming means 60. If a personal computer is the external programming means 60, it can monitor, analyze and display the data in addition to its programming functions.” Ex. 1001, 9:43–48; Ex. 1004, 269. “The remote communication station or base station by way of example but not limitation can include . . . a computer with wireless capabilities, a PDA [(personal digital assistant)] with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, the remote communication station can further transmit data both to another device including the subject’s treatment device and/or back.” Ex. 1001, 19:31–35 (emphasis added); Ex. 1004, 287. According to the '284 patent, “one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.” Ex. 1001, 19:14–17; Ex. 1004, 286.

Based on the above disclosures in the specification, we agree with Patent Owner that the '284 patent “provides specific examples of what a remote communication system is (for example, a cell phone) and the

functions the system performs (for example, receiving and displaying data).”
Prelim. Resp. 21.

Patent Owner further explains that in 2005, a skilled artisan would have appreciated that a cell phone is a computing device. Prelim. Resp. 21 (citing Ex. 2009, 1 (“Yes, smartphones and tablets are indeed considered computers. A computer is really any device that accepts input from a user, performs calculations on that input, and provides an output to the user.”); Ex. 2010 (“A mobile device is essentially a handheld computer. . . . The first mobile device, in this sense, was the personal digital assistant (PDA). Popular in the 1990s and early 2000s.”); Ex. 2011 at 3 (“In 1999, RIM launched the first Blackberry device, known as the Blackberry 850. The device featured a small screen, a physical keyboard, and wireless internet connectivity.”); Ex. 2012 at 10; Ex. 2013 at 2).

We agree with Patent Owner’s assessment that at the time the invention was made, cell phones and PDAs were considered computing devices that could be used for computing and displaying data and that a skilled artisan would have known how to program such a device. We also agree with Patent Owner that a person of ordinary skill in the art would have understood that by 2005, cell phones “had their own operating systems and processors that offered various mobile applications that display data.” *Id.* (citing Ex. 2011, 3; Ex. 2012, 10; Ex. 2013, 2).

Accordingly, Petitioner has not demonstrated that it is more likely than not that the ’284 patent claims lack written description support in the pre-AIA priority application for software executable by a processor and configured to be used with a cell phone to display information.

- d) *“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 and 14 recite that "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." Ex. 1001, 25:18–24, 25:40–26:4.

Petitioner acknowledges the '284 patent specification describes a remote internet site as receiving data for analysis, including data transmitted from a cell phone. Pet. 23 (citing Ex. 1001, 19:43–51). Petitioner, however, contends that the '284 patent does not disclose retransmitting anything. *Id.* (citing Ex. 1003 ¶¶ 73–74).

According to Patent Owner, "the '284 Patent specification adequately conveys to a skilled artisan that the inventors possessed a cell phone that receives the retransmission of data, including indices." Prelim. Resp. 23 (citing Ex. 1001, 19:20–51). Here, the '284 patent explains:

The remote communication station or base station *can be any device known to receive RF transmissions*. . . . The remote communication station or base station by way of example but not limitation can include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for *re-processing the transmission then relaying it to another remote communication station* [For example,] *the remote communication system is a PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and*

re-transmits the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis.

Ex. 1001, 19:20–51 (emphasis added); Ex. 1004, 287; Prelim Resp. 23.

The remote communication station or base station by way of example but not limitation can include . . . a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, *the remote communication station can further transmit data both to another device including the subject's treatment device and/or back.*

Ex. 1001, 19:25–35 (emphasis added); Ex. 1004, 287. Based on these disclosures in the '284 patent we agree with Patent Owner that there is sufficient written description support for a remote internet site configured to retransmit data to a cell phone, and we further agree with Patent Owner that a person of ordinary skill in the art would have understood that the retransmitted data includes the claimed types of data. Prelim. Resp. 23.

As we discuss above in connection with the other challenged claim limitations, the disclosed system calculates and displays data including the severity of the symptoms of the subject, indices of treatment efficacy, and data of usage related to the subject's treatment and the treatment's efficacy. Because the system can transmit these data to a cell phone, we find that a person of ordinary skill in the art would have understood that they could also be retransmitted to a cell phone.

Accordingly, Petitioner has not demonstrated that it is more likely than not that the '284 patent claims lack written description support in the pre-AIA priority application for a remote internet site configured to retransmit the claimed data to a cell phone.

2. *Enablement*

Under 35 U.S.C. § 112(a), enablement is separate and distinct from the written-description requirement. *Ariad*, 598 F.3d at 1344. “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). “[A] patent specification complies with the statute even if a ‘reasonable’ amount of routine experimentation is required in order to practice a claimed invention.” *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999). Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors, referred to as the *Wands* factors, include, for example, the nature of the invention, the state of the prior art, the level of ordinary skill, the level of predictability in the art, and the amount of direction provided by the inventor. *Id.*

Petitioner contends that the specification does not enable the challenged claims. Pet. 24–26. Specifically, Petitioner contends that “[t]he specification provides absolutely no direction or guidance on how to actually determine or use the ‘index of treatment efficacy.’” Pet. 24 (citing Ex. 1020 ¶ 52). Petitioner further contends that the specification does not provide working examples showing how the “index of efficacy” is determined. *Id.* at 25. In addition, Petitioner contends that 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.” *Id.*

Patent Owner submits that Petitioner has failed to show that the '284 patent claims are not enabled. Prelim. Resp. 24–30. We find that Petitioner has failed to demonstrate, more likely than not, that any experimentation would have been undue in view of the *Wands* factors. Prelim. Resp. 25 (citing *Wands*, 858 F.2d at 737). On this record, Petitioner has not demonstrated that the claimed subject matter is unpredictable or would require undue experimentation.

Petitioner argues that “the challenged claims are not enabled regarding the ‘index of treatment efficacy’ claim elements.” Pet. 24. But as Patent Owner establishes, Petitioner acknowledges that determining treatment efficacies was merely applying a known technique. *See* Prelim. Resp. 26 (citing Pet. 36 (determining treatment efficacy “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)”).

On this record, Patent Owner further demonstrates that “it was well-known in the art [] how to determine indices of treatment efficacy based on breathing metric data over a period of time.” Prelim. Resp. 26; Ex. 2001 at 175 (“Efficacy, in the context of [obstructive sleep apnea] OSA, reflects the ability of treatment to prevent the occurrence of obstructive breathing events during periods when the treatment is being physically applied.”); Ex. 2002 at 1–2 (based on the apnea-hypopnea index (AHI) the severity of obstructive sleep apnea (OSA) can be calculated); Ex. 2003 at 1 (“ResLink presents this efficacy information along with integrated oximetry data for simultaneous onscreen viewing and analysis.”)).

Petitioner also argues that there is “no disclosure of displaying the index of treatment efficacy on a cell phone or transmitting it to a remote internet site.” Pet. 25. Petitioner, however, has not demonstrated, more likely than not, that it would take undue experimentation to carry out such display or transmission. The Petition merely suggests that the specification lacks enablement of these claim limitations, but fails to provide any analysis of pertinent factors, such as the state of the prior art, the level of ordinary skill, or the level of predictability in the art with regard to displaying and transmitting data on a cell phone at the time of the invention.

In sum, we conclude that Petitioner has failed to show that it is more likely than not that the challenged claims are not enabled.

3. *Conclusion*

For the foregoing reasons, and on the current record, we determine that Petitioner has not satisfied its burden of proving that it is more likely than not that the pre-AIA priority applications fail to provide written description support for and fail to enable the challenged claims. Therefore, we determine that Petitioner has not demonstrated that the ’284 patent is eligible for post-grant review. Under these circumstances, we need not address Petitioner’s proposed grounds of unpatentability.

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition does not establish that the ’284 patent is eligible for post-grant review. Accordingly, we do not institute a post-grant review of claims 1–20 of the ’284 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* and no trial is instituted.

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