

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

IPR2025-00246
Patent 11,857,333 B1

Before SHERIDAN K. SNEDDEN, NEIL T. POWELL, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 15–29 of U.S. Patent No. 11,857,333 B1 (“the ’333 patent,” Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e). Having reviewed the parties’ arguments and cited evidence, for the reasons discussed below, we find that Petitioner has demonstrated by a preponderance of the evidence that claims 15–29 are unpatentable. Additionally, we deny Patent Owner’s contingent motion to amend.

A. *Procedural History*

Petitioner ResMed Corp. filed a Petition requesting *inter partes* review of claims 15–29 of the ’333 patent. Paper 1 (“Pet.”), 1. Patent Owner Cleveland Medical Devices, Inc. filed a Preliminary Response. Paper 9 (“Prelim. Resp.”).¹ We instituted trial. Paper 12 (“DI”).

After institution, Patent Owner filed a Response. Paper 27 (“PO Resp.”). Petitioner filed a Reply. Paper 30 (“Pet. Reply”). Patent Owner filed a Sur-reply. Paper 41 (“PO Sur-reply”).

Patent Owner filed a Contingent Motion to Amend. Paper 28 (“MTA”). Petitioner filed an Opposition to the Motion to Amend. Paper 31 (“MTA Opp.”). We provided Preliminary Guidance on the Motion to Amend. Paper 37 (“PG”). Patent Owner filed a Reply to the Motion to

¹ The parties also filed briefs directed to discretionary denial issues. *See* Papers 6, 8. The Director denied Patent Owner’s request for discretionary denial of the Petition and referred the case to the Board. *See* Paper 10.

Amend. Paper 40 (“MTA Reply”). Petitioner filed a Sur-reply to the Motion to Amend. Paper 47 (“MTA Sur-reply”).

Patent Owner filed an authorized Motion to Terminate, alleging that Petitioner failed to name its corporate parent, ResMed Inc., as a real party in interest. Paper 39. Petitioner filed an opposition. Paper 42. Patent Owner filed a reply. Paper 43. We denied the Motion to Terminate. Paper 51.

Patent Owner requested authorization to file a motion to terminate based on Petitioner’s failure to disclose allegedly contradictory claim construction positions taken in parallel district court litigation. We denied that request. Paper 52.²

On April 29, 2026, we held an oral hearing, the transcript of which is of record. Paper 54 (“Tr.”).

B. Real Parties in Interest

Petitioner and Patent Owner each identify only themselves as the real party in interest. Pet. 74; Paper 26, 1.

C. Related Matters

The parties identify *ResMed Corp. v. Cleveland Medical Devices, Inc.*, 1:23-cv-02221-BMB (N.D. Ohio) (the “Ohio case”) as a related matter involving the ’333 patent. Pet. 74; Paper 26, 1.

² Patent Owner also raised this issue in its Patent Owner Response, arguing that “the Board should terminate this case because ResMed advances a different construction for this term in this case than it did in the District Court, where it maintains that the term is indefinite.” PO Resp. 2 (citing *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00340, Paper 18 at 3–4 (Squires, Nov. 5, 2025) (informative)). We reject this contention for the same reasons discussed in Paper 52.

Petitioner identifies *inter partes* reviews for U.S. Patent No. 11,602,284 (IPR2025-00157), U.S. Patent No. 11,375,921 (IPR2025-00159), U.S. Patent No. 11,690,512 (IPR2025-00158), U.S. Patent No. 11,786,680 (IPR2025-00160), and U.S. Patent No. 11,872,029 (IPR2025-00247).
Pet. 74.

D. The '333 patent (Ex. 1001)

The '333 patent, titled “Integrated Sleep Diagnostic and Therapeutic System and Method,” issued on January 2, 2024, from U.S. Application 15/641,715, filed on July 5, 2017, and claims priority as a continuation or continuation-in-part to several utility applications, the earliest of which was filed on November 4, 2005. Ex. 1001, codes (21), (22), (45), (54), (63).

The '333 patent “relates to an integrated sleep diagnosis and treatment device.” *Id.* at 2:66–3:1. One embodiment of such a device is depicted in Figure 1 of the '333 patent, reproduced below.

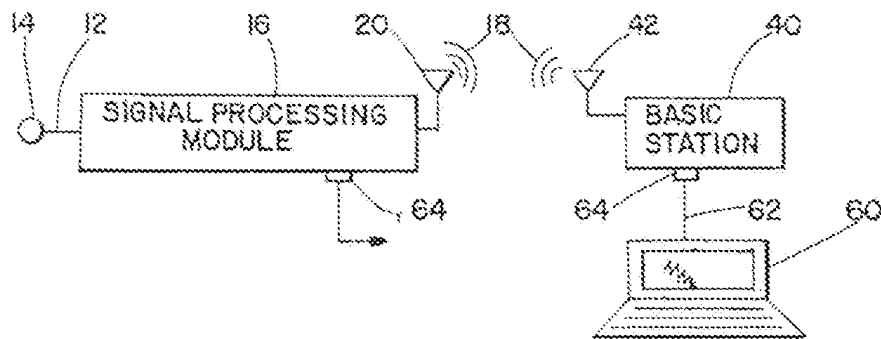


Fig. 1

Figure 1 of the '333 patent is a block diagram of part of a sleep diagnosis and treatment system, wherein external input 12 from sensor 14 is input to signal processing module 16. *Id.* at 35:39–42. Signal processing module 16 generates signal 18, which is “encoded with data corresponding to the

external input 12” and transmitted “by wireless means to a base station 40.”
Id. at 35:45–48.

Figure 8 of the '333 patent is reproduced below.

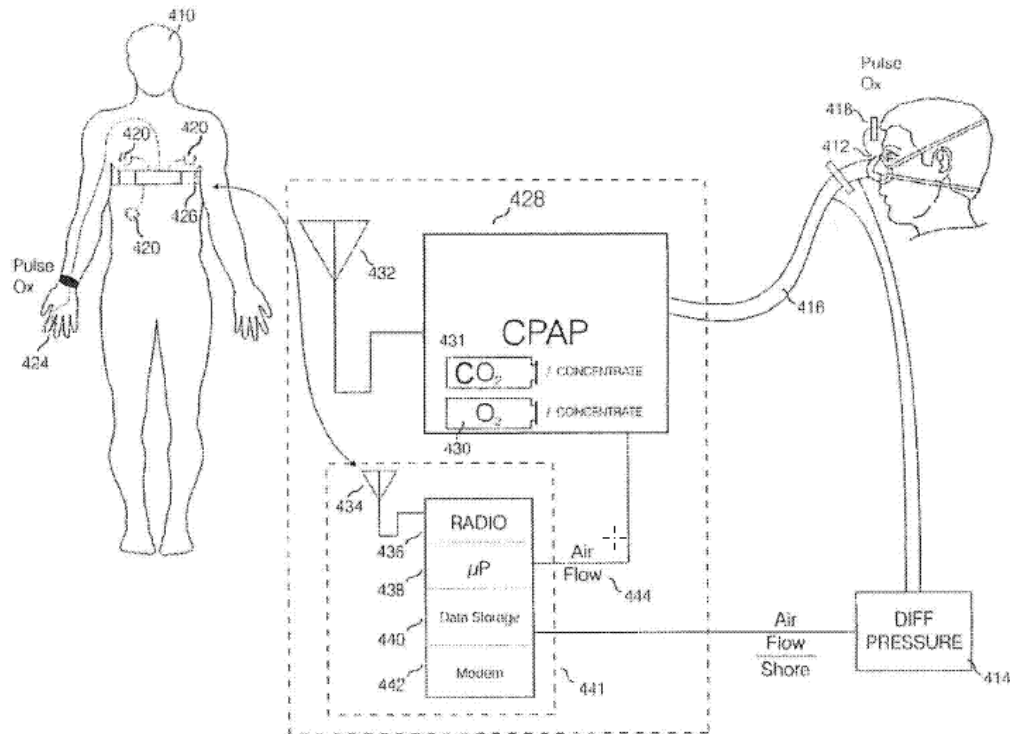


Fig. 8

Figure 8 shows a schematic view of a sleep disorder treatment system. *Id.* at 49:27–40. A “number of sensors 420, 424, 418, and 426 are connected to a subject 410.” *Id.* Subject 410 wears “respiratory mask 412, which is connected by an air hose or subject circuit 416 to a continuous positive air pressure device 428.” *Id.* “[S]ignal or data from one or more of these sensors is collected by a diagnostic device 441, which comprises a radio 436; an antenna 434; and a microprocessor 438 for processing the data or signals to determine a level of severity of the subject’s sleeping disorder or symptoms.” *Id.* “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." *Id.* at 22:47–50.

E. The Challenged Claims

Petitioner challenges claims 15–29 of the '333 patent. Claim 15, the only independent challenged claim, is reproduced below with bracketed notations added:³

15. A method of treating a subject's sleep apnea comprising steps of:

[15.a] providing a therapy to a subject using a PAP or CPAP device while sleeping, the PAP or CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device;

[15.b] collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy;

[15.c] analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;

[15.d] transmitting, in either order, both 1) the collected data and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone to a remote station via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician; and

[15.e] further determining the therapy efficacy data with either the processor of the PAP or CPAP device, the second processor or server configured with a second software at the

³ For ease of reference, we use the same bracketed notations Petitioner uses in the Petition. *See, e.g.*, Pet. 78.

remote station, or the cellular phone using the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider.

Ex. 1001, 60:14–43.

F. Asserted Grounds of Unpatentability

Petitioner asserts that claims 15–29 are unpatentable based on the following four grounds:

Claim(s) Challenged	35 U.S.C. §⁴	Reference(s)/Basis
15–17, 20–24, 26–29	103(a)	Toge, ⁵ Kumar ⁶
15–18, 20–29	103(a)	Toge, Kumar, Norman ⁷
19	103(a)	Toge, Kumar, Burton ⁸
19	103(a)	Toge, Kumar, Norman, Burton

⁴ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Petitioner applies “an effective filing date of no earlier than November 4, 2005.” Pet. 3. Patent Owner likewise employs a 2005 priority date. *See* PO Resp. 4. Accordingly, we apply the pre-AIA version of § 103; however, our Decision would be no different under the AIA version of the statute.

⁵ Toge, JP 2002-291889 A, published October 8, 2002 (“Toge,” Ex. 1044). Exhibit 1044 includes a Japanese-language document and a translation of that document to English. *See* Ex. 1052 (translator declaration for Toge).

⁶ Kumar et al., U.S. Patent App. Pub. 2002/0198473 A1, published December 26, 2002 (“Kumar,” Ex. 1008).

⁷ Norman et al., U.S. Patent App. Pub. 2005/0268912 A1, published December 8, 2005, filed June 4, 2004 (“Norman,” Ex. 1059).

⁸ Burton et al., WO 2004/032719 A2, published April 22, 2004 (“Burton,” Ex. 1050).

Pet. 1. Petitioner supports its contentions with the Declarations of Jason Kirkness, Ph.D. (Ex. 1003) and Dr. Sandeep Chatterjee (Ex. 1005), among other evidence. Patent Owner supports its contentions with the Declaration of Dr. David A. Borkholder (Ex. 2022), among other evidence.

II. UNPATENTABILITY ARGUMENTS RAISED IN THE PETITION

A. *Principles of Law*

In an *inter partes* review, “the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring inter partes review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). Petitioner ultimately bears the burden of persuasion to prove unpatentability of each challenged claim by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Under pre-AIA 35 U.S.C. § 103(a), a claim is unpatentable as obvious if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and

(4) any objective indicia of nonobviousness.⁹ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness determination requires finding a reason to combine accompanied by a reasonable expectation of achieving what is claimed in the challenged patent. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). “[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR*, 550 U.S. at 419–20.

B. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time the invention was made.¹⁰ *See Graham*, 383 U.S. at 17–18. The parties agree that a person of ordinary skill in the art (sometimes referred to herein as “POSITA”) would have had:

at least a bachelor’s degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems, such as networked PAP machines. Additional experience could substitute for less education, and additional education could likewise substitute for less experience.

Pet. 3–4 (citing Ex. 1003 (Kirkness Decl.) ¶ 44); PO Resp. 4.

⁹ Patent Owner does not assert any objective indicia of nonobviousness. *See generally* PO Resp.

¹⁰ For purposes of this Decision, we apply a priority date of November 4, 2005. *See supra* n.4.

Because the proposed level of ordinary skill in the art is consistent with the cited prior art and is undisputed on this record, we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (indicating that the prior art itself may reflect an appropriate skill level).

C. Claim Construction

In AIA proceedings we interpret a claim “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. § 42.100(b). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

Petitioner states that it adopts Patent Owner’s interpretation of the claim terms “transmitting” (limitation [15.d]) and “therapy efficacy data” (limitation [15.e.1]) as described in Patent Owner’s opening claim construction brief in the Ohio case. Pet. 4–6 (citing Ex. 1054, 21–25). The construction of these terms is not at issue in this case, and thus we do not construe these terms.

Patent Owner proposes constructions for the terms “quantified level of severity data” and “integrated into.” *See* PO Resp. 8–9, 13. We discuss these terms further below, and decide that no construction is necessary. *See supra* Sections II.E.1, II.F.1.

We find it unnecessary to address the constructions of any other claim terms to resolve the issues in this case. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that

“we 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))).

D. Overview of Asserted Prior Art

1. Toge (Ex. 1044)

Toge, titled “Remote monitoring method for a medical device,” is the October 8, 2002, publication of Japanese application P2001-96730. Ex. 1044, codes (21), (43), (54). Toge “pertains to a remote monitoring method for monitoring the condition of a patient using a positive pressure artificial respiration assisting device remotely.” *Id.* ¶ 1. We reproduce Toge’s Figure 1 below.

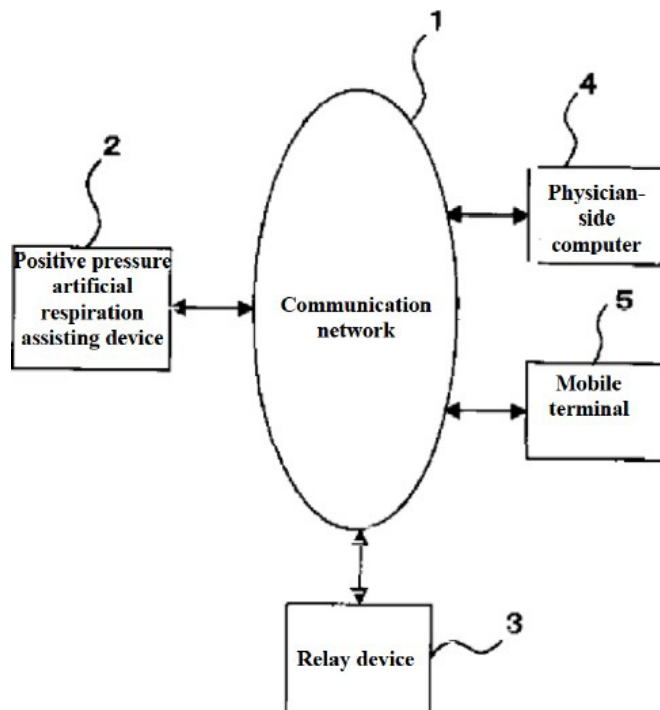


Figure 1 depicts a remote telemedicine system that includes positive pressure artificial respiration assisting device 2, relay device 3, and physician-side terminal devices, specifically physician-side computer 4 and mobile terminal

5, which are all connected to communication network 1. *Id.* ¶ 8.

Communication network 1 may be “a public telephone network, the Internet, a mobile communication network, or a dedicated line network.” *Id.* ¶ 9.

Toge teaches that relay device 3 receives data transmitted from positive pressure artificial respiration assisting device 2 and transmits it to the physician-side computer 4. *Id.* ¶ 16. “[M]edical institution personnel . . . can operate the physician-side computer 4 to send a data download request to the relay device 3 and download the necessary data onto the physician-side computer 4” and can operate physician-side computer 4 to set necessary data for positive pressure artificial respiration assisting device 2. *Id.* ¶ 18.

According to Toge, “mobile terminal 5, in the possession of a physician or nurse, is capable of being mobilized in emergencies by the physician-side computer 4, relay device 3, or other mobile terminals possessed by hospital personnel,” and can be used to set data for positive pressure artificial respiration assisting device 2. *Id.* ¶ 19. “[M]obile terminal 5 includes mobile phones.” *Id.*

We reproduce Toge’s Figure 2 below.

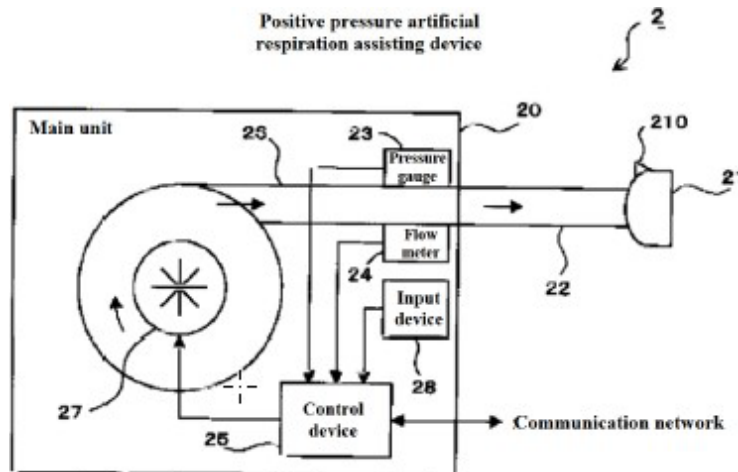


Figure 2 depicts details of positive pressure artificial respiration assisting device 2. *Id.* ¶ 20. Device 2 includes main unit 20 connected via air tube 22 to nasal mask 21. *Id.* ¶ 21. “[M]ain unit 20 is equipped with a pressure gauge 23, a flow meter 24, a control device 25, a flow path 26, a blower 27, and an input device 28.” *Id.* ¶ 23. “Positive pressure air is constantly delivered to the nasal mask 21 via the air tube 22 from the main unit 20” and “nasal mask 21 is equipped with an exhalation vent 210 to expel the patient’s exhaled breath to the exterior of the nasal mask 21.” *Id.* ¶ 22.

We reproduce Toge’s Figure 3 below.

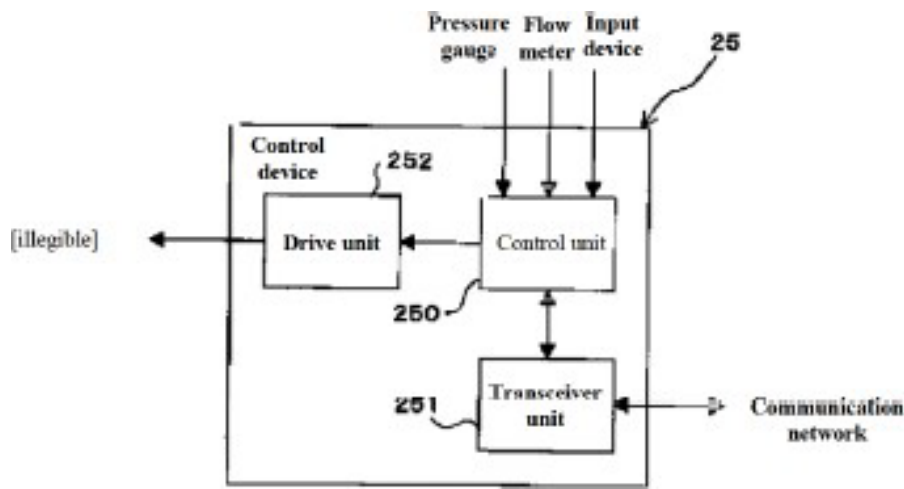


Figure 3 details control device 25 of positive pressure artificial respiration assisting device 2. *Id.* ¶ 20. Control device 25 “comprises a control unit 250, a transceiver unit 251, and a drive unit 252.” *Id.* ¶ 23. Control unit 250 can determine operational time, which physicians can use to “determine whether the patient is using the positive pressure artificial respiration assisting device 2 and assess the treatment (patient) compliance.” *Id.* ¶ 42.

Toge teaches that the functionality of relay device 3 can be integrated into the positive pressure artificial respiration assisting device 2, such that

device 2 can directly transmit treatment data to the physician-side computer 4 or mobile terminal 5 via the communication network 1. *Id.* ¶ 60.

“[P]hysician-side computer 4 or mobile terminal 5 then directly sets the thresholds on the positive pressure artificial respiration assisting device 2 and sends download requests.” *Id.* ¶ 61.

2. *Kumar (Ex. 1008)*

Kumar, titled “System and Method for Real-Time Monitoring, Assessment, Analysis, Retrieval, and Storage of Physiological Data Over a Wide Area Network,” is the December 26, 2002, publication of U.S. Application 10/109,958. Ex. 1008, codes (21), (43), (54).

Kumar “relates to remote monitoring of devices over a wide area network,” and “to network-based transmission of data from a physiological collecting device.” *Id.* ¶ 2. We reproduce Kumar’s Figure 1A below.

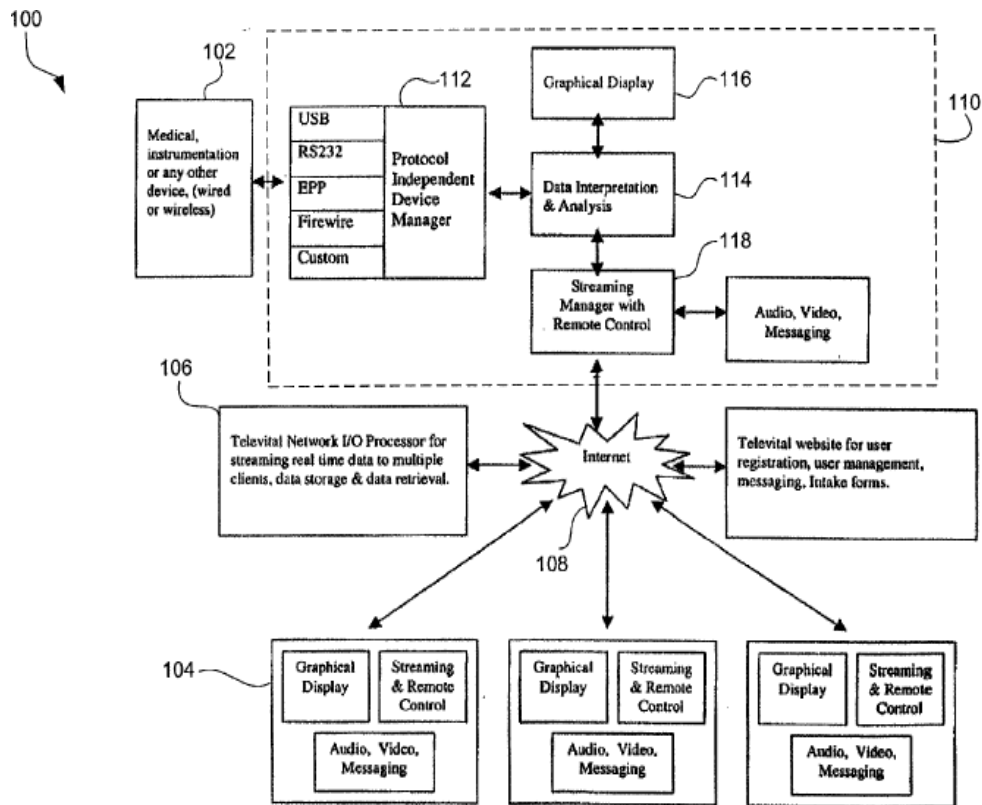


Fig. 1A

Figure 1A shows “an exemplary system architecture for network-based monitoring of data from a patient-side physiological collecting device.” *Id.* ¶ 22. Architecture 100 includes patient-side devices 102 for collecting data from a patient/client, provider-side devices 104, and central server 106 that implements an engine. *Id.* ¶ 67. “The devices and engine are connected to a wide area network (WAN) 108 such as the Internet, intranet, or extranet,” and “[t]he system allows for the real-time Streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider.” *Id.*

Patient-side devices 102 may “be connected via a computing device 110, such as a computer, handheld devices such as personal digital assistants (PDAs) and pocket PCs such as IPAQ with Windows CE operating System and Palm devices based on Palm OS[], wireless telephone, or any other

computing device, to the WAN.” *Id.* ¶ 72. “A protocol independent device manager 112 running on the computing device establishes a two-way communication with a vast array of client-side devices.” *Id.*

Kumar teaches “a modular architecture in which the patient-side device and/or the computing device coupled to the patient-side device can send a request to the engine with an identifier of the patient-side device, and the engine will send the appropriate plug-in which allows the computing device to communicate with the patient-side device.” *Id.* ¶ 74. Therefore, Kumar’s system “may support both plug-and-play web device drivers and customized graphical user interfaces (GUIs) for the various devices.” *Id.*

“The system may be implemented using Apache [W]eb Server, MySql on Linux, Oracle on Linux, Java servlets, Applets, HTML, JavaScript, Java, C#, Microsoft’s .NET etc.” and “the server may be implemented on the Internet, intranet, or an extranet.” *Id.* ¶ 87.

3. *Norman (Ex. 1059)*

Norman, titled “System and Method for Automated Titration of Continuous Positive Airway Pressure,” is the December 8, 2005, publication of US 2005/0268912 A1. Ex. 1059, codes (10), (43), (54). Norman describes “a method and system for the automated titration of CPAP.” *Id.* at code (57).

We reproduce below Norman's Figure 6:

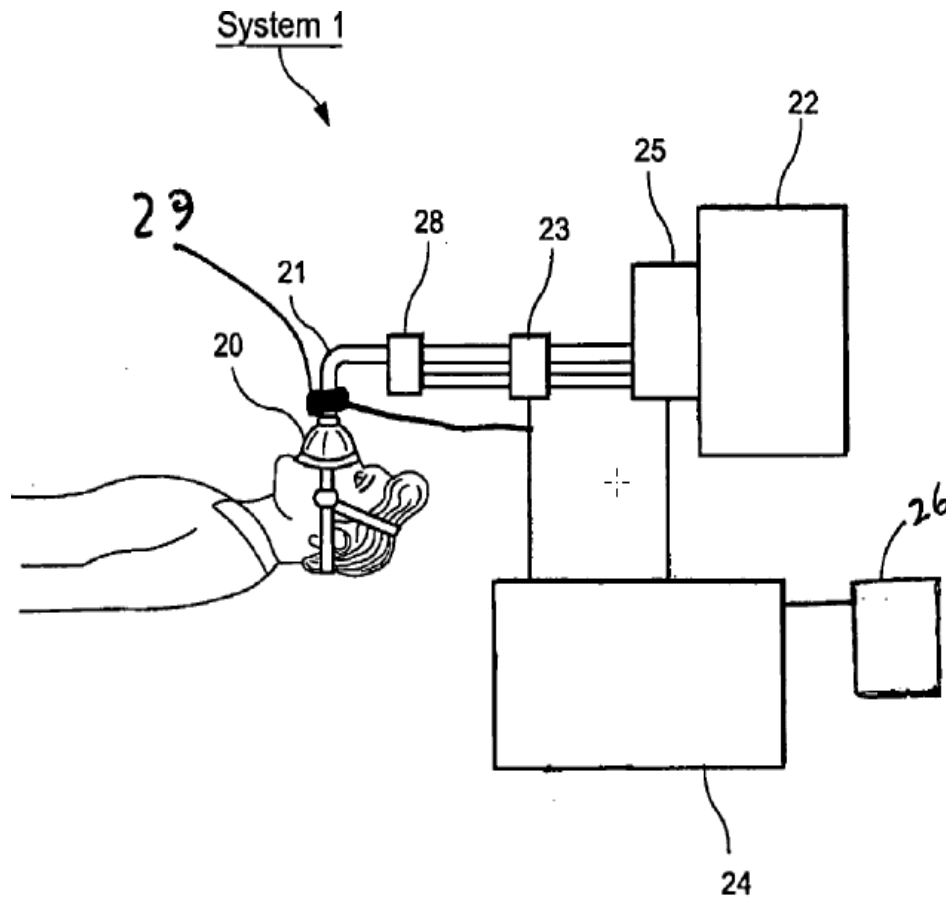


FIG. 6

Norman's Figure 6 depicts system 1, which includes mask 20, tube 21, flow and/or pressure sensors 23, generator 22, flow control device 25, processing arrangement 24, and titration device 26. Ex. 1059 ¶¶ 19, 20, 23. The titration device, which may be attachable to or built into processing arrangement 24, receives and analyzes data from the processing arrangement and adjusts the PAP pressure. *Id.* ¶¶ 23–33, Fig. 7.

4. *Burton (Ex. 1050)*

Burton, titled "Method and Apparatus for Maintaining and Monitoring Sleep Quality During Therapeutic Treatments," published on April 22, 2004,

from PCT Application PCT/US2003/032170. Ex. 1050, codes (21), (43), (54).

Burton relates to “a method and apparatus for delivering therapeutic treatments to patients without adversely affecting their sleep.” *Id.* at 1:4–6. We reproduce Burton’s Figure 1 below.

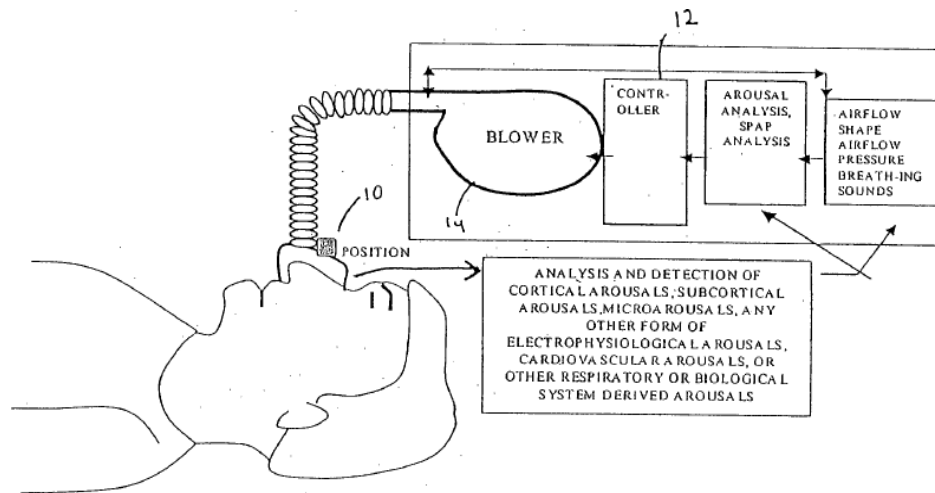


FIG. 1

Figure 1 shows Burton’s system, which “includes one or more sensors 10 which detect a patient’s physiological parameters, a controller 12 which monitors and determines arousal based on the physiological variables received from the sensor, and a gas delivery apparatus 14 which is controlled by the controller 12.” *Id.* at 6:12–15. Burton states that the system “is capable of maintaining the sleep quality of a patient undergoing a therapeutic treatment by sensitizing the therapeutic device to various physiological indicators which predict the onset of arousal and using an adaptive algorithm to modify a patient’s therapeutic treatment.” *Id.* at 3:21–24. The algorithm “has the capability to be adapted during real-time operation based on any combination of a) empirical clinical data, individual

patient collected or alternative (to laboratory) collected data (from diagnostic study within sleep laboratory or other alternative site) or real-time monitored and analyzed data.” *Id.* at 3:25–28.

Burton describes “an algorithm for detecting variation in airflow shape that could be indicative of the incidence or probable onset of upper airway resistance (UAR) or variations of UAR, respiratory event related arousals (RERA) or treatment event related arousals (TERA).” *Id.* at 4:24–27. For instance, Burton explains that the system “would record and note the likelihood of arousal or upper airway flow limitation by way of the shape characteristics of the airflow signal (as derived from a breathing mask circuit).” *Id.* at 4:18–20. According to Burton, “[t]his detection of waveshape characteristics could be achieved by detecting changes in the sequence (1 or more) breathing waveform shapes and then associating these changes with the onset probability or actual incidence of hypopnea, shallow breathing or UAR.” *Id.* at 4:20–23.

Burton teaches that a system using the techniques it describes “can predict the UAR, RERA and TERA events or the onset of such events and adjust the treatment to avoid such events.” *Id.* at 5:10–12. Burton further teaches that “[a]pnea events, shallow breathing, upper airway resistance and hypopnea events can also be detected and pre-empted by analysis of the change in shape of the high bandwidth monitoring of the airflow waveforms and pressure waveforms.” *Id.* at 13:23–26.

E. Alleged Obviousness of Claims 15–17, 20–24, and 26–29 Over Toge and Kumar

Petitioner asserts that claims 15–17, 20–24, and 26–29 are unpatentable as obvious over the combination of Toge and Kumar. Pet. 6–

49. Patent Owner disputes whether Petitioner sufficiently demonstrates that Toge teaches or suggests claim limitation [15.c] which recites, “analyzing with the processor the collected data to determine **a quantified level of severity data** based on the subject’s sleep apnea symptoms during the therapy.” *See* PO Resp. 7–9; Pet. 78 (emphasis added).

After considering all of the arguments and cited evidence of record, we determine that Petitioner shows by a preponderance of the evidence that the combination of Toge and Kumar teaches or suggests each limitation of challenged claims 15–17, 20–24, and 26–29—including a “quantified level of severity data” as recited in [15.c]—and that a person of ordinary skill in the art would have had a reason to combine the teachings of the cited references with a reasonable expectation of success, for the reasons asserted in the Petition. *See, e.g.*, Pet. 6–49. Accordingly, on the full trial record we find that Petitioner shows by a preponderance of the evidence that claims 15–17, 20–24, and 26–29 are unpatentable as obvious over the combination of Toge and Kumar. Below we address the dispute regarding claim limitation [15.c].

In arguing limitation [15.c], Petitioner cites Toge’s disclosure that control unit 250 (the claimed “processor”) analyzes air pressure and/or flow rate data (the claimed “collected data”) and uses this data to calculate tidal volume (the claimed “quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy”). Pet. 15 (citing Ex. 1044 (Toge) ¶¶ 33–38). Petitioner asserts that a person of ordinary skill in the art “would have understood that the calculated tidal volume represents the level of severity based on the patient’s sleep apnea symptoms during the treatment, because it represents, for example, level of airway obstruction the patient

experiences during the sleep apnea treatment using the PAP device.” Pet. 15 (citing Ex. 1003 (Kirkness Decl.) ¶ 157) (emphasis added).

In response, Patent Owner proposes a construction for the term “a quantified level of severity data” and disputes that Toge’s tidal volume is a “quantified level of severity data” as that term is properly construed. PO Resp. 7–12. We begin by addressing Patent Owner’s proposed claim construction, then turn to whether Petitioner has demonstrated that the combination Toge and Kumar teach or suggest limitation [15.c].

1. Construction of “a quantified level of severity data”

Patent Owner asserts that “[a] POSITA would understand that the claimed ‘quantified level of severity data’ is a value that indicates how dire a patient’s symptoms are.”¹¹ PO Resp. 8–9; *see also* Ex. 2022 (Borkholder Decl.) ¶¶ 32–34. Patent Owner bases its construction on testimony from three expert declarants: Dr. D’Ambrosio, Dr. Schwartz, and Dr. Borkholder.

First, Patent Owner states that its construction “is consistent with the plain language of the term and with the position [Patent Owner’s] expert, Dr. D’Ambrosio, advanced in the parallel litigation between the parties,” where Dr. D’Ambrosio stated: “Since the time of the invention, a commonly used term within the clinical sleep setting has been ‘level of severity’ which clinicians understand to represent the how dire a patient’s calculated

¹¹ Elsewhere and in the Sur-reply, Patent Owner adds the word “calculated” to the construction, stating that “a quantified level of severity data” is a “*calculated* value that indicates how dire a patient’s symptoms are.” *See* PO Resp. 9; Sur-reply 2.

symptom data may be.” PO Resp. 8–9 (citing Ex. 1058¹² (D’Ambrosio Decl.) ¶ 32). Patent Owner next asserts that its construction is “consistent with Petitioner’s expert, Dr. Schwartz’s, understanding in a related PGR proceeding,” where Dr. Schwartz allegedly asserted “that sleep apnea indices represent the level of severity of sleep disordered breathing with sleep apnea indices”). *Id.* at 9 (citing Ex. 2026¹³ (Schwartz Decl.) ¶ 46). Citing Dr. Borkholder, Patent Owner notes that “[a]n index such as AHI [apnea-hypopnea index] or RDI [respiratory disturbance index] is calculated based on breathing events that are collected over time and calculated to assess the severity of symptoms. *See id.* at 9; Ex. 2022 (Borkholder Decl.) ¶ 33; Ex. 2027, 175 (discussing AHI); Ex. 2016, 516 (same). Patent Owner asserts that its “construction encompasses known indices, like AHI and RDI, without limiting the claims to any specific index or indices in general.” PO Sur-reply 5.

Petitioner responds that Patent Owner “points to no intrinsic evidence to support its construction and that is because there is none.” Pet. Reply 3. According to Petitioner, “[n]either the ’333 patent nor the claims define a ‘quantified level of severity data,’” and “the patent specification’s disclosures regarding determining a level of symptom severity are broad, establishing that it can generally be derived from any sensor data and/or breathing events.” *Id.* at 3–4 (citing Ex. 1001, 3:44–46 (“Signals from the[]

¹² *Declaration of Carolyn M. D’Ambrosio, M.S., M.D. in Support of Defendant And Counterclaim Plaintiff Cleveland Medical Devices, Inc.’s Opening Claim Construction Brief*, submitted in the Ohio case.

¹³ Exhibit 2026 is the Declaration of Alan R. Schwartz, M.D., submitted in PGR2024-00012 regarding U.S. Patent No. 11,602,284.

sensors are then analyzed to determine the level of severity of the symptoms of the subject's sleep disorder."); *id.* at 22:25–28 ("The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein."); *id.* at 49:5–8 ("[T]he pressure can be increased by differing amounts depending on . . . the severity of the breathing events.")).

Petitioner further asserts that the proposed construction is not consistent with Dr. D'Ambrosio's statements or their purpose, given that she was opining on written description support, not claim construction. *Id.* at 4 (citing Ex. 1058 (D'Ambrosio Decl.) ¶¶ 26–27). Petitioner further asserts that neither Dr. D'Ambrosio nor Dr. Schwartz equated the claim term with the respiratory disturbance index (RDI) or apnea-hypopnea index (AHI). *Id.* at 5.

Petitioner concludes that "quantified level of severity data" should be given its plain and ordinary meaning. *Id.* at 6.

After considering the arguments and evidence of record, we find that the term "quantified level of severity data" does not need construction. The words of the term are clear on their face.

Patent Owner does not persuade us to construe the term as "a value [or calculated value] that indicates how dire a patient's symptoms are." Patent Owner points to nothing in the intrinsic record that purportedly supports this construction, and we agree with Petitioner that "the patent specification's disclosures regarding determining a level of symptom severity are broad, establishing that it can generally be derived from any sensor data and/or breathing events." Pet. Reply 3–4; *see also* Ex. 1001,

3:44–46 (“Signals from the[] sensors are then analyzed to determine the level of severity of the symptoms of the subject’s sleep disorder.”).

Patent Owner relies only on expert declarations to support its construction. But as indicated by the Federal Circuit, extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). This is especially applicable here, where neither Dr. D’Ambrosio’s nor Dr. Schwartz’s declaration was prepared for this proceeding, and neither declarant was subject to cross examination on their opinions. Moreover, neither of the declarants was opining on claim construction; rather, they were addressing indefiniteness and/or written description issues. *See* Ex. 1058 at 7 (heading addressing definiteness); Ex. 2026 at 18 (heading addressing written description). Further, Dr. Schwartz appears to have been making an argument about certain patent claims (not the challenged ’333 patent) based on Patent Owner’s own statements made during prosecution of a separate patent application. *See* Ex. 2026 ¶ 47 (“[T]he similar term used in the ’284 patent claims (‘data of severity of sleep disorder symptoms’) does not find written description support in the specification by a disclosure of the same statistics disclosed in Wright, **because CleveMed argued** those statistics are *not* related to severity of *sleep disorder* symptoms.” (emphasis added)). Patent Owner has not persuaded us that Dr. Schwartz’s testimony has direct applicability to the claim term at issue here.

Dr. Borkholder’s testimony is likewise unpersuasive. Aside from citing Dr. D’Ambrosio’s and Dr. Schwartz’s declarations, Dr. Borkholder cites Exhibits 2027 and 2016. These exhibits discuss indices such as AHI

and RDI that are used to assess the severity of a patient's symptoms, but Patent Owner has not adequately explained how they bear on construction of the claim term at issue here, which is not addressed in these exhibits.

Ex. 2022 ¶¶ 32–33. Accordingly, we accord Dr. Borkholder's claim construction opinions little weight, because they are unsupported by reference to objective, corroborating evidence of record. *See, e.g., Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) (“Lack of factual support for expert opinion going to factual determinations . . . may render the testimony of little probative value in a validity determination.”); *Xerox Corp. v. Bytemark*, IPR2022-00624, Paper 9, 15 (PTAB 2023) (precedential) (explaining that declaration testimony that “is conclusory and unsupported” and which “adds little to the conclusory assertion for which it is offered to support . . . is entitled to little weight”).

Accordingly, on this record Patent Owner has not provided sufficient basis to limit the plain and ordinary meaning of “a quantified level of severity data” as proposed by Patent Owner. Because the meaning of this term is otherwise clear and easy to understand, we do not construe it further.

2. Whether Toge Teaches or Suggests Limitation [15.c]

As noted above, for limitation [15.c] Petitioner cites Toge's disclosure that control unit 250 (the claimed “processor”) analyzes air pressure and/or flow rate data (the claimed “collected data”) and uses this data to calculate tidal volume, where tidal volume is the claimed “quantified level of severity data.” Pet. 15 (citing Ex. 1044 (Toge) ¶¶ 33–38; Ex. 1003 (Kirkness Decl.) ¶ 157). Petitioner asserts that tidal volume represents the level, or severity,

of airway obstruction. Reply 1; Pet. 15; Ex. 1003 (Kirkness Decl.) ¶¶ 157–59.

According to Patent Owner, tidal volume “is a breathing metric that might be analyzed to identify the patient’s symptoms and determine their severity, but without further analysis, the tidal volume does not represent the patient’s symptoms or the severity of those symptoms.” PO Resp. 7–8. It further characterizes tidal volume as “a mere statistic of the measured respiratory airflow.” PO Sur-reply 8. Patent Owner asserts that tidal volume data is “at least two steps removed from the claimed ‘quantified level of severity data.’” PO Sur-reply 4. That is, “[t]o determine a quantified . . . level of severity ‘based on the subject’s sleep apnea symptoms,’ Toge’s tidal volume would have to be analyzed to detect the subject’s apneas. Then the subject’s apneas would have to be analyzed to determine the quantified level of severity ‘based on the subject’s sleep apnea symptoms.’” *Id.* (citing Ex. 2028, 13–14; Ex. 2029, 1).

We find that Petitioner has the better argument. Tidal volume refers to “the volume of air that is inspired or expired during a respiratory cycle.” Ex. 2028, 13–14; PO Resp. 10. “[H]ypopnea events are defined as a reduction of $\geq 50\%$ or 74% in tidal volume from baseline and apnea events as absence of tidal volume for at least 10s.” Ex. 2028, 13–14 (emphasis omitted). Toge teaches that a control unit analyzes collected data (e.g., the flow rate) and calculates tidal volume. Ex. 1044 (Toge) ¶¶ 34–38. The calculated tidal volume is “*a quantified level of severity data* based on the subject’s sleep apnea symptoms during the therapy” because it represents, e.g., the “level of airway obstruction the patient experiences during the sleep apnea treatment using the PAP device.” Pet. 15. As Dr. Chatterjee explains:

Toge discloses that tidal volume Fp is a *quantified level* of data because Toge discloses that Fp is monitored with respect to threshold values (*id.*, [0051]) and because Fp is a function of Ft, Fa, and Fb, which are quantitative values. Toge discloses that tidal volume Fp is *severity data* because Toge discloses that tidal volume is indicative of whether the patient's breathing warrants "emergency measures" (*id.*, [0039]) and whether to "send an alert" in "an emergency where the patient's breathing has drastically weakened" (*id.*, [0055]).

. . . .

Because Toge discloses determining tidal volume (*determine a quantified level of severity data*) based on Ft, Fa, and Fb (*id.*, [0035]), which corresponds to the subject's condition (*subject's sleep apnea symptoms*) while using the device (*during the therapy*) (*id.*, [0036], [0037]), Toge discloses *determin[ing] a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy*.

Ex. 1005 (Chatterjee Decl.) ¶¶ 122–125.

Patent Owner's attempt to dismiss tidal volume as a mere "breathing metric" is unavailing. First, Petitioner correctly "notes that in the paragraph PO cites to in Dr. Schwartz's declaration, he indicates that breathing metrics are a level of severity data." Pet. Reply 8 (citing Ex. 2026 ¶ 46 ("standard sleep disordered breathing *metrics*" [] were well validated *indicators of the type and severity* of sleep disordered breathing")). Second, Dr. Kirkness explains that tidal volume represents the level of airway obstruction, e.g., apnea "is the most severe form of reduction in airflow [and] the absence of airflow results in quantified tidal volume of zero milliliters per breath."

Ex. 1003 (Kirkness Decl.) ¶¶ 157, 159; *see also* PO Resp. 10–11 (Patent Owner recognizing that an apnea is defined as absence of tidal volume for at least 10 seconds). The calculated tidal volume thus indicates severity because it is used to adjust the PAP system, e.g., in the case of decreasing

tidal volume, a medical professional can change the airflow settings “to counter/treat the more severe level of airway obstruction observed from the decreasing tidal volume.” Ex. 1003 (Kirkness Decl.) ¶ 158; Pet. 15–16; Ex. 1044 (Toge) ¶ 39.

For the above reasons, we find that Petitioner has adequately demonstrated that Toge’s tidal volume teaches or suggests claim limitation [15.c].¹⁴

3. Conclusion

In sum, after considering all of the arguments and cited evidence of record, we determine that Petitioner sufficiently shows that the combination of Toge and Kumar teaches or suggests each limitation of challenged claims 15–17, 20–24, and 26–29, and that a person of ordinary skill in the art would have had a reason to combine the teachings of the cited references with a reasonable expectation of success, for the reasons asserted in the Petition. *See* Pet. 6–49. Accordingly, on this record, Petitioner shows by a preponderance of the evidence that claims 15–17, 20–24, and 26–29 are unpatentable as obvious over the combination of Toge and Kumar.

F. Alleged Obviousness of Claims 15–18 and 20–29 Over Toge, Kumar, and Norman

Petitioner asserts that claims 15–18 and 20–29 are unpatentable as obvious over Toge, Kumar, and Norman. Pet. 49–65. Petitioner offers this

¹⁴ Even if Toge’s tidal volume does not teach or suggest this limitation, Patent Owner does not dispute that the prior art combination of Toge, Kumar, and Norman teaches or suggests this claim limitation, as discussed below. *See supra* Section II.F.

ground as an alternative to Ground 1, “[t]o the extent that Toge does not disclose limitation [15.c].” *Id.* at 51.

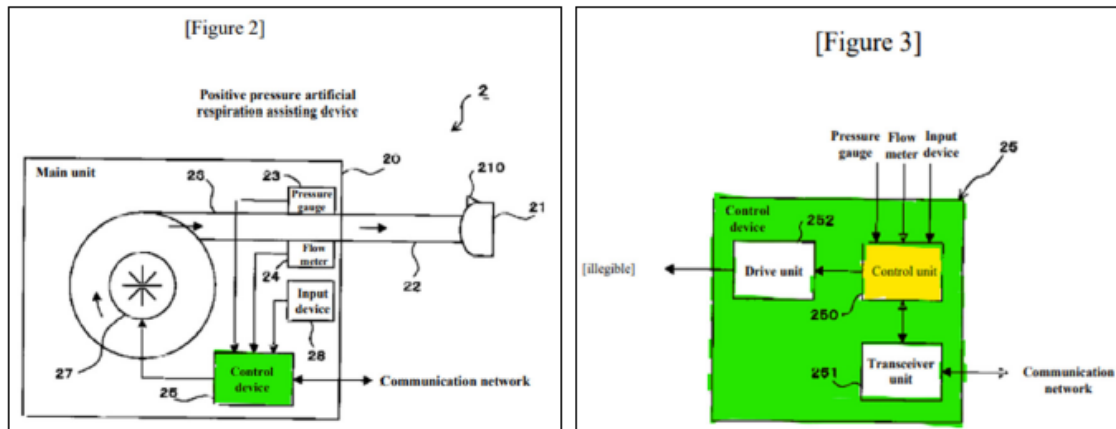
Limitation [15.c] is not at issue in this ground. Petitioner demonstrates, and Patent Owner does not dispute, that Norman teaches or suggests limitation [15.c] by determining “counts/indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.).” *Id.* at 57 (citing Ex. 1059 (Norman) ¶ 28; Ex. 1003 (Kirkness Decl.) ¶ 235; Ex. 1005 (Chatterjee Decl.) ¶ 227); *see also* Prelim. Resp. 1 (Patent Owner admitting that “Norman discloses calculating the level of severity of the patient’s symptoms.”).

The parties instead dispute (1) whether Norman teaches or suggests limitation [15.a], which requires calculating a quantified level of severity using a processor “*integrated into* the PAP or CPAP device”; and (2) whether a person of ordinary skill in the art would have modified Toge with Norman. *See* PO Resp. 12; *see also* Pet. 78 (limitation [15.a]).

After considering all of the arguments and cited evidence of record, we determine that Petitioner demonstrates by a preponderance of the evidence that the combination of Toge, Kumar, and Norman teaches or suggests each limitation of challenged claims 15–18 and 20–29, and that a person of ordinary skill in the art would have had a reason to combine the teachings of the cited references with a reasonable expectation of success for the reasons asserted in the Petition. *See* Pet. 49–62. We address each of the disputed issues below.

*1. Whether Norman Teaches or Suggests Limitation [15.a]
(Processor “integrated into” the PAP or CPAP device)*

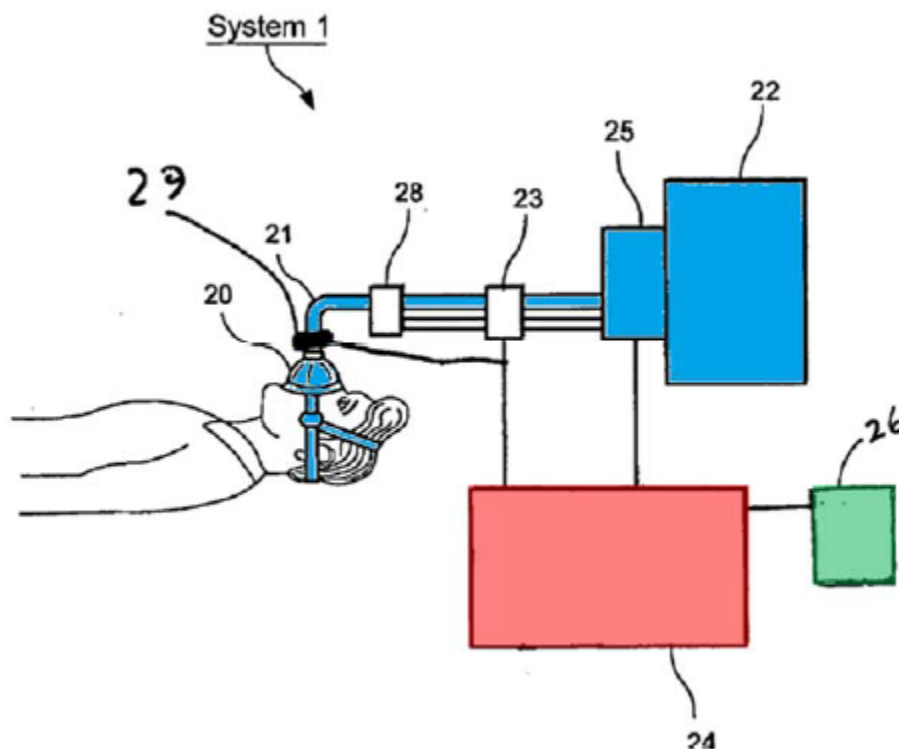
The Petition demonstrates that Toge discloses a processor (i.e., Toge’s “control device 25”), which “resides within main unit 20 of the PAP device.” Pet. 12. This is shown in Petitioner’s annotated versions of Toge’s Figures 2 and 3, reproduced below:



Pet. Reply 10. The above graphic shows Toge’s Figure 2 on the left and Figure 3 on the right. Petitioner colored the “control device” in green in both figures, and colored the “control unit” in yellow in Figure 3. We agree with Petitioner that “Figure 2 shows a PAP with internal control device 25, and Figure 3 shows control device 25 having internal control unit 250 (the processor).” *Id.* Thus we find that Petitioner establishes by a preponderance of the evidence that Toge discloses a processor “integrated into” the PAP or CPAP device as required by limitation [15.a].

Patent Owner disputes this conclusion. Patent Owner begins with claim construction, arguing that “‘integrated into’ means that the processor is inside the PAP/CPAP device.” PO Resp. 13 (citing Ex. 2030 (Cambridge Dictionary) 1 (defining “into” as “the inside . . . of a place”); Ex. 2031 (Merriam-Webster Dictionary) 1 (defining “into” as “insertion”)). Patent

Owner then argues that “[n]either Toge nor Norman discloses the claimed ‘processor . . . integrated into the PAP or CPAP device’ that ‘analyze[s] . . . the collected data to determine a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy’” because Toge discloses analyzing sensor data “on an external device, like the physician’s computer,” while Norman analyzes sensor data “at an external titration device rather than with a processor inside a PAP/CPAP device.” PO Resp. 12–13 (citing, e.g., Ex. 1059 (Norman) ¶¶ 25–26; Ex. 2022 (Borkholder Decl.) ¶ 42). According to Dr. Borkholder, “Norman’s **processing arrangement 24** and **titration device 26** (identified as the claimed “processor”) are external to the **PAP/CPAP device**, as the Figure 6 annotation” reproduced below:



Ex. 2022 (Borkholder Decl.) ¶ 42. Figure 6 depicts Norman’s CPAP system 1. Dr. Borkholder’s annotations purport to show Norman’s

processing arrangement 24 in red, titration device 26 (identified as the claimed “processor”) in green, and the PAP/CPAP device in blue.

We find that Patent Owner’s arguments do not undermine Petitioner’s showing. As an initial matter, although Patent Owner’s proposed construction appears to be consistent with the plain meaning of the term “integrated into” and Patent Owner’s cited dictionaries, we find that a construction is unnecessary because the words of the term are clear and understandable. Nevertheless, we agree with Petitioner that even under Patent Owner’s construction, Toge explicitly discloses a processor “integrated into” the PAP/CPAP. Toge ¶¶ 21, 23, Figs. 2, 3; Pet. Reply 9–10; Pet. 12–13; Ex. 1003 (Kirkness Decl.) ¶¶ 150–51; Ex. 1005 (Chatterjee Decl.) ¶¶ 113–15.

In arguing that Toge fails to disclose analysis of the data on the processor and Norman fails to disclose that the processor is integrated into the PAP device (*see, e.g.*, PO Resp. 12–13), Patent Owner fails to take into account the *combined* teachings of Toge and Norman. Petitioner’s obviousness combination relies on Toge’s teaching of a processor “integrated into” the PAP device, as improved by implementing Norman’s automated titration process in Toge’s systems. *See* Pet. 51 (relying on Ground 1 arguments, except as to limitations [15.c] and [15.e.1]), 49–50 (asserting that “a POSITA would have found it beneficial to implement an automated titration process as taught in Norman to improve the accuracy and efficacy of the CPAP treatment process in the Toge-Kumar combination”). In other words, Petitioner is relying on Toge’s processor augmented with Norman’s algorithm. The location of *Norman*’s processor is thus irrelevant.

And there is no dispute that Toge's processor is inside the PAP/CPAP device.

But even if the location of Norman's processor mattered, we agree with Petitioner that Norman "discloses a processor 'integrated into' the PAP/CPAP and, further, 'inside' of the PAP/CPAP." Pet. Reply 11 (citing Ex. 1059 (Norman) ¶ 23 ("Those skilled in the art will understand that the titration device 26 may be attached to any conventional PAP therapy system. *Alternatively, the titration device 26 may be built into the system 1* (e.g., the titration device 26 *may be combined with the processing arrangement 24.*")). Patent Owner asserts that Petitioner conflates Norman's PAP/CPAP *device* with Norman's CPAP *system*. PO Sur-reply 10. Patent Owner, however, does not cite any portion of Norman supporting such a narrow distinction between the CPAP "device" and "system."

For the above reasons, we determine that Petitioner has shown that the cited combination of prior art teaches or suggests limitation [15.a], which requires calculating a quantified level of severity using a processor that is "*integrated into the PAP or CPAP device.*"

2. Whether Petitioner Demonstrates a Motivation to Combine Toge and Kumar

We find that Petitioner demonstrates that a person of ordinary skill in the art would have "implement[ed] an automated titration process as taught in Norman to improve the accuracy and efficacy of the CPAP treatment process in the Toge-Kumar combination" with a reasonable expectation of success. Pet. 49–51; Ex. 1003 (Kirkness Decl.) ¶¶ 222–223 (noting that Norman's automated titration process allows the system to "evaluate the efficacy of the adjusted pressure" and "enhance[s] the accuracy with which

the appropriate pressure is determined”); Ex. 1005 (Chatterjee Decl.) ¶ 220 (“Norman discloses that more accuracy leads to more use of the PAP therapy.”).

Patent Owner disputes this finding, repeating its argument that Toge discloses analyzing sensor data on an external device (not on the PAP machine’s processor), while Norman’s processor is not integrated into the PAP device. *See* PO Resp. 15–16. Patent Owner also argues that although Petitioner explains *generally* why a person of ordinary skill in the art would have combined Toge and Norman, Petitioner “fails to explain why a POSITA would have modified Toge’s system to perform Norman’s analysis at Toge’s control unit rather than at the physician-side computer.” PO Sur-reply 12; PO Resp. 15.

These arguments again ignore Petitioner’s proposed combination, which adds Norman’s analysis functionality to Toge’s processor, and also ignore the motivations discussed above that Petitioner presents for why a person of ordinary skill in the art would have implemented Norman’s analysis functionality on Toge’s processor. Additionally, we agree with Petitioner that Patent Owner’s argument is based on a mischaracterization of Toge’s system. That is, Patent Owner’s suggestion that in Toge sensor data is analyzed only on an external device (not on the PAP machine’s processor) is incorrect. We agree with Petitioner that “Toge’s processor is not so limited that the PAP is dependent on the physician computer to analyze data;” rather, Toge’s PAP itself calculates tidal volume based on air pressure and flow rate. Pet. Reply 13; Ex. 1003 (Kirkness Decl.) ¶¶ 156–157; Ex. 1005 (Chatterjee Decl.) ¶¶ 122–125.

For the above reasons, we find that Petitioner adequately demonstrates that a person of ordinary skill in the art would have incorporated Norman's automated titration process into Toge's system, which would have led to benefits such as improved accuracy, efficacy, and compliance. Pet. 49–50.

3. Conclusion

In sum, after considering all of the arguments and cited evidence of record, we determine that Petitioner sufficiently shows that the combination of Toge, Kumar, and Norman teaches or suggests each limitation of challenged claims 15–18 and 20–29, and that a person of ordinary skill in the art would have had a reason to combine the teachings of the cited references with a reasonable expectation of success, for the reasons asserted in the Petition. *See* Pet. 49–62. Accordingly, on this record, Petitioner shows by a preponderance of the evidence that claims 15–18 and 20–29 are unpatentable as obvious over the combination of Toge, Kumar, and Norman.

G. Claim 19

Petitioner asserts that claim 19 is unpatentable as obvious over (1) the combination of Toge, Kumar, and Burton; and (2) the combination of Toge, Kumar, Norman, and Burton. *See* Pet. 65–73. Patent Owner does not offer any additional arguments for these grounds beyond the arguments we already addressed above. *See* PO Resp. 16.

We are persuaded on the full trial record that Petitioner has shown by a preponderance of the evidence that claim 19 is unpatentable as obvious over (1) the combination of Toge, Kumar, and Burton; and (2) the combination of Toge, Kumar, Norman, and Burton, for the reasoning set

forth in the Petition. *See* Pet. 65–73. We adopt Petitioner’s reasoning as our own.

III. MOTION TO AMEND

A. *Legal Principles*

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). A patent owner bears the burden to show by a preponderance of the evidence that the proposed amendment complies with the relevant regulatory and statutory requirements. *See Sisvel Int’l S.A. v. Sierra Wireless, Inc.*, 81 F.4th 1231, 1238 (Fed. Cir. 2023); 35 U.S.C. § 316(d); 37 C.F.R. § 42.121(d)(1); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4–8 (PTAB Feb. 25, 2019) (precedential). Specifically, a patent owner must demonstrate by a preponderance of the evidence that: (1) the amendment proposes a reasonable number of substitute claims; (2) the proposed substitute claims are supported in the original disclosure (and any earlier-filed disclosure for which the benefit of filing date is sought); (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the amendment does not seek to enlarge the scope of the claims or introduce new subject matter. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121(d)(1).

To show an amendment does not introduce new matter, a motion to amend must set forth written description “support in the original disclosure of the patent” and “in an earlier-filed disclosure for each claim for which the benefit of the filing date of the earlier-filed disclosure is sought.” 37 C.F.R. § 42.121(b)(1), (2). The test for compliance with the written description requirement of 35 U.S.C. § 112(a) “requires an objective inquiry into the

four corners of the specification from the perspective of a person of ordinary skill in the art.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). “The written description requirement is satisfied only if the inventor conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrates that by disclosure in the specification of the patent.” *Biogen Int’l GmbH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1341–42 (Fed. Cir. 2021) (cleaned up; citations omitted). “A precise definition of the invention is pivotal to establishing possession.” *Id.* “An applicant may show possession of the claimed invention by describing it with all of its limitations using ‘such descriptive means as words, structures, figures, diagrams, formulas, etc.’” *Id.*

“Whether a claimed invention satisfies the written-description requirement of § 112 will depend on the nature of the invention.” *Id.* “[T]he written-description analysis is highly dependent on the facts of each case,” and in general, “is judged based on the state of the art as of the priority date.” *Id.* (quoting *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1373–74 (Fed. Cir. 2017)).

A petitioner bears the burden to show by a preponderance of the evidence that any proposed substitute claim is unpatentable. *See Sisvel Int’l S.A.*, 81 F.4th at 1238; 37 C.F.R. § 42.121(d)(2); *see also Lectrosonics*, Paper 15 at 3–4.

B. Motion to Amend Statutory and Regulatory Requirements

As noted above (*supra* Section III.A), Patent Owner bears the burden to show by a preponderance of the evidence that the proposed amendment

complies with the relevant regulatory and statutory requirements. We address each requirement in turn below.

1. Reasonable Number of Substitute Claims

A motion to amend must “propose a reasonable number of substitute claims.” 35 U.S.C. § 316(d)(1)(B); *see also* 37 C.F.R. § 42.121(a)(3). “There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim.” *Lectrosonics*, Paper 15 at 4; *see also* 37 C.F.R. § 42.121(a)(3).

Patent Owner proposes to cancel claims 17, 18, and 20, and substitute claims 15, 16, 19, and 21–29 with claims 30–41. MTA 1–2, 23–27 (App. A). Thus, Patent Owner proposes a less than one-to-one substitution. Petitioner does not argue otherwise. *See generally* MTA Opp.

Based on the above, we determine that Patent Owner meets the requirement of proposing a reasonable number of substitute claims.

2. Respond to a Ground of Unpatentability

“A motion to amend may be denied where . . . [t]he amendment does not respond to a ground of unpatentability involved in the trial.” 37 C.F.R. § 42.121(a)(2)(i).

Patent Owner argues that “the amendments introduce novel and nonobvious features that avoid the prior art and Petitioner’s proposed combinations.” MTA 12; *see also id.* at 13–21 (arguing that the newly added limitations in proposed substitute independent claim 30 distinguish the claim from the teachings of Toge (Ex. 1044), Kumar (Ex. 1008), and Norman (Ex. 1059)).

Petitioner argues that the substitute claims do not respond to a ground of unpatentability because “the prior art of record employed in the proposed combinations still render[s] the Substitute Claims obvious.” MTA Opp. 8.

We find that Patent Owner has met this requirement by amending the claims in response to the unpatentability arguments presented in the Petition.

3. Scope of the Claims

A motion to amend may not enlarge the scope of the claims of the patent. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). Patent Owner’s Motion only adds narrowing limitations, and thus does not enlarge the scope of the patent claims. *See* MTA 3–4, 23–27 (App. A). Petitioner does not argue otherwise. *See generally* MTA Opp.

Because the proposed substitute claims include narrowing amendments, we find that Patent Owner does not seek to enlarge the scope of the claims.

4. New Matter

A motion to amend may not introduce new subject matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). Patent Owner contends the proposed substitute claims are supported by “U.S. Patent App. No. 15/641,715 (the ‘’715 Application,’ Ex. 1002), which issued as the ’333 Patent, filed on July 5, 2017, and U.S. Patent App. No. 11/266,899 (the ‘’899 Application’), which is the first non-provisional application in the chain of priority, filed on November 4, 2005.” MTA 4. Patent Owner provides a table of citations to the ’715 and ’899 Applications for each limitation of the proposed substitute claims. *Id.* at 5–12.

We focus here on disputed limitation [30.f],¹⁵ which recites in relevant part, “wherein the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cell phone.” MTA 7–8, 23–24.

Patent Owner cites several passages in the ’715 and ’899 Applications that allegedly disclose the requirement “that the patient’s cell phone . . . contain[s] software configured to adjust the therapy administered by the PAP or CPAP device.” *Id.* at 5, 7–8 (claim chart). Petitioner argues that the cited disclosures do not sufficiently disclose limitation [30.f]. MTA Opp. 2–8.

i. Whether the Asserted Written Description Support
is Carried Through the Entire Priority Chain

Before we review Patent Owner’s cited support in the ’715 and ’899 Applications for limitation [30.f], we note that the priority chain for the ’333 patent includes two applications that were filed between the ’715 and ’899 Applications. *See* Ex. 1001, code (63) (listing Application Nos. 13/074,901 and 11/879,934). As we stated in our Preliminary Guidance, to gain the benefit of the filing date of the ’899 Application under 35 U.S.C. § 120, Patent Owner must show that **each** application in the chain leading back to the ’899 Application “reasonably conveys to those skilled in the art that the inventor had possession of the [later-claimed] subject matter as of the filing date.” *Arthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328, 1343

¹⁵ For ease of reference, we refer to the claim limitations of proposed substitute claim 30 listed in Patent Owner’s table of citations as [30.preamble], [30.a], [30.b], [30.c], [30.d], [30.e], and [30.f], respectively. *See* MTA 5–8.

(Fed. Cir. 2022) (quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)); *see also* *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997) (“In order to gain the benefit of the filing date of an earlier application . . . each application in the chain leading back to the earlier application must comply with the written description requirement.”); PG 6. Patent Owner attempts to show written description support for the proposed substitute claims only in the ’715 and ’899 Applications, but not in the two intervening applications. Thus Patent Owner’s showing is fatally flawed because it has not carried its burden of showing that the proposed substitute claims are supported in every application back to the ’899 Application. *See* PG 6; MTA Sur-reply 1–2.

For the first time during the oral hearing, Patent Owner’s counsel suggested that Patent Owner need only show written description support in the most recent application (i.e., the ’715 Application which issued as the ’333 patent) because Patent Owner hasn’t “attempted to show priority all the way back to the first application in the priority chain, which would then require us to also show that the intervening applications also carried through the same disclosures that we are relying on.” Tr. 40:7–12. Patent Owner’s statement that it is not attempting to show priority back to any application older than the ’715 Application is flatly inconsistent with its Motion to Amend, which purported to demonstrate support for the proposed substitute claims in the ’899 Application. Patent Owner’s statement is also flatly inconsistent with its arguments in the MTA Reply that “[b]oth applications include statements . . . which ‘taken together’ provide written description support” for the proposed amended claims. MTA Reply 2.

In short, we find that Patent Owner's briefs did not attempt to establish written description support based solely on disclosures in the '715 Application. Instead, Patent Owner's briefs weave together citations from both the '715 and '899 Applications, and do not fairly attempt to show support based solely on disclosures in the '715 Application. It is too late for Patent Owner to raise this new argument at the oral hearing. We will not take on the task of excising citations to the '899 Application and determining whether the remaining citations to the '715 Application are sufficient for Patent Owner to meet its burden to show written description support for the proposed substitute claims.¹⁶

We find that Patent Owner fails to demonstrate by a preponderance of the evidence that its proposed amendments do not seek to enlarge the scope of the claims or introduce new subject matter. Nevertheless, for completeness, we additionally analyze whether Patent Owner's proffered citations provide written description support for the added limitations.

ii. The '715 Application (Ex. 1002)

Patent Owner argues that the '715 Application discloses that "the patient's cell phone and medical provider's remote computer contain software configured to adjust the therapy administered by the PAP or CPAP device." MTA 5. As support, Patent Owner cites the disclosure in the '715 Application at 5:2–12 as teaching that "the diagnostic device transmits output data to intermediary devices such as a cell phone, modem, or router,"

¹⁶ However, even if we were to consider Patent Owner's belated attempt to rely solely on disclosures from the '715 Application, we would conclude that the '715 Application alone does not adequately support the proposed substitute claims, for the same reasons discussed below.

and the disclosure at 34:20–24 as teaching that “the clinician or the subject can adjust the therapy administered by the PAP device based on the diagnostic device’s output data.” *Id.*; *see also id.* at 7.

Petitioner responds that the disclosure in the ’715 Application at column 5, lines 2–12 is insufficient because it “only discloses that a diagnostic device (e.g., sensors) can transmit signals” to an “intermediary device” which can be a cell phone, but does not disclose that the intermediary device “transmit[s] any signals to a treatment device” or “adjusts the PAP/CPAP therapy.” MTA Opp. 2–3 (emphasis omitted). Regarding the cited passage at column 34, lines 20–24 the ’715 Application, Petitioner asserts that it teaches that the patient can adjust the PAP/CPAP device, but it “does not disclose or suggest that it is a patient’s cell phone that adjusts the treatment device.” *Id.* at 4.

We find that Petitioner has the better view of the cited disclosure in the ’715 Application at column 5, lines 2–12 and column 34, lines 20–24. In short, we agree with Petitioner that neither citation “disclose[s] or suggest[s] a patient’s (‘subject’s’) cell phone is able to be configured to adjust PAP/CPAP therapy.” MTA Opp. 2.

Patent Owner additionally cites the ’715 Application at column 72, line 25 through column 73, line 18 as supporting limitation [30.f]. MTA 7–8. Patent Owner, however, fails to adequately explain the connection between limitation [30.f] and this disclosure. In the text of the Motion, Patent Owner asserts that “a subject’s cell phone and remote internet site receive the subject’s sleep data,” and specifically characterizes the disclosure at column 72, line 25 through column 73, line 18 as “disclosing the transmission of the subject’s sleep data to a remote internet site hosted on a

server.” *Id.* at 4–5. These assertions do not explain how the cited disclosure supports limitation [30.f].

Finally, Patent Owner’s Motion cites the ’715 Application at column 11, line 17 through column 12, line 1 as supporting limitation [30.f], but again fails to adequately explain the connection between the claim limitation and this disclosure. *See* MTA 7–8. We agree with Petitioner that this passage discusses remotely programming the PAP device, but does not disclose or describe the device or component that carries out the remote programming. MTA Opp. 3.

In its MTA Reply, Patent Owner adds citations to the ’715 Application at column 29, lines 22–29 and column 30, line 9 through column 31, line 12. MTA Reply 2–3. We agree with Petitioner that these citations do not tie the subject’s cell phone to adjusting PAP therapy. MTA Sur-reply 3. “The passage at 29:22-29 discloses a cell phone/receiver that transmits PAP data to a remote site ‘for analysis’ (no PAP therapy adjustment) and 30:9-31:12 discloses a cell phone/processor that can be tethered to sensors or be part of a remote communication station (no PAP therapy adjustment).” *Id.*

In sum, we find that Patent Owner has not adequately shown that the cited disclosures in the ’715 Application demonstrate the inventors had possession of a method of treating a subject’s sleep apnea “wherein the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cell phone.” *See* MTA 5–8, 23–24 (App. A). The portions of the ’715 Application cited by Patent Owner describe remotely adjusting the PAP/CPAP device’s settings and disclose that the subject may adjust the PAP/CPAP device, but considered

individually and together (and even together with the cited disclosures from the '899 Application), they do not demonstrate possession of software on the subject's cell phone can be used to adjust the PAP/CPAP device.

iii. The '899 Application (Ex. 2033)

Patent Owner points to two passages in the '899 Application that it alleges provide written description support for claim limitation [30.f]. MTA 7–8. First, regarding column 34, lines 9–21 of the '899 Application, Patent Owner asserts that “a subject's cell phone and remote internet site receive the subject's sleep data,” and specifically characterizes this disclosure as teaching “a remote internet site for analysis.” *Id.* at 4–57–8. These assertions do not explain how the cited disclosure supports the “cell phone” portion of limitation [30.f]. Additionally, we agree with Petitioner that although the text at column 34, lines 9–21 of the '899 Application “describes a ‘remote communication system’ as being a ‘wireless router’ ‘PDA, computer, or cell phone’ that can receive data from the PAP and send it ‘to a remote site for analysis,’ ‘preferably for further input by the subject’s physician or another clinician,’” this does not disclose “a ‘remote communication system’ sending signals or data to adjust the PAP/CPAP therapy” or “a patient cell phone that sends signals to the PAP or adjusts PAP therapy.” MTA Opp. 6.

Patent Owner next cites the '899 Application at column 38, line 24 through column 39, line 28, but does not explain the connection between the claim limitation and this disclosure. *See* MTA 5, 7–8. Additionally, we agree with Petitioner that this passage “discusses a ‘diagnostic device’ ‘used to provide an output’ that can be employed to adjust a ‘treatment device’ ‘automatically . . . or by a clinician or the subject’” and “describes an

embodiment in which the ‘CPAP can be adjusted during the treatment based on the sleep diagnosis results,’ preferably through the receipt of ‘some type of signal,’” but does not define the “diagnostic device” or disclose that it is a subject’s cell phone. MTA Opp. 7.

In its MTA Reply, Patent Owner adds a citation to the ’899 Application at column 33, lines 14–23. MTA Reply 2–3. Patent Owner characterizes this disclosure as indicating “the patient uses the output such as the level of severity to adjust their therapy and . . . this value is found on the patient’s cell phone.” *Id.* at 5. We agree with Petitioner that the cited passage states that a cell phone/processor can be tethered to sensors and analyze sensor data and that the processor can be “part of a remote communications station,” but this disclosure does not state that the patient’s cell phone can be used to adjust the PAP therapy. MTA Sur-reply 2. We also agree with Petitioner that “a ‘value’ displayed on a patient’s cell phone does not suggest that the patient adjusts the PAP therapy *using* a cell phone.” *Id.* Indeed, Dr. Chatterjee testified that “no disclosure in the specification describes an – expressly describes a cell phone of any kind that adjusts therapy there is no disclosure in the ’899 application of how a patient would adjust their PAP therapy.” *Id.* at 3 (citing Ex. 2051, 10:11–18).

In sum, we find that Patent Owner has not adequately identified disclosure in the ’899 Application demonstrating that the inventors had possession of a method of treating a subject’s sleep apnea “wherein the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cell phone.” *See* MTA 5–8, 23–24 (App. A). When considered individually and together (and even together with the cited disclosures from the ’715 Application), these disclosures

do not demonstrate possession of using the subject's cell phone to adjust the PAP or CPAP device.

iv. Other Arguments and Conclusion

Patent Owner criticizes Petitioner for allegedly “viewing in isolation passages for express recitation of a cell phone adjusting PAP therapy” and improperly demanding an express disclosure. MTA Reply 4. Patent Owner argues that the disclosures “in the aggregate convey a patient’s cell phone adjusting the therapy” because both the ’715 and ’899 Applications “include statements of a cell phone receiving sensor data, determining level of severity data based on the sensor data, and the patient adjusting their therapy, which ‘taken together’ provide written description support for a patient’s cell phone adjusting PAP/CPAP therapy.” *Id.* at 2–3 (citing *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1362–63 (Fed. Cir. 2018) (statements in the specification “[t]aken together” provide written description support); Ex. 2049 (Goodrich MTA Decl.) ¶¶ 8–16). Patent Owner argues that “[t]his conclusion is corroborated by the inventors’ statements on the disclosed inventions made during prosecution,” which indicate that the invention allows the patient to remotely adjust therapy and calculates apnea events on the PAP device or the patient’s cell phone. *Id.* at 3 (citing Ex. 1002, 308).

We do not agree with Patent Owner that Petitioner is “viewing in isolation passages for express recitation of a cell phone adjusting PAP therapy.” MTA Reply 4. Instead, we agree with Petitioner’s analysis that Patent Owner’s cited disclosures, both individually and collectively, do not explicitly disclose or imply possession of a subject’s cell phone that adjusts

PAP therapy.¹⁷ MTA Sur-reply 5. “[P]ointing to an amalgam of disclosures from which an artisan could have created the claimed invention does not satisfy [the written description] requirement.” *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, *3 (Fed. Cir. 2021). And “a description that merely renders the invention obvious does not satisfy the [written description] requirement.” *Ariad*, 598 F.3d at 1352.

Patent Owner contends that its conclusions are “corroborated by the inventors’ statements on the disclosed inventions made during prosecution.” MTA Reply 3. We disagree. First, the “four corners of the specification” must “show that the inventor actually invented the invention claimed.” *Ariad*, 598 F.3d at 1351. Subjective views as stated during prosecution cannot be used to augment the disclosures in the specification. Second, the statements Patent Owner cites are not even inventor statements, but are instead “bare applicant argument (EX1002, 308) made in an amendment.” MTA Sur-reply 4. Attorney argument, however, is “no substitute for evidence.” *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

Based on the foregoing, we find that Patent Owner has not demonstrated by a preponderance of the evidence that limitation [30.f] contains no new matter.

¹⁷ Although we have done so, viewing the citations to the ’715 and ’899 Applications in the aggregate is meaningless given that Patent Owner cannot rely on the ’899 Application because it did not cite any portions of the two intervening applications to show that the cited disclosure was carried through the entire priority change.

5. *Conclusion on Statutory and Regulatory Requirements*

For the above reasons, we determine that Patent Owner has not demonstrated by a preponderance of the evidence that the proposed substitute claims introduce no new matter as required by 37 C.F.R. § 42.121(b). Accordingly, we deny Patent Owner's Motion to Amend. For completeness, we address Petitioner's unpatentability arguments regarding the proposed amended claims below.

C. *Petitioner's Unpatentability Arguments*

Petitioner bears the ultimate burden to show that any proposed substitute claims are unpatentable. 37 C.F.R. § 42.121(d)(2). For the reasons discussed below, we find that Petitioner has not shown by a preponderance of the evidence that proposed substitute claim 30 is unpatentable.¹⁸ See 37 C.F.R. § 42.121(e)(1).

Petitioner argues that proposed substitute claim 30 is unpatentable as obvious over Kumar (Ex. 1008) and Toge (Ex. 1044). MTA Opp. 8–25. Petitioner addresses limitations [30.d], [30.e], and [30.f]. *Id.* We address the parties' arguments regarding these claim limitations below.

¹⁸ Petitioner's Opposition does not include unpatentability arguments specific to proposed substitute claims 31–41. See generally Opp. However, dependent claims are nonobvious under § 103 if the independent claims from which they depend are nonobvious. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Accordingly, because we find that Petitioner has not demonstrated that proposed independent claim 30 is unpatentable as obvious, it also necessarily has not done so for dependent proposed substitute claims 31–41.

1. Claim Limitation [30.d]

- i. Transmitting “the collected data and/or the quantified level of severity data to a subject’s cellular phone with downloadable first software”

Petitioner argues that Kumar and Toge teach “‘a subject’s cellular phone with downloadable first software’ that receives ‘a quantified level of severity data’ from ‘the PAP or CPAP device via a cellular system.’” MTA Opp. 10 (citing Pet. 18–41). Specifically, Petitioner contends that “Kumar discloses a plug-in (‘first software’) sent (‘downloaded’) to computing device 110 (‘cellular phone’) that communicates with patient-side devices (e.g., Toge’s PAP) through a wireless protocol, where, in particular, the patient cell phone receives data from the PAP.” *Id.* (citing Ex. 1008 (Kumar) ¶¶ 72, 74–75; Pet. 39; Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶ 14).

Petitioner argues that Kumar also “discloses that computing device 110 (‘cellular phone’) communicates with patient-side devices (e.g., Toge’s PAP) using a wireless protocol (wide area network (WAN)), through which the patient cell phone receives data from the patient-side device.” *Id.* (citing Ex. 1008 (Kumar) ¶¶ 67–68, 75; Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶¶ 13, 15).

Petitioner argues a person of ordinary skill in the art “would have found it obvious to configure Kumar’s patient-side cellular phone to receive a quantified level of severity data from the PAP/CPAP just as Toge’s physician-side cell phone receives such information” because it would have 1) allowed the patient to view and store treatment data; 2) “encouraged the patient to comply with the prescribed treatment;” and 3) “reduced the PAP device’s form factor” by eliminating the need for a display screen on the

PAP/CPAP, thereby “improv[ing] the device’s portability and/or result[ing] in a smaller and less expensive device.” MTA Opp. 11–12 (citing Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶¶ 12–19; Ex. 1071 (Kirkness MTA Opp. Decl.) ¶ 7).

Patent Owner responds that “Toge does not disclose the use of patient’s cell phone in its system,” and a person of ordinary skill in the art would not have been motivated to add one because “Toge is directed to the physician so there was no problem that needed solving that would have motivated this modification,” and “Toge’s PAP device includes a PAP display screen that already allows a patient to view their sleep data.” MTA 15–16.

We find that Petitioner has the better position. We agree with Petitioner that a person of ordinary skill in the art would have been motivated to add a patient’s cell phone (from Kumar) to Toge’s system because “Toge is not solely ‘directed to the physician.’” MTA Opp. 13. Instead, Petitioner demonstrates that Toge “contemplates the patient operating the PAP device,” and that regardless, a person of ordinary skill in the art “would have been motivated to add a patient’s cell phone to Toge’s PAP system” to increase patient convenience, engagement, and compliance. MTA Opp. 13; Ex. 1044 ¶¶ 26, 30; Ex. 1071 ¶ 7. Petitioner also adequately demonstrates that a person of ordinary skill in the art “would have had the skill and a reasonable expectation of success” to combine Kumar and Toge because it would have involved the combination of a known technology (e.g., cell phone already implemented in the Toge-Kumar system as a physician-side cell phone) according to known methods (e.g., methods of transmitting data between the physician-side cell phone and the PAP/CPAP)

to yield the predictable result of a PAP/CPAP system with a patient's cell phone that receives a quantified level of security data. MTA Opp. 13 (citing Ex. 1072 ¶ 19).

- ii. Transmitting “the collected data and/or the quantified level of severity data to a remote internet site hosted on at least one server”

Petitioner argues that a person of ordinary skill in the art would have implemented “Kumar’s remote engine/central server in Toge’s PAP system to enable Toge’s PAP to also wirelessly transmit data (e.g., a quantified level of severity data) to the remote server for storage, review, and data organization.” MTA Opp. 15 (citing Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶¶ 22, 24–25)). Petitioner asserts that “the remote server would increase the convenience, diagnosis, and treatment for patients.” *Id.* (citing Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶¶ 27–32); Ex. 1071 (Kirkness MTA Opp. Decl.) ¶ 12.

Patent Owner disputes Petitioner’s arguments about placing a remote server in Toge’s system, and whether the proposed modification would have interfered with Toge’s purpose. We address each argument in turn.

a. Location of Web Server

Petitioner argues that a person of ordinary skill in the art would have implemented Kumar’s browser-based “remote engine/central server” in Toge’s system because it would enable Toge’s PAP to wirelessly transmit data to the remote server for storage, review, and data organization and would allow access to the data from anywhere in the world, thus increasing “the convenience, diagnosis, and treatment for patients.” MTA Opp. 15 (citing Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶¶ 22, 24–25, 27–32;

Ex. 1071 (Kirkness MTA Opp. Decl.) ¶ 12). Petitioner proposes only one specific implementation, i.e., “implement[ing] Toge’s physician-side computer as a web server.” *Id.* (citing Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶ 26).

Patent Owner responds that a person of ordinary skill in the art “would **not** have implemented Toge’s physician-side computer as a web server” because running web servers and clients on the same machine is not suitable for web applications and cannot take advantage of the distributed computing environment, and because it presents security and performance issues. MTA Reply 10–11 (citing, *e.g.*, Ex. 2049 (Goodrich MTA Decl.) ¶¶ 27–31; Ex. 2054, 4 (noting that having “the client and server reside in the same machine” “is not suitable for a web application [because] it can only access data available in a single computer or server”); Ex. 2055, 4 (having client/server on same computer “is rarely used today because it will not take advantage of the distributed computing environment”).

Petitioner responds that “Toge’s physician-side computer implemented with Kumar’s web server would be part of a distributed computer system. It is not a personal computer (EX1044, [0017] (‘computer installed at a medical institution’)) or even a single computer.” MTA Sur-reply 11.

We reject Petitioner’s belated assertion that Toge’s physician-side computer implemented with Kumar’s web server would be part of a distributed computer system. Petitioner did not assert in its Opposition that Toge’s physician-side computer is actually multiple computers. Indeed, its declarant Dr. Chatterjee made clear that the physician-side computer and web server would be on a single machine, asserting that because “the

physician-side computer and the web server are on *one machine*, the physician would receive the data at the same time as the web server, communicating the data to the physician even more quickly.” Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶ 30. Accordingly, we find that Petitioner’s argument about a distributed computer system is waived.

We further find that Petitioner has not demonstrated that a person of ordinary skill in the art would have been motivated to implement Kumar’s web server on Toge’s physician-side computer. Petitioner’s opposition does not indicate *why* a person of ordinary skill in the art would have selected this particular implementation. Indeed, Petitioner has not pointed us to any disclosure in Toge or Kumar (or any other prior art reference of record) that teaches or suggests that a physician’s computer should act as a web server hosting sensitive patient data. Petitioner points to Kumar, paragraph 69, but that paragraph discusses provider-side devices *separate* from engines/central servers. MTA Sur-reply 11. Additionally, Patent Owner demonstrates that Petitioner’s proposed configuration of having “the client and server reside in the same machine” “is not suitable for a web application [because] it can only access data available in a single computer or server.” Ex. 2054, 4. Accordingly, Petitioner’s proposed modification is inconsistent with the very purposes it provides for making the combination, i.e., broadening access to data from anywhere in the world and thus increasing “the convenience, diagnosis, and treatment for patients.” MTA Opp. 15.

Although Petitioner’s brief proposes only one specific implementation (i.e., “implement[ing] Toge’s physician-side computer as a web server”), at deposition Petitioner’s declarant also asserted that a person of ordinary skill

in the art would have implemented the server “at various locations.” *Id.*; Ex. 2051 (Chatterjee Depo. Tr.) 21:25–27:3; MTA Reply 10.

We do not credit Petitioner’s contention that a person of ordinary skill in the art would have implemented the server at “various locations” because this contention is not stated in Petitioner’s brief and is thus waived. *See generally* MTA Reply. Even if we were to consider this contention, we would reject it because as Patent Owner’s declarant Dr. Goodrich states, “it is unclear what [Petitioner] ResMed means when it states that Kumar’s web server configuration can be implemented at ‘various locations’ in Toge’s system.” Ex. 2049 (Goodrich MTA Decl.) ¶ 27. Toge’s system includes “a PAP device, relay device for sending the data, and physician-side devices,” and it is unclear where among these devices Petitioner proposes to insert the server and how that configuration would allegedly meet the requirements of proposed substitute claim 30. *Id.*

For the above reasons, we find that Petitioner has not demonstrated by a preponderance of the evidence that a person of ordinary skill in the art would have combined Toge and Kumar in a manner that results in the subject matter recited in limitation [30.d].

b. Alleged Interference with Toge’s Purpose

Patent Owner argues that a person of ordinary skill in the art would not have modified Toge’s system with Kumar’s web server “because it would have interfered with Toge’s purpose of pushing crucial treatment data to the physician-side devices.” MTA 17 (citing Pet. 23–25; Ex. 2032 ¶¶ 41–48); *see also id.* at 20–21; *see also id.* at 18 (arguing that “Toge’s system pushes patient data to the doctor’s computer and mobile device for analysis and without request”); MTA Reply 11–12. According to Patent Owner,

“[b]ecause data is pulled only upon request [in Petitioner’s combination], Toge’s purpose of pushing, without request, ‘necessary’ or ‘crucial’ treatment data would be interfered with.” MTA 21 (citation omitted) (citing Ex. 2019, 25–26; Ex. 2020, 2–3).

Petitioner responds that “‘emergency action’ is not the only purpose of Toge because it also monitors the periodic condition of the patient and stores data for later transmission.” MTA Opp. 16 (citing Ex. 1044 (Toge) ¶¶ 7, 44, 46, 47); Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶ 32). Petitioner also asserts that Kumar’s system is designed for the “push” of real-time transmissions because it describes “real-time streaming” of data. *Id.* at 16–17 (citing, *e.g.*, Ex. 1008 (Kumar) ¶¶ 7, 9, 10, 14; Pet. 36, 42; Ex. 1005 (Chatterjee Decl.) ¶¶ 92, 146). Petitioner asserts that “[a]lternatively, the remote internet site/physician device could be implemented to continuously query the server for new data, making it functionally equivalent to a ‘push’ system.” *Id.* at 17 (citing Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶ 31).

Patent Owner responds that “a web server push protocol did not exist at the relevant time period” and “continuously querying the server to ‘[i]ncreas[e] the “pull” frequency’ would not have been done because of performance issues and practicality reasons.” MTA Reply 12 (citing Ex. 2049 (Goodrich MTA Decl.) ¶¶ 33, 37–38). Patent Owner also argues that “Kumar’s real-time streaming embodiment still requires the physician to log into the website to request the real-time data.” *Id.* (citing Ex. 1008 ¶¶ 91–93, Figs. 5, 8; Ex. 2049 (Goodrich MTA Decl.) ¶ 39).

We find that Patent Owner here identifies an important shortcoming flowing from Petitioner’s proposed combination, and that Petitioner does not adequately respond. As an initial matter, Petitioner does not persuasively

demonstrate that in the modified system, Toge's PAP would remain a push system. Petitioner's own declarant Dr. Chatterjee testifies that "[w]eb servers use HTTP," and "[t]hese HTTP servers store the Internet's data and provide the data *when it is requested* by HTTP clients." Ex. 1005 (Chatterjee Decl.) ¶ 32 (emphasis added); MTA 21. Other evidence of record similarly demonstrates that web servers operate as a pull model, where information is sent in response to a request. *See* Ex. 2019, 1 (discussing the sender-push models versus receiver-pull models like "the HTTP-based web access system"); Ex. 2035, 2–3 ("The client-server model operates on a request-response mechanism, where clients send requests to the server, and the server responds with the requested information or service."); Ex. 2020, 2–3 (describing HTTP as "a pull protocol" where "information can only be pulled from a web server after a client's request;" "[t]he web server never pushes information to a client without a request").

Dr. Chatterjee asserts that "[t]here is nothing about the implementation of Kumar's web server preventing Toge's PAP from pushing data as soon as it is received" and that "[i]f the server identifies an emergency, the server could automatically push out such data." Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶¶ 30–31. We find this testimony unpersuasive on this record because it is not supported by citation to any objective evidence of record. *See id.*; *see also* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."); *Xerox Corp. v. Bytemark*, IPR2022-00624, Paper 9, 16 (PTAB 2023) (precedential). This testimony is also inconsistent with statements in his opening declaration explaining that a web server "provide[s] the data when it is requested by HTTP clients"

(Ex. 1005 (Chatterjee Decl.) ¶ 32) and with other evidence of record discussed above which indicates that the web-based client-server model operates as a pull system. *See, e.g.*, Ex. 2019, 1; Ex. 2035, 2–3; Ex. 2020, 2–3.

In its MTA Sur-reply, Petitioner did not dispute or even engage with testimony from Patent Owner’s declarant that “a web server push protocol did not exist at the relevant time period,” and thus “the web client would need to perform repeated data *pull* action rather than receiving a single data push from the web server to receive an update.” Ex. 2049 (Goodrich MTA Reply Decl.) ¶ 33. Dr. Goodrich establishes that it was not “until after the priority date for the ’333 patent that general web push solutions such as HTTP/2 Server Push and Google Cloud Messaging” and the WebSockets technology cited by Dr. Chatterjee¹⁹ were introduced. *See id.* ¶¶ 33–34; Ex. 2058; MTA Reply 11–12. For at least these reasons, we find unpersuasive Dr. Chatterjee’s testimony that the server could automatically push data.

Petitioner’s alternative argument that “the remote internet site/physician device could be implemented to continuously query the server for new data, making it functionally equivalent to a ‘push’ system” is also unpersuasive. MTA Opp. 17; Ex. 1069 (Chatterjee MTA Opp. Decl.) ¶ 31. Dr. Chatterjee’s statement lacks any supporting citation to objective evidence of record. Patent Owner additionally persuades us that this proposal is impractical, because “continuously polling *all* of a physician’s patient PAP devices to see if any of them are in an emergency situation is a

¹⁹ *See* Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶ 31.

significant waste of network resources and would lead to performance degradation such that the server could no longer function effectively.” MTA Reply 12; Ex. 2049 (Goodrich MTA Reply Decl.) ¶ 38.

Petitioner argues that Kumar’s system is able to stream transmissions in real-time. MTA Opp. 16–17. However, given the state of the art as discussed above, we agree with Patent Owner that Kumar’s real-time streaming embodiment “still requires the physician to log into the website to request the data,” and thus “is still a pull solution.” Ex. 2059 (Goodrich MTA Reply Decl.) ¶ 39 (citing Ex. 1008 (Kumar) ¶¶ 89–93 (disclosing a physician logged into a web page displaying a list of patients and patient session information), 140–41, Figs. 5, 8 (depicting a physician logged into a webpage where logged information and data is available)); MTA Sur-reply 12. Accordingly, we find that Petitioner’s proposed modification would have the drawback of reducing the utility and convenience of Toge’s emergency alert feature, e.g., by requiring the physician to continuously query the server to see if new data had been received.

Petitioner argues that Toge’s system is not limited to operating in emergency situations because Toge teaches monitoring a patient’s periodic condition and storing data for later transmittal. *See, e.g.*, MTA Opp. 16; Ex. 1044 (Toge) ¶¶ 7, 44, 47. While we agree that Toge’s purpose is not *limited* to pushing emergency information, it is a feature that Toge repeatedly touts. *See, e.g.*, Ex. 1044 (Toge) ¶¶ 19, 39, 46–47, 55–57. As noted, Petitioner’s proposed modification would have the drawback of reducing the utility and convenience of this feature. On the flip side, Petitioner fails to establish any clear, tangible benefits gained from modifying Toge’s system as proposed. As discussed above, its proposed

configuration of having the server and physician computer on the same machine is inconsistent with its arguments about increasing access to data. *See, e.g.*, MTA Opp. 15. Our reviewing court advises that “the benefits, both lost and gained, should be weighed against one another.” *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000). Here, such a weighing does not favor Petitioner’s proposed modification.

Although a motivation to combine “does not require a combination to be the most preferred or most desirable prior art combination” (*see* MTA Sur-Reply 12 (citing *Novartis Pharms. Corp. v. West-Ward Pharms. Int’l Ltd.*, 923 F.3d 1051, 1059 (Fed. Cir. 2019); *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004))), an obviousness argument requires “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at 418. After considering the arguments and cited evidence of record, we find that Petitioner’s arguments lack the necessary articulated reasoning with some rational underpinning to support its obviousness argument. Instead, Petitioner’s arguments appear to be based “on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998).

For the above reasons, we find that Petitioner has not carried its burden of demonstrating that a person of ordinary skill in the art would have modified Toge in the manner proposed by Petitioner to result in a system that teaches or suggests claim limitation [30.d].

- iii. Transmitting “the collected data and/or the quantified level of severity data . . . for further analysis with a second processor on the at least one server and review of the collected data, the quantified level of

severity and/or this analysis by a clinician, technician, or physician at a remote computer”

Petitioner contends that Kumar and Toge “disclose a ‘second processor on the at least one server’” because a person of ordinary skill in the art “would have understood Kumar’s browser-based engine (remote internet site)/central server to contain a processor to analyze the data transmitted and stored therein.” MTA Opp. 17–18. Petitioner argues that “both Toge and Kumar disclose ‘a physician at a remote computer’ able to review the ‘quantified level of severity data.’” *Id.* at 18.

Patent Owner does not address these elements of limitation [30.d]. *See generally* MTA; MTA Reply.

We agree with Petitioner’s position that Kumar and Toge teach or suggest these elements of claim limitation [30.d]. *See* MTA Opp. 17–18.

2. Claim Limitation [30.e] (“further determining [[the]] therapy efficacy data with . . . the subject’s cellular phone using the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject”)

Petitioner argues that Kumar and Toge teach “further determining therapy efficacy data with . . . the subject’s cellular phone using the first software” because “Toge discloses ‘determining the therapy efficacy data’ for the reasons described in the Petition” and “Kumar discloses a patient cell phone (computing device 110) equipped with a ‘plug-in’ (downloadable software) (together ‘the subject’s cellular phone using the first software’).” MTA Opp. 20.

Patent Owner responds that Petitioner’s “alleged benefits of a smaller PAP device, adjusting parameters anywhere, later viewing of the data, and

increased treatment compliance would not have prompted a POSITA” to make the asserted modifications because these benefits require a smartphone, and only two percent of patients had one at the time, so there was no “design need or market demand for ResMed’s listed benefits.” MTA Reply 9. Patent Owner argues that “[t]his is corroborated by the fact that in 2011—roughly six years after the original filing—there still existed a lack of certainty and predictability in integrating patient cellular phone applications into medical device systems.” *Id.* (citing Ex. 2053, 4).

We disagree with Patent Owner. In addition to Toge and Kumar, other prior art references included cell phones in PAP and other telehealth systems. *See* MTA Sur-reply 9–10 (citing Ex. 1049, 7:15–29 and claim 51; Ex. 1045 ¶¶ 11–65, 77–79, 292). We agree with Petitioner that “[t]hese other systems belie PO’s baseless statement that a POSITA would not have utilized cell phones in telemedicine systems at the time due to consumer cell phone ownership.” *Id.* at 10. We further agree with Petitioner that “[a] POSITA’s understanding of the rapid uptake of cell phones, and trend in networked devices in general would have been ample motivation to add a cellular phone to systems to monitor and treat conditions like sleep disordered breathing.” *Id.*; Ex. 1005 (Chatterjee Decl.) ¶¶ 25–31, 88–89; Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶¶ 17–19; Ex. 1071 (Kirkness MTA Opp. Decl.) ¶¶ 18–20.

We find that Petitioner has demonstrated that Kumar and Toge teach or suggest claim limitation [30.e]. *See* MTA Opp. 18–21.

3. *Claim Limitation [30.f]* (“wherein the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cellular phone . . .”)

Petitioner contends that a person of ordinary skill in the art “would have found it obvious to configure Kumar’s patient-side cell phone to adjust the PAP/CPAP therapy” because it is “the same functionality that Toge’s physician-side cell phone possesses.” MTA Opp. 22–23. In particular, Petitioner argues that “the Petition establishes that Kumar discloses a communication device 102 (patient’s cell phone) that can communicate with the patient-side device 110 (PAP/CPAP);” “Kumar discloses that the patient cell phone has downloadable software;” and “Toge discloses a networked PAP system in which PAP data are transmitted to a physician’s cell phone and remote computer, and that, based on the data, the physician can direct the cell phone to remotely adjust the PAP therapy.” *Id.* at 22. Petitioner argues that the patient’s cell phone could have been used to “adjust the PAP/CPAP therapy after a physician (who has, e.g., analyzed/reviewed the PAP data) ‘mobilize[s]’ the patient’s cell phone by transmitting instructions (e.g., prescription pressure) from the physician’s computer to the patient’s cell phone.” *Id.* at 23. Alternatively, Petitioner argues that “Kumar’s patient cell phone, like Toge’s physician cell phone, could be alerted when the ‘quantified level of severity data’ exceeds or falls below a threshold value and appropriately adjust the PAP/CPAP therapy (e.g., air pressure) to remedy the situation.” *Id.*

Petitioner argues that a person of ordinary skill in the art would have incorporated these changes because 1) the patient’s cell phone “generally would have been more proximate to the PAP/CPAP device and, consequently, better able to make therapy adjustments more quickly than

remote physician-side devices;” 2) the changes would have resulted in a “PAP system that was capable of better fine-tuning PAP/CPAP pressure” and “would have further increased patient comfort and aided in patient motivation to the use the device;” 3) “moving the screen and controls from the PAP device itself to the patient’s cell phone . . . would have allowed the patient to adjust allowable PAP parameters from their phone while in bed connected to the device (prior to or during treatment);” and 4) the changes would have resulted in “a smaller form factor PAP device.” *Id.* at 24–25.

Petitioner contends a person of ordinary skill in the art “would have had a reasonable expectation of success in implementing a patient cell phone that adjusts the PAP/CPAP” because “the modification of the downloadable software on Kumar’s patient cell phone would have simply been a change of programming (e.g., updated downloadable software), and this programming would have already been known to a [person of ordinary skill in the art] as evidenced by Toge’s physician cell phone.” *Id.* at 25.

Patent Owner contends “no asserted art in the grounds discloses a PAP/CPAP device therapy being adjusted by the patient’s cell phone.” MTA 14. According to Patent Owner, “Toge’s system includes physician-side computers and physician-side mobile terminals that allow physicians to review patient sleep data and respond to medical emergencies, if necessary,” but “Toge’s system does not include a patient’s cell phone, let alone one that adjusts the PAP device.” *Id.* (citing Ex. 1044 ¶¶ 18–19, 39, 47, 54; Ex. 2032 ¶ 34). Patent Owner contends that although Kumar “discloses a patient-side computing device,” “this device simply manages the transmission of data between the patient-side medical device and the web server.” *Id.* (citing Ex. 1008 ¶¶ 18, 72, claims 5, 9).

We agree with Petitioner’s position that Kumar and Toge teach or suggest claim limitation [30.f]. *See* MTA Opp. 21–25. Toge teaches that “the therapy administered by the PAP or CPAP device is configured to be adjusted by . . . the remote computer of the clinician, technician, or physician” including via a cell phone. *See, e.g.,* Ex. 1044 ¶ 19. Petitioner demonstrates that a person of ordinary skill in the art would have been motivated to implement the same functionality in a patient’s cell phone such that “the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cellular phone.” *See* MTA Opp. 21–25.

Patent Owner responds that “Toge and Kumar fail to disclose adjusting a PAP/CPAP therapy with the patient’s cell phone” and Petitioner improperly uses “expert testimony to gap-fill the missing limitation,” contrary to case law and the Director’s memorandum on “Enforcement and Non-Waiver of 37 C.F.R. § 42.104(b)(4) and Permissible Uses of General Knowledge in Inter Partes Reviews” (the “Memo”). MTA Reply 5. Patent Owner acknowledges that “the Memo applies to petitions filed after September 1, 2025,” but argues that Petitioner’s opposition to the Motion to Amend is “effectively [a] renewed petition [that] should be subject to the Memo.” *Id.* at 5–6.

We disagree that Petitioner is “gap-filling.” Instead its showing is based on teachings in Toge and Kumar, e.g., “Toge discloses the transmission of PAP data to a physician’s cell phone that adjusts PAP therapy and Kumar discloses a patient cell phone with downloadable software that communicates with the PAP device,” and what these teachings would have suggested to a person of ordinary skill in the art. MTA Sur-

Reply 6–7. Although the Memo is not implicated here for this reason, we would also decline to apply it to the instant case given that it does not on its face treat motions to amend as “renewed petitions.”

Regarding the alleged benefits of the modification proposed by Petitioner, Patent Owner argues that it is speculative whether it would have been “faster to adjust PAP therapy from a patient’s cell phone than from the physician-side devices;” it was not known that “faster communication was a *known* benefit” or that a patient’s cell phone would be more “capable of better fine-tuning” than the physician’s cell phone; and the alleged benefit of moving the PAP controls from the PAP device to the patient’s cell phone is unsubstantiated because Petitioner does not contend that the “controls from the PAP device” were configured to adjust the PAP/CPAP therapy. MTA Reply 7–8.

We disagree with Patent Owner’s complaints and find that Petitioner’s proposed motivations to implement a patient cell phone that adjusts PAP therapy are persuasive and corroborated by Drs. Chatterjee and Kirkness. *See* MTA Opp. 11–14, 23–25; MTA Reply 7–8; Ex. 1072 (Chatterjee MTA Opp. Decl.) ¶¶ 18, 44–46; Ex. 1071 (Kirkness MTA Opp. Decl.) ¶¶ 7, 17–20.

4. Obviousness Conclusion

Based on the foregoing, we find that Petitioner has not shown by a preponderance of the evidence that Kumar and Toge would have rendered obvious the subject matter of proposed substitute claim 30, due to shortcomings in Petitioner’s arguments regarding limitation [30.d].

IV. CONCLUSION

For the foregoing reasons, we determine that Petitioner has demonstrated by a preponderance of the evidence that 15–29 of U.S. Patent No. 11,857,333 B1 are unpatentable. We deny Patent Owner’s Motion to Amend.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
15–17, 20–24, 26–29	103(a)	Toge, Kumar	15–17, 20–24, 26–29	
15–18, 20–29	103(a)	Toge, Kumar, Norman	15–18, 20–29	
19	103(a)	Toge, Kumar, Burton	19	
19	103(a)	Toge, Kumar, Norman, Burton	19	
Overall Outcome			15–29	

Motion to Amend Outcome	Claim(s)
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	30–41
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	30–41
Substitute Claims: Not Reached	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 15–29 of U.S. Patent No. 11,857,333 B1 are unpatentable;

FURTHER ORDERED that Patent Owner’s Motion to Amend is *denied*; and

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

IPR2025-00246
Patent 11,857,333 B1

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