

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*.

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

I. INTRODUCTION

Petitioner ResMed Corp. requests *inter partes* review of claims 15–29 of U.S. Patent No. 11,857,333 B1 (“the ’333 patent,” Ex. 1001). Paper 1 (“Pet.”), 1. Patent Owner Cleveland Medical Devices, Inc. filed a Preliminary Response.¹ Paper 9 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” After considering the briefing and cited evidence of record, we institute an *inter partes* review.

The following preliminary findings of fact and conclusions of law are made solely for determining whether to institute review. Any final decision will be based on the full trial record.

A. Real Parties in Interest

Petitioner and Patent Owner each identify only themselves as the real party in interest. Pet. 74; Paper 3 (Patent Owner Mandatory Notices), 1.

B. 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 3, 1.

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.

¹ The parties also filed briefs directed to discretionary denial issues. See Papers 6, 8. The Director ruled on discretionary denial issues. See Paper 10. We do not address discretionary denial issues here.

11,786,680 (IPR2025-00160), and U.S. Patent No. 11,872,029 (IPR2025-00247). Pet. 74.

C. 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.

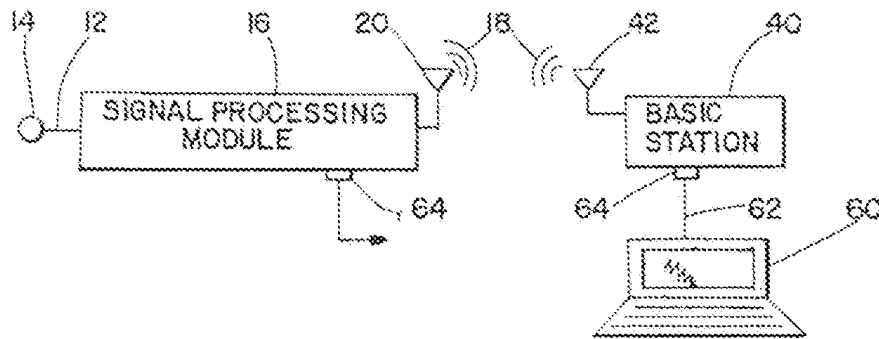


Fig. 1

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.

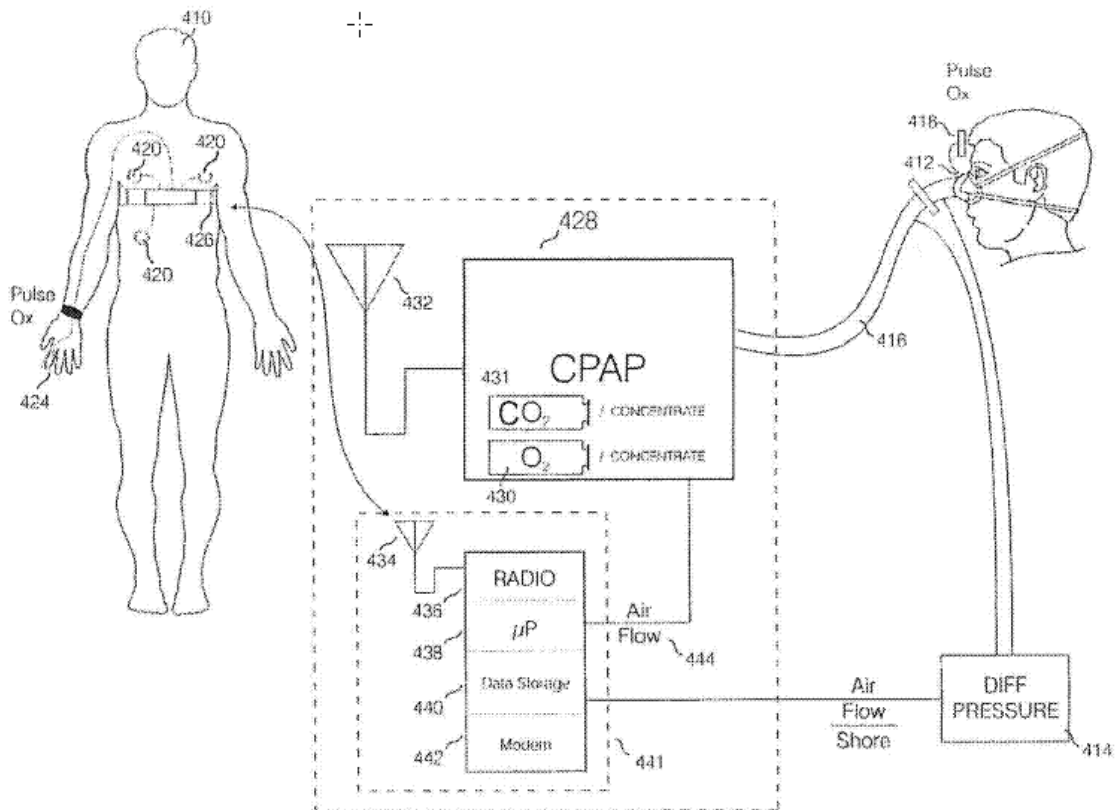


Fig. 8

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.

D. 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:²

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

² 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.

E. Asserted Grounds of Unpatentability

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

Ground	Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
1	15–17, 20–24, 26–29	103(a)	Toge, ⁴ Kumar ⁵
2	15–18, 20–24, 25–29	103(a)	Toge, Kumar, Norman ⁶
3	19	103(a)	Toge, Kumar, Burton ⁷
4	19	103(a)	Toge, Kumar, Norman, Burton

³ 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. Accordingly, we apply the pre-AIA version of § 103; however, our decision would be no different under the AIA version of the statute.

⁴ 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).

⁵ Kumar et al., U.S. Patent App. Pub. 2002/0198473 A1, published December 26, 2002 (“Kumar,” Ex. 1008).

⁶ Norman et al., U.S. Patent App. Pub. 2005/0268912 A1, published December 8, 2005, filed June 4, 2004 (“Norman,” Ex. 1059).

⁷ 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.

II. UNPATENTABILITY ARGUMENTS

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). The Board may authorize an *inter partes* review if we determine that the information presented in the briefing of record shows a reasonable likelihood that Petitioner will prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a).

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.⁸ *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.⁹ *See Graham*, 383 U.S. at 17–18. At this stage, 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.

⁸ At this stage, Patent Owner does not assert any objective indicia of nonobviousness. *See generally* Prelim. Resp.

⁹ For purposes of this Decision, we apply a priority date of November 4, 2005. *See supra* n.3.

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

Because the proposed level of ordinary skill in the art appears to be 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). Patent Owner does not address claim construction. *See generally* Prelim. Resp.

We find it unnecessary to construe any claim term to decide whether Petitioner satisfies the “reasonable likelihood” standard for instituting trial. *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))).

Any final written decision entered in this case may include express claim constructions, or may include discussion of claim scope that differs from that provided in our analysis below. Any final claim constructions will be based on the full trial record.

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.

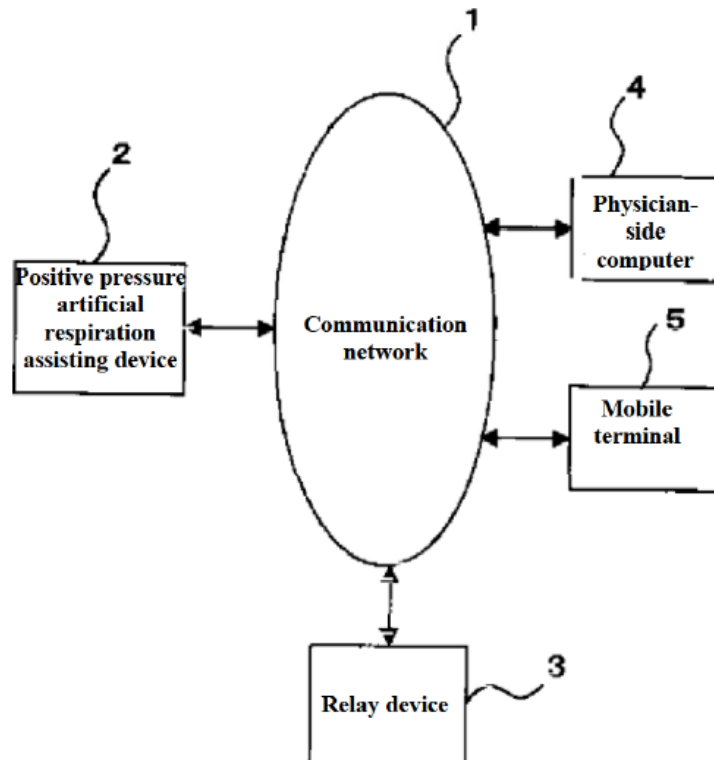


Figure 1 depicts a remote telemedicine system that includes positive pressure artificial respiration assisting device 2, relay device 3, and

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.

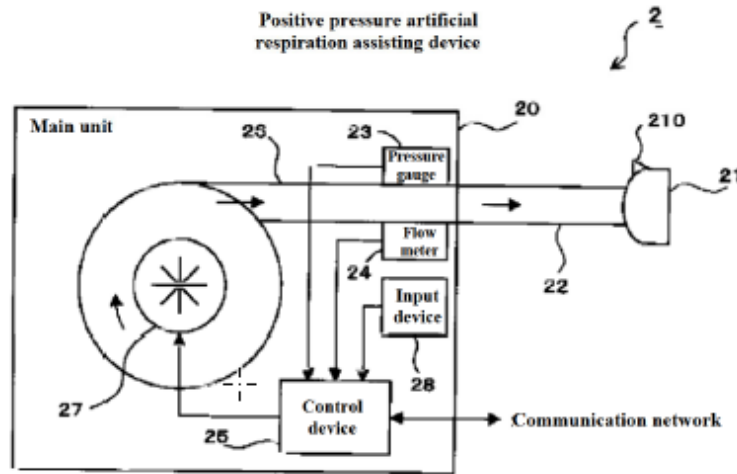


Figure 2 depicts details of positive pressure artificial respiration assisting device 2. *Id.* ¶ 20. Device 2 includes main unit 20 connected via air tube 22 to nasal mask 21. *Id.* ¶ 21. “[M]ain unit 20 is equipped with a pressure gauge 23, a flow meter 24, a control device 25, a flow path 26, a blower 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.

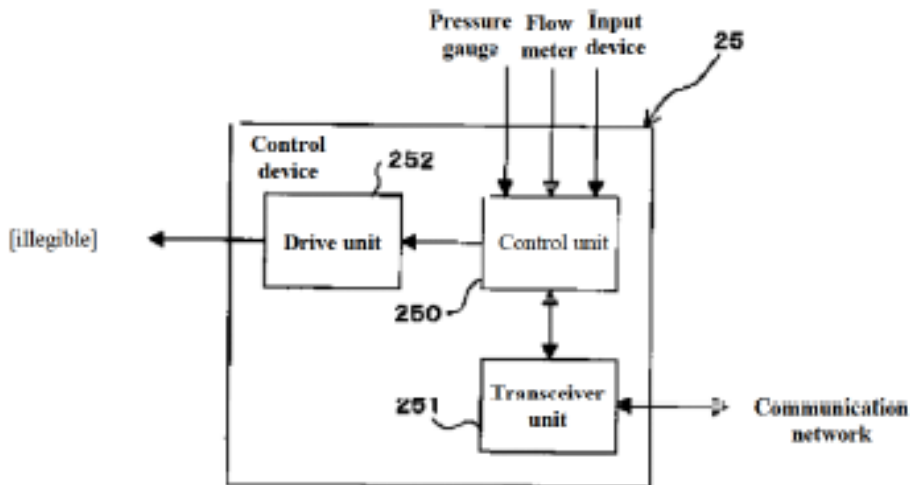


Figure 3 details control device 25 of positive pressure artificial respiration assisting device 2. *Id.* ¶ 20. Control device 25 “comprises a control unit 250, a transceiver unit 251, and a drive unit 252.” *Id.* ¶ 23. Control unit 250 can determine operational time, which physicians can use to “determine 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.

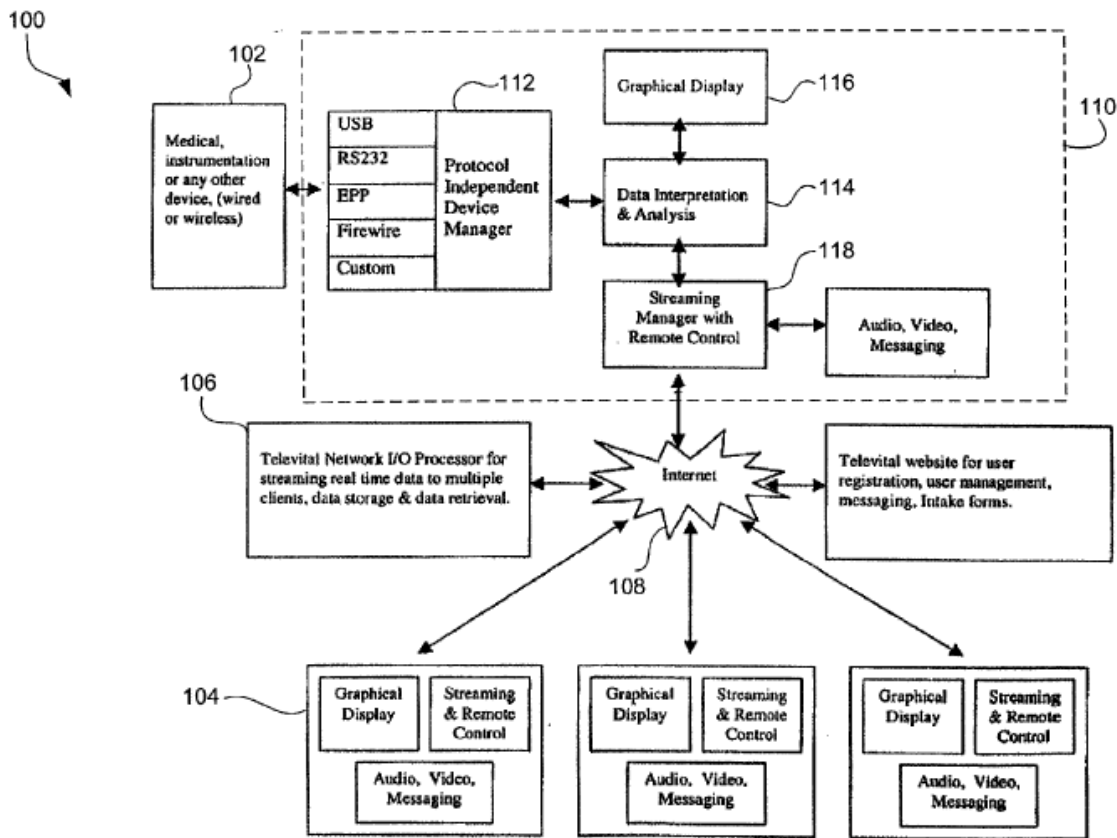


Fig. 1A

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:

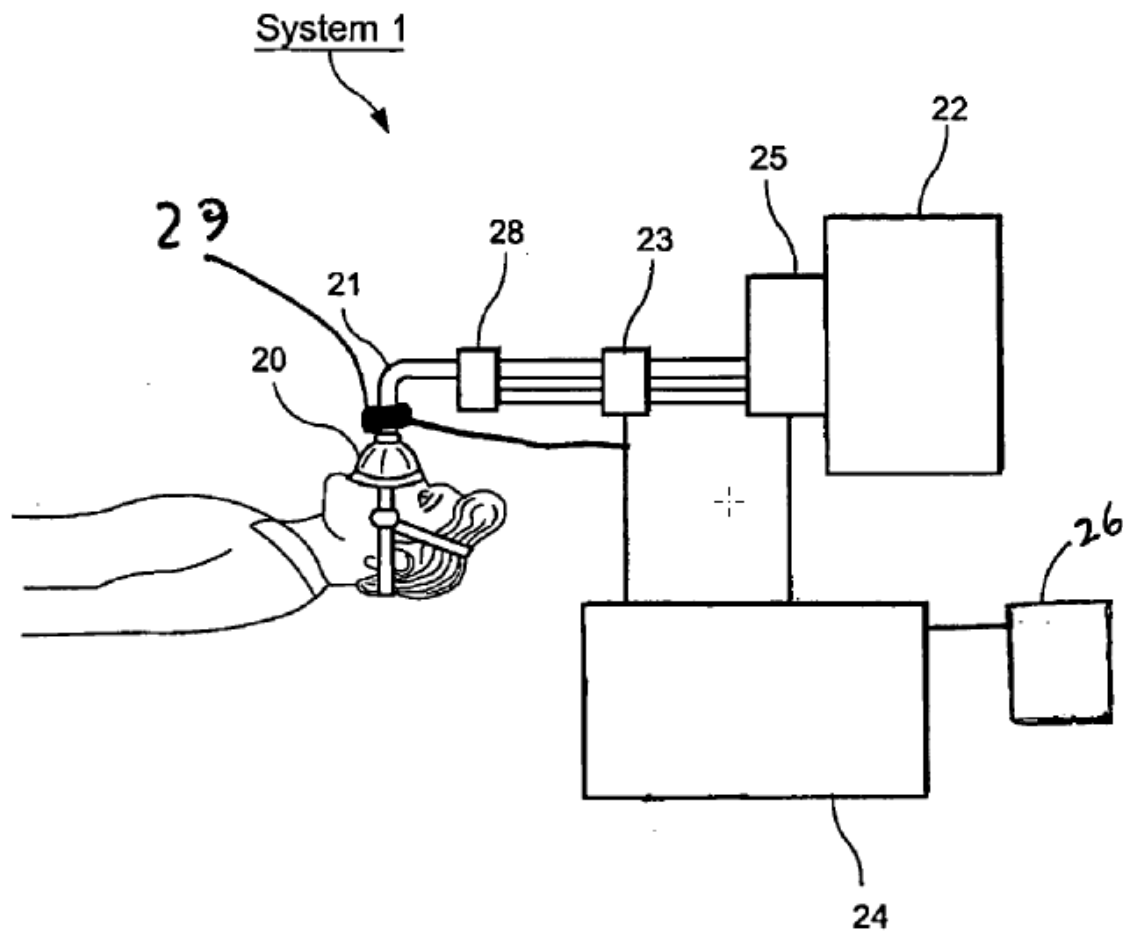


FIG. 6

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.* at ¶¶ 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.

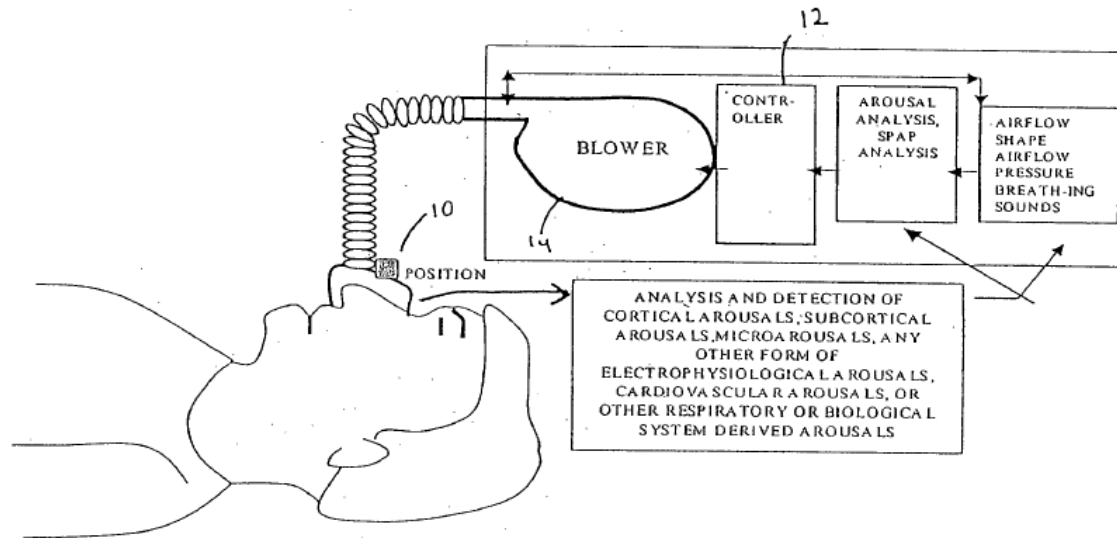


FIG. 1

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, b) individual patient collected or alternative (to laboratory) collected data (from diagnostic study within sleep laboratory or other alternative site) or c) 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. Ground 1 – Alleged Obviousness 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. At this stage, Patent Owner disputes whether Petitioner sufficiently demonstrates that Toge and Kumar teach or suggest 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 Prelim. Resp. 7–9; Pet. 78 (emphasis added).

After considering all of the arguments and cited evidence of record, we determine that for purposes of institution, 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—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 this record, Petitioner shows a reasonable likelihood of prevailing on Ground 1. 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. Pet. 15 (citing Ex. 1044 (Toge) ¶¶ 33–38). Petitioner asserts:

The tidal volume calculated/determined by control unit 250 is “**a quantified level of severity data** based on the subject’s sleep apnea symptoms during the therapy.” A POSITA 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).

Patent Owner disputes that Toge's tidal volume is a "quantified level of severity data." Prelim. Resp. 7. According to Patent Owner, tidal volume "is, at best, breathing metric data." *Id.* (citing Ex. 1001, 12:51–63). Patent Owner asserts that in the '333 patent, "breathing metrics, such as respiratory airflow, are *used 'for determining* a quantitative level of severity of a subject's sleeping disorder and/or symptoms," but are not themselves a "quantified level of severity data." *Id.* at 7–8 (citing Ex. 1001, 45:34–42).

At this stage, Petitioner has the better argument. Toge teaches that control unit 250 analyzes collected data (e.g., the flow rate) and calculates tidal volume. Ex. 1044 (Toge) ¶¶ 34–38. On this record, we agree with Petitioner that 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. On this record, Patent Owner's assertion that the tidal volume is a "breathing metric" instead of "a quantified level of severity data" is unavailing in view of Toge's teaching that control unit 250 calculates the tidal volume, and its teaching that the tidal volume is used to assess the patient's condition and determine whether system adjustments are needed. *See id.* at 15–16; Ex. 1044 (Toge) ¶ 39; Ex. 1003 (Kirkness Decl.) ¶ 157. In other words, on this record, the calculated tidal volume 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.

Accordingly, for purposes of institution, we determine that Petitioner demonstrates that Toge’s tidal volume teaches or suggests claim limitation [15.c]. But even if Toge’s tidal volume does not teach or suggest this limitation, we find for purposes of institution that Petitioner adequately demonstrates that the prior art combination set forth in Ground 2 teaches or suggests this claim limitation, as discussed below.

F. Ground 2 – Alleged Obviousness Over Toge, Kumar, and Norman

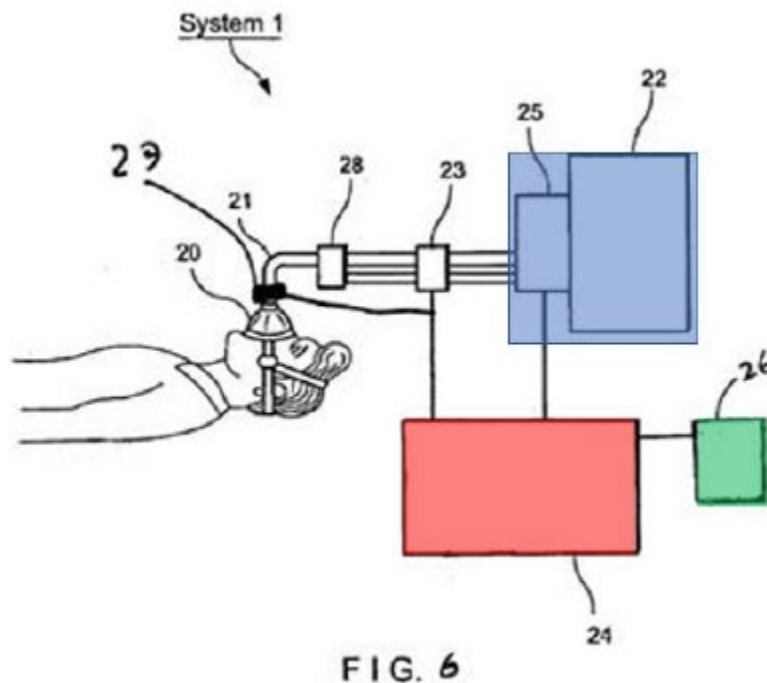
Petitioner asserts that claims 15–18, 20–24, and 25–29 are unpatentable as obvious over Toge, Kumar, and Norman. Pet. 49–65. Petitioner offers this ground as an alternative to Ground 1, “[t]o the extent that Toge does not disclose limitation [15.c].” *Id.* at 51.

At this stage, Patent Owner argues that (1) Norman does not teach or suggest calculating a quantified level of severity “using a processor integrated into the PAP device,” and (2) “a POSITA would not have modified Toge with Norman because they work at cross purposes.” Prelim. Resp. 1.

After considering all of the arguments and cited evidence of record, we determine that, for purposes of institution, Petitioner sufficiently shows that the combination of Toge, Kumar, and Norman teaches or suggests each limitation of challenged claims 15–18, 20–24, and 25–29, 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. In particular, Petitioner adequately demonstrates for purposes of institution that because Norman’s PAP system “analyzes the collected data by analyzing breathing patterns to ‘detect abnormal respiratory events and to identify the conditions under which they arise,’” it teaches or suggests limitation [15.c]. *Id.* at 56–57 (quoting Ex. 1059 (Norman) ¶ 27). Petitioner also adequately 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. *Id.* at 49–51. Accordingly, on this record, Petitioner shows a reasonable likelihood of prevailing on Ground 2. We address Patent Owner’s arguments below.

Patent Owner concedes that “Norman discloses calculating the level of severity of the patient’s symptoms.” Prelim. Resp. 1. It argues, however, that Norman “does not do so using a processor *integrated into* the PAP device” as recited in limitation [15.a] because “the analysis engine in Norman is on a separate machine.” *Id.* (emphasis added). In support of this argument, Patent Owner provides an annotated version of Norman’s Figure 6, as follows:



Prelim. Resp. 10. Figure 6 depicts Norman’s CPAP system 1. Patent Owner asserts that system 1 includes generator 22 and flow control device 25 (blue), processing arrangement 24 (red), and a titration device 26 (green). Patent Owner argues that “[b]oth the processing arrangement of 24 and titration device 26 are separate from the PAP/CPAP device, which delivers continuous flow of pressurized air to the patient’s airway.” *Id.* at 11 (citing Ex. 2018¹⁰; Ex. 1059 (Norman) ¶ 20).

On this record, Patent Owner’s argument is unavailing. It is not clear that Norman’s processor 24 and titration device 26 are “separate” from the PAP/CPAP device, as opposed to integrated into the same device (“system 1”). But even assuming, *arguendo*, that Patent Owner is correct that Norman’s processor is separate from (and thus not “integrated into”)

¹⁰ Exhibit 2018 appears to be a website printout titled, “How Does A CPAP Machine Work?”

Norman's CPAP device, this is not relevant to Petitioner's proposed combination. Petitioner proposes "implementing Norman's automated titration teachings" in Toge's PAP system and processor. *See* Pet. 50–51 (discussing "implementing Norman's automated titration teachings" into the "PAP device that controls the device operations using a processor based on received sensor data (Toge)"), 61. Patent Owner does not argue that Toge's processor is not "integrated into" the CPAP device.

Patent Owner next argues that "Toge's treatment system is premised on . . . the physician receiving information in a timely fashion," whereas "Norman's automated titration process relies on the machine to adjust the treatment." Prelim. Resp. 1. Patent Owner argues that "Norman's data would only introduce redundancy in what physicians already do based on the transmitted tidal volume data." *Id.* at 16. Thus, Patent Owner argues that Petitioner's proposed modification "would have defeated Toge's primary purpose of sending data directly to physicians who can take immediate action (such as adjusting the pressure) at any time." *Id.* at 11–12; *see also id.* at 13 ("Where Toge seeks physician involvement, Norman avoids through its automated titration process."). Patent Owner argues that "contrary to Petitioner's allegations, Norman's automated titration process would not have improved Toge's system, but worsened it." *Id.* at 15 (citing *Cook Grp. Inc. v. Bos. Sci. Scimed, Inc.*, 809 F. App'x 990, 1000 (Fed. Cir. 2020)).

On this record, Patent Owner's argument is unavailing. It is not clear that automating some functions that a physician does manually in Toge's system would "worsen" Toge's system. Toge's system sends the data to allow physicians to "take immediate action (such as adjusting the pressure)

at any time” (Prelim. Resp. 11–12), and on this record we agree with Petitioner that automating this process can “improve[] accuracy and efficacy of the treatment [and] would have improved the patient’s compliance and satisfaction” (Pet. 49–50). Moreover, automating this function at least some of the time does not render obsolete all physician involvement in the patient’s treatment. And even if Petitioner’s proposed combination did result in some loss of a desired function, “a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate a motivation to combine.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). Here, Petitioner adequately shows for purposes of institution that incorporating Norman’s automated titration process into Toge’s system would lead to benefits such as improved accuracy, efficacy, and compliance. Pet. 49–50.

In sum, after considering all of the arguments and cited evidence of record, we determine that for purposes of institution Petitioner sufficiently shows that the combination of Toge, Kumar, and Norman teaches or suggests each limitation of challenged claims 15–18, 20–24, and 25–29, 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 a reasonable likelihood of prevailing on Ground 2.

G. Remaining Grounds

For Ground 3, Petitioner asserts that claim 19 is unpatentable as obvious over Toge, Kumar, and Burton. *See* Pet. 65–70. For Ground 4, Petitioner asserts that claim 19 is unpatentable as obvious over Toge,

Kumar, Norman, and Burton. *Id.* at 72–73. At this stage, Patent Owner does not offer any additional arguments for these grounds beyond the arguments we already addressed above for Grounds 1 and 2. *See* Prelim. Resp. 16.

Because we determine above that Petitioner shows a reasonable likelihood of prevailing with respect to at least one challenged claim, and because Patent Owner does not present any additional arguments directed to claim 19, we do not address Grounds 3 and 4 at this stage of the proceeding, and they are best left for trial after full development of the record.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims of the '333 patent is unpatentable.

At this preliminary stage, we have not made a final determination regarding the patentability of any challenged claim or any underlying factual or legal issue. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that “there is a significant difference between a petitioner’s burden to establish a ‘reasonable likelihood of success’ at institution, and actually proving invalidity by a preponderance of the evidence at trial”). Any final decision in this proceeding will be based on the full trial record.

The Board will deem forfeited any issue not raised by Patent Owner in a timely response to the Petition, or as permitted in another manner during trial, even if asserted in the Preliminary Response or discussed in this Decision.

Nothing in this Decision authorizes Petitioner, in a manner not otherwise permitted by the Board's rules, to supplement the information pertaining to any ground advanced in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted based on all grounds asserted in the Petition; and

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

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