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Filed on behalf of ResMed Corp.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES,
Patent Owner

Case IPR2025-00157

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,602,284**

Claims 1-3, 6, and 12-20

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1007	U.S. Patent No. 6,644,311 to Truitt et al. (“Truitt”)
1008	U.S. Patent Pub. No. 2002/0198473 to Kumar et al. (“Kumar”)
1009	U.S. Patent No. 7,575,005 to Mumford et al. (“Mumford”)
1010	<i>ResMed Corp. v. Cleveland Medical Devices, Inc.</i> , PTAB-PGR2024-00012-6, PO’s Preliminary Response
1011	“ <i>T-Mobile USA and HP Launch the First Truly Integrated Wireless iPAQ Handheld - T-Mobile Newsroom</i> ” (July 2004) available at https://www.t-mobile.com/news/press/t-mobile-usa-and-hp-launch-the-first-truly-integrated-wireless
1012	WIPO Publication No. WO2005096737A2 to Farrell et al. (“Farrell”)
1013	U.S. Patent Pub. No. 2002/0185130 to Wright et al. (“Wright”)
1014	U.S. Patent No. 5,424,942 to Dong et al. (“Dong”)

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1015	M. Berthon-Jones, “Feasibility of a Self-Setting CPAP Machine,” <i>Sleep</i> 16:S120-123 (1993) (“Berthon-Jones 1993”)
1016	D. Rapoport, “Methods to Stabilize the Upper Airway Using Positive Pressure,” <i>Sleep</i> 19(9):S123-S130 (“Rapoport 1996”)
1017	File History for U.S. Patent No. 8,172,766
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1019	S. Thompson et al., “Sleep as a Teaching Tool for Integrating Physiology and Motor Control,” <i>Advances in Physiology Education</i> (2001)
1020	U.S. Patent No. 5,704,345 to Berthon-Jones (“Berthon-Jones345”)
1021	U.S. Patent No. 7,168,429 to Matthews et al. (“Matthews”)
1022	U.S. Patent No. 6,342,039 to Lynn et al. (“Lynn”)
1023	C. Sullivan, “Reversal of Obstructive Sleep Apnoea by Continuous Positive Airway Pressure Applied through the Nares,” <i>Lancet</i> 1981:1862-5 (“Sullivan 1981”)
1024	U.S. Patent No. 6,484,719 to Berthon-Jones (“Berthon-Jones719”)
1025	Teschler, H., et al., “Automated Continuous Positive Airway Pressure Titration for Obstructive Sleep Apnea Syndrome,” <i>Am. J. Respir. Crit. Care Med.</i> 54:734-740 (1996)
1026	ResMed, “AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1,” (1999)
1027	ResMed, “AutoSet T, Optimal Therapy for your OSA Patients,” (2000)

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1028	Sunrise Medical, “DeVillibis® AutoAdjust™ LT Nasal CPAP System Instructions Guide Model 8054,” (1999)
1029	Respironics, “Introducing the REMstar Auto. A simply smarter Smart CPAP” (2002)
1030	ResMed Origins, downloaded from https://document.resmed.com/en-us/documents/articles/resmed-origins.pdf on May 3, 2022.
1031	U.S. Patent No. 5,490,502 to Rapoport et al. (“Rapoport”)
1032	F. Roux, et al., “Continuous Positive Airway Pressure: New Generations,” <i>Clinics in Chest Medicine</i> (2003)
1033	Loube, D., “Technologic Advances in the Treatment of Obstructive Sleep Apnea Syndrome,” <i>CHEST</i> 116:1426-1433 (1999)
1034	American Academy of Sleep Medicine Task Force. (1999). <i>Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. Sleep</i> , 22(5), 667-689
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1036	S. Wilber, et. al., “Patient Monitoring and Anesthetic Management: A Physiological Communications Network,” <i>JAMA</i> 191:893-898) (1965)
1037	M. Weil, et. al., “Experience With a Digital Computer for Study and Improved Management of the Critically Ill,” <i>JAMA</i> 198:1011-1016 (1966)

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1038	C. Lilly, et. al., “Critical Care Telemedicine: Evolution and State of the Art,” <i>Critical Care Medicine</i> 42:2429-2436 (2014)
1039	M. Breslow, et. al., “Effect of a multiple-site intensive care unit telemedicine program on clinical and economic outcomes: An alternative paradigm for intensivist staffing,” <i>Critical Care Medicine</i> 32:31-38 (2004)
1040	K. Zundel, “Telemedicine: history, applications, and impact on librarianship,” <i>Bull Med Libr. Assoc.</i> 84:71-79 (1996)
1041	Y. Wang, et. al., “Validation of microMESAM as Screening Device for Sleep Disordered Breathing,” <i>Pneumologie</i> 57:734-740 (2003)
1042	A. Boudewyns, et. al., “Two months follow up of auto-CPAP treatment in patients with obstructive sleep apnoea,” <i>Thorax</i> 54:147-149 (1999)
1043	D. Lankford, “Wireless CPAP Patient Monitoring: Accuracy Study,” <i>Telemedicine Journal and e-Health</i> 10:162-169 (2004)
1044	Japan Patent Office Patent Application Pub. No. P2002-291889A to Toge (“Toge”)
1045	U.S. Pat. Pub. No. 2008/0214903 to Orbach (“Orbach”)
1046	D. Gourley, et. al., <i>HTTP The Definitive Guide</i> (2002)
1047	D. Mauro, et. al., <i>Essential SNMP</i> (2001)
1048	F. Adelstein, et. al., <i>Fundamentals of Mobile and Pervasive Computing</i> (2005)
1049	WIPO Publication No. WO0145014A1 to Quay (“Quay”)

I. INTRODUCTION

ResMed Corp. (“Petitioner”) respectfully requests *inter partes* review of claims 1-3, 6, and 12-20 of U.S. Patent No. 11,602,284 (EX1001, “’284 Patent”).

In 1981, the University of Sydney invented positive airway pressure (PAP) devices to treat chronic sleep disorders such as snoring and apnea. By the mid-1990s, automatically adjusting PAP devices were widely available. These devices would adjust pressure based on the degree of airway obstruction to provide adequate pressure to treat sleep disorders while minimizing side effects.

Concurrently, advancements in connectivity were driving the development of telemedicine—the use of network technology to diagnosis and treat patients. By the early 2000s, network technology had found its way into sensor diagnostic devices such as spirometers, heart monitors, and notably, PAP machines. Numerous benefits motivated such incorporation of sensor diagnostic devices into networked systems, including greater data access and convenience to patients, doctors, and providers as well as the ability to monitor compliance and adherence to therapy.

The ’284 Patent claims a networked PAP system that transmits symptom severity and usage data to a cell phone and remote internet site. But this system is nothing more than an obvious combination of known PAP devices, like U.S. Patent No. 6,644,311 to Truitt et al. (EX1007, “Truitt”), and known telemedicine systems, like U.S. Patent Pub. No. 2002/0198473 to Kumar et al. (EX1008, “Kumar”).

Indeed, Kumar teaches “virtually any device may be easily incorporated into [its] system,” including devices to address “[s]leep apnea-hypopnea syndrome” like Truitt. EX1008, ¶[0018].

Accordingly, Petitioner respectfully requests the Board institute review and find all challenged claims of the '284 Patent unpatentable.

II. IDENTIFICATION OF CHALLENGES

Ground 1: Claims 1-3, 6, 12-15, 18-19 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious over Truitt¹ (EX1007) and Kumar² (EX1008).

Ground 2: Claims 15, 16, and 18 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious in view of Truitt, Kumar, and Dong³ (EX1014).

Ground 3: Claims 17 and 20 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious over Truitt, Kumar, and Wright⁴ (EX1013).

¹ Truitt is §§102(a), (b), and (e) prior art.

² Kumar is §§102(a), (b), and (e) prior art.

³ U.S. Patent No. 5,424,942 to Dong et al. (“Dong”) is §§102(a), (b), and (e) prior art.

⁴ U.S. Patent Pub. No. 2002/0185130 to Wright et al. (“Wright”) is §§102(a), (b), and (e) prior art.

Ground 4: Claims 1-3, 6, 12-15, 18-19 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious over Truitt, Kumar, and Mumford⁵ (EX1009).

Ground 5: Claims 15, 16, and 18 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious in view of Truitt, Kumar, Dong, and Mumford.

Ground 6: Claims 17 and 20 are unpatentable under 35 U.S.C. § 103 as being obvious over Truitt, Kumar, Wright, and Mumford.

III. BACKGROUND

A. Overview of the Technology

1. PAP Machines

Obstructive sleep disorders are characterized by the obstruction of a patient's upper airway during sleep. Kirkness ¶64. The obstructions range from the total absence of airflow (apnea) to significant obstructions with or without reduced airflow (hypopnea and snoring). *Id.* These obstructions decrease blood oxygenation and elevate the risk of heart disease, among other health problems. *Id.* ¶65; EX1015, 1:27-28.

“[T]he most common method of treating...sleep apnea is by apply[ing] a continuous positive gas pressure to the patient's airway.” EX1001, 2:25-26. “[T]he upper airway during sleep mimics the behavior of a collapsible tube.” EX1016, 1.

⁵ U.S. Patent No. 7,575,005 to Mumford et al. (“Mumford”) is §102(e) prior art.

To prevent this collapse, positive airway pressure can oppose the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). *Id.*; *see also* Kirkness ¶¶70-71.

When PAP machines were first developed, a physician would prescribe a therapeutic pressure for the patient to use with a home-use PAP machine after a full night of observation in the laboratory. Kirkness ¶73. As PAP therapy developed, the industry began examining a variable approach that “would improve on, and possibly do away with, the one-size-fits-all pressure determination night.” EX1015, 1. By the mid-1990s, a self-setting machine that “adjusts CPAP pressure on a minute-by-minute basis according to the degree of upper airway obstruction” was widely available. EX1015, 1; Kirkness ¶74.

Metrics that physicians often use to determine the severity of sleep disorders include the Apnea-Hypopnea Index (AHI), Oxygen Desaturation Index (ODI), Respiratory Disturbance Index (RDI), snoring intensity and duration, arousal index, sleep fragmentation, and heart rate variability (HRV) during sleep. Kirkness ¶¶66-67. These indicators quantify the frequency and impact of breathing disturbances, sleep quality disruptions, and cardiovascular stress, helping to assess sleep disorder severity, guide treatment, and track therapy effectiveness. *Id.* ¶85. PAP machines often use one or a combination of these indicators to adjust pressure. *Id.* ¶67.

2. Telemedicine

During the 1960s, groundwork was laid for remote physiological monitoring in hospitals by anesthesiologists and acute care physicians by adapting process control computers—initially designed for industrial automation—to track vital signs in clinical settings. Kirkness ¶88. Building on these early advances, other researchers digitized analog medical data, enabling it to be transmitted across newly forming long-distance networks, which eventually supported nationwide remote monitoring. *Id.*

In the 1970s and 1980s, the success of technology advancements confirmed that physiological data could be transmitted and analyzed remotely to monitor and manage patients' health status. *Id.* ¶¶89-90. This included early work by NASA in monitoring astronauts' physiological data remotely, proving that vital signs could be reliably tracked from great distances. *Id.*; *see also* Chatterjee ¶77.

By the late 1990s and early 2000s, the focus on convenience and accessibility led to the development of home-based diagnostic tools, such as portable monitors capable of recording essential parameters. *Id.* ¶¶91-93. These tools enabled patients to undergo initial monitoring and diagnostic studies in their own homes, which often provided more relevant data as compared to a clinic (where they may experience more anxiety and atypical sleep routine). *Id.* ¶93; *see also* ¶¶94-103.

3. Intelligent Systems and Mobile Computing

In the early 2000s, there was a general market trend to implement consumer devices into intelligent systems, and to create a “smart home.” Chatterjee ¶70. The Internet of Things (also known as IoT) had just been coined in 1999, and the market was pushing to embed wireless transceivers into any daily “things” to connect them to the Internet. *Id.* The connection to the Internet would enable communications between people and things and between things themselves. *Id.*

This trend was spurred on by developments in mobile computing. *Id.* ¶56. Nokia launched 9000 Communicator in 1996, which rolled all of the features of a computer into a phone, and the first Blackberry smartphone was released in 2000. *Id.* ¶¶25-31. This mobile access to the Internet promoted the connection to more “things,” including medical devices. *Id.* ¶¶51-54.

B. '284 Patent

The claims of the '284 Patent describe well-known PAP sleep disorder treatment devices implemented in a networked system. The '284 Patent generally focuses on a PAP device “which analyzes a subject’s sleeping disorder or symptoms and adjusts a treatment device, based, in part on this analysis.” EX1001, 2:47-49. The specification discloses numerous embodiments, only briefly referencing one implemented in a “remote communication system.” *Id.*, 19:3-55.

The system includes a PAP device “that can be used to physically treat a subject’s sleep disorder” by adjusting pressure based on “the level of severity of the subject’s sleep disorder.” *Id.*, 22:49-52. As discussed below in Section VII.C.1, Truitt’s conventional PAP system 10 (Figure 1) is substantially similar to the ’284 patent’s PAP device (Figure 7). As shown below in Figure 7, the PAP device includes a blower, an airflow sensor, a processor, and a mask or nasal cannula.

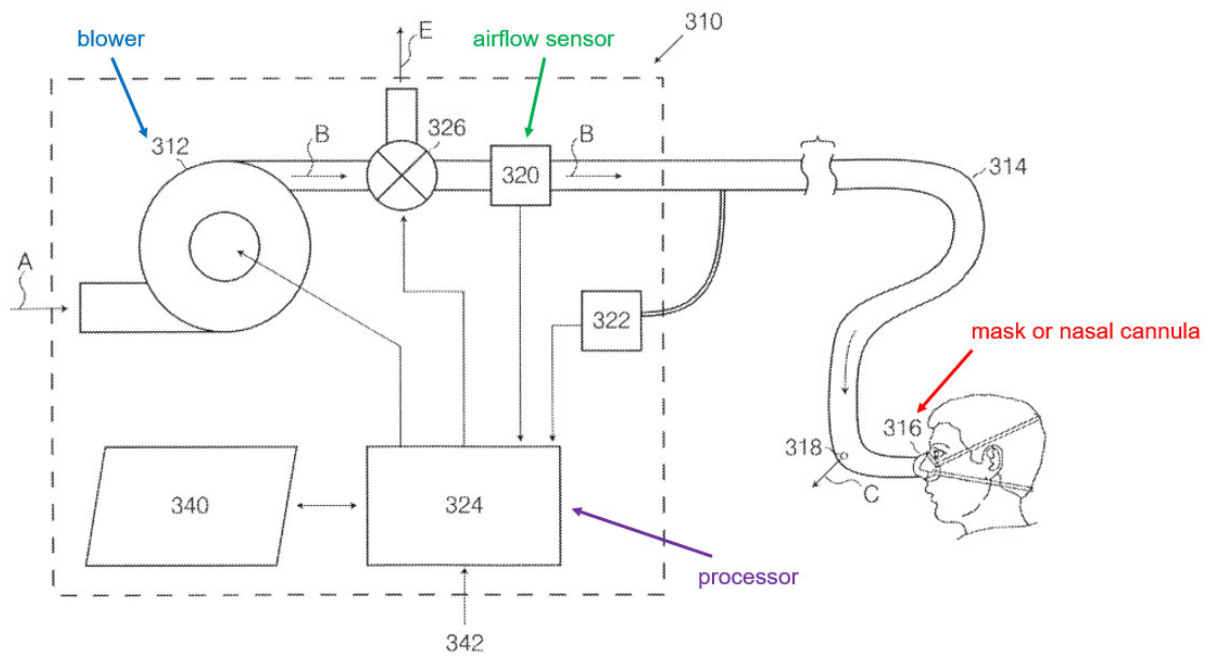


Fig. 7

EX1001, Figure 7 (annotated)

“Sensors which can be used are known to those skilled in the art.” *Id.*, 6:21-22. These sensors “measur[e] the subject’s respirations or oxygen levels” and can “include sensors to measure airflow, respiratory effort, oxygenation and ventilation.”

Id., 3:21-23. Using the processor, “[s]ignals from these sensors are then analyzed to determine the level of severity of the symptoms of the subject’s sleep disorder.” *Id.*, 3:37-39. The information from the sensor can also be used to “monitor the usage of the pressure support device.” *Id.*, 23:23-25. Notably, the specification includes no discussion of an “index of treatment efficacy” or how to base it in part “on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device of the subject.” *See id.*, cl. 1.

In the briefly discussed “remote communication system” embodiment, the specification notes “the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.” *Id.*, 19:14-17. “[A] PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information...to a remote site for analysis.” *Id.*, 19:46-51.

C. Challenged Claims

The challenged claims are entitled to an effective filing date of no earlier than November 4, 2005.⁶

⁶ Petitioner does not concede this priority date and breaking the priority chain is unnecessary for this petition.

The '284 Patent has 20 claims, 1 independent claim and 19 dependent claims. Independent claim 1 generally covers a networked PAP system with three components:

- (1) a computer readable medium comprising cell phone software to display
an index of treatment efficacy based on severity and usage data;
- (2) a PAP device including a wireless transceiver to transmit the severity data
and/or index and usage data;
- (3) a remote internet site to receive the severity data and/or index and usage
data.

Certain dependent claims further require an extended horizon, adaptive, predictive controller to adjust the flow based on the severity data. Certain other dependent claims require distinguishing between and calculating the severity of both obstructive apneas and central apneas.

D. Prosecution History

In the first office action, the Examiner indicated that all claims would be allowable if the applicant amended the claims to overcome the rejections under 35 U.S.C. §§101 and 112. EX1002, 105-106, 149-154, 160-163. The Examiner indicated that the prior art of record did not teach the following:

a first software stored on a non-transitory computer
readable medium and executable by a first processor, the

software configured to be used with and to display to the subject for viewing an index based in part on a data of severity of symptom data and data of usage related to a subject's treatment efficacy with the PAP device calculated by and received from a PAP device on a cell phone, the cell phone comprising at least a first radio frequency wireless transceiver, the first processor and a display;

EX1002, 109.

During the prosecution of an ancestor patent, PO admitted that the Apnea-Hypopnea Index (*see* Section III.A.1) was an “indicator of the level of severity of a patient’s sleep disordered breathing.” EX1017, 35-36, 39.

IV. THE PRIOR ART

A. Truitt (EX1007)

Truitt discloses the PAP device limitations recited in independent claim 1.

Truitt improves upon a conventional “continuous positive airway pressure (CPAP) device to supply a constant positive pressure to the airway of a patient to treat obstructive sleep apnea (OSA) as well as other disorders.” EX1007, 1:24-30. As shown in Figure 1 (virtually identical to Figure 7 of the '284 Patent), Truitt discloses a conventional prior art pressure support system 10 including a pressure generator 12 (e.g., a blower), “create[ing] a flow of breathing gas, as indicated by

arrows B.” *Id.*, 1:44-50. A patient interface device 16 (e.g., a mask or nasal cannula) delivers elevated pressure breathing gas to the airway of the patient. *Id.*, 1:50-61.

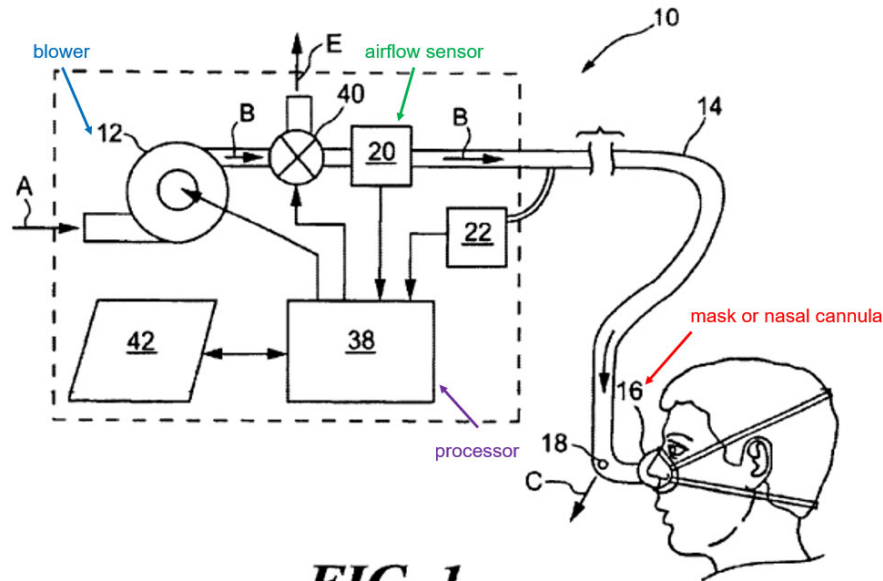


FIG. 1
(PRIOR ART)

EX1007, FIG. 1

The flow information provided by the sensors are used to “control the pressure or flow of gas provided to the patient, monitor the condition of the patient, monitor the usage of the pressure support device (patient compliance), or any combination thereof.” *Id.*, 2:1-11; *see also id.*, 2:12-56.

Truitt additionally discloses another PAP system 50 similar to system 10, but includes an improved flow sensor, i.e., flow sensing assembly 72, as shown in Figure 3 below. *Id.*, 4:61-67, FIG. 1.

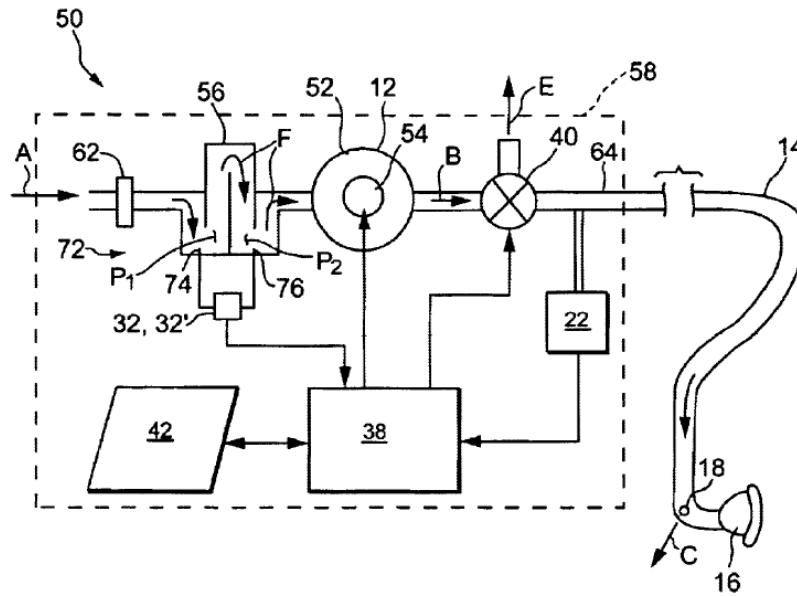


FIG. 3

PAP system 50 includes a housing 58, a pressure generator 12 in the form of a blower assembly 52 driven by a motor 54, providing a gas flow to patient circuit 14 for delivery to a patient. *Id.*, 5:1-3; *see also id.*, 5:4-35. Like PAP system 10, the pressure signal output by pressure sensor is provided to controller 38 for “controlling the operation of the pressure support system, monitoring the operation of the system, or monitoring the patient, for example.” *Id.*, 6:1-10. Under the control of controller 38, blower assembly 52 adjusts the flow or pressure of the gas delivered to the patient. *Id.*, 5:36-59.

The improved flow sensing assembly 72, like the conventional system 10, similarly provides a signal to controller 38 to “control the operation of the pressure

support system, monitor the operation of the system, or monitor the patient” (*id.*, 6:11-17; *see also id.*, 6:49-62).

B. Kumar (EX1008)

Kumar discloses networked monitoring limitations of claim 1, including features of the claimed “cell phone” in [1.a], the claimed “wireless transceiver” in the patient-side device in [1.b.v], and “remote internet site” in [1.c].

Kumar discloses a telemedicine system “for network-based monitoring of physiological data.” EX1008, Abstract. Figure 1A shows the system includes a patient-side device 102, computing device 110 (like a wireless phone or pocket PC such as the IPAQ), and central server 106 that hosts a browser-based engine that can be accessed through web pages. *See* EX1008, [0067] (“[T]he system includes one or more patient-side devices 102 for collecting data from a patient/client, one or more provider-side devices 104, and an engine implemented on a central server 106.”), [0072] (“The *patient-side device* may then 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.”). The computing device can download a plug-in to communicate with the patient-side device and the central server. *Id.*, [0018] (“[T]he engine will send

the appropriate *plug-in* which allows the computing device to communicate with the patient-side device.”).

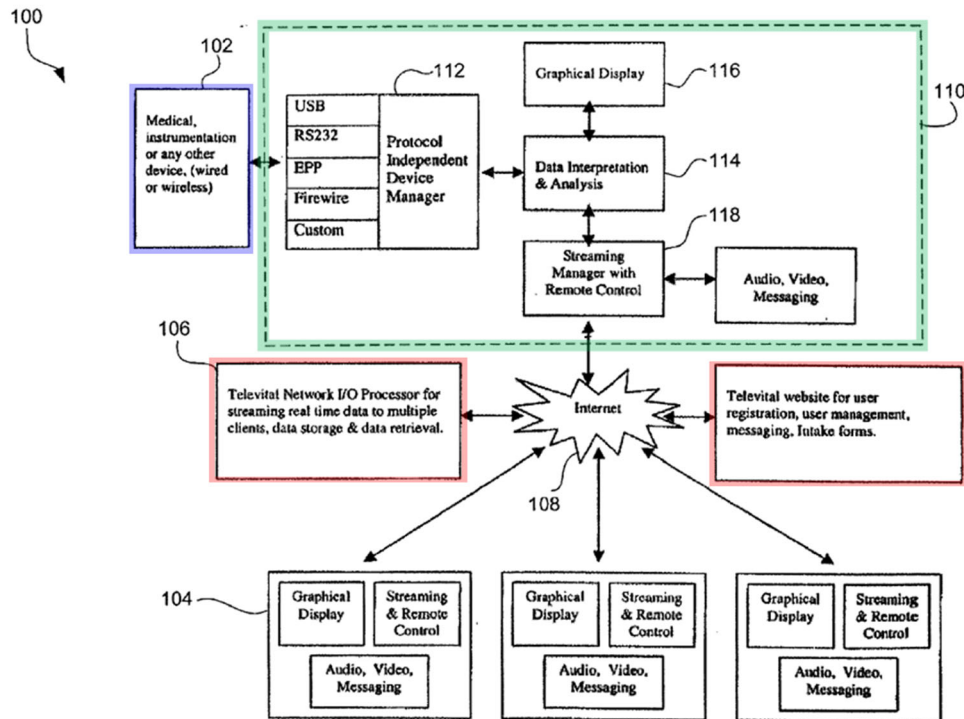


Fig. 1A

EX1008, FIG. 1A

Kumar teaches that “virtually any [patient-side] device may be easily incorporated into the system.” *Id.*, [0018]. One of the devices that Kumar teaches can be incorporated into the system is a device to address sleep apnea-hypopnea syndrome. Kumar recognizes that “[s]leep apnea-hypopnea syndrome is characterized by repetitive episodes of upper airway obstruction that occur during sleep usually associated with reduction in blood oxygen concentration.” *Id.*, [0240].

Kumar teaches that incorporating devices for sleep apnea-hypopnea “allows remote monitoring of such devices by providing in-home monitoring.” *Id.*, [0241].

C. Dong (EX1014)

Dong discloses features associated with “an extended horizon, adaptive, predictive controller” as recited in claims 15 and 18. Dong discloses an “extended horizon adaptive block predictive controller” (EX1014, Abstract) and is incorporated by reference in the ’284 Patent (EX1001, 20:55-59).

D. Wright (EX1013)

Wright discloses features associated with “distinguish[ing] between and calculate[ing] the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device” as recited in claims 17 and 20. Like Truitt, Wright discloses use of a CPAP device to assess and treat a patient’s sleep apnea. EX1013, Abstract. Wright explains that “CPAP devices can detect the presence of apneas, **distinguish between central and obstructive apneas** and provide an increased pressure if needed to stabilize an obstructed or partially obstructed airway.” EX1013, [0027].

E. Mumford (EX1009)

To the extent that Truitt does not disclose calculating “data of usage of the PAP device by the subject,” “data of severity of sleep disorder symptoms of the subject,” or “the index [of treatment efficacy of the subject using a PAP device is]

based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject,” Mumford discloses these features.

Like Truitt, Mumford discloses treatment systems for treating obstructive sleep apnea using a PAP device that includes sensors for measuring physiological signals of the wearer. EX1009, Abstract. The physiological signals are used “to determine the efficacy of the PAP treatment and to vary operational parameters of the PAP device.” *Id.* Specifically, Mumford discloses a “sleep efficacy control algorithm 36 [that] can generate sleep profile information for the wearer 18 (the sleep profile information may include data, such as a test score, related to efficacy and compliance).” EX1009, 7:42-46.

V. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art (“POSITA”) in 2005 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. Kirkness ¶¶44; *see also* ¶¶ 42-46.

This Petition does not turn on this precise definition, and the challenged claims would be unpatentable from the perspective of any reasonable person of ordinary skill in the art at the relevant time. *Id.* ¶62.

VI. CLAIM CONSTRUCTION

The Board construes the claims “using the same claim construction standard that would be used” in district courts. 37 C.F.R. §42.100(b). This Petition establishes the prior art meets each of the claim limitation under any reasonable construction.⁷ Thus, no express construction is required.

VII. GROUND 1: TRUITT IN VIEW OF KUMAR RENDERS OBVIOUS CLAIMS 1-3, 6, 12-15, 18-19

A. Motivation To Combine

A POSITA would have been motivated to combine the teachings of Truitt and Kumar to implement a networked PAP treatment system. Specifically, a POSITA looking to improve the PAP device of Truitt would have looked at known ways to incorporate medical devices into a telemedicine system as taught by Kumar for at least the following reasons.

⁷ Petitioner reserves the right to argue alternative constructions in other proceedings, including indefiniteness.

First, a POSITA would have been motivated to obtain more representative data. *See* Section III.A.2; Kirkness ¶¶141-42. A POSITA would have understood that if a patient is being monitored outside of their home the data they obtained would be less representative than data gathered while the patient is in their routine sleep environment. *Id.* By networking the PAP machine, the patient is able to sleep at home (in their routine sleep environment) and the physician is still able to access the data. *Id.*

Second, a POSITA would have been motivated by convenience and efficiency. *See* Section III.A.2; Kirkness ¶143. OSA is a chronic condition and PAP therapy requires ongoing management, support, and frequent follow-up between patient and care providers and physicians. Setting appointments and traveling to see providers requires an investment in time and resources for both the provider and patient. *See, e.g.,* EX1044, [0004] (“Conventionally, patients...using this positive pressure artificial respiration assisting device have typically communicated with a physician only during outpatient visits to report their condition, the usage status... and any malfunctions of said devices.”); Kirkness ¶143. Collecting data through a networked-home device would have allowed the patient to receive treatment at home with the PAP machine, and the provider to remotely monitor the data, assess therapy and prescribe motivation and/or changes without the hassle and expense associated with in person appointments. *Id.* Additionally, a patient’s condition may change

over time, and being able to remotely monitor the patient provides an added convenience by avoiding the additional time and cost associated with traveling to the doctor's office for follow-up appointments.

Third, a POSITA would have been motivated to provide health access to more people. Kirkness ¶144; Chatterjee ¶¶77-78. As Kumar observes, telemedicine has provided “access to health assessments, diagnoses, interventions, supervision, consultations, education, and information across a distance.” EX1008, ¶[0003]. This is why many early advancements in telemedicine came from NASA (to monitor the health of astronauts) and Indian Health Services (to provide health services to remote locations). Kirkness ¶144; Chatterjee ¶77.

Fourth, a POSITA would have been motivated to leverage the advances in mobile computing and wireless communications. Kirkness ¶¶145-46; Chatterjee ¶¶68-69. The early 2000s saw technological advances in semiconductors, energy-efficient wireless communication, and reduced budgets for computational devices that allowed wireless networks of smart sensors to become feasible for many applications, including medical applications. Chatterjee ¶68. The sensors of Truitt would have been ideal to improve with these advances. EX1005, 2:3-5; Kirkness ¶146; Chatterjee ¶71. This is particularly true given the diagnostic advantages of using wireless, as opposed to wired, sensors. Kirkness ¶146; Chatterjee ¶69.

Last, a POSITA would have been motivated by the general market trend to implement consumer devices into intelligent systems. Chatterjee ¶¶70-76. The “Internet of Things” had just been coined in the late 1990s, and the market was looking for any consumer device to connect to the Internet. *Id.* ¶70. For example, LG introduced the first smart refrigerator in early 2000. *Id.* A POSITA would have naturally looked at known design options for telemedicine like Kumar’s “plug-and-play” telemedicine system. *Id.* ¶71; Kirkness ¶147.

B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in implementing the Truitt PAP device as a networked system as taught by Kumar.

First, Kumar expressly teaches that a device, like the Truitt PAP device, can be incorporated into its system: “Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI. Thus, virtually any device may be easily incorporated into the system.” EX1008, ¶ [0018]; *see also* Kirkness ¶149; Chatterjee ¶80.

Second, the sensors in Truitt were known to be implemented wirelessly. Kirkness ¶150; Chatterjee ¶81. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, EX1044, Abstract, Fig. 5, EX1045, Fig. 3; EX1013, [0029]. Further, as Truitt teaches,

microphones are often used for flow sensors in PAP machines. EX1007, 3:4-9. Wireless microphones have been around since the 1950s. Chatterjee ¶¶81.

Third, the proposed modification would simply be a change of programming and the addition of wireless transceivers. This was a combination of known prior art elements (sensors and wireless transceivers) according to known methods and techniques (to collect and transmit data) to yield predictable results (networked data system). Kirkness ¶¶151; Chatterjee ¶¶82.

Lastly, in 2002, a telemedicine system (including a PAP device, mobile phone, and physician-side computer, all connected to a network) was demonstrated and known. EX1044, [0008] (The remote “telemedicine system comprises a positive pressure artificial respiration assisting device 2, a relay device 3, and...a physician-side computer 4 and a mobile terminal 5, all connected to communication network 1.”), FIG. 1; Kirkness ¶¶151.

C. Independent Claim 1

1. Preamble: PAP sleep disorder treatment system

To the extent limiting, Truitt discloses the preamble. Kirkness ¶¶154-63; Chatterjee ¶¶83-84. Truitt discloses a conventional *positive airway pressure (PAP) sleep disorder treatment system*. EX1007, 1:24-30 (“continuous positive airway pressure (CPAP) device to supply a constant positive pressure to the airway of a patient to treat obstructive sleep apnea (OSA) as well as other disorders.”)

The pressure of gas delivered to the patient may vary “with the patient’s breathing cycle” or “with the patient’s effort to increase the comfort to the patient.” *Id.*, 1:30-35. The pressure of gas may also vary “based on the detected conditions of the patient, such as whether the patient is snoring or experiencing an apnea, hypopnea or upper airway resistance,” where “the pressure support system automatically attempts to titrate the pressure support to suit the needs of the patient.” *Id.*, 1:35-43; Kirkness ¶154.

As shown in Figure 1, Truitt discloses a conventional pressure support system 10 (an exemplary PAP treatment system) including a pressure generator 12 (e.g., a blower), “create[ing] a flow of breathing gas, as indicated by arrows B.” EX1007, 1:44-50. A patient circuit 14 (e.g., a flexible conduit), which is coupled with a patient interface device 16 (e.g., a mask or nasal cannula) delivers elevated pressure breathing gas to the airway of the patient. EX1007, 1:50-61; Kirkness ¶155.

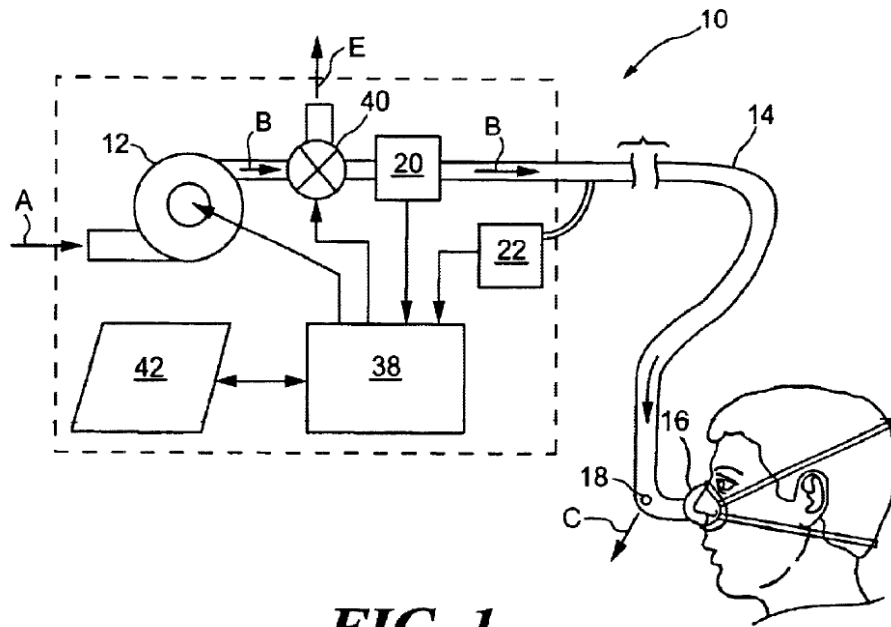


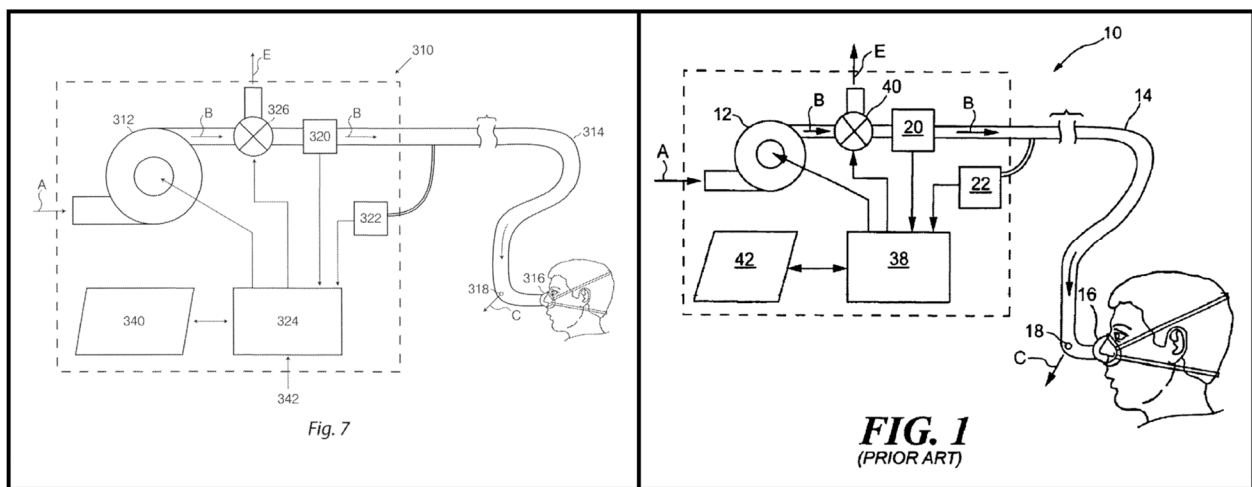
FIG. 1
(PRIOR ART)

EX1007, FIG. 1

As shown in Figure 1, PAP system 10 also includes a flow sensor 20 and pressure sensor 22 to monitor the flow and pressure of gas passing through patient circuit 14, where the flow information provided by the sensor(s) are used to “control the pressure or flow of gas provided to the patient, monitor the condition of the patient, monitor the usage of the pressure support device (patient compliance), or any combination thereof.” EX1007, 2:1-11; *see also id.*, 2:12-56 (discussions regarding flow and pressure sensors and associated pressure/flow control method). Kirkness ¶156.

PAP system 10 further includes a controller 38 that receives signals from flow sensor 20 used for “control[ing] the pressure or flow of gas provided to the patient or monitor[ing] the patient’s usage of the medical device.” EX1007, 2:38-48; *see also id.*, 2:48-56. For instance, “[c]ontroller 38 receives the signals output from sensors 20 and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof in a feedback fashion based on these received signals.” *Id.*, 2:57-60. Controller 38 may “monitor[] the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.” *Id.*, 2:60-64. Controller 38 may also receive the signals from flow sensor 20 and pressure sensor 22, and “uses this information to determine when the patient has transitioned from the inspiratory phase to the expiratory phase of the breathing cycle, or vice versa, to control the pressure accordingly.” *Id.*, 2:64-3:4. Moreover, the pressure level may be “controlled based on the conditions of the patient,” where “pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc.” and “[t]he pressure and/or flow is then controlled to counteract or prevent these conditions.” *Id.*, 3:4-11. Additionally, PAP system 10 includes an input/output device 42, e.g., a keypad and a display for entering information and commands to the system and to display information. *Id.*, 3:12-20. Kirkness ¶¶157-59.

Notably, Truitt's conventional PAP system 10, as shown in Figure 1, is substantially similar, if not identical, to the "pressure support system" of the 284 patent, as shown in Figure 7. *See* EX1007, FIG. 1; EX1001, FIG. 7, 5:31 ("FIG. 7 is a schematic view of a pressure support system"), 22:49-23:25 (description of the system's components).



EX1001, FIG. 7 (left); EX1007, FIG. 1 (right)

Truitt additionally discloses another PAP system 50 similar to system 10 described above, but includes an improved flow sensor, i.e., flow sensing system 72, as shown in Figure 3 below. EX1007, 4:61-67, FIG. 1; Kirkness ¶161.

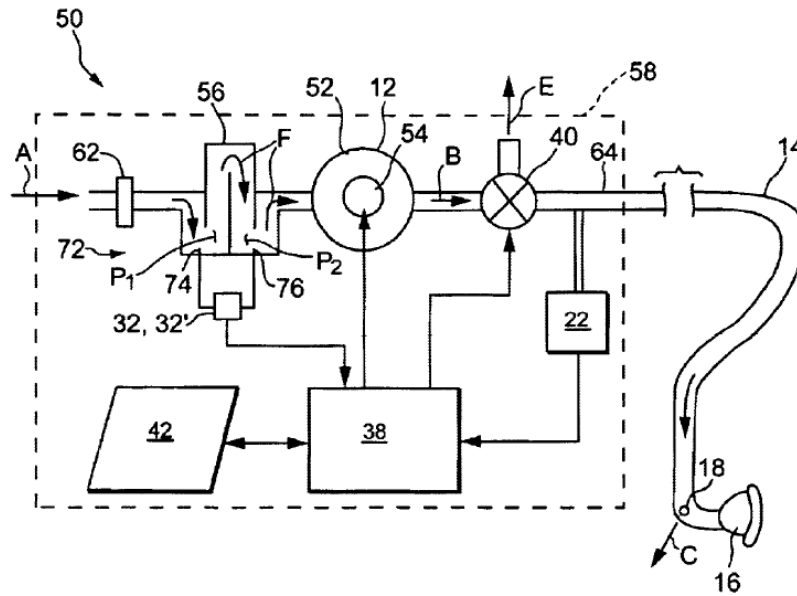


FIG. 3

In particular, PAP system 50 includes a housing 58, a pressure generator 12 in the form of a blower assembly 52 driven by a motor 54, providing a gas flow (as indicated by arrow B) to patient circuit 14 for delivery to a patient. EX1007, 5:1-3; *see also id.*, 5:4-35. Like PAP system 10, the pressure signal output by pressure sensor 22 is provided to controller 38 for “controlling the operation of the pressure support system, monitoring the operation of the system, or monitoring the patient, for example.” *Id.*, 6:1-10. Under the control of controller 38, blower assembly 52 and/or valve 40 may adjust the flow or pressure of the gas delivered to the patient. *Id.*, 5:36-59; Kirkness ¶162.

The improved flow sensing system 72, unlike the conventional system 10, does not require a dedicated flow element (EX1007, 6:18-25), but similarly provides

a signal to controller 38 to “control the operation of the pressure support system, monitor the operation of the system, or monitor the patient” (*id.*, 6:11-17; *see also id.*, 6:49-62); Kirkness ¶163.

2. [1.a]: cell phone to display severity data and/or index and usage data;

Truitt in view of Kumar discloses this limitation. Kirkness ¶¶165-208; Chatterjee ¶85-99.

First, Truitt discloses a PAP device calculating *data of usage of the PAP device by the subject* because the controller of the Truitt PAP device calculates the flow and volume of gas from the PAP device and uses that information to, among others, “monitor the usage of the pressure support device (patient compliance).” EX1007, 2:1-11. Truitt discloses that the output of the flow sensor is provided to controller 38 “for calculating the flow and/or volume of gas passing through conduit 56.” EX1007, 6:46-48; *see also id.*, 2:1-5, 2:21-26. Truitt also discloses that “[t]he signal from flow sensor 20...is provided to a controller 38...to control the pressure or flow of gas provided to the patient or monitor the patient’s usage of the medical device.” *Id.*, 2:38-42; *see also id.*, 2:1-11; Kirkness ¶¶166-69; Chatterjee ¶96.

Second, Truitt discloses the PAP device calculating “data of severity of sleep disorder symptoms of the subject” because it discloses monitoring the patient’s condition, and specifically detecting snoring, apneas, and hypopneas. Kirkness

¶¶170-76; Chatterjee ¶95. PO maintains “[a] skilled artisan would know that apnea and hypopnea events, which are indicated based on breathing metrics, represent data of severity of the patient’s sleep disorder symptoms.” EX1010, 27. This is consistent with PO’s position that the ’284 Patent equates “conditions” and “symptoms” and acknowledging that there are different levels conditions or symptoms, e.g., non-critical conditions versus critical conditions/symptoms. EX1001, 21:6-8 (“the subject’s physiological conditions moves toward various critical conditions or symptoms”).

Truitt discloses that “[i]n the auto-titration mode of pressure support, where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient, these pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc.,” where “[t]he pressure and/or flow is then controlled to counteract or prevent these conditions.” *Id.*, 3:4-11; *see also id.*, 2:57-59, 2:60-64. A POSITA would have understood that the patient’s conditions, such as snoring, apneas, and hypopneas, are different levels of severity of sleep disorder symptoms. Kirkness ¶¶173-75. As PO maintains, the degree of presence of these events indicates the degree of severity. *Id.*

Third, Truitt discloses that an “index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” Kirkness ¶¶177-

82; Chatterjee ¶97. Specifically, Truitt discloses controlling the PAP system's gas pressure/flow based on received sensor signals in "feedback fashion to meet the desired prescription pressure level" (EX1007, 2:57-3:4) or based on the patient's conditions to "counteract or prevent these conditions" (*id.*, 3:4-11). A POSITA would have understood that determining whether to increase/decrease pressure/flow requires calculating the effectiveness of the PAP system to meet the desired prescription pressure level and/or "counteract or prevent these conditions." Kirkness ¶179. A POSITA would have further understood that this determination would have been based on the patient's condition (the detection of snoring, apnea, and/or hypopneas) and patient compliance (whether the patient is using the PAP device as prescribed), since the patient's condition could be due to lack of compliance. *Id.* ¶180.

Truitt's PAP system operates in the materially same way as the '284 patent. Like Truitt, the '284 patent's PAP system uses sensor signals to adjust the treatment based on the patient's conditions/symptoms. EX1001, 22:37-45 ("With the present invention,...modifications can be made to a subject's treatment regiment as the severity or level of the subject's symptoms increase or decrease better regulating the therapeutic treatment of the subject's sleeping disorder. For example,...CPAP can be adjusted during the treatment based on the sleep diagnosis results."); *See also* EX1010, 10 (PO indicating that the disclosure of the '284 patent at 22:37-45

describes determining the claimed “index”). PO states that “[i]n this context—where the level of severity is determined during treatment (not to mention used to adjust that treatment)—the level of severity is just another name for an index of treatment efficacy.” EX1010, 10; *see also id.*, 12-14 (“a skilled artisan would recognize that ‘an index of treatment efficacy’ is just another term for the level of severity of a patient’s symptoms determined while the patient is being treated.”). Furthermore, the PO acknowledged that the “‘level of severity’ is...an ‘index of treatment efficacy...*based* in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject’ because it is *based on* breathing metrics collected while the patient is using the device.” EX1010, 3. Given that Truitt discloses using sensor signals collected while using the PAP device to adjust the treatment based on the patient’s conditions/symptoms, including at least an auto-titration mode, Truitt discloses an “index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” Kirkness ¶¶181-82.

Fourth, Truitt in view of Kumar discloses “*a non-transitory computer readable medium, the non-transitory computer readable medium comprising a first software, the first software executable by a first processor and configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using*

a PAP device, the first software used for displaying the index on the cell phone, the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display.” Kirkness ¶¶183-210; Chatterjee ¶¶86-93.

While Truitt does not expressly disclose the remaining features (as italicized above) of [1.a], a POSITA would have been motivated and found it obvious to implement these features in view of Kumar. Kirkness ¶¶183-87. Kumar discloses a telemedicine system “for network-based monitoring of physiological data.” EX1008, Abstract. Figure 1A shows the system includes a patient-side device 102 (like the Truitt PAP device), computing device 110 (“cell phone”), and central server 106 that hosts a browser-based engine that can be accessed through web pages. To communicate with the patient-side device and the central server, the computing device can download a plug-in (“first software”). *Id.*, [0018].

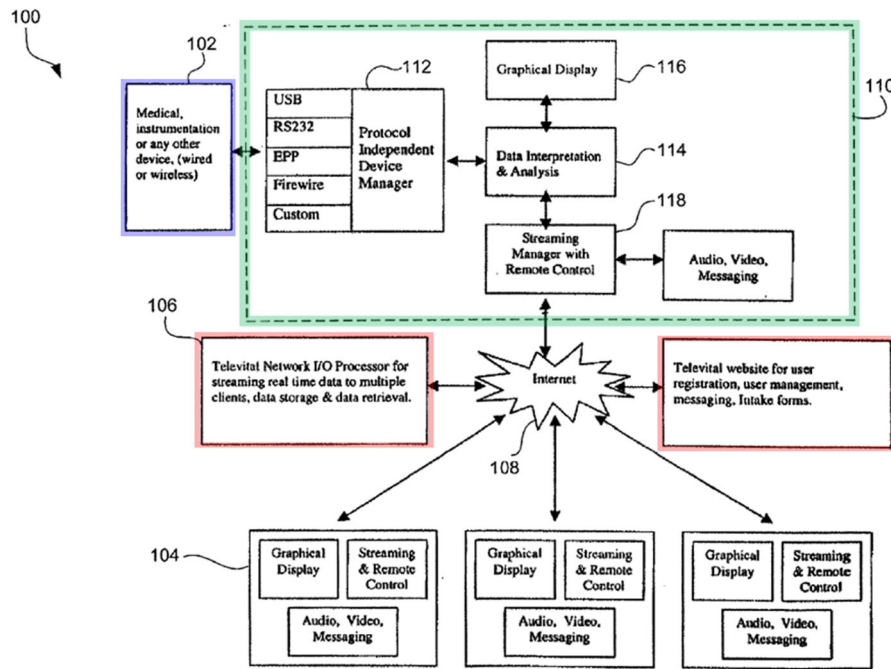


Fig. 1A

EX1008, FIG. 1A

Kumar discloses “a non-transitory computer readable medium.” Kirkness ¶¶203-204; Chatterjee ¶87. Specifically, Kumar discloses that “[t]he present invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium,” such as the memory on the computing device. EX1008, ¶ [0020].

Kumar discloses a “cell phone.” Kirkness ¶¶198-99; Chatterjee ¶92. Kumar discloses that computing device 110 may be a wireless phone or pocket PCs, e.g., an IPAQ device. EX1008, ¶ [0072]; EX111, 2 (“[T]he HP iPAQ h6315 is a voice calling, Wi-Fi hotspot finding, wireless emailing, Internet connecting, instant

message chatting, MP3 playing, picture taking, keypad typing, 64MB data storing powerhouse. The iPAQ h6315 is the first all-in-one wireless device to include built-in GSM global phone capabilities with integrated GPRS wireless data, Wi-Fi (802.11b) wireless broadband, and Bluetooth™ functionality to allow customers to easily navigate and wirelessly communicate through e-mail, text messaging, Internet and phone calls.”).

Kumar discloses “a first radio frequency wireless transceiver.” Kirkness ¶205; Chatterjee ¶93. Kumar teaches using the IPAQ device, which a POSITA would have understood included a radio frequency wireless transceiver to enable GPRS, Wi-Fi, and Bluetooth. EX1008, [0072]; EX1011, 2; Kirkness ¶205; Chatterjee ¶93.

Kumar discloses “a first software executable by a first processor and configured to be used with a cell phone . . . the first software used for displaying [data] on the cell phone” and “executable by a first processor and configured to be used with a cell phone.” Kirkness ¶¶197-204; Chatterjee ¶¶88-89. Specifically, Kumar discloses a plug-in (“first software”) downloaded by the computing devices, including a cellular device such as an IPAQ (“cell phone”) that allows communications with the patient-side devices (such as Truitt PAP device) through a wireless protocol. EX1008, [0074], [0073]. A POSITA would have understood that the plug-in allows the patient to access the patient’s data on the computing device

and display that data on the display of the computing device. Kirkness ¶¶186, 193, 203; Chatterjee ¶91. A POSITA would have further understood that the plug-in would be executable on the processor of the computing device (“first processor”) and configured to be used by the computing device, otherwise the plug-in would not function on the computing device. Kirkness ¶204; Chatterjee ¶89.

A POSITA would have had the skill and a reasonable expectation of success in combining the teachings of Truitt and Kumar. Kirkness ¶¶208-209; Chatterjee ¶¶98-99. Both references are in the same field of art and both relate to healthcare for sleep disorder. *Id.* Moreover, Kumar states that “virtually any device may be easily incorporated into the system” (EX1008, [0074]) and specifically discussed devices to monitor “[s]leep apnea-hypopnea syndrome” (*id.*, [0241]). Indeed, it was known at the time to interface a PAP device with a computing device via wireless communication. EX1012, 6:20-25 (“While this apparatus [a PAP device] is generally described as a single unit, it is understood that a combination of devices and/or computers linked by any available communications method may be used to accomplish the goals of the invention. For example, the apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication or it may interface with a network for 25 transmission between the devices.”), 7:2-6 (describing that the apparatus is a PAP device); EX1044, [0006] (“a positive pressure artificial respiration assisting device...is connected to a relay device and a

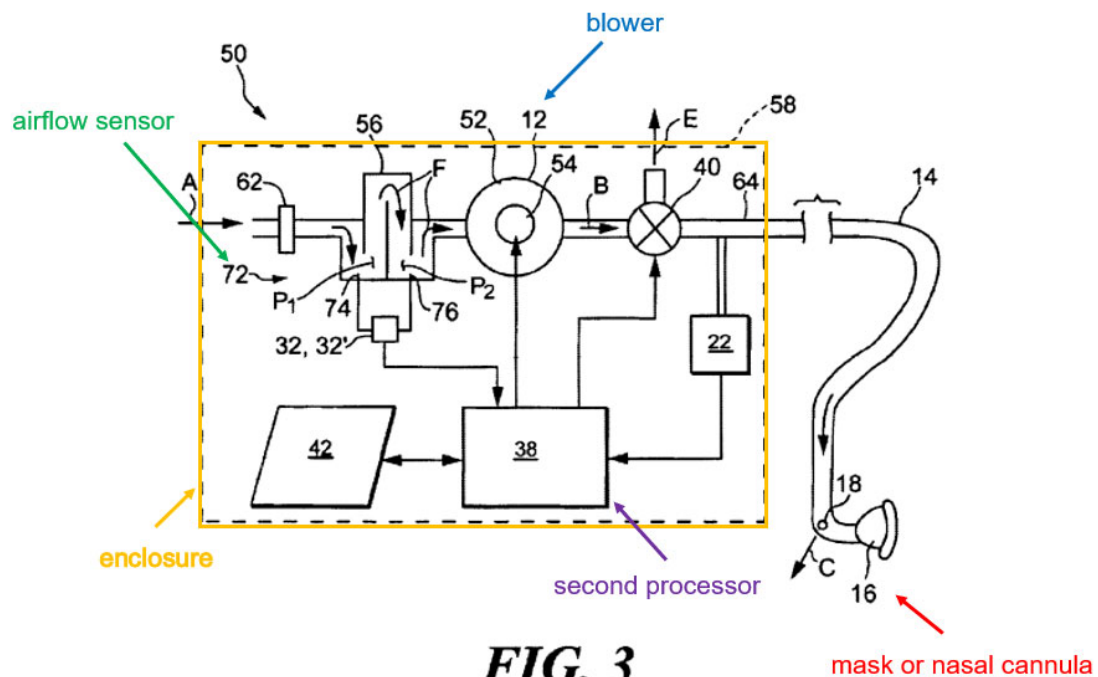
physician-side terminal device via a wireless...communication network to conduct remote monitoring of the positive pressure artificial respiration assisting device via the communication network”), [0008] (The remote “telemedicine system comprises a positive pressure artificial respiration assisting device 2, a relay device 3, and...a physician-side computer 4 and a mobile terminal 5, all connected to communication network 1.”), [0009] (“The communication network 1 may be any of a public telephone network, the Internet, a mobile communication network, or a dedicated line network; alternatively, it may also be a combination of these networks.”), FIG. 1; EX1009, 14:54-15:12 (use of wireless/Bluetooth protocol to transmit data associated with a CPAP device).

Moreover, it would have involved a combination of known technologies (PAP device that monitors the usage and calculates data) according to known methods (transmitting data via wireless protocols from patient-side device to computing device) to yield the predictable result of a system including a PAP device of improved portability and an associated system that improves patient compliance, as discussed above. *Kirkness* ¶210; *Chatterjee* ¶¶79-82; *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

3. [1.b]-[1.b.iv]: the PAP device

Truitt discloses limitations [1.b]-[1.b.iv]. *Kirkness* ¶¶211-15; *Chatterjee* ¶¶100-105. As shown in Figure 3, Truitt discloses that the PAP device includes a

housing 58 (“enclosure”). EX1007, 5:12-13. As discussed for the preamble, the PAP device includes a pressure generator 12 in the form of a blower assembly 52 (“blower having an air output”) driven by a motor 54 providing a gas flow as indicated by arrow B to patient circuit 14. EX1007, 5:1-3; *see also id.*, 5:4-35; Section VII.C.1 (Ground 1, Claim 1, Preamble).



EX1007, FIG. 3 (annotated)

Truitt also discloses that the PAP device includes flow sensing system 72 (“airflow sensor internal to the PAP device”) within housing 58, as shown in Figure 3, providing a signal to controller 38 for calculating gas flow and/or volume passing through conduit 56 and controlling operations of the PAP device, including

operations of motor 54 and/or valve 40 that control air flow and pressure provided to the patient (air flow sensor “adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data”). EX1007, 6:11-62; Kirkness ¶212; Chatterjee ¶103.

Additionally, as discussed for [1.a], Truitt discloses controller 38 (“second processor”) receives signals provided by flow sensing system 72 (“adapted for receiving the airflow sensor data”) (EX1007, 6:11-17) for calculating “the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device.” Kirkness ¶213; Chatterjee ¶104; *see also* Section VII.C.2 (Ground 1, Claim 1, Limitation [1.a])).

Truitt additionally discloses that the PAP device includes a patient interface device 16, e.g., a mask or a nasal cannula. EX1007, 1:56-61, 6:2; Kirkness ¶214; Chatterjee ¶105.

4. [1.b.v]: second radio frequency wireless transceiver

Truitt in view of Kumar discloses this limitation. Kirkness ¶¶216-223; Chatterjee ¶¶106-112. As discussed for [1.a], a POSITA would have been motivated to combine teachings of Truitt and Kumar such that the PAP device would wirelessly transmit to a patient’s cell phone data associated the patient’s treatment, including “an index of treatment efficacy of the subject using a PAP device,” “data of severity of sleep disorder symptoms of the subject,” and “data of usage of the PAP device by

the subject” and display on the cell phone the data/index to the patient. *See* Section VII.C.2 (Ground 1, Claim 1, Limitation [1.a]).

A POSITA would have been motivated and found it obvious to implement a radio frequency wireless transceiver in the PAP device to facilitate wireless communication with the cell phone to transmit the above-described data. Kirkness ¶220; Chatterjee ¶110.

Kumar discloses that the patient-side device is connected via computing device 110 to the WAN and a “two-way communication” is “establish[ed]” between computing device 110 and the patient-side device. EX1008, [0072]. Additionally, the “patient-side device can be...wireless, and communicates through...wireless...interface/protocol.” *Id.* Given that computing device 110 and the patient-side device establish a “two-way” “wireless” communication, a POSITA would have understood that each of computing device 110 and the patient-side device includes a wireless “transceiver” for the two-way (transmitting and receiving) wireless communication. Kirkness ¶218; Chatterjee ¶108.

As discussed for [1.a], a POSITA would have understood that computing device 110, i.e., wireless phone or an IPAQ device (“cell phone”) includes a radio frequency wireless transceiver to facilitate wireless communications using wireless protocols including, e.g., GSM, GPRS, Wi-Fi, and Bluetooth. Kirkness ¶220; Chatterjee ¶109. A POSITA would have been motivated to implement a radio

frequency wireless transceiver in the PAP device for using protocols similar to those used by computing device 110, e.g., GSM, GPRS, Wi-Fi, and Bluetooth, to enable the PAP device to wirelessly communicate with, e.g., computing device 110, including to transmit the “data” and/or “index,” as discussed above. *Id.*

For example, a POSITA would have understood that a Bluetooth-enabled radio frequency wireless transceiver would have allowed a short-range radio link between the PAP device and computing device 110 for data communication. Kirkness ¶221; Chatterjee ¶110; ; EX1018, 9:56-57 (“a short-range radio link, such as Bluetooth”); EX1009, 14:54-15:12 (use of wireless/Bluetooth protocol to transmit data associated with a CPAP device). A Wi-Fi-enabled radio frequency wireless transceiver would have allowed the PAP device to connect to both the cell phone and the remote engine for uploading data thereto. Kirkness ¶221; Chatterjee ¶110. A GSM- or GPRS-enabled radio frequency wireless transceiver would have allowed the PAP device to communicate with the remote engine when the PAP device is not connected to Wi-Fi. *Id.*

Moreover, there were only a handful of known techniques for transmitting data wirelessly, including radio frequency communication and optical wireless communications. Chatterjee ¶111. Thus, using a radio frequency wireless transceiver to implement communications via radio frequency would have been obvious because it would have been one of a “finite number of identified, predictable

solutions.” Chatterjee ¶111. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331 (Fed. Cir. 2009).

A POSITA would have had the skill and a reasonable expectation of success in implementing a radio frequency wireless transceiver in the PAP device. Kirkness ¶¶222-223; Chatterjee ¶112. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, EX1045, Fig. 3; EX1013, [0029] (a CPAP device including “a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12.”); EX1044, FIG. 3, [0006]-[0007], [0023], [0030], [0070]. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that monitors the usage and calculates data associated with sleep disorder treatment (Truitt)) according to known methods (e.g., known methods of transmitting data from patient-side device to computing device, e.g., cell phone, by using a radio frequency wireless transceiver (Kumar)) to yield the predictable result of a PAP device including a radio frequency wireless transceiver to facilitate wireless communication with the cell phone. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

5. [1.c]: a remote internet site

Truitt in view of Kumar discloses this limitation. Kirkness ¶¶224-239; Chatterjee ¶¶113-125. As discussed for [1.a], Kumar discloses “at least one patient-side device for collecting data from a patient/client, a provider-side device, and an engine, each coupled to the WAN,” such as the Internet. EX1008, [0011]; Section VII.C.2 (Ground 1, Claim 1, [1.a]). Also discussed for [1.a], a POSITA would have been motivated to consider the teachings of Kumar when implementing the method/system disclosed by Truitt. *Id.*

Kumar discloses “remote monitoring of medical and/or biofeedback devices over a wide area network (WAN) such as the Internet,” where a “browser-based engine” (“a remote internet site”) supports real-time streaming of information over the WAN. EX1008, [0010], [0087] (“The system may be implemented using Apache web server, MySql on Linux, Oracle on Linux, Java servlets, Applets, HTML, JavaScript, Java, C#, Microsoft's .NET etc. Note also that the server may be implemented on the Internet, intranet, or an extranet.”). “The engine manages transmission of the data from the patient-side device to the provider-side device” and “may configure the devices to transfer the data directly from one device to the other; may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device; may store the data for later transmission to the provider-side device, etc.” EX1008, [0011]; Kirkness ¶225; Chatterjee ¶116.

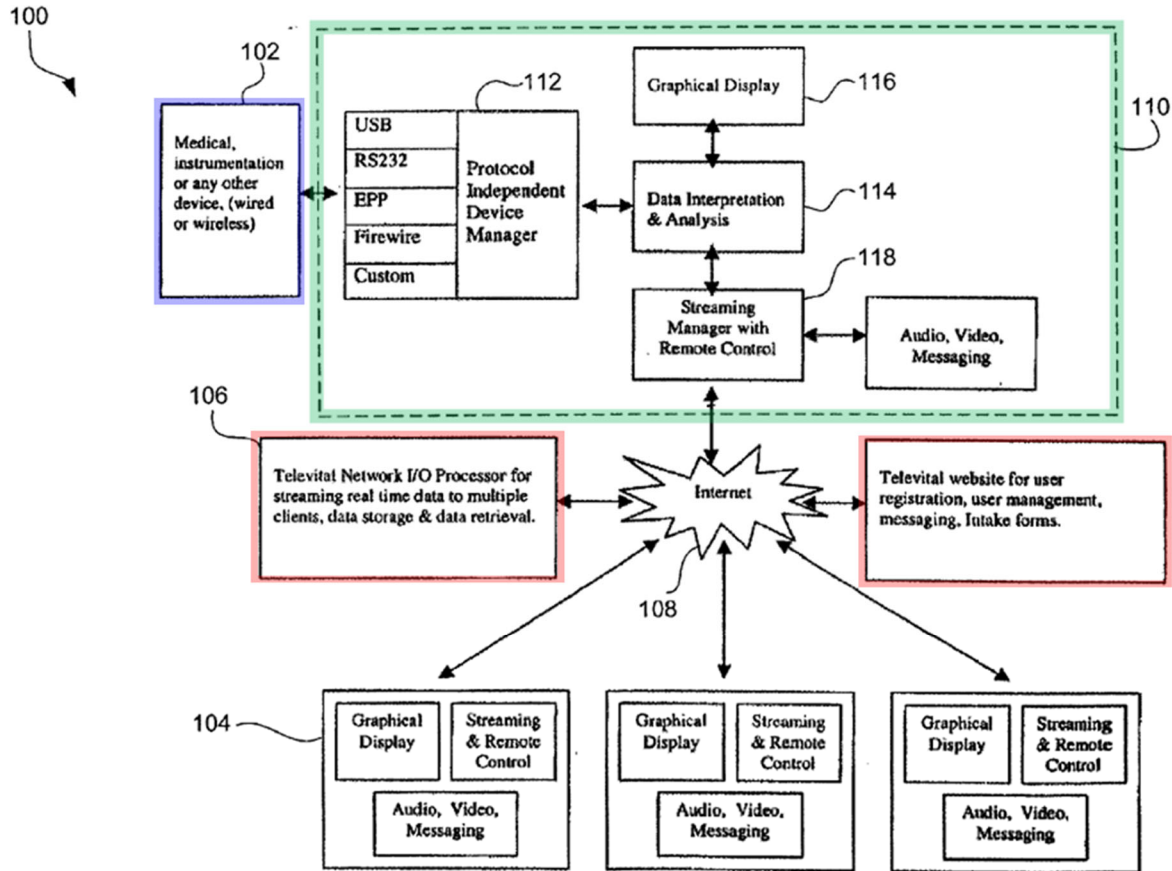


Fig. 1A

EX1008, FIG. 1A

For example, the system includes patient-side device(s) 102 for collecting data from a patient/client, provider-side device(s) 104, and an engine implemented on a central server 106, where the devices and engine are connected to a wide area network (WAN) 108 such as the Internet. EX1008, [0067]. “The 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.*; see *also id.*, [0068]. Kumar also discloses that the engine “may receive the data from

the patient-side device and transmit the raw or processed data to the provider-side device” and “may store the data for later transmission to the provider-side device, etc.” *Id.*, [0081], [0082]. Kumar also discloses that the patient-side device may communicate through a wireless interface and may communicate over the Internet. *Id.*, [0013]; Kirkness ¶226.

Kumar explains that “the entire system runs in the context of an Internet browser.” EX1008, [0086]-[0087]; *see also id.*, [0010] (“a browser-based engine”), [0015]. A patient can access the engine through a login, such as that in Figure 2. *Id.*, [0089], [0192] (“the system’s Internet browser-based software that allows the remote provider, and other healthcare providers, to remotely view their patient’s real-time physiology”); Kirkness ¶227; Chatterjee ¶117.

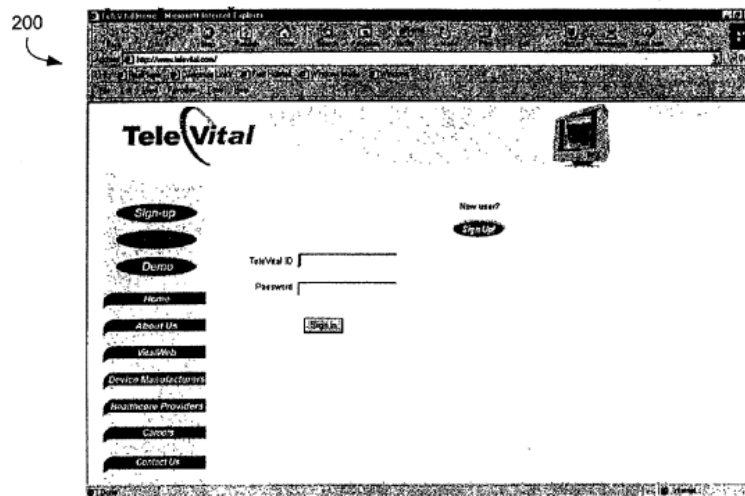


Fig. 2

EX1008, FIG. 2

A POSITA would have understood that the data sent to the engine could be accessed through web pages which serve as a graphical user interface, such as the “patient’s real-physiological data” depicted in Figure 7. EX1008, [0092], Figs. 6-8; *see also id.*, [0010], [0015] (“the communications are provided via a browser-based interface” and “the provider can start these devices remotely to read the data periodically or whenever needed”); Kirkness ¶¶227; Chatterjee ¶118.

A POSITA would have been motivated to implement a remote-monitoring feature, including a browser-based engine (“a remote internet site”) and similar to as described in Kumar (*see, e.g., above*), to enable the PAP device to wirelessly transmit to the remote engine data associated the patient’s treatment, including “an index of treatment efficacy of the subject using a PAP device,” “data of severity of sleep disorder symptoms of the subject,” and “data of usage of the PAP device by the subject.” Kirkness ¶¶228-29; Chatterjee ¶119-20.

Such a feature would have been beneficial as Kumar explains that “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis.” EX1008, [0083]. “The storage device may also be used to store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system,” “allow[ing] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device” *Id.* In fact, Kumar states that such a feature

is beneficial, e.g., by allowing a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. *Id.* Additionally, “[t]he system may also track trends during the recording, and using artificial intelligence, predict future behaviors and physiological responses based on the habits of the particular client hooked up.” *Id.*, [0084]; Kirkness ¶¶230-233; Chatterjee ¶¶122-123.

A POSITA would have also had a reasonable expectation of success in implementing the above-discussed feature in the Truitt-Kumar combination. Kirkness ¶¶234-39. Kumar states that “virtually any device may be easily incorporated into the system.” EX1008, [0074]. Additionally, it was well known to transmit data using wireless protocol(s) to a remote Internet site, e.g., for later access of the data. Chatterjee ¶¶55-56. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that monitors the usage and calculates data associated with sleep disorder treatment (Truitt)) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine on the Internet (Kumar)) to yield the predictable result of a system including a remote engine that receives and stores data received from a patient-side device, e.g., the PAP device, for simultaneous storage, retrieval, analysis, and play back from anywhere in the world, as discussed above. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Accordingly, the Truitt-Kumar

combination discloses a browser-based engine (“a remote internet site”) that receives the claimed “data” and “index” both related to the patient’s treatment and the treatment’s efficacy, generated by the PAP device and transmitted via the radio frequency wireless transceiver included in the PAP device. Kirkness ¶¶230-39; Chatterjee ¶¶124-25; *see also* Section VII.C.4 (discussions that a POSITA would have been motivated to implement a radio frequency wireless transceiver in the PAP device to facilitate wireless communication).

D. Dependent Claims

1. Claim 2: Bluetooth

The Truitt-Kumar combination discloses this limitation. Kirkness ¶¶240-43; Chatterjee ¶¶126-30. As discussed for [1.a], Kumar discloses that the computing device 110 (“cell phone”) may be an IPAQ device. Section VII.C.2 (Ground 1, Claim 1, Limitation [1.a]). At the time of the alleged invention, a POSITA would have understood that an exemplary cell phone, such as the IPAQ device may transmit/receive data using the Bluetooth wireless protocol. EX1011, 2 (“The iPAQ h6315 is the first all-in-one wireless device to include built-in GSM global phone capabilities with integrated GPRS wireless data, Wi-Fi (802.11b) wireless broadband, and Bluetooth™ functionality to allow customers to easily navigate and wirelessly communicate through e-mail, text messaging, Internet and phone calls.”).

A POSITA would have been motivated to implement similar Bluetooth capability in the PAP device to provide an additional or alternative wireless data communication channel between the PAP device and the IPAQ pocket PC (“cell phone”). Bluetooth protocol was known to provide a simple setup process for connecting two devices for data transmission, and was known for using relatively low power. Chatterjee ¶129.

A POSITA would have also had a reasonable expectation of success in implementing Bluetooth capability in the PAP device. Kirkness ¶¶241-42; Chatterjee ¶¶129-30. It was known at the time of the alleged invention to equip a PAP device with Bluetooth capability.

The monitoring unit 16 may be directly integrated within the CPAP device 14.... The monitoring unit 16 includes a control unit 600, a mask interface 602, a remote communications unit 604, a removable non-volatile memory 606, a memory unit 608, a power supply unit 610 and an external communications unit 612 connected as shown in FIG. 6.

....The remote communications unit 604 directs the transmission of data between the mask assembly and the monitoring unit 16. In the instance in which the mask assembly includes a wireless remote processing unit, the remote communications unit 604 employs an appropriate

*communications protocol such as the BLUETOOTH™
protocol....*

EX1009, 14:53-15:10. Moreover, it would have involved a combination of known technologies according to known methods (e.g., known use of Bluetooth protocol for wireless data communication between two devices) to yield the predictable result of a PAP device communicating with a cell phone using the Bluetooth protocol, as discussed above. Kirkness ¶243; Chatterjee ¶129; *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Accordingly, Truitt in view of Kumar discloses this limitation.

2. Claim 3: cell towers

The Truitt-Kumar combination discloses this limitation. Kirkness ¶¶244-48; Chatterjee ¶¶131-35. As discussed for [1.a], Kumar discloses that the computing device 110 (“cell phone”) may be an IPAQ device. Section VII.C.2 (Ground 1, Claim 1, Limitation [1.a]). At the time of the alleged invention, a POSITA would have understood that an exemplary cell phone, such as the IPAQ device may transmit/receive data using the GSM/GPRS wireless protocol that transmits data in part by cell towers. EX1011, 2 (“The lightweight HP iPAQ h6315 coupled with the muscle of T-Mobile’s national GSM/GPRS wireless voice and high-speed data network”).

As explained for [1.a], a POSITA would have been motivated to configure a PAP device, similar to as disclosed in Truitt, to wirelessly transmit to a patient's cell phone data associated the patient's treatment, including "an index of treatment efficacy of the subject using a PAP device," "data of severity of sleep disorder symptoms of the subject," and "data of usage of the PAP device by the subject" and display the "data" and "index" to the patient. *See* Section VII.C.2 (Ground 1, Claim 1, Limitation [1.a]). Kumar additionally discloses that the patient-side device may be connected via a computing device to the Internet, with which the engine/central server 106 is connected. EX1008, [0013], [0067], [0073], FIG. 1.

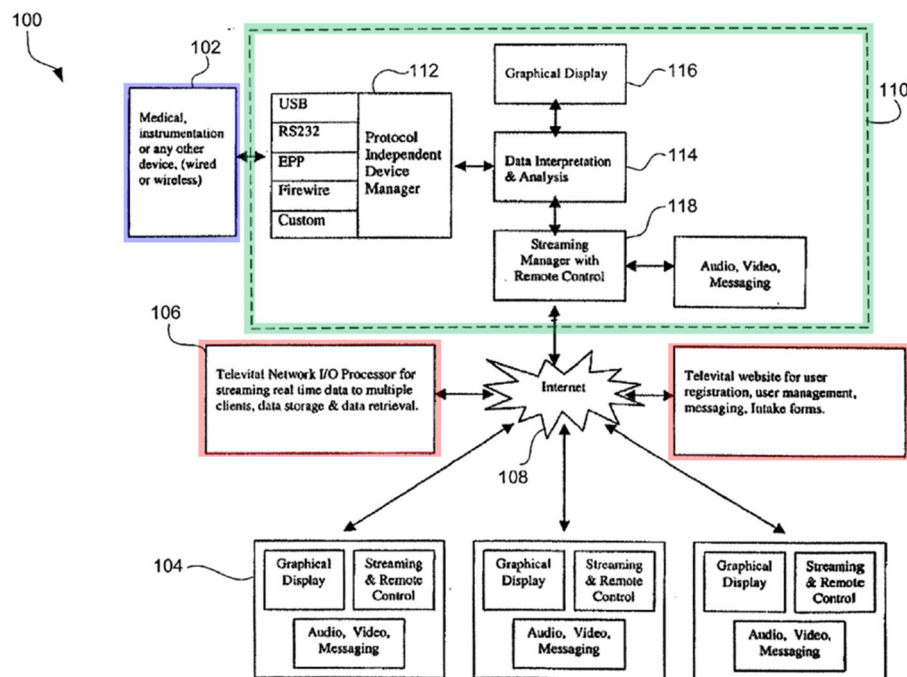


Fig. 1A

EX1008, FIG. 1A

The engine may “receive the data from the patient-side device and transmit the raw or processed data to the provider-side device.” *Id.*, [0081]. In view of the above and as discussed for 1 [1.b.v], the Truitt-Kumar combination discloses transmitting “data...of the data of the severity of the symptoms of the subject and/or the index” wirelessly from patient-side device 102 by a radio frequency wireless transceiver in the PAP device to computing device 110 (“cell phone”), which in turn transmits the “data” via the Internet to the central server. *See* Section VII.C.4; Kirkness ¶247. Given that an exemplary computing device, i.e., the IPAQ device may transmit/receive data using the GSM/GPRS wireless protocol, which transmits data in part via cell towers, the Truitt-Kumar combination discloses that the second radio frequency wireless transceiver of the PAP device transmits the “data” to the remote engine by using the IPAQ device’s wireless protocol “via in part by cell towers.” Chatterjee ¶133.

3. Claim 6: adjust remotely

Truitt in view of Kumar discloses this limitation. Kirkness ¶¶253-55; Chatterjee ¶¶136-42. As discussed for [1.c], the Truitt-Kumar combination discloses transmitting to the “remote internet site” “the data of the severity of the symptoms of the subject and/or the index” measured/calculated by the PAP device. *See* Section VII.C.5 (Ground 1, Claim 1, Limitation [1.c]).

Kumar discloses that the provider may “remotely control the client-side device[s],” e.g., “when the patient is sleeping in his/her home..., the provider can start these devices remotely to read the data periodically or whenever needed.” EX1008, [0015]. By “[u]sing optional remote control features built in to the system, remote providers can control the software on the patient’s end.” *Id.*, [0080], [0085]. Kumar explains that the remote engine is “responsible for streaming...remote control information between multiple clients and hosts.” *Id.*, [0082]; Kirkness ¶254.

A POSITA would have been motivated to implement these features as it would have allowed the provider to remotely control/adjust the PAP device, after receiving via the remote engine “the data of the severity of the symptoms of the subject and/or the index” measured/calculated by the PAP device. For example, the provider may monitor the received data and adjust the PAP device to operate in different modes, e.g., operating as “bi-level pressure support” or as “an auto-titration mode of pressure support,” as discussed in Truitt. EX1007, 1:30-43. Moreover, as explained in Kumar itself, the remote control features (e.g., those discussed above) would have been beneficial as the “patients do not need to know how to operate the software.” EX1008, [0080]. Additionally, a POSITA would have been motivated to modify the processor of the PAP device, e.g., controller 38 disclosed in Truitt, such that it may be adjusted remotely (“at least one electronic component adapted to allow the PAP device to be adjusted remotely”) given that such a

processor/controller controls operations of the PAP device, and thus adjustments to the PAP device operations may be readily executed by the processor. EX1007, 2:38-42, 2:57-64, 6:6-10; Kirkness ¶255; Chatterjee ¶¶139-42.

A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described remote control features as it would have would have been a routine and conventional implementation of known methods using known hardware components performing their known functions, well within a POSITA's skills and ability to accomplish. Accordingly, Truitt in view of Kumar discloses and/or suggests this limitation. Kirkness ¶255; Chatterjee ¶¶139-42.

4. Claim 12: signal processing techniques

Truitt in view of Kumar discloses this limitation. Kirkness ¶¶256-50; Chatterjee ¶¶143-47. As discussed for [1.c], a POSITA would have been motivated to combine Truitt and Kumar's teachings such that the remote engine ("the remote internet site") is configured to receive and store the various data/index generated/calculated by the PAP device. *See* Section VII.C.5 (Ground 1, Claim 1, Limitation [1.c]). As discussed therein, Kumar explains that "the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis." EX1008, [0083]. Moreover, "[t]he storage device may also be used to store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system,"

“allow[ing] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device.” *Id.*; Section VII.C.5 (Ground 1, Claim 1, Limitation [1.c]).

A POSITA would have been motivated to configure the Truitt-Kumar combination such that it enables the remote engine (“remote internet site”) to retransmit to the first radio frequency wireless transceiver on the cell phone the claimed data/index, in whole or part, calculated by the PAP device. Kirkness ¶259. For instance, as a POSITA would have understood, the patient would be interested in reviewing data/index associated with prior use of the PAP device and/or a set of data/index integrated/summarized by the remote engine (including those provided by a physician, for example). Moreover, given that the remote engine may store the analysis of the data/index (e.g., those analyzed by the doctor), a POSITA would have found it beneficial to configure the remote engine to transmit those data/index, in whole (e.g., data/index stored from prior treatment(s)) or in part (e.g., analysis of the data/index provided by the doctor), to the first radio frequency wireless transceiver on the cell phone to allow the patient to review those information, which would have improved user experience, communication between the patient and the medical care provider, and patient compliance. *Id.*

A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described feature as it would have would have been a

routine and conventional implementation of known methods using known hardware components performing their known functions, well within a POSITA's skills and ability to accomplish. Kirkness ¶259.

5. Claim 13: Fourier transform technique.

Truitt in view of Kumar discloses this limitation for the same reasons discussed for claim 12. Kirkness ¶261; Chatterjee ¶148; Section VII.D.4 (Ground 1, Claim 12).

6. Claim 14: retransmit

Truitt in view of Kumar discloses this limitation. Kirkness ¶¶262-67; Chatterjee ¶¶149-52. As discussed for [1.c], a POSITA would have been motivated to combine Truitt and Kumar's teachings such that the remote engine ("the remote internet site") is configured to receive and store the various data/index generated/calculated by the PAP device. *See* Section VIII.C.5 (Ground 1, Claim 1, Limitation [1.c]). Kumar explains that "the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis." EX1008, [0083]. Moreover, "[t]he storage device may also be used to store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system," "allow[ing] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with

access to the storage device.” *Id.*; Section VII.C.5 (Ground 1, Claim 1, Limitation [1.c]).

A POSITA would have been motivated to configure the Truitt-Kumar combination such that it enables the remote engine (“remote internet site”) to retransmit to the first radio frequency wireless transceiver on the cell phone the claimed data/index, in whole or part, calculated by the PAP device. Kirkness ¶¶262-63. For instance, as a POSITA would have understood, the patient would be interested in reviewing data/index associated with prior use of the PAP device and/or a set of data/index integrated/summarized by the remote engine (including those provided by a physician, for example). Moreover, given that the remote engine may store the analysis of the data/index (e.g., those analyzed by the doctor), a POSITA would have found it beneficial to configure the remote engine to transmit those data/index, in whole (e.g., data/index stored from prior treatment(s)) or in part (e.g., analysis of the data/index provided by the doctor), to the first radio frequency wireless transceiver on the cell phone to allow the patient to review those information, which would have improved user experience, communication between the patient and the medical care provider, and patient compliance. *Id.*

A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described feature as it would have would have been a routine and conventional implementation of known methods using known hardware

components performing their known functions, well within a POSITA's skills and ability to accomplish. Kirkness ¶265.

Given that Claim 10 recites "and/or" when describing the information to be retransmitted, claim 10 requires one of "the data of the severity of the symptoms of the subject," "the index," "a second index" **or** "the data of usage related to the subject's treatment and the treatment's efficacy," in whole or part, calculated by the PAP device to be retransmitted. To the extent that the claim is read to require all of the above-listed information, it was well within the skill of a POSITA to implement the features discussed in claim 1 to transmit a "second" index, e.g., an index associated with the treatment efficacy of another sleep disorder such as central apnea. Kirkness ¶266.

To the extent that "retransmit" means sending the same data to the first radio frequency wireless transceiver of the cell phone at least twice, this would have been obvious. *B/E Aerospace, Inc. v. C&D Zodiac, Inc.*, 962 F.3d 1373, 1379 (Fed. Cir. 2020) (modifying prior art combination to include second recess was obvious because it was "nothing more than the predictable application of known technology"); *Ex parte Thomas Lederer*, 2014 WL 4980020, at *3 (P.T.A.B. Sept. 25, 2014) (agreeing that "it would have been obvious to one of ordinary skill in the art to simply repeat the search function ... a second time").

7. Claims 15 and 18: extended horizon, adaptive, predictive controller

Truitt alone or in view of the knowledge of a POSITA discloses this limitation. Kirkness ¶¶268-73; Chatterjee ¶¶153-56. Truitt discloses controller 38 is configured to control the gas flow provided by pressure generator 12 (“blower”) based on the conditions of the patient to “counteract or prevent” these conditions. EX1007, 2:57-3:11. A POSITA would have understood that the process of counteracting or preventing the patient’s conditions require the PAP device operation to adapt and/or predict the patient’s condition. For example, to counteract an obstructed airway, the air flow/pressure of the blower would have to be increased adaptively. To prevent an obstructed airway, the air flow/pressure of the blower would have to be predictively increased prior to the condition occurs.

A POSITA would have recognized that one or a combination of (1) the software implementing the above-described adapting and/or predicting method(s) and (2) the hardware (e.g., controller 38 and associated sensor) performing the method(s) constitutes the claimed “extended horizon, adaptive, predictive controller.” EX1013, 1:18-22 (“High performance, computationally efficient real-time dynamic *controller software and hardware* are required for use in complex multi-input, multi-output, nonlinear, time-varying systems that are operating in

challenging environments.”). Accordingly, Truitt in view of Kumar discloses and/or suggests this limitation. Kirkness ¶271; Chatterjee ¶156.

8. Claim 19: remote communication system with a third processor

Truitt in view of Kumar discloses this limitation. Kirkness ¶¶274-278; Chatterjee ¶¶157-63. Kumar discloses that the engine (“remote internet site”) is hosted on central server 106 (“a remote communication system”), which includes a network I/O processor (“a third processor”) that runs the engine. EX1008, [0067], [0082]. Kumar explains that the network I/O processor “is responsible for streaming device data, audio, video, messages, and remote control information between multiple clients and hosts. The processor may also handle data storage and retrieval of the streamed data.” *Id.*, [0082]. Thus, Kumar discloses its network I/O processor (“a third processor”) is “for reprocessing and/or outputting data.”

Kumar further discloses that “wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.” For example, Kumar “may allow for simultaneous storage, retrieval, *print*, analysis, and play back from anywhere in the world with access to the storage device” of the central server, where “a statistical summary report” may be provided. EX1008, [0083], [0092]. Additionally, as shown in Figure 1, the provider-side device

includes a graphical display for outputting received data. EX1008, [0067], [0074], [0014]; Kirkness ¶275; Chatterjee ¶161.

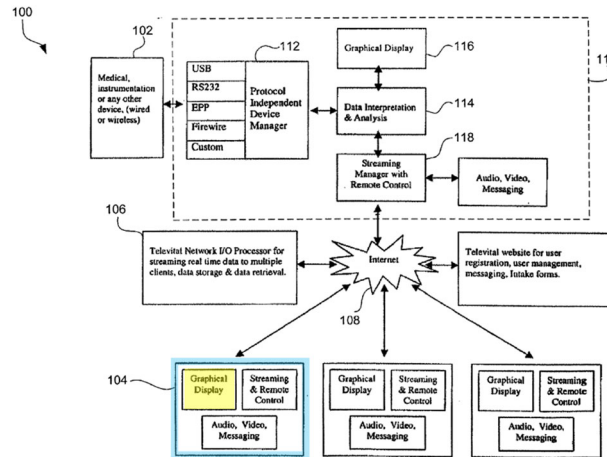


Fig. 1A

VIII. GROUND 2: TRUITT IN VIEW OF KUMAR AND DONG RENDERS OBVIOUS CLAIMS 15, 16, 18

A. Motivation To Combine

A POSITA would have been motivated to modify Truitt-Kumar to incorporate the controller teachings of Dong. Kirkness ¶279; Chatterjee ¶164. A POSITA would have incorporated the teachings of Dong, for example, to improve the performance of the Truitt-Kumar PAP controller. *Id.* The Dong controller addresses two potential limitations with existing adaptive controllers: computational complexity and sensitivity to the choice of input-output delays and model order prediction. EX1014, 1:38-42; Chatterjee ¶164. This is particularly relevant to process and identify respiratory patterns that are dependent on the patient. Kirkness ¶279.

B. Reasonable Expectation Of Success

A POSITA would have had a reasonable expectation of success in modifying Truitt-Kumar to incorporate the teachings of the Dong controller. Kirkness ¶¶280-82; Chatterjee ¶¶165-66. Specifically, a POSITA would have modified the Truitt-Kumar system to incorporate the Dong controller. Kirkness ¶280; Chatterjee ¶165. Neither Truitt nor Kumar specifies the use of any particular type of controller, and the Dong controller would have just been one of a limited number of design choices that a POSITA would have needed to select to implement the system. Kirkness ¶¶281-82; Chatterjee ¶¶166.

C. Claims 15 and 18: extended horizon, adaptive, predictive controller

Truitt in view of Kumar and Dong disclose this limitation. Kirkness ¶¶283-90, 292; Chatterjee ¶¶167-73, 176. To the extent that the Truitt-Kumar combination does not disclose the additional limitations of claims 15 and 18, a POSITA would have found it obvious to implement in view of Dong. Kirkness ¶288; Chatterjee ¶172.

Dong discloses that the controller is a “extended horizon adaptive block predictive controller” that includes a block control system and an adaptive block prediction system. EX1014, Abstract.

D. Claim 16: remote communication system with a third processor

Truitt in view of Kumar discloses this limitation for the same reasons discussed in claim 19 of Ground 1. *See* Section VII.D.8 (Ground 1, Claim 19); Kirkness ¶291; Chatterjee ¶¶174-75. The modification of the Truitt-Kumar combination in view of Dong does not materially affect the combination's disclosure of claim 19 as discussed in Ground 1. Kirkness ¶291; Chatterjee ¶175.

**IX. GROUND 3: TRUITT IN VIEW OF KUMAR AND WRIGHT
RENDERS OBVIOUS CLAIMS 17, 20**

A. Motivation To Combine

A POSITA would have been motivated to modify the Truitt-Kumar combination to incorporate the teachings of Wright to distinguish between and calculate the severity of obstructive and central apnea. Kirkness ¶¶293-97. A POSITA would have understood that the teachings of Wright would have advanced the purpose of Truitt “to provide a positive pressure therapy in which the pressure of gas delivered to the patient varies with the patient's breathing cycle, or varies with the patient's effort to increase the comfort of the patient.” EX1007, 1:30-34. Central apnea is not caused by the collapse of the upper airway, but by the nervous system, and therefore the treatment is not the same. Kirkness ¶294. For example, while continuous positive pressure is more commonly used for obstructive apnea, bi-level positive airway pressure (providing increased pressure at inhalation and decreased

pressure at exhalation) is more commonly used for central apnea. *Id.* ¶295. Thus, increasing positive pressure is more generally used to improve efficacy of treatment in obstructive apnea, but not central apnea. *Id.* As such, a POSITA would have been motivated to distinguish central apnea to minimize the pressure and increase comfort when such apnea occurs. *Id.* ¶296.

B. Reasonable Expectation Of Success

A POSITA would have had a reasonable expectation of success in modifying the Truitt-Kumar to incorporate the teachings of Wright. Kirkness ¶298. **First**, Truitt and Wright are analogous art. Both references describe CPAP systems that include flow sensors and processors. Like Truitt, Wright discloses that the processor analyzes the signals from the flow sensors. **Second**, the proposed modification involves a simple change in a programming. The modification involves nothing more than a combination of known prior art elements according to known methods and known techniques (programming a processor based on signals from flow sensors) to yield predictable results (provide signals that increase or decrease the gas pressure). Nothing in Kumar would have prevented the implementation of this modification. *Id.*

C. Claims 17 and 20: distinguish between and calculate the severity of obstructive apneas and central apneas

Truitt in view of Kumar and Wright discloses this limitation. Kirkness ¶¶299-310. To the extent that the Truitt-Kumar combination does not disclose the additional features of claims 17 and 20, a POSITA would have found it obvious to implement in view of Wright. Kirkness ¶299.

Wright explains that “CPAP devices can detect the presence of apneas, **distinguish between central and obstructive apneas** and provide an increased pressure if needed to stabilize an obstructed or partially obstructed airway.” EX1013, [0027]. In particular, Wright discloses that the CPAP device “has two treatment modes, a first mode for treating obstructive apneas and a second mode for treating central apneas,” where “[i]n the first mode, the device provides a generally constant pressure throughout a breathing cycle, but may vary the pressure in accordance with indications of partial or complete obstruction of the airway.” *Id.*, [0031]. In the second mode, “the apparatus provides a higher pressure to the mask during the inspiratory portion of the breathing cycle, the so-called IPAP, and a lower pressure to the mask during the expiratory portion of the breathing cycle, the so-called EPAP. This may be accomplished by monitoring the respiratory flow to the patient and defining a threshold level.” *Id.*, [0032]. Wright explains that “[t]he apparatus may be programmed with a particular protocol intended to identify

between alternative forms of CPAP treatment appropriate for the patient based upon an assessment of the patient's condition.” *Id.*, Abstract; Kirkness ¶¶304-303.

X. GROUNDS 4-6: THE COMBINATIONS OF GROUND 1-3 IN FURTHER VIEW OF MUMFORD RENDER OBVIOUS THE CHALLENGED CLAIMS

A. Motivation To Combine

A POSITA would have been motivated to modify the Truitt PAP device to incorporate the sleep efficacy algorithm of Mumford. Kirkness ¶¶311-15. **First**, it would have advanced the objective of Truitt “to provide a positive pressure therapy in which the pressure provided to the patient changes based on the detected conditions of the patient, such as whether the patient is snoring or experiencing an apnea, hypopnea or upper airway resistance.” EX1007, 1:35-39. A POSITA would have understood that “determin[ing] the efficacy of the CPAP treatment” and “vary[ing] operation parameters of the treatment,” would have improved the performance of the Truitt PAP device by increasing the pressure when obstructions may still be occurring. EX1009, Abstract; Kirkness, ¶312.

Second, it would have advanced the purpose of Truitt “to provide a positive pressure therapy in which the pressure of gas delivered to the patient varies with the patient’s breathing cycle, or varies with the patient’s effort to increase the comfort of the patient.” EX1007, 1:30-34. A major limitation of CPAP therapy was non-compliance due to discomfort. EX1016, 5. The modification would have been

advantageous to minimize the pressure applied, increase comfort, and therefore improve compliance. Kirkness, ¶313.

Nothing in Kumar, Dong, or Wright would have taught away from this modification. Kirkness, ¶314.

B. Reasonable Expectation Of Success

A POSITA would have had a reasonable expectation of success in modifying Truitt combinations with the teachings of Mumford. Kirkness ¶¶316-19. **First**, Truitt and Mumford are analogous art. Both references describe CPAP systems that include flow sensors and processors. Like Truitt, Mumford discloses that the processor analyzes the signals from the flow sensors. Kirkness, ¶317. **Second**, the proposed modification involves a simple change in a programming algorithm. The modification involves nothing more than a combination of known prior art elements according to known methods and known techniques (programming a processor based on signals from flow sensors) to yield predictable results (provide signals that increase or decrease the gas pressure). Kirkness, ¶318.

Nothing in Kumar, Dong, or Wright would have prevented the implementation of this modification. Kirkness, ¶319.

C. Challenged Claims

Grounds 1-3 establish that the combinations of prior art teachings a POSITA would have implemented to improve the Truitt PAP device disclose the challenged

claims. Sections VII-IX (Grounds 1-3). To the extent that Truitt does not disclose calculating “data of usage of the PAP device by the subject,” “data of severity of sleep disorder symptoms of the subject,” and/or “the index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject,” it would have been obvious to implement these features into the system resulting from these combinations in light of Mumford. Kirkness ¶¶320-21.

Like Truitt, Mumford discloses systems for treating obstructive sleep apnea using a PAP device that includes sensors for measuring physiological signals of the wearer. EX1009, Abstract. The physiological signals are used “to determine the efficacy of the PAP treatment” and “to vary operational parameters of the PAP device.” *Id.*; Kirkness ¶322.

Mumford discloses that “[t]he physiological information provided by the sensors is preprocessed by the monitoring unit 16 ... and then processed according to a sleep efficacy algorithm 36.” EX1009, 7:34-37. Specifically, Mumford discloses:

The sleep efficacy algorithm 36 *monitors the quality of sleep* for the wearer 18. ... Accordingly, the sleep efficacy control algorithm 36 can generate *sleep profile information for the wearer 18* (the sleep profile

information may *include data, such as a test score, related to efficacy and compliance*).

Id., 7:34-57.

Accordingly, Mumford discloses the various data features of claim 1. **First**, Mumford discloses calculating “data of usage of the PAP device by the subject,” as recited in claim 1, because Mumford tracks compliance. Mumford discloses that the sleep efficacy control algorithm can generate sleep profile information including a test score related to compliance. EX 1009, 7:42-46, 15:30-33. When a patient is not in compliance, the patient is not using the PAP device as prescribed. A POSITA would have understood that a test score related to compliance would refer to a measure of usage of the PAP therapy device. Kirkness ¶¶329-30.

Second, Mumford discloses calculating “data of severity of sleep disorder symptoms of the subject” because Mumford calculates data for the quality of sleep. For example, Mumford discloses that the sleep efficacy algorithm 36 monitors “the fragmentation of their sleep states” and “how many arousals the wearer 18 has experienced.” EX1009, 7:34-42. Mumford explains that Obstructive Sleep Apnea (OSA) is “caused by a blockage of the airway typically resulting from the collapse and closure of the soft tissue in the rear of the throat during sleep” and “[w]ith each apnea event, the brain arouses the individual in order for the individual to resume breathing, but consequently sleep is extremely fragmented and of poor quality.” *Id.*,

1:27-35; *see also id.*, 1:36-45, 1:46-55, 2:4-12. The more sleep fragmentation and arousals, the more severe the sleep disorder symptoms. A POSITA would have understood that the quality of sleep is “data of severity of sleep disorder symptoms of the subject.” Kirkness ¶¶332-33.

Third, Mumford discloses “the index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject” as a test score of efficacy. Mumford discloses a test score of efficacy (“index [of treatment efficacy of the subject using a PAP device is]”) is generated by sleep efficacy control algorithm 36 based on (1) quality of sleep, such as “the fragmentation of their sleep states” and “how many arousals the wearer 18 has experienced” and (2) compliance. EX1009, 7:34-46. Sleep fragmentation and “[a]rousals are important for determining ... the efficacy of therapy.” *Id.*, 11:44-47; Kirkness ¶334. A POSITA would have understood that by comparing the severity of the symptoms (the degree to which the patient is experiencing a high number of arousals and fragmentations) against the degree of compliance (the degree by which the patient is following the prescribed therapy), an index of efficacy of treatment can be determined. Kirkness ¶334.

Notably, “[t]he sleep efficacy algorithm 36 further generates a control signal to control the operational parameters of the CPAP device 14 such as activating or

deactivating the CPAP device 14 or altering the amount of pressure that is provided to the gas inlet 28 to improve the quality of sleep of the wearer 18.” *Id.*, 7:46-57. A POSITA would have understood that to generate the control signal to alter the pressure, the score related to efficacy would need to meet a certain threshold. Kirkness ¶335.

A POSITA would have been motivated and found it obvious to implement Mumford’s teaching in the Truitt-based combinations discussed in Grounds 1-3. Kirkness ¶336. For example, as discussed above, Mumford teaches using a sleep efficacy algorithm to adjust treatment. A POSITA would have understood that use the algorithm, with the Truitt’s air flow/pressure sensor(s), would have improved treatments. *Id.*

A POSITA would have also had the skill and reasonable expectation of success in combining the teachings of Mumford and Truitt (including Truitt-based combinations). Kirkness ¶337. Mumford states that “[t]he sleep efficacy algorithm 36 may use standard techniques, as is *commonly known to those skilled in the art.*” EX1009, 7:51-54. Moreover, it would have involved a combination of known technologies (PAP device that use sensors to detect and treat sleep disorder, as taught by the Truitt-based combinations) according to known methods (using sleep efficacy algorithm to adjust treatment as taught by Mumford) to yield the predictable result of a system including a PAP device of improved efficacy in treating sleep disorder,

as discussed above. Kirkness ¶¶337-38. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

XI. SECONDARY CONSIDERATIONS

There are no secondary considerations known to Petitioner that affect, let alone overcome—this strong case of obviousness. Should PO proffer any relevant evidence of secondary considerations, Petitioner reserves its rights to address.

XII. THE BOARD SHOULD REACH THE MERITS

A. No Denial Under *Advanced Bionics*

Institution is appropriate under § 325(d) because substantially the same art and arguments have never been presented to or considered by the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 6-11 (Feb. 13, 2020) (precedential). Specifically, neither Truitt nor Kumar were considered during prosecution, and therefore, these combinations were never before the Office.

B. No Denial Under *General Plastic*

Denial is not warranted under *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (Sept. 6, 2017) (precedential). Although Petitioner previously filed a PGR on the '284 Patent, the Board denied institution because it found the '284 Patent to be a pre-AIA patent. Thus, the Board never reached the merits. *Code 200, UAB, et al. v. Bright Data Ltd.*, IPR2022-00861, -

00862, Paper 18 (Aug. 23, 2022) (Director Decision) (“[A]llowing [petitioner] the opportunity to pursue a decision on the merits” in a second-filed petition, when the first-filed petition was not decided on the merits, “best balances the desires to improve patent quality and patent-system efficiency against the potential for abuse of the review process by repeated attacks on patents”).

C. No Denial Under *Fintiv*

Should PO seek denial under *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (Mar. 11, 2020) (precedential), Petitioner will seek permission to reply to address the facts and law as they stand at the time. Currently, there is no trial scheduled, thus *Fintiv* is inapplicable.

XIII. MANDATORY NOTICES

A. Real Parties-in-Interest

The real party-in-interest is ResMed Corp.

B. Related Matters

U.S. Patent Office records indicate that the '284 Patent is assigned to Cleveland Medical Devices Inc. (“PO”). Petitioner is currently asserting the '284 Patent in the following litigation filed on March 20, 2023: *ResMed Corp., v. Cleveland Medical Devices, Inc.*, 1:23-cv-02221-BMB (N.D. Ohio).

Petitioner will file petitions for *inter partes* review against U.S. Patent No. 11,375,921, U.S. Patent No. 11,690,512, U.S. Patent No. 11,786,680, U.S. Patent

No. 11,857,333, and U.S. Patent No. 11,872,029, which are also asserted in the same litigation.

Petitioner has filed requests for *ex parte* reexaminations on U.S. Patent No. 11,375,921 (90/019,700) and U.S. Patent No. 11,786,680 (90/019,705).

C. Notice of Counsel and Service Information

ResMed provides the following designation of counsel:

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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this petition. Petitioner consents to electronic service by e-mail.

D. Fee for *Inter Partes* Review

The Director is authorized to charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Account No. 50-2613.

E. Grounds for Standing

Petitioner certifies pursuant to 37 C.F.R. § 42.104(a) that the '284 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

XIV. CONCLUSION

For these reasons, Petitioner respectfully requests institution.

Respectfully submitted,

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CLAIM APPENDIX

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

[a] a non-transitory computer readable medium, the non-transitory computer readable medium comprising a first software, the first software executable by a first processor and configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the index on the cell phone, the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display;

[b] the PAP device with an enclosure further comprising:

[b.i] a blower having an air output,

[b.ii] an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data,

[b.iii] a second processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device,

[b.iv] a mask or a nasal cannula, and

[b.v] at least one second radio frequency wireless transceiver, the at least one second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor; and

- [c] a remote internet site, the remote internet site adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.
2. The system of claim 1, wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol.
 3. The system of claim 1, wherein the at least one second radio frequency wireless transceiver is configured to transmit the data to the remote internet site and/or the cell phone of the data of the severity of the symptoms of the subject and/or the index, and the data of usage via in part by cell towers.
 6. The system of claim 1, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the data measured, calculated and then transmitted to the remote internet site.
 12. The system of claim 1, wherein the airflow sensor data is processed by the second processor, in part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.
 13. The system in claim 12, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.
 14. The system of claim 1, wherein the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, calculated by the PAP device.

15. The system of claim 14, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.
16. The system of claim 15, wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.
17. The system in claim 16, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.
18. The system of claim 1, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.
19. The system of claim 1, wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.
20. The system in claim 1, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that foregoing
**PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO.
11,602,284** exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a),
contains 13,775 words and therefore complies with the type-volume limitations of
37 C.F.R. §42.24(a).

Dated: November 15, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO 11,602,284 AND EXHIBITS
EX1001-1049** are being served on November 15, 2024, via FedEx overnight mail
on counsel of record for U.S. Patent No. 11,602,284 as addressed below:

Robert Schmidt
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Cleveland, OH 44103
UNITED STATES

A courtesy copy is also being served on counsel for the patent holder in the
pending litigation):

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