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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, INC.,
Patent Owner

Case IPR2025-00247

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,872,029**

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1004	Curriculum Vitae of Jason Kirkness, Ph.D.
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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
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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.
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1032	F. Roux, et al., “Continuous Positive Airway Pressure: New Generations,” <i>Clinics in Chest Medicine</i> (2003)
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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)
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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)
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1050	WIPO Publication No. WO2004032719A2 to Burton et al. (“Burton”)
1051	U.S. Patent No. 5,309,921 to Kisner et al. (“Kisner”)
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1056	<i>ResMedica – clinical newsletter – An Interview with Dr. Michael Berthon-Jones</i> (2002)
1057	<i>Sleep Review – What’s New With CPAP Technology?</i> (2002), available at https://sleepreviewmag.com/sleep-treatments/therapy-devices/oral-appliances/whats-new-with-cpap-technology-2/
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1062	U.S. Pat. No. 11,602,284

I. INTRODUCTION

ResMed Corp. (“Petitioner”) respectfully requests *inter partes* review of claims 1-19 of U.S. Patent No. 11,872,029 (EX1001, “’029 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. By the early 2000s, network technology had found its way into sensor diagnostic devices such as PAP machines. Numerous benefits motivated such incorporation, including greater data access and convenience to patients, doctors, and providers as well as the ability to monitor compliance and adherence to therapy.

The ’029 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 ’029 Patent unpatentable.

II. IDENTIFICATION OF CHALLENGES

Ground 1: Claims 1-11, 13-16, 18-19 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious over Truitt¹ (EX1007) and Kumar² (EX1008).

Ground 2: Claims 14 and 15 are unpatentable under § 103 as being obvious in view of Truitt, Kumar, and Dong³ (EX1014).

Ground 3: Claims 12 and 17 are unpatentable under § 103 as being obvious over Truitt, Kumar, and Wright⁴ (EX1013).

Ground 4: Claims 1-11, 13-16, 18-19 are unpatentable under § 103 as being obvious over Truitt, Kumar, and Mumford⁵ (EX1009).

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

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

³ Dong is §§102(a), (b), and (e) prior art.

⁴ Wright is §§102(a), (b), and (e) prior art.

⁵ Mumford is §102(e) prior art.

Ground 5: Claims 10, 14-16 are unpatentable under § 103 as being obvious in view of Truitt, Kumar, Dong, and Mumford.

Ground 6: Claims 12 and 17 are unpatentable under § 103 as being obvious over Truitt, Kumar, Wright, and Mumford.

III. BACKGROUND

A. '029 Patent

The '029 Patent describes well-known PAP sleep disorder treatment devices implemented in a networked system. The specification discloses numerous embodiments, only briefly referencing one implemented in a “remote communication system.” *Id.*, 19:8-60.

B. Challenged Claims

The challenged claims are entitled to an effective filing date of no earlier than November 4, 2005.⁶ Petitioner challenges claims 1-19, where claim 1 is independent.

C. Prosecution History

In the first Office Action, the Examiner rejected most of the claims and indicated that then claims 30-31 would be allowable if rewritten to overcome the

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

rejection(s) under §101. EX1002, 116-117. Later, the applicant amended the claims and asserted, e.g., that the prior art does not teach “an airflow sensor being any type of sensor internal to the enclosure of the PAP device” (*id.*, 156) and “a second processor within the enclosure...” (*id.*, 158). *See also id.*, 145-165. The Examiner subsequently allowed the claims and provided reasons for allowance. *Id.*, 188-189.

IV. 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. Kirkness ¶44. Additional experience could substitute for less education, and additional education could likewise substitute for less experience. *Id.* ¶44; *see also* ¶¶45-46.

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.

V. 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). Notwithstanding, for

the purpose of this proceeding, this Petition adopts PO's interpretation of the following two phrase in the parallel district court action:

- “calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i) and ii)” (recited in limitation [1.b.iii])
- “related to the subject's treatment and the treatment's efficacy” (recited in limitation [1.c])

See Western Digital Corp. v. Spex. Techs., Inc., IPR2018-00084, Paper 14, 11 (Apr. 25, 2018) (petitioner need not “express its subjective agreement regarding correctness of its proffered claim construction or to take ownership of those constructions.”); *see also Polycom, Inc. v. directPacket Research, Inc.*, IPR2019-01235, Paper 19, 10 (Jan. 13, 2020); *VMWare, Inc. v. Cirba IP Inc.*, IPR2021-00008, Paper 10, 10 (May 7, 2021).

Specifically, PO's interprets limitation [1.b.iii] as definite (EX1054, 16-19) and asserts that “[f]or this calculation the system uses data regarding the severity of symptoms, data reflecting the subject's usage of the PAP device, and/or an index that is based on either or both of these categories of data.” EX1054, 16-17. PO asserts that a “POSITA would be able to use the severity and usage data to determine an index of the patient's sleep disorder symptoms and treatment efficacy.” *Id.*, 17.

PO states that “because the ’029 Patent is a continuation of the ’284 Patent, the Delaware Court’s claim construction order in regards to the ’269 calculating terms are...instructive” and goes on to state that “the Delaware Court acknowledged that a POSITA would recognize that each value calculated for a specific type of symptom data is representative of the level of severity of a subject’s sleeping disorder.” *Id.*, 19; *see also* 12, 13 (stating “generating and outputting” and “measuring and outputting” limitations are met when “[t]he claimed system can calculate when a subject has an apnea or hypopnea event using sensor data from the subject and the average number of such events over the total period of time spent sleeping, and determine a subject’s Apnea Hypopnea Index (“AHI”) severity level, which is an example of a medical measurement of the severity of a subject’s sleep disorder and is used to diagnose the severity of sleep apnea.”).

Further, PO interprets “related to the subject’s treatment and the treatment’s efficacy” (recited in limitation [1.c]) as definite (EX1054, 19-21) and asserts that “[t]wo terms at issue in the ’284 PGR involved data related to a subject’s treatment and its efficacy: ‘an index of treatment efficacy’ and a claim term covering retransmission of, inter alia, ‘the data of usage related to the subject’s treatment and the treatment efficacy, in whole or part, calculated by the PAP device’” and relies on the Patent Office’s determination that the ’284 specification disclosed that “the system uses data collected from the sensors to evaluate the severity of the subject’s

sleeping disorder and efficacy of the current treatment, and can adjust the treatment without human intervention as needed,’ such as by ‘regulat[ing] the physical or chemical treatment.’” EX1054, 21.

Otherwise, this Petition establishes the prior art meets each of the claim limitation under any reasonable construction.⁷ Kirkness¶142; Chatterjee, ¶66.

VI. GROUND 1: TRUITT IN VIEW OF KUMAR RENDERS OBVIOUS CLAIMS 1-11, 13-16, AND 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. Kirkness¶143; Chatterjee¶70. 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.

First, a POSITA would have been motivated to obtain more representative data. Kirkness¶¶144-145. A POSITA would have understood that if a patient is being monitored outside of their home, the data they obtained would be less

⁷ Petitioner reserves the right to argue alternative constructions in other proceedings, including indefiniteness. *See, e.g., Target Corp. v. Proxicom Wireless, LLC*, IPR2020-00904, Paper 11 at 11-13 (Nov. 10, 2020).

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. Kirkness¶146. 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]; Kirkness¶146. 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, 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" allowing "a provider to seek expert consultation for clinically difficult cases, by

sharing the patient history and medical test results online.” EX1008, [0083].” Kirkness¶146.

Third, a POSITA would have been motivated to provide health access to more people. Kirkness¶147; Chatterjee¶¶80-81. 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¶147; Chatterjee¶80.

Fourth, a POSITA would have been motivated to leverage the advances in mobile computing and wireless communications. Kirkness¶148; Chatterjee¶¶71-72. 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¶71. The sensors of Truitt would have been ideal to improve with these advances. EX1005, 2:3-5; Kirkness¶148; Chatterjee¶74. This is particularly true given the diagnostic advantages of using wireless, as opposed to wired, sensors. Kirkness¶148; Chatterjee¶72.

Last, a POSITA would have been motivated by the general market trend to implement consumer devices into intelligent systems. Chatterjee¶¶73-79. 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.*¶73. 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.*¶74; Kirkness¶149. Also connecting devices to the Internet has the additional benefit of more robust storage and processing of the data collected from the devices by central servers, such as that in Kumar. EX1008, ¶[0083]; Kirkness¶149.

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. Kirkness¶150; Chatterjee¶82.

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¶151; Chatterjee¶83.

Second, the sensors in Truitt were known to be implemented wirelessly. Kirkness¶152; Chatterjee¶84. At the time, many PAP devices and other sensor-based treatment and 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 in PAP machines to detect snoring and other conditions. EX1007, 3:4-9. Wireless microphones have been around since the 1950s. Chatterjee¶84.

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¶153; Chatterjee¶¶85.

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¶154.

C. Independent Claim 1

1. Preamble: PAP sleep disorder treatment system

To the extent limiting, Truitt discloses the preamble. Kirkness¶¶156-166; Chatterjee¶¶86-87. Truitt discloses a conventional “positive airway pressure (PAP) sleep disorder treatment system.” EX1007, 1:24-30.

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¶156.

As shown in Figure 1, Truitt discloses a conventional pressure support system 10 (an exemplary PAP sleep disorder 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¶157.

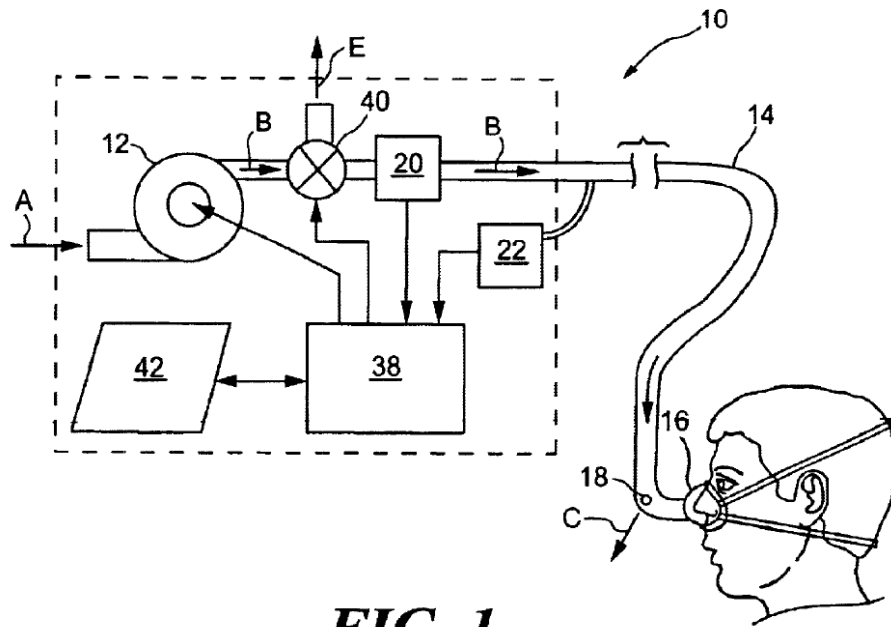


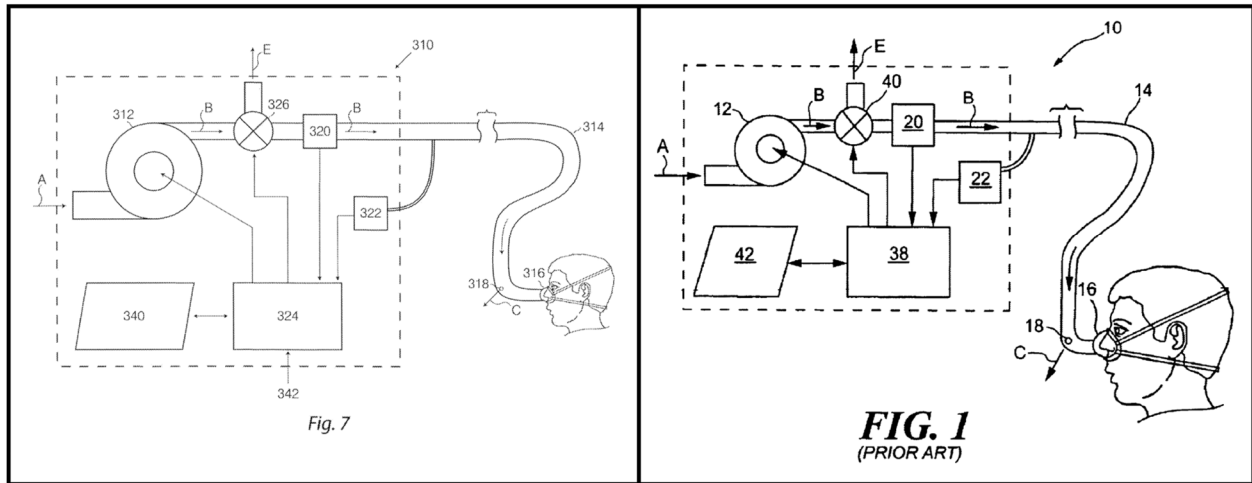
FIG. 1
(PRIOR ART)

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¶158.

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. 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 ¶¶159-161.

Truitt's conventional PAP system 10, as shown in Figure 1, is substantially similar, if not identical, to the “pressure support system” of the '029 patent, as shown in Figure 7. *See* EX1007, FIG. 1; EX1001, FIG. 7, 5:34, 22:54-23:30.



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. 3; Kirkness¶163.

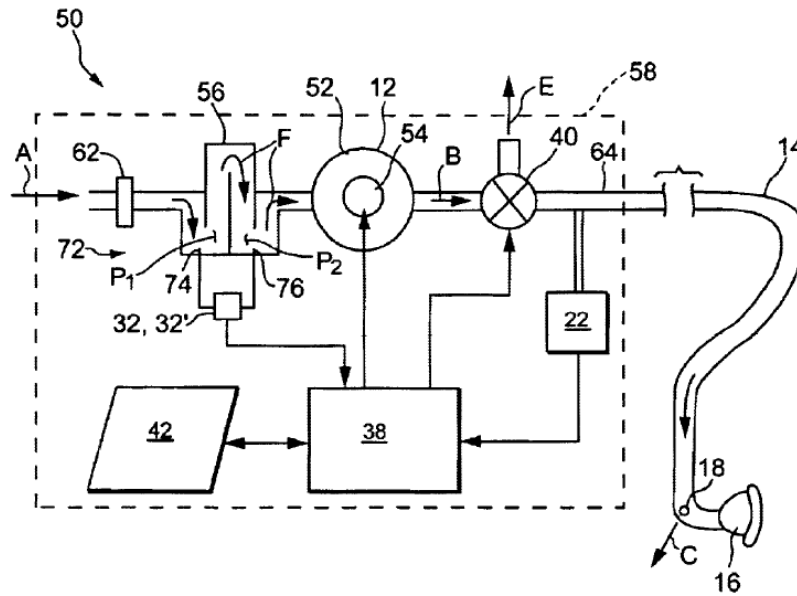


FIG. 3

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 (arrow B) to patient circuit 14 for delivery to a patient. EX1007, 5:1-3, 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.” *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 ¶164

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¶165.

2. [1.a]:cell phone to display an index of treatment efficacy based on a data of severity of sleep disorder symptoms and/or usage data

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶167-215; Chatterjee¶¶88-102.

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. 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. “The 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¶¶168-171; Chatterjee¶99.

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¶¶172-178; Chatterjee¶98.

Truitt discloses “[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.” EX1007, 3:4-11; *see also id.*, 2:57-59, 2:60-64. 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 ’029 Patent equates “conditions” and “symptoms” and acknowledging that there are different levels of conditions or symptoms, e.g., non-critical conditions versus critical conditions/symptoms. EX1001, 21:11-13 (“the subject’s physiological conditions moves toward various critical conditions or symptoms”). As PO maintains, the degree of presence of these events is data that indicates the degree of severity. *Id.*

A POSITA would have understood that the patient’s conditions, such as snoring, apneas, and hypopneas, are data of different levels of severity of sleep disorder symptoms. Kirkness ¶¶175-178.

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

Kirkness¶¶179-186; Chatterjee¶100. 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 (e.g., the number of apnea and hypopnea events) to "counteract or prevent these conditions" (*id.*, 3:4-11). A POSITA would have understood that determining whether to increase/decrease pressure/flow based on patient conditions requires calculating the effectiveness of the PAP treatment system (i.e., an index of treatment efficacy) to meet the desired prescription pressure level and/or "counteract or prevent these conditions." Kirkness¶¶179-180. The "apnea hypopnea index" or "AHI" is a measured number of apnea and hypopnea events per unit time. EX1012, 8:8-17. Because AHI includes the detection of hypopnea events (in addition to apnea events), a POSITA would have known that AHI could be calculated based on the number of apneas and hypopneas detected by Truitt. EX1007, 3:4-11 (controlling "the flow of breathing gas and the pressure level thereof" based on the detection of "snoring, apneas, hypopneas, etc."); Kirkness¶¶181-183. Moreover, PO expressly identified AHI severity level as an example of a medical measurement of the severity of a subject's sleep disorder. EX1054, 12 ("[A] subject's Apnea Hypopnea Index ('AHI') severity level, which is an example of a medical measurement of the severity of a subject's sleep disorder and is used to diagnose the severity of sleep apnea."), 13 ("a POSITA would

recognize that each value calculated for a specific type of symptom data or index is representative of the level of severity of a subject's sleeping disorder. Jafari¶39. And finally, a POSITA would understand the processor could be programmed to calculate a subject's AHI."); *see also*, EX1017, 35-36, 39 (PO admitting the Apnea- Hypopnea Index was an "indicator of the level of severity of a patient's sleep disordered breathing" during the prosecution of an ancestor patent).

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. Kirkness¶184.

Truitt's PAP system operates in the materially same way as the '029 patent. Kirkness¶182. Like Truitt, the '029 patent's PAP system uses sensor signals to adjust the treatment based on the patient's conditions/symptoms. EX1001, 22:43-50; *see also* EX1010, 10 (PO indicating U.S. Pat. No. 11,602,284 at 22:37-45 describes determining the claimed "index").⁸ PO states that "[i]n this context—

⁸ U.S. Patent No. 11,602,284 (EX1062) is the parent the '029 Patent. The '284 Patent and the '029 Patent share the same specification, including the disclosure PO

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 data collected while using the PAP device relating to the severity of the patient’s symptoms (e.g., the number of apnea and hypopnea events) to control the “pressure and/or flow” in order to “counteract or prevent these conditions” (EX1007, 3:4-11), including at least an auto-titration mode, Truitt discloses an “index [of treatment efficacy of the subject using a PAP device is] based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject.” Kirkness¶¶185-186.

indicated as describing determining the claimed “index.” *Compare* EX1001, 22:43-50 *with* EX1062, 22:37-45.

Fourth, Truitt in view of Kumar discloses “*a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone an index of treatment efficacy of the subject using a PAP device, the index based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, and a display.*” Kirkness¶¶187-215; Chatterjee¶¶89-96.

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¶189. 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].

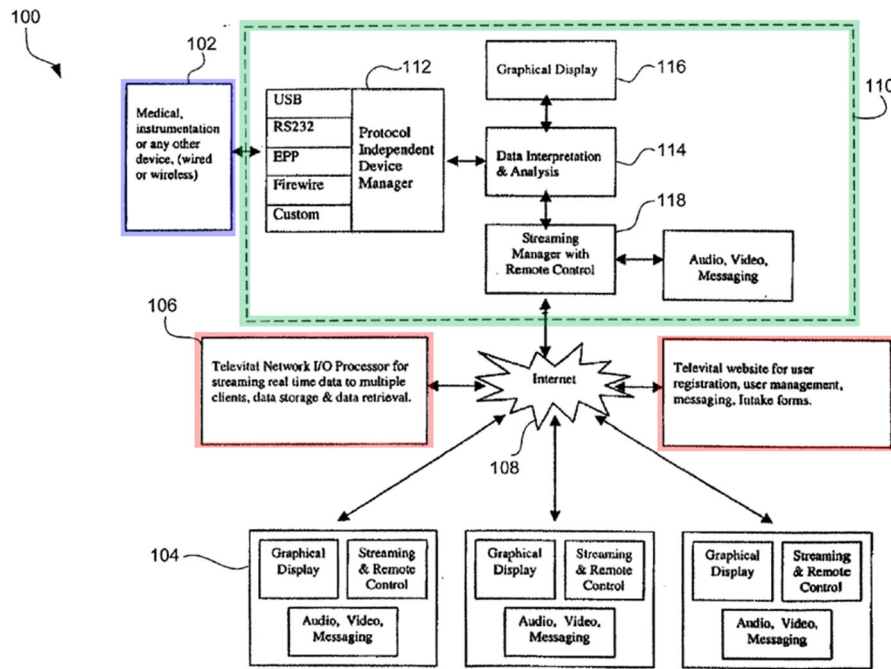


Fig. 1A

EX1008, FIG. 1A

Kumar discloses “a non-transitory computer readable medium.” Kirkness¶202; Chatterjee¶90. Specifically, Kumar discloses “[t]he present invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium,” e.g., the memory on the computing device. EX1008, ¶ [0020].

Kumar discloses a “cell phone.” Kirkness¶¶203-204; Chatterjee¶95. Kumar discloses computing device 110 may be a wireless phone (*cell phone*) or pocket PCs, e.g., an IPAQ device. EX1008, ¶ [0072]; EX111, 2.

Kumar discloses “at least one first radio frequency wireless transceiver.” Kirkness¶205; Chatterjee¶96. 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¶96.

Kumar discloses the “first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display [data] on the cell phone to display to a subject for viewing.” Kirkness¶¶206-209; Chatterjee¶¶92-94. 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 wireless telephone (*cell phone*) and display that data, including a index of treatment efficacy, on the display of the wireless telephone for the patient’s viewing (*display to a subject for viewing*). Kirkness¶¶210-211; Chatterjee¶94. 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¶211; Chatterjee¶92.

A POSITA would have been motivated and found it obvious to combine the teachings of Truitt and Kumar to implement the claimed features recited in limitation [1.a]. Chatterjee ¶¶ 101-102. A POSITA would have been motivated to configure the PAP device of Truitt to wirelessly transmit to a patient's cell phone data associated with the patient's treatment consistent with Kumar's teaching of computing device 110 receiving data wirelessly from patient-side device 102 and displaying data to the user described above. *Id.*

Such a configuration would provide for various data to be presented to the patient including “an index of treatment efficacy of the subject using a PAP device,” “a data of severity of sleep disorder symptoms of the subject,” and “a data of usage of the PAP device by the subject” and display the data/index and associated information to the patient. This feature/configuration would provide the patient with the ability to view the data/index on their personal cell phone and to store their medical information and treatment data for later viewing from their cell phone when they are away from their PAP device and to see first-hand how they are responding to treatment, and therefore encourage the patient to comply with the prescribed treatment. Additionally, the combined device would have a reduced form factor improving the device's portability and making the combination PAP device more suitable for use during travel or in confined spaces. Moreover, a POSITA would have been motivated to transmit the data/index from the PAP device to the cell phone

via certain wireless protocol(s) given that such a feature was known/prevalent at the time of the alleged invention. Kirkness¶¶212-214; Chatterjee¶¶70-81.

A POSITA would have had the skill and a reasonable expectation of success in combining the teachings of Truitt and Kumar. Kirkness¶¶215-217; Chatterjee¶¶82-85. 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, 7:2-6 (describing that the apparatus is a PAP device); EX1044, [0006], [0008]-[0009], 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¶217; Chatterjee¶85; *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

3. [1.b]-[1.b.iv] the PAP device and index

Truitt discloses limitations [1.b]-[1.b.iv]. Kirkness¶¶218-225; Chatterjee¶¶103-112. As shown in Figure 3, 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 within housing 58 (*blower having an air output within the enclosure*) 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 VI.C.1 (Ground 1, Claim 1, Preamble); Chatterjee¶¶104-105.

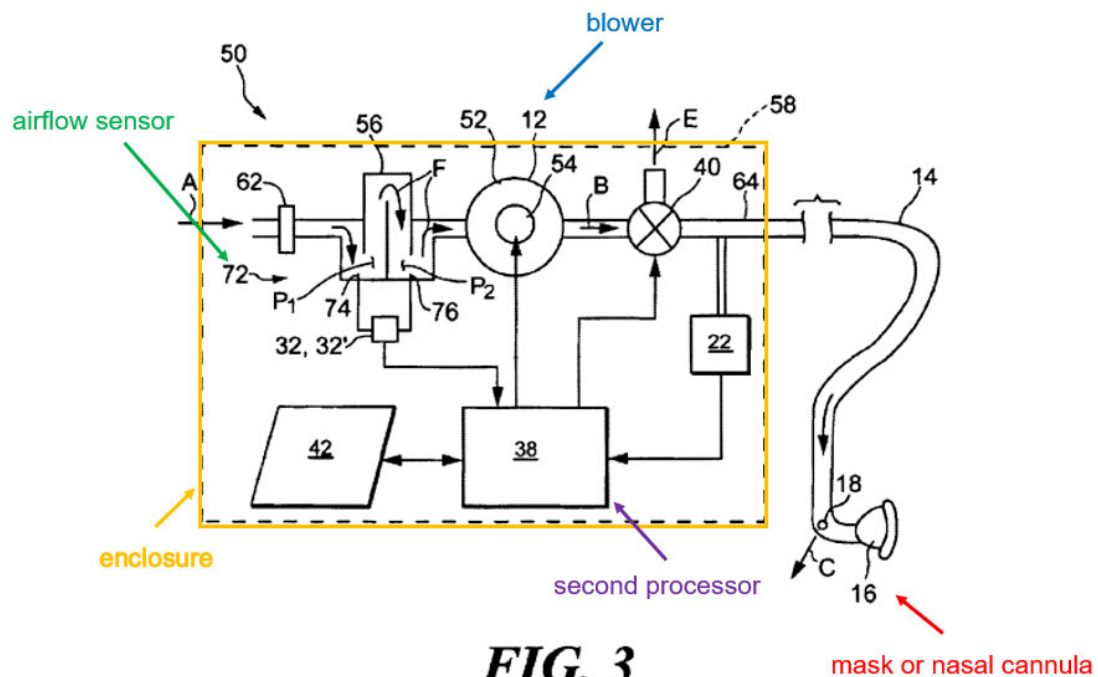


FIG. 3

EX1007, FIG. 3 (annotated)

Truitt also discloses the PAP device includes flow sensing system 72 within housing 58 (*airflow sensor being any type of sensor internal to the enclosure of the PAP device*), 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 device and outputting airflow sensor data*). EX1007, 6:11-62; Kirkness¶219; Chatterjee¶106.

Additionally, as discussed for [1.a], Truitt discloses controller 38 within housing 58 (*second processor within the enclosure*) receives signals provided by flow sensing system 72 (*adapted for receiving the airflow sensor data*) (EX1007, 6:11-17) for calculating “i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i) and ii)).” Kirkness¶220; Chatterjee¶107; *see also* Section VI.C.2 (Ground 1, Claim 1, Limitation [1.a])).

As discussed for [1a], Truitt discloses calculating “i) the data of a severity of the sleep disorder symptoms of the subject” because it discloses monitoring the patient’s condition, and specifically detecting snoring, apneas, and hypopneas. Kirkness¶221; Chatterjee¶110; *see also* Section VI.C.2 (Ground 1, Claim 1, Limitation [1.a])).

Also discussed for [1a], Truitt discloses calculating “ii) the 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. Kirkness¶222; Chatterjee¶111; *see also* Section VI.C.2 (Ground 1, Claim 1, Limitation [1.a])).

Additionally as discussed in [1a], Truitt discloses “iii) the index [of treatment efficacy of the subject using a PAP device is] based in whole or in part on either i) or ii) or both i) and ii).” Kirkness¶223; Chatterjee¶112; *see also* Section VI.C.2 (Ground 1, Claim 1, Limitation [1.a])).

Truitt additionally discloses the PAP device includes a patient interface device 16, e.g., a mask or a nasal cannula connected to the enclosure. EX1007, 1:56-61, 6:2; Kirkness¶224; Chatterjee¶113.

4. [1.b.v] second radio frequency wireless transceiver within the enclosure for transmitting i) and ii), and/or iii); and

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶226-234; Chatterjee¶¶114-123. 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 “i) the data of a severity of the sleep disorder symptoms of the subject,” “ii) the data

of usage of the PAP device by the subject” and/or the “iii) the index based in whole or in part on either i) or ii) or both i) and ii).” *See* Section VI.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 within housing 58 of the PAP device to facilitate wireless communication with the cell phone to transmit the above-described data. Kirkness¶227; Chatterjee¶115.

Kumar discloses 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¶228; Chatterjee¶226.

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¶229;

Chatterjee¶117. 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. Kirkness¶230; Chatterjee¶117.

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¶231; Chatterjee¶118; EX1018, 9:56-57; 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¶231; Chatterjee¶118. 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¶119. 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¶119. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331 (Fed. Cir. 2009).

Additionally, a POSITA would have been motivated to implement the radio frequency wireless transceiver within housing 58 of the PAP device to prevent inadvertently damaging the transceiver and to protect the transceiver in order to increase PAP device’s product lifetime. Kirkness¶232; Chatterjee¶120.

A POSITA would have had the skill and a reasonable expectation of success in implementing a radio frequency wireless transceiver within housing 58 of the PAP device. Kirkness¶¶233-234; Chatterjee¶¶121-122. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, EX1045, Fig. 3; EX1013, [0029]; EX1044, FIG. 3, [0006]-[0007], [0023], [0030], [0070]. It was also known to install a wireless communication transceiver and/or a network card within a housing of a PAP device. EX1013, [0029], FIG. 1 (showing that a communication port or module 10, which may be a wireless communication transceiver and/or a network card is implemented within a PAP device).

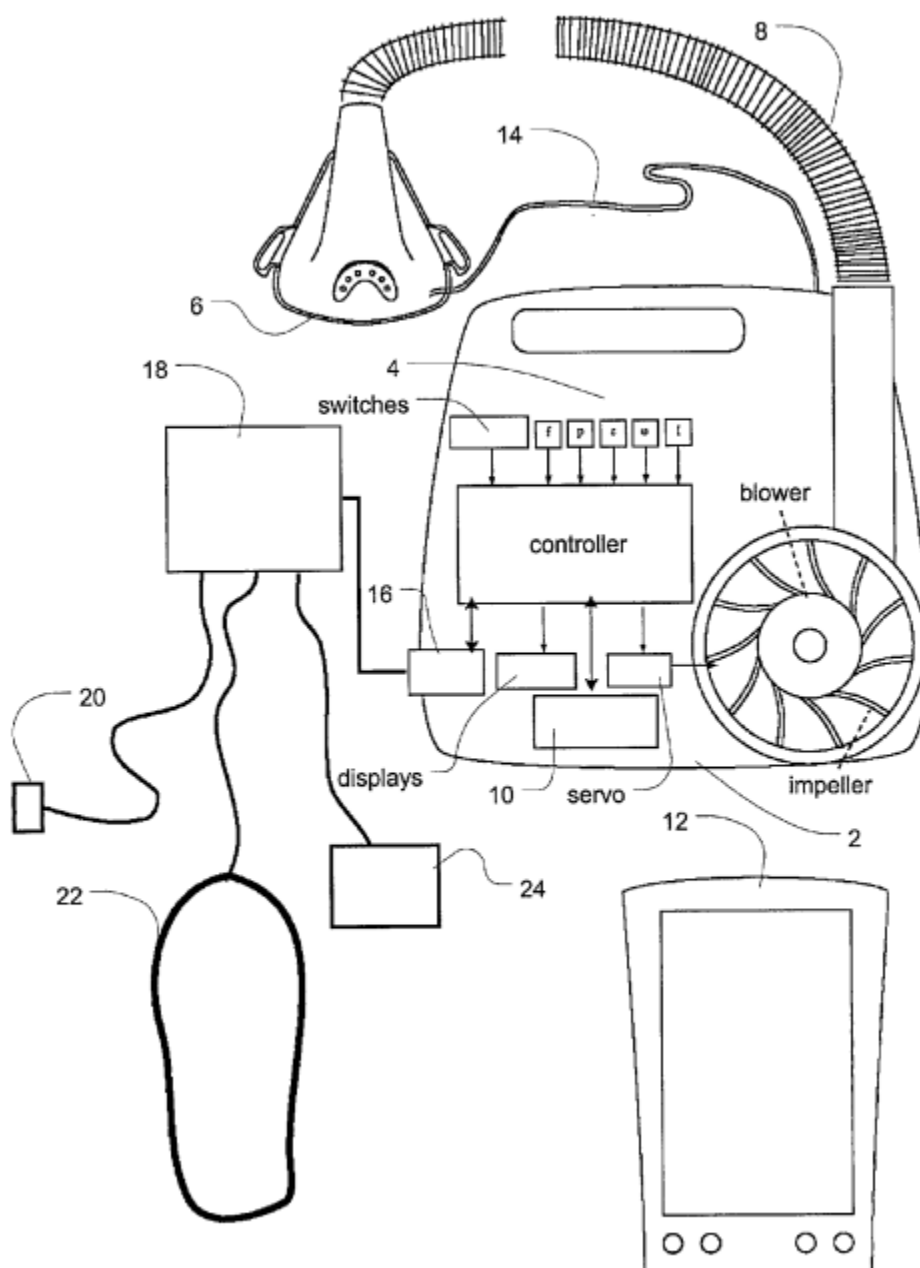


Fig. 1

EX1013, FIG. 1

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 within the PAP device's housing to facilitate wireless communication with the cell phone. Chatterjee¶123; *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 renders obvious this limitation. Kirkness¶¶235-251; Chatterjee¶¶124-137. 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 VI.C.2 (Ground 1, Claim 1, Limitation [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....”). “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¶236; Chatterjee¶¶126-127.

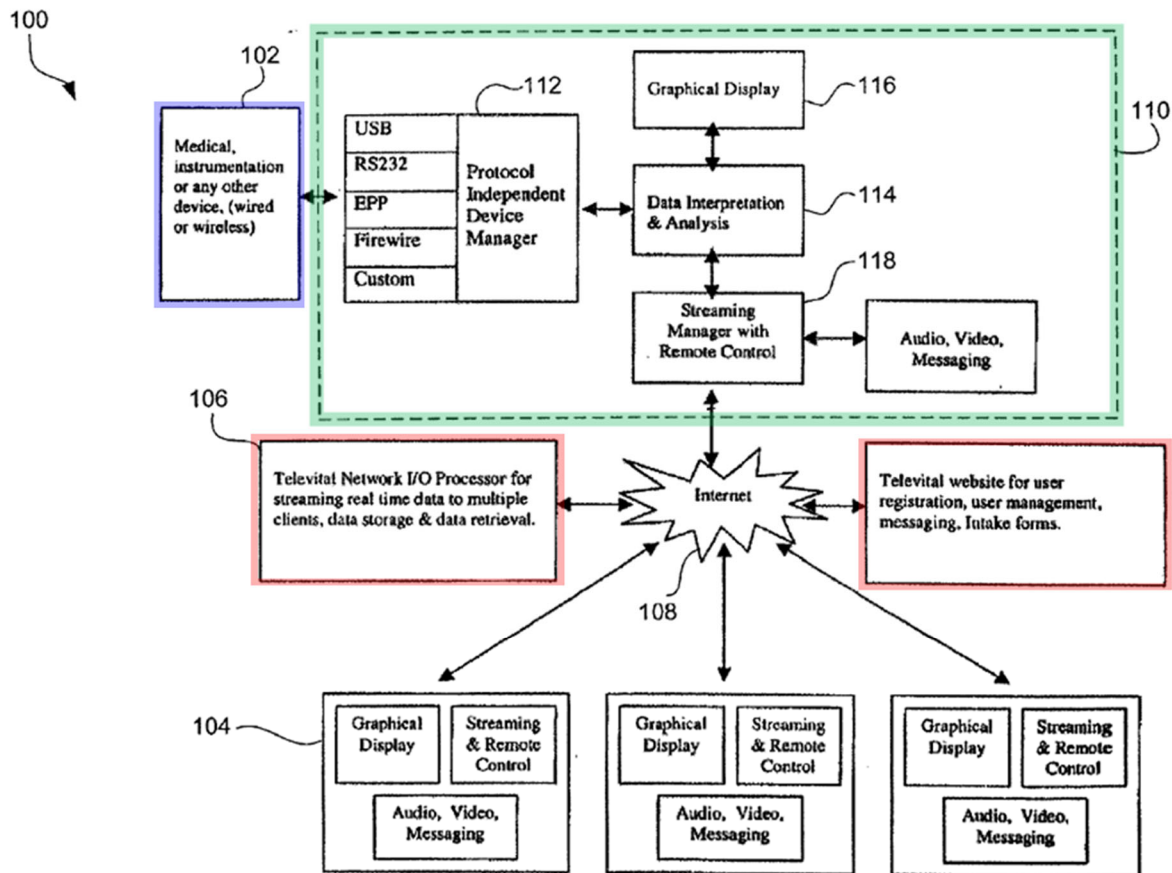


Fig. 1A

EX1008, FIG. 1A

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...from a patient to a health care provider.” *Id.*; *see also id.*, [0068]. 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]. The patient-side device may communicate through a wireless interface and may communicate over the Internet. *Id.*, [0013]; Kirkness¶237.

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¶238; Chatterjee¶128.

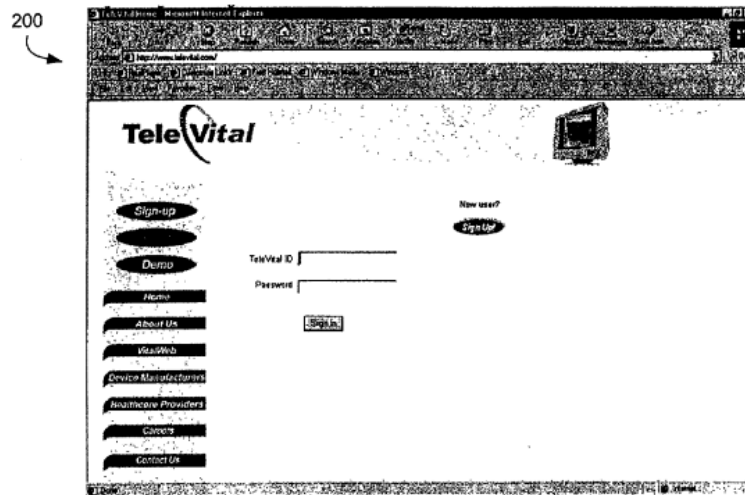


Fig. 2

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 to allow real-time remote access by the doctor/patient. 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¶¶239-240; Chatterjee¶129.

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 “i) the data of a severity of the sleep disorder symptoms of the subject,” “ii) the data of

usage of the PAP device by the subject” and “iii) the index based in whole or in part on either i) or ii) or both i) and ii).” Kirkness¶¶241-244; Chatterjee¶¶132-135.

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¶¶243-244; Chatterjee¶¶133.

Moreover, a POSITA would have understood that storing data at the secured storage of the engine would have provided a backup of the data. A POSITA would have appreciated that a copy of the data stored at the engine would have beneficially served as backup data in the event when the PAP device and/or the patient’s cell

phone is misplaced or malfunctioned, losing access to the data thereon. Kirkness¶245; Chatterjee¶135.

A POSITA would have also had a reasonable expectation of success in implementing the above-discussed feature in the Truitt-Kumar combination. Kirkness¶¶246-249. 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¶136. 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. Kirkness¶250; Chatterjee¶136; *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¶251; Chatterjee¶137; *see also* Section VI.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. remote communication system with third processor and recording medium for reprocessing, storing and/or outputting data

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶252-256; Chatterjee¶¶138-144. 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 VI.C.2 (Ground 1, Claim 1, Limitation [1.a]). Kumar additionally discloses 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.

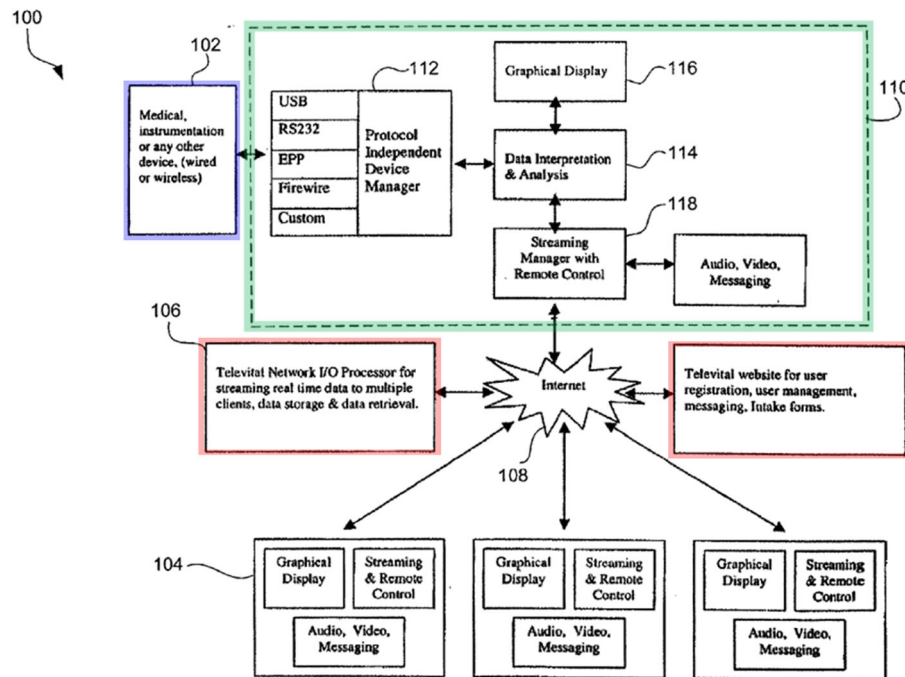


Fig. 1A

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.b.v], the Truitt-Kumar combination discloses transmitting “i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i) and ii)” 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 VI.C.4; Kirkness¶254. The Truitt-Kumar combination

therefore discloses that the patient data received from the first RF wireless transceiver (of the cell phone or computing device 110) and/or the second RF wireless transceiver (of the PAP device) is transmitted to the remote internet site. Kirkness¶254.

Kumar discloses the engine (*remote internet site*) is adapted to be hosted on central server 106 (*a remote communication system*), which includes a network I/O processor (*a third processor*) that runs the engine, and a secured storage device (*a recording medium*). Kirkness¶255; Chatterjee¶¶139-141; EX1008, [0067], [0082], [0083]. 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]. Additionally, “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis.” *Id.*, [0083]. Thus, Kumar discloses its network I/O processor (*a third processor*) and a secure storage device (*a recording medium*) is “for reprocessing, storing and/or outputting data.”

Kumar further discloses “the remote internet site is adapted...to further output the reprocessed and/or outputted data.” Kirkness¶256; Chatterjee¶141. 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].

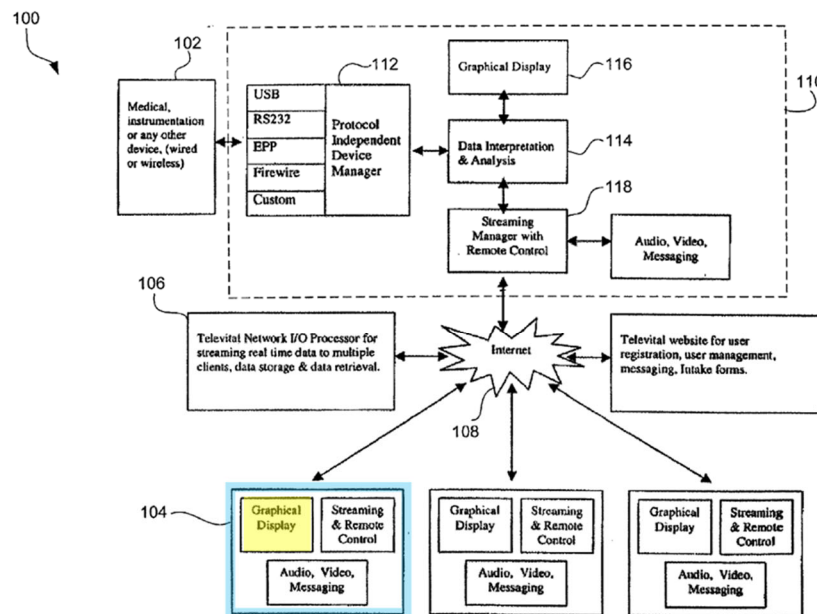


Fig. 1A

2. Claims 3/5: Bluetooth

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶257-260, 263; Chatterjee¶¶145-149. As discussed for [1.a], Kumar discloses the computing device 110 (*cell phone*) may be an IPAQ device. Section VI.C.2 (Ground 1, Claim 1, Limitation [1.a]). 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.

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¶148.

A POSITA would have also had a reasonable expectation of success in implementing Bluetooth capability in the PAP device. Kirkness¶259; Chatterjee¶. It was known at the relevant time to equip a PAP device with Bluetooth capability. 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¶260; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

3. Claim 4: cell towers

Truitt in view of Kumar combination renders obvious this limitation. Kirkness¶¶261-262; Chatterjee¶¶150-153. As discussed for [1.a], Kumar discloses that the computing device 110 may be an IPAQ device. Section VI.C.2 (Ground 1,

Claim 1, Limitation [1.a]). At the relevant time, 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.

As discussed for limitation [1.b.v], the Truitt-Kumar combination discloses transmitting data wirelessly from patient-side device 102 by a radio frequency wireless transceiver in the PAP device (*second radio frequency wireless transceiver*) to computing device 110 (*cell phone*), which in turn transmits the “data” via the Internet to the central server. *See* Section VI.C.4 (Ground 1, Claim 1, Limitation [1.b.v]). 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 is adapted to transmit the data to the remote engine (*remote internet site*) by using the IPAQ device’s wireless protocol “in whole or in part via cell towers.” Chatterjee¶153.

4. Claims 6/7: reprogram or modify second software from remote internet site

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶264-267; Chatterjee¶¶154-159. As discussed for the preamble, Truitt discloses that its PAP device includes controller 38 (*second processor*) for “controlling the operation of

the pressure support system, monitoring the operation of the system, or monitoring the patient.” EX1007, 6:1-10; *see also id.*, 2:57-60 (“[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.”), 5:36-59. A POSITA would have understood that Truitt’s PAP device includes a certain program/code (*at least one second software*) that is executed by controller 38 to perform the disclosed processes, including calculating “data of usage of the PAP device by the subject,” “data of severity of sleep disorder symptoms of the subject,” and “index [of treatment efficacy of the subject using a PAP device],” as discussed for limitations [1.a] and [1.b.iii]-[1.b.iii.3]. Kirkness¶264; Chatterjee¶156. Moreover, a POSITA would have understood that such a program/code is stored on a certain storage medium (*memory*) to allow the PAP device to repeatedly perform the disclosed processes after power cycles. *Id.*

Kumar discloses “remote control features built in to the system,” where “remote providers can control the software on the patient’s end.” EX1008, [0080]. Additionally, a “remote client module...allows remote hosts to view the data being streamed in real time” and “can also control the software being run on the patient’s and/or provider's end.” *Id.*, [0085]. Moreover, Kumar explains that “[i]ntegration of the **client-side device driver** is performed in two steps”: “[f]irst, the appropriate device driver is incorporated into the system, preferably via a web page,” and “[a]

customized or standard GUI is incorporated or developed based on user and/or device manager specifications.” *Id.*, [0086]. “Thus, a user does not have to install any software, and **updates to the software are done by simply running the latest software from a website.**” *Id.* Kumar’s therefore discloses the ability to reprogram or to modify the patient-side device (e.g., Truitt’s PAP device) or the software on the patient-side device (e.g., the second software on the PAP device) from the remote internet site. Kirkness¶265; Chatterjee¶156.

A POSITA would have been motivated to implement these features as they would allow the PAP device to be reprogrammed or its software modified remotely from the browser-based engine (*wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site*). Chatterjee¶158. 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, 8:13-24. 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]) and “a user does not have to install any software, and updates to the software are done by simply running the latest software from a website” (*id.*, [0086]). Additionally or alternatively, for similar reasons as discussed above, a

POSITA would have likewise been motivated to modify the processor of the PAP device, e.g., controller 38 disclosed in Truitt, such that it may 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 and run by the software. EX1007, 2:38-42, 2:57-64, 6:6-10; Kirkness¶265; Chatterjee¶158.

A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described reprogramming/modifying 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. Kirkness¶¶266-267; Chatterjee¶159.

5. Claim 8/11: signal processing techniques

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶268-271; Chatterjee¶¶160-166. As discussed in Ground 1 above for limitation [1.b.iii]-[1.b.iii.3], Truitt discloses “a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i).” Thus, Truitt discloses that “the airflow sensor data is processed by the second processor.”

While Truitt does not expressly disclose the airflow sensor data is processed/calculated by the second processor, at least in part, using “a discrete Fourier transform technique” or “a fast Fourier transform technique,” a POSITA would have found it obvious to implement this feature in view of Kumar. Chatterjee¶164. Kumar discloses that data received by the patient-side device may be analyzed “using FFT, DFT, etc.” EX1008, [0075]. A POSITA would have understood that FFT and DFT each refers to the claimed “fast Fourier transform technique” and “discrete Fourier transform technique,” which is consistent with the ’029 patent. In fact, the ’029 Patent states that “[a] Discrete Fourier transform (DFT), and its numerically efficient complement the Fast Fourier Transform (FFT), both provide frequency information of a digitized signal or data from the sensors.” EX1001, 21:32-34; Kirkness¶269; Chatterjee¶164.

A POSITA implementing the Truitt-Kumar combination would have been motivated to use the FFT and DFT techniques to process/calculate the received airflow sensor data as these techniques were well-known and Truitt itself does not expressly teach the techniques used to process/calculate the data. Kirkness¶270; Chatterjee¶165.

A POSITA would have also had a reasonable expectation of success in implementing this feature in the Truitt-Kumar combination. Moreover, it would have involved a combination of known technologies, e.g., a known PAP device that

processes/calculates airflow sensor data (Truitt)) according to known methods of analyzing patient-side device data using FFT or DFT (Kumar)) to yield the predictable result of a PAP device where the airflow sensor data is processed/calculated by the second processor, in part, using the FFT or DFT technique, as discussed above. Kirkness¶271; Chatterjee¶166.

6. Claim 9/13: retransmit

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶272-276; Chatterjee¶¶167-177. 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 adapted to receive and store the various data/index generated/calculated by the PAP device. *See* Section VI.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 VI.C.5 (Ground 1, Claim 1, Limitation [1.c]).

A POSITA would have been motivated to implement Kumar's teaching 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 (*the data, in whole or in part, the data of i) and ii), or i), ii), and iii) or a second index related to the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device*). Kirkness¶¶273-274. 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, e.g., those provided by a physician). Kirkness¶¶273-274; Chatterjee¶175. Moreover, given that the remote engine may store the analysis of the data/index (e.g., those analyzed by the doctor) and "for later access" and "retrieval" (EX1008, [0083]), 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¶¶275; Chatterjee¶¶176-177. 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¶¶276. 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. Claim 10/16: output for review by clinician to determine treatment efficacy

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶277, 283; Chatterjee¶¶178-184. Kumar discloses that “wherein the remote communication

system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer and/or a second display for review by a clinician to determine the treatment efficacy.” Kumar “allow[s] 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]; Chatterjee¶184. As such, “a provider is able to monitor the patient/client’s physiology for research, keeping track of documentation, performing analysis, managing and maintaining records, diagnosing the patient/client, providing treatment in real-time to the patient/client, etc.” and “the patient/client may be remotely ‘examined’ by an expert or other medical personnel.” *Id.*, [0014].

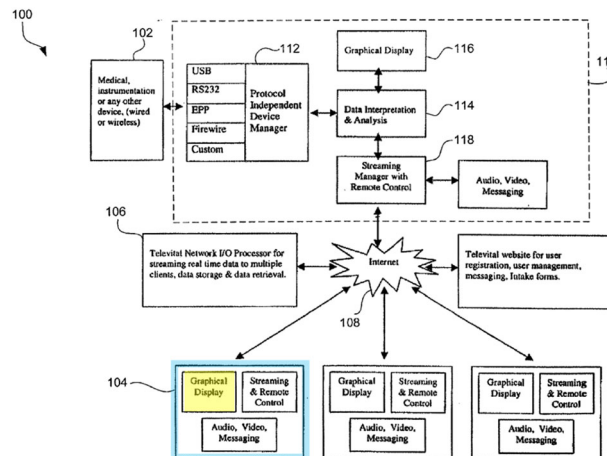


Fig. 1A

8. Claim 14/15: adaptive controller

Truitt alone or in view of the knowledge of a POSITA renders obvious these additional limitations. Kirkness¶¶280-282; Chatterjee¶¶185-188. 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. 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 “adaptive controller” of claim 14 and the claimed “adaptive predictive controller” of claim 15. 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.”); Chatterjee¶186.

9. Claim 18: remote adjustment

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶284-288; Chatterjee¶¶189-196. As discussed for [1.c], the Truitt-Kumar combination discloses the “remote internet site” “receiv[es] i) and ii), or i), ii), and iii), related to the subject's treatment and the treatment's efficacy in whole or part, generated by the PAP device.” *See* Section VI.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¶286.

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 “i) and ii), or i), ii), and iii), related to the subject's treatment and the treatment's efficacy in whole or part, generated by the PAP device,” i.e., “the data received by the remote internet site.” Chatterjee¶194. 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¶287; Chatterjee¶195.

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. Kirkness¶288; Chatterjee¶196.

10. Claim 19: reprogrammed/modified remotely

Truitt in view of Kumar renders obvious this limitation. Kirkness¶¶289-292; Chatterjee¶¶197-203. Kumar discloses that the engine sends “plug-in which allows the computing device to communicate with the patient-side device.” EX1008, [0018], [0074]. Moreover, Kumar explains that “the entire system runs in the

context of an Internet browser” and that “a user does not have to install any software, and updates to the software are done by simply running the latest software from a website.” *Id.*, [0086]. Thus, Kumar discloses and/or suggests the software on the cell phone (*first software*) may be “reprogrammed or modified remotely.”

A POSITA would have been motivated to implement these features as it would allow the software running on the patient’s cell phone to be reprogrammed or modified without having the cell phone user to reprogram or modify the software. Moreover, the remote reprogram/update features may reflect any updates made to the software running on the PAP device. If there was a new feature implemented in an update to the software on the PAP device, a POSITA would have been motivated to also update the software on the patient’s cell phone to reflect the availability of this new feature. Kirkness¶291; Chatterjee¶202.

A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described reprogramming 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. Kirkness¶292; Chatterjee¶203.

VII. GROUND 2: TRUITT IN VIEW OF KUMAR AND DONG RENDERS OBVIOUS CLAIMS 14 AND 15

A. Motivation to Combine

A POSITA would have been motivated to modify Truitt-Kumar to incorporate the controller teachings of Dong. Kirkness¶293; Chatterjee¶204. A POSITA would have incorporated Dong’s teachings 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¶204. This is particularly relevant to process and identify respiratory patterns that are dependent on the patient. Kirkness¶293.

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¶294; Chatterjee¶¶205-206. Specifically, a POSITA would have modified the Truitt-Kumar system to incorporate the Dong controller. *Id.* 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. *Id.*

C. Claims 14 and 15: adaptive predictive controller

To the extent Truitt-Kumar does not disclose these additional limitations, a POSITA would have found it obvious in view of Dong. Kirkness¶¶295-299; Chatterjee¶¶207-213.

Like Truitt, which discloses a controller determining a PAP device's operation based on input from sensors, Dong discloses a controller determining a system's operation (e.g., operations of actuators) based on multiple inputs (e.g., input from sensors). EX1014, Abstract, Fig. 15, 19:5-20:56; Kirkness¶296; Chatterjee¶208.

Dong additionally 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. The system performs “a block of k output predictions, consisting of output predictions at each future time step up to the prediction horizon k, for dynamic systems with N outputs, M inputs and model parameter order n,” where “[t]he prediction system is organized for performing the calculation of a k-step ahead predictor in a highly computationally and memory efficient manner.” *Id.* Figure 1 of Dong discloses an “overall structure of extended horizon adaptive block predictive controller with an efficient prediction system,” where the “[a]daptive Block Predictive Controller 8 resides within a computational engine.” *Id.*, 8:14-16; *see also id.*, 7:60-8:53. Kirkness¶297; Chatterjee¶209.

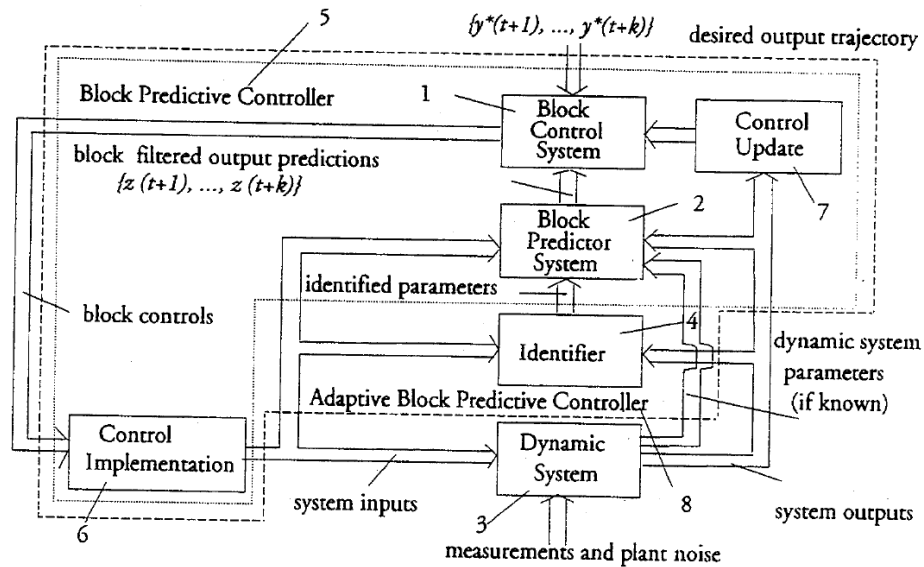


FIG. 1

EX1014, Fig. 1

A POSITA would have been motivated to include in the Truitt-Kumar combination an extended horizon adaptive block predictive controller, similar to that of Dong. Chatterjee¶212. As Dong explained, because a “dynamic system has an input-output delay, predictive controllers are used to account for such a delay. EX1014, 1:49-54. A POSITA would have understood that using such a controller would have been beneficial because “predictive controllers that consider time horizons beyond the system input-output delay (extended horizon predictive controllers) have been used in engineering applications” to maintain “the system input-output stability.” *Id.*, 1:54-68. Moreover, Dong’s controller/system “avoids computation of a large number of the predictor parameters associated with the prior

art...method, so that memory requirements and computational complexity are significantly reduced.” *Id.*, Abstract; *see also id.*, 6:42-46. Kirkness¶298; Chatterjee¶212.

A POSITA would have had the skill and a reasonable expectation of success in implementing features similar to those disclosed in Dong in the Truitt-Kumar combination. Chatterjee¶213. Dong explains that “[t]here are many computational engines which can work in conjunction with the extended horizon adaptive block predictive controller with efficient prediction system,” such as microcontrollers/microprocessors, which Truitt-Kumar already uses to control the PAP device. EX1014, 19:5-9. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that includes sensors to monitor physiological information of a patient and a controller/processor to control the PAP operation based on the physiological information (Truitt-Kumar combination)) according to known methods (e.g., known methods of using an extended horizon adaptive block predictive controller capable of controlling a dynamic system associated with multiple input and output (Dong)) to yield the predictable result of a system including a PAP device with an improved control without requiring significant memory resource or computational complexity while achieving system stability, as discussed above.

**VIII. GROUND 3: TRUITT IN VIEW OF KUMAR AND WRIGHT
RENDERS OBVIOUS CLAIMS 12, 17**

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¶¶300-303. 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¶301. 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.*¶302. 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.*

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¶¶304-306. **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 12 and 17: distinguish between and calculate the severity of obstructive apneas and central apneas

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¶¶307-309. 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¶309.

IX. GROUNDS 4-6: THE COMBINATIONS OF GROUNDS 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¶¶310-313. **First**, it would have further 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 ¶311.

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 of Truitt in light of Mumford’s sleep efficiency algorithm would have been advantageous to minimize the pressure applied, increase comfort, and therefore improve compliance. Kirkness, ¶312. Further, Mumford describes that it’s “sleep efficacy algorithm may also use the sleep profile information to vary the CPAP titration pressure depending on the sleep stage. More pressure may be delivered in the REM sleep stage in which the incidence of sleep apnea increases due to the relaxation of the throat muscles.” EX1009. 16:8-13. Therefore, the modification of Truitt in light of Mumford’s sleep efficiency algorithm would also have been advantageous to increase the

effectiveness of CPAP treatments in preventing apneas during REM sleep. Kirkness¶312.

Nothing in Kumar, Dong, or Wright would have taught away from this modification. Kirkness¶313.

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¶¶314-317. **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¶315. **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¶316.

Nothing in Kumar, Dong, or Wright would have prevented the implementation of this modification. Kirkness¶317.

C. Challenged Claims 1-19

To the extent 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 whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a 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¶318-331.

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¶319.

Mumford discloses “[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. Kirkness¶321. **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 the sleep efficacy control algorithm generates 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 a test score related to compliance would refer to a measure of usage of the PAP therapy device. Kirkness¶322.

Second, Mumford discloses calculating “data of severity of sleep disorder symptoms of the subject” because Mumford calculates data for the quality of sleep. 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¶323. 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.* PAP machines often use one or a combination of these indicators to adjust pressure. *Id.*

Mumford discloses 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 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.

Similar to AHI, the more sleep fragmentation and arousals, the more severe the sleep disorder symptoms. A POSITA would have understood the quality of sleep is “data of severity of sleep disorder symptoms of the subject.” Kirkness¶323.

Third, Mumford discloses “the index [of treatment efficacy of the subject using a PAP device is] based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject” as a test score of efficacy. Kirkness¶¶324-331. 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, 1:32-34 (“With 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.); Kirkness¶234. A POSITA would have understood, 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¶325. Along with AHI, the arousal index and sleep fragmentation are metrics physicians often use to determine the severity of sleep disorders and to adjust treatments. *Id.*¶326.

Notably Mumford’s “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¶327. Mumford describes the sleep efficacy algorithm can “vary the titration pressure depending on the sleep stage. More pressure may be delivered in the REM sleep stage in which the incidence of sleep apnea increases due to the relaxation of the throat muscles.” EX1009. 16:8-13; Kirkness¶327.

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¶328. As discussed above, Mumford teaches using a sleep efficacy

algorithm to adjust treatment. A POSITA would have understood using the algorithm, with the Truitt's air flow/pressure sensor(s), would improve treatments. *Id.* ¶329.

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 ¶330. Mumford states “[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 using 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 ¶331. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

X. 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.

XI. 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 Kumar, Dong, Wright, or Mumford were considered during prosecution, and therefore, these combinations were never before the Office. While Truitt was identified during prosecution (*see* EX1001, p. 2), the Examiner did not apply it in any office action. Thus, Truitt has not been materially considered by the Office.

B. 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.

XII. 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 '029 Patent is assigned to Cleveland Medical Devices Inc. Patent Owner is currently asserting the '029 Patent in the following litigation in an amended answer and counterclaims filed on April 11, 2024: *ResMed Corp., v. Cleveland Medical Devices, Inc.*, 1:23-cv-02221-BMB (N.D. Ohio).

Petitioner has filed, or 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. 11,602,284, which are also asserted in the same litigation.

Petitioner has filed a petition for *inter partes* review against the related U.S. Patent No. 10,076,269.

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 '029 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.

XIII. CONCLUSION

For these reasons, Petitioner respectfully requests institution.

Dated : January 10, 2025

Respectfully submitted,

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CLAIM LISTING APPENDIX

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

[1.a] a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone an index of treatment efficacy of the subject using a PAP device, the index based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, and a display;

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

[1.b.i] a blower having an air output within the enclosure,

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

[1.b.iii] a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating:

[1.b.iii.1] the data of a severity of the sleep disorder symptoms of the subject,

[1.b.iii.2] the data of usage of the PAP device by the subject, and/or

[1.b.iii.3] the index based in whole or in part on either i) or ii) or both i) and ii),

[1.b.iv] a mask or a nasal cannula connected to the enclosure, and

[1.c] a remote internet site, the remote internet site adapted for receiving i) and ii), or i), ii), and iii), 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 remote internet site is adapted to be hosted on a remote communication system with a third processor and a recording medium for reprocessing, storing and/or outputting data received from the first and/or second radio frequency wireless transceiver in whole or part, and to further output the reprocessed and/or the outputted data.

3. The system of claim 2, 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.
4. The system of claim 2, wherein the at least one second radio frequency wireless transceiver is adapted to transmit the data to the remote internet site in whole or in part via cell towers.
5. The system of claim 4, 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.
6. The system of claim 5, the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is adapted for calculating the data in whole or in part, wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site.
7. The system of claim 4, the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is adapted for calculating the data in whole or in part, wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site.
8. The system of claim 4, wherein the airflow sensor data is processed by the second processor, at least 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
9. The system of claim 4, wherein the remote internet site is adapted to retransmit to the first radio frequency wireless transceiver on the cell phone the data, in whole or in part, the data of i) and ii), or i), ii), and iii) or a second index related to the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device.

10. The system of claim 9, wherein the remote communication system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer and/or a second display for review by a clinician to determine the treatment efficacy.

11. The system of claim 2, wherein the airflow sensor data is processed by the second processor, at least 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.

12. The system in claim 11, 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.

13. The system of claim 2, wherein the remote internet site is adapted to retransmit the data to the first radio frequency wireless transceiver on the cell phone, in whole or in part, of i) and ii), or i), ii), and iii) related to the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device.

14. The system of claim 2, wherein the PAP device further comprises an adaptive 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.

15. The system of claim 14, wherein the PAP device further comprises an 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 2, wherein the remote communication system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer and/or a second display for review by a clinician to determine the treatment efficacy.

17. The system in claim 2, 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 at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data received by the remote internet site.

19. The system of claim 1, wherein the first software is adapted to be reprogrammed or modified remotely.

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.
11,872,029** exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a),
contains 13,994 words and therefore complies with the type-volume limitations of
37 C.F.R. §42.24(a).

Dated : January 10, 2025

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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 11,872,029 AND EXHIBITS
EX1001-EX1062** are being served on January 10, 2025, via FedEx overnight mail
on counsel of record for U.S. Patent No. 11,872,029 as addressed below:

Robert Schmidt
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A courtesy copy is also being served on counsel for the patent holder in the
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Dated : January 10, 2025

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