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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 IPR2025-00160

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,786,680**

Claims 1-5, 7, 8, 10-13, 15-18, and 20-31

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1001	U.S. Patent No. 11,786,680 to Kayyali (“the ’680 Patent”)
1002	File History of U.S. Patent No. 11,786,680
1003	Declaration of Jason Kirkness, Ph.D. (“Kirkness”)
1004	Curriculum Vitae of Jason Kirkness, Ph.D.
1005	Declaration of Sandeep Chatterjee, Ph.D. (“Chatterjee”)
1006	Curriculum Vitae of Sandeep Chatterjee, Ph.D.
1007	RESERVED
1008	U.S. Patent Pub. No. 2002/0198473 to Kumar et al. (“Kumar”)
1009	U.S. Patent No. 7,575,005 to Mumford et al. (“Mumford”)
1010	RESERVED
1011	“ <i>T-Mobile USA and HP Launch the First Truly Integrated Wireless iPAQ Handheld - T-Mobile Newsroom</i> ” (July 2004) available at https://www.t-mobile.com/news/press/t-mobile-usa-and-hp-launch-the-first-truly-integrated-wireless
1012	WIPO Publication No. WO2005096737A2 to Farrell et al. (“Farrell”)
1013	U.S. Patent Pub. No. 2002/0185130 to Wright et al. (“Wright”)
1014	U.S. Patent No. 5,424,942 to Dong et al. (“Dong”)

Exhibit No.	Description
1015	M. Berthon-Jones, “Feasibility of a Self-Setting CPAP Machine,” <i>Sleep</i> 16:S120-123 (1993) (“Berthon-Jones 1993”)
1016	D. Rapoport, “Methods to Stabilize the Upper Airway Using Positive Pressure,” <i>Sleep</i> 19(9):S123-S130 (“Rapoport 1996”)
1017	File History for U.S. Patent No. 8,172,766
1018	U.S. Patent No. 7,591,265 to Lee et al. (“Lee”)
1019	S. Thompson et al., “Sleep as a Teaching Tool for Integrating Physiology and Motor Control,” <i>Advances in Physiology Education</i> (2001)
1020	U.S. Patent No. 5,704,345 to Berthon-Jones (“Berthon-Jones345”)
1021	U.S. Patent No. 7,168,429 to Matthews et al. (“Matthews”)
1022	U.S. Patent No. 6,342,039 to Lynn et al. (“Lynn”)
1023	C. Sullivan, “Reversal of Obstructive Sleep Apnoea by Continuous Positive Airway Pressure Applied through the Nares,” <i>Lancet</i> 1981:1862-5 (“Sullivan 1981”)
1024	U.S. Patent No. 6,484,719 to Berthon-Jones (“Berthon-Jones719”)
1025	Teschler, H., et al., “Automated Continuous Positive Airway Pressure Titration for Obstructive Sleep Apnea Syndrome,” <i>Am. J. Respir. Crit. Care Med.</i> 54:734-740 (1996)
1026	ResMed, “AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1,” (1999)

Exhibit No.	Description
1027	ResMed, “AutoSet T, Optimal Therapy for your OSA Patients,” (2000)
1028	Sunrise Medical, “DeVillibis® AutoAdjust™ LT Nasal CPAP System Instructions Guide Model 8054,” (1999)
1029	Respironics, “Introducing the REMstar Auto. A simply smarter Smart CPAP” (2002)
1030	ResMed Origins, downloaded from https://document.resmed.com/en-us/documents/articles/resmed-origins.pdf on May 3, 2022.
1031	U.S. Patent No. 5,490,502 to Rapoport et al. (“Rapoport”)
1032	F. Roux, et al., “Continuous Positive Airway Pressure: New Generations,” Clinics in Chest Medicine (2003)
1033	Loube, D., “Technologic Advances in the Treatment of Obstructive Sleep Apnea Syndrome,” CHEST 116:1426-1433 (1999)
1034	American Academy of Sleep Medicine Task Force. (1999). <i>Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. Sleep</i> , 22(5), 667-689
1035	J. Meurice, et al., “Efficacy of Auto-CPAP in the Treatment of Obstructive Sleep Apnea/Hypopnea Syndrome,” Am. J. Respir. Crit. Care Med. 153:794-8 (1996)
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1037	M. Weil, et. al., “Experience With a Digital Computer for Study and Improved Management of the Critically Ill,” JAMA 198:1011-1016 (1966)
1038	C. Lilly, et. al., “Critical Care Telemedicine: Evolution and State of the Art,” Critical Care Medicine 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,” Critical Care Medicine 32:31-38 (2004)
1040	K. Zundel, “Telemedicine: history, applications, and impact on librarianship,” Bull Med Libr. Assoc. 84:71-79 (1996)
1041	Y. Wang, et. al., “Validation of microMESAM as Screening Device for Sleep Disordered Breathing,” Pneumologie 57:734-740 (2003)
1042	A. Boudewyns, et. al., “Two months follow up of auto-CPAP treatment in patients with obstructive sleep apnoea,” Thorax 54:147-149 (1999)
1043	D. Lankford, “Wireless CPAP Patient Monitoring: Accuracy Study,” Telemedicine Journal and e-Health 10:162-169 (2004)
1044	Japan Patent Office Patent Application Pub. No. P2002-291889A to Toge (“Toge”)
1045	U.S. Pat. Pub. No. 2008/0214903 to Orbach (“Orbach”)
1046	D. Gourley, et. al., HTTP The Definitive Guide (2002)
1047	D. Mauro, et. al., Essential SNMP (2001)

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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”)
1052	Toge Certification of Translation
1053	Order Granting Request for <i>Ex Parte</i> Reexamination in <i>Ex Parte</i> Reexamination No. 90/019,705 (Dec. 3, 2024)
1054	RESERVED
1055	WIPO Publication No. WO2006090371A2 to Orbach (“Orbach 2006”)
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/

I. INTRODUCTION

ResMed Corp. (“Petitioner”) respectfully requests *inter partes* review of claims 1-5, 7, 8, 10-13, 15-18, and 20-31 of U.S. Patent No. 11,786, 680 (EX1001, “’680 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 including PAP machines. Numerous benefits motivated such incorporation of sensor diagnostic devices into networked systems, including greater data access and convenience to patients, doctors, and providers as well as the ability to monitor compliance and adherence to therapy.

The ’680 Patent claims a networked PAP system that transmits treatment efficacy data to a cell phone and remote internet site. But this system is nothing more than an obvious combination of features from known PAP systems, like Toge (EX1044), Burton (EX1050), and Kumar (EX1008).

Accordingly, Petitioner respectfully requests the Board institute review and find all challenged claims of the '680 Patent unpatentable.

II. IDENTIFICATION OF THE CHALLENGES

Ground 1: Claims 1-5, 7, 8, 10-13, 15-18, and 20-31 are obvious under pre-AIA 35 U.S.C. § 103 over Toge¹ in view of Kumar and Burton.

Ground 2: Claims 10, 15, and 20 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious over Toge, Kumar, Burton, in view of Kisner² (EX1051).

III. BACKGROUND

A. Overview of the Technology

1. PAP Machines

Obstructive sleep disorders are characterized by the obstruction of a patient's upper airway during sleep. Kirkness ¶¶64. The obstructions range from the total absence of airflow (apnea) to significant obstructions with or without reduced airflow (hypopnea and snoring). *Id.* ¶¶65. These obstructions elevates the risk of certain health problems. *Id.*

“[T]he most common method of treating...sleep apnea is by apply[ing] a continuous positive gas pressure to the patient's airway.” EX1001, 2:12-14. “[T]he

¹ Toge is §§102(a) and (b) prior art. EX1052 is a certification of translation.

² Each of Kumar, Burton, and Kisner is §§102(a), (b), and (e) prior art.

upper airway during sleep mimics the behavior of a collapsible tube.” EX1016, 1. To prevent this collapse, positive airway pressure can oppose the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). *Id.*; see also Kirkness¶¶70-71.

As PAP therapy developed, the industry began examining a variable approach that “would improve on, and possibly do away with, the one-size-fits-all pressure determination night.” EX1015, 1. By the mid-1900s, a self-setting machine that “adjusts CPAP pressure on a minute-by-minute basis according to the degree of upper airway obstruction” was widely available. EX1015, 1; Kirkness¶74.

The key metrics that physicians often use to determine the severity of sleep disorders include the Apnea-Hypopnea Index (AHI), oxygen saturation level, Respiratory Disturbance Index (RDI), snoring intensity and duration, arousal index, sleep fragmentation, and heart rate variability (HRV) during sleep. Kirkness¶¶66-67. PAP machines often use one or a combination of these indicators to adjust pressure. *Id.* ¶67.

2. Telemedicine

In the 1970s and 1980s, the success of technology advancements confirmed that physiological data could be transmitted and analyzed remotely to monitor and manage patients’ health status. *Id.* ¶¶88-89. This included early work by NASA in

monitoring astronauts' physiological data remotely, proving that vital signs could be reliably tracked from great distances. *Id.*; *see also* Chatterjee¶81.

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

3. Intelligent Systems and Mobile Computing

In the early 2000s, there was a general market trend to implement consumer devices into intelligent systems, and to create a “smart home.” Chatterjee¶73. The Internet of Things (also known as IoT) had just been coined in 1999, and the market was pushing to embed wireless transceivers into any daily “things” to connect them to the Internet. *Id.* The connection to the Internet would enable communications between people and things and between things themselves. *Id.*

This trend was spurred on by developments in mobile computing. *Id.* ¶54. This mobile access to the Internet promoted the connection to more “things,” including medical devices. *Id.*

B. '680 Patent

The claims of the '680 Patent describe well-known PAP sleep disorder treatment devices implemented in a networked system. The '680 Patent generally focuses on a PAP device that “adjust[s] the treatment gas flow or pressure delivered to the subject based on the subject’s current physiological state or symptoms.” EX1001, 2:53-56.

The system, as shown in Figure 8 below, includes a PAP device 428 that provides positive air pressure to a subject 410 with a mask 412 connected by air hose 416. *Id.*, 53:64-54:3. The system also includes “a diagnostic device 441, which comprises a radio 436; an antenna 434; and a microprocessor 438 for processing the data or signals to determine a level of severity of the subject’s sleeping disorder or symptoms.” *Id.*, 54:3-10. “The diagnostic device 441 then transmits a signal based on this level of severity by either a tether 444 or radio signal...to an actuator...in the CPAP device 428, which controls the flow of air or gas provided to the subject by the air hose or subject circuit 416.” *Id.*, 54:10-16.

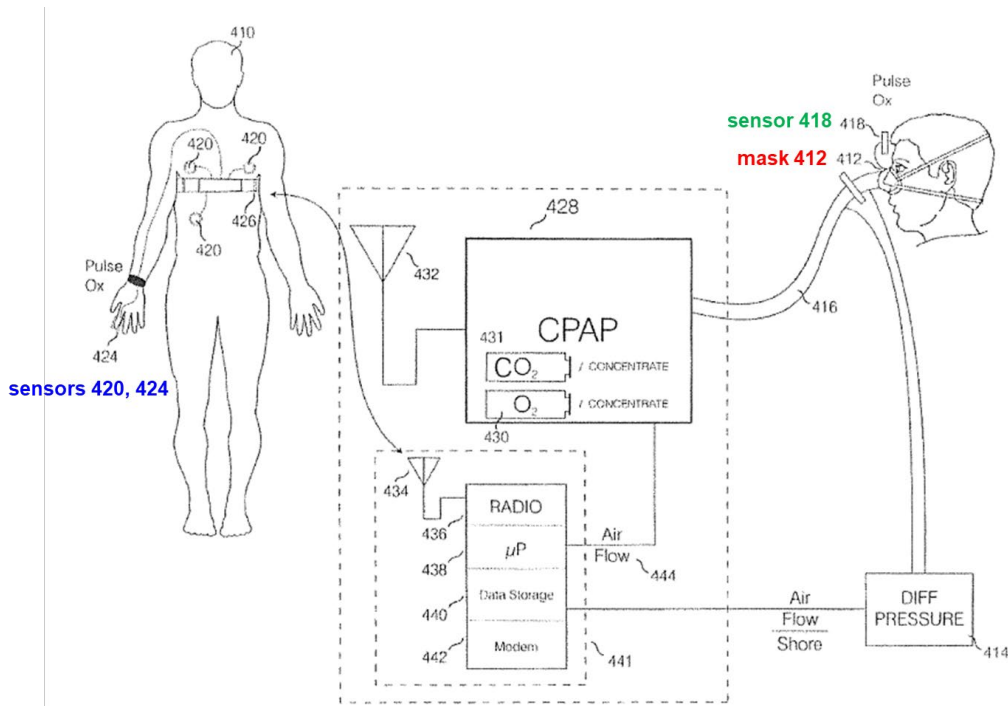


Fig. 8

EX1001, FIG. 8 (annotated)

The '680 patent also discloses that a wireless data acquisition system 50 may receive signals from sensors and transmit the signals to a server 70 for analysis via the Internet. *Id.*, 56:8-45. The '680 patent acknowledges that various claimed features were known in the art. For example, the '680 patent acknowledges that “a sensor for providing a sensor data to determine airflow,” “radio frequency wireless transceiver,” calculation of “data related to a quantitative measure of symptom severity,” and “signal processing techniques [e.g.,] wavelet analysis,” as recited in the '680 patent claims were known. *Id.*, 17:7-10 (“[m]ethods of **determining airflow or air pressure from sensors**...are generally known in the art”), 24:61-65

(“The receiver...can be **any device known to receive RF transmissions** used by those skilled in the art”), 26:42-45 (“algorithms **known to those skilled in the art are used to...quantify the level of severity** of the subject’s sleeping disorder or symptoms”), 26:67-27:5 (“signal processing algorithms known to those skilled in the art, such as **wavelet analysis**”).

C. Challenged Claims

The challenged claims are entitled to an effective filing date of no earlier than November 4, 2005.³

The ’680 Patent has 32 claims, including 1 independent claim and 31 dependent claims. Independent claim 1 generally covers a PAP system with the following components:

- (1) one or more PAP device(s);
- (2) a first non-transitory computer readable medium comprising first software downloaded to a cell phone of a subject(s) receiving treatment;
- (3) a second non-transitory computer readable medium comprising second software for a remote internet site and a database.

³ Petitioner does not concede this priority date and breaking the priority chain is unnecessary for this petition.

D. Prosecution History

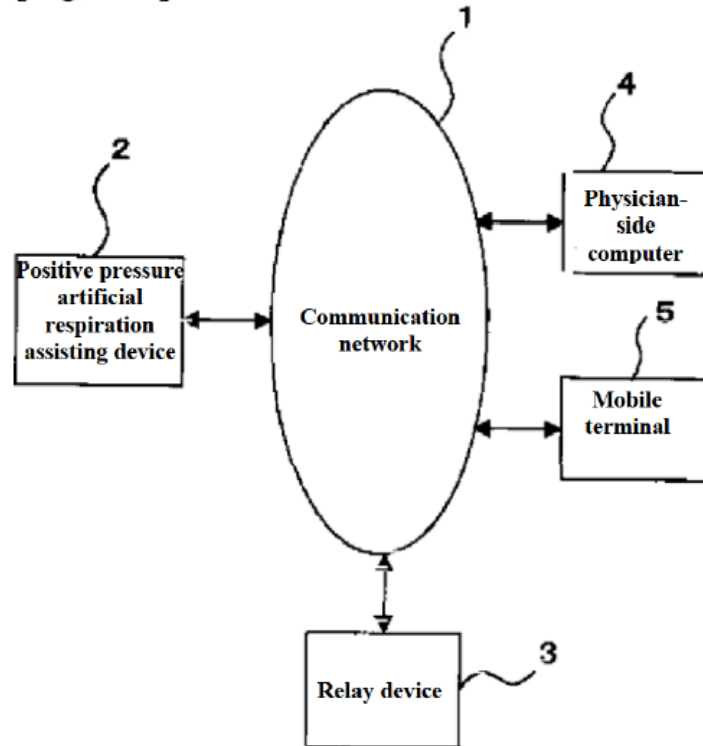
Patent Owner attempted to overcome the multitude of rejections apparently by amending the claims. *Id.*, 214-237. The examiner subsequently indicated that then claims 21-52 would be allowable if rewritten to overcome the rejection(s) under §§101 and 112. *Id.*, 260-269. Following an interview (*id.*, 285-293) and Patent Owner's amendment (*id.*, 295-304), the Examiner allowed the claims (*id.*, 316-324). The Examiner also explained that the prior art reference of record does not teach features recited in then claim 21. *Id.*, 322-323.

IV. OVERVIEW OF THE PRIOR ART

A. Toge (EX1044)

Toge discloses a remote monitoring method for a patient using a positive pressure artificial respiration assisting device as shown by Figure 1.

[Figure 1]



EX1044, Figure 1

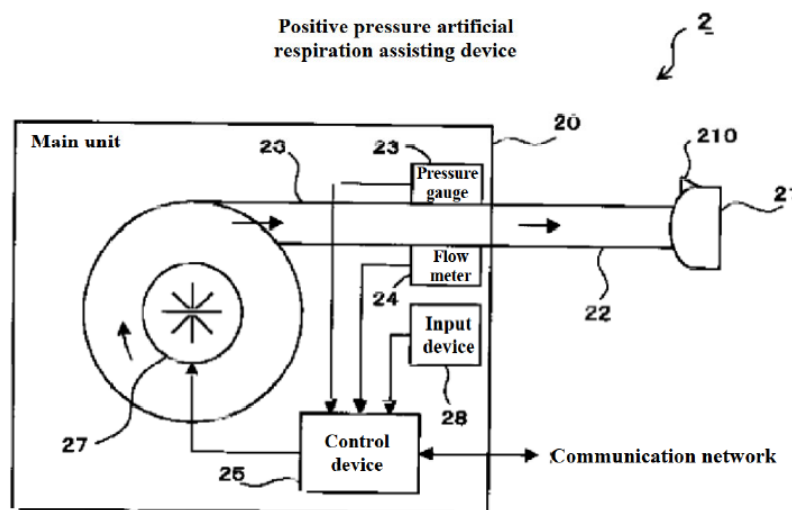
Toge discloses a three-component telemedicine device comprising a positive pressure artificial respiration assisting device (2), a relay device (3), and physician-side terminal devices (4 and 5) all connected to a communication network (1). EX1044, [0008].

The communications network (1) may be any of the following: a public telephone network, the Internet, a mobile communication network, or a dedicated line network. It may also be a combination of these networks. *Id.*, [0009].

The functionality of the relay device (3) can be incorporated into the device (2), specifically the control unit (250) of the control device (25), allowing it to be configured as an integrated unity with the device (2). *Id.*, [0060]. These processes done by the relay device (3) can be implemented by either a program describing these processes and a CPU, or microcomputer with peripheral circuits to execute this program, or by hardware circuits dedicated to the executing the above processes. *Id.*, [0062].

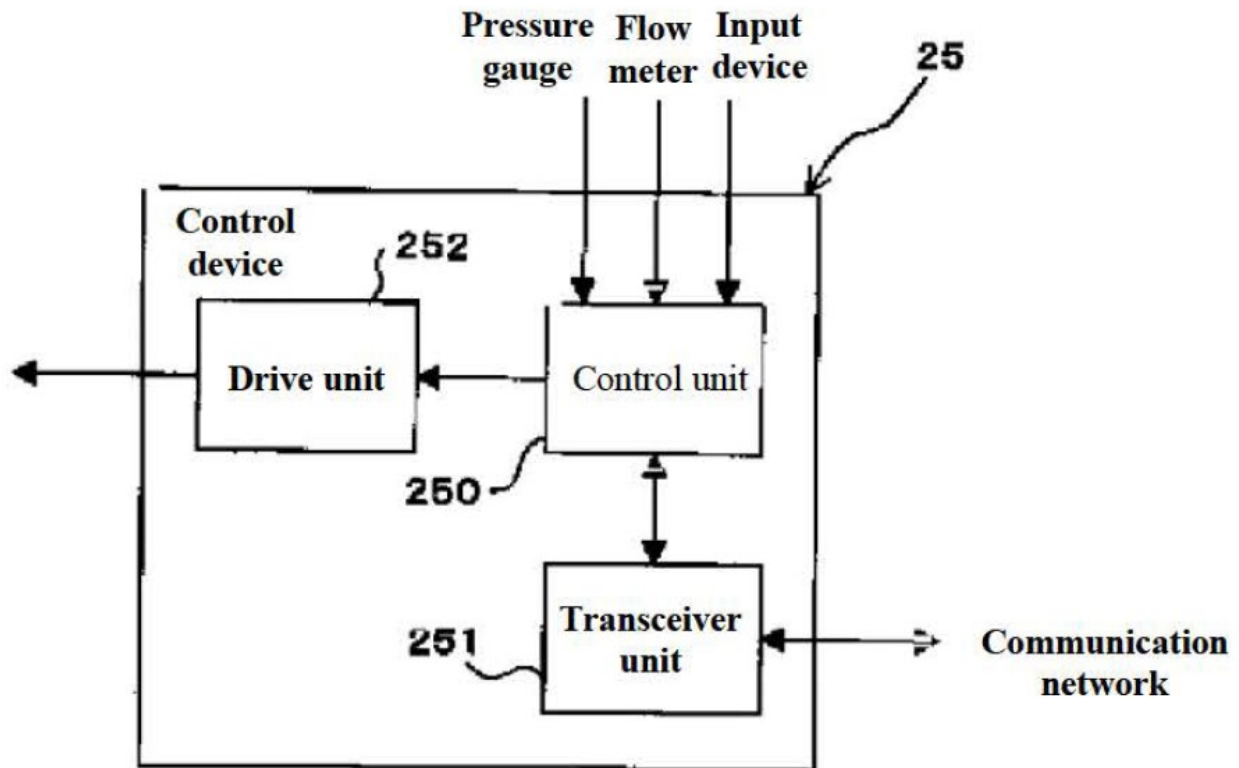
The physician-side devices (4 and 5), which can be mobile devices, PHS, PDAs, or PocketBells (*id.*, [0019]), are devices that receive all or part of the data transmitted from the device (2) shown in Figure 2. *Id.*, [0017].

[Figure 2]



EX1044, FIG. 2

The device 2 comprises a nasal mask (21) attached to the patient's nose. *Id.*, [0021]. Within the main unit (20) is a pressure gauge (23), a flow meter (24), a control device (25), a blower (27), and an input device (28). *Id.*, [0023].



EX1044, FIG. 3

The control device (25) as shown in Figure 3, further comprises a control unit (250), a transceiver unit (251), and a drive unit (252). *Id.*, [0023]. The transceiver unit (251) provides the reception data to the control unit (250).

Toge explains that its system enables “remote monitoring of the patient’s condition during the use of a [PAP] device, or the condition of the [PAP] device”

via the wireless communication network. *Id.*, Abstract, [0001], [0005], [0006] (disclosing that the PAP device is “connected to a relay device and a physician-side terminal device via a wireless...communication network to conduct remote monitoring of the [PAP] device via the communication network”). Toge describes that by “transmitting the tidal volume F_p almost in real-time or at regular intervals (such as every hour), physicians can remotely monitor the patient’s condition during the use of the [PAP] device 2 remotely from hospitals or other locations. Furthermore, if there is a decreasing trend in the tidal volume F_a , emergency measures, such as adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4 or mobile terminal 5.” *Id.*, [0039]. Additionally, Toge allows a physician “remotely monitor both the patient’s condition during the use of the positive pressure artificial respiration assisting device and the status of the device itself.” *Id.*, [0085].

B. Kumar (EX1008)

Like Toge, Kumar discloses a system/method for monitoring physiological data collected by a patient-side device (EX1008, Abstract), including monitoring “sleep apnea-hypopnea syndrome” (*id.*, [0240]).

Kumar additionally discloses “remote monitoring of medical and/or biofeedback devices over a wide area network (WAN) such as the Internet,” allowing “real-time streaming of raw, interpreted, and processed physiological data

as well as...data from a patient/client to a health care provider.” *Id.*, [0010]. The system includes “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,” where “[t]he engine manages transmission of the data from the patient-side device to the provider-side device.” *Id.*, [0011]. The engine “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.” *Id.*, [0011], [0012], [0069]. The patient-side device may be “a medical and/or biofeedback device that communicates through a...wireless...interface” and “may then be connected via a computing device, such as a computer, personal digital assistant (PDA), etc., to the WAN.” *Id.*, [0013], [0014].

As shown in Figure 1 below, Kumar discloses system 100 for “network-based monitoring of data from a patient-side physiological collecting device,” where 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.” *Id.*, [0067]. The devices and engine are connected to a wide area network (WAN) 108, e.g., the Internet, and the system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as...data from a patient to a health care provider. *Id.*

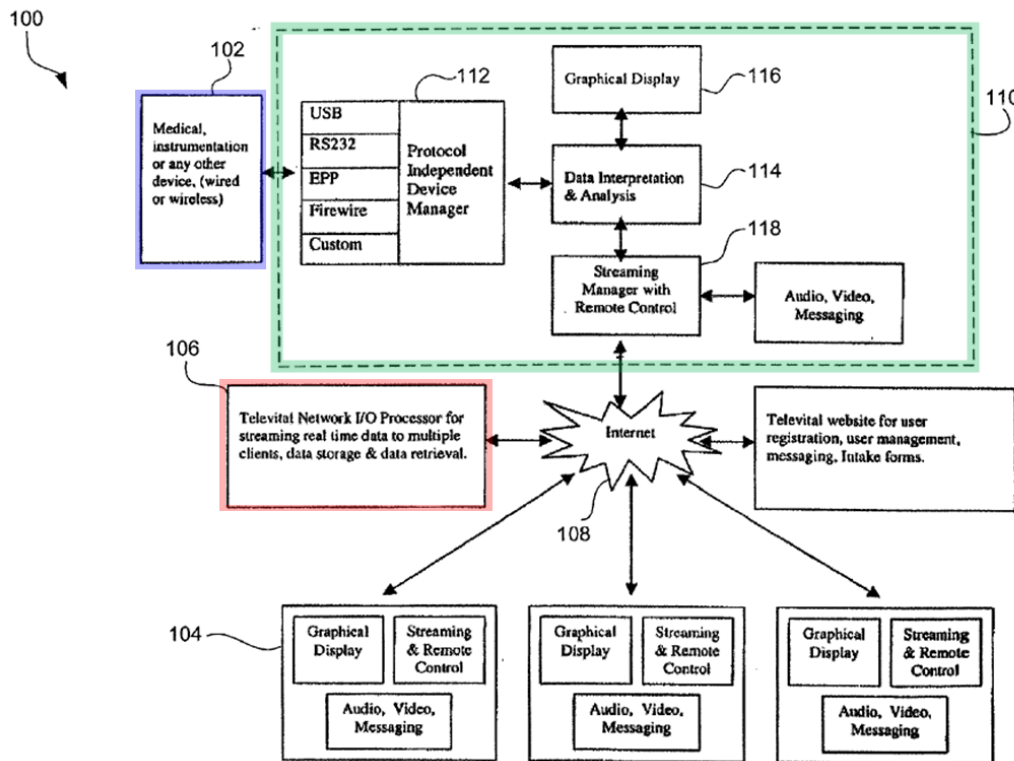


Fig. 1A

EX1008, FIG. 1A

The system allows for various applications, including, e.g., “telemedicine, remote sleep studies, physical evaluations, remote monitoring,...home health care, disease management applications, biofeedback,..., wireless monitoring....” *Id.*, [0068], [0069].

Kumar explains that patient-side device 102 is located with a patient and can be any device that gathers physiological data from the patient” (*id.*, [0071]) and may be connected to the WAN via a computing device 110, e.g., PDAs, pocket PCs, wireless telephone. *Id.*, [0072], FIG. 1B. Computing device 110 may also

communicate directly with patient-side devices (*id.*) and each patient-side device may communicate through a wireless protocol (*id.*; *see also id.*, [0073]).

Computing device 110 may send a request to the engine to download plug-in which facilitates communications between the computing device and the patient-side device. *Id.*, [0074], claim 5. The data may also be sent to remote providers for real-time or post-session analysis, storage, and retrieval of raw or interpreted data via the Internet connection. *Id.*, [0076]-[0077]. “By receiving data from the patient-side device, a provider is able to monitor the patient’s physiology for research, keeping track of documentation, performing analysis, managing and maintaining records, diagnosing the patient, providing treatment in real-time to the patient, etc,” “allow[ing] for daily or periodic monitoring of patients without the need for the patient to travel to the provider's location.” *Id.*, [0078], [0079]. Kumar discloses that computing device 110 may be a wireless phone or pocket PCs, e.g., an IPAQ device. *Id.*, [0072]. Kumar also explains that computing device 110 downloads a plug-in, i.e., a software module, to facilitate communications with the patient-side device (EX1006, [0074], claim 5), provides customized graphical user interfaces (GUIs) (*id.*, [0074]), and analyzes/processes received data (*id.*, [0075]).

C. Burton (EX1050)

Burton relates to providing PAP treatments to patients. EX1050, 1:20-27. While PAP treatments may achieve intended results, “they also often severely affect

the quality of sleep” of the patient undergoing these treatments, “causing transient arousals.” *Id.*, 1:9-19, 2:1-3:13. For example, the PAP device’s inaccuracy in detecting the upper airway resistance (UAR) events may cause “[e]xcessively rapid or excessively insensitive pressure changes” of the air delivered to the patient, leading to patient’s arousal and sleep fragmentation. *Id.*, 2:2-31.

To resolve these issues, Burton discloses a system that “deliver[es] therapeutic treatments to patients without adversely affecting their sleep.” EX1050, 1:4-6, 3:15-16. The system “maintain[s] the sleep quality of a patient” by “predict[ing] the onset of arousal and using **an adaptive algorithm to modify a patient’s therapeutic treatment.**” *Id.*, 3:21-24, 3:24-28.

Burton explains that, when a patient receives CPAP treatment, arousal monitoring “includes **monitoring pressure and airflow associated with a patient’s breathing**” and “[t]o prevent RERA, it is necessary to **detect a number of patterns which are indicative of sleep apnea symptoms, namely inspiratory flow limitation (flattening), snoring and flow amplitude reduction.**” EX1050, 14:1-7; *see also id.*, 14:8-18. Based on the analysis of the pressure and airflow, the controller “**generates pressure adjustment signal.**” *Id.*, 14:19-22; *see also id.*, 14:23-30, 23:20-24:12.

Moreover, the process of minimizing arousals “includes the capability to **automatically adjust the therapeutic treatment based on at least one index or derived data set,**” which includes, e.g., Upper Airway Resistance (UAR), Respiratory Effort-Related Arousal (RERA), Therapeutic-control Event-Related Arousal (TERA), **Respiratory Disturbance Index (RDI)**, Respiratory Arousal Index (RAI), **Apnea-hypopnea index (AHI)**, Sleep efficiency Index. *Id.*, 21:4-22:21.

V. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art (“POSITA”) in 2005 would have had at least a bachelor’s degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems, such as networked PAP machines. Additional experience could substitute for less education, and additional education could likewise substitute for less experience. Kirkness¶¶44; *see also* ¶¶45-63.

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

VI. CLAIM CONSTRUCTION

The Board construes the claims “using the same claim construction standard that would be used” in district courts. 37 C.F.R. §42.100(b). This Petition establishes the prior art meets each of the claim limitation under any reasonable construction.⁴ Thus, no express construction is required.

VII. GROUND 1: TOGE IN VIEW OF KUMAR AND BURTON RENDERS OBVIOUS THE CHALLENGED CLAIMS

A. Motivation To Combine

A POSITA would have been motivated to combine the teachings of Toge and Kumar to implement a networked PAP treatment system. Specifically, a POSITA would have improved the physician-side computer of Toge by implementing it with the browser-based engine accessible through web pages as taught by Kumar for at least the following reasons. Kirkness¶137; Chatterjee¶¶70-81.

First, a POSITA would have been motivated by convenience and efficiency. *Id.* ¶138. OSA is a chronic condition and PAP therapy requires ongoing management/support, and frequent follow-up between patient and physicians. Appointments/traveling to see providers requires an investment in time/resources for

⁴ Petitioner reserves the right to argue alternative constructions in other proceedings, including indefiniteness.

both the provider and patient. *See, e.g.*, EX1044, [0004]; Kirkness¶138. Collecting data accessible anywhere by the provider and physicians through web pages to remotely monitor the data, assess therapy and prescribe modification and/or changes avoids or reduces the hassle and expense associated with in person appointments. *Id.* Additionally, the physician or provider can access the data anywhere using an Internet browser, as opposed to downloading specialized software *Id.*; Chatterjee¶¶71-72.

Second, a POSITA would have been motivated to provide health access to more people. Kirkness¶139; Chatterjee¶¶80-81. As Kumar observes, telemedicine has provided “access to health [care] 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). Kumar’s plug-and-play user interfaces would allow anyone with an Internet browser to access the data. Kirkness¶139; Chatterjee¶¶80-81.

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. A POSITA would have naturally looked at known design options for telemedicine like Kumar’s “plug-and-play” user interface. Kirkness¶¶140-141.

Additionally, a POSITA would have been motivated to modify the Toge-Kumar PAP device and system to incorporate Burton's efficacy data analysis. Kirkness¶142; Chatterjee¶¶82-84.

First, including Burton's efficacy data analysis would have advanced the objective of Toge to "enable remote monitoring of the patient's condition during the used of the positive pressure artificial respiration assisting device and the condition of the positive pressure artificial respiration assisting device." Ex. 1044, [0005]. Toge discusses setting limits and adjusting the prescription pressure based on the patient's condition. Ex. 1044, [0039], [0055]. A POSITA would have understood that "determin[ing] the efficacy of the CPAP treatment" and "vary[ing] operation parameters of the treatment," as taught by Burton would have improved the performance of the Toge-Kumar PAP system by incorporating the Burton's ability "recognize[s] when the pressure adjustment of the gas delivery device is either too severe and leading to the promotion of [e.g., unwanted arousals]." Burton., 5:16-20. Kirkness¶143; Chatterjee¶¶83.

Second, it would have advanced the purpose of Toge "enabling remote monitoring of the patient's condition during the use of a positive pressure artificial respiration assisting device" and preventing "leakage causing discomfort and potentially affecting the patient's ability to sleep." Ex. 1044, Abstract, [0040]. A major limitation of CPAP therapy was non-compliance due to discomfort. Ex. 1016,

5. The modification would have been advantageous to minimize the pressure applied, increase comfort, and therefore improve compliance. Kirkness¶144.

B. Reasonable Expectation Of Success

A POSITA would have had a reasonable expectation of success in implementing the Toge PAP device as a networked system as taught by Kumar and then incorporating Burton's algorithm. Kirkness¶146; Chatterjee¶85.

First, Toge and Kumar are structurally and functionally similar. Toge itself utilized wireless communication. Kirkness¶147; Chatterjee¶86. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, EX1044, Abstract, Fig. 5, EX1045, Fig. 3; EX1013, [0029]. Kumar expressly teaches that the user interface of Kumar can be incorporated into systems like Toge: "Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI." EX1008, [0018].

Second, Toge and Burton are analogous art as both references describe CPAP systems that include flow sensors and processors. Kirkness¶148; Chatterjee¶¶87-89. Both further discloses that the processor analyzes the signals from the flow sensors. *Id.*

Third, the modifications would simply be a change of programming. Toge already discloses a telemedicine system (including a PAP device, mobile phone, and

physician-side computer, all of which are connected to a network). Ex. 1044, [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. The modifications would simply be a change of programming to the control unit 250 of Toge to output the PAP therapy efficacy data analysis of Burton, and a change of programming on the physician-side computer to allow it to host web pages. Given this, a POSITA would have had a reasonable expectation of success in implementing the system resulting from the combination of the teachings of Toge, Burton, and Kumar. Kirkness¶149; Chatterjee¶89.

C. Independent Claim 1

1. Preamble: internet based sleep disorder treatment system

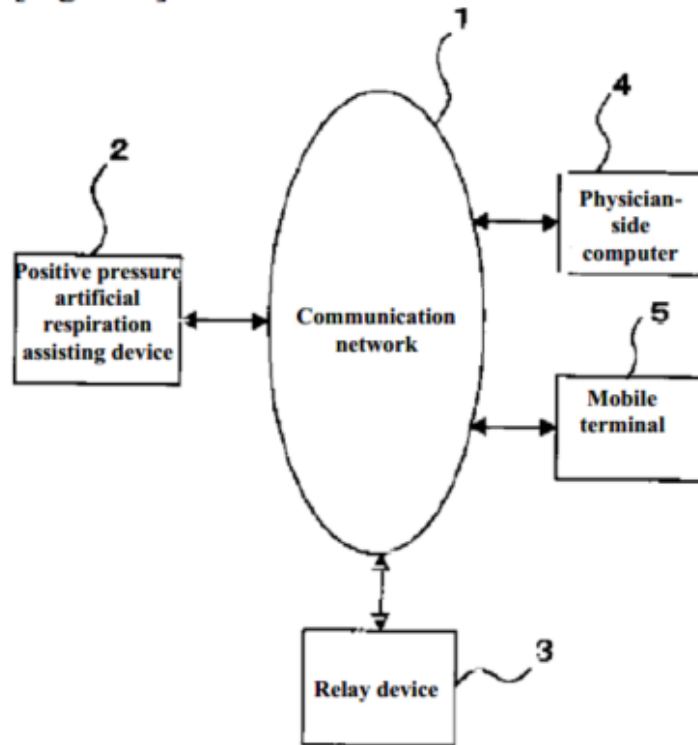
To the extent limiting, Toge in view of Kumar discloses the preamble. Kirkness¶¶150-168-; Chatterjee¶¶90-100.

Toge discloses “one or more positive airway pressure (PAP) device(s) for sleep disorder treatment.” As shown in Figure 1, Toge discloses a remote-medical (telemedicine) system including a positive pressure artificial respiration assisting device (“one or more positive airway pressure (PAP) device(s)”) for treating patients having sleep apnea (“sleep disorder treatment”). EX1044, [0008], [0015]. Toge’s system includes a positive pressure artificial respiration assisting device 2 (referred

to as “PAP device 2” hereafter), a relay device 3, physician-side terminal devices, *e.g.*, a physician-side computer 4, and a mobile terminal 5, all of which are connected to communication network 1. *Id.*, [0008]. Toge discloses that functionality of relay device 3 can be “incorporated into [PAP] device 2 (the control unit 250 of the control device 25), allowing it to be configured as an integrated unit.” *Id.*, [0060]; *see also id.*, [0016]-[0018] (describing functionalities of relay device 3). Toge explains that in this case the “[PAP] device 2 then directly transmits all or part of the treatment data” to physician-side computer 4 or mobile terminal 5 “via the communication network 1.” *Id.*, [0061]. Physician-side computer 4 or mobile terminal 5 then directly sets the thresholds on PAP device 2 and sends download requests. *Id.*, [0061], [0063]-[0076], [0085]. Kirkness¶151.

Network 1 may be the “Internet” or “a mobile communication network.” EX1044, [0009].

[Figure 1]



EX1044, FIG. 1

PAP device 2 provides treatments to patients having “weakened spontaneous breathing ability” and/or “conditions such as sleep apnea” at the patient’s residence. *Id.*, [0010], [0015]; *see also id.*, [0011]-[0014]. Kirkness¶153; Chatterjee¶¶92.

Computer 4, installed at, *e.g.*, a hospital or clinic, receives data from a relay device 3 (data transmitted from PAP device 2 to relay device 3) and allows physicians to access the transmitted data using the computer. EX1044, [0017]-[0018]. By using computer 4, care providers may send a “data download request” to relay device 3 to download data onto computer 4 and may also “set the necessary data...for [PAP] device 2.” *Id.*, [0018]. Kirkness¶154; Chatterjee¶¶92.

Mobile terminal 5 may be “mobile phones” or “PDAs.” EX1044, [0019]. Mobile terminal 5, possessed by care providers, may be “mobilized in emergencies by the physician-side computer 4, relay device 3, or other mobile terminals possessed” by the care provider. *Id.*, [0019]. Care providers may operate the mobile terminal 5 to “set the necessary data...for [PAP] device 2.” *Id.* PAP device 2, relay device 3, and physician-side computer 4 are wirelessly connected to network 1 for transmitting data, e.g., “treatment data.” *Id.*, [0006]-[0007], [0063], [0070], [0078], [0080]-[0081], claim 1. Kirkness¶155; Chatterjee¶93.

Toge’s system enables “remote monitoring of the patient’s condition during the use of a [PAP] device, or the condition of the [PAP] device” via the wireless communication network. EX1044, Abstract, [0001], [0005], [0006] (“a wireless...communication network to conduct remote monitoring of the [PAP] device via the communication network”), [0039], [0085]. PAP device 2 may transmit treatment data via network 1 to physician-side computer 4 (*id.*, [0006], [0016]-[0017]) or mobile terminal 5 (*id.*, [0019]), by which a physician may “access the transmitted data” and update the settings on PAP device 2 based on the physician’s diagnosis of the patient’s conditions (*id.*, [0018], [0027], [0039]-[0042], [0046]-[0047]). Given that Toge discloses a physician accessing the treatment data and updating/adjusting settings of PAP device 2 for patient’s sleep disorder treatment based on the received data, Toge discloses “diagnostic monitoring with

one or more positive airway pressure (PAP) device(s) for sleep disorder treatment.”
Kirkness¶156.

Toge discloses a system for “diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment” via network 1 (*e.g.*, “Internet”), as discussed above, but Toge does not expressly close such a system is “remote internet server-based.” Nevertheless, a POSITA would have found it obvious to implement a “remote internet server-based” system in view of Kumar. Kirkness¶157; Chatterjee¶90.

Like Toge, Kumar discloses a system “for network-based monitoring of physiological data,” including monitoring data for sleep apnea-hypopnea syndrome. EX1008, Abstract, [0068], [0239]-[0241]. Kirkness¶158; Chatterjee¶90.

Figure 1A of Kumar shows the system includes a patient-side device 102 (like the Toge PAP device), computing device 110, and **central server 106 that hosts a browser-based engine that can be accessed through web pages.** EX1008, [0067], [0072]; *see also id.*, [0018].

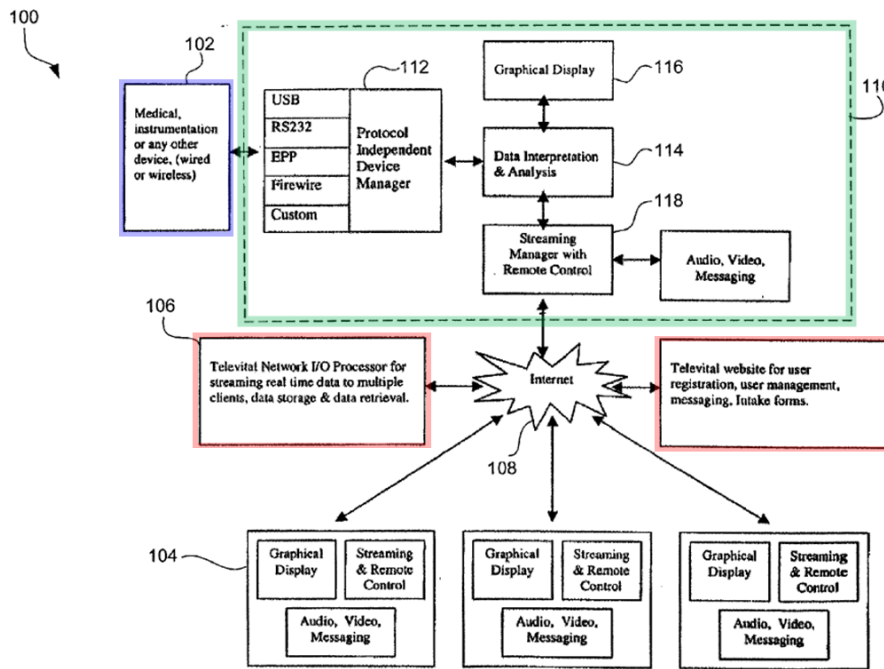


Fig. 1A

EX1008, FIG. 1A

The browser-based engine supports real-time streaming of information over the Internet. EX1008, [0010], [0087]. “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”, “receive the data from the patient-side device and transmit the raw or processed data to the provider-side device,” “store the data for later transmission to the provider-side device, etc.” *Id.*, [0011]; Kirkness¶¶159-160; Chatterjee¶96.

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 WAN 108, *e.g.*, **Internet**. EX1008, [0067]. The system allows for the real-time streaming of raw/interpreted/processed physiological data and textual/audio/video data from a patient to a healthcare provider. *Id.*, [0067]-[0068]. Kumar also discloses that the patient-side device may communicate through a wireless interface and may communicate over the Internet. *Id.*, [0013]. Thus, Kumar discloses a “remote internet server-based” system for remote studies/monitoring physiological data associated with sleep apnea-hypopnea syndrome. Kirkness¶¶161.

Kumar explains that “the entire system runs in the context of an Internet browser.” EX1008, [0086]-[0087]; *see also id.*, [0010], [0015]. A patient accesses the engine through a login, such as that in Figure 2. *Id.*, [0089], [0192]; Kirkness¶¶162; Chatterjee¶97.

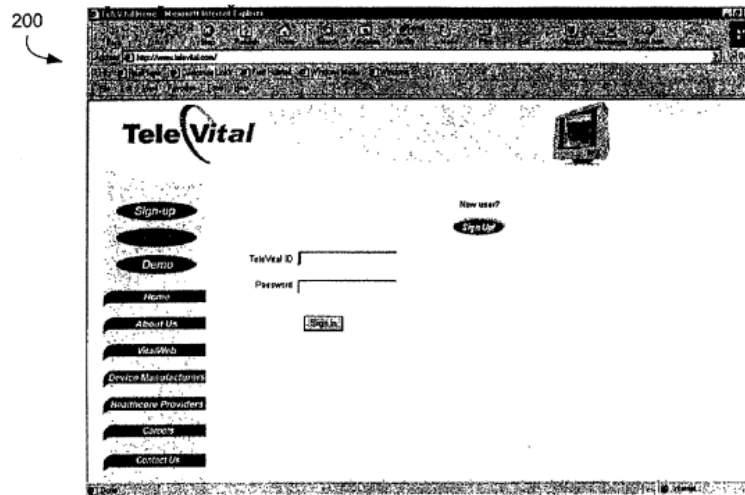


Fig. 2

EX1008, FIG. 2

A POSITA would have understood that the data sent to the engine could be accessed through web pages which serve as a graphical user interface, such as the “patient’s real-physiological data” depicted in Figure 7. EX1008, [0092], Figs. 6-8; *see also id.*, [0010], [0015]; Kirkness¶163.

A POSITA would have been motivated to implement the “remote internet server-based” features, including a browser-based engine implemented on an Internet web server similar to as described in Kumar to enable access to data by anyone with a browser. Kirkness¶¶164.

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]. Kumar explains that such a feature is beneficial, e.g., by allowing a provider to seek expert consultation for difficult cases, by sharing the patient history and medical test results online. *Id.*; *see also id.*, [0084]. Kirkness¶¶165.

A POSITA would have also had a reasonable expectation of success in combining the above-discussed features with the Toge system. Kirkness¶166; EX1008, [0074] (“Existing devices (which are not web-enabled) ***may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI.***”). It was well known to transmit data using wireless protocol(s) to a remote Internet site that is implemented on a server, e.g., for later access of the data. EX1044, [0060]-[0061].

It would have involved a combination of known technologies (e.g., known PAP device that provides data relate to the subject's treatment through a network/Internet (Toge)) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine implemented on an Internet server (Kumar)) to yield the predictable result of a system including an Internet server-based remote engine that receives/stores data received from a patient-side device, e.g., the PAP device, for simultaneous storage, retrieval, analysis, and play back from anywhere in the world, as discussed above. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

2. [1.a]: one or more PAP devices

As discussed for the preamble, Toge discloses a PAP device 2. *See, e.g.*, EX1044, [0008]; Kirkness¶¶169-70; Chatterjee¶¶101-102. Burton also discloses a PAP device. *See, e.g.*, EX1050, 1:20-27; Kirkness¶¶169-70.

3. [1.b]-[1.b.iv]: subject(s) receiving treatment's cell phone;

Toge in view of Kumar discloses [1.b]-[1.b.iv]. Kirkness¶¶171-183; Chatterjee¶¶103-112. A POSITA would have found it obvious to implement these features in view of Kumar. Kirkness¶¶172. As discussed for the preamble, Kumar discloses a system that includes a patient-side device 102 (like the Toge PAP device), computing device 110 ("cell phone"), and central server 106 hosting a browser-based engine that is 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].

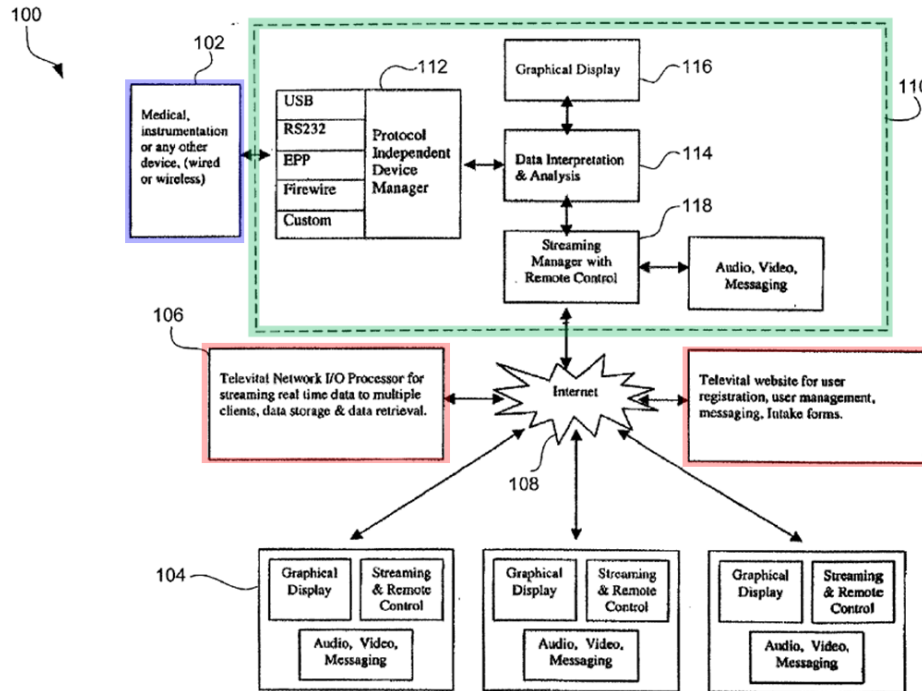


Fig. 1A

Kumar discloses “a first non-transitory computer readable medium.” Kumar discloses that “[t]he present invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium,” e.g., the memory on the computing device. EX1008, ¶[0020]. A POSITA would have understood that the downloaded plug-in is stored on Kumar’s “non-transitory computer readable medium.” Kirkness¶174; Chatterjee¶105.

Kumar discloses a “cell phone” that includes “a display.” Kirkness¶¶175-176; Chatterjee¶¶106, 112. Computing device 110 may be a wireless phone or

pocket PCs, e.g., an iPAQ device. EX1008, [0072]; EX1011, 2. Moreover, Kumar explains that computing device 110 may display data on a display module 116 (“display”). EX1008, [0075].

Kumar discloses “a first radio frequency wireless transceiver.” Kumar teaches using the iPAQ device (“cell phone”), which a POSITA would have understood included a radio frequency wireless transceiver to enable GPRS, Wi-Fi, and Bluetooth. EX1008, [0072]; EX1011, 2; Kirkness¶177; Chatterjee¶110.

Kumar discloses “the first software adapted to be executed by a first processor when the first software is downloaded to a cell phone of a subject(s) receiving treatment.” Kirkness¶¶178-180; Chatterjee¶¶107-109. Kumar discloses a plug-in (“first software”) downloaded by the computing devices, e.g., a cellular device such as an iPAQ (“cell phone”) that allows communications with the patient-side devices (such as Toge PAP device) through a wireless protocol. EX1008, [0074], [0073]. A POSITA would have understood that the plug-in allows the patient to access the patient’s data on the computing device and display that data on the display of the computing device. Kirkness¶179. Kumar, following the discussions of the plug-in, discloses that “[t]he data may be displayed graphically on the display module 116” of the computing device. EX1008, [0075]. 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¶180.

A POSITA would have found it obvious to implement the “cell phone” and associated features recited in [1.b]-[1.b.iv]. Kirkness¶181. The cell phone associated features would have allowed the patient to view the treatment data on the patient’s personal cell phone and storing such information for later viewing even when away from the PAP device. Kirkness¶181. Toge already expressly describes that the doctor or other medical professionals are able to access treatment related data via a mobile phone. EX1044, [0019]. It would have been beneficial for the patient to review such information indicating how the patient responded to the treatment and encouraging the patient to comply with the prescribed treatment. Kirkness¶181. Additionally, such a modification would have reduced the PAP device’s form factor as the PAP device would not need to include a screen suitable for displaying data to the patient, which in turn improves the device’s portability as PAP devices may be used during travel. Kirkness¶181; EX1056, 4; EX1057, 1.

A POSITA would have had the skill and a reasonable expectation of success in combining the teachings of Toge and Kumar. Kirkness¶182. Both references are in the same field of art and both relate to healthcare for sleep disorder. EX1044, [0019]; EX1012, 6:20-25, 7:2-6 (describing that the apparatus is a PAP device);

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 according to known methods to yield the predictable result of a system including a PAP device of improved portability and a cell phone that allows the patient to review the associated treatment data, which improves patient compliance, as discussed above. *Kirkness* ¶183; *KSR*, 550 U.S. at 416.

4. [1.b.v]-[1.b.v.A]: software on subject's cell phone receiving efficacy data

The Toge-Kumar combination in view of Burton discloses this limitation. *Kirkness* ¶¶184-208; *Chatterjee* ¶¶113-124. As discussed for [1.b]-[1.b.iv], the downloaded plug-in (“first software”) allows computing device 110 (“cell phone”) to communicate with the patient-side devices (such as Toge PAP device) through a wireless protocol and also to **receive data from the patient-side device**. *See, e.g.*, EX1008, [0075]. Further, Toge already expressly describes that the doctor or other medical professionals are able to access treatment related data via a mobile phone. EX1044, [0019]. Accordingly, the Toge-Kumar combination at least suggests the subject receiving treatment's cell phone “receiving” data based on the treatment of the subject from the PAP device.

A POSITA would have been motivated to implement in the Toge-Kumar combination these features in view of Burton. Kirkness¶185; Chatterjee¶126. To begin, Toge at least suggests “*generating the PAP therapy efficacy data based on a first data and a second data...*,” as recited in [1.d.iii]. For example, Toge’s control unit 250 (corresponding to “second processor” recited in [1.d.iii]) **generates “transmission data”** (“*generating the PAP therapy efficacy data*”). EX1044, [0030], [0033]. Toge explains that the **transmission data** includes “the patient’s **treatment data** such as the **tidal volume Fp**.” *Id.*, [0031]. **Tidal volume Fp** (including its trend) is calculated based on the measurements of **flow meter 24** (“sensor data”) and is used to assess and treat the patient’s condition when using the PAP device. *Id.*, [0033]-[0035], [0038]-[0039]. Thus, the patient’s tidal volume Fp is “the first data related to a quantitative measure of symptom severity during use of the PAP device.” Kirkness¶186.

Moreover, Toge discloses that the **treatment data** also includes “the **operational time T** of [PAP] device 2.” EX1044, [0031]. Toge discloses control unit 250 calculating “*the second data related to a usage of the PAP device by the subject*” because Toge discloses calculating operational time T, which represents the amount time the patient uses the PAP device. *Id.*, [0042]. In fact, Toge explains that “[b]y analyzing this operational time, physicians can determine whether the

patient is **using** the [PAP] device 2 and assess the treatment (patient) **compliance.**”
Id.; Kirkness¶188.

To the extent that Toge does not disclose “generating *the PAP therapy efficacy data*” as recited in [1.d.iii], a POSITA would have found it obvious to implement the recited features in the Toge-Kumar combination in view of Burton. Kirkness¶189.

Like Toge, Burton teaches providing PAP treatments to patients. EX1050, 1:20-27. Burton explains that, while PAP treatments may achieve intended results, they may “affect the quality of sleep” of the patient undergoing treatments by “causing transient arousals.” *Id.*, 1:9-19, 2:1-3:13. For example, the PAP device’s inaccuracy in detecting the upper airway resistance (UAR) events may cause “[e]xcessively rapid or excessively insensitive pressure changes” of the air delivered to the patient, leading to patient’s arousal and sleep fragmentation. *Id.*, 2:2-31. Kirkness¶190.

To resolve these issues, Burton discloses a system that “deliver[s] therapeutic treatments to patients without adversely affecting their sleep.” EX1050, 1:4-6, 3:15-16. It does so by “predict[ing] the onset of arousal and using **an adaptive algorithm to modify a patient’s therapeutic treatment.**” *Id.*, 3:21-24. The algorithm is “**adapted during real-time operation** based on any combination of a) empirical clinical data, b) individual patient collected or alternative (to laboratory) collected

data (from diagnostic study within sleep laboratory or other alternative site) or c) real-time monitored and analyzed data.” *Id.*, 3:24-28. Kirkness¶191.

“[T]o minimize arousals..., rates [of pressure change] and absolute pressure changes are adjusted in accordance to various patient states including [e.g.,] the patient’s current sleep state....” EX1050, 3:29-4:7. Burton’s algorithm “**detect[s] variation in airflow shape**...indicative of the incidence or probable onset of upper airway resistance (UAR) or variations of UAR, respiratory event related arousals (RERA) or treatment event related arousals (TERA).” *Id.*, 4:24-32; *see also id.*, 5:1-5. It allows a PAP device to “predict the UAR, RERA and TERA events or the onset of such events and adjust the treatment to avoid such events.” *Id.*, 5:10-12. “[T]he process of detecting and monitoring for arousals could occur simultaneously or **in virtual real-time** with automated gas delivery treatment algorithms which are able to **adapt to reduce or eliminate both sleep breathing disorders and sleep fragmentation**.” *Id.*, 5:13-16. The algorithm also “recognize[s] when the pressure adjustment of the gas delivery device is either too severe and leading to the promotion of RERAs or TERAs or avoid[s] the failure to compensate for less obvious (without comprehensive shape analysis and possibly patient specific calibration) or more subtle SBD such as UARs, hypopnea events, and shallow breathing.” *Id.*, 5:16-20. Kirkness¶192.

Specifically, Burton discloses using “the **shape characteristics of the airflow signal**” to record/determine “the likelihood of arousal or upper airway flow limitation.” EX1050, 4:18-20. “[A]rousals are detected by monitoring the presence of waveform signal disturbance evident” from the “**analysis...of the airflow waveform and pressure waveform.**” *Id.*, 13:21-23. “Apnea events, shallow breathing, upper airway resistance and hypopnea events can also be detected and pre-empted by analysis of the change in shape of the high bandwidth **monitoring of the airflow waveforms and pressure waveforms.**” *Id.*, 13:23-26. Kirkness¶193.

Burton explains that, when a patient receives CPAP treatment, arousal monitoring “includes **monitoring pressure and airflow associated with a patient’s breathing** in order to determine UAR (which may induce RERA)” and “[t]o prevent RERA, it is necessary to **detect a number of patterns which are indicative of sleep apnea symptoms, namely inspiratory flow limitation (flattening), snoring and flow amplitude reduction.**” EX1050, 14:1-7; *see also id.*, 14:8-18. Based on the analysis of the pressure and airflow, the controller “**generates pressure adjustment signal.**” *Id.*, 14:19-22, 14:23-30, 23:20-27, 23:28-24:12, 24:14-15. Kirkness¶194.

Additionally, Burton discloses using “profiles...determined from **patient-specific diagnostic studies**” and “changes in airflow pressure” to “determine whether the changes in the airflow shape resulting from these subtle treatment

changes are able to counteract the shape or profile characteristics indicative of the incidence or on-set of arousals (TERA or RERA) or OSAH and UAR.” EX1050, 20:8-13. Burton’s system may also “down-load from sleep laboratory studies or other types of **previous sleep, respiratory and/or cardiac related investigations**,” where the data is “associated with a subject’s breathing and sleep arousal parameters and is used to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of [e.g., unwanted arousal], while still minimizing sleep fragmentation and optimizing sleep quality.” *Id.*, 20:14-23, 26:9-15. Kirkness¶195.

The process of minimizing arousals “includes the capability to **automatically adjust the therapeutic treatment based on at least one index or derived data set**,” which includes, e.g., UAR, RERA, TERA, **Respiratory Disturbance Index (RDI)**, Respiratory Arousal Index (RAI), **Apnea-hypopnea index (AHI)**, Mixed Sleep Apnea events, Sleep Quality index, Obstructive Sleep Apnea/Hypopnea event or syndrome. EX1050, 21:4-22:21. Kirkness¶196.

Burton discloses [1.d.iii]. Kirkness¶¶197-198. **First**, Burton discloses “receiving sensor data,” e.g., from an airflow sensor. As discussed above, Burton’s algorithm uses received airflow and pressure sensor data to analyze, e.g., “**the shape characteristics of the airflow signal**,” including “the airflow waveform and pressure waveform.” EX1050, 4:18-20, 13:21-26. **Second**, Burton discloses “calculating...i) the first data related to a quantitative measure of symptom severity

during use of the PAP device.” For example, Burton’s algorithm **detects or calculates** “a number of patterns which are indicative of sleep apnea symptoms, namely inspiratory flow limitation (flattening), snoring and flow amplitude reduction (hypopneas and apneas),” where, as a POSITA would have understood, such patterns are “*related to*” the patient’s “*symptom severity during use of the PAP device.*” *Id.*, 14:1-7; *see also id.*, 14:8-18; Kirkness¶¶198-199. Additionally, Burton discloses calculating an index of a subject’s symptoms measured during use of the PAP device. For example, as discussed above, Burton discloses “automatically adjust[ing] the therapeutic treatment based on at least one index or derived data set,” which includes, e.g., RDI and AHI. *Id.*, 21:4-22:21. A POSITA would have understood that each of the above-described indices is “*related to*” the patient’s “*symptom severity during use of the PAP device.*” **Third**, Burton discloses “calculating...ii) the second data related to a usage of the PAP device by the subject.” As discussed above, Burton discloses using “profiles...determined from patient-specific diagnostic studies” (EX1050, 20:8-13) and information from patient’s “**previous sleep, respiratory...related investigations**” (*id.*, 20:14-23, 26:9-15) to customize the algorithm and the gas delivery device. Additionally, as discussed above, Burton discloses determining, e.g., AHI and RDI, which involves calculating sleep disorder events **per unit time during the patient’s usage of the PAP device.** Kirkness¶200.

Burton discloses “*generating the PAP therapy efficacy data based on a first data and a second data by receiving the sensor data, and calculating both i) the first data related to a quantitative measure of symptom severity during use of the PAP device and ii) the second data related to a usage of the PAP device by the subject*” in two ways. **First**, As discussed above, Burton’s controller/algorithm uses the received sensor data, calculations of patterns indicative of sleep apnea symptoms, index/indices or derived data set, and the patient’s prior sleep analysis as well as patient’s usage of the PAP device to control/adjust the therapeutic treatment. A POSITA would have understood that corresponding signals/data (that is generated and output by the algorithm) used to control/adjust the treatment are “the PAP therapy efficacy data” because these signals/data are derived from data collected during the treatment/therapy and for adjusting the treatment based on the received sensor signal indicating the efficacy and/or severity of the patient’s symptoms. Indeed by analyzing breathing patterns - ranging from snoring to complete apnea - this data serves as both a measure of therapy effectiveness and an indicator of the underlying severity of sleep apnea symptoms. Kirkness¶¶201-202.

Burton discloses this limitation in **a second way**. Burton discloses that its system is “adapted to...**display**...a number of sleep or arousal related physiological data or statistics,” where “[s]tatistics and indexes such as RAI, AHI, RERA, RDI, arousals, sleep fragmentation, or sleep architecture index are derived from the

monitored parameters and this information is stored for analysis.” EX1050, 27:11-13. Moreover, Burton includes “graphical and statistical tools,” enabling a user to manipulate/display “raw data or derived values in a meaningful format,” including “displaying raw data and then using visual clues to mark the occurrence of an event such as arousal in the raw data” and “link[ing] an event or events to specific index values or derived values which reflect the occurrence of the event.” *Id.*, 28:20-25. Given that Burton discloses displaying the above-described data/index (“the PAP therapy efficacy data”), Burton discloses “generating” these data/index in this second way. Kirkness¶203.

A POSITA would have been motivated to implement the above-described features of Burton such that a PAP device’s processor (*e.g.*, Toge’s processor in the PAP device corresponding to “second processor” as recited in [1.d.iii]) is implemented with the above-described algorithm. Kirkness¶204. These features would have been beneficial as they would have minimized/avoided arousals when the patient is undergoing PAP treatments and would have improved the patient’s sleep quality. The disclosed algorithm would have provided an improved accuracy in detecting arousals and treating patient’s sleep disorders given that it uses individual patient’s collected data to “customize a gas delivery device to be more sensitive and accurate....” EX1050, 20:14-23, 26:9-15.

As such, a POSITA would have been motivated to implement the above-described algorithm (as disclosed in Burton) in control unit 250 (e.g., as disclosed in the Toge-Kumar combination) such that the modified control unit is configured to receive and analyze the sensor data (e.g., data provided by pressure gauge 23 and flow meter 24, either component or collectively being the claimed “airflow sensor”), determine/calculate the airflow’s shape characteristics, patterns indicative of sleep apnea symptoms, indices of a subject’s symptoms measured during use of the PAP device, and data of usage of the PAP device, all of which are used to generate data for adjusting the PAP device operation and/or displayed to the user for additional analysis, for example. Kirkness¶205.

A POSITA would have had a reasonable expectation of success in implementing the above-discussed feature in the Toge-Kumar combination. Kirkness¶206. Burton’s disclosed features are “adapted for use with a CPAP machine” (EX1050, 19:25-26) and “[o]ne skilled in the art can readily appreciate that the subject invention is **easily adapted for use with, or incorporated within, other known therapeutic devices**” (*id.*, 19:26-28). Moreover, it would have involved a combination of known technologies (e.g., known PAP device that controls the device operations using a processor based on received sensor data (Toge-Kumar)) according to known methods (e.g., known methods/algorithm implemented on a controller/processor to generate/output data relating to PAP

therapy efficacy data based on sensor data and calculations of associated information (Burton)) to yield the predictable result of a PAP device implemented with an algorithm that minimizes/avoids transient arousals when the patient is receiving PAP treatments and improves the patient's sleep quality, as discussed above. Kirkness¶206; *KSR*, 550 U.S. at 416. Accordingly, the Toge-Kumar-Burton combination discloses [1.d.iii].

The Toge-Kumar-Burton combination discloses [1.b.v]-[1.b.v.A]. As discussed above, Kumar discloses that the downloaded plug-in (“first software”) allows computing device 110 (“cell phone”) to communicate with the patient-side devices (such as Toge PAP device) through a wireless protocol and also **receive data from the patient-side device**. *See, e.g.*, EX1008, [0075] (“The data interpretation and analysis module 114 [on computing device 110] is used to interpret the data stream from the client-side device....”). Kirkness¶207.

As discussed for [1.b]-[1.b.iv], a POSITA would have found it obvious to implement the “cell phone” and associated features because, for example, they would have allowed the patient to view the treatment data on the patient's personal cell phone, storing such information for later viewing even when away from the PAP device, and would have encouraged the patient to comply with the prescribed treatment. Kirkness¶208. Thus, for reasons similar to those discussed for [1.b]-[1.b.iv], a POSITA would have been motivated and found it obvious to configure

the downloaded plug-in (“first software”) on the cell phone such that the cell phone receives “PAP therapy efficacy data or a modified PAP therapy efficacy data based in part on the PAP therapy efficacy data both based on treatment of the subject and its efficacy in whole or in part.” Kirkness¶208.

5. [1.b.v.B]: outputting measures(s) on cell phone;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶209-211; Chatterjee¶¶125-128. As discussed for [1.b.v.A], the Toge-Burton-Kumar combination discloses a “cell phone” in multiple ways including mobile terminal 5 of Toge and computing device 110 of Kumar receiving “PAP therapy efficacy data.” Kumar discloses that computing device 110 may process the received data, *e.g.*, “perform mathematical analysis” and/or “generate statistics,” and then display the processed data. EX1008, [0075]. A POSITA would have understood that the processed “PAP therapy efficacy data” are “PAP therapy efficacy measures(s)” given that the process involves performing mathematical analysis and/or generating statistics. Kirkness¶¶210-211.

6. [1.c]: remote internet site and a database;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶212-14; Chatterjee¶¶129-131. As discussed for the preamble, Kumar discloses a browser-based engine (“remote internet site”), which can be accessed through web pages and is implemented on an Internet web server. *See, e.g.*, EX1008,

[0010], [0018], [0067], [0072], [0087]. Kumar also discloses that “the data may be stored in a **secured storage device at the central server** for later access, replay, and/or analysis” and “storage of the data allows for the creation of statistical **databases.**” *Id.*, [0083]. Kumar discloses that “[t]he present invention may be implemented on a program or code that can be stored in a computer-readable...medium.” EX1008, [0020].

7. [1.c.1]: 1) be hosted on at least one server, and

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶215-216; Chatterjee¶¶132-133. Kumar discloses that the engine is “implemented on a central server 106” (EX1008, [0067]) and that the “secured storage device [is] at the central server” (*id.*, [0083]). *See also* Kirkness¶216; Chatterjee¶133.

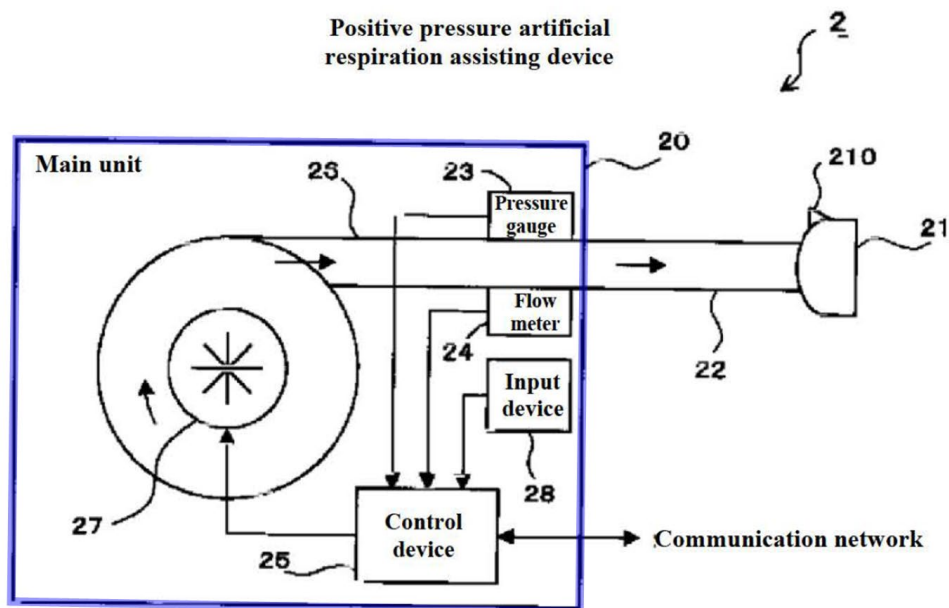
8. [1.c.2]: 2) be used for remote monitoring of multiple subjects receiving PAP therapy;

The Toge-Kumar-Burton combination discloses this limitation. Kirkness¶¶217-218; Chatterjee¶¶134-135. Toge discloses that “**multiple [PAP] devices 2** are provided for each of several patients.” EX1044, [0058]. Likewise, Kumar discloses “[t]he embodiments presented herein contemplate connection of **multiple patient-side devices**, provider-side devices, and engines.” EX1008, [0012].

9. [1.d]- [1.d.ii]: the PAP device

Toge discloses this limitation. Kirkness¶¶219-222; Chatterjee¶¶136-140.

As shown in Figure 2, Toge's PAP device 2 is configured to be a single enclosure (highlighted in blue), where the PAP device includes a main unit 20, a nasal mask 21, an air tube 22, a pressure gauge 23, a flow meter 24, a control device 25, a flow path 26, a blower 27, and an input device 28. EX1044, [0021], [0023]-[0024]. Toge explains that positive pressure air is delivered to nasal mask 21 via the air tube 22 from main unit 20, where nasal mask 21 is equipped with an exhalation vent 210 to expel the patient's exhaled breath to the exterior of the nasal mask 21. *Id.*, [0022]; Kirkness¶222. Toge's blower 27 supplies air to nasal mask 21 via air tube 22. EX1044, [0024]-[0025]; Chatterjee¶138.



EX1044, FIG. 1 (annotated)

As discussed above, Toge's PAP device includes pressure gauge 23 and flow meter 24 (either component or collectively being the claimed "sensor for providing a sensor data to determine airflow"). EX1044, [0021], [0023]-[0024]. As shown in Figure 2, both pressure gauge 23 and flow meter 24 reside within main unit 20 of the PAP device (sensor "internal to the PAP device"). Toge explains that "pressure gauge 23 detects and **measures** the air pressure inside the flow path 26" and the "measured air pressure is provided to the control unit 250 of the control device 25." *Id.*, [0028]. Flow meter 24 "detects and **measures** the airflow" within the flow path 26 and the "measured flow rate is then provided to the control unit 250 of the control device 25." *Id.*

Burton similarly discloses these limitations. *See, e.g.*, EX.1050, 6:12-19, FIG.1.

10. [1.d.iii]: generating the PAP therapy efficacy data

The Toge-Kumar-Burton combination discloses this limitation for the reasons discussed for [1.b.v.A]. Kirkness¶¶223; Chatterjee¶141.

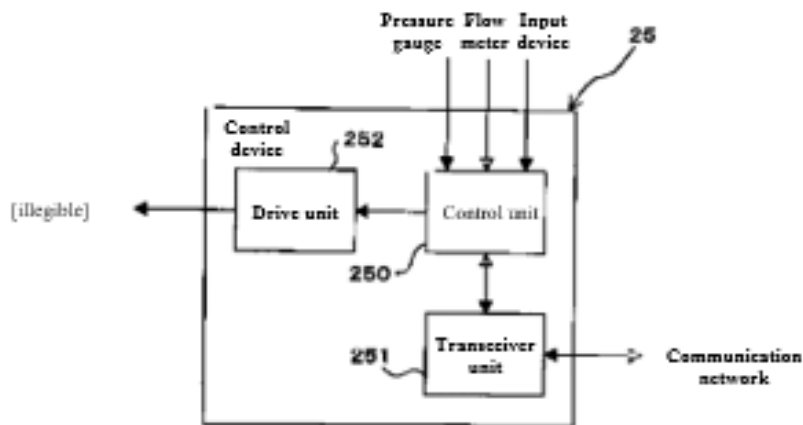
11. [1.d.iv]: second radio frequency wireless transceiver

The Toge-Kumar-Burton combination discloses this limitation. Kirkness¶¶224-231; Chatterjee¶¶142-148. As discussed for [1.b.v.A] and [1.b.v.B], a POSITA would have been motivated to **transmit "the PAP therapy efficacy**

data” from the PAP device to the patient’s cell phone, e.g., to allow the patient to view the associated data.

As show in Figure 3 below, Toge discloses control device 25 includes a transceiver unit 251. EX1044, [0023].

[Figure 3]



EX1044, FIG. 3

Toge discloses that, under the control of control unit 250, transceiver unit 251, via network 1, transmits data provided from the control unit 250 to the relay device 3, and receives data from the physician-side computer 4 or mobile terminal 5. *Id.*, [0030]; *see also id.*, [0008]-[0009], FIG. 1. Toge explains that the functionality of “relay device 3 can be incorporated into the [PAP] device 2 (the control unit 250 of the control device 25), allowing it to be configured as an integrated unit with the positive pressure artificial respiration assisting device 2.” *Id.*, [0060]. Toge also

explains that in this case the “[PAP] device 2 then directly transmits all or part of the treatment data to the physician-side computer 4 or mobile terminal 5 via the communication network 1. The physician-side computer 4 or mobile terminal 5 then directly sets the thresholds on the positive pressure artificial respiration assisting device 2 and sends download requests.” *Id.*, [0061].

As discussed for the preamble, Toge discloses that network 1 may be “a **mobile** communication network” (*id.*, [0009]) and that PAP device 2, relay device 3, physician-side computer 4 are **wirelessly** connected to communication network 1 for transmitting data (*id.*, [0006]-[0007]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1). Given Toge’s disclosures that PAP device 2 is wirelessly connected to network 1, which may be a mobile network, a POSITA would have understood that PAP device 2 includes a radio frequency wireless transceiver (“at least one second radio frequency wireless transceiver”) in order to connect and communicate via network 1 operating mobile/wireless network protocols. Kirkness¶228; Chatterjee¶146.

To the extent that Toge does not disclose that the PAP device includes “at least one second radio frequency wireless transceiver,” such a feature would have been obvious to a POSITA. Kirkness¶229; Chatterjee¶147. Indeed, there were only a handful of known techniques for transmitting data wirelessly, including radio frequency communication and optical wireless communications. Chatterjee¶147.

Thus, using a radio frequency wireless transceiver to implement communications via radio frequency would have been obvious because it was one of a “finite number of identified, predictable solutions.” *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331 (Fed. Cir. 2009).

A POSITA would have had the skill and a reasonable expectation of success in implementing a radio frequency wireless transceiver in the PAP device. Kirkness¶¶230-231. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, EX1045, Fig. 3; EX1013, [0029]. Moreover, it would have involved a combination of known technologies (PAP device that transmits treatment data via a mobile network) according to known methods (known methods of transmitting data using a radio frequency wireless transceiver) to yield the predictable result of a PAP device using a RF wireless transceiver to communicate via a mobile network, as discussed above. *KSR*, 550 U.S. at 416.

12. [1.d.v]: mask or nasal cannula

Toge discloses this limitation. Kirkness¶¶232-233; Chatterjee¶¶149-150. Toge discloses positive pressure device 2 includes nasal mask 21. EX1044, [0021].

13. [1.e]: remote internet site and database receive PAP therapy

efficacy data

The Toge-Kumar-Burton combination discloses this limitation. Kirkness¶¶234-236; Chatterjee¶¶151-153. As discussed for the preamble and [1.c], Kumar discloses a browser-based engine (“remote internet site”), where “the data may be stored in a secured storage device...for later access, replay, and/or analysis” and “storage of the data allows for the creation of statistical databases.” EX1008, [0010], [0018], [0067], [0072], [0083], [0087]. As discussed for [1.c], a POSITA would have understood that Kumar’s a browser-based engine (“remote internet site”) and secured storage device (“database”) are implemented on program(s)/code (“second software”).

As discussed in the preamble, a POSITA would have been motivated to implement the remote internet site to enable the PAP device to wirelessly transmit to the remote engine data associated the patient’s treatment. As discussed for [1.b.v.A] and [1.d.iii], the modified PAP device generates “the PAP therapy efficacy data” based on “treatment of the subject and its efficacy.” Consistent with the reasons discuss for the preamble, a POSITA would have been motivated to implement the remote internet site, including configure the “second software for the remote internet site and the database” such that it is adapted to receive data associated the patient’s treatment, including “the PAP therapy efficacy data,” wirelessly transmitted from the PAP device. For example, 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]. A POSITA would have had the motivations, capabilities, and reasonable expectation of success discussed for the preamble to modify the Toge-Burton-Kumar combination to provide the above-discussed feature. Kirkness¶235.

Moreover, as discussed for [1.d.iv], the Toge-Kumar-Burton combination discloses that the PAP device includes a “second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data.”

D. Dependent Claims 2-5, 7, 8, 10, 11-13, 15-18, 20-31

1. Claim 2: “The system of claim 1, wherein the one or more

PAP therapy efficacy measure(s) includes an index.”

The Toge-Kumar-Burton combination discloses this limitation. Kirkness¶¶237-239; Chatterjee¶¶154-155.

As discussed for [1.b.v.A], Burton discloses that calculating an index of a subject’s symptoms measured during use of the PAP device, including, e.g., Respiratory Disturbance Index (RDI) and Apnea-hypopnea index (AHI), is a part of the process of “generating the PAP therapy efficacy data.” EX1050, 21:4-22:21. As discussed for [1.b.v.B], “PAP therapy efficacy measures(s),” as disclosed by the Toge-Burton-Kumar combination, is an output of the processed/analyzed “PAP therapy efficacy data.” Accordingly, the Toge-Burton-Kumar combination discloses “the one or more PAP therapy efficacy measure(s) includes an index,” such as the RDI and AHI. Kirkness¶¶238; Chatterjee¶¶155.

2. Claims 3, 21: PAP device(s) utilize a cellular network to be adjusted remotely

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶240-245; Chatterjee¶¶156-158.

Toge discloses Network 1 may be “a **mobile** communication network” (*id.*, [0009]) and that PAP device 2, relay device 3, physician-side computer 4 are **wirelessly** connected to communication network 1 for transmitting data (*id.*, [0006]-[0007]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1). Thus, a

POSITA would have understood that the PAP device includes an electronic component, such as control unit 250 (incorporating relay device 3, as discussed in EX1050, [0060]), adapted to utilize a mobile network (“cellular network”).

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 browser-based engine is “responsible for streaming...remote control information between multiple clients and hosts.” *Id.*, [0082]; Kirkness¶242. As discussed for [1.b.v.A], Burton discloses controlling/adjusting the treatment based on “the PAP therapy efficacy data.”

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 (“remote internet site”) “the PAP therapy efficacy data.” Kirkness¶244. 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., control unit 250, such that it may be adjusted remotely (“an electronic component adapted

to utilize a cellular network and allow the one or more PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site”) 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. EX1044, [0025]; Kirkness¶244.

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¶245.

3. Claim 4: index is based on both the first and second data;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶247-249; Chatterjee¶¶159-161. As discussed for claim 2, the index includes, e.g., Respiratory Disturbance Index (RDI) and Apnea-hypopnea index (AHI). A POSITA would have understood that AHI is a measured number of apnea and hypopnea events per unit time determined during the patient’s usage of the PAP device. Kirkness¶248. Accordingly, The Toge-Burton-Kumar combination discloses the index is based on both the first data (which is “related to a quantitative measure of symptom severity during use of the PAP device”) and the second data (which is “related to a usage of the PAP device by the subject”). *Id.*

4. Claim 5: PAP device adjusted based on efficacy data received by the remote internet site;

The Toge-Kumar-Burton combination discloses this limitation. Kirkness¶¶250-252; Chatterjee¶¶162-165. As discussed for [1.b.v.A], Burton’s controller/algorithm uses “the PAP therapy efficacy data” generated by a PAP device to adjust the treatment, and a POSITA would have been motivated to implement the algorithm in control unit 250 (e.g., as disclosed in the Toge-Kumar combination) for adjusting the PAP device operation.

Moreover, as discussed for [1.e], a POSITA would have been motivated and found it obvious to transmit “the PAP therapy efficacy data” to the browser-based engine (“remote internet site”) because, e.g., “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis.” EX1008, [0083]. Kirkness¶252; Chatterjee¶165.

5. Claim 7: cell phone receives and retransmits PAP therapy efficacy data and/or a reprocessed data to the remote internet site

The Toge-Kumar-Burton combination discloses this limitation. Kirkness¶¶253-257; Chatterjee¶¶166-169. As discussed for [1.b.v] and [1.b.v.A], the first software implemented on the computing device 110 (“cell phone”) receives “PAP therapy efficacy data” that is “based on treatment of the subject and its efficacy” (“first software adapted to be executed by the cell phone receives, in whole

or part, the PAP therapy efficacy data related to treatment of the subject generated by the one or more PAP device(s)").

As discussed for [1.b.v.B], Kumar discloses that computing device 110 ("cell phone") may process the received data, e.g., "perform mathematical analysis" and/or "generate statistics," and then display the processed data. EX1008, [0075]. A POSITA would have been motivated and found it obvious to transmit from computing device 110 ("cell phone") by using its RF transmitter ("first radio frequency wireless transceiver") the processed data to the browser-based engine ("remote internet site") for secured storage, later access, replay, and/or analysis. Kirkness¶255; Chatterjee¶168; EX1008, [0083], [0084].

A POSITA would have also had a reasonable expectation of success in implementing the above-described features. Kirkness¶256. 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 that is implemented on a server, e.g., for later access of the data. Moreover, it would have involved a combination of known technologies (a cell phone that processes received data) according to known methods (receiving from the cell phone the processed data for storage at a browser-based engine) to yield the predictable result of a system including a browser-based engine receiving processed

data from a cell phone for secured storage, later access, replay, and/or analysis, as discussed above. Kirkness¶257; *KSR*, 550 U.S. at 416.

6. Claim 8: PAP device and patient's cell phone communicate using Bluetooth;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶258-262; Chatterjee¶¶170-172. To begin, Bluetooth wireless protocol is one of the well-known wireless protocols for data transmission at the time of the alleged invention. Kirkness¶259; Chatterjee¶171; EX1009, 14:54-15:12 (use of wireless/Bluetooth protocol to transmit data associated with a CPAP device); EX1011, 2 (disclosing that an iPAQ cell phone is capable of communicating using Bluetooth protocol).

Burton explains that “user data viewing and reports” can be interfaced using “W-LAN and even BluetoothTM wireless devices.” EX1050, 8:28-9:2. Moreover, Kumar explains that the data from the PAP device may be processed and displayed on computing device 110 (“cell phone”). EX1008, [0075]. Thus, as a POSITA would have recognized, following a treatment session, the patient would have been interested in downloading and viewing the data related to the treatment on the cell phone. Kirkness¶260.

In addition to Burton's express teaching using Bluetooth for data/report viewing, there were only a handful of other protocol for transmitting data wirelessly,

including WiFi, mobile network protocol, optical connection, for example. Chatterjee¶172. Thus, using the Bluetooth protocol for wireless transmission would have been obvious because it would have been one of a “finite number of identified, predictable solutions.” *Perfect Web*, 587 F.3d at 1331.

7. Claims 10, 15, 20: PAP sensor data signal processing techniques;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶263-264; Chatterjee¶¶173-177. Burton discloses processing the airflow sensor data by “calculat[ing] some statistical measurements...such as mean, **deviation**, average and maximum error....” EX1050, 17:22-25. A POSITA would have understood that calculating deviation encompasses calculating one of the known types of deviation, e.g., mean deviation, standard deviation, and quartile deviation. Chatterjee¶175; EX1055, 28-30 (disclosing various processing techniques known at the time including “wavelet analysis”, “standard deviation or variance”, and “Fast Fourier Transform (FFT) algorithm”). Thus, processing sensor data using a known signal processing technique such as the standard deviation technique would have been obvious because it would have been one of a “finite number of identified, predictable solutions.” *Perfect Web*, 587 F.3d at 1331.

8. Claim 11, 16, 22: symptom data related to both obstructive,

and central apneas;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶265-266; Chatterjee¶¶178-179. As discussed for [1.b.v.A], the “first data” includes “at least one index or derived data set,” which may include “**Mixed Sleep Apnea** events, **Central Sleep Apnea** events, Upper Airway Resistance Syndrome (UARS) events, **Obstructive sleep apnea** and hypopnea syndrome (OSAHS) events....” EX1050, 21:4-22:21. A POSITA would have understood that “Mixed Sleep Apnea events” include events of both central apnea and obstructive apnea. Kirkness¶266.

9. Claim 12: retransmitted;

The Toge-Kumar-Burton combination discloses this limitation. Kirkness¶¶267-269; Chatterjee¶¶180-183. As discussed for claim 7, a POSITA would have been motivated and found it obvious to transmit from computing device 110 (“cell phone”) by using its RF transmitter (“first radio frequency wireless transceiver”) the processed “PAP therapy efficacy data generated by the one or more PAP device” to the browser-based engine (“remote internet site”) for secured storage, **later access, replay, and/or analysis**. Kirkness¶269; Chatterjee¶¶182-183; EX1008, [0083], [0084]. For similar reasons, a POSITA would have found it obvious to receive/download those “data” previously transmitted to the browser-

based engine (“the remote internet site”) for “later access, replay, and/or analysis.”
Id.

10. Claim 13: PAP device and cell phone communicate via a cellular network or Internet

The Toge-Kumar-Burton combination discloses this limitation. Kirkness¶¶270-271; Chatterjee¶¶184-185. As discussed for [1.b.iv], Toge discloses that network 1 may be “a **mobile** communication network” (*id.*, [0009]) and that **PAP device 2**, relay device 3, physician-side computer 4 are wirelessly **connected to communication network 1** for transmitting data (*id.*, [0006]-[0007]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1).

11. Claim 17: independent receipt of data

The Toge-Burton-Kumar combination discloses this limitation. As discussed for [1.e], the Toge-Kumar-Burton combination discloses a browser-based engine (“remote internet site”) that receives “PAP therapy efficacy data” generated by the PAP device. Kirkness¶¶272-273; Chatterjee¶¶186=187. Kumar additionally discloses that data may be transferred “**directly** from one device to the other” (EX1008, [0081]), e.g., from the PAP device to the computing device 110 (“cell phone”).

12. Claim 18: PAP device communication pathways;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶274-276; Chatterjee¶¶188-190. As discussed for [1.e], the Toge-Burton-Kumar combination discloses that the PAP device transmits “the PAP therapy efficacy data” to the browser-based engine (“remote internet site”). As discussed for the preamble, Toge discloses the PAP device is connected to a mobile network (“cellular network”). A POSITA would have understood that the PAP device “further comprises an electronic component adapted to transmit the PAP therapy efficacy data to the remote internet site at least in part via a cellular network.”

As discussed for claim 8, the Toge-Burton-Kumar combination discloses using the Bluetooth protocol to transmit “PAP therapy efficacy data” from the PAP device to the cell phone.

13. Claims 23, 25: remote internet site and the database accessible to a clinician or doctor;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶277-278; Chatterjee¶¶191-192. As discussed for [1.c] and [1.c.1], the Toge-Burton-Kumar combination discloses that a browser-based engine (“remote internet site”) and database/storage are implemented/hosted on a central server. *See*, e.g., EX1008, [0010], [0018], [0067], [0072], [0083], [0087]. Kumar explains that

“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.” *Id.*, [0192]; *see also id.* [0067] (“The system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider”).

14. Claims 24, 26: second software performs automatic data analysis with a third processor;

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶279-280; Chatterjee¶¶193-194. Kumar discloses that storing data at the browser-based engine allows “the creation of statistical databases.” EX1008, [0083]. Moreover, Kumar explains that “the healthcare provider can view a statistical summary report” and “a graphical report that can also be displayed” for use with remote monitoring. *Id.*, [0092]. A POSITA would have understood that the statistical summary report and/or the graphical report are automatically generated by the central server, on which the “software” is executed. Additionally, a POSITA would have understood that either of the statistical summary report or the graphical report is an example of “data analysis.”

15. Claim 27: monitor subjects in another country

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶281-282; Chatterjee¶¶195-196. Kumar discloses that “[t]he system can

also be adapted to make such specialized treatment available worldwide via the Internet, by allowing the provider to use his existing protocol to treat patients in another state or **country**.” EX1008, [0181].

16. Claims 28-31: database functionality

The Toge-Burton-Kumar combination discloses claims 28-31. Kirkness¶¶283-290; Chatterjee¶¶197-205. As discussed for [1.e], based on the teachings of Toge, Burton, and Kumar, a POSITA would have been motivated to implement the remote internet site, including configure the “second software for the remote internet site and the database” such that it is adapted to receive data associated the patient’s treatment, including “the PAP therapy efficacy data.” 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].

Kumar also explains that the database may “**integrate** the [stored] data, whether as raw data, **trended data**, or **summary data**, into any electronic medical records system” and “allows for the creation of **statistical databases**.” EX1008, [0083]. Accordingly, Kumar discloses and/or suggests performing additional analysis, e.g., data integration, data trend recognition, and statistical analysis on the data stored at the database (e.g., the PAP therapy efficacy data stored at the database as disclosed by the Toge-Burton-Kumar combination). Kirkness¶284.

Kumar and Burton each discusses various techniques to analyze data. For example, Kumar discloses “using **artificial intelligence**” to “**track trends**” and “predict future behaviors and physiological responses.” EX1008, [0084]. Burton discloses that its algorithm detects “**patterns** which are indicative of sleep apnea symptoms.” EX1050, 14:1-7. Burton also discloses techniques including “**neural networks** or other methods that are capable of **adopting self-learning and algorithm adaptation techniques.**” *Id.*, 4:29-32. Kirkness¶285.

A POSITA would have been motivated to use the above-described techniques to analyze the PAP therapy efficacy data stored at the database because, for example, Kumar expressly discloses that data stored at the database allows for “**later access...and/or analysis**” from “anywhere in the world,” which “beneficially allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online.” EX1008,[0083]; Kirkness¶286. A POSITA would have understood that subsequent studies of the data stored on the database would have allowed the care providers to analyze patterns and statistical significances of the patients’ long-term or cumulative data associated with the sleep disorder treatment/efficacy. Kirkness¶286.

A POSITA would have had a reasonable expectation of success in implementing the above-discussed features in the Toge-Kumar-Burton combination. Kirkness¶287. Indeed, it would have involved a combination of known technologies

(e.g., known database storing the PAP therapy efficacy data for later access/analysis (Toge-Kumar-Burton)) according to known methods (e.g., known techniques to analyze data associated with sleep disorder (Kumar and Burton)) to yield the predictable result of database storing the PAP therapy efficacy data adapted for later access and analysis based on various known techniques, as discussed above. *KSR*, 550 U.S. at 416.

Thus, the Toge-Kumar-Burton combination discloses claim 28 (“the PAP therapy efficacy data is adapted to be analyzed to **recognize patterns** of sleep disorders or therapy for sleep disorders”) given that Kumar discloses applying techniques to recognize data trends (EX1008, [0083]) and Burton discloses detecting patterns on data associated with sleep disorder (EX1050, 14:1-7). The Toge-Kumar-Burton combination discloses claim 29 (“the database with the PAP therapy efficacy data is adapted to be analyzed to train **a neural network**”) because Burton discloses applying techniques including “neural networks or other methods that are capable of adopting self-learning and algorithm adaptation techniques.” EX1050, 4:29-32. *Kirkness*¶288; *Chatterjee*¶202.

Additionally, the Toge-Kumar-Burton combination discloses claim 30 (“the database with the PAP therapy efficacy data is adapted to be analyzed to **correlate more robust data from multiple subjects to teach or train the sensor on the one or more PAP device(s)**”). Burton explains that data analysis may be based on

“individual patient collected or collected data (from diagnostic study within sleep laboratory or other alternative site.” EX1050, 26:12-15. A POSITA would have understood that “collected data (from diagnostic study within sleep laboratory or other alternative site” are “data from multiple subjects,” as claimed. Kirkness¶289. Moreover, as discussed above, Burton discloses applying “self-learning and algorithm adaptation techniques.” A POSITA would have understood that such techniques involve using data (including those from various patients) to improve/train the algorithm on the PAP device that operates based on sensor data. *Id.*

Lastly, the Toge-Kumar-Burton combination discloses claim 31 (“the database with the PAP therapy efficacy data is adapted to be **analyzed with a relationship algorithm**”) given that Kumar discloses applying “using artificial intelligence” to “predict future behaviors and physiological responses.” EX1008, [0084]. Furthermore, Burton discloses “down-load[ing] [data] from sleep laboratory studies or other types of previous sleep, respiratory...related investigations.” EX1050, 20:14-15. These data are “associated with a subject’s breathing and sleep arousal parameters,” are “used to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of [different types of arousal events], while still minimizing sleep fragmentation and optimizing sleep quality.” *Id.*, 20:15-19. Kirkness¶290; Chatterjee¶205.

**VIII. GROUND 2: TOGE IN VIEW OF KUMAR, BURTON, AND KISNER
RENDERS OBVIOUS CLAIMS 10, 15, 20**

A. Motivation To Combine

A POSITA would have been motivated to implement Kisner's teaching in the Toge-Kumar-Burton combination. Kirkness¶¶291-292; Chatterjee¶¶210-213. Kisner teaches analyzing sensor data on a processor, including using the wavelet analysis to extract breathing parameters. EX1051, 13:36-53. Based on the extracted parameters, the processor may alert the care provider of the patient's condition. *Id.* Kirkness¶291.

Moreover, a POSITA would have understood that wavelet analysis is known to be used for assessing breathing patterns because it can analyze signals at multiple time scales, capturing both short-term fluctuations and long-term trends. Chatterjee¶¶211-212. Indeed, wavelet analysis allows for signal decomposition into various frequency bands, and by classifying various frequency component, relevant breathing signal features, properties and classifications of the breathing signal can be determined. Real time monitoring of signals using a wavelet analysis is one of the known ways to examine dynamic breathing patterns that change over time, such as for apnea or hypopnea classification/detection. Chatterjee¶¶208-209.

B. Reasonable Expectation Of Success

A POSITA would have had a reasonable expectation of success in implementing Kisner's teaching in the Toge-Burton-Kumar combination. Kirkness¶¶293-296; Chatterjee¶¶214-218.

First, similar to the Toge-Kumar-Burton combination, where the PAP device control algorithm is implemented in a processor (*see* Section VII.C.5, [1.b.v.A]), Kisner explains that the algorithm for the wavelet analysis is implemented in a microprocessor system. EX1051, 13:36-53. Kirkness¶294; Chatterjee¶215.

Second, similar to Burton that discloses using neural networks to detect airflow shape variations (EX1050, 4:29-32), Kisner also discloses using neural networks to analyze/process the sensor signals (EX1051, 13:42-45). Kirkness¶295.

Third, such an implementation would have involved a combination of known technologies (PAP device that use sensors to detect and treat sleep disorder, as taught by the Toge-Kumar-Burton combination) according to known methods (using a wavelet analysis algorithm to extract breathing patterns as taught by Kisner) to yield the predictable result of a system including an improved PAP device in treating sleep disorder. Kirkness¶296; Chatterjee¶216.

C. Dependent Claims 10, 15, and 20

Ground 1 establishes that the combinations of prior art teachings a POSITA would have implemented to improve the Toge PAP device in view of Kumar and

Burton that discloses the challenged claims. Section VII (Ground 1). To the extent that the prior art combination does not disclose claims 10, 15, and 20, reciting “wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of...a wavelet analysis,” it would have been obvious to implement this feature into the system resulting from these combinations in light of Kisner. Kirkness¶297; Chatterjee¶¶206-209.

Like Toge and Burton, Kisner discloses a method for monitoring a patient’s respiration, including monitoring sleep disorders, *e.g.*, apnea. EX1051, Abstract, 12:59-13:11 (“In the case of the apnea monitor, this system performs the following digital signal processing actions....”). Kirkness¶298. Kisner additionally discloses the monitoring process may be implemented in a microprocessor system that extracts “[b]reathing parameters...using **wavelet analysis** or similar means,” where the extracted signals “are processed using threshold, fuzz-logic, neural networks or similar processing technique...to determine if an alarm or other desired output condition exists.” *Id.*, 13:36-53. In particular, as shown in Figure 11 below, Kisner explains that sensor signals 104 are first reconstructed using neural networks or other algorithms, then breathing patterns are extracted using wavelet analysis or similar means to determine if an alarm or other desired output condition. *Id.*, 13:49-53.

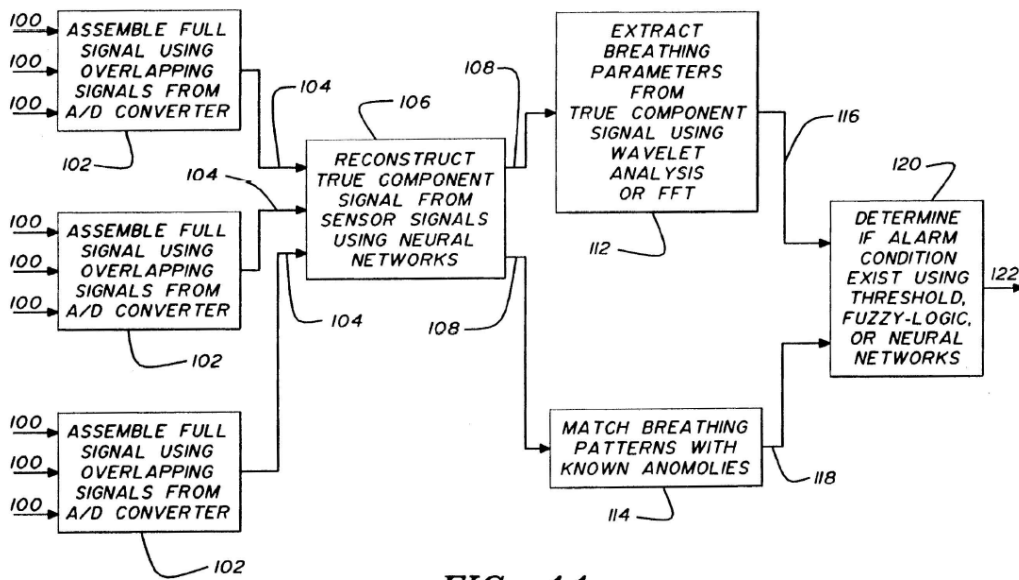


FIG. 11

EX1051, FIG. 11

Accordingly, Kisner discloses “wherein the signal from the sensor...is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of...a wavelet analysis” as recited in claims 10, 15, and 20.

Kirkness¶299-300.

A POSITA would have been motivated and found it obvious to implement Kisner’s teaching in the Toge-Burton-Kumar combination discussed in Ground 1. Kirkness¶301. As discussed above, Kisner teaches using the result from the wavelet analysis to notify the care provider. EX1051, 15:27-31. Moreover, a POSITA would have understood that wavelet analysis is known at the time (EX1055, 28-30 (disclosing various processing techniques known at the time including “wavelet analysis”, “standard deviation or variance”, and “Fast Fourier Transform (FFT)

algorithm”)) and is used for assessing breathing patterns because it can analyze signals at multiple time scales, capturing both short-term fluctuations and long-term trends. Indeed, wavelet analysis allows for signal decomposition into various frequency bands, and by classifying various frequency component, relevant breathing signal features, properties and classifications of the breathing signal can be determined. Real time monitoring of signals using a wavelet analysis is one of the known ways to examine dynamic breathing patterns that change over time, such as for apnea or hypopnea classification/detection. Thus, a POSITA would have understood that using the disclosed feature with the air flow/pressure sensor(s) disclosed in the Toge-Kumar-Burton combination would have improved treatments and/or remote monitoring. *Id.* Kirkness¶301.

A POSITA would have also had the skill and reasonable expectation of success in implementing the teachings of Kisner in the Toge-Kumar-Burton combination. Kirkness¶302. Similar to the Toge-Kumar-Burton combination, where the PAP device control algorithm is implemented in a processor (*see* Section VII.C.5, [1.b.v.A]), Kisner explains that the algorithm for the wavelet analysis is implemented in a microprocessor system. EX1051, 13:36-53. Additionally, similar to Burton that discloses using neural networks to detect airflow shape variations (EX1050, 4:29-32), Kisner also discloses using neural networks to analyze/process the sensor signals (EX1051, 13:42-45). Furthermore, the '680 patent acknowledges

that the wavelet analysis is one of the “signal processing algorithms known to those skilled in the art.” EX1001, 26:67-27:5. Moreover, it would have involved a combination of known technologies (PAP device that use sensors to detect and treat sleep disorder, as taught by the Toge-Kumar-Burton combination) according to known methods (using a wavelet analysis algorithm to extract breathing patterns as taught by Kisner) to yield the predictable result of a system including an improved PAP device in treating sleep disorder, as discussed above. Kirkness¶302; KSR, 550 U.S. at 416.

IX. 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.

X. THE BOARD SHOULD REACH THE MERITS OF THIS PETITION

A. No Denial Under § 325(d)

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 Toge nor Kumar were considered during prosecution.

Additionally, discretionary denial is also not warranted in view of the pending *ex parte* reexamination proceedings, since this petition does not present the same or substantially the same prior art or arguments presented in the reexamination, and there are material differences between the art/arguments here with those presented in the pending EPR. None of the positions in the reexamination rely on Burton, which is asserted is each of the grounds presented in this petition. *See*, EX1050, Sections VII-VIII. Thus there is no substantial overlap between the grounds here and the grounds in the pending EPR.

Further, given the statutory deadline to file an IPR, ResMed could not have waited until the conclusion of the reexamination to file this IPR. *See Mueller Sys., LLC v. Rein Tech, Inc.*, IPR2020-00100, Paper 9 at 12-14 (P.T.A.B. May 12, 2020) (“Petitioner would be barred from challenging claims...following the Reexamination Proceeding.”). Additionally, the reexamination remains at an early stage, which counsels against discretionary denial. *See Mueller* at 13. Accordingly, discretionary denial is not warranted in view of the EPR. *See Pfizer Inc. v. Hoffman-LA Roche Inc.*, IPR2018-01219, Paper 12 at 5-10 (P.T.A.B. Dec. 18, 2018) (instituting IPR where “the grounds differ” from those in the pending EPR).

B. No Denial Under § 314(a)

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. Under the current facts, *Fintiv* is not applicable. There is no trial scheduled.

XI. 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 '680 Patent is assigned to Cleveland Medical Devices Inc. ("PO". Petitioner is currently asserting the '680 Patent in the following litigation filed on March 20, 2023: *ResMed Corp., v. Cleveland Medical Devices, Inc.*, 1:23-cv-02221-BMB (N.D. Ohio.)

Petitioner has filed, at substantially the same time that this Petition was filed, petitions for *inter partes* review against U.S. Patent No. 11,375,921, U.S. Patent No. 11,690,512, U.S. Patent No. 11,786,680, U.S. Patent No. 11,857,333, and U.S. Patent No. 11,872,029.

C. Notice of Counsel and Service Information

ResMed provides the following designation of counsel:

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	Fax: 213.996.2112 Email: PH-ResMed-CleveMed@paulhastings.com
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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 '680 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.

XII. CONCLUSION

For these reasons, Petitioner respectfully requests institution.

Dated: December 6, 2024

Respectfully submitted,

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CLAIM APPENDIX

1. A system for remote internet server-based diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment comprising

- [a] A. one or more PAP device(s);
- [b] B. a first non-transitory computer readable medium comprising a first software stored on the first non-transitory computer readable medium, the first software adapted to be executed by a first processor when the first software is downloaded to a cell phone of a subject(s) receiving treatment, the cell phone requiring:
 - [b.i] 1) at least one first radio frequency wireless transceiver,
 - [b.ii] 2) the first processor,
 - [b.iii] 3) the first software, and
 - [b.iv] 4) a display,
 - [b.v] the first software further adapted for:
 - [b.v.A] i) receiving a PAP therapy efficacy data or a modified PAP therapy efficacy data based in part on the PAP therapy efficacy data both based on treatment of the subject and its efficacy in whole or in part, and
 - [b.v.B] ii) outputting one or more PAP therapy efficacy measures(s) on the display of the cell phone for viewing by the subject based in whole or in part on the data received by the first software; and
- [c] C. a second non-transitory computer readable medium comprising at least one second software for a remote internet site and a database, the remote internet site and the database stored on a non-transitory computer readable medium and adapted to:

- [c.i] 1) Be hosted on at least one server, and
 - [c.ii] 2) be used for remote monitoring of multiple subjects receiving PAP therapy;
 - [d] wherein the one or more PAP device(s) that is each used for treating the sleeping disorder of the subject(s) or their symptoms, and further comprises:
 - [d.i] a blower having an air output,
 - [d.ii] a sensor for providing a sensor data to determine airflow, the sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of the subject while using the PAP,
 - [d.iii] a second processor adapted for generating the PAP therapy efficacy data based on a first data and a second data by receiving the sensor data, and calculating both i) the first data related to a quantitative measure of symptom severity during use of the PAP device and ii) the second data related to a usage of the PAP device by the subject,
 - [d.iv] at least one second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data, and
 - [d.v] a mask or a nasal cannula; and
 - [e] the at least one second software for the remote internet site and the database is further adapted to receive the PAP therapy efficacy data, in whole or in 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 one or more PAP therapy efficacy measure(s) includes an index.
 3. The system of claim 2, wherein the one or more PAP device(s) further comprises an electronic component adapted to utilize a cellular network and

allow the one or more PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site.

4. The system of claim 2, wherein the index is based on both the first data and the second data from the one or more PAP device(s).
5. The system in claim 4, wherein the PAP device for treating the sleeping disorder of the subject is adjusted based in whole or part on the PAP therapy efficacy data generated by the one or more PAP device(s) and then received by the remote internet site.
8. The system in claim 7, wherein the second radio frequency wireless transceiver of the one or more PAP device and the first software adapted to use the at least one first radio frequency wireless transceiver of the cell phone are further adapted to transmit PAP therapy efficacy data and/or a reprocessed data based in part on the PAP therapy efficacy data from the one or more PAP device(s) to the cell phone using a Bluetooth wireless protocol.
10. The system in claim 7, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or 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 time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.
11. The system of claim 7, wherein the first data of the PAP therapy efficacy data includes specific symptom data related to both obstructive, and central apneas.
12. The system in claim 4, wherein the first software adapted to be executed by the first processor of the cell phone to receive, in whole or part, the PAP therapy efficacy data generated by the one or more PAP device and/or the modified therapy efficacy data based in part on the PAP therapy efficacy data that is first received at least in part from the PAP device by the remote internet site and then retransmitted to the first software from the remote internet site.

13. The system in claim 12, wherein the one or more PAP device(s) and the first software adapted for use with the cell phone are further adapted to transmit and receive data based on the PAP therapy efficacy via a cellular network or through the Internet.
15. The system in claim 12, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device is processed, in whole or 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 time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.
16. The system of claim 12, wherein the first data of the PAP therapy efficacy data includes specific symptom data related to both obstructive, and central apneas.
17. The system in claim 4, wherein the first software is adapted to be executed by the first processor of the cell phone and the remote internet site both independently receives, in whole or part, the PAP therapy efficacy data generated by the one or more PAP device and/or the modified therapy efficacy data based in part on the PAP therapy efficacy data.
18. The system in claim 17, the one or more PAP device(s) further comprises an electronic component adapted to transmit the PAP therapy efficacy data to the remote internet site at least in part via a cellular network, and the second radio frequency wireless transceiver of the one or more PAP device(s) is used to transmit PAP therapy efficacy data of the subject to the first software adapted to use the first radio frequency wireless transceiver of the cell phone using a Bluetooth wireless protocol.
20. The system in claim 17, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device is processed, in whole or 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 time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

21. The system of claim 17, wherein the one or more PAP device(s) further comprises an electronic component adapted to utilize a cellular network and allow the one or more PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site.
22. The system of claim 17, wherein the first data of the PAP therapy efficacy data includes specific symptom data related to both obstructive, and central apneas.
23. The system of claim 4, wherein the at least one second software with the remote internet site and the database are adapted to be accessible to a clinician or doctor of the subject for a remote monitoring of the patient and/or their PAP therapy when hosted on the at least one server.
24. The system of claim 23, wherein the at least one second software is adapted to perform automatic data analysis for the clinician or doctor for use with the remote monitoring when hosted on the at least one server or with a third processor.
25. The system of claim 2, wherein the at least one second software with the remote internet site and the database are adapted to be accessible to a clinician or doctor of the subject for a remote monitoring of the patient and/or their PAP therapy when hosted on the at least one server.
26. The system of claim 25, wherein the at least one second software is adapted to perform automatic data analysis for the clinician or doctor for use with the remote monitoring when hosted on the at least one server or with a third processor.
27. The system in claim 1, wherein the remote internet site and/or the database are adapted to be accessible one or more of clinicians, technicians, researchers or doctors for analysis or a remote monitoring of one or more of the subjects in another country.
28. The system in claim 1, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to recognize patterns of sleep disorders or therapy for sleep disorders.

29. The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to train a neural network.
30. The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to correlate more robust data from multiple subjects to teach or train the sensor on the one or more PAP device(s).
31. The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed with a relationship algorithm.

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.
11,786,680** exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a),
contains 13,975 words and therefore complies with the type-volume limitations of
37 C.F.R. §42.24(a).

Dated: December 6, 2024

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RESMED CORP.

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 11,786,680 AND EXHIBITS EX1001-1057** are being served on December 6, 2024, via FedEx overnight mail on counsel of record for U.S. Patent No. 11,602,284 as addressed below:

Robert Schmidt
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Cleveland, OH 44103
UNITED STATES

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

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