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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 IPR2025-00159

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,375,921**

Claims 1, 2, 4, 5, 7-9, 11-14, 16

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TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,375,921 to Kayyali (“the ’921 Patent”)
1002	File History of U.S. Patent No. 11,375,921
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”)

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1014	U.S. Patent No. 5,424,942 to Dong et al. (“Dong”)
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”)
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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

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1035	J. Meurice, et al., “Efficacy of Auto-CPAP in the Treatment of Obstructive Sleep Apnea/Hypopnea Syndrome,” <i>Am. J. Respir. Crit. Care Med.</i> 153:794-8 (1996)
1036	S. Wilber, et. al., “Patient Monitoring and Anesthetic Management: A Physiological Communications Network,” <i>JAMA</i> 191:893-898 (1965)
1037	M. Weil, et. al., “Experience With a Digital Computer for Study and Improved Management of the Critically Ill,” <i>JAMA</i> 198:1011-1016 (1966)
1038	C. Lilly, et. al., “Critical Care Telemedicine: Evolution and State of the Art,” <i>Critical Care Medicine</i> 42:2429-2436 (2014)
1039	M. Breslow, et. al., “Effect of a multiple-site intensive care unit telemedicine program on clinical and economic outcomes: An alternative paradigm for intensivist staffing,” <i>Critical Care Medicine</i> 32:31-38 (2004)
1040	K. Zundel, “Telemedicine: history, applications, and impact on librarianship,” <i>Bull Med Libr. Assoc.</i> 84:71-79 (1996)
1041	Y. Wang, et. al., “Validation of microMESAM as Screening Device for Sleep Disordered Breathing,” <i>Pneumologie</i> 57:734-740 (2003)
1042	A. Boudewyns, et. al., “Two months follow up of auto-CPAP treatment in patients with obstructive sleep apnoea,” <i>Thorax</i> 54:147-149 (1999)
1043	D. Lankford, “Wireless CPAP Patient Monitoring: Accuracy Study,” <i>Telemedicine Journal and e-Health</i> 10:162-169 (2004)

Exhibit No.	Description
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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1049	WIPO Publication No. WO0145014A1 to Quay (“Quay”)
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	’921 Patent Ex Parte Re Examination Order
1054	Clevemed Opening Claim Construction Brief
1055	WIPO Publication No. WO2006090371A2 to Orbach (“Orbach 2006”)

I. INTRODUCTION

ResMed Corp. (“Petitioner”) respectfully requests *inter partes* review of claims 1-2, 4-5, 7-9, 11-14, and 16 of U.S. Patent No. 11,375,921 (EX1001, “’921 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 ’921 Patent claims a networked PAP system that transmits symptom and usage data to a cell phone and remote internet site. But this system is nothing more than an obvious combination of known PAP devices, like Toge (EX1044) and Burton (EX1050), and known telemedicine systems, like Kumar et al. (EX1008).

Petitioner respectfully requests the Board institute review and find all challenged claims of the '921 Patent unpatentable.

II. IDENTIFICATION OF CHALLENGES

Ground 1: Claims 1-2, 4-5, 7-9, 11-14, and 16 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious over Toge¹, Burton, and Kumar; and

Ground 2: Claims 1-2, 4-5, 7-9, 11-14, and 16 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious over Toge, Burton, Kumar, and 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.* These obstructions decrease blood oxygenation and elevate the risk of heart disease, among other health problems. *Id.* ¶65; EX1015, 1:27-28.

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.

¶¶By the mid-1990s, a self-setting machine that “adjusts CPAP pressure on a minute-by-minute basis according to the degree of upper airway obstruction” was widely available. EX1015, 1; Kirkness¶¶74; *see also id.*, ¶¶75-84.

Metrics that physicians often use to determine the severity of sleep disorders include the Apnea-Hypopnea Index (AHI), Oxygen Desaturation Index (ODI), Respiratory Disturbance Index (RDI), snoring intensity and duration, arousal index, sleep fragmentation, and heart rate variability (HRV) during sleep. Kirkness¶¶66-67, 85. These indicators quantify the frequency and impact of breathing disturbances, sleep quality disruptions, and cardiovascular stress, helping to assess sleep disorder severity, guide treatment, and track therapy effectiveness. *Id.* ¶¶66-67, 85. PAP machines often use one or a combination of these indicators to adjust pressure. *Id.* ¶¶67, 74, 77, 80, 82, 86.

2. Telemedicine

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.* ¶¶91-93.

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¶¶79. 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.*, ¶¶25-31; *see also id.*, ¶¶25-30. This mobile access to the Internet promoted the connection to more “things,” including medical devices. *Id.*, ¶¶48-53; *see also id.*, ¶¶32-47.

B. The '921 Patent

The claims of the '921 Patent describe well-known PAP sleep disorder treatment devices implemented in a networked system, generally focusing on a PAP device “which analyzes a subject’s sleeping disorder or symptoms and adjusts a treatment device based, in part, on this analysis.” EX1001, 2:34-36. The specification discloses numerous embodiments, only briefly referencing one implemented in a “remote communication system.” *Id.*, 19:8-45.

The system includes a PAP device “that can be used to physically treat a subject’s sleep disorder” by adjusting pressure based on “the level of severity of the subject’s sleep disorder.” *Id.*, 22:41-44. As discussed below in Sections VII.C.2-4,

Toge's conventional PAP system 10 (Figure 1) is substantially similar to the '921 patent's PAP device (Figure 7). As shown below in Figure 7, the PAP device includes a blower, an airflow sensor, a processor, and a mask or nasal cannula.

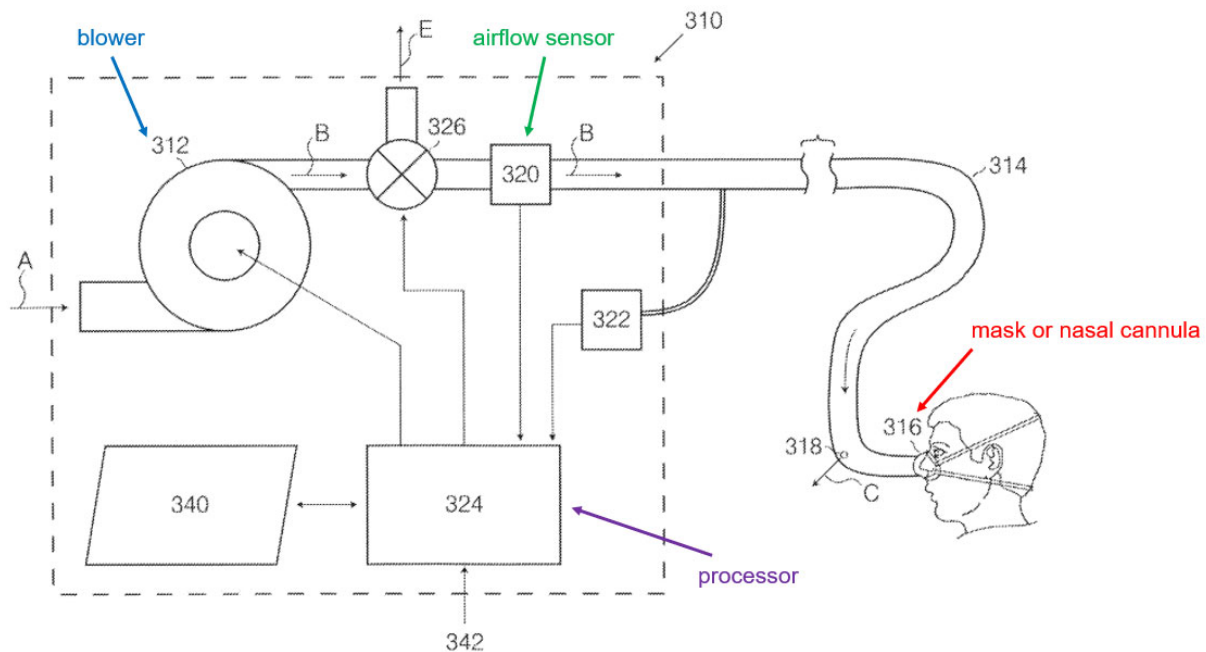


Fig. 7

EX1001, Figure 7 (annotated)

“Sensors which can be used are known to those skilled in the art.” *Id.*, 6:10-11. These sensors “measur[e] the subject’s respirations or oxygen levels” and can “include sensors to measure airflow, respiratory effort, oxygenation and ventilation.” *Id.*, 3:19-21. Using the processor, “[s]ignals from these sensors are then analyzed to determine the level of severity of the symptoms of the subject’s sleep disorder.” *Id.*, 3:35-37. The information from the sensor can also be used to “monitor the usage of

the pressure support device.” *Id.*, 23:15-17. Notably, the specification includes no discussion of “generating and outputting the data related to the subject's treatment and the treatment's efficacy” or how to generate and output it “by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device.” *See id.*, cl. 1.

In the briefly discussed “remote communication system” embodiment, the specification notes “the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.” *Id.*, 19:12-15. “[A] PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information...to a remote site for analysis.” *Id.*, 19:44-49.

C. CHALLENGED CLAIMS

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

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

The '921 Patent has 16 claims, 3 independent claim and 13 dependent claims. Independent claims 1, 7, and 12 generally covers a PAP system with three components:

- (1) a PAP device including a processor for outputting the data related to the subject's treatment and the treatment's efficacy and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device;
- (2) a computer readable medium comprising software to display the data by using a base station, a cell phone or a PDA; and
- (3) a remote internet site to receive the data relate to the subject's treatment and the treatment's efficacy.

Certain dependent claims further require “using Bluetooth wireless protocol” for transmitting certain data. Certain other dependent claims require transmitting certain data “via cell towers or cable.”

D. PROSECUTION HISTORY

The Examiner rejected the claims under 35 U.S.C. §§101 and 112. EX1002, 173-184. Patent Owner amended the claim language to specify where the software is stored and stated that the claims are “not limited as a means plus function.” *Id.*, 213-214. Subsequently, the Examiner amended the claims and allowed the same. *Id.*, 225-235. The Examiner also indicated that the prior art of record did not teach the following:

wherein the sensor data from the sensors is processed 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 kernals, and a wavelet analysis.

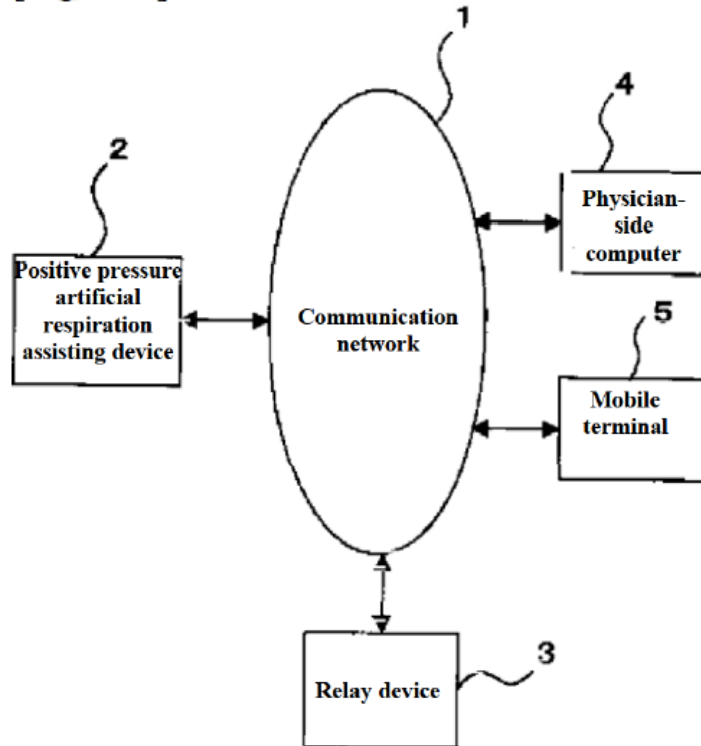
EX1002, 235.

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 telemedicine system where a PAP device is connected to a communications network by a relay device (3), and physician-side terminal devices (4 and 5) all connected to a communication network (1). EX1044, [0008]. Toge's 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].

B. Kumar (EX1008)

Kumar discloses a telemedicine system “for network-based monitoring of physiological data.” EX1008, Abstract. Figure 1A shows the system includes a patient-side device 102, computing device 110 (e.g., wireless phone or pocket PC such as the IPAQ), and central server 106 that hosts a browser-based engine that can be accessed through web pages. EX1008, [0067], [0072]. The computing device downloads a “plug-in” to communicate with the patient-side device and the central server. *Id.*, [0018].

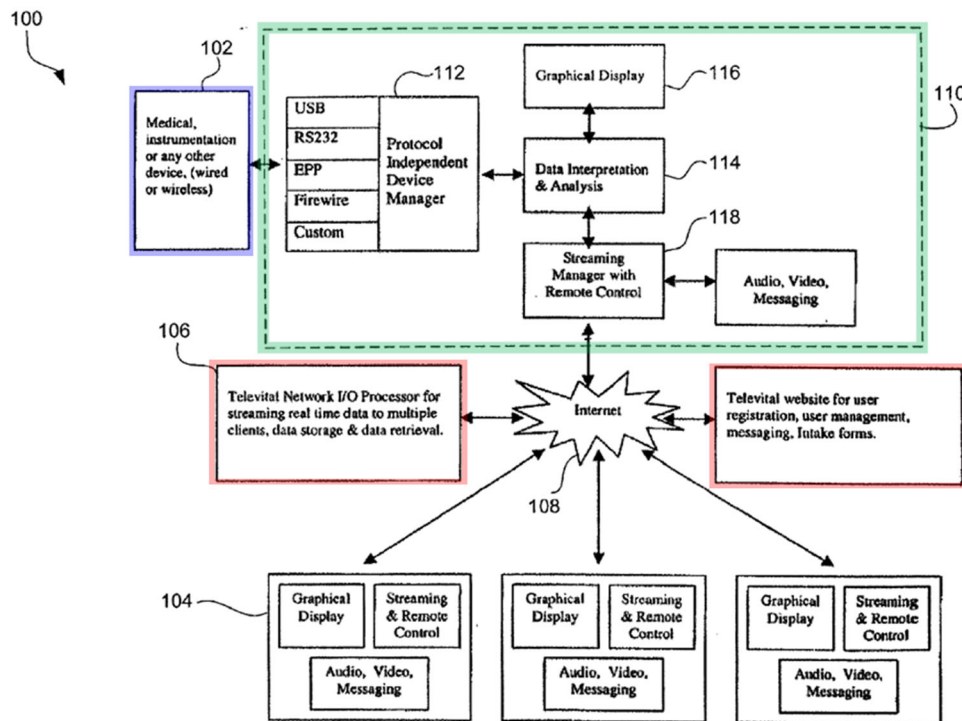


Fig. 1A

EX1008, FIG. 1A

Kumar teaches that “virtually any [patient-side] device may be easily incorporated into the system.” *Id.*, [0018]. One of the devices that Kumar teaches can be incorporated into the system is a device to address sleep apnea-hypopnea syndrome, which “allows remote monitoring of such devices by providing in-home monitoring.” *Id.*, [0239]-[0241].

C. Burton (EX1050)

Burton relates to providing PAP treatments to patients. EX1050, 1:20-27. Burton explains that, while PAP treatments may achieve intended results, “they also often severely affect the quality of sleep.” *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 “maintain[s] the sleep quality of a patient undergoing a therapeutic treatment” by “predict[ing] the onset of arousal and using **an adaptive algorithm to modify a patient’s therapeutic treatment.**” *Id.*, 3:21-24. The therapeutic control algorithm is “**adapted during real-time operation** based on any combination of [e.g., empirical clinical data, individual patient collected or real-time monitored and analyzed data].” *Id.*, 3:24-28.

D. Kisner (EX1051)

Kisner discloses a method for monitoring the respiration of a patient, including monitoring sleep disorder, e.g., apnea. EX1051, Abstract, 12:59-13:11. “Breathing parameters are extracted from true component signals 108 using wavelet analysis...to generate signal 116,” and “signal 108 are [also] matched with known anomalies at 114 to generate signals 118.” *Id.*, 11:45-49. “Signals 116 and 118 are processed...to determine if an alarm or other desired output condition exists which is expressed and communicated by signal 122.” *Id.*, 11:49-53.

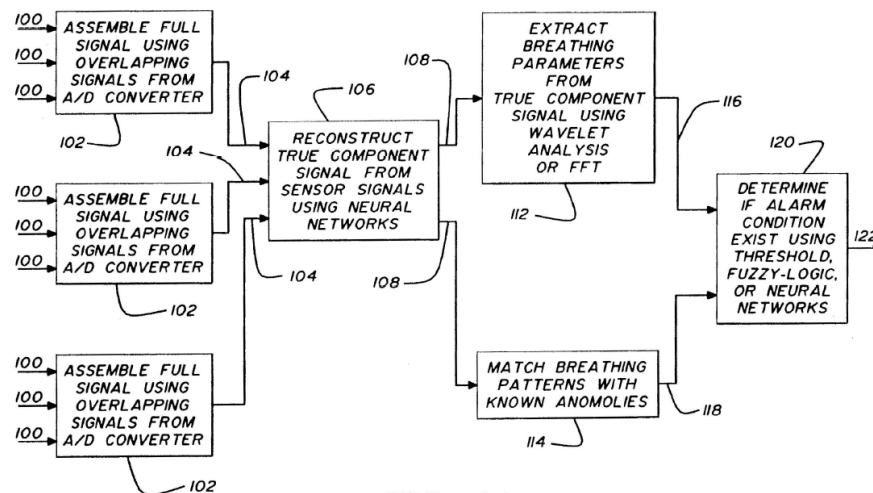


FIG. 11

EX1051, FIG. 11

V. LEVEL OF SKILL IN THE ART

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 ¶¶44-46; *see also id.*, ¶¶1-42, 47-63; Chatterjee, ¶¶20-23.

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. Kirkness ¶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). Notwithstanding, for the purpose of this proceeding, this Petition adopts PO’s interpretation of the following terms as described in PO’s opening claim construction brief in the parallel district court action:

- “generating and outputting the data related to the subject’s treatment and the treatment’s efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device, and

data of usage of the PAP device” (recited in claim limitation 1[a.iii]/7[a.iii]/12[a.iii]).

- “measuring and calculating a data of a quantitative output of the severity of a subject’s sleeping disorder symptoms during a treatment and further providing for a data related the subject’s treatment and the treatment’s efficacy” (recited in limitation 1[a.vi]/7[a.vi]/12[a.vi])

Specifically, PO states these limitations are met when “[t]he claimed system can calculate when a subject has an apnea or hypopnea event using sensor data from the subject and the average number of such events over the total period of time spent sleeping, and determine a subject’s Apnea Hypopnea Index (“AHI”) severity level, which is an example of a medical measurement of the severity of a subject’s sleep disorder and is used to diagnose the severity of sleep apnea.” Ex. 1054, 12, 13 (“A POSITA would understand from the claims and specification what types of symptom data that are calculable, *i.e.*, airflow and apneic events, and indexes, such as AHI Further, a POSITA would recognize that each value calculated for a specific type of symptom data or index is representative of the level of severity of a subject’s sleeping disorder.”); *see also Western Digital Corp. v. Spex. Techs., Inc.*, IPR2018-00084, Paper 14, 11 (Apr. 25, 2018) (petitioner need not “express its subjective agreement regarding correctness of its proffered claim construction or to take ownership of those constructions.”); *see also Polycom, Inc. v. directPacket*

Research, Inc., IPR2019-01235, Paper 19, 10 (Jan. 13, 2020); *VMWare, Inc. v. Cirba IP Inc.*, IPR2021-00008, Paper 10, 10 (May 7, 2021).

Otherwise, this Petition establishes the prior art meets each of the claim limitation under any reasonable construction.⁴ Kirkness¶¶133-134; Chatterjee, ¶¶71-75.

VII. GROUND 1: TOGE IN VIEW OF BURTON AND KUMAR 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¶¶135-140; Chatterjee¶¶76-90.

First, a POSITA would have been motivated by convenience and efficiency. *Id.*, ¶136. OSA is a chronic condition and PAP therapy requires ongoing management, support, and frequent follow-up between patient and care providers

⁴ Petitioner reserves the right to argue alternative constructions in other proceedings, including indefiniteness. *See, e.g., Target Corp. v. Proxicom Wireless, LLC*, IPR2020-00904, Paper 11 at 11-13 (Nov. 10, 2020).

and physicians. Setting appointments and traveling to see providers requires an investment in time and resources for both the provider and patient. *See, e.g.*, EX1044, [0004]; Kirkness¶136. Collecting data accessible anywhere by the provider and physicians through web pages to remotely monitor the data, assess therapy and prescribe modifications and/or changes reduces or avoids 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. Kirkness¶136; Chatterjee¶¶76-78.

Second, a POSITA would have been motivated to provide health access to more people. Kirkness¶137; Chatterjee¶86. As Kumar observes, telemedicine has provided “access to health assessments, diagnoses, interventions, supervision, consultations, education, and information across a distance.” EX1008, ¶[0003]. This is why many early advancements in telemedicine came from NASA (to monitor the health of astronauts) and Indian Health Services (to provide health services to remote locations). Kirkness¶137; Chatterjee¶¶86-87. Kumar’s plug-and-play user interfaces would allow anyone with an Internet browser to access the data. Kirkness¶137; Chatterjee¶¶79-86.

Third, a POSITA would have been motivated to leverage the advances in mobile computing and wireless communications. Kirkness¶¶138-139; Chatterjee¶¶48-53, 76-78. The early 2000s saw technological advances in

semiconductors, energy-efficient wireless communication, and reduced budgets for computational devices that allowed wireless networks of smart sensors to become feasible for many applications, including medical applications. Chatterjee ¶¶79. This also meant more shared analysis and data that could be leveraged. Kirkness ¶¶138-139.

Last, a POSITA would have been motivated by the general market trend to implement consumer devices into intelligent systems. Chatterjee ¶¶78-79. 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.*, ¶¶78-79. A POSITA would have naturally looked at known design options for telemedicine like Kumar’s “plug-and-play” user interface. *Id.*, ¶¶80-87; Kirkness ¶140.

Additionally a POSITA would have been motivated to modify the Toge-Kumar PAP device and system to incorporate Burton’s efficacy and severity data. Kirkness ¶¶141-144; Chatterjee ¶¶88-90.

First, including Burton’s efficacy and severity data 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 a positive pressure artificial respiration assisting device itself.” EX1044, [0005]. Toge also discusses setting limits and adjusting the prescription pressure based on the patient’s condition. EX1044, [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 Burton’s ability to “recognize 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.” EX1050, 5:16-20; Kirkness¶142; Chatterjee¶¶88-89.

Second, it would have advanced the purposes of Toge to “enable remote monitoring of the patient’s condition during the use of a positive pressure artificial respiration assisting device, ” (EX1044, [0005]) to “assess the fit of the nasal make 21 and the level of discomfort” (*Id.*, [0040]) and to “determine whether the patient is using the positive pressure artificial respiration assisting device 2 and assess the treatment (patient) compliance.” *Id.*, [0042]. A major limitation of CPAP therapy was non-compliance due to discomfort. EX1016, 5. The modification would have been advantageous to minimize the pressure applied, increase comfort, and therefore improve compliance. Kirkness ¶¶143-144; Chatterjee¶¶89-90.

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¶¶145-148; Chatterjee¶¶91-95.

First, Toge and Kumar are structurally and functionally similar. Toge itself utilized wireless communication. Kirkness¶¶146; Chatterjee ¶92. 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]; *see also* Kirkness¶¶146; Chatterjee¶¶92.

Second, Toge and Burton are analogous art as both references describe CPAP systems that include flow sensors and processors. EX1044, [0023] ("control unit 250"); EX1050, 10:10-12 ("controller...includes a processor"). Both further disclose that the processor analyzes the signals from the flow sensors. EX1044, [0028]; EX1050, FIG. 1, 6:12-15, 10:3-5, claim 43. Both have the objective of treating sleep disordered breathing using CPAP. EX1044, [0008]; EX1050, 1:20-27; Kirkness¶147; Chatterjee¶¶93-95.

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], Fig. 1. The modifications would simply be a change of programming to the control unit 250 of Toge to output the efficacy and severity data 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 ¶148; Chatterjee ¶¶94-95.

C. Independent Claims 1, 7, 12

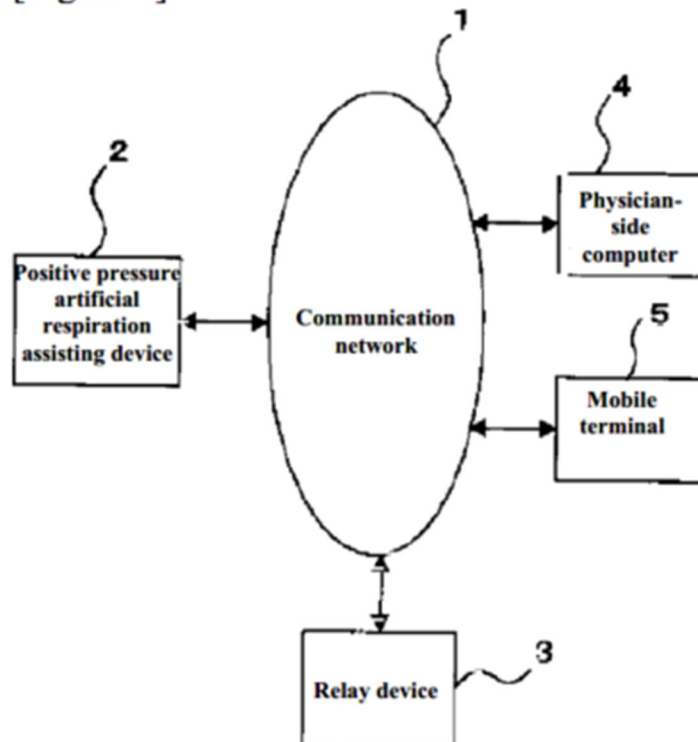
1. Preamble: a sleeping disorder treatment system

To the extent limiting, Toge discloses the preamble. Kirkness¶¶149-156; Chatterjee¶¶96-97. As shown in Figure 1, Toge discloses a remote medical (telemedicine) system for treating patients having sleep apnea (“sleeping disorder treatment system”). 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 “the functionality of such a relay device 3 can be incorporated into the positive pressure artificial respiration assisting 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 explains that in this case “[PAP] device 2 then directly transmits all or part of the treatment data to the physician-side computer 4 or mobile terminal 5 via...network 1. The 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] (examples of remote monitoring), [0085]. Kirkness¶¶149-151.

Additionally, Toge discloses that network 1 may be the “Internet” or “a mobile communication network.” *Id.*, [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¶¶151-152; Chatterjee¶¶96-97.

Relay device 3 receives data from PAP device 2 and transmits “all or part” of the data to physician-side computer 4. EX1044, [0016]. Computer 4 receives data from relay device 3 and allows care providers, e.g., physicians, to access the transmitted data using the computer. *Id.*, [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¶¶153; Chatterjee¶¶96-97.

Mobile terminal 5 may be “**mobile phones**” or “PDAs.” EX1044, [0019]. Mobile terminal 5, possessed by the care provider, 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]. The care provider may operate the mobile terminal 5 to “set the necessary data...for [PAP] device 2.” *Id.* Toge also discloses that the PAP device 2, relay device 3, and physician-side computer 4 are wirelessly connected to communication network 1 for transmitting

data, e.g., “treatment data.” *Id.*, [0006]-[0007]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1. Kirkness¶¶154; Chatterjee¶¶96-97.

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. EX1044, Abstract, [0001], [0005]-[0006], [0039], [0085]; Kirkness¶¶155-156; Chatterjee¶¶96-97.

2. 1[a]/7[a]/12[a]: a PAP device comprising:

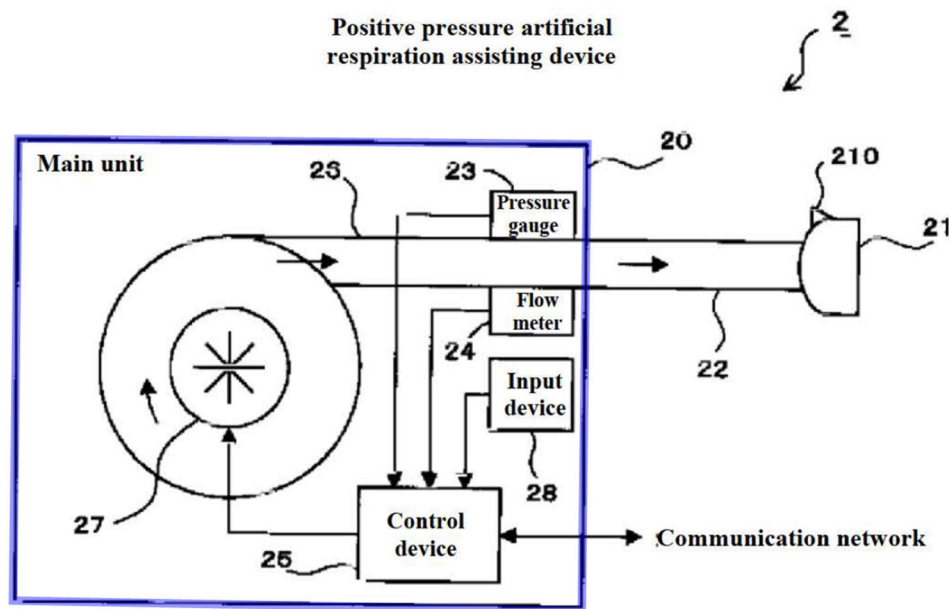
1[a.i]/7[a.i]/12[a.i]: a blower;

1[a.ii]/7[a.ii]/12[a.ii]: an airflow sensor;

Toge discloses these limitations. Kirkness¶¶157-161; Chatterjee¶¶98-102.

Toge discloses “a PAP device configured to be a single enclosure.” 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]. Positive pressure air is delivered to nasal mask 21 from main unit 20, where nasal mask 21 is equipped with an exhalation vent 210. *Id.*, [0022]; Kirkness¶¶158e¶. Further, Toge disclosed that relay device 3 can be “incorporated into the positive pressure artificial respiration assisting 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.” EX1044, [0060], [0016]. Blower 27 supplies air to nasal mask 21 via air tube 22. EX1044, [0024]-[0025]. Thus, Toge discloses that the PAP device includes “a blower having an air output.” Kirkness¶¶158-159; Chatterjee¶¶98-101.



EX1044, FIG. 2 (annotated)

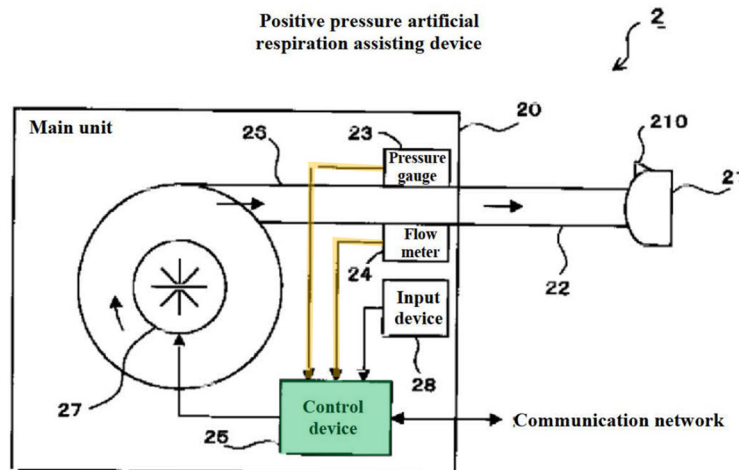
As discussed above, Toge’s PAP device includes pressure gauge 23 and flow meter 24 (either component or collectively being the claimed “airflow sensor”). EX1044, [0021], [0023]-[0024]. As shown in Figure 2, both pressure gauge 23 and flow meter 24 reside within main unit 20 of the PAP device (airflow 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....” *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.* Accordingly, Toge discloses limitations [1/7/12.a], [1/7/12.a.i], [1/7/12.a.ii]; Kirkness¶¶160-161; Chatterjee¶¶101-102.

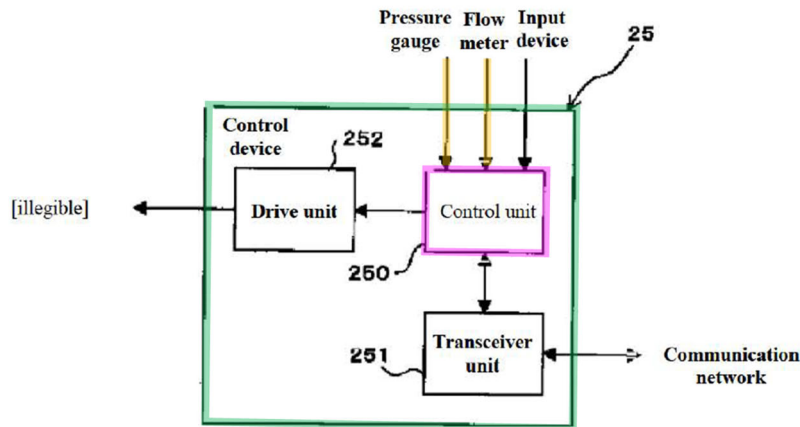
3. 1[a.iii]/7[a.iii]/12[a.iii]: a first processor adapted for generating and outputting the data;

Toge discloses this limitation. Kirkness¶¶162-168; Chatterjee¶¶103-110. Alternatively, Toge in view of Burton renders obvious this limitation. Kirkness¶¶169-189; Chatterjee¶¶111-115.

Toge discloses that the PAP device includes a “first processor.” As shown in Figures 2 and 3 below, Toge discloses that the PAP device includes control device 25, which comprises a control unit 250 (“first processor”). EX1044, [0023].



EX1044, FIG. 2 (annotated)



EX1044, FIG. 3 (annotated)

Toge explains that “control unit 250 can be constructed using a program describing the processing of the control unit 250..., along with a CPU....” *Id.*, [0048]; Kirkness ¶¶163; Chatterjee, ¶¶103-104.

Toge discloses that control unit 250 (“first processor”) “receiv[es] sensor data from the airflow sensor.” For example, consistent with as shown in Figures 2 and 3 above, control unit 250 receives measured air pressure and measured flow rate (“sensor data”) respectively from pressure gauge 23 and flow meter 24 (either component or collectively being the claimed “airflow sensor”). EX1044, [0028]. Additionally, Toge discloses control unit 250 calculating “data of usage of the PAP device” 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**.”

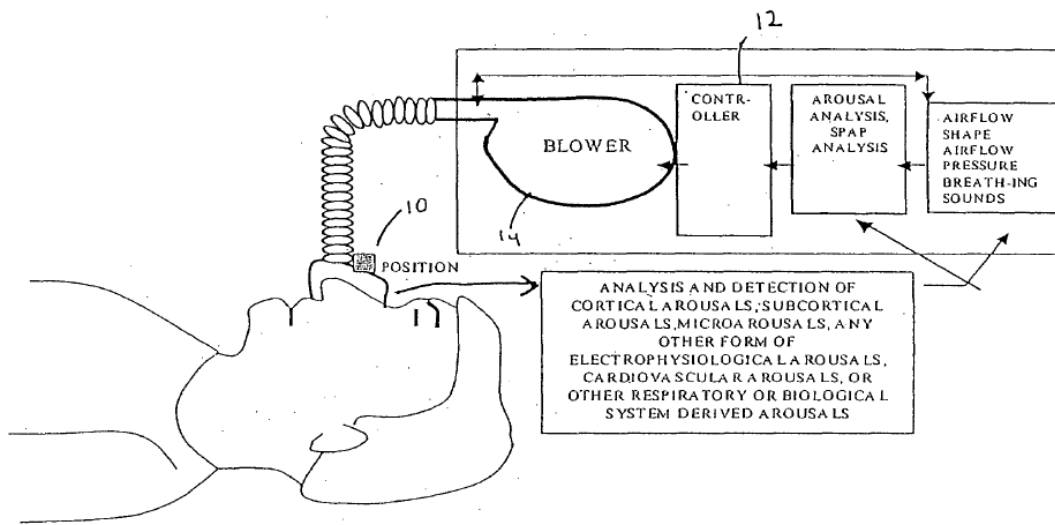
Id.; Kirkness ¶¶164-165e. Additionally, Toge's first processor generates and outputs data related to the patient's tidal volume F_p , which is data related to the subject's treatment and the treatment's efficacy. The tidal volume (including its trend) calculated by Toge's first processor is quantified symptom data of the severity of the sleeping disorder symptoms measured during used of the PAP device. EX1044, [0033]-[0035], [0038]). Further, given that **tidal volume F_p** (including its trend), which is calculated based on the measurements of flow meter 24, is used to assess and treat the patient's condition when using the PAP device (*id.*, [0039]), Toge discloses "outputting the data related to the subject's treatment and the treatment's efficacy." Kirkness ¶¶166-167; Chatterjee, ¶¶105-106.

A POSITA would have understood that treatment related data including, e.g., "**tidal volume F_p , the operational time T of [PAP] device 2, the air leakage volume F_b ...from...mask 21 , the internal pressure P of...mask 21 , the minute breathing rate N , the inspired oxygen concentration FiO_2 , and the operating status of this [PAP] device 2 (such as alarms if the nasal mask is detached)**" (*id.*, [0031]) are "data *related to* the subject's treatment and the treatment's efficacy." Indeed, Toge refers to the transmitted data as "patient's **treatment data.**" *Id.*, [0031]. For example, Toge describes that "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]. Kirkness¶¶168; Chatterjee¶¶107-111.

To the extent that Toge does not disclose control unit 250 (“first processor”) performing the following italicized processes: “*generating and outputting the data related to the subject’s treatment and the treatment’s efficacy* by receiving sensor data from the airflow sensor, *and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device, and data of usage of the PAP device,*” a POSITA would have been motivated and found it obvious to implement these features when implementing the Toge system in light of Burton. Kirkness¶¶169. Chatterjee¶¶111-115.

Like Toge, Burton teaches providing PAP treatments to patients. EX1050, 1:20-27. For example, Burton discloses a sleep disorder treatment device as shown in Figure 1 below.



EX1050, FIG. 1

See Burton explains that, 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.” EX1050, 1:9-12. “While these arousals do not result in the awakening of the patient, they often pull patients from deeper stages or higher quality states of sleep.” *Id.*, 1:12-14; *see also id.*, 1:15-19, 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¶¶170-172; Chatterjee¶¶112-113.e¶

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. The system “maintain[s] the sleep quality of a patient undergoing a therapeutic treatment” by “predict[ing] the onset of arousal and using **an adaptive algorithm to modify a patient’s therapeutic treatment.**” *Id.*, 3:21-24. The therapeutic control 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¶¶173.e¶

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.*, 3:29-4:7, 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¶¶174.e¶

Specifically, Burton discloses using “the **shape characteristics of the airflow signal**” to record and determine “the likelihood of arousal or upper airway flow limitation.” EX1050, 4:18-20, 13:21-23. “**Apnea events, shallow breathing, upper airway resistance and hypopnea events can also be detected** and preempted by analysis of the change in shape of the high bandwidth **monitoring of the airflow waveforms and pressure waveforms.**” *Id.*, 13:23-26. Kirkness¶¶175.e¶

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; *see also id.*, 14:23-30, 23:20-27 (describing that “[t]he controller 12 is implemented as a combination of rules for pressure change”), 23:28-24:12 (describing conditions for various pressure change rules “represent a number of physiological scenarios”), 24:14-15 (“The

present invention is capable of overcoming varying arousal dependent factors by applying adaptive algorithm techniques.”). Kirkness¶¶176.e¶

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. Kirkness¶¶177.e¶

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, Pressure change rate, Mixed Sleep Apnea events, Sleep Quality index, classification of respiratory events with noisy or poor quality effort signals, Obstructive Sleep Apnea/Hypopnea event or syndrome (OSA, OSH, OSAHS). EX1050, 21:4-22:21. Kirkness¶¶178. Chatterjee¶¶114.

Burton discloses limitation 1[a.iii]/7[a.iii]/12[a.iii]. **First**, Burton discloses “*receiving sensor data from the 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...the quantified symptom data of the severity of the sleeping disorder symptoms.*” 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 represents “*the severity of the sleeping disorder symptoms.*” *Id.*, 14:1-7; *see also id.*, 14:8-18; Kirkness¶¶179-180. For example, the severity of sleep disorder symptoms can be extracted by categorizing upper airway obstruction events, with inspiratory flow limitation (flattening) and snoring representing milder disruptions, hypopneas indicating moderate severity due to partial flow reductions, and apneas representing the most severe events with complete cessation of airflow. Kirkness¶¶180. **Third**, Burton discloses “*calculating...an index of a subject’s symptoms measured during use of the PAP device.*” As discussed, Burton discloses “automatically adjust[ing] the therapeutic treatment based on at least one index or derived data set,” which includes, e.g., Respiratory Disturbance Index (RDI), Respiratory Arousal Index (RAI), Apnea-hypopnea index (AHI), Sleep efficiency Index, Mixed Sleep Apnea events, Sleep Quality index, Obstructive Sleep Apnea/Hypopnea event or syndrome

(OSA, OSH, OSAHS). *Id.*, 21:4-22:21. **Fourth**, Burton discloses “*calculating...data of usage of the PAP device.*” 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 and/or cardiac 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¶¶ 181-182. Chatterjee¶¶ 113-115.

Additionally, Burton discloses “*generating and outputting the data related to the subject’s treatment and the treatment’s efficacy* by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device” 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 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 “*data related to the subject’s treatment and the treatment’s efficacy*”

because these signals/data are derived from data collected during the treatment and for adjusting the treatment based on the received sensor signal indicating the severity of the patient's symptoms. Kirkness¶¶183. Chatterjee¶¶113-115.

Burton discloses this limitation in **a second way**. Burton discloses that its system is “adapted to record, meter, index or **display**, in real time or on a replay or review basis, 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...to enable a user to manipulate and display raw data or derived values in a meaningful format.” *Id.*, 28:20-25. Given that Burton discloses displaying the above-described data/index (“data related to the subject's treatment and the treatment's efficacy”), Burton discloses “generating and outputting” these data/index in this second way. Kirkness¶¶184. Chatterjee¶¶113-115.

Additionally, as discussed Section VI and consistent with PO's interpretation of limitation 1[a.iii]/7[a.iii]/12[a.iii], given that Burton discloses calculating when a patient has an apnea or hypopnea event using sensor data from the patient and determining a patient's AHI severity level (which requires measuring number of

apnea and hypopnea events per unit time), Burton discloses limitation 1[a.iii]/7[a.iii]/12[a.iii]. Kirkness¶¶185. Chatterjee¶¶103-115.

A POSITA would have been motivated to implement the above-described features (similar to those disclosed in Burton) such that a PAP device's processor (e.g., Toge's processor in the PAP device) is implemented with the above-described algorithm. Kirkness¶¶186e¶. These features would have been beneficial as they would have minimized or avoided transient arousals when the patient is undergoing PAP treatments and would have improved the patient's sleep quality. Additionally, 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 "to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of UARS, OSAHS, RERAs and TERAs, while still minimizing sleep fragmentation and optimizing sleep quality." EX1050, 20:14-23; *see also id.*, 26:9-15. Kirkness¶¶186e¶.

As such, a POSITA would have been motivated to implement the above-described algorithm (e.g., as disclosed in Burton) in control unit 250 (e.g., as disclosed in Toge) 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¶¶187; Chatterjee¶¶88-90.

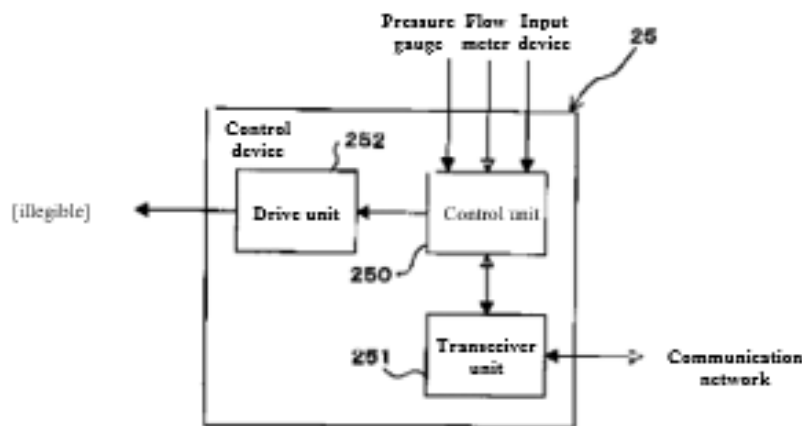
A POSITA would have had a reasonable expectation of success in implementing the above-discussed feature in Toge. Kirkness¶¶188; Chatterjee, ¶¶93-95. Burton's disclosed features are "adapted for use with a CPAP machine." EX1050, 19:25-26. Additionally, Burton explains that "[o]ne skilled in the art can 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)) according to known methods (e.g., known methods/algorithm implemented on a controller/processor to generate/output data relating to patient's treatment and the treatment's efficacy 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. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

Accordingly, the Toge-Burton combination discloses limitation 1[a.iii]/7[a.iii]/12[a.iii]. Kirkness¶¶188-189.

4. 1[a.iv]/7[a.iv]/12[a.iv]: first RF wireless transceiver;

Toge discloses this limitation or renders this limitation obvious. Kirkness¶¶190-195; Chatterjee¶¶116-121. As show in Figure 3 below, 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]; Kirkness¶¶192; Chatterjee, ¶¶117-118.

As discussed for limitation [1pre], 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 that Toge discloses that PAP device 2 are 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 (“a first radio frequency wireless transceiver”) in order to connect and communicate via network 1 operating mobile/wireless network protocols. Kirkness¶¶193; Chatterjee¶¶119.

To the extent that Toge does not disclose that the PAP device includes “a first radio frequency wireless transceiver,” such a feature would have been obvious to a POSITA. Kirkness¶194; Chatterjee¶¶120. Indeed, there were only a handful of known techniques for transmitting data wirelessly, including radio frequency communication and optical wireless communications. Chatterjee¶¶120. Thus, using a radio frequency wireless transceiver to implement communications via radio frequency would have been obvious because it would have been one of a “finite number of identified, predictable solutions.” Chatterjee¶¶120. *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¶¶195e¶. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, EX1045, Fig. 3; EX1013, [0029] (a CPAP device including “a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12.”); EX1044, FIG. 3, [0006]-[0007], [0023], [0030], [0070]. Moreover, it would have involved a combination of known technologies (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. Kirkness¶¶195; Chatterjee¶¶121; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

5. 1[a.v]/7[a.v]/12[a.v]: mask;

Toge discloses this limitation because Toge's PAP device includes nasal mask 21. EX1044, [0021]; Kirkness¶¶196; Chatterjee¶¶122-123.

6. 1[a.vi]/7[a.vi]/12[a.vi]: the airflow sensor and the first processor are adapted for measuring and calculating data;

Toge discloses this limitation. Kirkness¶¶197-198; Chatterjee¶¶124-126. Alternatively, Toge in view of Burton renders obvious this limitation. Kirkness¶¶199-201; Chatterjee¶¶127.

Toge's control unit 250 uses the measured value from flow meter 24 to determine/calculate, e.g., the patient's **tidal volume Fp** (EX1044, [0033]-[0035], [0038]). Given that **tidal volume Fp** (including its trend), which is calculated based on the measurements of flow meter 24, is used to access and treat the patient's condition when using the PAP device, Toge discloses "the airflow sensor and the first processor are adapted for measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment." *Id.*, [0039]; Kirkness¶¶198.

Additionally, Toge discloses “the airflow sensor and the first processor are adapted for...providing for a data related the subject’s treatment and the treatment’s efficacy.” For example, “control unit 250 **generates** the transmission data” to be transmitted to via network 1 to relay device 3 (EX1044, [0033]), physician-side computer 4 (*id.*, [0016]), mobile terminal 5 (*id.*, [0019], [0027], [0039], [0047], [0054]-[0055], [0059]). As discussed for limitation [1/7/12.a.3], a POSITA would have understood that the transmission/transmitted data (*id.*, [0031]) are “data ***related to*** the subject’s treatment and the treatment’s efficacy.” As discussed for limitation [1/7/12.a.3], thresholds are set by physicians to determine when to transmit patient’s tidal volume and/or minute respiratory rate to monitor the patient’s condition/treatment/efficacy. *Id.*, [0051]-[0052], [0055]-[0056], [0060]-[0061]. Indeed, Toge refers to the transmitted data as “patient’s **treatment** data.” *Id.*, [0031]. Given that the control unit 250 generates/transmits patient’s treatment data (“data related the subject’s treatment and the treatment’s efficacy”) calculated using information from the airflow sensor measurements, Toge discloses “the airflow sensor and the first processor are adapted for...providing for a data related the subject’s treatment and the treatment’s efficacy.” Kirkness¶198.

As discussed for limitation 1[a.iii]/7[a.iii]/12[a.iii], pressure gauge 23 and flow meter 24 (either component or collectively being the claimed “airflow sensor”)

measures air pressure and flow rate and provide the same to control unit 250. EX1044, [0028]. Kirkness¶¶198-199; Chatterjee¶¶124-127.

To the extent that Toge does not disclose this limitation, as discussed for limitation 1[a.iii]/7[a.iii]/12[a.iii], the combined Toge-Burton control unit discloses this limitation. Kirkness¶¶199; Chatterjee¶¶127. The Toge-Burton control unit (implemented with the algorithm similar to as disclosed in Burton) 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)” (“a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment”). EX1050, 14:1-7; *see also id.*, 14:8-18. Additionally, as discussed for limitation 1[a.iii]/7[a.iii]/12[a.iii], the modified controller uses the received sensor data and calculations of the number of patterns indicative of sleep apnea symptoms, index/indices or derived data set, and the patient’s prior sleep analysis to control/adjust the therapeutic treatment, where corresponding signals/data used to control/adjust the treatment or disclosed to a user for review/analysis are “data related to the subject’s treatment and the treatment’s efficacy.” Kirkness¶¶200; Chatterjee¶¶127.

Additionally, as discussed Section VI and consistent with PO’s interpretation of limitation 1[a.vi]/7[a.vi]/12[a.vi], given that Burton discloses calculating when a

patient has an apnea or hypopnea event using sensor data from the patient and determining a patient's AHI severity level (which requires measuring number of apnea and hypopnea events per unit time), Burton discloses limitation 1[a.vi]/7[a.vi]/12[a.vi]. Kirkness¶¶201. Chatterjee¶¶127. Accordingly, the Toge-Burton combination discloses this limitation.

7. 1[a.vii]/7[a.vii]/12[a.vii]: the blower, and the mask for treating sleeping disorder symptoms,

Toge discloses this limitation. Kirkness¶¶202-203; Chatterjee¶¶128-131. As discussed for the preamble, Toge discloses remote medical (telemedicine) system that includes PAP device 2 for treating patients having sleep apnea (“a subject's sleeping disorder symptoms”). EX1044, [0008], [0015]. As discussed for limitations 1[a.i]/7[a.i]/12[a.i] and 1[a.ii]/7[a.ii]/12[a.ii], PAP device 2 includes mask 21, air tube 22, and blower 27, where blower 27 supplies air to nasal mask 21 via air tube 22. *Id.*, [0021]-[0025]. As such, the PAP device delivers positive pressure air “to assist the patient's breathing.” *Id.*, [0006]; *see also id.*, [0015] (“continuous positive airway pressure devices are primarily provided to patients with conditions such as sleep apnea”). Accordingly, by providing a positive airway pressure using mask 21 and blower 27 to treat a patient's sleep apnea, Toge discloses “the blower, and the mask...are adapted for physically...treating a subject's sleeping disorder symptoms.”

8. 1[a.viii]/7[a.viii]/12[a.viii]: wherein the first processor is configured to adjust the blower using the data;

Toge discloses this limitation. Kirkness¶¶204-205; Chatterjee¶¶132-133. Alternatively, Toge in view of Burton renders obvious this limitation. Kirkness¶¶206; Chatterjee¶¶134.

Toge describes that: “if there is a decreasing trend if there is a decreasing trend in the tidal volume Fa, 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.”). EX1044, [0039], [0025] (“The blower 27 functions by rotating to supply air into the flow path 26. The air pressure supplied is adjusted based on the rotational speed of the blower 27. The blower 27 is driven by the drive unit 252 of the control device 28. The drive of the drive unit 252 is controlled by the control unit 250 of the control device 25, thereby controlling the rotation of the blower 27.”). Kirkness¶¶205.

To the extent that Toge doesn’t disclose this limitation, Toge as modified by Burton discloses this limitation. Kirkness¶¶206; Chatterjee¶¶134. As discussed for limitation 1[a.iii]/7[a.iii]/12[a.iii], the modified control unit in the Toge-Burton combination uses sensor data, calculations based on the number of patterns indicative of sleep apnea symptoms (“the data of the quantitative output of the level of severity of the subject’s sleeping disorder symptoms during treatment”),

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. Consistent with Toge's teaching, a POSITA would have understood that this would have involved modifying the airflow and pressure delivered to the patient by adjusting/re-adjusting the blower of the PAP device. Kirkness¶¶206; EX1044, [0029] (describing that "[t]he air pressure supplied is adjusted based on the rotational speed of the blower 27," which is controlled by control unit 250.); *see also id.*, [0025] ("The blower 27 functions by rotating to supply air into the flow path 26. The air pressure supplied is adjusted based on the rotational speed of the blower 27. The blower 27 is driven by the drive unit 252 of the control device 28. The drive of the drive unit 252 is controlled by the control unit 250 of the control device 25, thereby controlling the rotation of the blower 27."), [0026]-[0027], [0032] ("control unit 250 controls the drive unit 252 based on...prescription pressure").

9. 1[b]/7[b]/12[b]: a software executable by a second processor to display the data to the subject or a care provider by a cell phone/PDA; and

Toge discloses this limitation. Kirkness¶¶207-209; Chatterjee¶¶135-144. Alternatively, Toge in view of Burton renders obvious this limitation. Kirkness¶¶210-212; Chatterjee¶¶135-144.

Toge discloses mobile terminal 5 may be "mobile phones" or "PDAs" (claimed "cell phone" or "PDA"). EX1044, [0019]. Mobile terminal 5 is "in the

possession of a physician or nurse” (“care provider”), who “can operate the mobile terminal 5 to set necessary data” for PAP device 2, e.g., adjusting the prescription pressure based on data received from PAP device 2. *Id.*, [0019], [0027], [0039], [0047], [0054]-[0055], [0059]. A POSITA would have understood that mobile terminal 5, such as a wireless phone or a PDA, includes a processor (“second processor”) that executes software stored on non-volatile memory (“non-transitory computer readable medium”) to perform the above-described processes, and that mobile terminal 5 also includes a display in order to display the received data to the care provider, who may then adjust the prescription pressure. Kirkness¶¶208; Chatterjee¶¶137.

Moreover, given that network 1 may be a mobile/wireless network, through which the treatment data is transmitted to mobile terminal 5 (EX1017, [0009] (“network 1 may be...a mobile communication network”)), a POSITA would have understood that mobile terminal 5 includes a radio frequency wireless transceiver (“second radio frequency wireless transceiver”) in order to connect and communicate via network 1 operating mobile/wireless network protocols. Kirkness¶¶209; Chatterjee¶¶138-140.

To the extent Toge does not disclose this limitation, Toge as modified by Burton discloses this limitation. Kirkness¶¶210e¶. As discussed for limitation 1[a.iii]/7[a.iii]/12[a.iii], 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...to enable a user to manipulate and display raw data or derived values...,” 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. Thus, a POSITA would have been motivated and found it obvious to transmit “the data related to the subject’s treatment and the treatment’s efficacy,” as disclosed by the Toge-Burton combination (*see* limitation 1[a.iii]/7[a.iii]/12[a.iii]), to mobile terminal 5 allow the care provider to review/analyze such transmitted “data.” A POSITA would have had the motivations, capabilities, and reasonable expectation of success discussed for limitation 1[a.iii]/7[a.iii]/12[a.iii] to modify the Toge-Burton combination to provide the above-discussed feature. Kirkness¶¶211-212; Chatterjee¶¶141-144.

10. 1[c]/7[c]/12[c]: a remote internet site to receive the data,

Toge in view of the knowledge of a POSITA renders obvious this limitation. Kirkness¶¶213-214e¶. Alternatively, Toge in view of Kumar renders obvious this limitation. Kirkness¶¶215-224; Chatterjee¶¶145-155.

Toge discloses that its remote monitoring method includes a CPAP device “connected to a relay device and a physician-side terminal device via a wireless or wired communication network” and that the “physician-side terminal device is configured to receive all or part of the treatment data transmitted from the relay device.” EX1044, [0006]. Toge further discloses that “communication network 1 may be any of a public telephone network, **the Internet**, a mobile communication network, or a dedicated line network; alternatively, it may also be a combination of these networks.” EX1044, [0009]. In light of the above, it would have been obvious to a POSITA to utilize a “remote internet site” to receive the data related to the subject’s treatment and the treatments efficacy from Toge’s wireless PAP on the physician side devices of Toge. Kirkness¶¶214; Chatterjee¶¶146.

To the extent that Toge and the knowledge of a POSITA does not disclose this limitation, Toge in view of Kumar discloses this limitation. Kirkness¶¶215; Chatterjee¶¶147. A POSITA would have been motivated and found it obvious to implement these features, including the remote internet site of Kumar, in the Toge system. Kirkness¶¶215; Chatterjee¶¶147.

Like Toge, Kumar discloses a telemedicine system “for network-based monitoring of physiological data,” including remote studies and monitoring physiological data associated with sleep apnea-hypopnea syndrome. EX1008, Abstract, [0068], [0239]-[0241]. Kirkness¶¶216; Chatterjee¶¶148.

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].

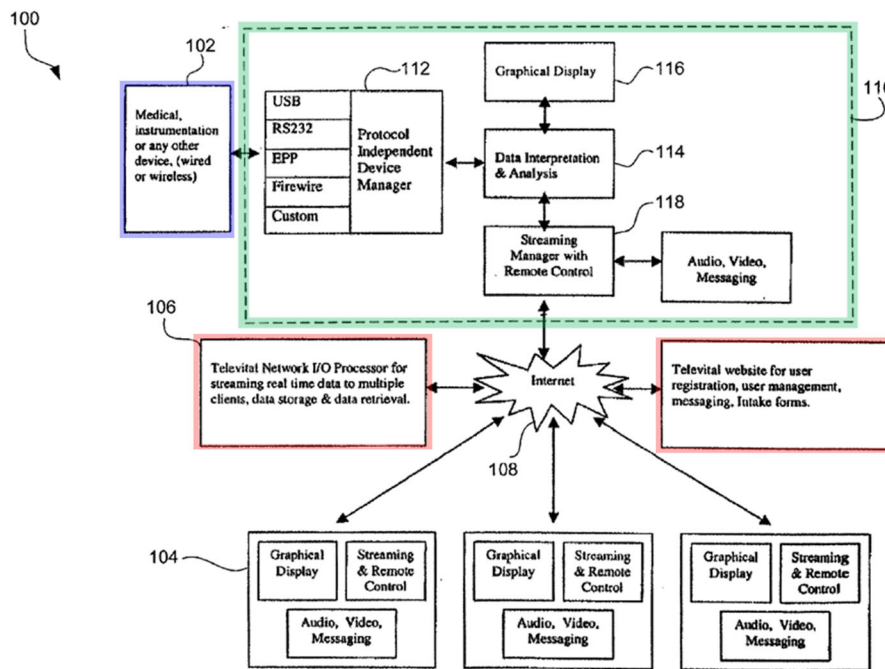


Fig. 1A

EX1008, FIG. 1A

Kumar additionally discloses that the browser-based engine (“a remote internet site”) supports real-time streaming of information over the Internet. EX1008, [0010], [0087] (“The system may be implemented using Apache web server, MySQL on Linux, Oracle on Linux, Java servlets, Applets, HTML, JavaScript, Java, C#, Microsoft's .NET etc. Note also that the server may be implemented on the Internet,

intranet, or an extranet.”). “The engine manages transmission of the data from the patient-side device to the provider-side device” and “may configure the devices to transfer the data directly from one device to the other; may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device; may store the data for later transmission to the provider-side device, etc.” EX1008, [0011]; Kirkness¶¶217-218; Chatterjee¶¶149-150.

For example, the system includes patient-side device(s) 102 for collecting data from a patient/client, provider-side device(s) 104, and an engine implemented on a central server 106, where the devices and engine are connected to a wide area network (WAN) 108 such as the Internet. EX1008, [0067]. “The system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider.” *Id.*; *see also id.*, [0068]. Kumar also discloses that the engine “may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device” and “may store the data for later transmission to the provider-side device, etc.” *Id.*, [0081], [0082]. Kumar also discloses that the patient-side device may communicate through a wireless interface and may communicate over the Internet. *Id.*, [0013]; Kirkness¶¶219; Chatterjee¶¶150-153.

Kumar explains that “the entire system runs in the context of an Internet browser.” EX1008, [0086]-[0087]; *see also id.*, [0010] (“a browser-based engine”),

[0015]. A patient can access the engine through a login, such as that in Figure 2. *Id.*, [0089], [0192] (“the system’s Internet browser-based software that allows the remote provider, and other healthcare providers, to remotely view their patient’s real-time physiology”); Kirkness¶¶220; Chatterjee¶¶150-153.

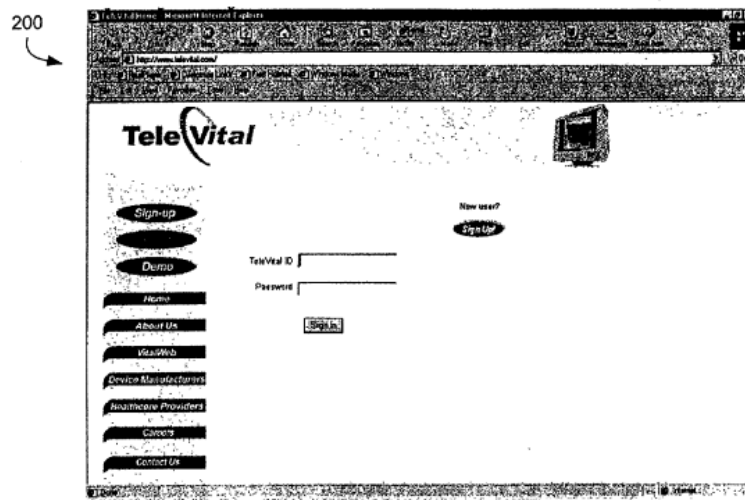


Fig. 2

EX1008, FIG. 2

A POSITA would have understood that the data sent to the engine could be accessed through web pages which serve as a graphical user interface, such as the “patient’s real-physiological data” depicted in Figure 7. EX1008, [0092], Figs. 6-8; *see also id.*, [0010], [0015] (“the communications are provided via a browser-based interface” and “the provider can start these devices remotely to read the data periodically or whenever needed”); Kirkness¶¶221; Chatterjee¶¶150-153.

A POSITA would have been motivated to implement a remote-monitoring feature, including a browser-based engine (“a remote internet site”) and similar to

as described in Kumar (*see, e.g., above*), to enable the PAP device to wirelessly transmit to the remote engine data associated the patient's treatment, including data/index generated and provided, e.g., for review/display as discussed for limitation 1[a.iii]/7[a.iii]/12[a.iii] ("the data relate to the subject's treatment and the treatment's efficacy"). Kirkness¶¶222; Chatterjee¶¶150-154.

Such a feature would have been beneficial as Kumar explains that "the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis." EX1008, [0083]. "The storage device may also be used to store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system," "allow[ing] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device." *Id.* In fact, Kumar states that such a feature is beneficial, e.g., by allowing a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. *Id.* Additionally, "[t]he system may also track trends during the recording, and using artificial intelligence, predict future behaviors and physiological responses based on the habits of the particular client hooked up." *Id.*, [0084]; Kirkness¶¶223; Chatterjee¶¶150-153.

A POSITA would have also had a reasonable expectation of success in implementing the above-discussed feature in the Toge-Burton combination.

Kirkness¶¶223. Kumar states that “virtually any device may be easily incorporated into the system.” EX1008, [0074]. Additionally, it was well known to transmit data using wireless protocol(s) to a remote Internet site, e.g., for later access of the data. e¶Moreover, it would have involved a combination of known technologies (e.g., known PAP device that provides data relate to the subject’s treatment and the treatment’s efficacy (Toge-Burton)) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine on the Internet (Kumar)) to yield the predictable result of a system including a remote engine that receives and stores data received from a patient-side device, e.g., the PAP device, for simultaneous storage, retrieval, analysis, and play back from anywhere in the world, as discussed above. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Accordingly, the Toge-Burton-Kumar combination discloses a browser-based engine (“a remote internet site”) that receives the claimed “data relate to the subject’s treatment and the treatment’s efficacy, in whole or part, generated by the PAP device” and transmitted via the radio frequency wireless transceiver included in the PAP device. Kirkness¶¶223-224; Chatterjee¶¶145-155; *see also* Section VII.C.4 (discussions that a POSITA would have been motivated to implement a radio frequency wireless transceiver in the PAP device to facilitate wireless communication).

11. 1[c.i]: the software is adapted to retransmit data,

Toge in view of the knowledge of a POSITA or Kumar discloses this limitation. Kirkness¶¶225-230; Chatterjee¶¶156-162. As discussed for limitation 1[b]/7[b]/12[b], Toge discloses the software on physician side computer 4 and mobile terminal 5 receives (from the radio frequency wireless transceiver of the PAP device) and displays to the care provider “data related to the subject’s treatment and the treatment’s efficacy” for the care provider’s review/analysis. Further, the physician-side computer 4 of Toge can: 1) “send a data download request to the relay device 3 and download the necessary data onto the physician side computer 4”; 2) “set the necessary data (as described later) for the positive pressure artificial respiration assisting device 2”; and 3) “mobilize the mobile terminal 5, in the possession of a physician or nurse.” EX1044, [0018]-[0019]. In light of these disclosures, it would have been obvious to a POSITA to implement the Toge system in such a way that the software is adapted to retransmit a data related to the subject’s treatment and the treatment’s efficacy received by the software from the first radio frequency wireless transceiver of the PAP device. Kirkness¶¶225; Chatterjee¶¶156-159.

To the extent that Toge-in view of the knowledge of a POSITA does not disclose this limitation, the Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶226-228e¶.

Kumar discloses that “[b]y 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....**” EX1008, [0078]. Kumar explains that the browser-based engine includes a “secured storage device” for storing data for “later access, replay, and/or analysis” and may “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.” *Id.* A POSITA would have been motivated and found it obvious to retransmit the “data related to the subject’s treatment and the treatment’s efficacy” received from the PAP device, along with the care provider’s comments/analysis with regarding to such received “data” to the browser-based engine (“a remote internet site”) for secured storage and later access. Kirkness¶¶229e¶. Additionally, a POSITA would have had the motivations, capabilities, and reasonable expectation of success discussed for limitation 1[c]/7[c]/12[c] to modify the Toge-Burton-Kumar combination to provide the above-discussed feature. Kirkness¶¶230; Chatterjee¶¶156-162.

12. 7[c.i]: the software adapted to receive the data, and

Toge in view of the knowledge of a POSITA or Kumar discloses this limitation. Kirkness¶¶231-237; Chatterjee¶¶163-168. As discussed for limitation 1[b]/7[b]/12[b], Toge discloses the software on physician side computer 4 and

mobile terminal 5 receives (from the radio frequency wireless transceiver of the PAP device) and displays to the care provider “data related to the subject’s treatment and the treatment’s efficacy” for the care provider’s review/analysis. Further, the physician-side computer 4 of Toge can: 1) “send a data download request to the relay device 3 and download the necessary data onto the physician side computer 4”; 2) “set the necessary data (as described later) for the positive pressure artificial respiration assisting device 2”; and 3) “mobilize the mobile terminal 5, in the possession of a physician or nurse.” EX1044, [0018]-[0019]. In light of these disclosures, it would have been obvious to a POSITA to implement the Toge system in such a way that the software is adapted to receive, in whole or part, the data related to the subject’s treatment and the treatment’s efficacy generated by the PAP device that is first received by then retransmitted from the remote internet site. Kirkness¶¶231-233; Chatterjee¶¶163-166.

To the extent that Toge in view of the knowledge of a POSITA does not disclose this limitation, the Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶234; Chatterjee¶¶163-168.

As discussed for limitation 1[b]/7[b]/12[b], the Toge-Burton combination discloses the software on mobile terminal 5 receives (from the radio frequency wireless transceiver of the PAP device) and displays to the care provider “data related to the subject’s treatment and the treatment’s efficacy” for the care provider’s

review/analysis. As discussed for limitation 1[c]/7[c]/12[c], a POSITA would have also been motivated to transmit such data from the PAP device to the browser-based engine for storage and for later access, replay, and/or analysis. Kirkness¶¶234-235; Chatterjee¶¶163-168.

Kumar discloses that the browser-based engine may “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**.” EX1008, [0083]. In other words, the browser-based engine may store medical record of a patient, including “data related to the subject’s treatment and the treatment’s efficacy” **from multiple prior treatments (e.g., medical records or integrated data)**, where at least one of the prior treatments had been transmitted to the care provider’s device for review (consistent with as discussed for limitation 1[b]/7[b]/12[b]). Kirkness¶¶235; Chatterjee¶¶163-168.

Since a care provider would have been interested in reviewing the entire medical record of the patient, which includes “data” from multiple prior treatments, a POSITA would have found it obvious to transmit the entire medical record from the browser-based engine to the care provider’s device (e.g., cell phone or PDA, which includes the software adapted to receive the record/data). Kirkness¶¶236e¶; EX1008, [0083] (“allow for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device”; “[t]his

beneficially allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online.”). Given that the entire medical record contains “data” from at least one prior treatment that has been previously transmitted to the care provider’s device for care provider’s review, transmitting the medical record containing “data” from multiple prior treatments discloses “the data related to the subject’s treatment and the treatment’s efficacy generated by the PAP device that is first received by then retransmitted from the remote internet site.”.

13. 12[c.i]: the software and the remote internet site independently receive the data, and

Toge in view of the knowledge of a POSITA or Kumar discloses this limitation. Kirkness¶¶238-241; Chatterjee¶¶169-171.

As discussed for limitation 1[c.i], the software on the mobile terminal 5 first receives the “data related to the subject’s treatment and the treatment’s efficacy generated by the PAP device” and then retransmits it. Thus, “the software [of the cell phone or PDA] . . . independently receive[s], in whole or part, the data.” Further, as discussed for limitation 7[c.i], the physician-side computer first receives the “data related to the subject’s treatment and the treatment’s efficacy generated by the PAP device” and then retransmits it. Thus, “the remote internet site independently receive[s], in whole or part, the data.” Consequently “both” the software of the cell

phone or PDA and the remote internet site independently receive the data. Kirkness¶¶239; Chatterjee¶¶169-171.

Further, 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 provider-side device (such as the care device’s device). Accordingly, the Toge-Burton-Kumar combination discloses the software on mobile terminal 5 (“the software”) and the browser-based engine (“remote internet site”) each separately/independently receive “the data related to the subject's treatment and the treatment’s efficacy generated by the PAP device.” Kirkness¶¶240-241; Chatterjee¶¶169-171.

14. 1[c.ii]/7[c.ii]/12[c.ii]: the sensor data processed using signal processing technique(s).

The Toge-Burton-Kumar combination renders obvious this limitation. Kirkness¶¶242-247; Chatterjee¶¶172-178.

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. Further, Burton discloses that its controller includes a first processor “which receives the digital signal and determines the patient state and an appropriate setting for the gas delivery or other therapeutic device.” *Id.* at 10:3-5, 32 at claim 49 (“The apparatus of claim 40, wherein the processor is adapted

to display raw data and derived indexes from the physiological parameters according to user selected formats.”). 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. Kirkness¶¶243e¶. Further, Kumar discloses that data received by the patient-side device may be analyzed “using FFT, DFT, etc.” on the patient-side device by the first processor. Ex. 1008, [0075]. A POSITA would have understood that FFT and DFT each refers to the claimed “fast Fourier transform technique” and “discrete Fourier transform technique,” which is consistent with the ’921 patent. In fact, the ’921 Patent states that “[a] Discrete Fourier transform (DFT), and its numerically efficient complement the Fast Fourier Transform (FFT), both provide frequency information of a digitized signal or data from the sensors.” Ex. 1001, 21:17-22; 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 Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331 (Fed. Cir. 2009). Kirkness¶¶244-247; ¶¶172-178e¶.

D. Dependent Claims

1. Claim 2: the PAP device adjusted in real time based on the data.

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶248-252; Chatterjee¶¶179-181. As discussed for limitation 1[a.iii]/7[a.iii]/12[a.iii], a POSITA would have implemented an algorithm (Burton) in a controller for controlling a PAP device (Toge). Toge discloses that a physician can adjust the treatment being received by the patient in real time based on the treatment and its efficacy. For example, Toge discloses that settings such as “prescription pressure and minute breathing rate (as well as mode settings) values (prescription values) are set using the input device 28 by a physician or a nurse following the physician’s instructions. ... Additionally, as mentioned earlier, settings can also be configured via communication network 1 through the physician-side computer 4 or mobile terminal 5.” EX1044, [0027].

Toge also discloses that its data transmission to the physician is “almost in real-time” allowing the physicians to “remotely monitor the patient’s condition during the use of the positive pressure artificial respiration assisting device” and that “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.” EX1044, [0039], [0040]. Kirkness¶¶249-250; Chatterjee¶¶179-181.

Burton additionally discloses that “[t]he therapeutic control algorithm...has the capability to be adapted during **real-time** operation based on” various real-time and analyzed data. EX1050, 3:21-28. “[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.*, 5:13-20; *see also id.*, 26:9-11. Kirkness¶¶251-252; Chatterjee¶¶179-181.

2. Claims 4, 13: Bluetooth wireless protocol.

The Toge-Burton-Kumar combination discloses this limitation. To begin, Bluetooth wireless protocol is one of the well-known wireless protocols for data transmission at the time of the alleged invention. Kirkness¶¶253-258; Chatterjee¶¶182-184; 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. Kumar explains that “[b]y receiving data from the patient-side device, a provider is able to...keeping track of documentation, performing analysis, managing and maintaining records....” EX1008, [0014]. Thus, as a POSITA would have recognized, the care provider would have been interested in downloading and

viewing the data related to the treatment on the provider's device. Kirkness¶¶253-256; Chatterjee¶¶182-184; EX1008, [0081] (disclosing a directly data transfer from a patient-side device to the provider-side device).

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¶¶182-184. 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 Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331 (Fed. Cir. 2009). Thus, a POSITA would have been motivated and found it obvious to use the Bluetooth protocol for communications (including transmission of the data related to treatment) between the PAP device and care provider device ("cellular phone or PDA") to allow the care provider to view/analyze the treatment data following the PAP treatment. Kirkness¶¶257-258; Chatterjee¶¶182-184.

3. Claims 5, 9,14: respiratory disturbance index.

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶259-260; Chatterjee¶¶185-186. As discussed for limitation [1/7/12/a.iii], Burton discloses "automatically adjust the therapeutic treatment based on at least one index or derived data set," which includes, e.g., Respiratory Disturbance Index (RDI) and Apnea-hypopnea index (AHI). EX1050, 21:4-22:21.

4. Claim 8: transmit the data via cell towers or cable.

Toge in view of a POSITA discloses this limitation. Kirkness¶¶261-262; Chatterjee¶¶187-188. As discussed for limitation [1/7/12/a.iv], 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). A POSITA would have understood that mobile networks are connected via cell towers. Chatterjee¶¶187-188. Given that in the modified Toge-Kumar combination the PAP device, the browser-based engine (“remote internet site”), and the software adapted for mobile terminal 5 (“cellular phone or PDA”) are all wirelessly connected to the mobile network, a POSITA would have understood that “the PAP device and the remote internet site” as well as “the remote internet site and the software adapted for the base station, cellular phone or PDA” are all adapted to transmit “data related to the subject's treatment and the treatment's efficacy via cell towers.”

5. Claims 11, 16: the PAP device adjusted remotely.

The Toge-Burton-Kumar combination discloses this limitation. Kirkness¶¶263-266; Chatterjee¶¶189-190. 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.” 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¶¶263-264. As discussed for limitation [1/7/12/a.iii], Burton discloses controlling/adjusting the treatment based on “data related to the subject’s treatment and the treatment’s efficacy.”

A POSITA would have been motivated to implement these features as it would have allowed the provider to remotely control/adjust the PAP device, after receiving via the remote engine “the data related to the subject’s treatment and the treatment’s efficacy.” 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 (“first processor”), such that it may be adjusted remotely (“an electronic component adapted to allow the PAP device to be adjusted remotely”) given that such a processor/controller controls operations of the PAP device, and thus adjustments to the PAP device operations may be readily executed by the processor. EX1044, [0025]; Kirkness¶¶265; Chatterjee¶¶189-190.

A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described remote control features as it would have would have been a routine and conventional implementation of known methods using known hardware components performing their known functions, well within a POSITA's skills and ability to accomplish. Accordingly, the Toge-Burton-Kumar combination discloses and/or suggests this limitation. Kirkness ¶¶266; Chatterjee ¶¶189-190.

VIII. GROUND 2: TOGE IN VIEW OF BURTON, KUMAR, AND KISNER RENDERS OBVIOUS THE CHALLENGED CLAIMS

A. Motivation To Combine

A POSITA would have been motivated to implement Kisner's teaching in the Toge-Burton-Kumar combination. 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 ¶267; Chatterjee ¶¶191-198.

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. 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-Burton-Kumar combination would have improved treatments and/or remote monitoring. Kirkness ¶268; Chatterjee ¶¶191-198.

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 ¶¶269-272; Chatterjee ¶¶199-203.

First, similar to the Toge-Burton-Kumar combination, where the PAP device control algorithm is implemented in a processor (*see* Section VII.C.3, limitation 1[a.iii]/7[a.iii]/12[a.iii]), Kisner explains that the algorithm for the wavelet analysis is implemented in a microprocessor system. EX1051, 13:36-53. Kirkness ¶270; Chatterjee ¶¶199-203 .

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 ¶271; Chatterjee ¶¶199-203 .

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-Burton-Kumar 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 ¶¶272; Chatterjee ¶¶199-203 .

C. Challenged Claims

Ground 1 establishes that the combinations of prior art teachings a POSITA would have implemented to improve the Toge PAP device in view of Burton and Kumar that discloses the challenged claims. Section VII (Ground 1). To the extent that the prior art combination does not disclose limitation 1[c.ii]/7[c.ii]/12[c.ii], reciting “wherein the sensor data from the sensors is processed by the first processor 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 ¶¶273.

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 ¶¶274. 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 to form true components signals 108. *Id.*, 13:42-45. Then, “[b]reathing parameters are extracted from...signals 108 using wavelet analysis or similar means to generate signal 116,” where “signal 108 are [also] matched with known anomalies at 114 to generate signals 118.” *Id.*, 13:45-49. “Signals 116 and 118 are processed using threshold, fuzz-logic, neural networks or similar processing technique at 120 to determine if an alarm or other desired output condition exists which is expressed and communicated by signal 122.” *Id.*, 13:49-53.

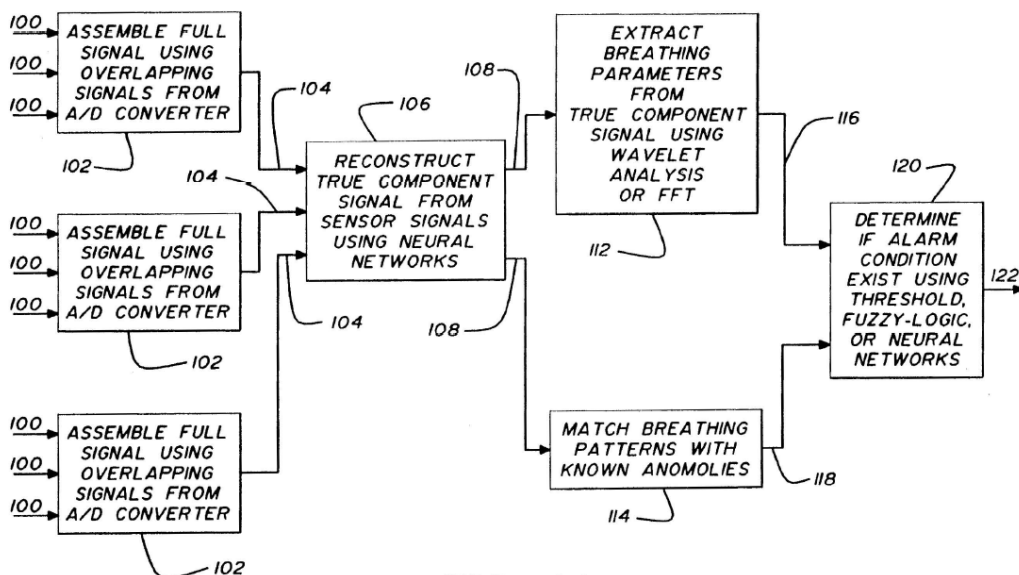


FIG. 11

EX1051, FIG. 11

Accordingly, Kisner discloses “sensor data from the sensors is processed by [a] processor using one or more of the signal processing techniques from the group consisting of a standard deviation technique...a wavelet analysis” as recited in claim 1. Kirkness¶¶275.

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¶¶276. As discussed above, Kisner teaches using the result from the wavelet analysis to notify the care provider. EX1051, 15:27-31 (“The output signal can be used as the input signal to any desired output device such as a digital display or an audio alarm which would alert the caregiver or person monitoring the subject to a change in the subject’s condition.”). 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. 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-Burton-Kumar combination would have improved treatments and/or remote monitoring. *Id.* Kirkness¶¶276-277.

A POSITA would have also had the skill and reasonable expectation of success in implementing the teachings of Kisner in the Toge-Burton-Kumar combination. Kirkness¶¶278. Similar to the Toge-Burton-Kumar combination, where the PAP device control algorithm is implemented in a processor (*see* Section VII.C.3, limitation 1[a.iii]/7[a.iii]/12[a.iii]), 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 '921 patent acknowledges that the wavelet analysis is one of the “signal processing algorithms known to those skilled in the art.” EX1001, 20:26-31; EX1055, 28-30 (disclosing various processing techniques known at the time including “wavelet analysis”, “standard deviation or variance”, and “Fast Fourier Transform (FFT) algorithm”). 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-Burton-Kumar 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 ¶¶279-281. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

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 the original prosecution of the '921 patent.

Additionally, discretionary denial is also not warranted in view of the pending *ex parte* reexamination proceeding, 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 Kumar

(EX1008) which is asserted is each of the grounds presented in this petition. Compare EX1053 with Sections VII and VIII.

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 '921 Patent is assigned to Cleveland Medical Devices Inc. ("PO"). Petitioner is currently asserting the '921 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 a petition for *inter partes* review against U.S. Patent No. 11,602,284 (IPR2025-00157) and will file petitions for *inter partes* review against U.S. Patent No. 11,690,512, U.S. Patent No. 11,786,680, U.S. Patent No. 11,857,333, and U.S. Patent No. 11,872,029, which are also asserted in the same litigation.

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

C. Notice of Counsel and Service Information

ResMed provides the following designation of counsel:

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

D. Fee for *Inter Partes* Review

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

E. Grounds for Standing

Petitioner certifies pursuant to 37 C.F.R. § 42.104(a) that the '921 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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RESMED CORP.

CLAIM APPENDIX

1. A sleeping disorder treatment system comprising:
 - [a] a PAP device configured to be a single enclosure, the PAP device comprising:
 - [a.i] a blower having an air output;
 - [a.ii] an airflow sensor internal to the PAP device and adapted for measuring the respiratory airflow of a subject while using the PAP device;
 - [a.iii] a first processor adapted for generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device;
 - [a.iv] a first radio frequency wireless transceiver;
 - [a.v] a mask or a nasal cannula;
 - [a.vi] wherein the airflow sensor and the first processor are adapted for measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment and further providing for a data related the subject's treatment and the treatment's efficacy;
 - [a.vii] wherein the blower, and the mask or the nasal cannula are adapted for physically or chemically treating a subject's sleeping disorder symptoms,
 - [a.viii] wherein the first processor is configured to adjust or re-adjust the blower using, in part, the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment;

[b] a software stored on a non-transitory computer readable medium and executable by a second processor, the software adapted to be used with and to display the data related to the subject's treatment and the treatment's efficacy to the subject or a care provider by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display; and

[c] a remote internet site, the remote internet site adapted to receive the data relate to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

[c.i] wherein the software is further adapted to retransmit a data related to the subject's treatment and the treatment's efficacy received by the software from the first radio frequency wireless transceiver of the PAP device, in whole or part, to the remote internet site, and

[c.ii] wherein the sensor data from the sensors is processed by the first processor 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 kernals, and a wavelet analysis.

2. The system in claim 1, wherein the PAP device for physically or chemically treating a subject's sleeping disorder is adjusted in real time based on the data related to the treatment and the treatment's efficacy generated by the PAP device and received by the remote internet site.

3. The system in claim 2, wherein the PAP device is adjusted automatically with a signal from the remote internet site based on the data related to the treatment and the treatment's efficacy received.

4. The system in claim 1, wherein the first radio frequency wireless transceiver of the PAP device and the software adapted to use second radio frequency wireless transceiver of the base station, cellular phone or PDA to transmit the data related to treatment between each other using Bluetooth wireless protocol.

5. The system in claim 1, wherein the index of the subject's symptoms is a respiratory disturbance index.
6. The system in claim 1, wherein the software adapted for use with the base station, cellular phone or PDA is configured to be reprogrammed or modified remotely.
7. A sleeping disorder treatment system comprising:
 - [a] a PAP device configured to be a single enclosure, the PAP device comprising:
 - [a.i] a blower having an air output;
 - [a.ii] an airflow sensor internal to the PAP device and adapted for measuring the respiratory airflow of a subject while using the PAP device;
 - [a.iii] a first processor adapted for generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device;
 - [a.iv] a first radio frequency wireless transceiver;
 - [a.v] a mask or a nasal cannula;
 - [a.vi] wherein the airflow sensor and the first processor are adapted for measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment and further providing for a data related the subject's treatment and the treatment's efficacy;
 - [a.vii] wherein the blower, and the mask or the nasal cannula are adapted for physically or chemically treating a subject's sleeping disorder symptoms,

[a.viii] wherein the first processor is configured to adjust or re-adjust the blower using, in part, the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment;

[b] a software stored on a non-transitory computer readable medium and executable by a second processor, the software adapted to be used with and to display the data related to the subject's treatment and the treatment's efficacy to the subject or a care provider by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display; and

[c] a remote internet site, the remote internet site adapted to receive the data related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

[c.i] wherein the software is further adapted to receive, in whole or part, the data related to the subject's treatment and the treatment's efficacy generated by the PAP device that is first received by then retransmitted from the remote internet site, and

[c.ii] wherein the sensor data from the sensors is processed by the first processor 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.

8. The system in claim 7, wherein the PAP device and the remote internet site as well as the remote internet site and the software adapted for the base station, cellular phone or PDA transmit the data related to the subject's treatment and the treatment's efficacy via cell towers or cable.

9. The system in claim 7, wherein the wherein the index of the subject's symptoms is a respiratory disturbance index.

10. The system in claim 7, wherein the software adapted for use with the base station, cellular phone or PDA is configured to be reprogrammed or modified remotely.

11. The system of claim 7, wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the data related to the subject's treatment and the treatment's efficacy transmitted to the remote internet site.

12. A sleeping disorder treatment system comprising:

[a] a PAP device configured to be a single enclosure, the PAP device comprising:

[a.i] a blower having an air output;

[a.ii] an airflow sensor internal to the PAP device and adapted for measuring the respiratory airflow of a subject while using the PAP device;

[a.iii] a first processor adapted for generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device;

[a.iv] a first radio frequency wireless transceiver;

[a.v] a mask or a nasal cannula;

[a.vi] wherein the airflow sensor and the first processor are adapted for measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment and further providing for a data related the subject's treatment and the treatment's efficacy;

[a.vii] wherein the blower, and the mask or the nasal cannula are adapted for physically or chemically treating a subject's sleeping disorder symptoms,

[a.viii] wherein the first processor is configured to adjust or re-adjust the blower using, in part, the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment;

[b] a software stored on a non-transitory computer readable medium and executable by a second processor, the software adapted to be used with and to display the data related to the subject's treatment and the treatment's efficacy to the subject or a care provider by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display; and

[c] a remote internet site, the remote internet site adapted to receive the data related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

[c.i] wherein both the software and the remote internet site independently receive, in whole or part, the data related to the subject's treatment and the treatment's efficacy generated by the PAP device, and

[c.ii] wherein the sensor data from the sensors is processed by the first processor 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.

13. The system in claim 12, wherein the first radio frequency wireless transceiver of the PAP device and the software adapted to use second radio frequency wireless transceiver of the base station, cellular phone or PDA to transmit the data related to the subject's treatment and the treatment's efficacy between each other using Bluetooth wireless protocol.

14. The system in claim 12, wherein the wherein the index of the subject's symptoms is a respiratory disturbance index.
15. The system in claim 12, wherein the software adapted for use with the base station, cellular phone or PDA is configured to be reprogrammed or modified remotely.
16. The system of claim 12, wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the data related to the subject's treatment and the treatment's efficacy treatment transmitted to the remote internet site.

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.
11,375,921** exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a),
contains 13,995 words and therefore complies with the type-volume limitations of
37 C.F.R. §42.24(a).

Dated : December 6, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO 11, 375,921 AND EXHIBITS EX1001-1055** are being served on December 6, 2024, via FedEx overnight mail on counsel of record for U.S. Patent No. 11, 375,921 as addressed below:

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

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