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Filed on behalf of ResMed Corp.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

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Case IPR2025-00246

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**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,857,333**

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## I. INTRODUCTION

ResMed Corp. ("Petitioner") respectfully requests *inter partes* review of claims 15-29 of U.S. Patent No. 11,857,333 (EX1001, "'333 Patent") and a finding that all challenged claims of the '333 Patent are unpatentable.

## II. IDENTIFICATION OF CHALLENGES

**Ground 1**: Claims 15-17, 20-24, and 26-29 are unpatentable under pre-AIA 35 U.S.C. § 103 as being obvious over Toge[1] in view of Kumar.

**Ground 2**: Claims 15-18, 20-24, and 25-29 are unpatentable under § 103 as being obvious over Toge in view of Kumar and Norman.

**Ground 3**: Claim 19 is unpatentable under § 103 as being obvious over Toge in view of Kumar and Burton[2].

**Ground 4**: Claim 19 is unpatentable under § 103 as being obvious over Toge in view of Kumar, Norman, and Burton.

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

[2] Each Kumar and Burton is §§102(a), (b), and (e) prior art. Norman is at least §102(e) prior art.

## III. BACKGROUND

### A. ’333 Patent

The ’333 Patent describes well-known methods for PAP sleep disorder treatment devices implemented in a networked system. The ’333 Patent generally focuses on a PAP device that collects data “based on the subject’s current physiological state or symptoms” and sends that data to a cell phone, for example. EX1001, 2:45-48.

The ’333 Patent acknowledges that “collecting data with the PAP or CPAP device from the flow or pressure sensor,” “radio frequency wireless link,” “determine a quantified level of severity data,” and “Wavelet signal analysis” as recited in the ’333 Patent claims were known. *Id.*, 13:9-11; Kirkness¶¶104-106; *see also id.*, ¶¶64-103 (discussions regarding technical background), ¶¶107-128 (summary of prior art); Chatterjee¶¶24-54 (discussions regarding technical background).

### B. Challenged Claims

The challenged claims 15-29 are entitled to an effective filing date of no earlier than November 4, 2005.[3]

### C. Prosecution History

Patent Owner ("PO") faced rejections across Office Actions, an Advisory Action, and Examiner's Answer to Appeal Brief. EX1002, 155-158 (first Office Action), 190-196 (final Office Action), 269 (Advisory Action), 274-280 (Examiner's Answer). After PO made significant amendments and added new claims (*id*., 292-315), the Examiner allowed the claims. *Id*., 384-387, 429-441; *see also id.,* 158-159.

## IV. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art ("POSITA") in 2005 would have had at least a bachelor's degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems, such as networked PAP machines. Additional

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

experience could substitute for less education, and additional education could likewise substitute for less experience. Kirkness¶¶42-63; 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¶¶42-63.

## V. CLAIM CONSTRUCTION

The Board construes the claims "using the same claim construction standard that would be used" in district courts. 37 C.F.R. §42.100(b). Notwithstanding, for the purpose of this proceeding, this Petition adopts PO's interpretation of the following limitations as described in PO's opening claim construction brief in the parallel district court action:

- The "transmitting" limitation (as recited in claim limitation [15.d]).
- "therapy efficacy data" (as recited in limitation [15.e.1])

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

Specifically, PO interprets limitation [15.d] as definite (EX1054, 22; *see also id.*, 21-23) and asserts the '333 Patent includes exemplary methods for transmitting data or the level of severity (*id.*, 22) and "the data transferred is the collected data or the quantified level of severity" (*id.*, 23). PO's expert in the district court litigation opines that "a commonly used term within the clinical sleep setting has been 'level of severity' which clinicians understand to represent the how dire a patient's calculated symptom data may be." EX1058, ¶32; EX1054, 23 (citing to EX1058, ¶32).

Further, PO interprets "therapy efficacy data" (recited in limitation [15.e.1]) as definite (EX1054, 25; *see also id.*, 23-25) and asserts that "[a] POSITA would understand the term 'therapy efficacy data' to mean data calculated based on data collected while a subject is undergoing treatment to determine the severity of a subject's sleep disorder symptoms and whether the PAP device that is part of the method needs to be adjusted." *Id.*, 23-24.

Otherwise, this Petition establishes the prior art meets each of the claim limitation under any reasonable construction.[4] Kirkness¶¶129-131; Chatterjee, ¶¶81-84.

## VI. GROUND 1: TOGE IN VIEW OF KUMAR RENDERS OBVIOUS CLAIMS 15-17, 20-24, AND 26-29

### A. Motivation to Combine

A POSITA would have been motivated to combine Toge and Kumar to implement a remote-monitoring feature, including a browser-based engine ("remote station") as described in Kumar, to enable the PAP device to wirelessly transmit to the remote engine data associated the patient's treatment, including "the collected data and/or the quantified level of severity data." Kirkness¶¶132-34; Chatterjee¶¶85-96.

First, such a feature would have been beneficial because Kumar explains that "the data may be stored in a secured storage device…for later access, replay, and/or analysis," "allow[ing] for simultaneous storage, retrieval, print, analysis,

[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 play back from anywhere in the world with access to the storage device." EX1008, [0083]. 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…." *Id*., [0084]; Kirkness¶133; Chatterjee¶¶85-96.

Second, a POSITA would have understood that storing data at the secured storage of the engine would have provided a backup of the data. While Toge discloses that the data may be transmitted from the PAP device to physician-side device 4, a POSITA would have appreciated that a copy of the data stored at the engine would have beneficially served as backup data in the event when the PAP device and/or physician-side device 4 is misplaced or malfunctioned, losing access to the data thereon. Kirkness¶134; Chatterjee¶¶85-96.

### B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in implementing Kumar's remote-monitoring features in Toge. Kirkness¶¶135-38; Chatterjee¶¶97-98.

First, Kumar states that "virtually any device may be easily incorporated into the system." EX1008, [0074]; Kirkness¶136. 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]; Chatterjee¶98.

Second, Toge and Kumar are structurally and functionally similar. Toge itself utilized wireless communication. Kirkness¶137; Chatterjee¶98. 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].

Third, it would have involved a combination of known technologies (e.g., known PAP device that is wirelessly connected to a mobile communication network and provides sensor data and/or the quantified level of severity data (Toge)) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine (Kumar)) to yield the predictable result of a system including a remote engine that receives and securely 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. Kirkness¶138; Chatterjee¶¶97-98.

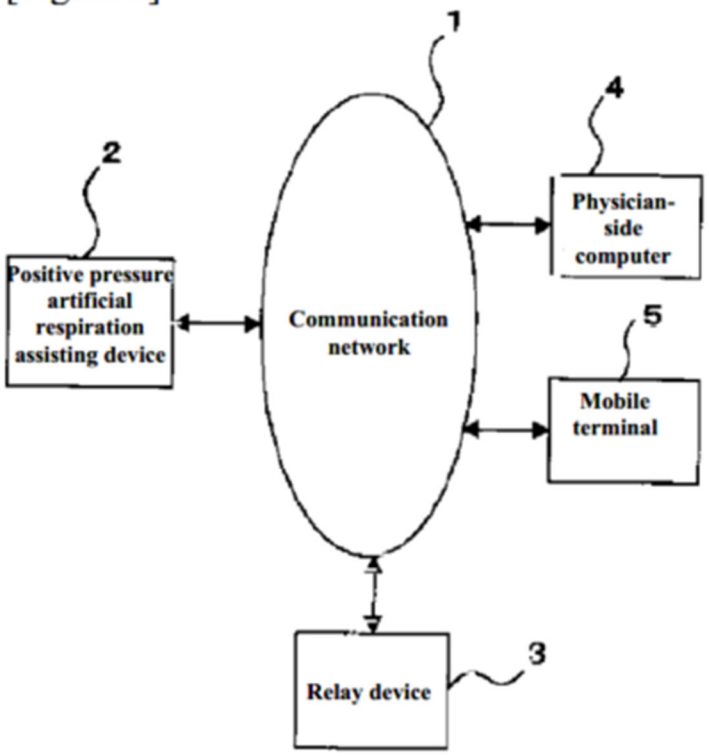
### C. Independent Claim 15

#### 1. Preamble: "A method of treating a subject's sleep apnea comprising steps of:

To the extent limiting, Toge discloses the preamble. Kirkness¶¶139-45; Chatterjee¶¶99-105. As shown in Figure 1 and discussed below, Toge discloses a remote medical (telemedicine) system for treating patients having sleep apnea ("method of treating a subject's sleep apnea"). EX1044, [0008], [0015].

Toge's system includes a positive pressure artificial respiration assisting device 2 (referred to as "PAP device 2" hereafter) which provides PAP therapy, collect data, and analyze the data. *Infra* [15.a]-[15.c]. Toge enables "remote monitoring of the patient's condition during the use of a [PAP] device, or the condition of the [PAP] device" via a network connection. EX1044, Abstract. Toge's system includes 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 to transmit and analyze the data among them. *Id.*, [0008]; *see also infra* [15.d]-[15.e]. Kirkness, ¶140; Chatterjee¶100-101.

[Figure 1]



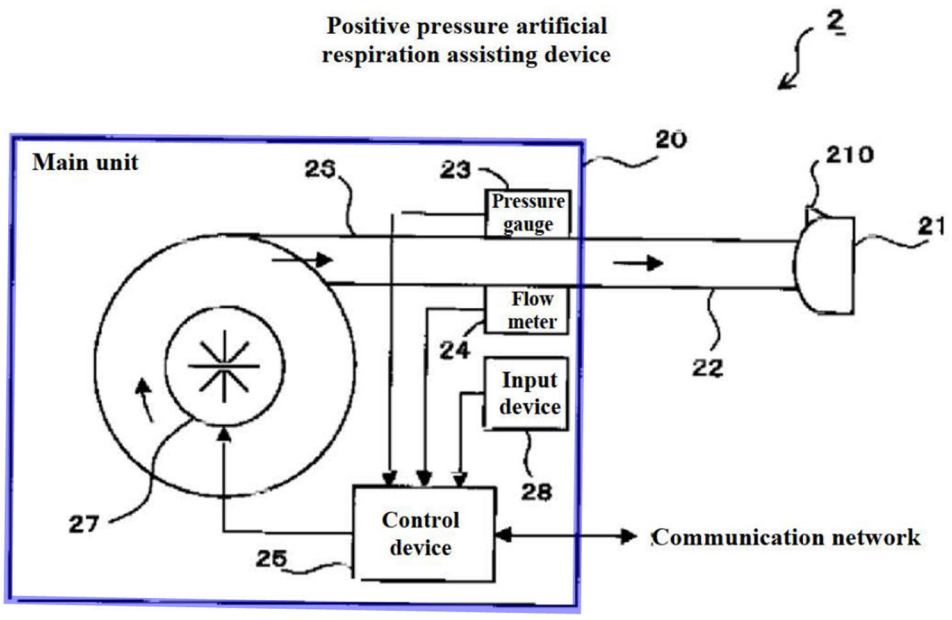

**EX1044, Fig. 1**

Settings of the PAP device, e.g., the prescribed air pressure, may be configured/adjusted via network 1 through physician-side computer 4 or mobile terminal 5. EX1044, [0039]. Given that Toge discloses treating a patient's sleep apnea using a PAP device, including remote monitoring of the patient and remote adjustment of the PAP device, Toge discloses "[a] method of treating a subject's sleep apnea." Kirkness, ¶¶141-45; Chatterjee¶102-105.

**2. [15.a]: "providing a therapy to a subject using a PAP or CPAP device while sleeping, the PAP or CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device;"**

Toge discloses this limitation. Kirkness¶¶146-52; Chatterjee¶¶106-15. As discussed for the preamble, Toge discloses treating a patient by using a PAP device. *See* EX1044, [0008], [0015]. PAP device 2 treats 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]. It is "designed to deliver positive pressure air…to assist the patient's breathing." *Id.*, [0010]. The pressure of the PAP device is "set to the prescribed pressure…by the physician." *Id.*, [0013]. Toge explains that the treatment occurs "during sleep." *Id.*, [0015], [0040]. Thus, Toge discloses "providing a therapy to a subject using a PAP or CPAP device while sleeping." Kirkness¶¶146-47; Chatterjee¶¶106-09.

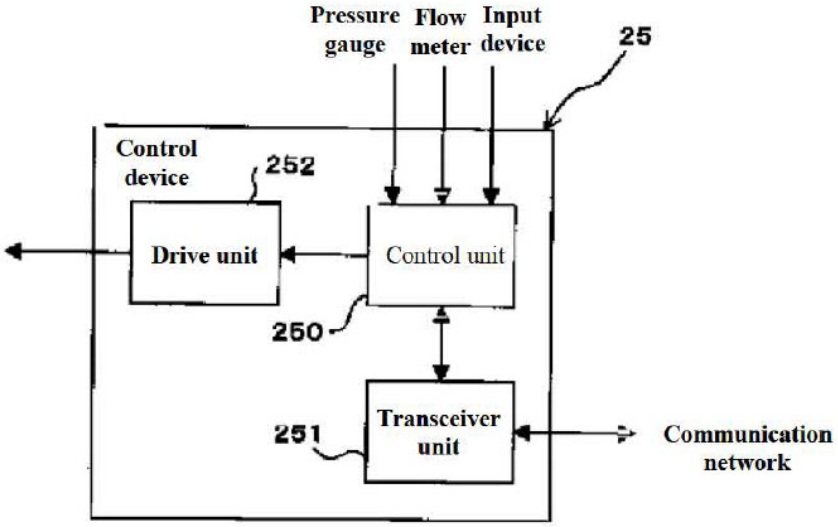
Toge discloses "the PAP or CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device." As shown in Figure 2, Toge's PAP device 2 has an enclosure (highlighted in blue), which includes a main unit 20, a nasal mask 21, an air tube 22, a pressure gauge 23, a flow meter 24, a control device 25, a flow path 26, a blower 27, and an input device 28. EX1044, [0021]-[0024]. Positive pressure air is delivered to nasal mask 21 from main unit 20. *Id.*, [0022]; *see also id.*, [0024]-[0025]; Kirkness¶148; Chatterjee¶¶110-11.




**EX1044, FIG. 2 (annotated)**

"[P]ressure gauge 23 detects and measures the air pressure inside the flow path 26." EX1044, [0028]. Flow meter 24 "detects and measures the airflow." *Id.* Thus, flow meter 24 and pressure gauge 23 are respectively the claimed "flow [sensor]" and "pressure sensor." As shown in Figure 2, both pressure gauge 23 and flow meter 24 reside within main unit 20 which encloses the PAP device. Thus, they are "integrated into the PAP or CPAP device." Kirkness¶149; Chatterjee¶112.

Toge discloses a "processor…integrated into the PAP or CPAP device." As shown in Figures 2 (above) and 3 (below), control device 25 resides within main unit 20 of the PAP device and comprises a control unit 250 ("processor").




**EX1044, Figure 3**

"[C]ontrol unit 250 can be constructed using a program describing the processing of the control unit 250…, along with a CPU." EX1044, [0048]. Relay device 3 may 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 [PAP] device 2." *Id.*, [0060]; *see also id.*, [0016]; Kirkness¶¶150-51; Chatterjee¶¶113-15.

Relay device 3 (incorporated into control unit 250) data transmits from PAP device 2 "all or part" of the data to physician-side computer 4. *Id.*, [0016], [0060], [0061]; Kirkness¶152; Chatterjee¶114.

### 3. [15.b] "collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy;"

Toge discloses this limitation. Kirkness¶¶153-55; Chatterjee¶¶116-19. Toge explains that "air pressure" measured by pressure gauge 23 ("pressure sensor") and "flow rate" measured by flow meter 24 ("flow [sensor]") are both "provided to the control unit 250" of the PAP device. EX1044, [0028].

Toge explains that the positive air pressure is delivered to the patient during the treatment (EX1044, [0022]) ("during a time period of the therapy") according to the prescribed air pressure (*id.*, [0027]), and the air pressure and/or flow rate provided to control unit 250 are used to determine various parameters and control the PAP device (*id.*, [0032]-[0038], [0046]). *See also id.*, [0031] (describing transmitted data including sensor data as "treatment data"); Kirkness¶154; Chatterjee¶¶117.

A POSITA would have understood that because Toge discloses that device 2 transmits data "at regular intervals" (*id.*, [0030], [0039]-[0041], [0044], [0047]), device 2 discloses "collecting data" between transmissions. Kirkness¶155; Chatterjee¶¶117-19. A POSITA would have understood that Toge discloses "during a time period of the therapy" because Toge discloses that the time between the transmissions is a time period/interval. Moreover, control unit 250 determines "[t]he operational time T…measuring the time, from 'power on' to 'power off' using its

internal timer (internal clock)." *Id.*; EX1044, [0042]. "By analyzing this operational time, physicians can determine whether the patient is using the [PAP] device 2 and assess the treatment (patient) compliance." *Id.*

#### 4. [15.c] "analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;"

Toge discloses this limitation. Kirkness¶¶156-60; Chatterjee¶¶120-25. Toge discloses that air pressure measured by pressure gauge 23 and/or flow rate measured by flow meter 24 (either or both, the "collected data") is used by control unit 250 ("processor") to calculate/determine certain parameters. For example, control unit 250 calculates the tidal volume (EX1044, [0038]) based on the air pressure and/or flow rate (*id.*, [0033]-[0037]). *See*, *e.g.*, *id.*, [0035] (explaining tidal volume Fp is a function of Ft, Fa, and Fb, where "Ft is the flow rate measured by the flow meter 24"), [0036]-[0037].

The tidal volume calculated/determined by control unit 250 is "a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy." A POSITA would have understood that the calculated tidal volume represents the level of severity based on the patient's sleep apnea symptoms during the treatment, because it represents, for example, level of airway obstruction the patient experiences during the sleep apnea treatment using the PAP device. Kirkness¶157. Toge explains that the physician, through the tidal volume

information, can monitor the "patient's condition" which, as a POSITA would have understood, corresponds to "subject's sleep apnea symptoms during the therapy," as claimed. EX1044, [0039]; Kirkness¶157; EX1001, 2:9-12 (showing that the '333 Patent uses "symptoms" and "condition" interchangeably), 2:45-48, 22:25-28. Toge explains that "if there is a decreasing trend in the tidal volume…, 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]. Such an adjustment, as a POSITA would have understood, is used to counter/treat the more severe level of airway obstruction observed from the decreasing tidal volume. Kirkness¶¶157-58.

Additionally, threshold values associated with the patient's tidal volume can be set for triggering the transmission the tidal volume to physician-side computer 4. *Id.*, [0051]. Thus, a POSITA would have understood that the tidal volume is "a quantified level of severity data." Kirkness¶159. For example, during apnea, the most severe form of reduction in airflow, as a POSITA would have understood, the absence of airflow results in tidal volume of zero milliliters per breath, which corresponds to a quantified level of severity data based on the subject's sleep apnea symptoms that they are experiencing during the therapy. *Id.* Given that the tidal volume, which is determined by control unit 250 based on analyzing collected data, corresponds to a quantified level of patient's severity that is based on the patient's

sleep apnea symptoms (e.g., level of airway obstruction) during the treatment, Toge discloses "analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy."

Moreover, for reasons discussed above, Toge's tidal volume is consistent with PO expert's interpretation of the claimed "level of severity" as discussed in Section V. *See* Section V; EX1058, ¶32 ("'level of severity' which clinicians understand to represent the how dire a patient's calculated symptom data may be"); EX1054, 23 (citing to EX1058, ¶32); Kirkness¶160.

**5. [15.d] "transmitting, in either order, both**
**1) the collected data and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and**
**2) the collected data and/or the quantified level of severity data to the remote station from either**
**a) the PAP or CPAP device via a cellular system, or**
**b) the cellular phone to a remote station via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician; and"[5]**

Toge alone or in combination with Kumar discloses this limitation. Kirkness¶¶161-91; Chatterjee¶¶126-62. For clarity, the Petition addresses limitation [15.d] in subsections (i)-(v).

**(i) "transmitting…1)…the quantified level of severity data to a cellular phone via a radio frequency wireless link."**

Toge discloses "transmitting…1)…the quantified level of severity data to a cellular phone via a radio frequency wireless link." Kirkness¶¶162-64; Chatterjee¶127. Toge's mobile terminal 5 may be "mobile phones" or "PDAs"

[5] Given the alternative language recited in limitation [15.d], Petitioner color codes the step to identify language to which it addresses.

(either the claimed "cell phone"). EX1044, [0019]. Mobile terminal 5, possessed by the care provider, may be "mobilized in emergencies by the physician-side computer 4…" by the care provider. *Id.* The care provider may operate the mobile terminal 5 to "set the necessary data…for [PAP] device 2." *Id.*; Kirkness¶162; Chatterjee¶¶128-31.

Toge discloses that the treatment data, including tidal volume ("the quantified level of severity data"), is transmitted to mobile terminal 5 from PAP device 2, which is also connected to network 1, e.g., a mobile network. EX1044, Abstract ("relay device 3…transmits…treatment data to…mobile terminal 5 via…network 1"), [0008]-[0009] (network 1 may be a mobile network), [0019] (mobile terminal 5 includes "mobile phones" or "PDAs"). A POSITA would have understood that network 1 and its communication with Toge's mobile terminal 5 is "via a radio frequency wireless link," for example, via mobile protocol such as GSM or GPRS transmitted using RF wireless communication. Chatterjee¶131; EX1011, 2. Thus, Toge discloses "transmitting…1)…the quantified level of severity data to a cellular phone via a radio frequency wireless link." Kirkness¶163; Chatterjee¶131, 133.

To the extent that limitation [15.d] requires "transmitting…1)…the quantified level of severity data to a cellular phone via a radio frequency wireless link…**from**…**a) the PAP or CPAP device via a cellular system**," Toge likewise discloses the bolded claim features. As discussed above, the treatment data,

including tidal volume ("the quantified level of severity data"), is transmitted to mobile terminal 5 ("cellular phone") from PAP device 2 ("the PAP or CPAP device"), which is also connected to network 1 that may be a mobile network. A POSITA would have understood that **mobile** networks (e.g., Toge's mobile communication network 1) are connected via "**a cellular system**." Kirkness¶164; Chatterjee¶¶132-35.

**(ii) "transmitting…2)…the quantified level of severity data to the remote station from…a) the PAP or CPAP device via a cellular system."**

Toge discloses this limitation. Kirkness¶¶165-68; Chatterjee¶¶136-141. Toge discloses that network 1 may be "a **mobile** communication network" (EX1044, [0009]) and that PAP device 2 ("PAP"), relay device 3, physician-side computer 4 ("remote station") are **wirelessly** connected to network 1 for transmitting data (*id.*, [0006]-[0007]; *see also id.*, [0016], [0060], [0063], [0070], [0078], [0080]-[0081], claim 1). PAP device 2, relay device 3, and physician-side computer 4 are wirelessly connected to network 1 for transmitting and receiving "treatment data," including tidal volume ("the quantified level of severity data"). *Id.*, [0008], [0009], [0016]-[0018], [0031]; *see also id.*, [0063], [0070], [0078], [0080], [0081], claim 1; Kirkness¶165; Chatterjee¶¶136-40.

PAP device 2 may transmit data by having "the functionality of…relay device 3…incorporated into the [PAP device 2] (the control unit 250 of the control device 25)" and may transmit "all or part" of the data to physician-side computer 4. EX1044, [0039]; *see also id.*, [0016], [0060]. Physician-side computer 4 ("remote station") receives the data from PAP device 2 and allows care providers, e.g., physicians, to access the transmitted data using the computer. *Id.*, [0017]-[0018]. Toge also explains that PAP device 2 "transmits all or part of the treatment data to the physician-side computer 4…**via…network 1**." EX1044, [0061]. "By transmitting the tidal volume…physicians can remotely monitor the patient's condition during the use of the [PAP] device 2." *Id.*, [0039]; *see also id.*, [0051], [0061], [0063]-[0076] (examples of remote monitoring), [0051], [0085]; Kirkness¶166; Chatterjee¶137.

A POSITA would have understood that **mobile** networks (e.g., Toge's mobile communication network 1) are connected via "**a cellular system**." Kirkness¶167; Chatterjee¶140. Additionally, a POSITA would have understood that physician-side computer 4 is a "**remote station**," as claimed, given that it receives treatment data from the PAP device and/or provides physicians remote access to monitor the patient's condition. EX1044, Abstract, [0006], [0017], [0018], [0039]. Moreover, Toge explains that "physician-side computer 4 is a **computer**," which, as a POSITA would have understood, includes a processor, consistent with claim 15's recitation

of "a second **processor**…at the remote station." EX1044, [0017]. Petitioner notes that the term "remote station" is not recited in the '333 patent specification. *See generally* EX1001. To the extent that PO argues that the "remote communication station" discussed in the specification corresponds to the claimed "remote station," physician-side computer 4 likewise discloses the claimed "remote station." EX1001, 22:20-24 ("Another example is where the remote communication system is a **computer** or processor, which receives the data transmission and displays the data or records it on some recording medium, which can be displayed or transferred for analysis at a later time."); *see also id.*, 21:54-22:20 (describing various non-limiting examples of a "remote communication station"); Kirkness¶167; Chatterjee¶138.

Given that Toge discloses transmitting the tidal volume ("quantified level of severity data") from PAP device 2 to physician-side computer 4 ("remote station") via mobile communication network 1 (including "a cellular system"), Toge discloses "transmitting…2)…the quantified level of severity data to the remote station from…a) the PAP or CPAP device via a cellular system." Kirkness¶168; Chatterjee¶141.

**(iii) "transmitting…2)…the quantified level of severity data to the remote station from…a) the PAP or CPAP device via a cellular system."**

To the extent that Toge does not disclose the claimed "remote station" or "transmitting…2)…the quantified level of severity data to the remote station from…a) the PAP or CPAP device via a cellular system," Toge in view of Kumar renders obvious this limitation. Kirkness¶¶169-181; Chatterjee¶142-54.

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, ¶170; Chatterjee¶143.

Figure 1A shows that the Kumar system includes a patient-side device 102 for collecting data from a patient/client (in blue, similar to Toge's PAP device), computing device 110 (in green), provider-side device(s) 104, and central server 106 (in red) that hosts a browser-based engine accessible through web pages. EX1008, [0018], [0067], [0068], [0072], [0089].

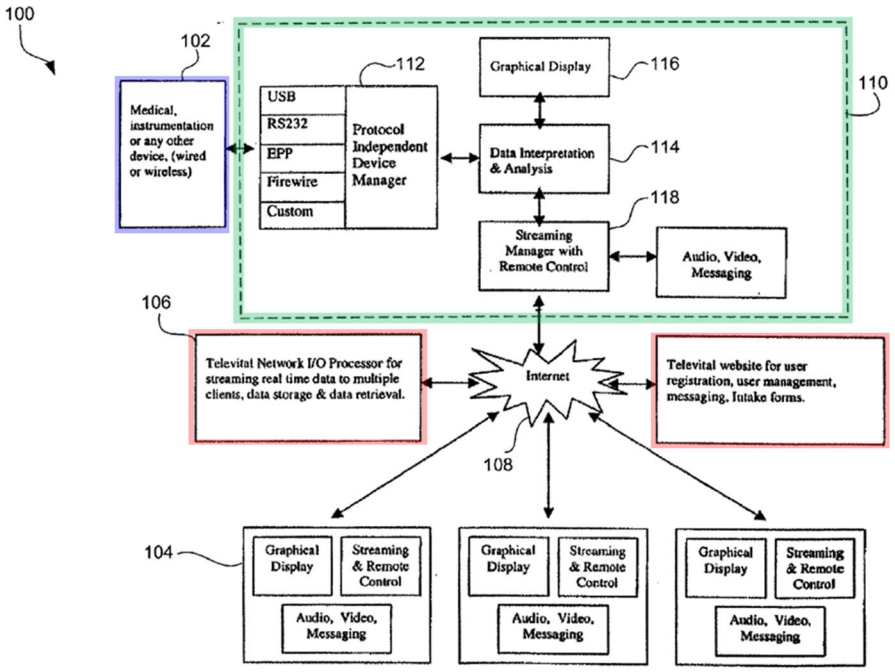



Fig. 1A

**EX1008, FIG. 1A**

The aforementioned devices and engine are connected to a wide area network (WAN) 108, e.g., the Internet. EX1008, [0067]-[0068]. The patient-side device may communicate through a wireless interface and communicate over the Internet. *Id.*, [0013]. Kirkness, ¶¶171-172; Chatterjee¶144.

The browser-based engine supports real-time streaming of information over the Internet and provides secured data storage, e.g., for later access, analysis, and integration of the patient's data into an electronic medical records system. EX1008, [0010], [0081]-[0082], [0083], [0087]. "The engine manages transmission of the data from the patient-side device to the provider-side device" and "may receive the

data from the patient-side device and transmit the raw or processed data to the provider-side device; **may store the data for later transmission to the provider-side device**, etc." *Id.*, [0081], [0082]. Kirkness, ¶173; Chatterjee¶145.

Accordingly, a POSITA would have understood that the browser-based engine hosted on a central server is a "remote station" as claimed because it provides remote monitoring and, e.g., relaying/storing/processing patient's data as well as providing access to the data. As discussed above, Petitioner notes that the term "remote station" is not recited in the '333 patent specification. To the extent that PO argues that the "remote communication station" discussed in the specification corresponds to the claimed "remote station," Kumar's browser-based engine likewise discloses the claimed "remote station." EX1001, 21:61-65 ("The remote communication station…by way of example…can include a communications device for relaying the transmission, a communications device for re-processing the transmission…."); *see also id.*, 21:54-22:20; Kirkness, ¶174; Chatterjee¶¶146-47.

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]. The engine provides a secured storage and access, e.g., where one can access the engine through a login, such as that in Figure 2. *Id.*, [0089], [0192]. A POSITA would have understood that the data sent to the engine could be accessed through web pages which serve as a graphical user interface, such as the "patient's real-

physiological data" depicted in Figure 7. EX1008, [0092], Figs. 6-8; *see also id.*, [0010], [0015]; Kirkness, ¶175; Chatterjee¶145.

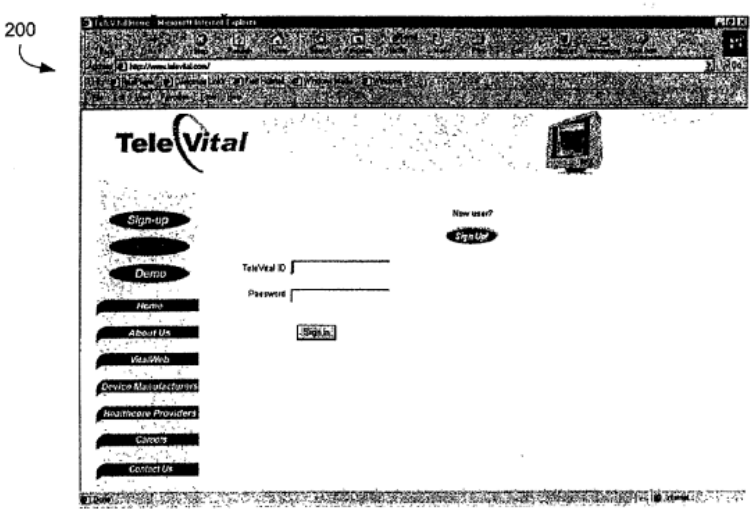



Fig. 2

**EX1008, FIG. 2**

Accordingly, in addition to disclosing the claimed "remote station," Kumar discloses "transmitting…2)…data to the remote station from…a) the [patient-side] device…," because Kumar discloses transmitting data, such as raw, interpreted, and processed physiological/patient data, to the engine ("remote station") from the patient-side device. *Supra*; *see also* EX1008, [0072] (patient-side device may communicate "over the WAN"), [0081] (the engine "may receive the data from the patient-side device"). Kirkness, ¶176; Chatterjee¶148.

A POSITA would have been motivated to implement a remote-monitoring feature, including a browser-based engine implemented on a server ("remote station") similar to as described in Kumar (*see supra*), to enable the PAP device to

wirelessly transmit to the browser-based engine data associated the patient's treatment, including "the collected data and/or the quantified level of severity data," such as the measured air pressure and/or flow rate ("collected data") and/or tidal volume ("quantified level of severity data") disclosed in Toge for, e.g., secured storage, data backup, later analysis, creation of a database, and sharing of data. Kirkness, ¶177; Chatterjee¶149.

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…store **all** patient data…, 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.* 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, ¶178; Chatterjee¶150.

Moreover, a POSITA would have understood that storing data at the secured storage of the engine would have provided a backup of the data. While Toge discloses that the data may be transmitted from the PAP device to physician-side device 4, a POSITA would have appreciated that a copy of the data stored at the engine would have been beneficial as it would serve as backup data in the event when the PAP device and/or physician-side device 4 is misplaced or malfunctioned, losing access to the data thereon. Kirkness, ¶179; Chatterjee¶151.

A POSITA would have understood that Toge and Kumar disclose similar goals of providing access to data collected/analyzed by a treatment device. For example, Toge discloses "download all or specified data received from [PAP] device 2 to the physician-side computer or mobile terminal 5…" (EX1044, [0059]; *see also id.*, [0018], [0061]) and Kumar discloses that its "the engine manages transmission of the data from the patient-side device" (EX1008, [0081]). Kirkness, ¶180; Chatterjee¶149.

A POSITA would have had a reasonable expectation of success in combining the above-discussed feature with Toge's teaching. Kirkness¶181; Chatterjee¶152. 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 engine, e.g., for later access of the data. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that

is wirelessly connected to a mobile communication network and provides sensor data and/or the quantified level of severity data (Toge)) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine (Kumar)) to yield the predictable result of a system including a remote engine that receives and securely 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).

**(iv) transmitting "in either order" both…**

Toge alone and/or the Toge-Kumar combination renders obvious transmitting both (1) and (2) "in either order." Kirkness, ¶¶182-187; Chatterjee¶¶153-57.

Toge discloses that PAP device 2 "transmits all or part of the treatment data to the physician-side computer 4 **or** mobile terminal 5 via the communication network 1." EX1044, [0061]. Each of physician-side computer 4 and mobile terminal 5 may request all data from PAP device 2, and the data is sent to the requested computer/terminal. *Id.*, [0059]. Thus, Toge discloses that the treatment data may be transmitted to both of computer 4 and terminal 5. Based on the above disclosure, Toge at least discloses a scenario where the treatment data, which includes the tidal volume ("the quantified level of severity data"), is transmitted to either "the physician-side computer 4 **or** mobile terminal 5" instead of being

simultaneously transmitted to both of them. For example, the data may be transmitted to computer 4 ("remote station") that requested the data, and then transmitted to terminal 5 ("cellular phone") that subsequently requested the data. Kirkness, ¶183; Chatterjee¶153.

Toge in view Kumar also discloses transmitting both (1) and (2) **in "either order**." Kumar's system includes patient-side device 102 (e.g., Toge's PAP device), computing device 110, provider-side device(s) 104, and central server 106 hosting an engine. EX1008, [0018], [0067]-[0068], [0072], [0089]. The aforementioned devices and engine are connected to WAN 108. EX1008, [0067]-[0068]. "[T]he provider-side device can be any type of computing device, such as a computer, PDA, wireless telephone" ("cellular phone") and "has a wireless connection to the WAN," allowing the doctor to "be consulted remotely without the need to rush to the hospital." *Id.*, [0072]. Kirkness, ¶184; Chatterjee¶154.

Kumar discloses that "the engine manages transmission of the data from the patient-side device to the provider-side device," which "means that the engine may configure the devices to **transfer the data directly from one device to the other**." EX1008, [0081]. Thus, Kumar discloses that the provider-side device ("cellular phone") may directly receive data from a patient-side device. As discussed above, a POSITA would have been motivated to store the patient's data, such as the air pressure and/or flow rate ("collected data") and/or tidal volume ("quantified level of

severity data") disclosed in Toge, at the engine's storage to allow later access/analysis, integration of data into a medical records system, and a secured backup. For similar reasons, a POSITA would have been motivated to transmit patient's data ("collected data and/or the quantified level of severity data"), having received by the provider-side device ("cellular phone") directly from the patient-side device (e.g., PAP device)), to the engine ("remote station") from the provider-side device. Such a process would have allowed storage of the physician's analysis/diagnosis/notes along with the patient's data in the secured storage of the engine, as discussed above. Kirkness, ¶185; Chatterjee¶156.

A POSITA would have also had a reasonable expectation of success in implementing this feature in the Toge-Kumar combination as it would have involved a combination of known technologies (e.g., known PAP device that analyze collected data (Toge)) according to known methods (e.g., known methods of transmitting data amongst devices and providing secured storage (Kumar)) to yield the predictable result of a PAP device transmitting patient's data to a physician's computing device for physician's analysis, where the patient's data and the physician's analysis are then transmitted to a remote engine for secured storage, as discussed above. Kirkness¶186; Chatterjee¶157; *KSR*, 550 U.S. at 416.

Lastly, the "order[ed]" data transmission feature recited in claim 15 would have been obvious to a POSITA. Indeed, there were only three options to execute

the above-described two transmission steps with respect to the timing of the transmissions. The first option is to execute both transmission steps simultaneously, the second option is to transmit to the "cellular phone" first and then to the "remote station" (disclosed by Toge or the Toge-Kumar combination), and the third option is to transmit to the "remote station" and then to the "cellular phone." Kirkness, ¶187; Chatterjee¶155. Thus, the "order[ed]" data transmission feature recited in claim 15 would have been obvious because it was one of a "finite number of identified, predictable solutions." *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331 (Fed. Cir. 2009).

**(v) "for further analysis with a second processor or a server at the remote station and review of…the quantified level of severity…by a clinician, technician or physician"**

Toge alone or in combination with Kumar renders obvious this limitation. Kirkness, ¶¶188-191; Chatterjee¶¶158-62.

Toge discloses that physicians may "access the transmitted data [including tidal volume] using the physician-side computer 4" and "operate…computer 4 to…download the necessary data." EX1044, [0018]; *see also id.*, [0050], [0051]. "[M]edical institution personnel can operate…computer 4 to set the necessary data…for [PAP] device 2," including adjusting the PAP device's prescription

pressure based on the received data, e.g., tidal volume. *Id.*, [0018], [0027], [0039], [0055], [0059], [0061]. Kirkness, ¶189; Chatterjee¶¶159-60.

A POSITA would have understood that the physician would have reviewed/analyzed the received tidal volume data before/while adjusting the PAP device's pressure using computer 4 ("remote station"). A POSITA would have understood that physician-side computer 4, which is capable of receiving treatment data and allows physicians to access the data as well as controlling the PAP device, includes a processor ("second processor"). EX1044, [0016], [0018]; *see also supra*. Accordingly, Toge discloses transmitting the tidal volume "**for further analysis with a second processor**…**at the remote station and review of** the collected data, **the quantified level of severity and/or this analysis** by a clinician, technician or **physician**." Kirkness, ¶190; Chatterjee¶161.

The Toge-Kumar combination also discloses this limitation. As discussed above, in view of Toge and Kumar's teachings, a POSITA would have been motivated to transmit to the remote engine (hosted on server 106) data associated with the patient's treatment, including "the collected data and/or the quantified level of severity data" for "secured storage device at the central server for **later** access, replay, and/or **analysis**" e.g., which **allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online**. EX1008, [0083], [0084]. Accordingly, Toge discloses transmission

the data "**for further analysis with**…**a server at the remote station and review of** the collected data, **the quantified level of severity and/or this analysis** by a clinician, technician or **physician**." Kirkness, ¶191; Chatterjee¶162.

**6. [15.e.1] "further determining the therapy efficacy data with either the processor of the PAP or CPAP device, the second processor or server configured with a second software at the remote station, or the cellular phone using the first software"**

Toge alone or in combination with Kumar renders obvious this limitation. Kirkness, ¶¶192-197; Chatterjee¶¶163-73. Toge discloses that "physician-side computer 4 is a computer installed at a medical institution." EX1044, [0017]. A POSITA would have understood that computer 4 ("remote station") includes a processor ("second processor") that executes code/program ("second software") to receive the treatment data (which may be based on a physician's download request) and allow the care provider/physician to review/analyze the received treatment data as well as setting certain parameters for PAP device 2. Kirkness¶192; Chatterjee¶164; *see*, *e.g.*, EX1044, [0018], [0047].

PAP device 2 receives mode settings/parameters for adjusting the PAP device from physician-side computer 4. EX1044, [0030]-[0031]. "The control unit 250 [of PAP device 2] controls the drive unit 252 **based on the configured mode and prescription pressure**, [and] the pressure value from the pressure gauge 23 that is entered…." *Id.*, [0032]. Kirkness¶193; Chatterjee¶165.

A POSITA would have understood that the data for adjusting mode settings/parameters corresponds to the claimed "therapy efficacy data" because these are data that physician provides to PAP device 2 to adjust the mode settings/parameters of the PAP device when treating the patient based on monitoring and analysis of the treatment data (including, e.g., tidal volume, which is calculated based on the sensor data), representing the patient's condition and efficacy of the treatment. For example, Toge discloses that "[b]y **transmitting the tidal volume**…, physicians can remotely **monitor the patient's condition**…. Furthermore, if there is a decreasing trend in the tidal volume…, emergency measures, such as **adjusting the prescription pressure to a higher level, can be taken remotely from**…**computer 4**…." EX1044, [0039]; *see also id.*, [0040]-[0041], [0044]-[0047]. Accordingly, Toge discloses "**further determining the therapy efficacy data with**…**the second processor**…**configured with a second software at the remote station**…." Moreover, for reasons discussed above, Toge's data for adjusting mode settings/parameters is consistent with PO's interpretation in the district court for the claimed "therapy efficacy data" as discussed in Section V. *See* Section V; EX1054, 23-24 ("therapy efficacy data" means "data calculated based on data collected while a subject is undergoing treatment to determine the severity of a subject's sleep disorder symptoms and whether the PAP device that is part of the method needs to be adjusted."). Kirkness¶194; Chatterjee¶¶166-69.

The Toge-Kumar combination also discloses this limitation. As discussed for limitation [15.d], in view of Toge and Kumar's teachings, a POSITA would have been motivated to transmit to the remote engine (hosted on server 106) data associated the patient's treatment, including "the collected data and/or the quantified level of severity data" for "secured storage device at the central server for **later** access, replay, and/or **analysis**" e.g., which allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. EX1008, [0083]. Kumar explains that "[a] remote client module…allows remote hosts to **view the data**…. The remote client module can **also control the software being run on the patient's**…**end**." *Id.*, [0085]. "[B]ased on real-time streaming of vital patient information, [Kumar's system] may be tailored to **forward proper responses to the patient**." *Id.*, [0088]. Kirkness¶195; Chatterjee¶¶170-71.

For instance, a physician may use the browser-based engine to "view streaming and/or saved data relating to the patient." EX1008, [0091], [0092].

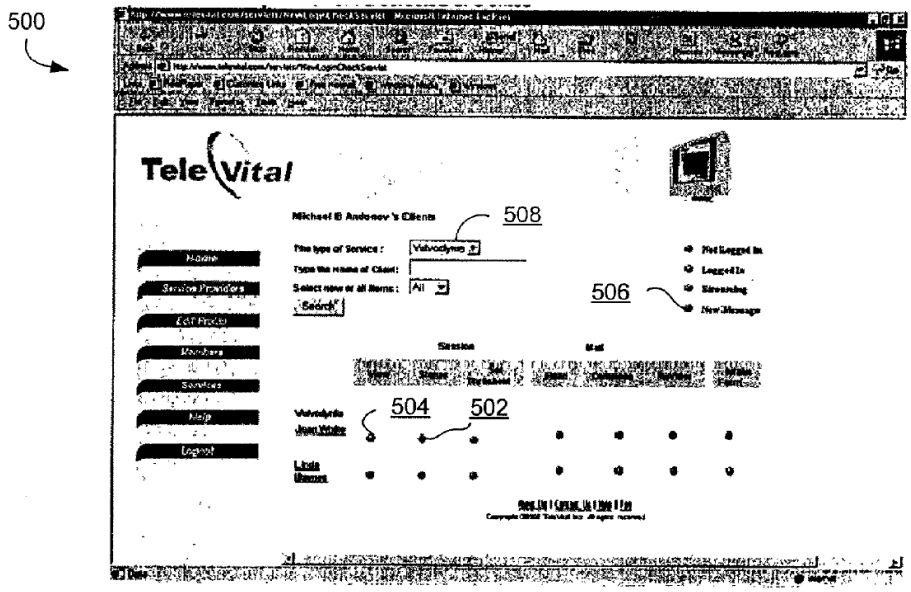



**Fig. 5**

EX1008, FIG. 5

Given that Kumar discloses a physician using the browser-based engine ("remote station") that is implemented on a server to adjust/control the patient-side device based on the received patient data and for similar reasons discussed for Toge, the Toge-Kumar combination discloses "**further determining the therapy efficacy data with**…the…**server configured with a second software at the remote station**…." Kirkness¶¶196-197; Chatterjee¶¶172-73.

**7. [15.e.2] "further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider."**

Toge alone or in view of Kumar renders obvious this limitation. Kirkness¶¶198-200; Chatterjee¶¶174-80. As discussed for limitation [15.d], tidal

volume ("quantified level of severity data") is provided to and received by computer 4 for physician's analysis. EX1044, [0030], [0031], [0039]-[0042]. By using computer 4, care providers may send a "data download request" to download data onto computer 4 and "set the necessary data…for [PAP] device 2." *Id.*, [0018]; Chatterjee¶175.

Toge's system enables "remote monitoring of the patient's condition during the use of a [PAP] device, or the condition of the [PAP] device." EX1044, Abstract, [0001], [0005]-[0006], [0039], [0085]. Settings of the PAP device, e.g., the prescribed pressure, can be configured/adjusted using computer 4 or mobile terminal 5. *Id.*, [0027], [0039]. A POSITA would have understood that, for the physicians to monitor and analyze the tidal volume ("quantified level of severity data"), such information is displayed to the physicians ("a care provider") on physician-side computer 4. Likewise, a POSITA would have understood that the data for adjusting mode settings/parameters ("therapy efficacy data") is displayed on computer 4 to allow the physician to review/monitor/adjust/provide associated settings. Kirkness, ¶199; Chatterjee¶¶176-79.

The Toge-Kumar combination also discloses this limitation. For example, as discussed for limitation [15.e.1], Kumar discloses that a physician may use a browser-based engine to receive/review patient data (e.g., "quantified level of severity data"). A POSITA would have understood that, for the physicians to

monitor/analyze the patient data (e.g., "quantified level of severity data"), such information is displayed to the physicians ("a care provider") via the web-browser user interface. Likewise, a POSITA would have understood that the data for adjusting mode settings/parameters ("therapy efficacy data") is displayed via the web-browser user interface to allow the physician to review/monitor/adjust/provide associated settings. Kirkness¶200; Chatterjee¶180.

### D. Dependent Claims 16, 17, 20-24, and 26-29

#### 1. Claim 16: Bluetooth

Toge in view of Kumar renders obvious this limitation. Kirkness¶¶201-204; Chatterjee¶181-89. While Toge does not expressly disclose this limitation, a POSITA would have found it obvious to implement the recited features in Toge in view of Kumar.

Kumar discloses that a patient-side device may establish with "a two-way communication" with a computing device 110, e.g., a "wireless phone" or an "IPAQ." EX1008, [0072]; *see also id.*, [0071], [0239]-[0241]. A POSITA would have understood that a "wireless phone" or an "IPAQ" is capable of establishing wireless communications using the Bluetooth protocol. Chatterjee¶182; EX1011, 2. Moreover, Kumar explains that the patient-side device may likewise communicate through a "wireless…protocol." *Id.*, [0072]. Thus, Kumar at least suggests that the patient-side device (e.g., Toge's PAP device) may communicate with a

wireless/mobile phone using the Bluetooth protocol. Kirkness¶202; Chatterjee¶¶183-85.

A POSITA would have been motivated to configure Toge's PAP device 2 and mobile terminal 5 ("cell phone") such that they can communicate directly with each other through the Bluetooth protocol, which a POSITA would have understood as a real-time connection given that the Bluetooth protocol is a short-range communication protocol. Chatterjee¶186; EX1009 (Mumford), 14:35-37 (Bluetooth protocol "suitable for short-range communication"). PAP device 2 has an input device 28 allowing a physician to adjust/control operations such as power on/off, mode selection, prescription pressure settings. EX1044, [0026]. Providing Bluetooth capability would have allowed the physician to conveniently control/adjust the PAP device as well as to download/review data directly from the PAP device using mobile terminal 5 wirelessly, e.g., during the patient's initial/follow-up appointment(s) with the physician. A POSITA would have also been motivated to implement such a wireless capability because Toge expressly teaches that "settings can be adjusted by the physician using a **separate** input terminal…**detached** from the main unit 20 [of PAP device 2]." *Id.*, [0027]. Kirkness¶203; Chatterjee¶187-88.

A POSITA would have also had the skill and reasonable expectation of success in implementing the above-discussed modification. Kirkness¶204;

Chatterjee¶189. It was known to use the Bluetooth protocol to transmit and/or view data associated with a PAP device. EX1009, 14:54-15:12; EX1050, 8:28-9:2. Moreover, it would have involved a combination of known technologies according to known methods to yield the predictable result of a method allowing a PAP device to communicate wirelessly with a mobile terminal through the Bluetooth protocol for improved convenience, as discussed above. Kirkness¶204; *KSR*, 550 U.S. at 416. Additionally, there were only a handful of other protocols for transmitting data wirelessly, including Wi-Fi, mobile network protocol, optical connection, for example. Chatterjee¶189. 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).

**2. Claim 17: therapy can be modified base in part on transmitted data**

Toge discloses this limitation. Kirkness¶205; Chatterjee¶190-92. Toge discloses the transmitted tidal volume allows physicians to "remotely monitor the patient's condition during the use of the [PAP] device 2" and "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…computer 4 or mobile terminal 5." EX1044, [0039]. As discussed for limitation [15.d], the PAP device

and the physician-side computer 4 are wirelessly connected to communication network 1 for data transmission. EX1044, [0006]-[0007]; *see also id.*, [0016], [0060], [0063], [0070], [0078], [0080]-[0081], claim 1. Thus, Toge discloses "the therapy can be modified based in part on the wirelessly transmitted data or information."

#### 3. Claim 20: adjusted or titrated through wireless connection from remote location

Toge discloses this limitation for the same reasons discussed for claim 17. Kirkness¶206; Chatterjee¶193; *see* Section VI.D.2 (Ground 1, Claim 17).

#### 4. Claim 21: adjusted or titrated in real-time from remote location

Toge discloses this limitation. Kirkness¶¶207-208; Chatterjee¶¶194-96. As discussed for claim 17, Toge's PAP device may be adjusted by a physician from a remote location. Toge further discloses that "[b]y transmitting the tidal volume…almost in real-time or at regular intervals (such as every hour), physicians can remotely monitor the patient's condition during the use of the [PAP] device 2 remotely" and "if there is a decreasing trend in the tidal volume…, emergency measures, such as adjusting the prescription pressure to a higher level, can be taken remotely from…computer 4 or mobile terminal 5." EX1044, [0039]. Moreover, Toge explains that "[b]y transmitting the operating status in real-time, physicians can address emergencies involving the patient." *Id.*, [0046].

The '333 patent explains that "[b]y real-time it is meant that the quantitative diagnosis step is **accomplished predictively** or **within a short period of time** after symptoms occur which allows for immediate treatment…" and "preferably the diagnosis is **accomplished within 24 hours of receiving the signals** from the one or more sensors on the subject." EX1001, 22-31-46; Kirkness¶208; Chatterjee¶¶195-96.

**5. Claim 22: storing on database**

The Toge-Kumar combination renders obvious this limitation. Kirkness¶209; Chatterjee¶197-99. As discussed for limitation [15.d], in view of Toge and Kumar's teachings, a POSITA would have been motivated to transmit data to a browser-based engine ("remote station"), including "the collected data, the quantified level of severity data from…the PAP or CPAP device," because, e.g., "the data may be stored in a secured storage device…for later access, replay, and/or analysis." EX1008, [0083]. "[S]torage of the data allows for the creation of statistical databases, including development of **a database of biomedical test results**, for example." *Id.*, [0083]. Accordingly, for reasons discussed for limitation [15.d], a POSITA would have been motivated to implement this feature in the Toge-Kumar combination and would also have a reasonable expectation of success in doing so. Toge explains that the PAP treatment may be provided to "several patients" (*see*, *e.g.,* EX1044, [0015], [0058]) and thus, a POSITA would have likewise found it

obvious to store each patient's data on the same database of the browser-based engine for the creation of a statistical database. Kirkness¶209; Chatterjee¶199.

**6. Claim 23: database stored on central server**

The Toge-Kumar combination renders obvious this limitation. Kirkness¶¶210-211; Chatterjee¶¶200-02. As discussed for claim 22, a POSITA would have been motivated to implement a database for storing, e.g., the collected data and the quantified level of severity data. Toge further discloses that the database or the storage of the data is "at the central server." EX1044, [0083]. Consistent with Kumar's disclosure of "remote monitoring" (*id.*, [0010]), "telemedicine, remote sleep studies" (*id.*, [0068]) and that "patient-side device is remotely controlled" (*id.*, claim 22), a POSITA would have understood that the central server (on which the browser-based engine is implemented) is remote to the patient-side device (e.g., the PAP device of Toge). *See also id.*, [0087]. Thus, the Toge-Kumar combination discloses "the database is stored on a central server…remote to the test location." Kirkness¶210; Chatterjee¶201.

Kumar also discloses that "[t]he present invention may be implemented on a program or code that can be stored in a computer-readable…medium" ("second software is stored on a computer readable medium"). EX1008, [0020], [0087]. A POSITA would have understood that the implemented program/code is executed by the central server. Kirkness¶211; Chatterjee¶202.

### 7. Claim 24: analyzing data in database with relationship algorithm

Toge in view of Kumar renders obvious this limitation. Kirkness¶212; Chatterjee¶¶203-04. Kumar discloses that storing data "in a secured storage device at the central server" allows "**for later**…**analysis**" and "the creation of statistical databases, including development of a database of biomedical test results." EX1008, [0083]. Additionally, Kumar discloses that the system may "track trends" and "using artificial intelligence, predict future behaviors and physiological responses based on the habits of the particular client hooked up." *Id.*, [0084]. A POSITA would have understood that these analyses are used to improve/optimize treatments for the patient ("determine an optimal treatment for the subject"). Moreover, a POSITA would have understood that use of "artificial intelligence" involves applying "a relationship algorithm or a neural network," as claimed. Kirkness¶212; Chatterjee¶204.

### 8. Claim 26: Discrete Fourier Transform or Fast Fourier Transform

Toge in view of Kumar renders obvious this limitation. Kirkness¶¶213-215; Chatterjee¶¶205-07. Kumar discloses that data may be analyzed "using FFT, DFT, etc." EX1044, [0075]. A POSITA would have understood that FFT and DFT each refers to the claimed "fast Fourier transform technique" and "discrete Fourier

transform technique," consistent with the '333 patent's use of DFT and FFT. Kirkness¶213; Chatterjee¶206; *see also* EX1001, 23:63-65.

A POSITA implementing the Toge-Kumar combination would have been motivated to use the FFT and/or DFT techniques to analyze the collected data to determine, e.g., the tidal volume, as these techniques were well-known and commonly used at the time of the alleged invention to determine physiological parameters. Kirkness¶214; Chatterjee¶207; EX1060, 12:1-11; EX1061, claim 1.

A POSITA would have also had a reasonable expectation of success in implementing this feature in the Toge-Kumar combination as it would have involved a combination of known technologies (e.g., known PAP device that analyze collected data (Toge)) according to known methods (e.g., known methods of analyzing data using FFT or DFT (Kumar)) to yield the predictable result of a PAP device where the collected data is analyzed by the PAP device's processor, in part, using the FFT or DFT technique, as discussed above. *KSR*, 550 U.S. at 416. Accordingly, Toge in view of Kumar discloses this limitation. Kirkness¶215; Chatterjee¶207.

**9. Claim 27: time-frequency signal analysis**

Toge in view of Kumar renders obvious this limitation. Kirkness¶216; Chatterjee¶¶208-10. As discussed for claim 26, the Toge-Kumar combination teaches using Discrete Fourier Transform (DFT) and/or Fast Fourier Transform

(FFT) to analyze the collected data to determine tidal volume ("quantified level of severity data"). A POSITA would have understood that the Fourier Transform analysis, including DFT and FFT, itself is a "time-frequency signal analysis" technique because the Fourier Transform analysis because that it transforms **time**-domain signals/data into **frequency**-domain signals/data. Kirkness¶216; Chatterjee¶¶209-10.

### 10. Claim 28: third software which along with the first software can be updated

Toge in view of Kumar renders obvious this limitation. Kirkness¶¶217-220; Chatterjee¶211-15. Toge discloses that the PAP 2 is controlled based on "configured mode and prescription pressure" (EX1044, [0032]) and the "the control unit 250 can be constructed using a **program** describing the processing of the control unit 250" (*id.*, [0048]). Thus, Toge discloses "the PAP or CPAP further comprises…a third software." Kirkness¶217; Chatterjee¶212.

Toge discloses that "medical institution personnel can operate the mobile terminal 5 ("cellular phone") to set the necessary data…for the [PAP] device 2." EX1044, [0019]. "The mobile terminal 5 includes mobile phones…, PDAs...." *Id.* Thus, a POSITA would have understood that mobile terminal 5 operates by executing a program/software ("first software"). Kirkness¶218; Chatterjee¶213.

Given that each of PAP device 2 (operating based on "third software") and mobile terminal 5 (operating based on "first software") are connected to network 1 (EX1044, [0008], [0061]), a POSITA would have found it obvious to update the software on these devices using a remote server ("remote station" or "a different remote server"). Kumar discloses that "updates to the software are done by simply running the latest software from a website." EX1008, [0086]; *see also id.,* [0067]. Thus, in view of Kumar's teaching, a POSITA would have found it obvious to have the software of PAP device 2 and mobile terminal 5 updated from a "remote station" or any "different remote server." Kirkness¶219; Chatterjee¶214.

A POSITA would have been motivated to have the software of the PAP device 2 and the mobile terminal 5 updated from a browser-based engine or any server. A POSITA would have looked to Kumar's teaching of updating software and been motivated to have the software of the device 2 and the mobile terminal 5 ("cellular phone") updated from the engine ("remote station") or a "different remote server." A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described remote update feature as it would have would have been a routine and conventional implementation of known methods using known hardware components performing their known functions, well within a POSITA's skills and ability to accomplish. Likewise, a POSITA would have had the skill and a reasonable expectation of success in updating the software of devices

from an engine or a different server. Accordingly, the Toge-Kumar combination discloses this limitation. Kirkness¶220; Chatterjee¶215.

#### 11. Claim 29: alerting

Toge discloses "send[ing] an alert to both or either of…computer 4 and the mobile terminal 5, marking the situation as an emergency where the patient's breathing has drastically weakened," when the tidal volume falls below certain threshold value(s). EX1044, [0055]. A POSITA would have understood that patient's weakened breathing indicates issues relating to the efficacy of the PAP treatment. Accordingly, Toge discloses this limitation. Kirkness¶221; Chatterjee¶216-217.

## VII. GROUND 2: TOGE IN VIEW OF KUMAR AND NORMAN RENDERS OBVIOUS CLAIMS 15-18, 20-24, AND 25-29

### A. Motivation to Combine

A POSITA would have been motivated to modify the Toge-Kumar combination in view of Norman's teaching. First, Toge discloses a CPAP device, where the provided pressure may be adjusted, and Norman teaches an improvement to such a CPAP device that allows "automated titration." EX1059, Abstract, [0007]. Such an automated titration process allows the system to "evaluate the efficacy of the adjusted pressure" and also "enhance[s] the accuracy with which the appropriate pressure is determined." *Id.*, [0031]. Thus, a POSITA would have found it

beneficial to implement an automated titration process as taught in Norman to improve the accuracy and efficacy of the CPAP treatment process in the Toge-Kumar combination. Kirkness¶222; Chatterjee¶¶218-21.

Second, consistent with a POSITA's understanding and as expressly taught by Norman, improved accuracy and efficacy of the treatment would have improved the patient's compliance and satisfaction. EX1059, [0033]. Kirkness¶222.

Third, a POSITA would have been motivated to implement Norman's teaching of collecting patient's data "over a several time periods" to "evaluate the efficacy of the adjusted pressure" in the Toge-Kumar combination because Norman expressly teaches that using multiple types of data collected from multiple nights of treatment would have enhanced the accuracy of the treatment. Kirkness¶223.

### B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in implementing Norman's automated titration teachings in the Toge-Kumar combination. Norman teaches that these features may be implemented in "*any variety of PAP systems* supplying constant or varying pressure to patients." EX1059, [0017]. Additionally, 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) combined with remote engine that stores patient's data (Kumar)) according to known methods (e.g., known methods implemented on

a processor to analyze sensor data to determine counts/index associated with respiratory events (Norman)) to yield the predictable result of a PAP device having automated titration capability to improve accuracy and treatment efficacy. Kirkness¶¶224-225; Chatterjee¶¶222-23.

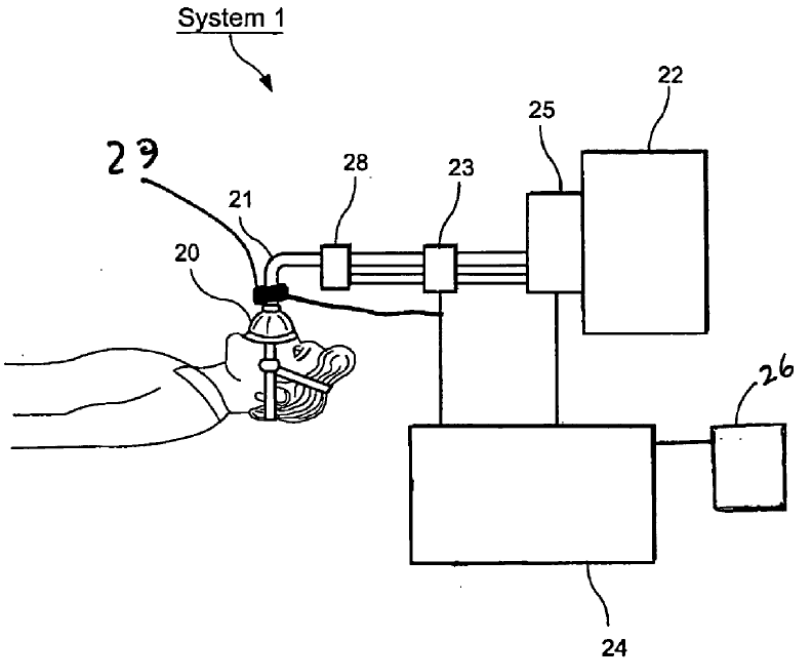
### C. Claims 15-17, 20-24, and 26-29

Ground 1 establishes that the Toge-Kumar combination renders obvious claims 15-17, 20-24, and 26-29. Section VI (Ground 1). To the extent that Toge does not disclose limitation [15.c] and limitation [15.e.1], it would have been obvious to implement the recited features in the Toge-Kumar combination in light of Norman. Kirkness¶226; Chatterjee¶224.

Like Toge, Norman discloses a CPAP system including "an air pressure supply providing air pressure to a patient's airways and a sensor detecting input data corresponding to a patient's breathing patterns of a plurality of breaths." EX1059, Abstract. Kirkness¶227.

Specifically, Norman discloses a CPAP system 1 including a mask 20 that is connected via a tube 21 to receive airflow at a particular pressure from a flow generator 22, where "[t]he amount of pressure provided to a particular patient varies depending on that patient's particular condition." EX1059, [0019]. "Flow and/or pressure sensors 23" detect "the volume of the airflow to and from the patient and the pressure supplied to the patient," where "sensors 23 may be internal…to the

generator 22." *Id.*, [0020]. "Signals corresponding to the airflow and the pressure from the sensors 23 are provided to a processing arrangement 24," which then "generates pressure control outputs signals to a flow control device 25 that "controls the pressure applied to the flow tube 21 by the flow generator 22." *Id.*; Kirkness¶228.

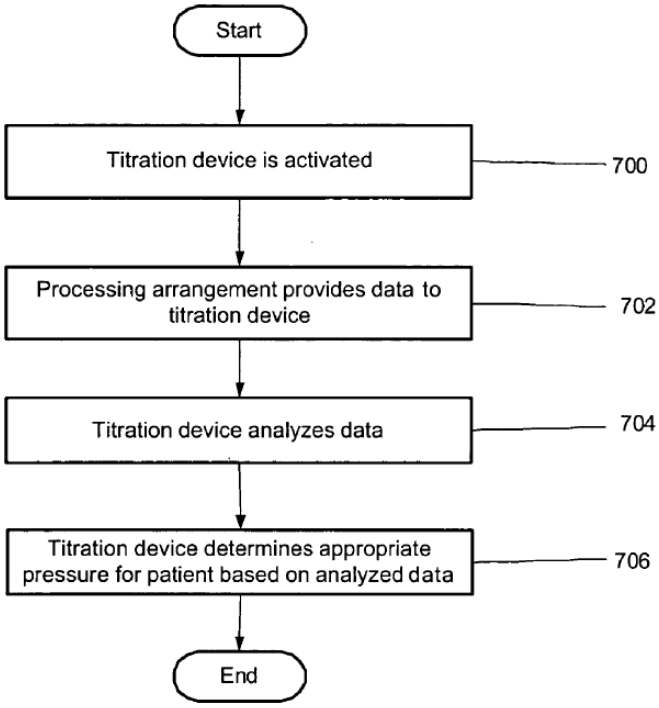



**EX1059, FIG. 6**

Norman's system may "detect[] abnormal respirations and flow limitations in the patient's airway" and/or detect "sleeping disorders (e.g., flow limitations), and may be used for "autotitration and treatment of such sleeping disorders." EX1059, [0022]. "[S]ystem 1 also includes an automatic titration device 26 which provides an initial titration (i.e., determination of an appropriate pressure or an appropriate

varying pressure function for a particular patient) as well as subsequent retitrations." *Id.*, [0023]. Titration device 26 may be "built into the system 1 (e.g., the titration device 26 may be combined with the processing arrangement 24)." *Id.*; Kirkness¶229.

As shown in Figure 7, Norman discloses "an exemplary method…for automatic titration to determine an appropriate pressure or varying pressure function for the PAP therapy." EX1059, [0024].




**EX1059, FIG. 7**

**In step 700**, the titration device 26 is activated, e.g., "to obtain appropriate data for calculation of the pressure or pressure function for the PAP therapy" or "at such times as may be determined are desired to retitrate to ensure the PAP therapy

is properly tailored to the patient's current condition." EX1059, [0024]. "Once activated, the titration device 26 may remain active for a predetermined period of time," e.g., "for a specific period of time (e.g., a single sleeping cycle of 6-8 hours)…." *Id.*, [0025]. **In step 702**, "[w]hile active, the titration device 26…process[es] and analyz[es] data collected by the processing arrangement 24 (step 702)." *Id.* "[P]rocessing arrangement 24 transmits data to the titration device 26," where the data "includes…the patient's airflow and the pressure applied to the airways of the patient" and "[s]uch data may be provided continuously or periodically." *Id.* The data collected by the titration device 26 may be stored in a database with, e.g., data related to each particular patient collected during various titration procedures, where the stored data may be accessed and analyzed by the titration device 26 to determine appropriate pressure controls for that patient. *Id.*, [0026]. Data for multiple patients may be stored in a single memory arrangement that may be a part of system 1 or "situated at a remote location that can be accessed via a communications network. (e.g., the Internet, VPN, etc.)." *Id.*; Kirkness¶¶230-231.

In **step 704**, the titration device 26 analyzes the collected data. EX1059, [0027]. Norman explains that titration device 26 analyzes patient airflow data to "accurately map patient's breathing patterns." *Id.* The titration device 26 analyzes breathing patterns to "detect abnormal respiratory events and to identify the

conditions under which they arise", where "[a]bnormal respiratory events…identified include apnea, hypopnea and events of elevated upper airway resistance." *Id.* Specifically, "[a]pnea is identified by a cessation of respiratory airflow in the patient, where the cessation can last, for example, approximately ten seconds" and "[h]ypopnea is identified by a decrease in amplitude of the airflow signal relative to a baseline value, where the decrease can last, for example, approximately ten seconds." *Id.* "Elevations in the resistance of the upper airway may be identified by changes in the shape of the inspiratory airflow contour." *Id.* Norman explains that the "airflow signal from the entire collection period may be analyzed for the presence of sleep disordered breathing events." *Id.*; Kirkness¶232.

Lastly, in **step 706**, "based on the analysis of respiratory events, the titration device 26 determines, using a predefined algorithm, an appropriate pressure or a varying pressure function to be supplied to the patient." EX1059, [0028]. "The **counts [or] other indexes of respiratory events** (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) that occurred during the previous collection period **indicate the efficacy of the pressure administered**." *Id.* **The pressure provided by the CPAP may be adjusted** based on whether "the count or index increases to beyond a preset absolute value or relative value (compared to previous values for that patient)" or "[i]f the number of events is below a preset value." *Id.*; *see also id.*, [0028]-[0029].

"If the titration device 26 is used to adjust a variable pressure…, based on the number of abnormal events identified and the circumstances under which they occurred, any number of modifications of the pressure supply function may be initiated." *Id.*, [0029]; *see also id.*, [0030]. The titration process may be "repeated during the subsequent time period using the adjusted pressure to evaluate the efficacy of the adjusted pressure." *Id.*, [0031]. Norman explains that such a process "enhance[s] the accuracy with which the appropriate pressure is determined." *Id.* Alternatively, "the titration device 26 may be adapted to continually collect data for the entire duration of the treatment so that the titration process is continuously updated." *Id.*, [0031]; *see also id.*, [0033]. Kirkness¶233.

**1. Limitation [15.c]**

Norman discloses this limitation. Kirkness¶¶234-235; Chatterjee¶¶225-27. As discussed above, Norman discloses that titration device 26 may be combined with processing arrangement 24 (collectively the claimed "processor"). EX1059, [0023]. Norman explains that airflow volume and pressure supplied (either or both, the claimed "collected data") are detected by flow and/or pressure sensors 23, provided to processing arrangement 24 (*id.*, [0020]), and processed/analyzed by titration device 26, e.g., in step 702 (*id.*, [0025]). Norman further explains that titration device 26 analyzes the collected data by analyzing breathing patterns to "detect abnormal respiratory events and to identify the conditions under which they arise",

where "[a]bnormal respiratory events…identified include apnea, hypopnea and events of elevated upper airway resistance." *Id.*, [0027]. Kirkness¶234; Chatterjee¶226.

"[B]ased on the analysis of respiratory events, the titration device 26 determines, using a predefined algorithm, an appropriate pressure or a varying pressure function to be supplied to the patient." EX1059, [0028]. "**The counts [or] other indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) that occurred during the previous collection period indicate the efficacy of the pressure administered**." *Id.* Given that processing arrangement 24 and titration device 26 (collectively the claimed "processor") receive and analyze the collected sensor data ("collected data") to determine the counts/indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) ("a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy"), Norman discloses limitation [15.c]. Kirkness¶235; ; Chatterjee¶227. Moreover, for reasons discussed above, counts or indexes of respiratory events disclosed in Norman are consistent with PO's interpretation of the claimed "level of severity" as discussed in Section V. *See* Section V; EX1058, ¶32 ("'level of

severity' which clinicians understand to represent the how dire a patient's calculated symptom data may be"); *see also* EX1054, 23 (citing to EX1058, ¶32).

**2. Limitation [15.e.1]**

Norman discloses this limitation. Kirkness¶236. For example, Norman discloses that "[t]he counts [or] other indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) that occurred during the previous collection period **indicate the efficacy of the pressure administered**." EX1059, [0028]. For instance, Norman explains that "[w]hen the count or index increases to beyond a preset absolute value or relative value… the pressure may be increased for the next CPAP period." *Id.* Additionally, Norman discloses that the titration process may be "repeated during the subsequent time period using the adjusted pressure to **evaluate the efficacy of the adjusted pressure**." *Id.*, [0031]. A POSITA would have understood that these data for adjusting the provided pressure correspond to the claimed "therapy efficacy data" because these are data for adjusting the settings/parameters of the PAP device when treating the patient based on monitoring and analysis of the sensor data, representing the patient's condition and efficacy of the treatment. Kirkness¶236. Accordingly, Norman discloses "further determining the therapy efficacy data with…the processor of the PAP or CPAP device…." Moreover, for reasons discussed above, Norman's data for adjusting the PAP's

pressure is consistent with PO's interpretation in the district court for the claimed "therapy efficacy data" as discussed in Section V. *See* Section V; EX1054, 23-24 ("therapy efficacy" means "data calculated based on data collected while a subject is undergoing treatment to determine the severity of a subject's sleep disorder symptoms and whether the PAP device that is part of the method needs to be adjusted."). Kirkness¶236.

### 3. A POSITA Would Have Been Motivated to Modify the Toge-Kumar Combination in view of Norman

A POSITA would have been motivated to modify the Toge-Kumar combination in view of Norman's teaching discussed above. Kirkness¶237; Chatterjee¶¶228-34. While Toge discloses a CPAP device, where the provided pressure may be adjusted, Norman teaches an improved CPAP device that allows "automated titration." EX1059, Abstract, [0007]. As discussed above, such an automated titration process allows the system to "evaluate the efficacy of the adjusted pressure" and also "enhance[s] the accuracy with which the appropriate pressure is determined." *Id.*, [0031]. Accordingly, a POSITA would have found it beneficial to implement an automated titration process as disclosed in Norman to improve the accuracy and efficacy of the CPAP treatment process similar to as disclosed by the Toge-Kumar combination. Moreover, consistent with a POSITA's understanding and as expressly disclosed by Norman, improved accuracy and

efficacy of the treatment would have improved the patient's compliance and satisfaction. EX1059, [0033]. Kirkness, ¶237; Chatterjee¶228.

Moreover, similar to reasons discussed for limitation [15.d]-(iii) in Ground 1, a POSITA would have been motivated and have had reasonable expectation of success to enable the PAP device (as modified in view of Norman) to wirelessly transmit to the browser-based engine data associated the patient's treatment, including, e.g., "the collected data", "the quantified level of severity data," and "therapy efficacy data," as discussed above and disclosed in Norman for, e.g., secured storage, data backup, later analysis/access by the physicians/patients, creation of a database, and sharing of data. Kirkness¶238; Chatterjee¶¶229-30. Additionally, as discussed for limitations [15.d]-(iii) and [15.e.2] in Ground 1, Kumar explains that the remote engine provides a secured storage and access of the stored data to the patient or care provider through web pages which serve as a graphical user interface. EX1008, [0092], Figs. 6-8; *see also id.*, [0010], [0015]. Accordingly, the Toge-Kumar-Norman combination also discloses limitation [15.e.2] ("further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider"). Kirkness¶238.

A POSITA would have had a reasonable expectation of success in implementing the above-discussed features in the Toge-Kumar combination in view of Norman's teaching and a POSITA's knowledge. Kirkness¶239. As discussed

above for limitations [15.a]-[15.c] in Ground 1, Toge already discloses a CPAP device that collects sensor data and analyzes the sensor data using a processor. Norman explains that its disclosed features may be implemented in "any variety of PAP systems supplying constant or varying pressure to patients." EX1059, [0017]. 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) combined with remote engine that stores patient's data (Kumar)) according to known methods (e.g., known methods implemented on a processor to analyze sensor data to determine counts/index associated with respiratory events (Norman)) to yield the predictable result of a PAP device having automated titration capability to improve accuracy and treatment efficacy, as discussed above. *KSR*, 550 U.S. at 416. Accordingly, the Toge-Kumar-Norman combination discloses these limitations and thus claim 15. Kirkness¶239; Chatterjee¶231.

The Toge-Kumar-Norman combination also discloses dependent claims 16-17, 20-24, and 26-29 for reasons similar to those discussed for the same claims in Ground 1. The Toge-Kumar-Norman combination discloses claims 16, 20, 22-24, and 26-28 for the same reasons discussed for the same claims in Ground 1 given that the modification of the Toge-Kumar combination in view of Norman (discussed above) does not substantively impact the disclosed features corresponding to claims 16, 20, 22-24, and 26-28. Kirkness¶240; Chatterjee¶232.

With respect to dependent claims 17, 21, and 29, the Toge-Kumar-Norman combination also discloses these claims. For example, Toge discloses alerts may be sent to the physician based on the patient's condition wirelessly and the PAP device may be remotely controlled/adjusted in real-time. EX1044, [0019], [0039], [0046], [0055]. Kumar likewise discloses that the care provider "may remotely control the client-side device" (e.g., the PAP device). EX1008, [0015]. Thus, a POSITA would have been motivated to enable the PAP device (modified in view of Norman) such that the PAP device (provided treatment) may be adjusted in real-time by a physician remotely based on the wirelessly transmitted data/information, and also that the PAP device may alert the physician issues relating to the therapy efficacy. Kirkness¶241; Chatterjee¶233.

For example, a POSITA would have found it obvious to adjust, for example, the frequency of the titration process based on the patient's condition and data/alert provided to the physician. Indeed, Norman discloses that "the titration device 26 may be activated by…medical personnel initially to obtain appropriate data for calculation of the pressure or pressure function for the PAP therapy" and "**can be again activated** at **such times as may be determined are desired to retitrate to ensure the PAP therapy is properly tailored to the patient's current condition**." EX1059, [0024]. Accordingly, the Toge-Kumar-Norman combination discloses dependent claims 17 ("the therapy can be modified based in part on the wirelessly

transmitted data or information"), 21 ("the PAP or CPAP is adjusted or titrated in real-time by the…physician from a remote location"), and 29 ("further comprising the step of alerting the subject's…physician of issues related to the therapy efficacy"). Kirkness¶242; Chatterjee¶234.

### D. Claim 18: rich data set

Toge in view of Kumar and Norman renders obvious this claim. Kirkness¶¶243-249. As discussed for claim 22 in Ground 1, based on Kumar's teaching and because Toge explains that the PAP treatment may be provided to several patients, a POSITA would have found it obvious to store each patient's data on the same database of the browser-based engine for the creation of a statistical database.

To the extent that the Toge-Kumar combination does not disclose claim 18, a POSITA would have found it obvious to implement those features in the Toge-Kumar combination in view of Norman. Kirkness¶244.

Norman discloses that the titration device "analyze[s] [airflow and pressure sensor] data collected during…a predetermined time period" and repeats the titration process "over a several time periods" to "evaluate the efficacy of the adjusted pressure." EX1059, [0023], [0030]-[0031]. Thus, the PAP therapy "operat[es] over the course of **several sleeping cycles** to arrive at a more accurate image of the patient's breathing patterns" and "enhance the accuracy with which the appropriate

pressure is determined." *Id.*, [0031], [0033]. Norman explains that "**the predetermined time period may be a single sleeping cycle** such as **one night of observation**." *Id.*, [0030]. Given that Norman discloses collecting more than one type of data from multiple time periods/cycles to determine/enhance the accuracy of the air pressure provided for the sleep apnea treatment, Norman discloses "a rich data set is used to determine treatment from the collected data from multiple nights of treatment." EX1059, [0023], [0031], [0033]; Kirkness¶¶245-246.

A POSITA would have been motivated to implement the above-described features from Norman given that Norman expressly discloses that these features would have enhanced the accuracy of the treatment. Kirkness¶¶247-248.

A POSITA would have also had a reasonable expectation of success in implementing these features in the Toge-Kumar combination because it would have involved a combination of known technologies (e.g., known PAP device that collects both air flow and pressure sensor data (Toge)) according to known methods (e.g., known methods of collecting multiple types of data from multiple nights of sleep apnea treatments (Norman)) to yield the predictable result of a method using a rich data set based on data collected from multiple nights of treatment to improve the accuracy of the treatment, as discussed above. Kirkness¶249; *see also KSR*, 550 U.S. at 416.

### E. Claim 25: determine total sleep time

The Toge-Kumar-Norman combination renders obvious this claim. Norman discloses the PAP device analyzes data collected over a "predetermined time period," including a time period encompassing "a single sleeping cycle such as one night of observation." EX1059, [0030]. A POSITA would have understood analyzing data over a "single sleeping cycle" encompasses one night of observation that involves a determination of "total sleep time." Kirkness¶250.

## VIII. GROUND 3: TOGE IN VIEW OF KUMAR AND BURTON RENDERS OBVIOUS CLAIM 19

### A. Motivation to Combine

A POSITA would have been motivated to implement Burton's features in Toge's PAP device. Kirkness¶¶251-254; Chatterjee¶¶235-36.

First, Burton's features, including adaptive algorithm to modify a patient's therapeutic treatment and "automatically adjust[ing] the therapeutic treatment based on at least one index or derived data set," including, e.g., "Mixed Sleep Apnea events," "Central Sleep Apnea events," and "Obstructive sleep apnea and hypopnea syndrome," 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. Kirkness, ¶252; Chatterjee¶235.

Second, 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 [upper airway resistance, apnea/hypopnea syndromes, unwanted arousals], while still minimizing sleep fragmentation and optimizing sleep quality." EX1050, 20:14-23; *see also id.*, 26:9-15. Kirkness, ¶¶253-254; Chatterjee¶236.

### B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in implementing Burton's features in the Toge-Kumar combination. Kirkness¶¶255-258; Chatterjee¶¶237-39.

First, 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; Kirkness¶256; Chatterjee¶237.

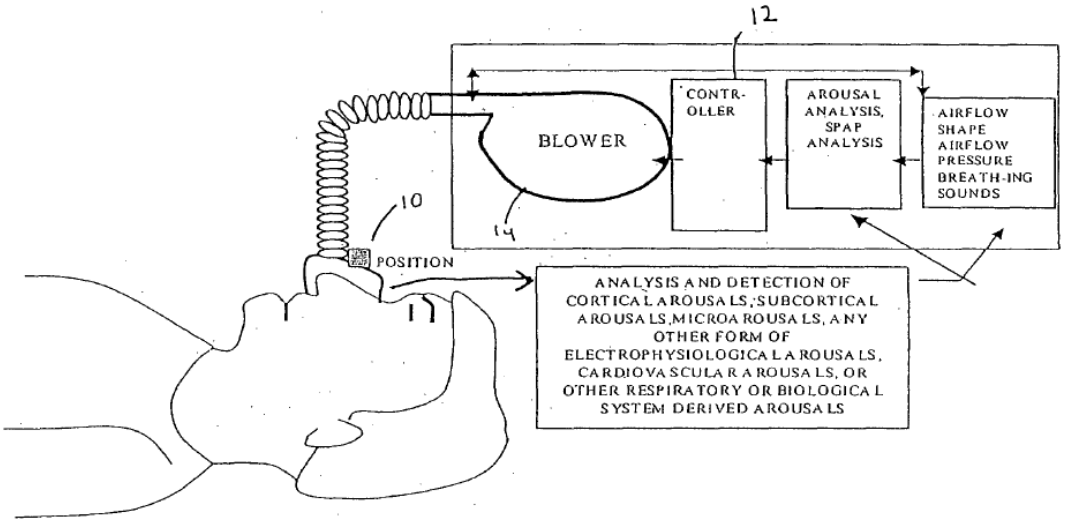
Second, it would have involved a combination of known technologies (e.g., known PAP device that controls the device operations using a processor based on received sensor data (Toge)) according to known methods (e.g., known methods/algorithm implemented on a controller/processor to generate/output data

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 that is capable of self-learning/self-training, based on data from a prior time period, to adjust for better identifying and distinguishing between obstructive, central and complex sleep apneas during a subsequent period of time. Additionally, Kumar states that "virtually any device may be easily incorporated into the system." EX1008, [0074]. Thus, no implementation details of Kumar would prevent incorporating Toge's PAP device as modified by Burton into its networked system. Kirkness¶¶257-258; Chatterjee¶¶238-39.

### C. Claim 19: identify and distinguish between obstructive, central and complex apnea

Toge in view of Kumar and Burton renders obvious this claim. Kirkness, ¶¶259-268; Chatterjee¶¶240-47. To the extent that the Toge-Kumar combination does not disclose the recited features, a POSITA would have found it obvious to implement those features in the Toge-Kumar combination in view of Burton. Kirkness¶259; Chatterjee¶¶240-47.

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**

Burton explains that, while PAP treatments may achieve intended results, they "often severely affect the quality of sleep" of the patient undergoing treatments, "causing transient arousals." EX1050, 1:9-12. These arousals "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. 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 arousal and sleep fragmentation. *Id.*, 2:2-31. Kirkness¶¶260-261; Chatterjee¶241-42.

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¶262; Chatterjee¶243.

Burton discloses "automatically adjust[ing] the therapeutic treatment based on at least one index or derived data set," including, e.g., "Mixed Sleep Apnea events," "Central Sleep Apnea events," and "Obstructive sleep apnea and hypopnea syndrome." EX1050, 21:4-22:21. A POSITA would have understood that the mixed sleep apnea events correspond to the claimed "complex sleep apneas" as mixed apneas are sleep disordered breathing events that are characterized by both reduced breathing effort (central) and airway obstruction (obstructive). Thus, Burton discloses automatically adjusting the PAP operation based on various analysis/data, including the above-mentioned indices which involve "identify[ing] and distinguish[ing] between obstructive, central and complex sleep apneas," as claimed. Kirkness¶¶263-264; Chatterjee¶¶244-45.

Burton discloses that "[t]he detection capability…enable…analysis techniques such as neural networks or other methods that are capable of **adopting**

**self-learning** and algorithm adaptation techniques." EX1050, 4:29-32. Burton discloses "down-load[ing] from sleep laboratory studies or other types of **previous sleep…investigations**" and associating those data with the patient's "breathing and sleep arousal parameters and is used to customize a gas delivery device to be **more sensitive and accurate** for both minimizing incidence of [unwanted arousal events], while still minimizing sleep fragmentation and optimizing sleep quality." *Id.*, 20:14-23. Thus, Burton discloses enabling the PAP device to self-learn/self-train using the collected sensor data ("data from the first sensor") from a prior period to improve treatment in a subsequent period ("second time period"). Accordingly, Burton discloses and/or suggests "train[ing] the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during a second time period with data from the first sensor." Kirkness¶¶265-266; Chatterjee¶¶243-45.

A POSITA would have been motivated to implement these features (adaptive algorithm disclosed in Burton) in a PAP device (e.g., Toge's PAP device). These features would have been beneficial as they would minimize/avoid transient arousals and thus improve sleep quality. The disclosed algorithm would have improved accuracy in detecting arousals and treating sleep disorders because it uses individual patient's collected data to "to customize a gas delivery device to be more sensitive and accurate." EX1050, 20:14-23, 26:9-15. Kirkness¶267; Chatterjee¶246.

A POSITA would have had a reasonable expectation of success in implementing the above-discussed feature in the Toge-Kumar combination. Kirkness¶268; Chatterjee¶247. Burton's disclosed features are "adapted for use with a CPAP machine." EX1050, 19:25-26. Burton explains that a POSITA "can readily appreciate that the subject invention is **easily adapted for use with, or incorporated within, other known therapeutic devices**." *Id.*, 19:26-28. It would have involved a combination of known technologies (e.g., known PAP device controlling 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 that is capable of self-learning/self-training, based on data from a prior time period, to adjust for better identifying and distinguishing between obstructive, central and complex sleep apneas during a subsequent period of time, as discussed above. Kirkness¶268; *KSR*, 550 U.S. at 416.

# IX. GROUND 4: TOGE IN VIEW OF KUMAR, NORMAN AND BURTON RENDERS OBVIOUS CLAIM 19

## A. Claim 19

The Toge-Kumar-Norman combination in view of Burton renders obvious this claim. Kirkness¶¶269-270; Chatterjee¶248-49. As discussed in Ground 2, to the extent that Toge does not disclose limitations [15.c] and [15.e.1], it would have been obvious to implement these features in the Toge-Kumar combination in light of Norman, and that the Toge-Kumar-Norman combination discloses claim 15, from which claim 19 depends.

As discussed in Ground 3, a POSITA would have been motivated to implement Burton's teaching in the Toge-Kumar combination and would have understood that the Toge-Kumar-Burton combination renders obvious claim 19. For the same reasons discussed in Ground 3, a POSITA would have been motivated to implement Burton's teaching in the Toge-Kumar-Norman combination (as discussed in Ground 2). A POSITA would have had the same motivations/capabilities and reasonable expectation of success discussed above in Ground 3 and knowledge of those discussed above regarding Burton to modify the Toge-Kumar-Norman combination to train the PAP/CPAP device to adjust/titrate itself to better identify/distinguish between obstructive, central and complex sleep apneas during a second time period with data from the first sensor. Nothing in

Norman or Burton would have taught away or prevented the combination. Therefore, the Toge-Kumar-Norman-Burton combination discloses claim 19. Kirkness¶270; Chatterjee¶249.

## X. SECONDARY CONSIDERATIONS

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

## XI. THE BOARD SHOULD REACH THE MERITS

### A. No Denial Under *Advanced Bionics*

Institution is appropriate under § 325(d) because substantially the same art and arguments have never been presented to or considered by the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinishche Geräte GmBH*, IPR2019-01469, Paper 6 at 6-11 (Feb. 13, 2020) (precedential). Specifically, each of Toge, Kumar, Norman, and Burton were not considered during prosecution, and therefore, combinations based on these references were never before the Office.

### B. No Denial Under *Fintiv*

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

# XII. MANDATORY NOTICES

## A. Real Parties-in-Interest

The real party-in-interest is ResMed Corp.

## B. Related Matters

U.S. Patent Office records indicate that the '333 Patent is assigned to Cleveland Medical Devices, Inc. PO is currently asserting the '333 Patent in the following litigation in an amended answer and counterclaims filed on April 11, 2024: *ResMed Corp., v. Cleveland Medical Devices, Inc.*, 1:23-cv-02221-BMB (N.D. Ohio.)

Petitioner has filed, or will file, petitions for *inter partes* review against U.S. Patent No. 11,602,284, U.S. Patent No. 11,375,921, U.S. Patent No. 11,690,512, U.S. Patent No. 11,786,680, and U.S. Patent No. 11,872,029, which are also asserted in the same litigation.

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

## C. Notice of Counsel and Service Information

ResMed provides the following designation of counsel:

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

### D. Fee for *Inter Partes* Review

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

### E. Grounds for Standing

Petitioner certifies pursuant to 37 C.F.R. § 42.104(a) that the '333 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

## XIII. CONCLUSION

For these reasons, Petitioner respectfully requests institution.

Respectfully submitted,

Dated: January 10, 2025

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**RESMED CORP.**

CLAIM LISTING APPENDIX

15. A method of treating a subject's sleep apnea comprising steps of**:**
[15.a] providing a therapy to a subject using a PAP or CPAP device while sleeping, the PAP or CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device;
[15.b] collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy;
[15.c] analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;
[15.d] transmitting, in either order, both 1) the collected data and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone to a remote station via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician; and
[15.e] further determining the therapy efficacy data with either the processor of the PAP or CPAP device, the second processor or server configured with a second software at the remote station, or the cellular phone using the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider.

16. The method of claim 15, wherein the cellular phone and the PAP or CPAP device each have a Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time.

17. The method of claim 15, wherein the therapy can be modified based in part on the wirelessly transmitted data or information.

18. The method of claim 17, where a rich data set is used to determine treatment from the collected data from multiple nights of treatment.

19. The method of claim 15, wherein the steps of the method can be used to train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during a second time period with data from the first sensor.

20. The method of claim 15, wherein the therapy can be adjusted or titrated through a wireless connection from the remote location by the technician, clinician or physician.

21. The method of claim 20, wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician from a remote location.

22. The method of claim 15, including the step of storing the collected data, the quantified level of severity data from either the PAP or CPAP device transmitted to the remote station, and/or data based on the transferred data on a database with similar data from treatments of many other subjects.

23. The method of claim 22, wherein the database is stored on a central server or on a group of servers remote to the test location, the central servers or the group of servers upon which the second software is stored on a computer readable medium and executed by the central server or the group of servers.

24. The method of claim 23, including the step of analyzing the data on the database with a relationship algorithm or a neural network to determine an optimal treatment for the subject.

25. The method of claim 23, wherein the PAP or CPAP device, the software on the cellular phone or the remote station determine a total sleep time.

26. The method of claim 23, wherein the processor of the PAP or CPAP device analyzes the collected data, in part, using one or more of a Short-Time Fourier Transform, a Discrete Fourier Transform, a Fast Fourier Transform, a recursively identified system model, a standard deviation technique, a time-frequency signal analysis and/or a Wavelet signal analysis to determine the quantified level of severity data.

27. The method of claim 23, wherein the processor of the PAP or CPAP device analyzes the collected data, in part, using a time-frequency signal analysis to determine the quantified level of severity data.

28. The method of claim 15, wherein the PAP or CPAP further comprises a firmware and/or a third software which along with the first software can be updated from the remote station or a different remote server.

29. The method of claim 15, further comprising the step of alerting the subject's technician, clinician or physician of issues related to the therapy efficacy.

## 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. 11,857,333** exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 13,968 words and therefore complies with the type-volume limitations of 37 C.F.R. §42.24(a).

Dated : January 10, 2025

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 11,857,333 AND EXHIBITS EX1001-1060** are being served on January 10, 2025, via FedEx overnight mail on counsel of record for U.S. Patent No. 11,857,333 as addressed below:

Robert Schmidt
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Cleveland, OH 44103
UNITED STATES

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

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