



Petitioner's Demonstratives

Resmed Corp. v. Cleveland Medical Devices, Inc.

April 29, 2026

IPR2025-00246

U.S. Patent No. 11,857,333

Agenda

Overview

The '333 Patent

State of the Art

Asserted Prior Art

Grounds

'333 Original Claim Disputes

“Quantified Level of Severity Data”
(Grounds I and III)

“Integrated Into” (Grounds II and IV)

Motivation to Combine Toge and Kumar
with Norman

Agenda

'333 Motion to Amend Disputes

Written Description Support for
Substitute Claims

Subject's Cell Phone That Receives and
Displays PAP Data

Subject's Cell Phone That Adjusts
PAP Therapy

“Remote Internet Site”

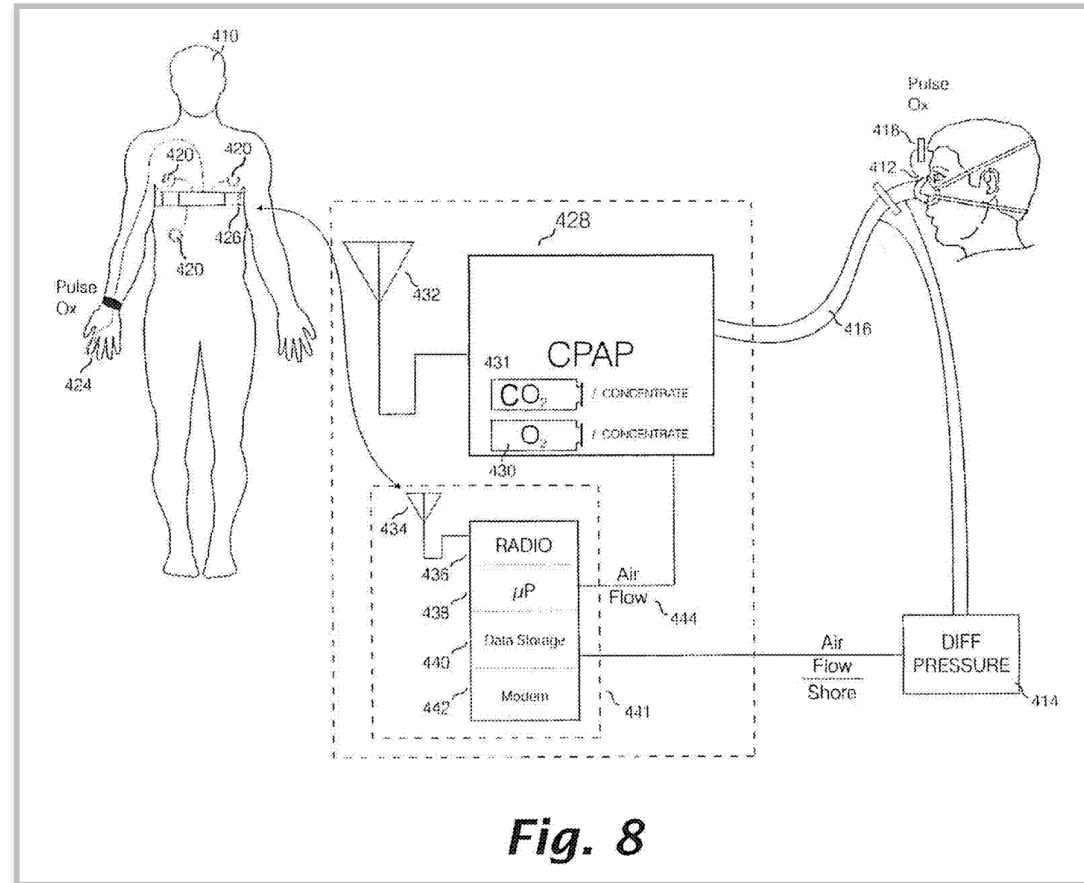
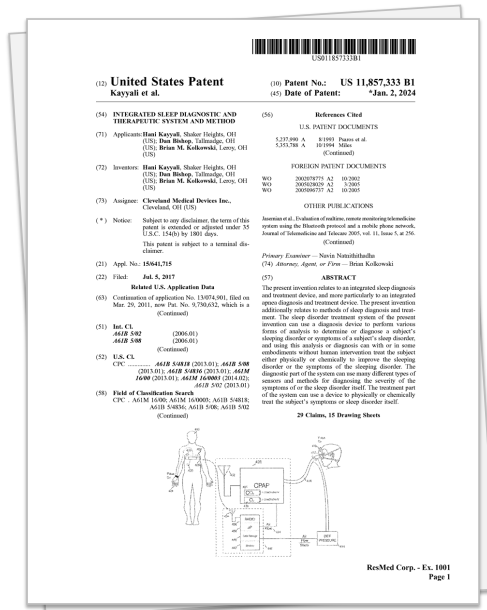
Overview

The '333 Patent

The Purported Invention

Methods of treating sleep apnea using a networked PAP system that sends data to a cell phone

The '333 Patent



EX1001, Fig. 8

Pet., 2; EX1003, ¶105

State of the Art

A Number of Auto-Adjusting PAPs Were Available at the Time

Table 1
Comparison of parameters detected by automatic positive airway devices

Device	Manufacturer	Parameters detected			
		Sn	A/H (flow)	A/H (FOT)	FL
Autoset	ResCare/ResMed, Sydney, Australia, San Diego, CA, Saint Priest, France	+	+		+
Autoset Clinical					
Autoset Portable					
Autoset T					
Autoset Spirit					
Eclipse Auto	Taema, Antony, France	+	+		
Goodknight TM418A	Puritan Bennett, Pleasanton, CA/Mallinckrodt, Les Ulis, France	+	+		
Goodknight TM418P	Puritan Bennett, Pleasanton, CA/Mallinckrodt, Les Ulis, France	+	+		+
Horizon AutoAdjust	DeVilbiss Healthcare, Inc./Sunrise Medical, Somerset, PA, Parçay Meslay, France	+	+		
Morphee Plus Cloudnine	Pierre Medical, Verrieres-Le-Buisson, France/Nellcor-Puritan Bennett, Minneapolis, MN		+		
REM + with MC + REM + Auto	SEFAM/Nellcor-Puritan Bennett, Nancy, France	+	+		
REMstar Auto	Respironics Inc., Murrysville, PA	+	+		+
Somnosmart	Weiman, Hamburg, Germany			+	
Tranquility Auto	Respironics Inc., Murrysville, PA		+		+
Virtuoso LX	Respironics Inc., Murrysville, PA	+			

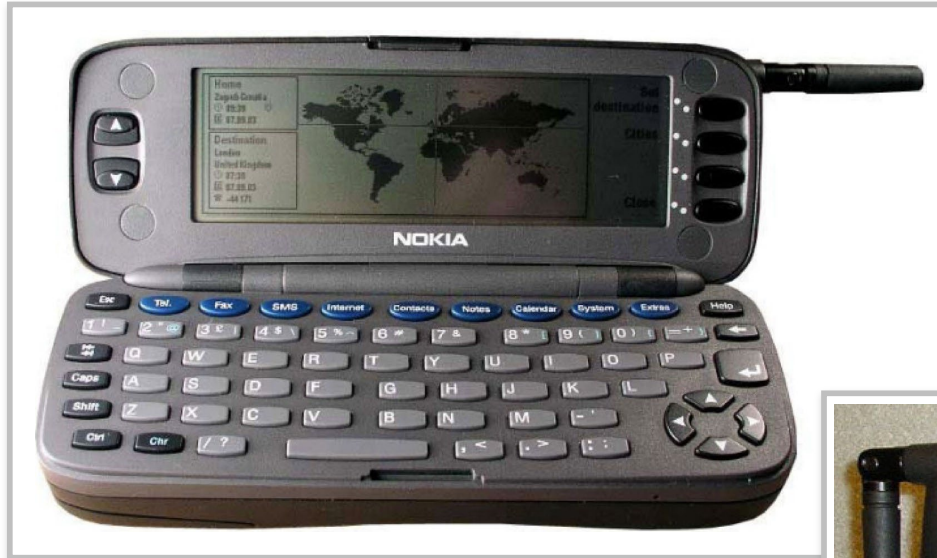
Abbreviations: Sn, snoring (detected by mask pressure vibration); A, apnea; H, hypopnea; flow, airflow detected by pneumotachograph, nasal pressure, or changes in compressor speed; FOT, forced oscillation technique; FL, flow limitation (detected by flow versus time profile).

EX1032, 2-3

Pet., 2; EX1003, ¶182

Graphical Web-Based Mobile Phones Were Available to Consumers at the Time

The Nokia 9000 Communicator

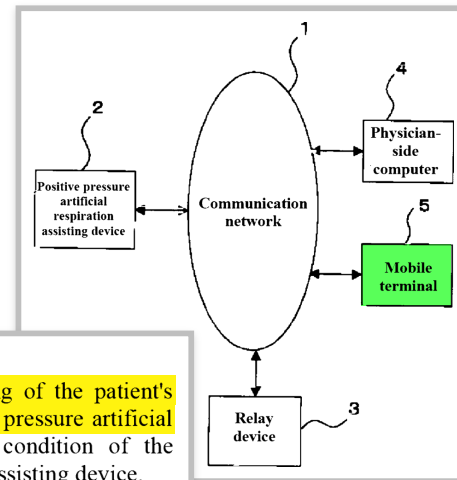


EX1005, ¶¶25-31



Pet., 2, 39; EX1005, ¶¶25-31

Cell Phones Were Being Incorporated Into Telemedicine Systems



(57) [Abstract]

[Problem] Enabling remote monitoring of the patient's condition during the use of a positive pressure artificial respiration assisting device, or the condition of the positive pressure artificial respiration assisting device.

[Solution to Problem] The positive pressure artificial respiration assisting device 2 requests treatment data on the patient using the device, and transmits the requested treatment data to the relay device 3 via communication network 1. The relay device 3 receives the treatment data transmitted from the positive pressure artificial respiration assisting device 2, and transmits all or part of the received treatment data to the physician-side computer 4 or mobile terminal 5 via the communication network 1. The physician-side computer 4 or mobile terminal 5 receives all or part of the treatment data transmitted from the relay device 3.

EX1044 (Toge),
Cover
(annotated),
Abstract

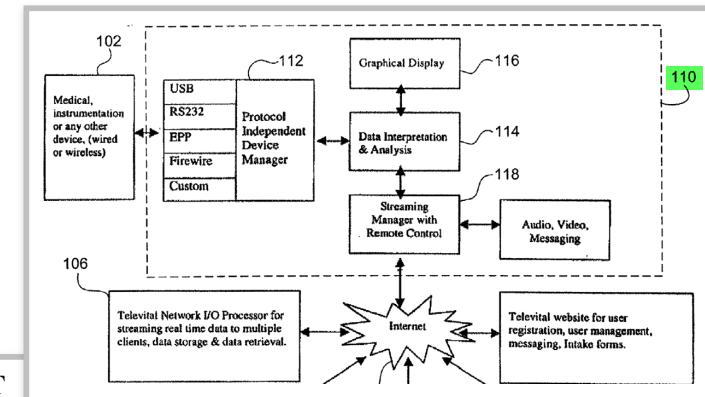
Pet., 7-8, 19-20; Kirkness, ¶¶117, 137;
Chatterjee, ¶¶135, 182

(57)

ABSTRACT

A system and method are provided for network-based monitoring of physiological data. At least one patient-side device collects physiological data from a patient. A provider-side device receives the data from at least one patient-side device via a wide area network. An engine communicates with at least one patient-side device and the provider-side device. The engine manages transmission of the data from the patient-side device to the provider-side device.

[0072] The patient-side device may then be connected via a computing device 110, such as a computer, handheld devices such as personal digital assistants (PDAs) and pocket PCs such as IPAQ with Windows CE operating System and Palm devices based on Palm OS), wireless telephone, or any other computing device, to the WAN.



EX1008 (Kumar), Cover (annotated)

EX1008,
Abstract, [0072]

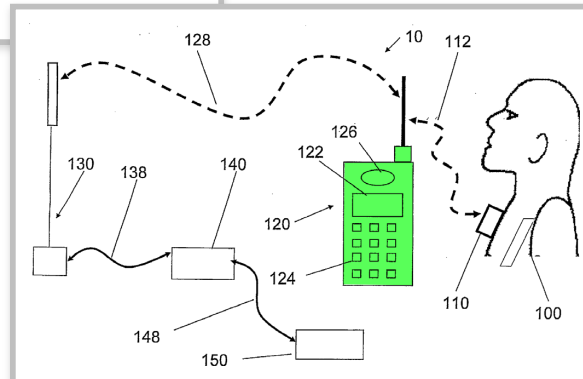
Cell Phones Were Being Incorporated Into Telemedicine Systems

(57)

ABSTRACT

The invention provides a system and method for monitoring one or more physiological parameters of a user. The system of the invention includes one or more wearable sensor modules sensing the one or more physiological parameters. One or more transmitters wirelessly transmit signals indicative of values of the one or more physiological parameters to a mobile monitor. The mobile monitor includes a processor processing the signals received from the transmitter in real time using expert knowledge. A device provides one or more indications of results of the processing. The invention also provides wearable mobile sensors for use in the system of the invention. The method of the invention includes obtaining values of the physiological parameters of the user from one or more wearable sensor modules. Signals indicative of values of the one or more physiological parameters are wirelessly transmitted to a mobile monitor. The signals are processed in real time using expert knowledge, and one or more indications of results of the processing are provided to the mobile unit.

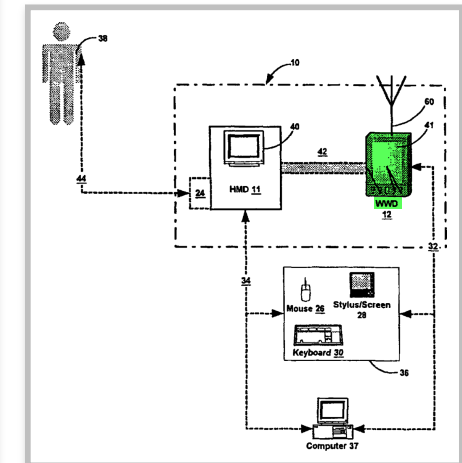
EX1049 (Quy),
Cover (annotated), Abstract



Pet., 2, 8; Kirkness, ¶137;
Chatterjee, ¶¶54, 135

(57) Abstract: Embodiments of the invention provide a method and apparatus for a wireless health monitoring system for interactively monitoring a disease or health condition of a patient (38) by connecting an internet-enabled wireless web device ("WWD") (12) to a health monitoring device (11) which may be a medical device or other health related device such as an exercise machine. The WWD (12) may be connected to the health monitoring device directly by a wired connection (42) to a generic input/output device port of the WWD (12) using an optional adaptor if necessary. Alternatively, the WWD (12) may be wirelessly connected (16) to the health-monitoring device, such as via an infrared or radio frequency connection, including using protocols such as Bluetooth or 802.11. The wireless connection (16) may also employ an adaptor if necessary. The user may also input data to the WWD (12) manually, such as by a keypad, keyboard, stylus, or optionally by voice command (36). The health related data is transmitted from the WWD (12) to a server (37) using standard internet protocols. The server (37) calculates a response using a software

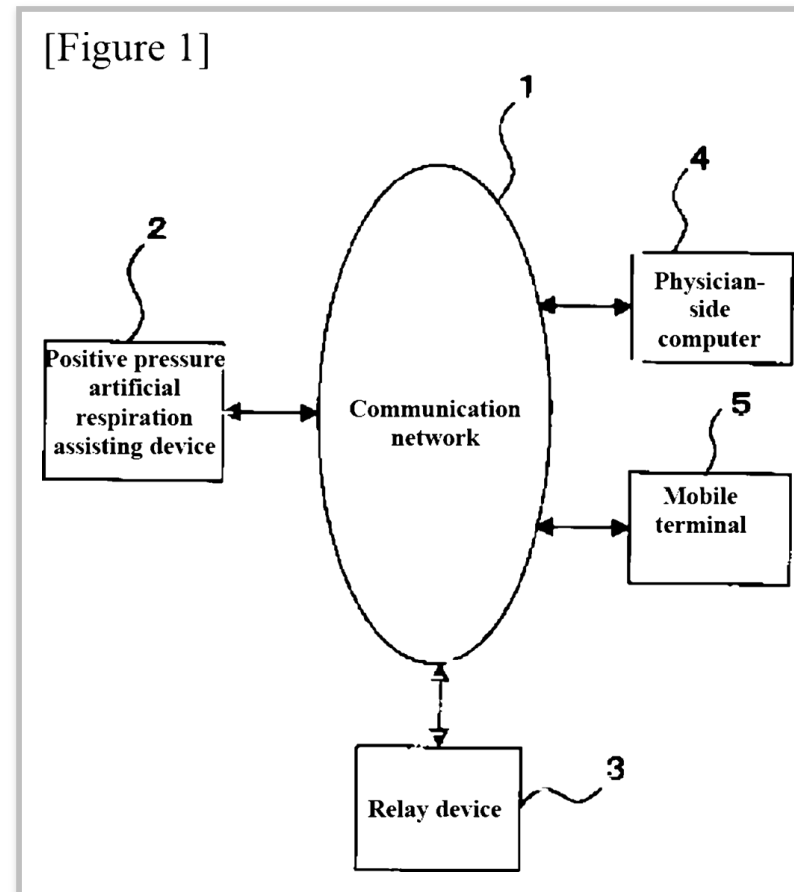
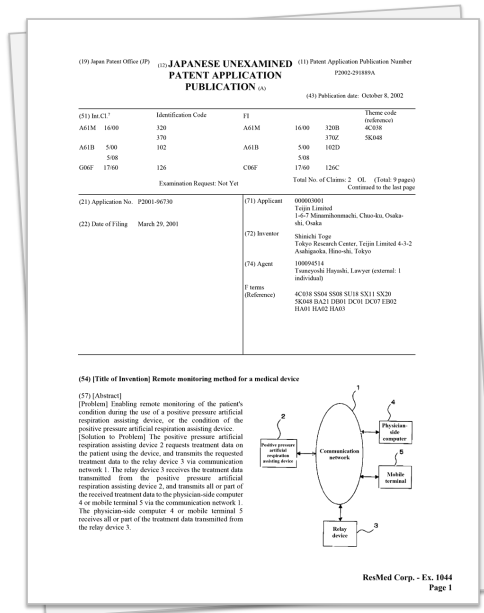
EX1045 (Orbach), Abstract



EX1045 (Orbach), Cover (annotated)

Asserted Prior Art

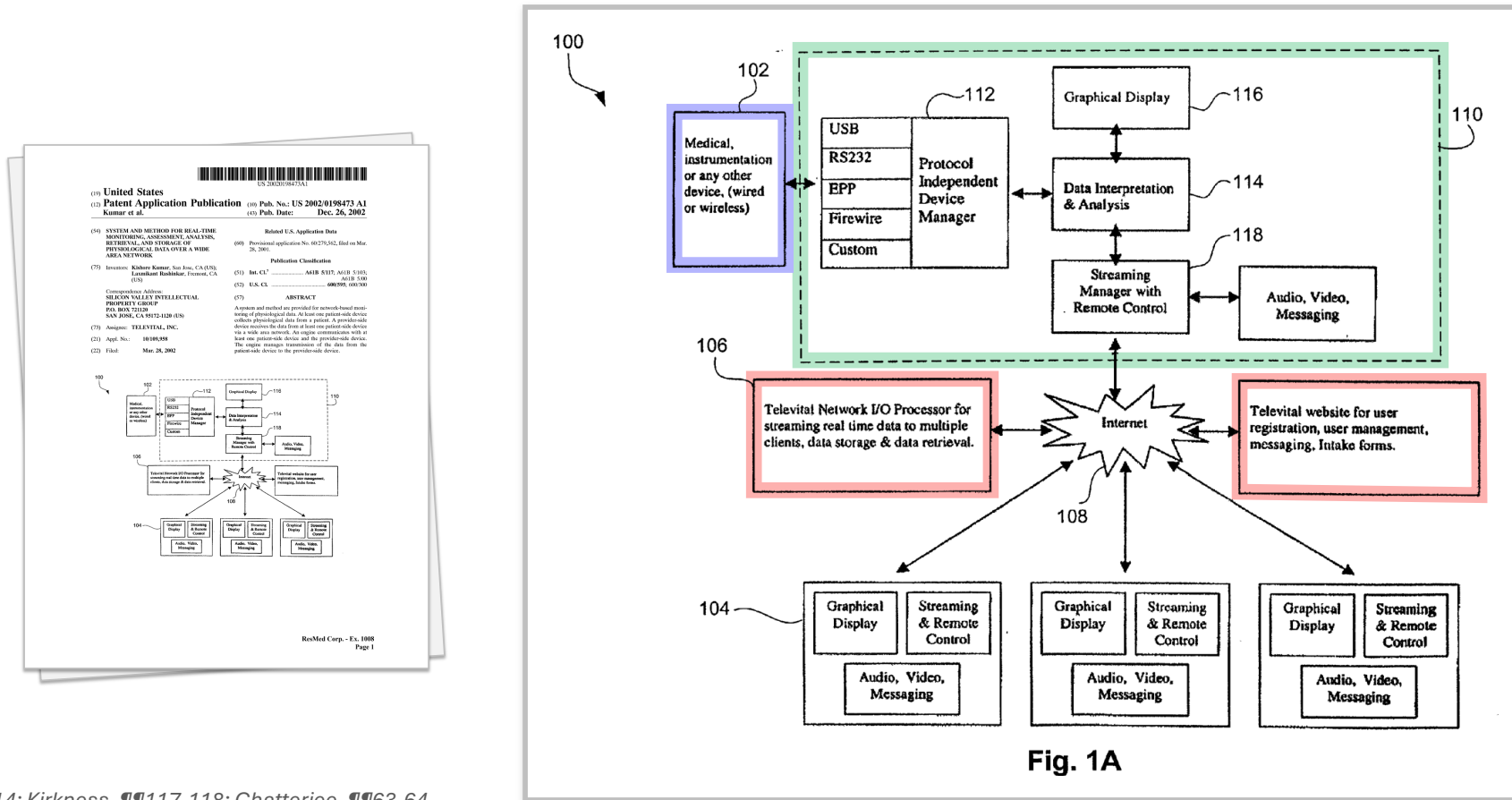
Toge Discloses a Networked PAP Telemedicine System



EX1044 (Toge),
Fig. 1

Pet., 2; Kirkness, ¶¶107-116; Chatterjee, ¶¶58-60

Kumar Discloses a Networked Multi-Purpose Telemedicine System

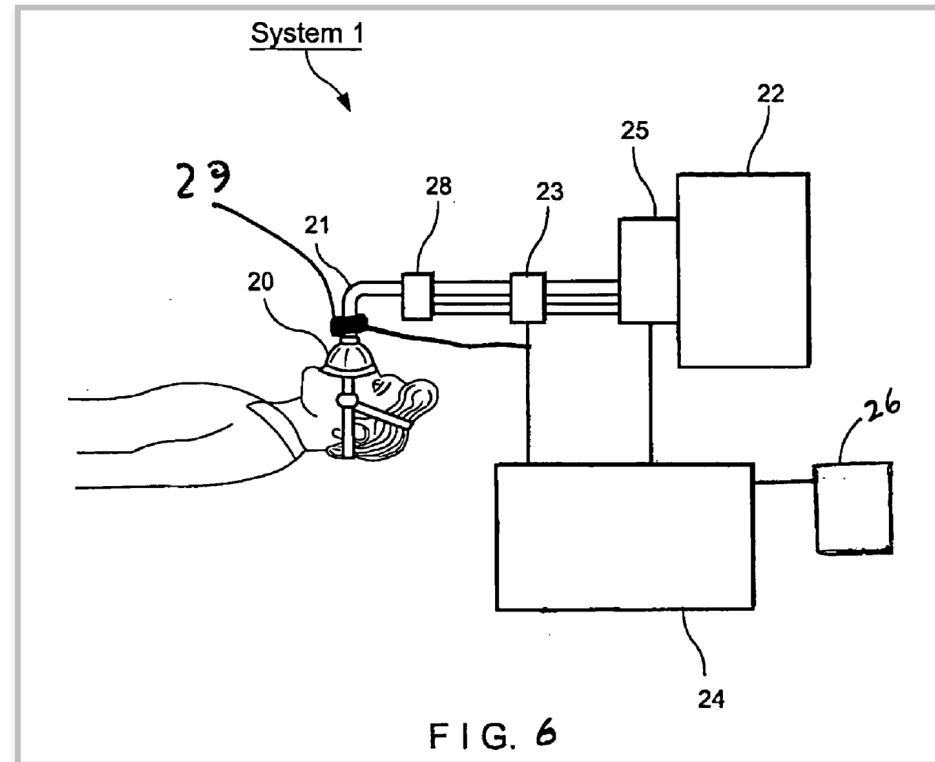
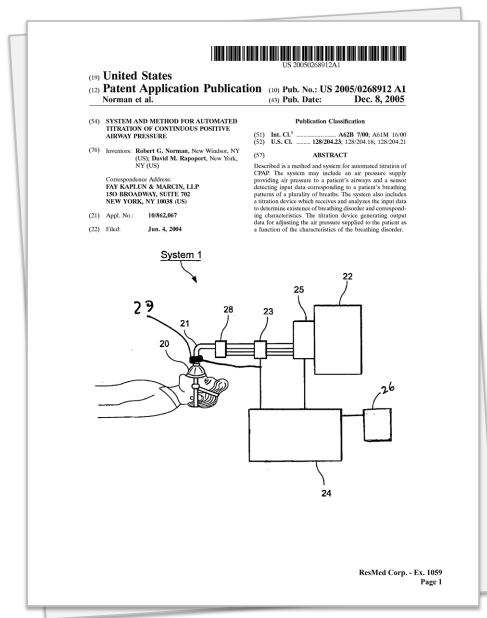


EX1008 (Kumar),
Fig. 1A (annotated)

Pet., 2, 14; Kirkness, ¶¶117-118; Chatterjee, ¶¶63-64

Norman Discloses a CPAP System

Norman Discloses a Processor to Analyze Respiratory Airflow, Detect Abnormal Respirations, and Direct a Titration Device to Adjust Air Pressure Accordingly



EX1059 (Norman),
Fig. 6

Pet., 2, 14-15; Kirkness, ¶¶119-121; Chatterjee, ¶¶65-80

Grounds

Petition Grounds

Ground	Claim(s)	Challenge
1	15-17, 20-24, and 26-29	35 U.S.C. § 103 as being obvious over Toge in view of Kumar
2	15-18, 20-24, and 25-29	35 U.S.C. § 103 as being obvious over Toge in view of Kumar and Norman
3	19	35 U.S.C. § 103 as being obvious over Toge in view of Kumar and Burton
4	19	35 U.S.C. § 103 as being obvious over Toge in view of Kumar, Norman, and Burton

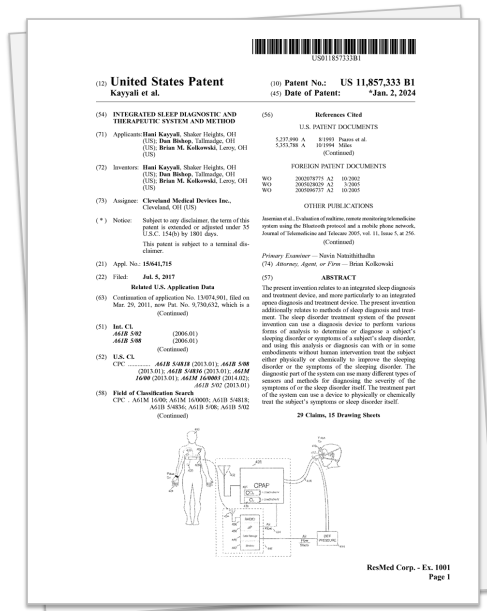
Pet., 1

Disputed Limitations

Grounds I and III: Toge in View of Kumar

“Determine a Quantified Level of Severity Data”

'333 Patent, Claim 15



15. A method of treating a subject's sleep apnea comprising steps of:

* * *

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;

* * *

EX1001, cl. 15 (excerpt)

No Dispute That Toge Discloses Determining Metrics Based on Apnea Symptoms

with severity of the subject's apnea symptoms. As ResMed explained in the Petition, total obstruction of the airway, "zero milliliters per breath" corresponds to an apnea, so tidal volume data may be analyzed to identify apneas (or hypopneas or snores).

Sur-Reply, 3

Sur-Rep., 3

“A Quantified Level of Severity Data” Should Be Given Its Plain and Ordinary Meaning

“quantified level of severity data”	
Petitioner’s Construction	PO’s Construction
plain and ordinary meaning	a [calculated] value that indicates how dire a patient’s symptoms are

POR, 8; Rep., 2-6; Sur-Rep., 7

There Is No Intrinsic Support for PO's Construction

- “Quantified level of severity” is not defined in the specification
- No language in the specification resembling or even consistent with PO's construction
- Specification discussion of “level of severity” is broad
- “Quantitative level of severity” can be derived from a variety of different measurements

Signals from these sensors are then analyzed to determine the level of severity of the symptoms of the subject's sleep disorder and in some cases to diagnose the sleep disorder

EX1001,
3:44-46

The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein. More preferably, this

EX1001,
22:25-28

One or more sensors are used to develop the data or signals used in the present invention for determining a quantitative level of severity of a subject's sleeping disorder and/or symptoms. In various embodiments, preferably at least two EEG electrodes are used to develop this data. In other embodiments, preferably, at least two ECG electrodes are used. In still other embodiments, preferably a pulse oximeter is used. In still even other embodiments, preferably, either an O₂ or CO₂ blood gas monitor is used.

EX1001,
45:34-42

Rep., 3-4; EX1058 ¶32

The Only Extrinsic Support for PO's Construction Is PO's Experts

- PO's construction differs from its expert's description
- Relied on no medical dictionary or treatises for a "commonly used term"
- Dr. D'Ambrosio's opinion was on whether the term was indefinite, not its meaning for claim construction

32. Based upon the disclosures in the '921, '029 and '333 Patents, a POSITA understands how to calculate the symptom data in order to derive the severity of the patient's symptoms. '921 Patent at 18:51-21:67; '333 Patent at 22:36-24:45, 45:34-46:51; '029 Patent at 18:66-22:13. Since the time of the invention, 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. For example, a clinician would recognize a

EX1058
¶32

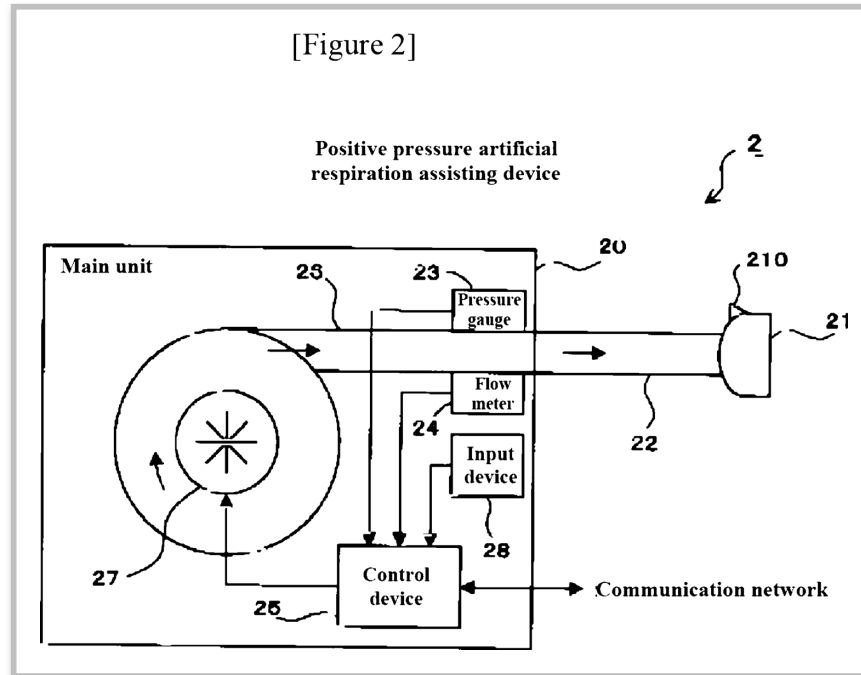
27. I have been asked for my opinion as to whether the claim terms described below are definite under these standards. As described below, it is my opinion that all of the claims are definite because they satisfy these standards.

28. The following are the claim terms that ResMed alleges are indefinite, because of the terms "symptom data," "severity of the sleep disorder symptoms," "index of a subject's symptoms," "treatment efficacy," and "therapy efficacy data."

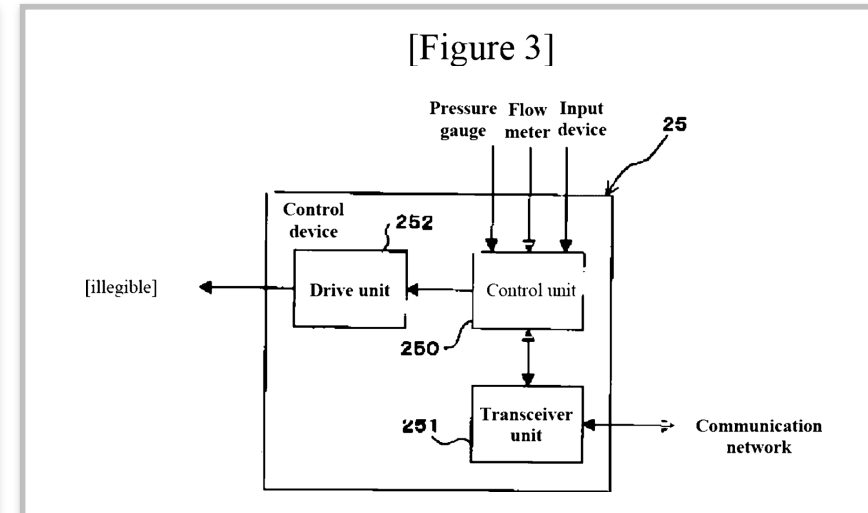
EX1058
¶¶27-28

Rep., 3-4, POR, 8-9

Toge Discloses “determin[ing] a quantified level of severity data”



EX1044, Fig. 2



EX1044, Fig. 3

[0038] The control unit 250 substitutes the determined values of F_t , F_a , and F_b into the above formula (1) to calculate the tidal volume F_p . Additionally, since the exhalation volume and inhalation volume are the same, it is implicitly understood that either the exhalation volume or inhalation volume can be used for tidal

EX1044, [0038]

PO's Own Evidence Confirms That Tidal Volume Measures Severity

5.2. Tidal volume

Tidal volume refers to the volume of air that is inspired or expired during a respiratory cycle. It is typically derived by integrating the nasal airflow signal or by detecting tracheal breath sound or chest movement, and intrathoracic electrical impedance oscillations [[56], [65], [83], [84]]. While tidal volume is not used for event detection in PSG, in portable monitoring, hypopnea events are defined as a reduction of $\geq 50\%$ or 74% in tidal volume from baseline and apnea events as absence of tidal volume for at least 10s [56,85].

EX2028, 13-14

Tidal Volume is “a quantified level of severity data based on the subject’s sleep apnea symptoms”

[0034] If the flow meter is not provided, the tidal volume F_p can be determined using the following formula (1):

[0035] $F_p = F_t - F_a - F_b \dots (1)$

EX1044, [0034]-[0035]

[0039] By transmitting the tidal volume F_p almost in real-time or at regular intervals (such as every hour), physicians can remotely monitor the patient's condition during the use of the positive pressure artificial respiration assisting device 2 remotely from hospitals or other locations. Furthermore, if there is a decreasing trend in the tidal volume F_a , emergency measures, such as adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4 or mobile terminal 5.

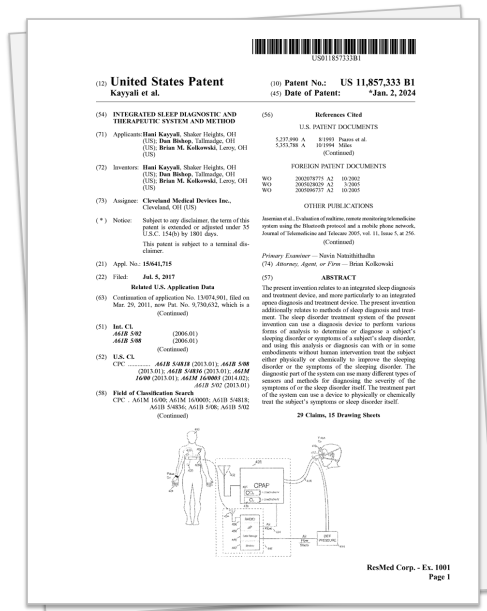
EX1044, [0039]

157. 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.” In my opinion, 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. In fact, Toge explains that the physician, through the tidal volume information, can monitor the “patient’s condition” which, in my opinion, a POSITA would have understood, corresponds to “subject’s sleep apnea symptoms during the therapy,” as claimed. *Id.*, [0039]. I note that the ’333 patent uses “symptoms” and “condition” (or patient’s “state”) interchangeably. For example, the ’333 patent

Grounds II and IV: Toge in View of Kumar and Norman

“Integrated Into”

'333 Patent, Claim 15



15. A method of treating a subject's sleep apnea comprising steps of:
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;

* * *

EX1001, cl. 15 (excerpt)

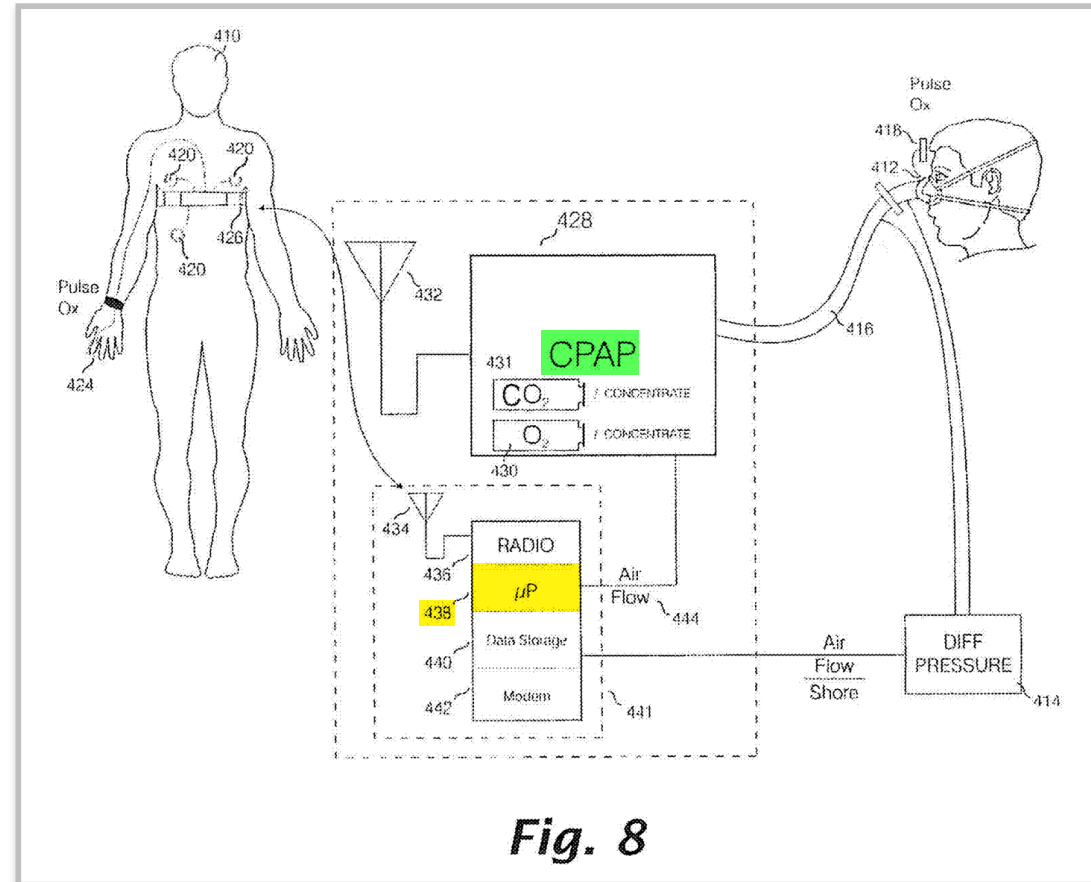
“Integrated Into” Should Be Given Its Plain and Ordinary Meaning

“Integrated Into”	
Petitioner	PO’s Construction
plain and ordinary meaning	“the processor is inside the PAP/CPAP device”

Pet., 6; *Rep.*, 8-9; *POR*, 13; *Sur-Rep.*, 10; *Kirkness*, ¶129; *Chatterjee*, ¶81

PO's Construction Is Unsupported by the '333 Specification

- The '333 specification does not define “integrated into”
- “integrated into” is not described in the specification
- Primary embodiment does not depict a processor “inside” of the CPAP device



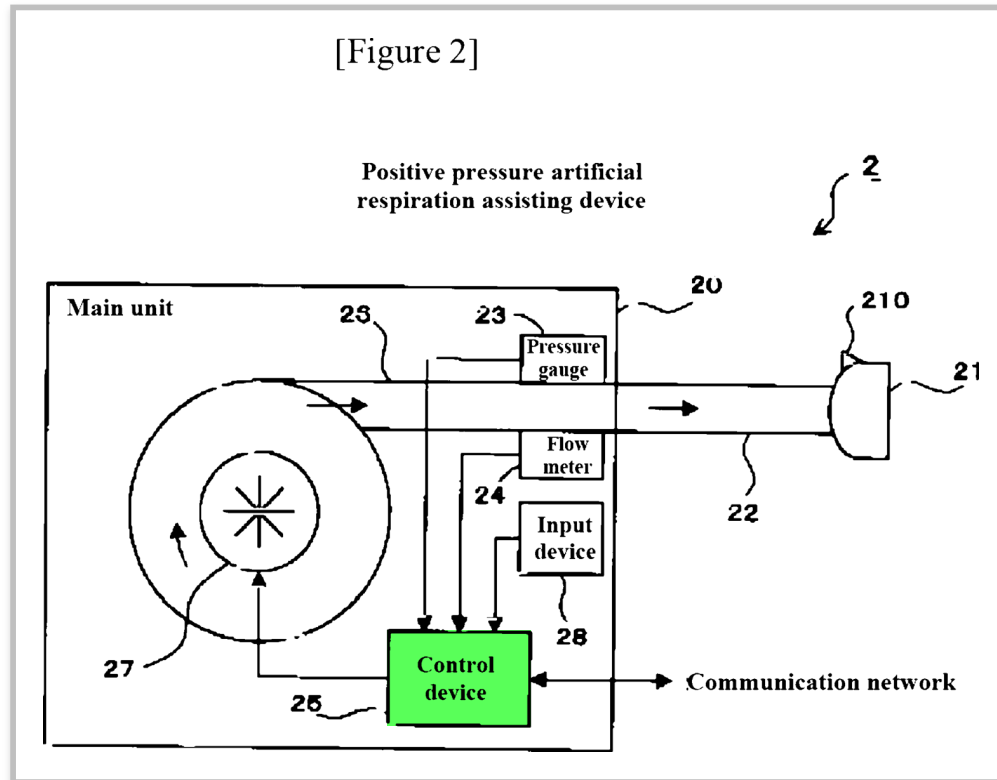
EX1001,
Fig. 8

Rep., 8-12

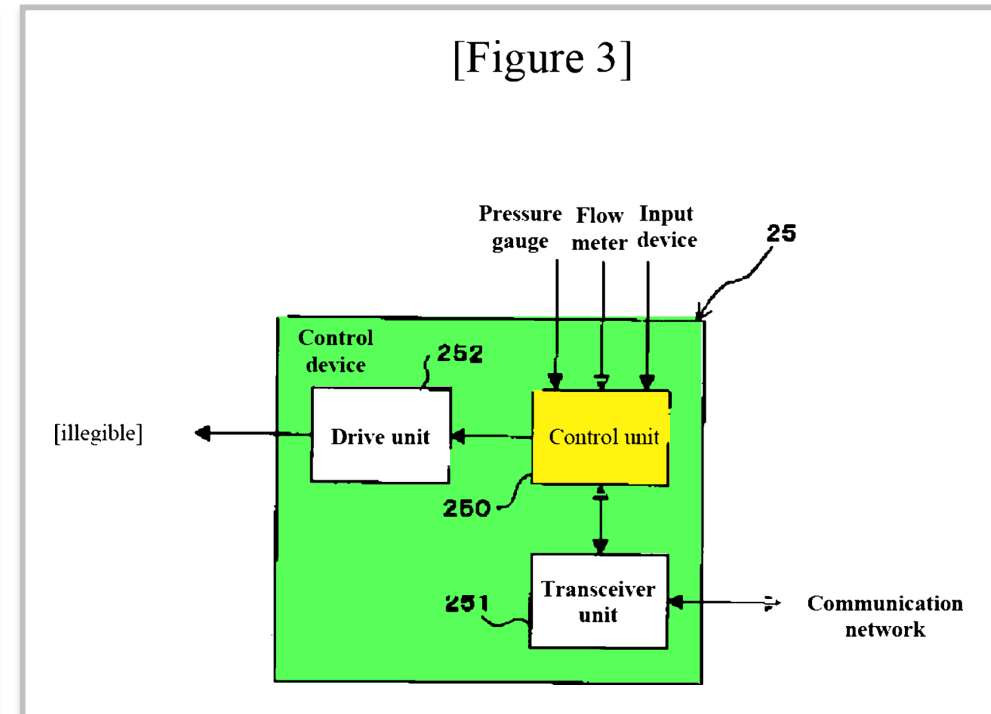
A claim construction that excludes the preferred embodiment is rarely, if ever, correct

SynQor, Inc. v. Artesyn Techs., Inc., 709 F.3d 1365, 1378-79 (Fed. Cir. 2013)
(internal quotation marks omitted)

No Dispute That Toge Discloses a Processor Integrated Into the PAP/CPAP



EX1044, Fig. 2



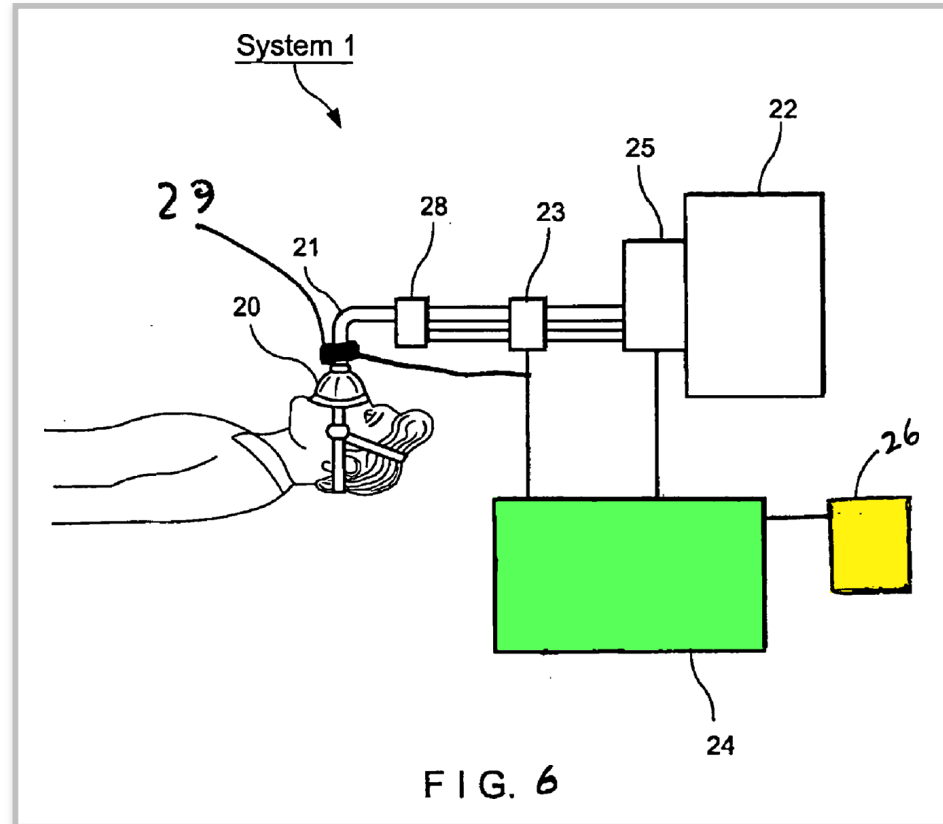
EX1044, Fig. 3

Pet., 11-13; Rep., 9-11; Sur-Rep., 11

Norman Discloses a Processor Integrated Into the PAP/CPAP

[0020] The mask 20 covers the patient's nose and/or mouth and conventional flow and/or pressure sensors 23 are coupled to the tube 21 to detect the volume of the airflow to and from the patient and the pressure supplied to the patient by the generator 22. The sensors 23 may be internal or external to the generator 22. Signals corresponding to the airflow and the pressure from the sensors 23 are provided to a processing arrangement 24. The processing arrangement 24 generates pressure control outputs signals to a conventional flow control device 25 that controls the pressure applied to the flow tube 21 by the flow generator 22. Those skilled in the art will understand that, for certain types of

therapy or to update previously calculated pressures. Those skilled in the art will understand that the titration device 26 may be attached to any conventional PAP therapy system. Alternatively, the titration device 26 may be built into the system 1 (e.g., the titration device 26 may be combined with the processing arrangement 24).



EX1059, [0020], [0023]

EX1059, Fig. 6 (annotated)

Rep., 11

Motivation to Combine Toge and Kumar in View of Norman

A POSITA Would Have Been Motivated to Integrate Norman's Automated Titration System With the Toge-Kumar System

- Increase accuracy and efficacy of the PAP treatment

222. In my opinion, a POSITA would have been motivated to modify the Toge-Kumar combination in view of Norman's teaching. While Toge discloses a CPAP device, where the provided pressure may be adjusted, Norman teaches an improved CPAP device that allows "automated titration." Ex. 1059, 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 similar to as disclosed in Norman in order 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. Ex. 1059, [0033] ("the more accurate the pressure supplied to a particular patient, the more likely the patient will regularly make use of this PAP therapy.").

EX1003,
¶222

Pet., 49-50; *Rep.*, 12-13

A POSITA Would Have Been Motivated to Integrate Norman's Automated Titration System With the Toge-Kumar System

- Increase accuracy and efficacy of the PAP treatment

223. In my opinion a POSITA would have also 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 discloses that using multiple types of data collected from multiple nights of treatment would have enhanced the accuracy of the treatment.

EX1003, ¶223

A POSITA Would Have Been Motivated to Integrate Norman's Automated Titration System With the Toge-Kumar System

- Improve patient compliance

[0033] The system 1 may determine appropriate pressures by adjusting pressure only at the beginning of a sleeping cycle and by operating over the course of several sleeping cycles to arrive at a more accurate image of the patient's breathing patterns. For example, some patients may have "good" or "bad" nights which may not be representative of an "average" night for the patient. In contrast, conventional automatic titrating systems may generate immediate feedback responses to the abnormal respiratory events from which they attempt to determine a single therapeutic pressure. Conventional titration systems generally obtain data only during a single sleeping cycle, since multiple visits to sleep clinics, where these systems are located, are unlikely. Furthermore, the more accurate the pressure supplied to a particular patient, the more likely the patient will regularly make use of this PAP therapy.

Pet., 49-50; Rep., 12-13

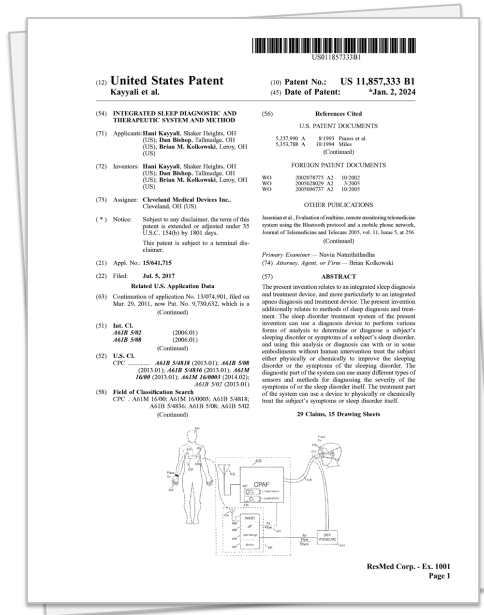
EX1059, ¶33

Contingent Motion to Amend

37 C.F.R. § 42.121 Written Description Requirements

PO Failed to Satisfy the 37 C.F.R. § 42.121 Written Description Requirement for All Applications in the Priority Chain

PO Did Not Show Written Description Support in U.S. Patent App. Nos. 13/074,901 and 11/879,934 for the Substitute Claims



(21) Appl. No.: 15/641,715

(22) Filed: Jul. 5, 2017

Related U.S. Application Data

(63) Continuation of application No. 13/074,901, filed on Mar. 29, 2011, now Pat. No. 9,730,632, which is a continuation of application No. 11/879,934, filed on Jul. 19, 2007, now Pat. No. 7,942,824, which is a continuation-in-part of application No. 11/266,899, filed on Nov. 4, 2005, now Pat. No. 8,172,766.

EX1001, Cover

Sur-Rep. MTA, 1-2

The specification disclosure “must clearly allow [a POSITA] to recognize that the inventor invented what is claimed.”

Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010)
(en banc) (internal quotation marks and brackets omitted)

The written description must demonstrate that “the inventor possessed the invention.”

LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005)

The '715 Application Lacks Written Description Support for a Subject's Cell Phone That Adjusts PAP Therapy

PO's '715 Cites Neither Disclose Nor Suggest a Subject's Cell Phone That Adjusts PAP Therapy

Citation	Disclosure	Disclose or Suggest Cell Phone PAP therapy adjustment
5:2-12	transmission of PAP data from a diagnostic device to an intermediary device/cell phone	N
11:17-12:1	remote programming of the PAP (while the subject sleeps)	N
29:22-29	cell phone/receiver that transmits PAP data to a remote site for analysis	N
30:9-31:12	cell phone/processor that can be tethered to sensors or be part of a remote communication station	N
34:20-24	diagnostic device output used for clinician or subject adjustment of PAP	N
72:25-73:18	signal from remote site that adjusts the treatment device (Fig. 10)	N

Mot. Amd., 7-8; Opp., 5-8; Rep., 2-3; Sur-Rep. MTA, 3-4

EX1002 ('715 File History)

The '899 Application Lacks Written Description Support for a Subject's Cell Phone That Adjusts PAP Therapy

PO's '899 Cites Neither Disclose Nor Suggest a Subject's Cell Phone That Adjusts PAP Therapy

Citation	Disclosure	Disclose or Suggest Cell Phone PAP therapy adjustment
33:14-23	cell phone/processor can be tethered to sensors and analyze sensor data	N
33:22-23	processor can be part of a remote communications station	N
34:9-21	remote communication station/cell phone transmits data to a remote site	N
38:24-39:28	a clinician or the subject adjusts a treatment device based on an output from a diagnostic device	N

EX2033 ('899 File History)

Mot. Amd., 7-8; Opp., 2-5; Rep., 2-3; Sur-Rep. MTA, 3-4

[P]ointing to an amalgam of disclosures from which an artisan could have created the claimed invention does not satisfy this requirement.

Flash-Control, LLC v. Intel Corp., 2021 WL 2944592, *3 (Fed. Cir. 2021)
(internal quotation marks omitted)

Applicant's Argument in an Amendment Are Not Corroborating Evidence

Statements by counsel in the brief cannot take the place of evidence

In re Cole, 326 F.2d 769, 773 (CCPA 1964)

[A]rguments presented by applicant cannot take the place of factually supported objective evidence

MPEP § 2145

Sur-Rep. MTA, 3-4; *EX1002*, 308

Disputed Limitations – Motion to Amend

A Subject's Cell Phone That Receives and Displays PAP Data

Kumar Discloses a Patient Cell Phone That Receives and Displays PAP Data

[0072] The patient-side device may then be connected via a computing device 110, such as a computer, handheld devices such as personal digital assistants (PDAs) and pocket PCs such as IPAQ with Windows CE operating System and Palm devices based on Palm OS), wireless telephone, or any other computing device, to the WAN. Optionally, the patient-side device may have a built-in computing device for communication over the WAN. A protocol independent device manager 112 running on the computing device establishes a two-way communication with a vast array of client-side devices, including but not

[0075] The data interpretation and analysis module 114 is used to interpret the data stream from the client-side device, perform mathematical analysis on the data using FFT, DFT, etc., and generate statistics. The data may be displayed graphically on the display module 116.

EX1008 (Kumar), [0072], [0075]

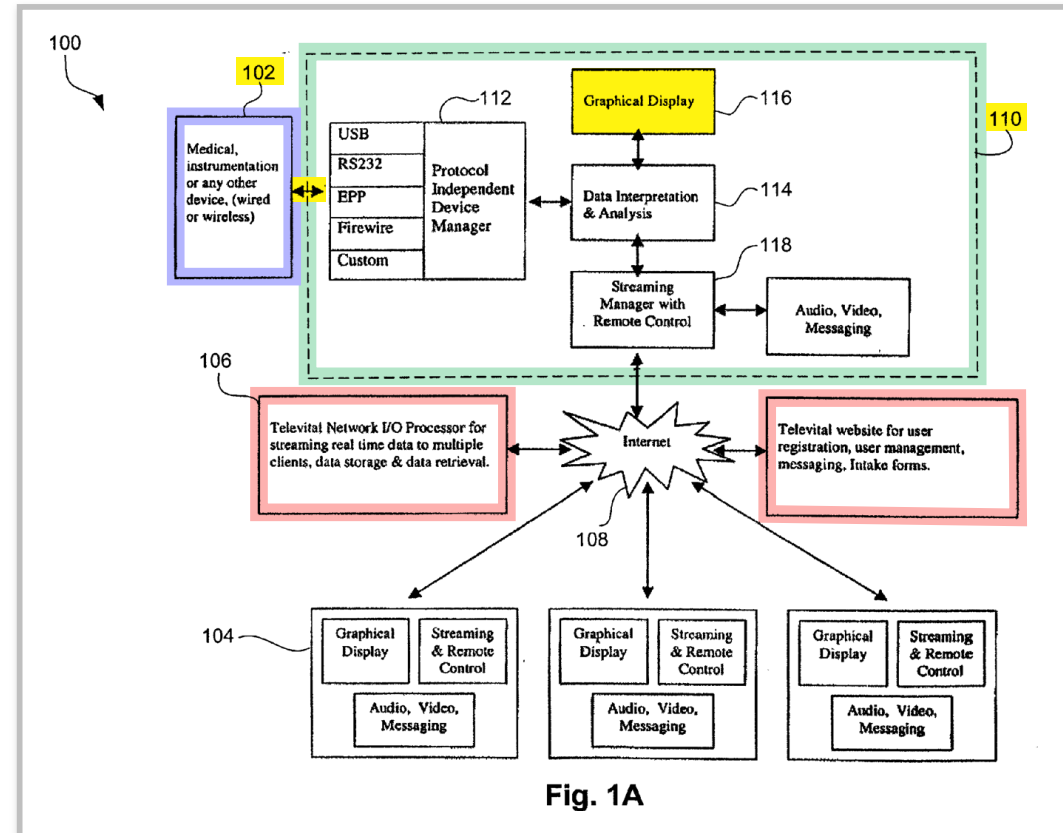


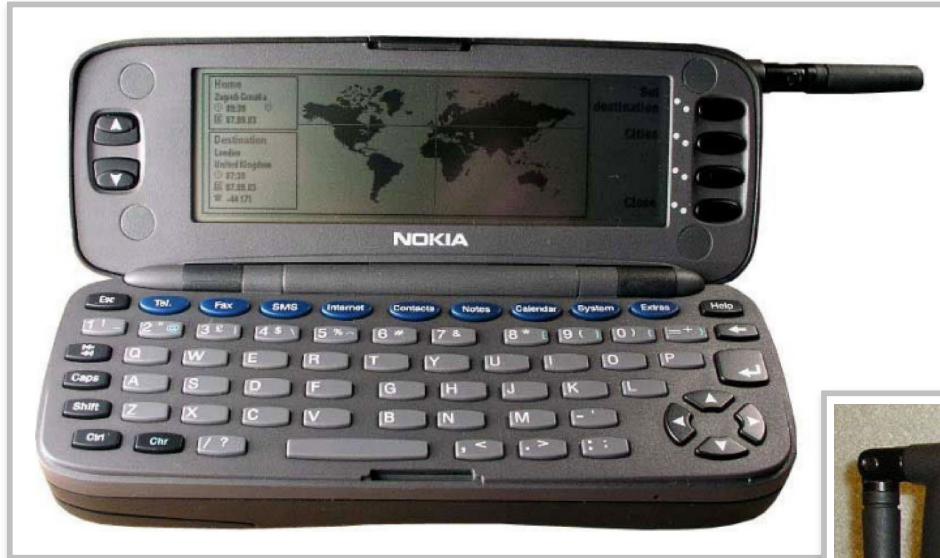
Fig. 1A

EX1008 (Kumar), Fig. 1A (annotated)

Opp., 10-14, 19-21;
Chatterjee Opp., ¶¶13-16, 38

A POSITA Would Have Been Motivated to Integrate a Patient's Cell Phone With Toge's PAP System

Cell Phones That Displayed Data Were Readily Available at the Time



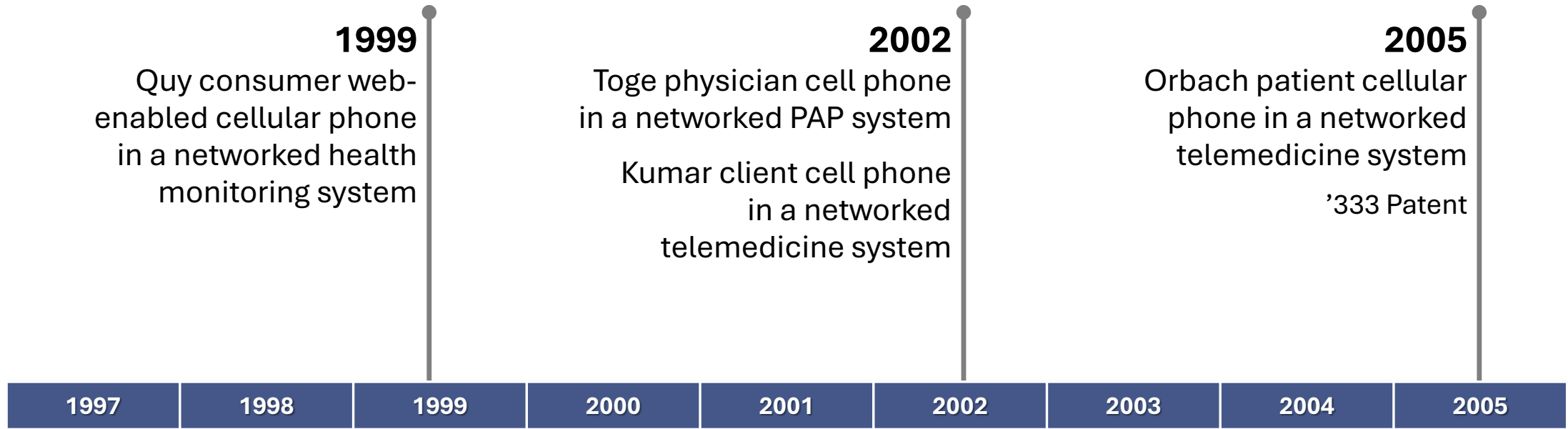
EX1005, 1/125-31



Pet., 39; Opp., 11-14, 20-21; Sur-Rep. MTA, 9-10

A POSITA Would Have Been Motivated to Integrate a Patient's Cell Phone With Toge's PAP System

Inventors Routinely Implemented Cell Phones With Telemedicine Systems



Sur-Rep. MTA, 9-10; EX1049 7:15-29; cl. 51; EX1045, [0011]-[0065], [0077]-[0079], [0292]; EX1044, Abstract; EX1008, Abstract, [0072]

Toge Is Not Directed to the Physician

[0026] The input device 28, operated by the **patient** or physician, consists of components such as a control panel, input buttons, and input terminals that are detachable (e.g., ventilation condition setters) from the main unit 28. The input device 28 enables operations such as power on/off, mode selection (S mode, T mode, ST mode, CPAP mode), prescription pressure settings, and settings for the minute breathing rate in T mode or ST mode. The values or modes set are provided to the control unit 250 of the control device 28 and stored in its internal memory (RAM, disk memory, etc.).

EX1044, [0026]

[0030] Under the control of the control unit 250, the transceiver unit 251 of the control device 25 communicates with the communication network 1, transmitting data (transmission data) provided from the control unit 250 to the relay device 3, and receiving data (reception data) from the physician-side computer 4 or mobile terminal 5. Transmission can occur either in real-time or at regular intervals (e.g., every hour). Additionally, transmission can be initiated if the **patient** operates the input device 28 to request transmission.

EX1044, [0030]

A POSITA Would Have Been Motivated to Integrate a Patient's Cell Phone With Toge's PAP System

- Enable patients to easily view treatment data
- Allow storage of patient data for later viewing any time or any place
- Encourage patient compliance
- Increase patient engagement
- Reduce PAP form factor

Opp., 11-14; Sur-Rep. MTA, 8-10

A POSITA Would Have Been Motivated to Integrate a Patient's Cell Phone With Toge's PAP System

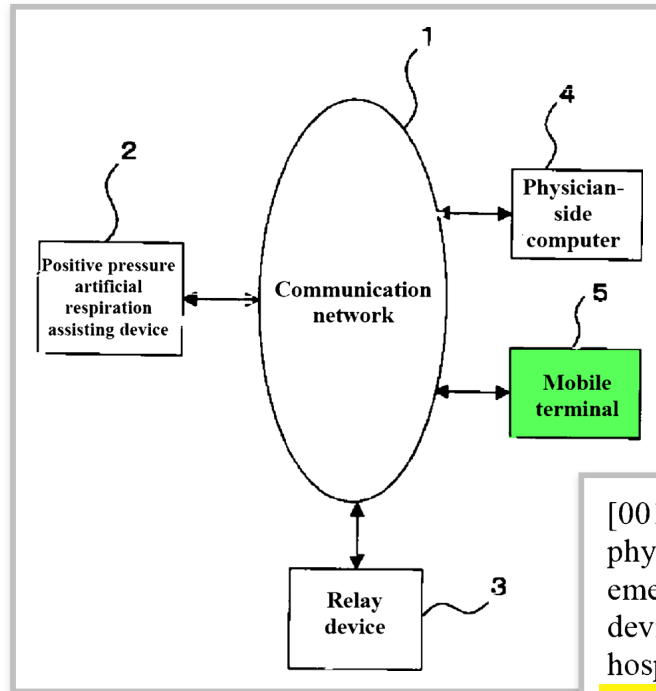
18. A POSITA also would have been motivated to incorporate into Toge's PAP system a patient cell phone like that of Kumar's which receives PAP data ("quantified level of severity data"). Like the physician cell phone used by providers to access patient data in Toge, a patient cell phone would have allowed a patient to easily and quickly access their PAP data, and do so any time or any place, an advantage unavailable when PAP data is only accessible to the patient on the PAP device itself. Moreover, moving patient data display to a patient's cell phone would have minimized or dispensed with the need for the existing display screen on the PAP device itself, which would have resulted in either a smaller display screen or its complete elimination. In either case, the PAP device would have advantageously been smaller, more portable, and less expensive.

EX1072, ¶18

Opp., 11-14; Sur-Rep. MTA, 8-10

Subject's Cell Phone That Adjusts PAP Therapy

Toge Discloses a Cell Phone That Adjusts PAP Therapy



[0019] The mobile terminal 5, in the possession of a physician or nurse, is capable of being mobilized in emergencies by the physician-side computer 4, relay device 3, or other mobile terminals possessed by hospital personnel. Furthermore, medical institution personnel can operate the mobile terminal 5 to set the necessary data (as described later) for the positive pressure artificial respiration assisting device 2. The mobile terminal 5 includes mobile phones, PHS, PDAs and PocketBell (registered trademark), etc.

“And so the mobile device that can adjust the PAP -- the therapy provided by the PAP was clearly disclosed and known at the relevant time period, for example, because Toge talks about it.”

EX2051, 41:13-17

Pet., 18-19, 39-40;
Opp., 10-11, 22;
Sur-Rep. MTA, 6-7;
EX1044, [0019], [0027]

EX1044,
Fig. 1 (annotated),
[0019]

Kumar Discloses a Patient Cell Phone With Downloadable Software

[0072] The patient-side device may then be connected via a computing device 110, such as a computer, handheld devices such as personal digital assistants (PDAs) and pocket PCs such as IPAQ with Windows CE operating System and Palm devices based on Palm OS), wireless telephone, or any other computing device, to the WAN. Optionally, the patient-side device may have a built-in computing device for communication over the WAN. A protocol independent device manager 112 running on the computing device establishes a two-way communication with a vast array of client-side devices, including but not

EX1008, [0072]

[0074] Preferably, the present invention is built on a modular architecture in which the patient-side device and/or the computing device coupled to the patient-side device can send a request to the engine with an identifier of the patient-side device, and the engine will send the appropriate plug-in which allows the computing device to communicate with the patient-side device. Thus, the present invention may support both plug-and-play web device drivers and customized graphical user interfaces (GUIs) for the various devices.

EX1008, [0074]

Pet., 39-40; *Kirkness*, ¶117; *Chatterjee* ¶ 63; *Opp.*, 10-14, 22

A POSITA Would Have Found It Obvious to Implement Toge's PAP Adjustment Functionality on Kumar's Patient Cell Phone

Toge Contemplates Patient Adjustment of PAP Therapy

[0026] The input device 28, operated by the patient or physician, consists of components such as a control panel, input buttons, and input terminals that are detachable (e.g., ventilation condition setters) from the main unit 28. The input device 28 enables operations such as power on/off, mode selection (S mode, T mode, ST mode, CPAP mode), prescription pressure settings, and settings for the minute breathing rate in T mode or ST mode. The values or modes set are provided to the control unit 250 of the control device 28 and stored in its internal memory (RAM, disk memory, etc.).

EX1044, [0026]

“Well, I think even this portion in Paragraph 27 that you pointed me to, it's talking about to prevent the patient from setting incorrect values. So this is express disclosure in Toge where Toge is talking about that a patient could have access to a device that can control the values that are set for the patient's PAP device. It's simply stating that there should be guard rails provided, for example, by providing a password.”

EX2051, 48:17-23 (discussing EX1044, [0027])

Pet., 39-40; *Opp.*, 13-14, 22-25; *Sur-Rep. MTA*, 6-8

A POSITA Would Have Found It Obvious to Implement Toge's PAP Adjustment Functionality on Kumar's Patient's Cell Phone

43. In my opinion, a POSITA would have found it obvious to configure Kumar's patient-side cell phone to adjust the PAP therapy. As discussed above, Toge already discloses a cell phone with the required functionality, that is, the ability to adjust the PAP therapy. A POSITA would have found it obvious to configure the software downloadable on the patient cell phone disclosed in Kumar to adjust the PAP therapy, giving it the same capability as Toge's physician-side cell phone to "set the necessary data" or "adjust the prescription pressure" of the PAP. See EX1044, [0019], [0039].

Chatterjee Opp., ¶43

"To the contrary, Toge expressly talks about that if a patient is doing this, then there should be guard rails. And again, in the combination one of ordinary skill would have seen that Kumar's expressly disclosing a patient-side cell phone. Kumar is expressly disclosing the use of a downloadable software, a plug-in, that allows that patient's cell phone to communicate with the PAP device, and it would have been natural, very natural, and there would be significant motivation for one of ordinary skill in that combined system to implement this functionality at the patient-side cell phone."

EX2051, 46:25-47:12

Opp., 22-25; *Sur-Rep. MTA*, 6-8

A POSITA Would Have Been Motivated to Implement PAP Adjustment Functionality on a Patient's Cell Phone

- Allow patient to more easily adjust PAP while connected to device

18. In my opinion, a POSITA would have been motivated to incorporate a patient cell phone that adjusts PAP therapy into Toge's PAP system for at least the scenarios discussed above (*see* ¶¶4-9 *supra*), resulting in advantages like better proximity, response time, and consistency. Moreover, a patient having the ability to adjust allowable parameters on their cell phone as opposed to the PAP tremendously increases the ease and convenience for, and engagement of the patient. And because the patient could hold the cell phone in their hand, they would be able to modify permitted parameters *while connected to the PAP device* (e.g., wearing the PAP mask) in bed, and, potentially, even in the dark. Importantly, despite being attached to the PAP machine, a patient would have the ability to make these adjustments to

Kirkness Opp., ¶18

Opp., 22-25; Sur-Rep. MTA, 8-9; Chatterjee Opp., ¶¶43-45; Kirkness Opp., ¶¶16-19

A POSITA Would Have Been Motivated to Implement PAP Adjustment Functionality on a Patient's Cell Phone

■ Increase patient engagement and compliance

18. In my opinion, a POSITA would have been motivated to incorporate a patient cell phone that adjusts PAP therapy into Toge's PAP system for at least the scenarios discussed above (*see* ¶¶4-9 *supra*), resulting in advantages like better proximity, response time, and consistency. Moreover, a patient having the ability to adjust allowable parameters on their cell phone as opposed to the PAP tremendously increases the ease and convenience for, and engagement of the patient. And because the patient could hold the cell phone in their hand, they would be able to modify permitted parameters *while connected to the PAP device* (e.g., wearing the PAP mask) in bed, and, potentially, even in the dark. Importantly, despite being attached to the PAP machine, a patient would have the ability to make these adjustments to

Kirkness Opp., ¶18

19. Finally, having patient data and PAP information display on a patient's cell phone instead of the PAP device itself would realize a couple of advantages. For one, a patient able to look at stored and/or analyzed PAP data on their cell phone would more frequently monitor their treatment progress, generally increasing patient engagement with their therapy. This is crucial given the number of patients who are not fully compliant- underutilizing their PAP devices and/or discounting therapeutic recommendations. And, as I have discussed previously (*see* ¶7 *supra*), off-loading the primary display from the PAP device to the cell phone would allow for the development of a PAP with a reduced or even eliminated display, making for a smaller, lighter weight, more portable, and potentially less expensive PAP device. A POSITA would have been motivated to produce a PAP device having such a decreased form factor.

Kirkness Opp., ¶19

Opp., 22-25; Sur-Rep. MTA, 8-9; Chatterjee Opp., ¶¶43-45; Kirkness Opp., ¶¶16-19

A POSITA Would Have Been Motivated to Implement PAP Adjustment Functionality on a Patient's Cell Phone

- Allow physician device to direct proximate patient cell phone to adjust prescription pressure

17. For example, a physician who has analyzed and/or reviewed a patient's PAP data, could "mobilize" the patient's cell phone to adjust the prescription pressure for a patient's future PAP session.¹ The proximity of the patient's cell phone to the PAP device would make mobilizing the patient's cell phone to adjust the prescription pressure particularly attractive, as the patient's cell phone has the potential to do so more quickly and/or at a specified time/date in response to the physician's prior instruction compared to remotely doing so with the physician's cell phone. And in emergency situations like those described in Toge- when the tidal volume/quantified level of severity data drops below a particular threshold value- a

Kirkness Opp., ¶17

Opp., 22-25; Sur-Rep. MTA, 8-9; Chatterjee Opp., ¶¶43-45; Kirkness Opp., ¶¶16-19

A POSITA Would Have Been Motivated to Implement PAP Adjustment Functionality on a Patient's Cell Phone

- Adjust PAP expeditiously in an emergency

17. For example, a physician who has analyzed and/or reviewed a patient's PAP data, could "mobilize" the patient's cell phone to adjust the prescription pressure for a patient's future PAP session.¹ The proximity of the patient's cell phone to the PAP device would make mobilizing the patient's cell phone to adjust the prescription pressure particularly attractive, as the patient's cell phone has the potential to do so more quickly and/or at a specified time/date in response to the physician's prior instruction compared to remotely doing so with the physician's cell phone. And in emergency situations like those described in *Toge*- when the tidal volume/quantified level of severity data drops below a particular threshold value- a patient's cell phone could more rapidly detect ("receive") the data and more quickly instruct the PAP to increase the pressure to mitigate the patient's disordered breathing. Thus, the patient cell phone could provide the same functionality as the remote physician cell phone but perform those functions more quickly. See EX1044,

*Kirkness
Opp.,
¶17*

Opp., 22-25; *Sur-Rep. MTA*, 8-9; *Chatterjee Opp.*, ¶¶43-45 ; *Kirkness Opp.*, ¶¶16-19

A POSITA Would Have Been Motivated to Implement PAP Adjustment Functionality on a Patient's Cell Phone

- Decrease PAP device form factor

19. Finally, having patient data and PAP information display on a patient's cell phone instead of the PAP device itself would realize a couple of advantages. For one, a patient able to look at stored and/or analyzed PAP data on their cell phone would more frequently monitor their treatment progress, generally increasing patient engagement with their therapy. This is crucial given the number of patients who are not fully compliant- underutilizing their PAP devices and/or discounting therapeutic recommendations. And, as I have discussed previously (*see* ¶7 *supra*), off-loading the primary display from the PAP device to the cell phone would allow for the development of a PAP with a reduced or even eliminated display, making for a smaller, lighter weight, more portable, and potentially less expensive PAP device. A POSITA would have been motivated to produce a PAP device having such a decreased form factor.

Opp., 22-25; *Sur-Rep. MTA*, 8-9; *Chatterjee Opp.*, ¶¶43-45 ; *Kirkness Opp.*, ¶¶16-19

Kirkness Opp., ¶19

“Remote Internet Site”

A POSITA Would Have Been Motivated to Implement Kumar's Remote Internet Site With Toge's PAP System

A remote server implemented on Toge's physician computer would not inherently have security or performance issues

[0017] The physician-side computer 4 is a computer installed at a medical institution (hospital, clinic, medical office, etc.) that receives data from a relay device 3 (namely, all or part of the data transmitted from the positive pressure artificial respiration assisting device 2 to the relay device 3).

EX1044, [0017]

[0069] The embodiments presented herein contemplate connection of multiple patient-side devices, provider-side devices, and engines/central servers. Because a plurality of devices and engines may be in operation, the system may be capable of networking the numerous devices and/or engines into individual, group, clinic, hospital, or other electronic record systems. For simplicity, the discussion will proceed with description of a system having a single patient-side device, provider-side device, and engine/central server; it being understood that one skilled in the art would be able to use the system with multiple devices connected without undue experimentation.

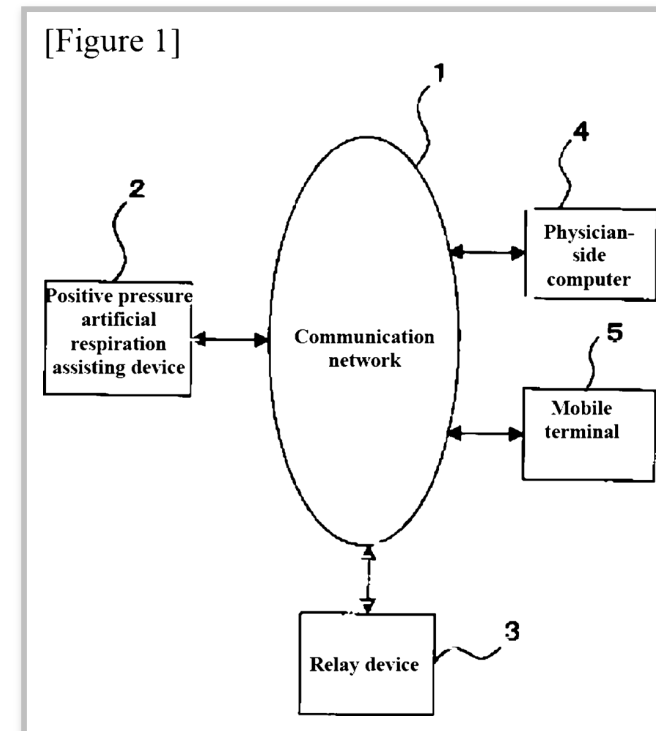
EX1008, [0069]

Opp., 15-17; Sur-Rep. MTA, 10-12

A POSITA Would Have Been Motivated to Implement Kumar's Remote Internet Site With Toge's PAP System

A remote server implemented on Toge's physician computer would not interfere with Toge's purpose

- Toge PAP still able to send data in emergencies as before modification with remote internet site



EX1044 (Toge),
Fig. 1

Opp., 16-17; Sur-Rep. MTA, 10-12; EX2051, 28:10-29:11, 30:11-21; 29:12-24, 32:8-33:12; 31:22-32:4

A POSITA Would Have Been Motivated to Implement Kumar's Remote Internet Site With Toge's PAP System

A remote server implemented on Toge's physician computer would not interfere with Toge's purpose

- Toge-Kumar system still sends data in real time through server
 - Long-polling
 - Continuous query
 - TCP/web packets

Opp., 16-17; *Sur-Rep. MTA*, 10-12; *EX2051*, 28:10-29:11, 30:11-21; 29:12-24, 32:8-33:12; 31:22-32:4

A POSITA Would Have Been Motivated to Implement Kumar's Remote Internet Site With Toge's PAP System

31. But even if the web clients could only “pull” information, the design of the system could always be implemented in a way to address emergency situations. If the server identifies an emergency, the server could automatically push out such data, using mechanisms that had been well known to a POSITA for years. For example, a push system could be implemented using standard WebSockets, a well-known concept and technology typically used to implement push notifications. Further, when active, the remote internet site/physician's web client could continuously query the server to see if new data had been received. Increasing the “pull” frequency in such a manner would achieve functionality akin to a “push” protocol.

Opp., 16-17; *Sur-Rep. MTA*, 10-12; *EX1072*, ¶ 31

[O]ur case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention.

In re Fulton, 391 F.3d 1195, 1200 (Fed. Cir. 2004)

[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate a motivation to combine

Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006)

Real Party in Interest

“[A] party that funds and directs and controls an IPR or [PGR] proceeding constitutes a ‘real party-in-interest.’”

Wi-Fi One, LLC v. Broadcom Corp., 887 F.3d 1329, 1336 (Fed. Cir. 2018)

The RPI analysis examines the “relationship between a party and a proceeding,” not “between parties.”

Par Pharm. v. Jazz Pharm., Inc., IPR2015-00546, Paper 25, at 14 (July 28, 2015)

Resmed Corp. Is the Only Real Party in Interest

Invoice Number	Invoice Date	Payee	ResMed Matter Reference	Invoice Total with Currency (Use this for currency)	Type Reader	Matter Type	Source Currency	Raw Status Category	Owner	Client
2420617	11/25/2024	Paul Hastings LLP - Los Angeles	J344		J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp
2423487	12/19/2024	Paul Hastings LLP - Los Angeles	J344		J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp
2431735	2/28/2025	Paul Hastings LLP - Los Angeles	J344		J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp
2440932	5/13/2025	Paul Hastings LLP - Los Angeles	J344		J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp
2445470	6/24/2025	Paul Hastings LLP - Los Angeles	J344		J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp
2449361	7/31/2025	Paul Hastings LLP - Los Angeles	J344		J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp
JP33015	12/11/2024	Jason Paul Kirkness PhD (NLV), S J344			J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp
JP33016	2/2/2025	Jason Paul Kirkness PhD (NLV), S J344			J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp
JP33017	2/2/2025	Jason Paul Kirkness PhD (NLV), S J344			J	Litigation	USD	litigation	ResMed Corp.	ResMed Corp

Owner

Client

ResMed Corp.

ResMed Corp

Owner

Client

ResMed Corp.

ResMed Corp

EX1080

Opp. Mot. Term., 2

Resmed Corp. Is the Only Real Party in Interest

Conflict / Dispute Reference J344

J344 - Live - US - Cancellation - RMD v CleveMed IPR

Relationship	Organization Name	Organization Name (National)	Firm Code	Comments
Client	ResMed Corp.		RMCORP	
Law Firm	Paul Hastings LLP		PHLLP	

RMD v CleveMed IPR

Organization Name

ResMed Corp.

Paul Hastings LLP

ADD

Record created on 27 Oct 2024 by Piyush Tikoo

Law Engine Status: Enabled

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Opp. Mot. Term., 2

EX1081

