

ResMed Corp. v. Cleveland Medical Devices, Inc.

IPR2023-00565
U.S. Patent No. 10,076,269

Petitioner's Demonstrative Slides

Before Hon. Ulrike W. Jenks, Sheridan K. Snedden, and Cynthia M. Hardman

February 4, 2025

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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'269 Patent, Claim 1

1.pre	A positive airway pressure (PAP) sleep disorder treatment system comprising:
1.a	a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data;
1.b	a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module further comprising:
1.b.1	a blower having an air output,
1.b.2	a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,
1.b.3	<i>an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject</i> using the PAP device, and
1.b.4	a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device;
1.c	a mask or a nasal cannula; and
1.d	a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location.

'269 Patent, Claim 5

5.pre	A sleep disorder treatment system comprising:
5.a	a data acquisition system;
5.b	a positive airway pressure (PAP) device; and
5.c	a processor;
5.d	the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device;
5.e.1	the PAP device comprising: a hose
5.e.2	a blower
5.e.3	<i>an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject,</i>
5.e.4	a second input for receiving pulse oximetry sensor data from the data acquisition device; and
5.e.5	a mask or nasal cannula for treating a subject's sleep disorder symptoms; and

5.f.1	the processor adapted for receiving pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor, the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device,
5.f.2	the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to <i>a nonvolatile memory</i> to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.

'269 Patent, Claim 8

8.pre	A sleep disorder treatment system comprising:
8.a	a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and
8.b	a positive airway pressure apparatus for providing pressurized air and <i>dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent</i> , the positive airway pressure apparatus comprising a controller adapted to <i>adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder</i> from the data acquisition system.

'269 Patent, Claim 15

15.pre	A positive airway pressure (PAP) sleep disorder treatment system comprising:
15.a	a PAP device with an enclosure further comprising:
15.a.1	a blower having an air output,
15.a.2	<i>an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject</i> while using the PAP and outputting airflow sensor data;
15.a.3	a processor adapted for receiving the airflow sensor data, and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device;
15.b	a mask or a nasal cannula;
15.c	a first radio frequency wireless module transceiver; and
15.d	a base station, cellular phone, or PDA;
15.e	the first radio frequency wireless module transceiver adapted for receiving and <i>transmitting</i> the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and the data of usage <i>to the base station, cellular phone or PDA;</i>
15.f	the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display, the <i>base station, cellular phone, or PDA adapted to display</i> the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, <i>and to retransmit</i> the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.

Petition, 1-2.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

6

'269 Patent Prior Art

Genger
WO 02/078775A2

Schmidt
U.S. 6,167,258

Farrell
WO 2005/096737A2

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International office [Emblem] [Barcode]

(43) International publication date October 10, 2002 (10.10.2002) PCT (10) International publication number WO 02/078775 A2

(51) International Patent Classification: A61M 16/06, G06F 19/00, A61B 5/00 (71) Applicant (for all designated states except US): BEPTEC GmbH [DE 01], Building 111, 13 Bismarckstrasse, 90447 Dusseldorf (DE)

(72) Inventor and (73) Invention/Applicant (US only): Genger, Harold [DE 01], c/o Waldfrieden, 82119 Wangen bei Ursberg (DE 01), c/o L&M, Michael [DE 01], c/o Bismarckstrasse, 90447 Dusseldorf (DE)

(74) Agent: HELLMICH, Wolfgang; 56 Maximilianstrasse, 80795 Munich (DE)

(81) Designated states (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BY, BZ, CA, CH, CN, CO, CR, DE, CU, CZ, DK, DM, DZ, EC, EE, ES, FI, GB, GR, HU, IL, IN, JP, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MU, MV, MW, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PK, PL, PT, RU, SA, SD, SE, SG, SI, SK, SL, SM, SN, SR, ST, SV, SY, TD, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VE, VN, YU, ZA, ZM, ZW

(54) Title: RADIO MODULE, RESPIRATOR AND MONITORING DEVICE THEREFOR, THERAPEUTIC DEVICE FOR CARRYING OUT CPAP TREATMENT AND MONITORING DEVICE THEREFOR, SYSTEMS AND METHODS

(57) Abstract: The invention relates to further realization in the healthcare field. The invention relates in particular to CPAP treatment devices, which communicate, in a wireless manner, with sensor units and monitoring devices, to radio modules that are suitable for use in the medical field, to respiratory devices, which likewise communicate, in a wireless manner, with sensor units and monitoring devices and to an intelligent network of treatment rooms in a hospital, of a hospital network, of national organizations, of medical establishments and also of domestic environments.

(57) Abstract: The invention relates to further realization in the healthcare field. The invention relates, in particular, to CPAP treatment devices, which communicate, in a wireless manner, with sensor units and monitoring devices, to radio modules that are suitable for use in the medical field, to respiratory devices, which likewise communicate, in a wireless manner, with sensor units and monitoring devices and to an intelligent network of treatment rooms in a hospital, of a hospital network, of national organizations, of medical establishments and also of domestic environments.

7 Claims, 4 Drawing Sheets

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7 Claims, 4 Drawing Sheets

Petition, 3-4, 25.

EX1005.

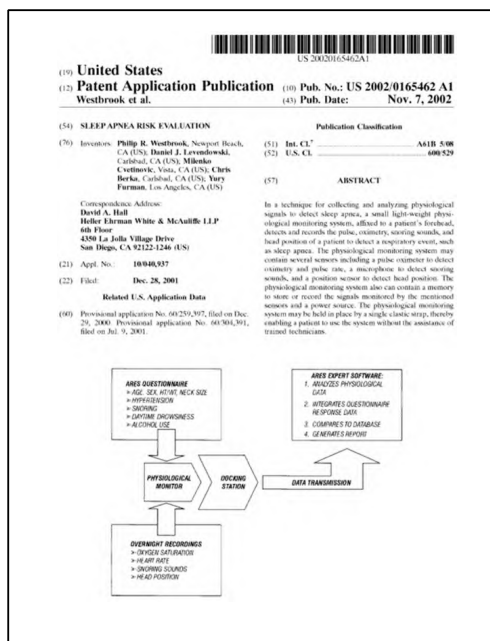
EX1006.

EX1008.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

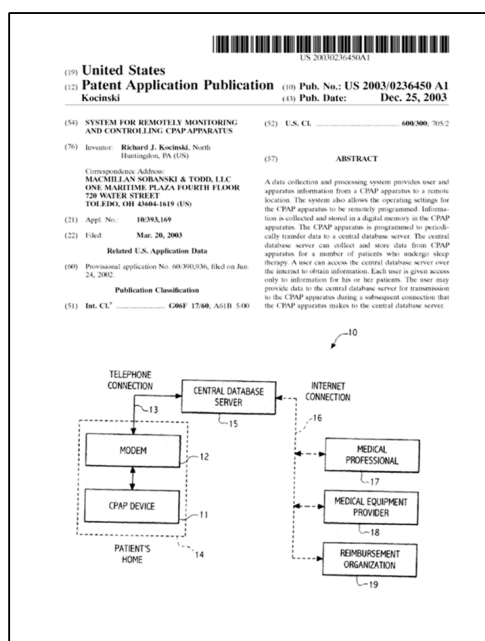
'269 Patent Prior Art

Westbrook
U.S. 2002/0165462A1



EX1007.

Kocinski
U.S. 2003/0236450A1



EX1012.

Petition, 3-4, 25, 61.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

8

Stahmann
WO 2005/028029A2

Edgar
U.S. 2005/0171160A1

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(43) International Publication Date
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100796-229 11 March 2004 (11.03.2004)

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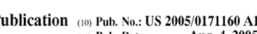
(73) Patenting Agent: HAN, Joon-Ho, 1500 Lehigh Avenue, Suite 100

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(75) Patenting Agent: HAN, Joon-Ho, 1500 Lehigh Avenue, Suite 100

	
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(19)	United States
(12)	Patent Application Publication
	(110) Pub. No.: US 2005/0171160 A1 (43) Pub. Date: Aug. 4, 2005
Edgar et al.	
(64) DOXEPIN ANALOGS AND METHODS OF USE (70) Inventors: Dale M. Edgar, Weyland, MA (US); David G. Hingamer, East Amherst, NY (US); James F. White, Canfield, MA (US); Michael Solomon, Concord, MA (US) Related U.S. Application Data (63) Continuation-in-part of application No. 10/831,423, filed on Apr. 23, 2004. (66) Provisional application No. 60/528,393, filed on Dec. 10, 2003.	
Correspondence Address: MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPOLO, P.C., ONE FINANCIAL CENTER BOSTON, MA 02111 (US) Publication Classification (51) Int. Cl.⁷ A61K 31/452 (52) U.S. Cl. 514/320	
(21) Appl. No.:	11,008,891
(22) Filed:	Dec. 10, 2004
ABSTRACT The invention relates to novel dextropropazac analogs, compounds and methods of modulating sleep by administering such compounds, or a pharmaceutically effective salt thereof.	

Petition, 3-4, 49.

EX1010.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

EX1011.

Grounds

Ground	Claims	Basis	Prior Art
1	<u>1</u> -3, <u>5</u> , 7	§103	Genger, Schmidt, Westbrook, Farrell, POSITA knowledge
2	4, 6	§103	Genger, Schmidt, Westbrook, Farrell, Paradiso, POSITA knowledge
3	<u>8</u> -11, 13	§103	Stahmann, Edgar, POSITA knowledge
4	12	§103	Stahmann, Edgar, Schmidt, POSITA knowledge
5	14	§103	Stahmann, Edgar, Paradiso, POSITA knowledge
6	<u>15</u> -16, 18-19	§103	Kocinski, Farrell, Bluetooth, POSITA knowledge
7	17	§103	Kocinski, Farrell, Bluetooth, Guilleminault-2004, Westbrook, POSITA knowledge
8	20	§103	Kocinski, Farrell, Bluetooth, Paradiso, POSITA knowledge

'269 Patent Overview

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

11

'269 Patent – Relies on Well-Known Prior Art

2. Technical Background

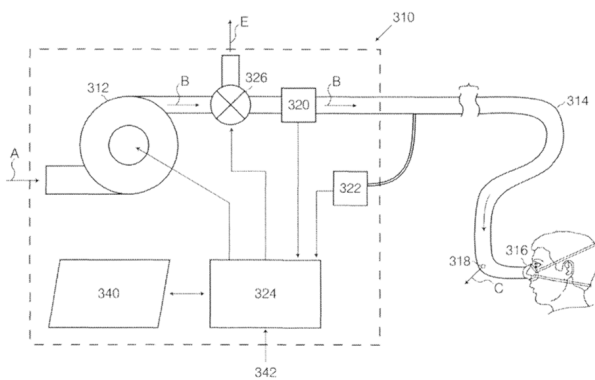


Fig. 7

EX1001, Fig. 7

For example, the most common method of treating the sleeping disorder of sleep apnea is by apply a continuous positive gas pressure to the patient's airway, which has the effect of forcing the patient to breath through application of the pressure. More advanced, but still very basic devices have been developed that adjust this continuous positive gas pressure through sensors built into the device for creating the positive gas pressure, which measure gas flow through the device. These basic adjustable devices have been found

EX1001, 2:17-25.

'269 Patent

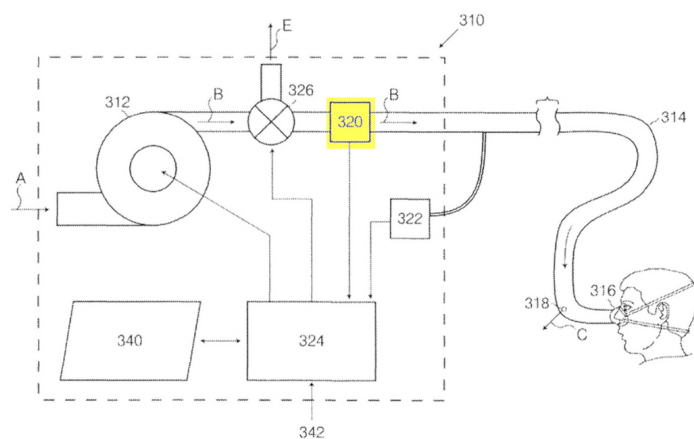


Fig. 7

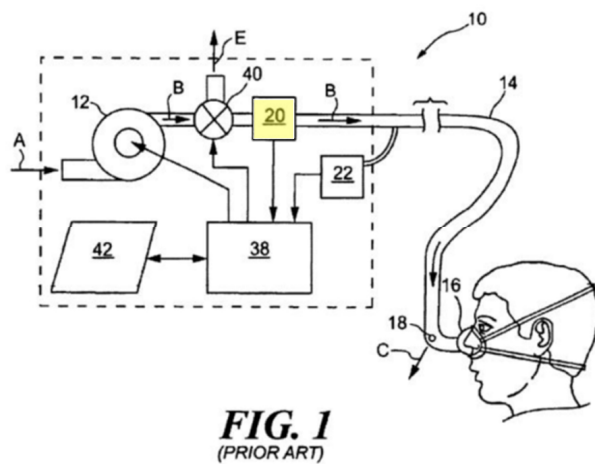
particularly, FIG. 7 shows a particular type of physical treatment device known as continuous positive airway pressure (CPAP) device. This conventional pressure support system 310 shown in FIG. 7 includes a pressure generator 312, a blower, piston or bellows, that receives a supply of gas from a gas source, such as ambient atmosphere, as indicated by arrow A, or pressurized gas tanks (not shown) and creates a flow of breathing gas, as indicated by arrows B, having a pressure greater than the ambient atmospheric pressure. A patient or subject circuit 314, which is typically

EX1001, 22:41-54.

A more sophisticated pressure support device of the present invention includes a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit 314. The flow information can also be used to determine the volume of gas passing through the subject circuit 314. The information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to control the pressure or flow of gas provided to the subject, monitor the condition of the subject, monitor the usage of the pressure support device, any combination thereof, or the like.

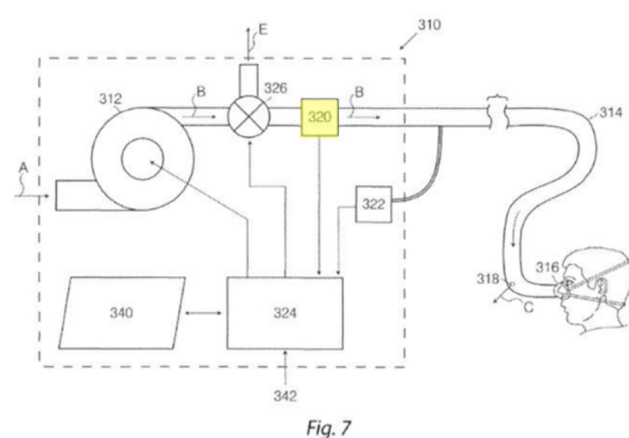
'269 Patent – Relies on Well-Known Prior Art

Truitt - Prior Art



EX1026, Fig. 1.

'269 Patent



EX1001, Fig. 7.

Reply, 1-3, 15-16 (see also POR characterizing Figure 7 as "novel").

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

'269 Patent – Relies on Well-Known Prior Art

Truitt - Prior Art

More sophisticated pressure support devices include a flow sensor 20, pressure sensor 22 or both that monitor the flow and/or pressure of gas passing in patient circuit 14. The flow information can also be used to determine the volume of gas passing through patient circuit 14. The information from flow sensor 20 and/or pressure sensor 22 is used, for example, to control the pressure or flow of gas provided to the patient, monitor the condition of the patient, monitor the usage of the pressure support device (patient compliance), or any combination thereof. FIG. 1 illustrates a flow sensor 20

EX1026, 2:1-11.

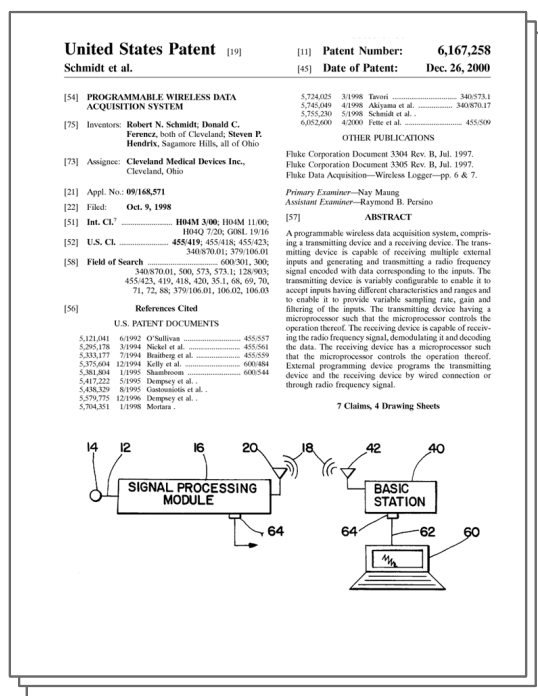
'269 Patent

A more sophisticated pressure support device of the present invention includes a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit 314. The flow information can also be used to determine the volume of gas passing through the subject circuit 314. The information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to control the pressure or flow of gas provided to the subject, monitor the condition of the subject, monitor the usage of the pressure support device, any combination thereof, or the like.

EX1001, 23:12-17.

'269 Patent – Relies on Well-Known Prior Art

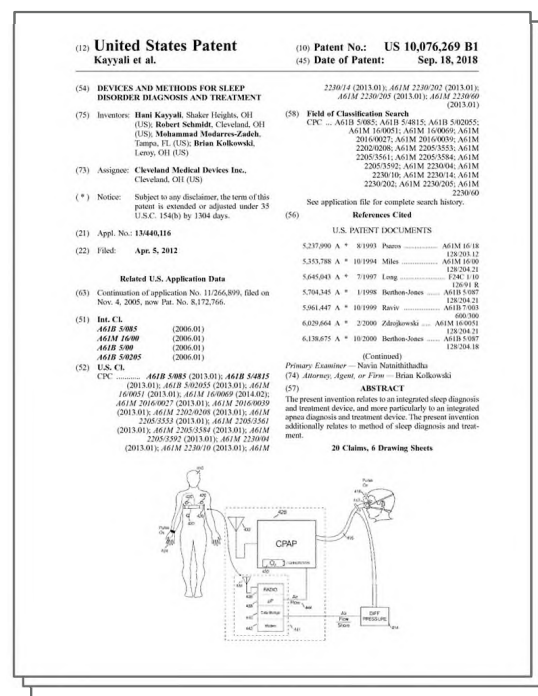
Schmidt - Prior Art



Petition, 11-12.

EX1006.
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

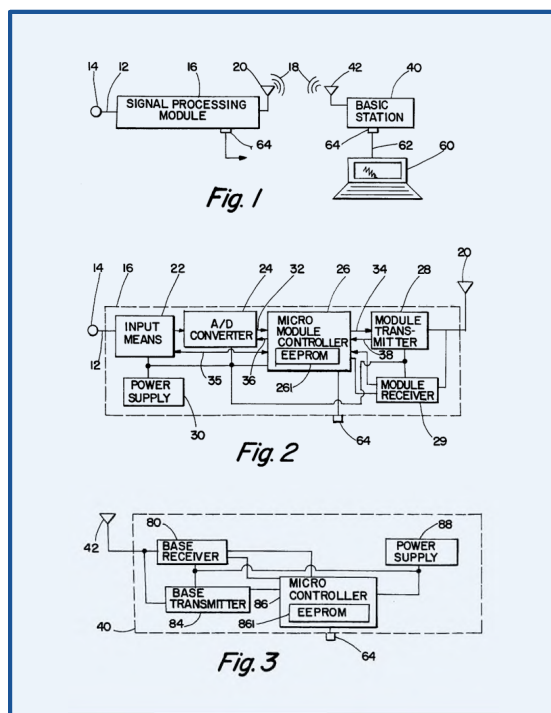
'269 Patent



EX1001.

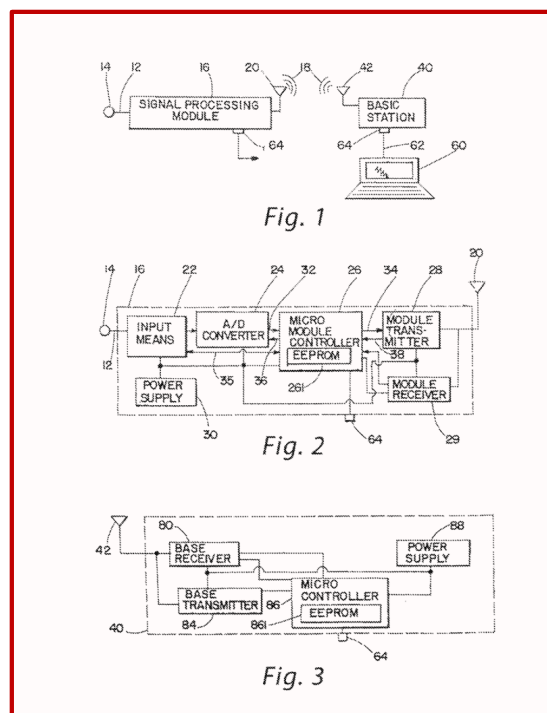
'269 Patent – Relies on Well-Known Prior Art

Schmidt - Prior Art



EX1006,
Fig. 1-3.

'269 Patent



EX1001,
Fig. 1-3.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

'269 Patent – Relies on Well-Known Prior Art

Schmidt - Prior Art

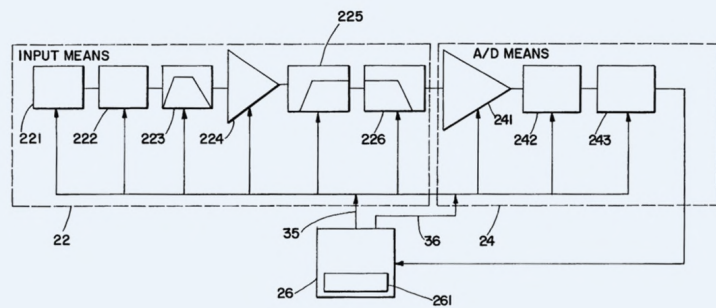


Fig. 4

EX1006, Fig. 4.

'269 Patent

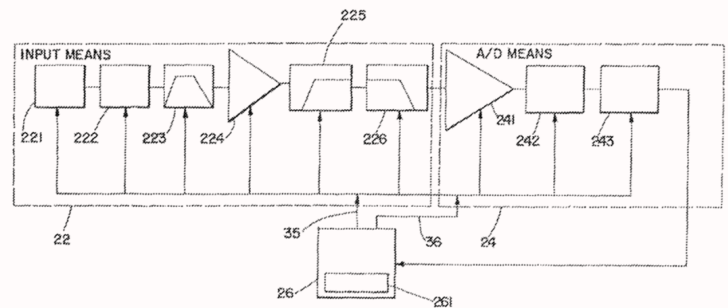


Fig. 4

EX1001, Fig. 4.

Schmidt - Prior Art



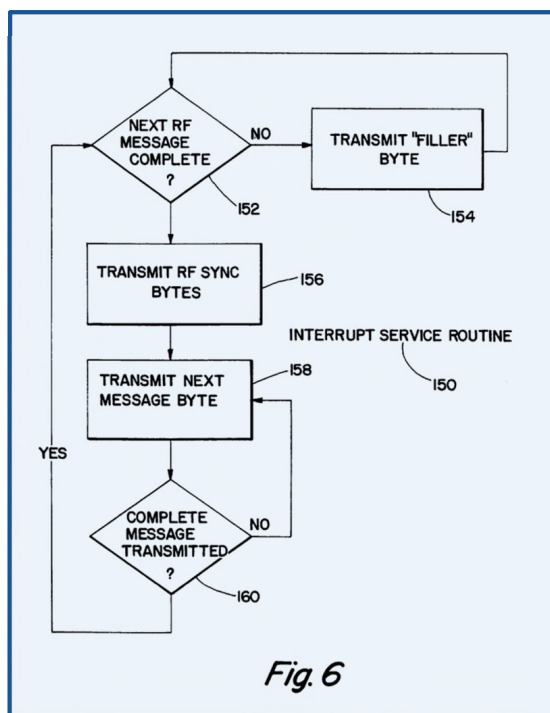
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE



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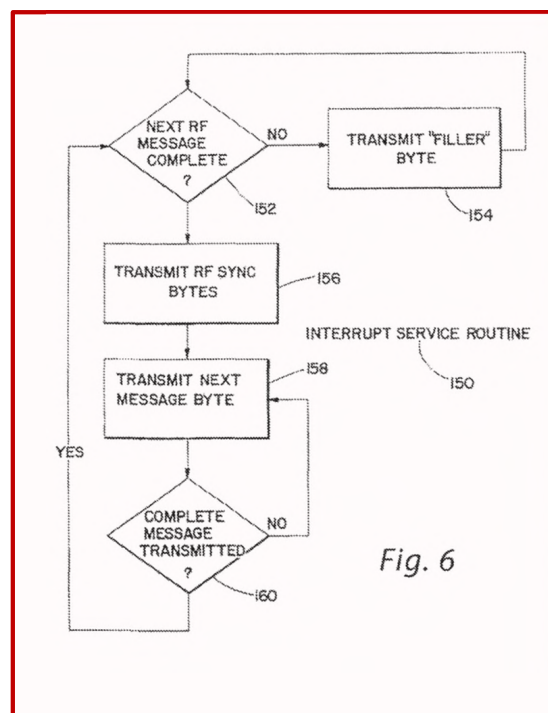
'269 Patent – Relies on Well-Known Prior Art

Schmidt - Prior Art



EX1006,
Fig. 6.

'269 Patent



EX1001,
Fig. 6.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

'269 Patent – Relies on Well-Known Prior Art

Schmidt - Prior Art

Referring now to the drawings and, in particular to FIG. 1, there is shown a block diagram of the present invention. An external input 12 from sensor 14 is inputted to signal processing module 16. Although, one sensor 14 and one external input 12 are shown, the signal processing module 16 is capable of accepting multiple external inputs 12 from multiple sensors 14. The signal processing module 16 generates a signal 18 encoded with data corresponding to the external input 12. The signal processing module 16 transmits the signal 18 by wireless means, to base station 40. In FIG. 1, the wireless means is shown as radio frequency (RF). In

EX1006, 4:63-14:54.

Because of the phase locked loop based frequency synthesizer used in the present invention, the module transmitter 28 and base transmitter 84 are frequency agile over the frequency range. Since the module receiver 29 and the base receiver 80 employ automatic frequency control, the present invention consumes relatively low power as the module transmitter 28 and base transmitter 84 can be intermittently powered down without losing reception due to drift or sacrificing data transmission accuracy. The utilization of programmable firmware allows inexpensive and flexible operation for the inputting, conditioning and processing of any type, character and range of the external inputs. This also allows the module microcontroller 26, in response to the variation of the external inputs 12 or, in response to instructions received by RF signal through the module receiver 29, to adapt the signal processing module 16 based upon the variations allowing the signal processing means 16 to input, condition, process and transmit said external input notwithstanding said variation. The present invention performs this adaptation without the need to modify or alter hardware or select or use different hardware already present in the device. In other words all adaptation can be accomplished by software programming totally.

'269 Patent

Referring now to the drawings and, in particular to FIG. 1, there is shown a block diagram of the present invention. An external input 12 from sensor 14 is input to signal processing module 16. Although, one sensor 14 and one external input 12 are shown, the signal processing module 16 is capable of accepting multiple external inputs 12 from multiple sensors 14. The signal processing module 16 generates a signal 18 encoded with data corresponding to the external input 12. The signal processing module 16 transmits the signal 18 by wireless means to a base station 40. In FIG. 1, the wireless means is shown as radio frequency (RF). In

EX1001, 8:57-18:50.

Because of the phase locked loop based frequency synthesizer used in the present invention, the module transmitter 28 and base transmitter 84 are frequency agile over the frequency range. Since the module receiver 29 and the base receiver 80 employ automatic frequency control, the present invention consumes relatively low power as the module transmitter 28 and base transmitter 84 can be intermittently powered down without losing reception due to drift or sacrificing data transmission accuracy. The utilization of programmable firmware allows inexpensive and flexible operation for the inputting, conditioning and processing of any type, character and range of the external inputs. This also allows the module microcontroller 26, in response to the variation of the external inputs 12 or, in response to instructions received by RF signal through the module receiver 29, to adapt the signal processing module 16 based upon the variations allowing the signal processing means 16 to input, condition, process and transmit said external input notwithstanding said variation. The present invention performs this adaptation without the need to modify or alter hardware or select or use different hardware already present in the device. In other words all adaptation can be accomplished by software programming totally.

Petition, 11-12.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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'269 Patent – Relies on Well-Known Prior Art

The treatment device can be any device known to those skilled in the art. The treatment device can either physically or chemically treat the subject's sleeping disorder. An example of physically treating the subject's sleeping disorder would be a device to provide positive airway pressure to a subject. An example of chemically treating the subject's sleeping disorder would be to have a medication reservoir where a drug is delivered to the subject in order to treat symptoms of the sleeping disorder. A few of the many

EX1001, 3:48-56.

Sensors which can be used are known to those skilled in the art. These sensors include electrodes for measuring

EX1001, 6:10-11.

Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms. This filtered data is then preferably analyzed using the techniques described in the following paragraph. In addition to these sleeping disorder data or signal analysis techniques various controller schemes can be used.

EX1001, 20:1-8.

kernels. The present invention would also include other on-line signal processing algorithms known to those skilled in the art, such as wavelet analysis, which is similar to time-frequency analysis with a particular kernel function, to identify the shift in power spectrum associated with imminent flow separation that is discussed herein.

EX1001, 20:26-31.

'269 Patent – Relies on Well-Known Prior Art

The processor or microprocessor of various embodiments of the present invention can be part of a remote communication station or base station. The remote communication station or base station can also be used only to relay a pre- or post-processed signal. Preferably, the remote communication station or base station can be any device known to receive RF transmissions such as those transmitted by the wireless data acquisition system described herein. The remote communication station or base station by way of example but not limitation can include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, the remote communication station can further transmit data both to another device including the subject's treatment device and/or back.

Further optionally, two different remote communication stations can be used, one for receiving transmitted data and another for sending data. For example, with the sleep diagnosis and treatment system of the present invention, the remote communication system of the present invention can be a wireless router, which establishes a broadband internet connection and transmits the physiological signal to a remote internet site for analysis, preferably for further input by the subject's physician or another clinician. Another example is where the remote communication system is a PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis. 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.

EX1001, 19:8-45.

Internal Airflow Sensor

Ground 1: Genger (Ex. 1005) and Farrell (Ex. 1008)
Ground 6: Kocinski (Ex. 1012) and Farrell (Ex. 1008)

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Claims 1, 5, 15 – Internal Airflow Sensor

Ground 1	Genger and Farrell	1.b.3	<i>an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject</i> using the PAP device, and
		5.e.3	[the PAP device comprising:] <i>an airflow sensor</i> with a second signal <i>adapted for measuring respiratory airflow of a subject</i> ,
Ground 6	Kocinski and Farrell	15.a.2	<i>an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject</i> while using the PAP and outputting airflow sensor data;

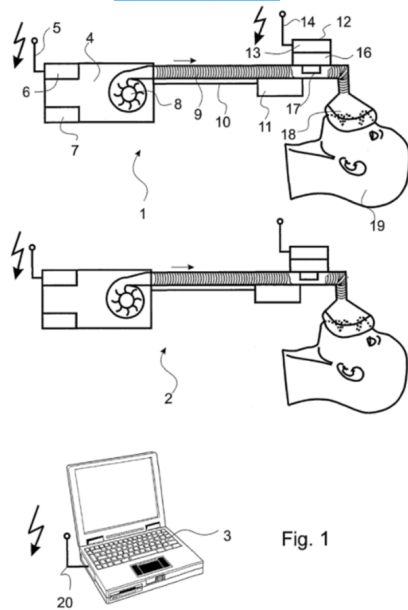
Ground 1 – Genger and Farrell

Genger in view of Farrell renders obvious the PAP device comprising an internal airflow sensor adapted for measuring respiratory airflow of a subject

- PO does not dispute Genger discloses an airflow sensor “adapted for measuring the respiratory airflow data of a subject” (claim 5 omits the word “data”)
- PO admits the only disclosure in the '269 patent of an “internal” respiratory airflow sensor is a “conventional PAP device” (see POR at 14-15, citing Fig. 7)
- PO does not dispute the obviousness motivations identified in the Petition

Genger Figures 1, 2, 8

Sleep Laboratory Environment



EX1005, Fig. 1, 11:21.

Domestic Environment

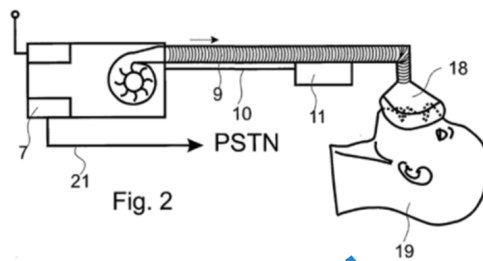


Fig. 2

EX1005, Fig. 2, 12:18-19.

Combined Hospital and Domestic Network

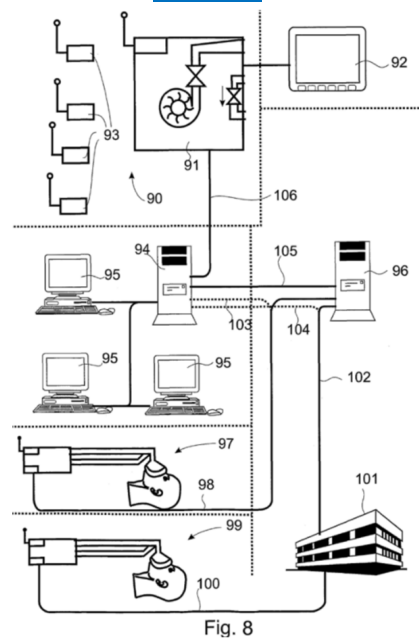


Fig. 8

EX1005, Fig. 8, 10:11-12, 17:1-18:16.

Petition, 26-28.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Genger Figure 1

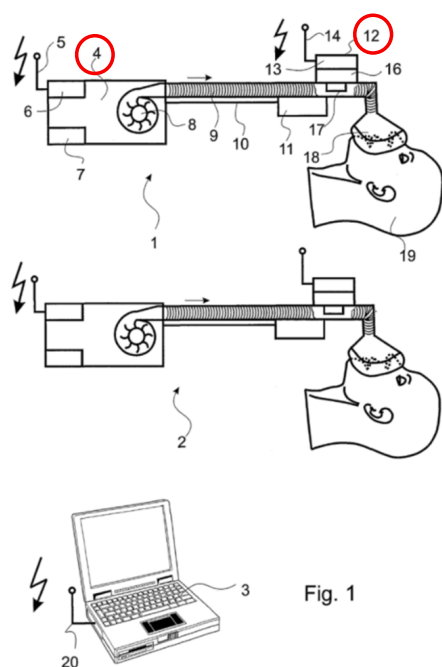
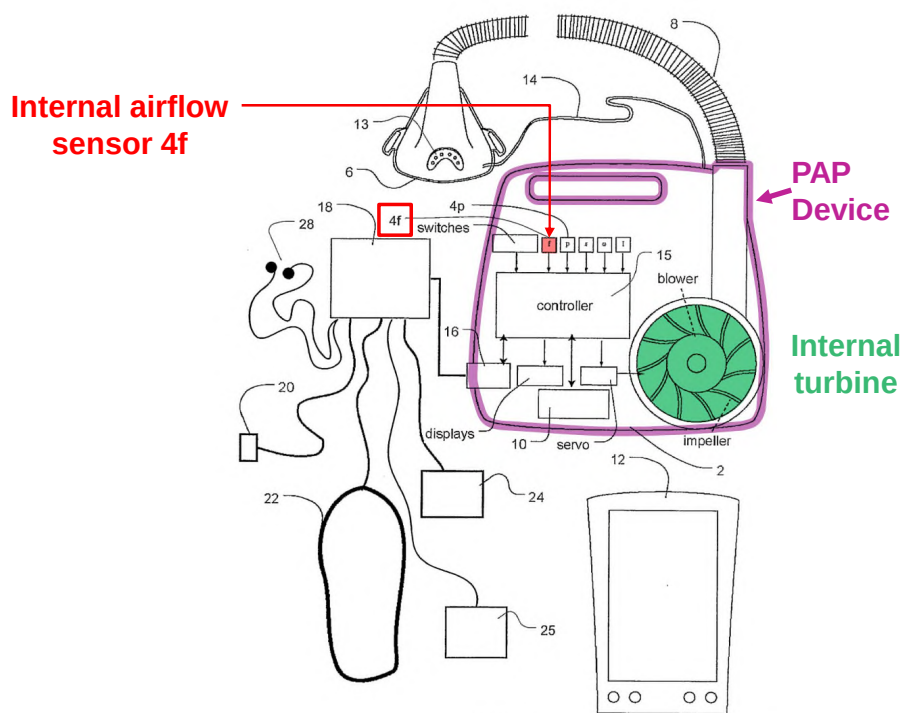


Fig. 1 shows a first CPAP set-up station 1, a second CPAP set-up station 2, and a monitoring device 3, which is a laptop computer. Each CPAP set-up station comprises a CPAP treatment device and a patient 19. The CPAP treatment device in turn comprises a compressor 4, a tube 9, a ventilation mask 18, and multiple sensors. As an example, a pressure sensor 11 is shown, which is connected to the compressor 4 via a measuring line 10. To generate a positive pressure, the compressor contains a turbine 8. Furthermore, an air humidifier may be provided, which is either integrated into the compressor or arranged as an external device between the compressor outlet and the ventilation mask 18.

Furthermore, the compressor is equipped with a radio module 6, which preferably operates to Bluetooth standard. Furthermore, a modem 7 may be provided in the compressor for connecting the compressor to the public switched telephone network (PSTN) (see Fig. 2). Both treatment devices are supplemented by a wireless flow sensor unit as an example. Instead of or in addition to the flow sensor unit 12, the CPAP treatment device may be equipped with sensor units for EEG, EMG, ECG, EOG signals (see Fig. 7). Furthermore, wireless sensor units may be provided for recording the respiration volume, the air pressure with which the patient is ventilated, or the patient's blood oxygen content.

EX1005, Fig. 1, 10:14-30.

Farrell Discloses an Airflow Sensor Internal to the PAP Device



Petition, 35-36; Reply, 9-10, 13.

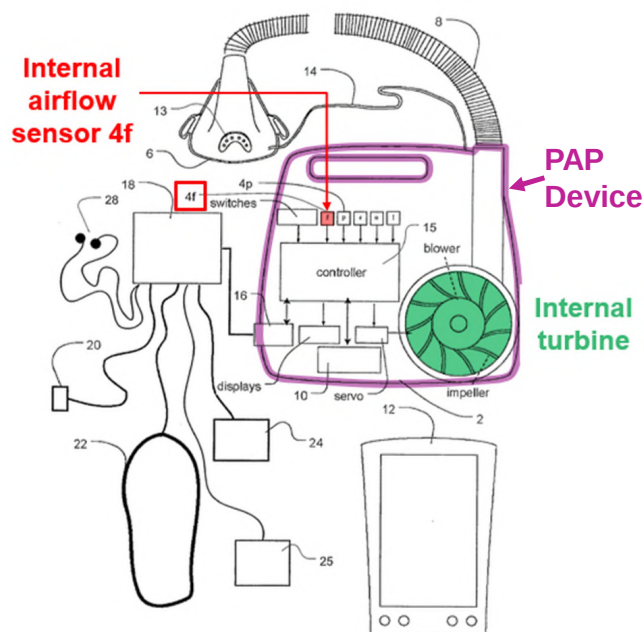
FIG. 1
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

EX1008, Fig. 1.

Farrell Discloses an Airflow Sensor Internal to the PAP Device

With reference to FIG. 1, the invention involves a pressure delivery device that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6. Exhaust gas is vented via exhaust 13. Optionally, a flow sensor 4f and/or pressure sensor 4p may also be utilized in which case mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal $F(t)$, and mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{mask}(t)$. The pressure sensor 4f and flow sensor 4p have only been shown symbolically in FIG. 1 since it is understood that those skilled in the art would understand how to measure flow and pressure. Flow $F(t)$ and pressure $P_{mask}(t)$ signals are sent to a controller or microprocessor 15 to derive a pressure request signal $P_{request}(t)$. Alternatively, a flow signal $f(t)$ and pressure signal $P_{mask}(t)$ may be

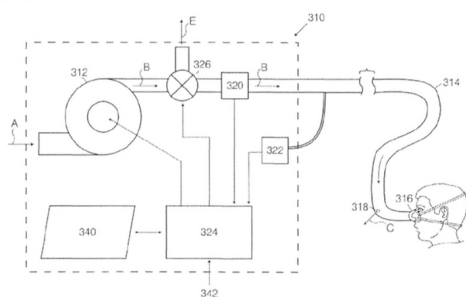
EX1008, 5:3-17, Fig. 1.



Internal Airflow Sensors Were Conventional

omitted)); see also Borkholder Decl. at ¶¶ 33-34. The '269 Patent discloses a PAP device that “includes a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit” where 320 and 322 are sensors that reside inside the enclosure of the PAP device. '269 Patent at 23:7-10; Borkholder Decl. at ¶ 35.

Unlike Farrell's design, which discloses a pneumotachograph that measures exhalation at or near an exhaust port on the mask, the '269 Patent discloses an embodiment where the patient's respiratory airflow is measured with an airflow sensor internal to the CPAP machine:



PO argues '269 patent Figure 7 discloses the claimed internal airflow sensor

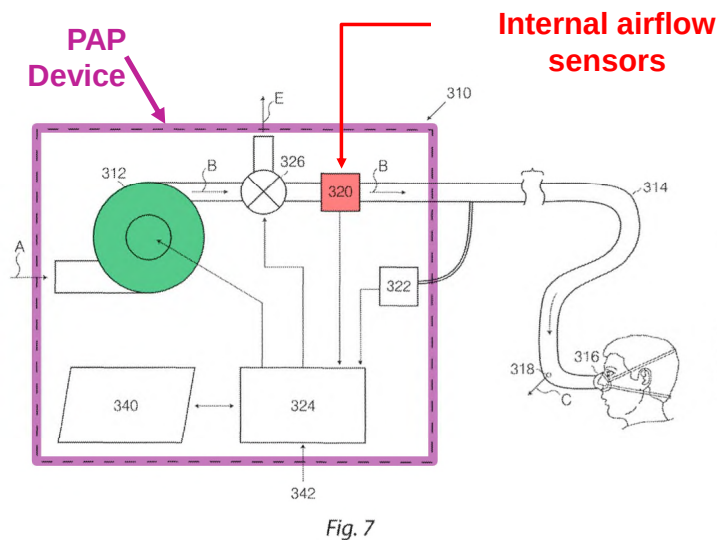
- '269 Patent admits Figure 7, copied from the prior art, is a “conventional” system (22:47-48)
- '269 Patent relies on drawing (not text) to show placement inside the enclosure
- Farrell provides the same disclosure

Reply, 9, 15-16, 23-24.

Farrell Discloses an Airflow Sensor Internal to the PAP Device

'269 Patent

Farrell



EX1001, Fig. 7.

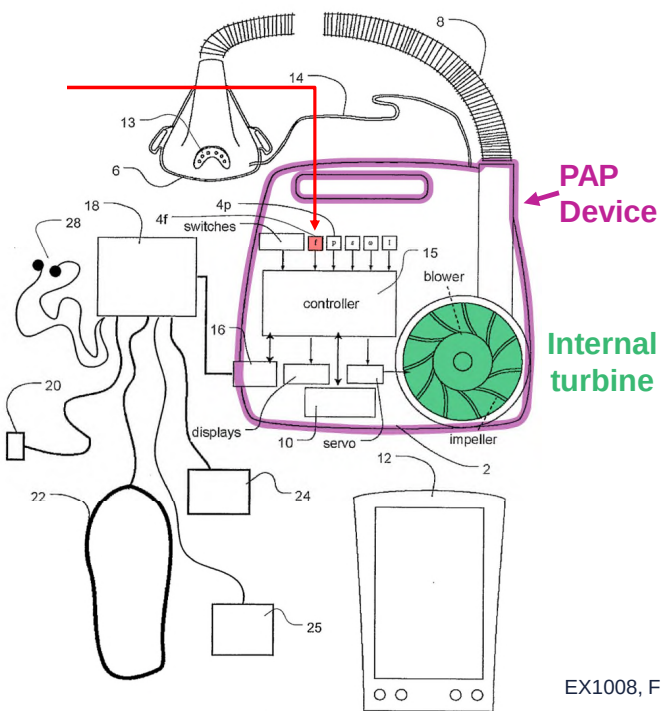


FIG. 1

EX1008, Fig. 1.

Petition, 12, 35; Reply, 9, 15-16, 23-24 (Ground 6).

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Motivations for Internal Airflow Sensor

Petition:

Motivation for modifying Genger's CPAP would also have come from the fact that Genger wants the CPAP device 4/5/6/7/8 to have the airflow data. That is, Genger's external flow sensor sends its data to radio module 6 of the CPAP device. *Id.*, 11:7-9. Providing the airflow sensor *within* Genger's CPAP device puts the airflow data where Genger wants it, and avoids the need to transmit airflow data from an external sensor or change external sensor batteries. EX1004, ¶88.

Petition, 36; EX1004 (Sharony Decl.), ¶88.

Genger:

20 Fig. 2 shows the use of a CPAP treatment device in a domestic environment. Here, preferably, no radio-connected sensor units are used, to avoid changing or recharging the batteries in the radio modules. A controller in the compressor controls the operation of the CPAP treatment device; in particular, the speed of the turbine, and optionally, the temperature of an air humidifier. Optionally, the controller determines trend data from the sensor signals, which it transmits via modem 7 and the PSTN public telephone network to a server 94 in the hospital,

EX1005, Fig. 2, 12:18-23.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Motivations for Internal Airflow Sensor

Dr. Sharony:

**10 It's a matter of engineering.
11 You don't put the sensor in a tubing that
12 is flexible and it can crack, can break.
13 It's replaceable. It is more secure to put
14 it inside the mask, inside the device or
15 inside the generator.**

Sharony Dep. Tr. (EX2016), 59:10-15;
Reply, 12.

Berthon-Jones (EX2015):

The pressure $p_g(t)$ occurring at the pressure generator 34 outlet is measured by a pressure transducer 70. The flow $f_g(t)$ through tubing 32 is measured with flow sensor 72 provided at the output of the turbine 34.

Farrell:



Farrell Discloses an Airflow Sensor Internal to the PAP Device

PO Argues:

Unlike Farrell's design, which discloses a pneumotachograph that measures exhalation at or near an exhaust port on the mask, the '269 Patent discloses an embodiment where the patient's respiratory airflow is measured with an airflow sensor internal to the CPAP machine:

PO Resp., 15 (citing '269 patent, Figure 7).

Farrell:

With reference to FIG. 1, the invention involves a pressure delivery device that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6. Exhaust gas is vented via exhaust 13. Optionally, a flow sensor 4f and/or pressure sensor 4p may also be utilized in which case mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal F(t), and mask pressure is

EX1008, 5:3-17, Fig. 1.

PO Mischaracterizes Farrell

- Farrell does not limit flow sensor to pneumotachograph
 - Farrell discloses “flow sensor 4f” which “may be” pneumotachograph “or similar device” Reply, 11.
- Farrell does not limit location of flow sensor or pneumotachograph to the mask Reply, 10.
- Pneumotachograph can be located internal to the PAP device enclosure Reply, 10-11.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

36

PO Misrepresents the Record

PO Argues:

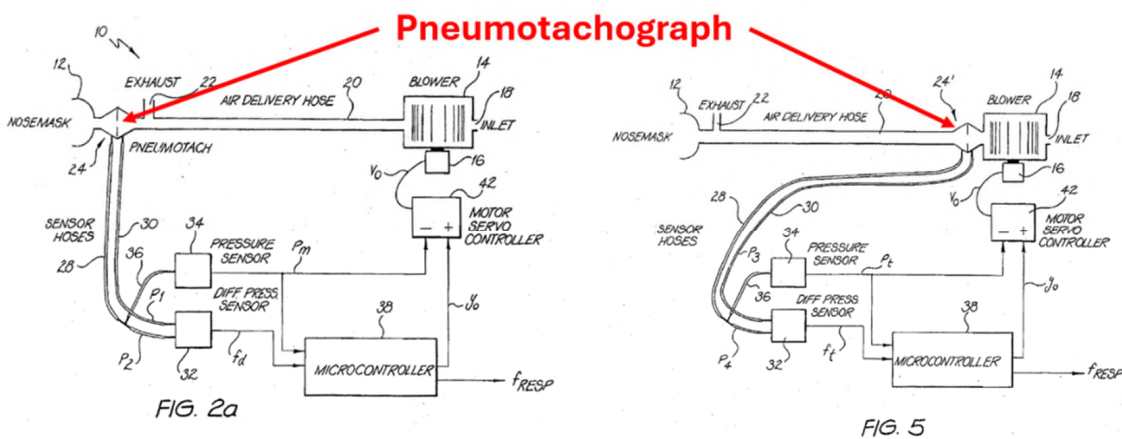
Third, Petitioner has not established that it would have been obvious to relocate Genger's pneumotachograph based on the teachings of Berthon-Jones because Berthon-Jones' airflow sensor is not a pneumotachograph. *See* Borkholder Decl. at ¶ 46. A POSITA would recognize that pneumotachographs directly sense a patient's respiratory airflow, whereas the airflow sensor disclosed in Berthon-Jones measures respiratory airflow indirectly. *See id.* at ¶ 46 (citing Ex. 2015 at 8:31-62). Accordingly, Berthon-Jones does not establish that "POSITA would have found it obvious to locate [Genger's] airflow sensor internally because that location was common," as Dr. Sharony states, because that location was not common or possible for pneumotachographs. *See* Borkholder Decl. at ¶¶ 46-47; Ex. 1004 at ¶ 86.

PO Resp., 20-21.

- Genger discloses a "flow sensor unit" does not say "pneumotachograph"
EX1005, 10:26-27
Reply, 8.
- Petition relies on Farrell, not Berthon-Jones for disclosure of *internal* sensor
Reply, 12, 14.
- PO is wrong that it was not "common or possible for pneumotachographs" to be located internally to a PAP device – relies solely on unsupported expert testimony
Reply, 10-11.

PO Misrepresents the Record

EX1030 (also to Berthon-Jones):



- Fig. 5 “removes the pressure sensing hoses and pneumotachograph from the region of the mask 12.”
EX1030, 8:15-16, Fig. 2a, 5

Ground 6 (Claim 15) – Kocinski and Farrell

- Kocinski and Farrell render obvious “an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject”
(Pet. 64-65)
 - PO’s Response relied exclusively on its arguments for Ground 1
(POR, 34-35)
 - PO’s Sur-reply raised new arguments
(PO Sur-reply, 24-26)
 - “Patent Owner is cautioned that any arguments not raised in the response may be deemed waived.”
(Paper 24 at 9)

Internal Airflow Sensor – PO's Sur-Reply Arguments

- 1) Board should reject new arguments as untimely
- 2) PO's new arguments contradict its characterization of '269 patent disclosure
- 3) Board correctly found that Farrell's pneumotachograph is a device for measuring airflow

Paper 23 (I.D), 49

'269 Patent:

present invention includes a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit 314. The flow information

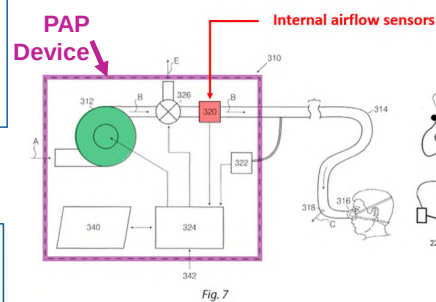
'269 Patent (EX1001), 23:8-10.

Farrell:

13. Optionally, a flow sensor 4f and/or pressure sensor 4p may also be utilized in which case mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal $F(t)$, and mask pressure is

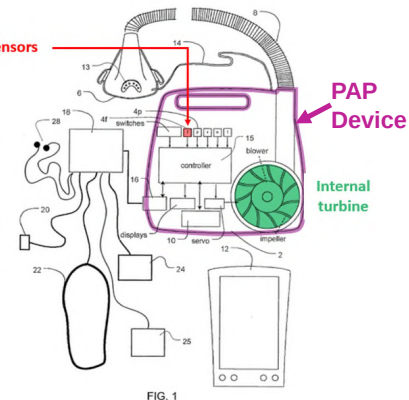
EX1005, 5:5-7.

'269 Patent



EX1001, Fig. 7.

Farrell



EX1008, Fig. 1.

Nonvolatile Memory (Claim 5)
Ground 1: Genger (Ex. 1005) and Westbrook (Ex. 1007)

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Genger Renders Obvious Nonvolatile Memory

5.pre	A sleep disorder treatment system comprising:
5.a	a data acquisition system;
5.b	a positive airway pressure (PAP) device; and
5.c	a processor;

* * *

5.f.2	the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.
-------	--

- *No dispute it was a known advantage to not lose data when power is removed*

Reply, 16-18.

Genger Renders Obvious Nonvolatile Memory

1) PO wrongly limits Genger's disclosure to "immediate transmission" and memory for the modem

humidifier. Optionally, the controller determines trend data from the sensor signals, which it transmits via modem 7 and the PSTN public telephone network to a server 94 in the hospital, or to a server 96 of a national organization, for example a health insurance company or also to a medical and health care supplier 101 (cf. Fig. 8).

EX1005 (Genger), 12:22-25.

2) PO wrongly limits Westbrook's flash memory to a flash card

patient's physiological parameters. The micro-controller has an associated flash memory 44, such as a multi-media flash memory card, capable of storing forty hours of sleep data, and a high-speed data transfer connection 46 to a multi-media flash card reader or an RS-232 serial interface for uploading and downloading data to and from the physiological monitoring system 12 to a host computer system 20, an on/off switch 50, and an LED diode 52 for indicating operation status of the physiological monitoring system.

EX1007 (Westbrook), [0058].

Petition, 46; Reply, 16-18.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Transmission and Display of Data
Ground 6: Kocinski (Ex. 1012) and Farrell (Ex. 1008)

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

44

Claim 15 – Kocinski and Farrell

15.d	a base station, cellular phone, or PDA;
15.e	the first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and the data of usage to the base station, cellular phone or PDA ;
15.f	the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display, the base station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.

- PO does not dispute that Kocinski discloses a “base station,” or that alternatively, Farrell discloses the claimed “PDA”
- PO does not dispute Kocinski and Farrell disclose symptom data
- PO ignores disclosures that symptom data is transmitted and retransmitted
- PO’s “display” argument mischaracterizes the Petition and prior art

Kocinski – Figure 1

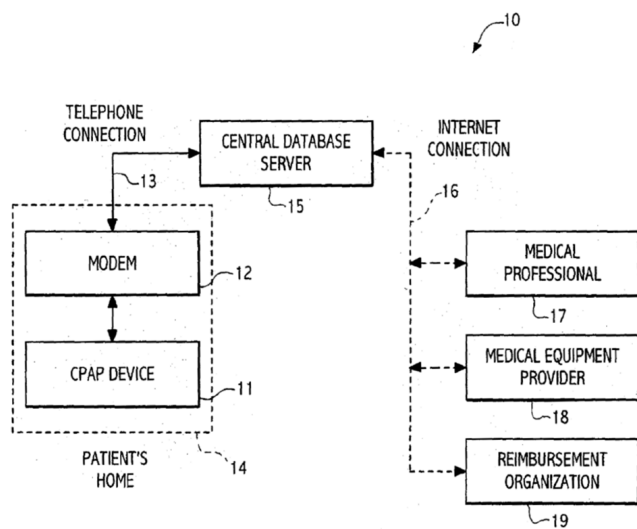
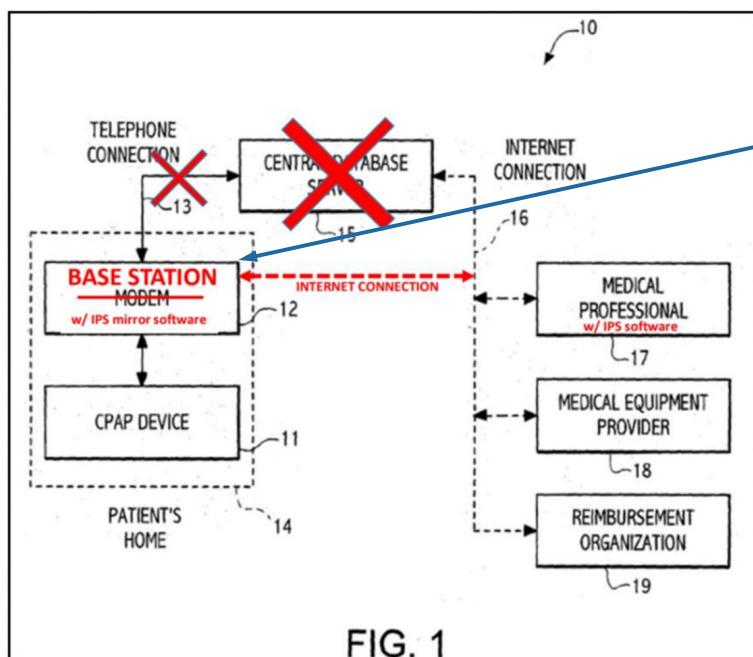


FIG. 1

[0035] Two-way communication between the CPAP apparatus 11 and the central database server 15 is accomplished via an internet processing system (IPS). The IPS collects compliance data and other parametric data from the CPAP apparatus 11 in the patient's home 14, transmits the data to a central database server 15, for example, by the telephone connection 13 via the modem 12, and makes the data available to the medical professional 17, the medical equipment provider 18, and the reimbursement organization 19 via the internet connection 16. The IPS permits the medical professional 17 and the equipment provider 18 to control the parameters of the CPAP apparatus 11 via the internet connection 16 to the central database server 15 and further to the CPAP apparatus 11 in the patient's home 14 via the telephone connection 13. Additionally, the IPS prompts the

EX1012 (Kocinski), [0035].

Kocinski – Computer Embodiment

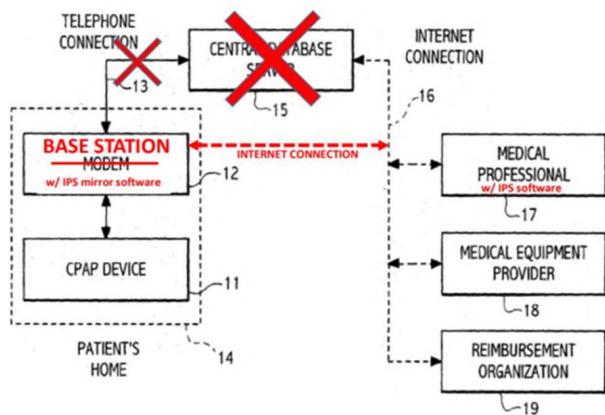


Petition, 70 (annotating EX1012 (Kocinski), Fig. 1).

[0049] It should be appreciated that the CPAP apparatus 11 can optionally be connected directly to a computer (not shown). The computer can communicate with the central database server 15 via the modem 12 or can have the same software as the central database server 15 and thus function as the central database server 15 and bypass the modem 12. The direct connection can be set up via a “Direct Connection” window 86, as shown in FIG. 12, by selecting “Direct Connection” from the menu selection of the IPS. This will establish communication between the CPAP apparatus 11 and the computer. Compliance data can be downloaded to the computer and settings can be sent to the CPAP apparatus 11 via an internet connection 16 simply by pressing the “Exchange Data” button in the “Direct Connection” window.

EX1012 (Kocinski), [0049].

Kocinski Discloses the Claimed Data is Transmitted/Retransmitted



[0028] Depending on the sophistication of the CPAP apparatus 11, different amounts of data may be collected and transferred to the central database server 15. At a minimum, it is preferable that the CPAP apparatus 11 collect and transfer information on patient usage compliance of the CPAP apparatus 11. Information may be collected and stored regarding the output pressure, startup delays and pressures in which a lower pressure is initially applied to the patient, and the frequency and nature of events detected while the patient sleeps, such as apnea events, maintenance warnings. The CPAP apparatus 11 may be programmed, for example, to send a message to the central database server 15 which is relayed to the medical professional 17 if the number of apnea events per hour exceed a programmed threshold, or if the number of hypoapnea events per hour exceed a programmed threshold, or if the blood desaturation exceeds a programmed threshold. The CPAP apparatus 11 also can be programmed to send a message to the medical professional 17 via the central database server 15 if there is no or very little patient usage of the CPAP apparatus 11 over a predetermined period of time, such as a preset number of days. The medical professional 17 may program multiple thresholds for the patient in the CPAP apparatus 11. The maintenance warnings may be made available only to the medical equipment provider 18 and the pressures and sleep events may be made available only to the medical professional 17, since others do not need this information. The CPAP appa-

“apnea events”

Threshold message example

Kocinski – Display

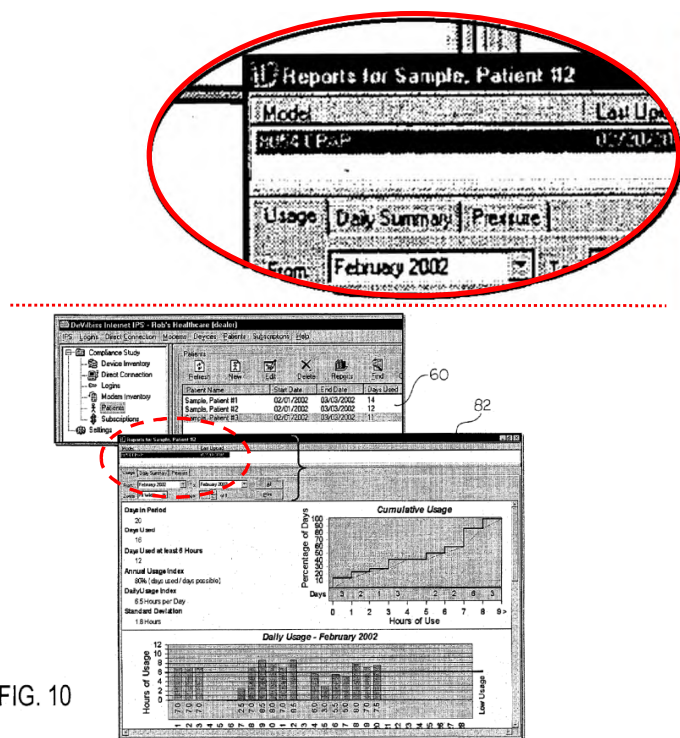


FIG. 10

Petition, 71-72, 74-75; Reply, 26-27.

[0045] After the initial call to the central database server 15, the modem 12 can automatically call in data to the center database server 15 at certain time intervals, as indicated in function step 42. During the call, data will be immediately transferred from the CPAP apparatus 11 to the central database server 15, which stores and analyzes usage compliance data. If non-compliance behavior is detected, the medical professional 17 can be remotely notified by email. Authorized users will get reports, such as the report 82 as illustrated in FIG. 10. Reports can be viewed by selecting a patient from the "Patient" window 60. This is accomplished by highlighting the patient and then clicking the "Reports" button. To view the patient's compliance data, the viewer can scroll through and select a period, such as a month, or select all and print a graph. Reports will vary depending on the model of the CPAP apparatus 11. The patient's name will appear in the title bar of the window. Tabs can be used to move between reports.

EX1012 (Kocinski), [0045], Fig. 10.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petition: Kocinski Discloses or Renders Obvious “Display”

that communicates with the CPAP. Being a base station (or PDA), POSITA would understand it has a processor that, using software, controls its communications, settings, and a display to assist the user with connecting the base station to the CPAP and to an external network, and **to display information like Kocinski’s Figures 10-12**. EX1004, ¶147.

Petition, 71-72.

Kocinski displays patient-specific data (*e.g.*, Figure 10), and to the extent Figure 10 does not explicitly display the calculated symptom data and/or index (or usage data), POSITA would have found it obvious to do so, and likewise to display such information on the base station (or PDA). Motivation would have been to allow the patient, patient’s family, and visiting medical professionals to see the patient’s data on-site, and because “two-way” **Internet Processing Software (and its displays in Figures 3-8, 10-12) is necessarily present on the home-located base station in order to exchange data with the IPS software at third parties 17-19**. *See* Kocinski, [0035]-[0039], [0049], Figure 12. EX1004, ¶149.

Petition, 74-75.

Kocinski – Reports Not Limited to Medical Professional

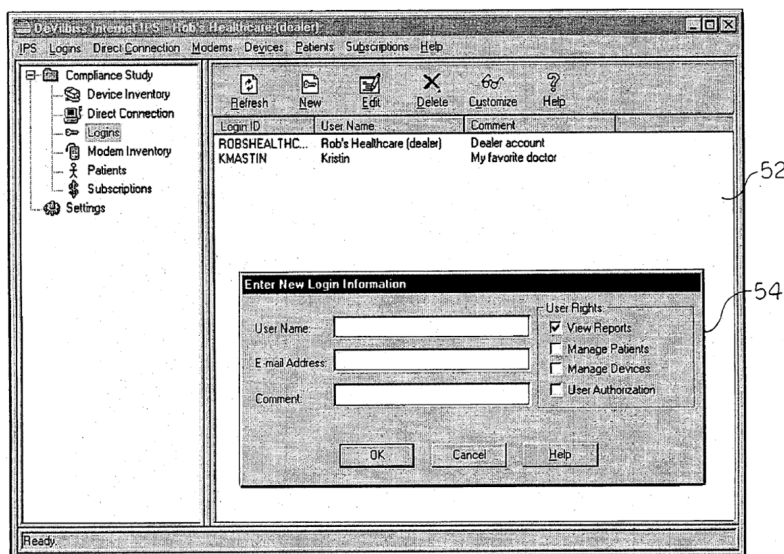


FIG. 5

[0035] Two-way communication between the CPAP apparatus 11 and the central database server 15 is accomplished via an internet processing system (IPS). The IPS collects compliance data and other parametric data from the CPAP apparatus 11 in the patient's home 14, transmits the data to a central database server 15, for example, by the telephone connection 13 via the modem 12, and makes the data available to the medical professional 17, the medical equipment provider 18, and the reimbursement organization 19 via the internet connection 16. The IPS permits the medical

EX1012 (Kocinski), [0035].

[0039] Authorized users and viewers can be entered, as indicated in function step 26, through a "Login" window 52, as shown in FIG. 5, that can be opened by selecting "Login" from a menu selection. To make a new entry, click the "New" button in the "Login" window. An "Enter New Login Information" window 54 will solicit new login information, such as the user name, email address, and optional comments. User rights, such as permission to view reports, manage patients, manage devices, and user authorization, can be entered, as indicated in function step 28, for example,

Farrell Discloses a “PDA”

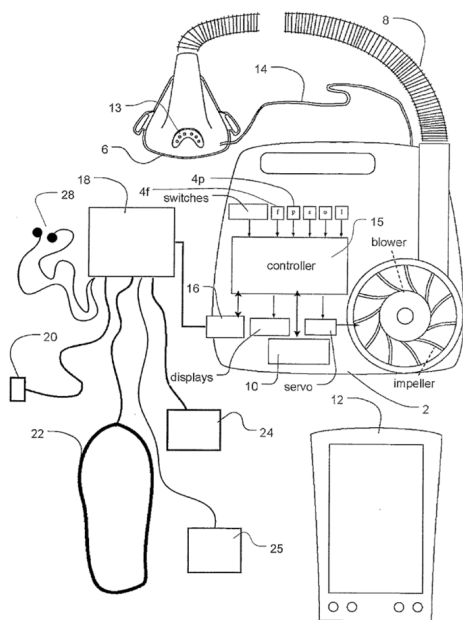


FIG. 1

The apparatus preferably also includes a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12. The apparatus may further include additional interface 16 for connection

EX1008 (Farrell), 5:28-31, Fig. 1.

While this apparatus is generally described as a single unit, it is understood that a combination of devices and/or computers linked by any available communications method may be used to accomplish the goals of the invention. For example, the apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication or it may interface with a network for transmission between the devices. With such a device or system, a physician may,

EX1008 (Farrell), 6:20-25.

Claims 8-14

Ground 3: Stahmann (Ex. 1010) and Edgar (Ex. 1011)

Ground 4: Stahmann, Edgar, Schmidt (Ex. 1006)

Ground 5: Stahmann, Edgar, Paradiso (Ex. 1009)

Claim 8

8.pre	A sleep disorder treatment system comprising:
8.a	a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and
8.b	a positive airway pressure apparatus for providing pressurized air and <i>dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent</i> , the positive airway pressure apparatus comprising a controller adapted to <i>adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder</i> from the data acquisition system.

Stahmann Discloses Chemically Treating a Sleep Disorder With a Pharmaceutical Agent

8.b a positive airway pressure apparatus for providing pressurized air and *dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent*, the positive airway pressure apparatus comprising a controller adapted to *adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system.*

Drug therapy may also be used to treat disordered breathing. Drugs may be delivered to the patient through one or more automatically controllable drug delivery devices, e.g., a drug pump, a controllable nebulizer, or an electrically activated drug patch, for example.

EX1010 (Stahmann), 236:12-15, 273:3-6; Pet. 55.

Stahmann Discloses “adjust[ing]”

8.b a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure apparatus comprising a controller adapted to **adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system.**

The flowchart of Figure 54C illustrates a method of providing feedback information in accordance with an embodiment of the invention. The monitoring device senses 5430 one or more patient conditions associated with sleep. Sleep is detected 5432 based on the sleep-related conditions. The monitoring device senses 5434 one or more conditions associated with disordered breathing during sleep. One or more disordered breathing events occurring during sleep are detected 5436. **Characteristics of the sleep disordered breathing events, such as, severity, frequency, and/or duration, may be determined 5438.** Determination of the one or more characteristics of the sleep disordered breathing events may involve calculation of one or more indices characterizing the disordered breathing events. The indices may include, for example, an apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB), among other indices. **Feedback information is provided 5440 to a device delivering therapy for sleep disordered breathing based on the one or more characteristics of the sleep disordered breathing events.**

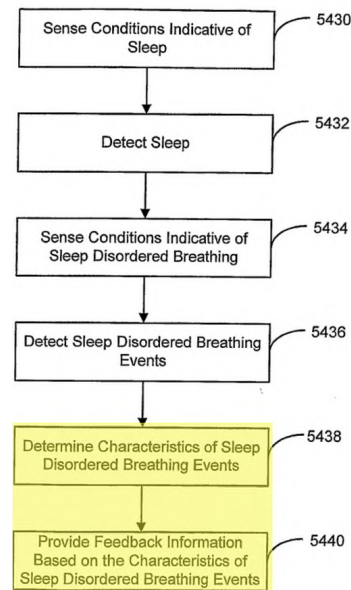


Figure 54C

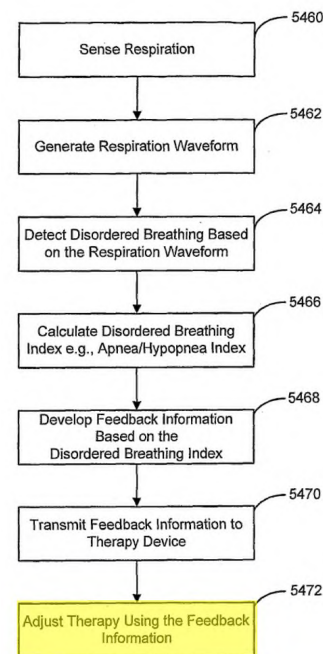


Figure 54E

Petition, 50-51, 53-57; Reply, 18-20. EX1010 (Stahmann), 241:31-242:9; Pet. 54-55.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Edgar Discloses a System for Providing a Pharmaceutical Compound to a Patient Via a CPAP Device

Petition:

POSITA would have found it obvious, and expected success, by using Edgar's pharmaceutical delivery in Stahmann's adjustable-therapy PAP device. The motivation would have been to let patients "sleep better and more soundly" (Edgar, [0364]) to accomplish Stahmann's goal of improving patient's sleep through therapy feedback. EX1004, ¶124.

Petition, 56-57;
EX1004, ¶124.

Edgar:

[0407] In one aspect, the compound of the invention is administered in conjunction with a CPAP device to promote sleep. In another aspect, the compound of the invention is administered in conjunction with a CPAP device to improve sleep. In another aspect, the compound of the invention is administered in conjunction with a CPAP device to improve compliance regarding with CPAP treatment. Without wishing to be bound by theory, it is thought that by administering an effective amount of a sleep promoting compound of the invention to a patient in conjunction with CPAP treatment, the patient will sleep better and more soundly and therefore, not be as likely to remove the mask.

EX1011, [0407]-[0409]; see
[0392]-[0393].

Additional Slides

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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POSITA Definition

A. Level of Ordinary Skill in the Art

A POSITA as of the priority date of the Challenged Patent (November 4, 2005) would have had a bachelor's degree in mechanical engineering, electrical engineering, computer science or an equivalent field and two years of industry experience working with diagnostic sensor systems and networked data systems. An increase in experience could compensate for less education, and vice-versa. EX1004, ¶70.

Petition, 24; POR, 8.

PO's Expert's Admissions

28. Stahmann discloses adjusting breathing therapy based on AHI (Ex. 1010 at 232) and adjusting a drug therapy based on the patient's cardiopulmonary status (Ex. 1010 at 302). A medical professional would understand that treatments for different conditions are not interchangeable, so there is no medical basis undergirding Dr. Sharony's attempt to suggest an "obvious" treatment for a sleep disorder based on the level of severity of the patient's sleep disorder symptoms from the disclosure of providing drug therapy to a patient suffering from a cardiopulmonary disorder.

EX2018 (Patil Declaration), ¶128.

1789. Rebuttal regarding file history. Mr. Irving and Dr. Jensen argue that statements that CleveMed made in response to ResMed's IPR petition somehow support materiality of the disclosure of Truitt. Irving Report, ¶¶82-84; Jensen Report, ¶445. I disagree with these opinions. In attempting to support these opinions, Mr. Irving and Dr. Jensen cite to the portion of CleveMed's response to ResMed's IPR petition where CleveMed provided background describing the '269 Patent, which included cites to portions of the '269 Patent that Mr. Irving and Dr. Jensen argue correspond to portions of Truitt (i.e., Figure 7 and 23:7-17 of the specification), and where CleveMed described Figure 7 as an "exemplary embodiment of the CPAP device." POPR, 4-6. This description is consistent with the '269 Patent specification, which as explained above, makes clear that that Figure 7 shows "a conventional pressure support system," and "a particular type of physical treatment device known as [CPAP] device." Thus, these statements in the IPR proceeding provide no support for materiality of Truitt.

EX1032 (Borkholder District Court Declaration), ¶1789.

Reply, 20.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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DEMONSTRATIVE EXHIBIT – NOT EVIDENCE