



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/019,705	10/17/2024	11786680		1083

31013 7590 07/24/2025
Herbert Smith Freehills Kramer (US) LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

REICHLE, KARIN M

ART UNIT	PAPER NUMBER
----------	--------------

3992

MAIL DATE	DELIVERY MODE
-----------	---------------

07/24/2025

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DO NOT USE IN PALM PRINTER

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

GREENBERG TRAURIG, LLP (BOS)
ONE INTERNATIONAL PLACE, SUITE 2000
ATTN: PATENT ADMINISTRATOR
BOSTON, MASSACHUSETTS 02110

***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/019,705.

PATENT UNDER REEXAMINATION 11786680.

ART UNIT 3992.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

DETAILED *EX PARTE* REEXAMINATION FINAL ACTION

This Office Action is responsive to Patent Owner's response filed June 9, 2025 hereinafter also referred to as the Response, in this *ex parte* reexamination of claims 1-32 of US Patent No. 11,786,680 (hereinafter also referred to as '680 or Kayyali '680) for which a Substantial New Question of Patentability affecting claims 1-32 of '326 has been deemed to exist.

The status of the claims is as follows:

Patent claims 1-32 as well as new claim 33 are rejected.

Patent Owner Response

The Response filed on June 9, 2025 by Patent Owner included claim amendments and remarks. The amendments added claim 33.

The amendment is in improper reexam format. All new claims, i.e. claim 33, must be entirely underlined, including the numeral and parenthetical. See 37 CFR 1.530(f)(2) and MPEP 2234.

Applicant should file a corrected amendment in response to this office action.

Response to Patent Owner's Arguments

Sections I-V

Pages 8-11, Sections I-V have been considered. With regard to Section II, it is noted that a decision to institute trial was rendered on June 13, 2025.

Section VI-A. Ground 1: Claims 1-26 and 28-32 are Patentable over Sun in View of Quy

1. Claim 1: Sun Does Not Disclose Calculating a Quantitative Measure of Symptom Severity or PAP Therapy Efficacy Data

As an initial matter and as set forth in the last paragraph of page 11 of the non-final Office Action (NFOA), the claim limitation at issue is:

a second processor adapted for **generating** the PAP therapy efficacy data¹ **based on** a first data and a second data by receiving the sensor data², and calculating both

- 1) the first data **related** to a quantitative measure of symptom severity during use of the PAP device and
- 2) the second data **related** to a usage of the PAP device by the subject.

(bold emphasis added). Therefore, as shown in bold emphasis above, claim 1 does not recite calculating a quantitative measure of symptom severity nor calculating PAP therapy efficacy data.

Continuing, the Response on pages 11-12 begins:

As a preliminary matter, Patent Owner respectfully submits that the Office Action is not in compliance with the Administrative Procedure Act or 37 C.F.R. § 1.104(c)(2) because the portion of Sun that the Examiner contends teaches this limitation is not “apparent” or “clearly explained.” After several quotations to portions of Sun and Axe (which Sun incorporates by reference) that do not “apparently” disclose the claimed “quantitative measure of symptom severity,” the Examiner concludes with the following summation, which also does not identify what the Examiner contends is the “quantitative measure of symptom severity”:

Therefore, ‘973/[sic]747 teaches a PAP device, e.g., device 54 used for treating sleeping disorders or symptoms of a subject having a compressor/blower with an output, a sensor internal to the device for measuring air flow, a mask, a processor receiving the sensor data and **generating/calculating efficacy data which is based on data related to quantitative symptom severity data and PAP/mask usage data, e.g., ‘mask off’ data**, and an rf frequency bidirectional

¹ See section A., i) of claim 1, i.e. “a PAP therapy efficacy data or a modified PAP therapy efficacy data based in part on the PAP therapy efficacy data both based on treatment of the subject and its efficacy in whole or in part”. It is noted that the terminology “PAP therapy efficacy data” only appears in the claims.

² See section C., 2), i.e., “a sensor for providing a sensor data to determine airflow, the sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of the subject while using the PAP”.

information transmission/rf link between the device 54 and patient interface appliance 44.

NFOA at 21-22 (emphasis added). In particular, it is unclear to Patent Owner whether the Examiner contends that the “mask off” data is (1) “the PAP therapy efficacy data based on a first data and a second data, (2) “the first data related to a quantitative measure of symptom severity data during use of the PAP device,” or (3) “the second data related to a usage of the PAP device by the subject.”
[sic]680 Patent at Claim 1.

However, the cited paragraph singled out from pages 21-22 of the NFOA by PO, refers back to, i.e. “Therefore..”, the prior seven pages of describing the teachings of Sun/Axe. As set forth above Patent Owner merely summarizes the prior seven pages as “several quotations to portions of Sun and Axe (which Sun incorporates by reference) that do not ‘apparently’ disclose the claimed ‘quantitative measure of symptom severity,’ ...”. However, and as also set forth in the rejections below, those portions of the NFOA not only referred back to the discussion of the preamble of claim 1 but also to ‘973 (Sun) at, e.g., Figures 2-3, element 54, and ¶¶[0054], [0058]-[0060] (“....To achieve that auto-titration pressure support, where the pressure level varies with the condition of the patient, for example by increasing the pressure levels if the patient experiences snoring, apneas, or obstructed breathing, the present invention contemplates providing other sensors, such as a microphone, respiratory belt, and oximeter, either alone or in combination with flow and/or pressure sensors 63 and 65, for monitoring the condition of the patient and controlling the pressure support based thereon.”), [0092] (“...In a more sophisticated example, the medical device that the patient has been prescribed, such as a CPAP device, has the ability to monitor the patient's use of the device and report such use directly to the medical information management system without any patient interaction. The compliance data gathered...) and [0061]-[0062] (“...Examples of an auto-titration system pressure support system are disclosed in U.S. Pat. Nos. ... 6,085,747 all to Axe et al. ...”), and to the entirety of, e.g., U.S

Patent No. 6,085,747 (e.g., Fig. 1, compressor 43, differential pressure transducer 45, processor 57, mask 39, abstract (“A system including methods and apparatus for treatment of a medical disorder such as obstructive sleep apnea or congestive heart failure. ... a flow sensor that determines the estimated patient flow rate. A leak computer can be included to instantaneously calculate gas leakage from the system.”), col. 2, lines 27-57 (“The method and apparatus of the invention provide for the detection and control of sleep disorder breathing in a person. ... For sleep, a patient is fitted with a nasal mask adapted to deliver air from a source of compressed air to the patient's nasal passages. A hose connects the compressed air source and nasal mask.

Detection of sleep disorder breathing involves monitoring of face mask pressure and pressure difference (ΔP) between two spaced points along the hose. Specific conditions, including occurrence of apnea, hypopnea and pharyngeal wall vibration are identified.

Also detectable are nasal mask problems such as dislodgement of the mask or leakage from the mask. Inhalation and exhalation by the patient are also detected. Diagnosis of apnea, hypopnea, pharyngeal wall vibration and complete or partial closure of the breathing path is based on measurements of breathing by the patient. Pressure selection is microprocessor controlled and is responsive to detection of specific conditions. Pressure may be adjusted to multiple levels during and following occurrences of sleep disorder breathing. Increased pressure for inhalation, exhalation, or both may be used to suppress sleep disorder breathing, with the pressure level adjusted to achieve suppression of the condition. Mask dislodgement results in reduction of pressure to a minimum level. (emphasis added), col. 3, lines 37-60

(“... The differential pressure transducer 45 senses the dynamic pressure difference between the output of the compressor 43 and the mask 39. Differential pressure transducer 45 has one sensing tube 46 connected to the interior of mask 39. Another sensing tube 47 connects to the output of

compressor 43. Mask sensing tube 46 is downstream from output pressure sensing tube 47. **The pressure difference between sensing tubes 46 and 47 corresponds to the quantity of air flow through the hose 41. Normal breathing causes the difference in pressure sensed by the pressure transducer 45 to fluctuate.**) (emphasis added), and col. 4, lines 10-44 (“The microprocessor 57 is programmed to sample the incoming signals from converter 55 at a rate of 4000 times per second and process the sampled signals at the rate of 10 times per second. For every 400 pressure difference values collected, a mean pressure difference value and a pressure difference standard deviation value are calculated and stored. The mean pressure difference value calculation is, in effect, a low pass filter, whereas the standard deviation calculation is, in effect, a high pass filter. The mean pressure difference values are used to calculate a mean pressure difference base line, which is arbitrarily defined as the signal level dividing inspiration and expiration. If the mean value is larger than the pressure difference base line value by a threshold for more than 15 seconds, the algorithm responds with a ‘mask off’ signal. Experience has shown that if the mask 39 is removed, the pressure difference becomes very large and will exceed an pressure difference base line value established before the mask was dislodged. The microprocessor 57 algorithm uses the pressure difference standard deviation values to calculate the energy of disturbances in the pressure difference signal greater than an arbitrarily defined threshold. The threshold level is determined according to the following formula: $\text{standard deviation threshold} = (\text{command pressure} - A) * B + C$ where A, B and C are fixed empirical values that set the threshold above the level of disturbances caused by ordinary turbulence in the hose 41. Alternately, the standard deviation threshold values could be adaptive and changed based on past standard deviation values calculated for the person utilizing

the mask 39. If the standard deviation value is equal to zero for 10 seconds then the system responds with a 'power off' signal.”³(emphasis added.).

Accordingly, '973/'747 teaches a PAP device having a sensor 45 (sensing tubes 46-47) for providing a sensor data to determine airflow, the sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of the subject while using the PAP device and a processor which receives such airflow data and calculates data, e.g. mean pressure difference value and a pressure difference standard deviation values, related to a quantitative measure of symptom severity (e.g. “apnea, hypopnea, pharyngeal wall vibration and complete or partial closure of the breathing path”), and related to a usage of the PAP device by the subject (e.g. mask being used/on or mask not being used/off) as was also summarized in the singled out paragraph cited above. Therefore, the reference to “, e.g., ‘mask off’ data” referred back to data related to usage of the PAP device by the subject, i.e. “PAP/mask usage data”.

The processor of Sun/Axe is also adapted to generate PAP therapy efficacy data based on a first data and a second data (e.g. “Pressure selection is microprocessor controlled and is responsive to detection of specific conditions. Pressure may be adjusted to multiple levels during and following occurrences of sleep disorder breathing. Increased pressure for inhalation, exhalation, or both may be used to suppress sleep disorder breathing, with the pressure level adjusted to achieve suppression of the condition.”) See again “the entirety of, e.g., U.S Patent No. 6,085,747”, e.g., Figs. 9-23, col. 7, line 3-col. 12, line 21 and claims 1-6.

Patent Owner continues on page 12:

³ Col. 4, lines 10-44 also conversely describes mask on data/determination, i.e. when the average measured pressure difference between the mask and compressor does not exceed a baseline value for more than 15 seconds. Note also, e.g., Fig. 22 of Axe.

To the extent that the Examiner contends that Axe's "mask off" [sic] signal is a "quantitative measure of symptom severity" or the PAP therapy efficacy data, Patent Owner respectfully traverses the Examiner's rejection. Axe's "mask off signal" is generated when the average measured pressure difference between the mask and compressor exceeds a base line value for more than 15 seconds. Axe at 4:10-44 ("Experience has shown that if the mask 39 is removed, the pressure difference becomes very large and will exceed an [sic] pressure difference base line value established before the mask was dislodged."). Because such a signal is sent when the patient's mask is off, neither the signal nor the pressure data used to determine the signal accurately represents the patient's respiratory airflow or sleep-disordered breathing symptoms. And if the signal and pressure data cannot even be used to detect the patient's symptoms (because the mask is off and not accurately measuring the patient's respiration), it plainly cannot represent "a quantitative measure of symptom severity," as claimed. Sun's mask off signal also cannot represent the PAP therapy efficacy data, which must be "based on treatment of the subject," as claimed. However, because the mask-off signal is sent when the patient's mask is off, neither it nor the underlying data, is "based on treatment of the subject."

However, it is again noted that the claim does not require "a quantitative measure of symptom severity" but rather calculated "data related to a quantitative measure of symptom severity." Furthermore, as discussed above it is not contended that the "mask off" signal represents "a quantitative measure of symptom severity". However, Examiner disagrees that Axe's mask usage determination is not representative of the PAP therapy efficacy data. As claimed, the PAP therapy efficacy data as claimed is "based on treatment of the subject and its efficacy in whole or in part" and "generating the PAP therapy efficacy data based on a first data and a second data". Even if the patient's mask is off, i.e. first data related to usage of the device or in this case, no or partial use of the mask, such still generates PAP therapy efficacy data representative of "treatment of the subject and it's efficacy in whole or in part, e.g. treatment of the subject, e.g. none or partial, and it's efficacy in whole or in part, e.g. none or partial,

On pages 12-13 Patent Owner further advances:

In any event, Sun does not disclose or suggest equipping a PAP device with a processor that generates therapy efficacy data based on "first data related to a

quantitative measure of symptom severity during use of the PAP device.” Rather, Sun discloses the type of PAP device “automatically adjust the gas pressure based on sensors built into the device” distinguished in the 680 Patent. ’680 Patent at 2:32-33.

Any suggestion that Sun discloses this limitation merely because it discloses the ability to detect the patient’s symptoms would rely on overly-broad interpretation of the term “quantitative measure of symptom severity.” The ’680 Patent discloses quantitatively determining or estimating the patient’s condition based on data from one or more sensors fed into one or more algorithms. ’680 Patent at 26:20-41. As the Board determined for a related patent, such data requires a quantitative determination of the severity of the symptoms, not the mere identification of an event. **PGR2024-00012, Paper 7 at 16** (“*Based on the above disclosures in the specification, we agree with Patent Owner that the specification discloses that the gathered information is processed to monitor the condition of the subject (i.e., the system quantitatively estimates or determines the ‘severity of sleep disorder symptoms’) and how much pressure/flow of gas is to be provided to the subject (i.e., the system calculates the ‘usage of the PAP device by the subject’).*”). While detected snoring, apnea, and hypopnea events may represent detected symptoms, they are not “PAP therapy efficacy data based on a first data and a second data” or “first data related to a quantitative measure of symptom severity during use of the PAP device,” as claimed. Emphasis added.

Thus, rather than calculating severity data,...

However, the Board’s determination in the PGR of the related patent, i.e. 11,602,284, regarding written description support for different claim language⁴ construed according to a different construction standard⁵ is not persuasive with regard to the interpretation of the claim language of claim 1 set forth above. In any case, the Board’s discussion appears to set forth that processing of gathered information to monitor the condition of the subject is representative of “the system quantitatively estimates or determines the ‘severity of sleep disorder symptoms’”. See again the

⁴ I.e. “the data of severity of sleep disorder symptoms of the subject”, as compared to the instant claim language, i.e. “data related to a quantitative measure of symptom severity”.

⁵ I.e. *Phillips v. AWH Corp.* (PGR2024-0012, Paper 7 at page 8) v. *In re Yamamoto*, see Claim Interpretation section below.

cited portion of Axe discussed above with regard to processing of gathered information to monitor the condition of the subject.

PO continues:

Thus, rather than calculating severity data, Sun's conventional PAP device merely receives flow and/or pressure signals and adjusts the flow or pressure accordingly:

As shown in FIG. 4, a pressure generator 59, which preferably operates under the control of processor 47, generates a flow of breathing gas, as indicated by arrow A, for delivery to an airway of patient. With an appropriate pressure controller 61, such as a pressure control valve, and/or through controlling the operating speed of pressure generator 59, the patient interface appliance provides variable pressure levels to the patient, either during each respiratory cycle[sic], as done by a ventilator or bi-level pressure support system, or over periods of time, as done by an auto-titration pressure support system [sic] or by a CPAP device with a selectable pressure level or a pressure level that can vary in some manner, such as a ramp pressure [sic], which allows the patient to receive a low pressure while trying to fall asleep and gradually increases.

Sun at ¶ [0059]. Using this feedback technique, conventional PAP devices like Sun's could (1) provide bi-level pressure support, where the pressure different during inspiration and expiration, or (2) auto- titrate pressure to counteract or prevent "snoring, apneas, hypopneas, etc." *Id.*; *see also id.* at ¶ [0059]- [0061]. Accordingly, while Sun discloses detecting sleep disorder symptoms like the conventional PAP devices distinguished in the 680 Patent, Sun does not disclose calculating "first data related to a quantitative measure of symptom severity during use of the PAP device" or PAP therapy efficacy data based on such "first data."

The balance of Sun's specification also fails to teach or suggest a processor that calculates "quantitative measure of symptom severity." For example, Sun discloses allowing the patient to "review, at least in a summary form, the information provided by that patient to the patient interface appliance." Sun at ¶[0129]. However, the data presented is merely flow data. *Id.* at ¶[0130]. It is not symptom data (e.g., the detection of an apnea event), let alone a "quantitative measure of symptom severity." Accordingly, while Sun discloses a PAP device is able to adjust pressure or flow in response to pressure or flow signals, but does not disclose a processor that receives airflow data and calculates data relating to the treatment efficacy or data related to a quantitative measure of the severity of the subject's sleep disorder symptoms. For at least the foregoing reasons, Sun does not disclose "generating PAP therapy efficacy data based on a first data and

a second data by receiving the sensor data,” or calculating “first data related to a quantitative measure of symptom severity during use of the PAP device.”

Again, since the claim language does not require “calculating severity data” or “calculating ‘first data related to a quantitative measure of symptom severity during use of the PAP device.’”, PO’s assertions are not persuasive. Furthermore, PO’s discussion of Sun is devoid of any discussion of the incorporated teachings of Axe, see again, e.g. ¶¶ [0059] and [0061] of Sun.

In any case, it is again noted that the teachings of Sun/Axe describe “the data presented” is more than “merely flow data”. It is “symptom data (e.g., the detection of an apnea event)”, see again Axe at col. 2, lines 27-57 and col. 4, lines 10-44 as well as, e.g., the graphs of Figs. 2-8.⁶ See also Figs. 9-23.

For at least the foregoing reasons and the rejection below, the prior art discloses calculating “first data related to a quantitative measure of symptom severity during use of the PAP device” and “generating PAP therapy efficacy data based on a first data and a second data by receiving the sensor data,”.

2. Claim 27: Sun does not Disclose the Claimed Index

On page 14 of the Response:

Patent Owner respectfully traverses the Examiner’s suggestion that Figure 7E of Sun illustrates an “index of sensor measurement.” NFOA, pg. 27. “FIG. 7E illustrates an example of a physiological parameter display page 284 that is provided to the user” and “illustrates the medical data collected over a period of

⁶ Note again PGR2024-00012, Paper 7 at 16 (“.. gathered information is processed to monitor the condition of the subject (i.e., the system quantitatively estimates or determines the ‘severity of sleep disorder symptoms’) and how much pressure/flow of gas is to be provided to the subject (e., the system calculates the ‘usage of the PAP device by the subject’).”).

⁷ I.e., The system of claim 1, wherein one or more PAP therapy efficacy measure(s) includes an index. See also B. ii) of claim 1, i.e. “ii) outputting one or more PAP therapy efficacy measures(s) on the display of the cell phone for viewing by the subject based in whole or in part on the data received by the first software;”.

time.” Sun, ¶ [0130]. But the Examiner does not explain what makes “medical data collected over a period of time” an “index” in the context of the ‘680 Patent. Although the Examiner states that the “specifics of ‘the index’ have not been claimed,” the term “index” is a term of art, and the ‘680 Patent uses the term as it is commonly used in the art. See, e.g., ‘680 Patent at 18:28-37 (“These accelerometers can be used to detect when patients go to sleep or to detect movements during sleep which are important factors in assessing the actual sleep time which is an important parameter used to generate an accurate assessment of nocturnal respiratory events (such as apnea/hypopnea events, which is the sum of all apneas and hypopneas divided by sleep time; or apnea/hypopnea index [AHI]).”); *see also id.* at 34:2-5 (“Sleep-wake data will be used to determine the total sleep time for the calculation of the apnea/hypopnea index and other sleep related indices.”).

The “physiological parameter display” of Sun’s FIG. 7E is not an “index” of this type, it is merely flow data. For at least the foregoing reasons, Sun does not disclose that “one or more PAP therapy efficacy measure(s) includes an index.”

PO’s assertion are narrower than the claim language, the evidence of record and the teachings of Sun/Axe. As set forth in the rejection, the claim only sets forth “an index”. Continuing, as set forth in the Claim Interpretation section below, the proper meaning of the patent claims is their broadest reasonable interpretation consistent with the specification (see *In re Yamamoto*, 740 F.2d 1569 (Fed. Cir. 1984)). PO asserts that the terminology “index” is “a term of art” and that “the ‘680 Patent uses the term as it is commonly used in the art” as presents two portions of the patent as evidence. The first portion discusses accelerometers used to assess nocturnal respiratory events expressed as an index “[AHI]”. The second portion discusses “sleep-wake” data used to calculate AHI and “other sleep related indices”. Therefore, it appears that the term “index” as proposed/interpreted by PO as being “in the context of ‘680” is a sleep/wake related/type index such as AHI. However, the ‘680 patent also discusses other indices, see, e.g., col. 59, lines 51-62, i.e. “WAVlet index” which is not a sleep related index/type. Therefore, the evidence of record does not support PO’s interpretation of “index” as being the “broadest reasonable interpretation” of the claim language “index”.

Finally with regard to the assertion that Sun's Fig. 7E is not "an index of this type", such assertion is not only deemed narrower than the claim language for the reasons set forth above but also the NFOA and thereby, teachings of Sun as well as Axe incorporated thereby e.g., ("e.g., '973 at [0058]-[0062] (and thereby, '747) [0129]-[0130] and Figure 7E, e.g. index of sensor measurement, and '747 at Tables 1-2 and Figs. 2-8." For example, Figure 7E and Tables 1-2 and Figs 2-8 indicate results of various determinations/measures during PAP therapy treatment.⁸

3. Claim 3⁹: Sun Does Not Disclose Remotely Adjusting a PAP device Based on PAP Therapy Efficacy Data

On pages 15-16, PO contends:

First, as established above, Sun and Quay do not disclose generating or transmitting PAP therapy efficacy data from a PAP device, so there is no basis for the alleged remote adjustment. See Section VI.A.1, *supra*.

Second, Sun and Quay do not disclose this limitation under any reasonable interpretation of "adjusted remotely." As discussed in detail above, Sun discloses a device that immediately adjusts PAP pressure directly to the patient's measured airflow, such as using bi-level pressure support or auto-titration that is incompatible with waiting for input from a remote location. The '680 Patent distinguishes these types of device in its Background section. '680 Patent at 2:32-34 ("Slightly more advanced PAP devices automatically adjust the gas pressure based on sensors built into the device."). Quay does not cure Sun's deficiencies. Indeed, the cited passage from Quay says nothing about remotely adjusting PAP treatment:

In more detail, the present invention provides a method and system for assisting patients to manage a disease or maintain healthy lifestyle by

⁸ See again, e.g., PGR 2024-00012, Paper 6 at 1, ("When the '284 Patent discloses "determin[ing] the level of severity of the subject's sleeping disorder or symptoms" while simultaneously applying treatment, the resulting "level of severity" is an "index of treatment efficacy.")

⁹ I.e. The system of claim 2, wherein the one or more PAP device(s) further comprises an electronic component adapted to utilize a cellular network and allow the one or more PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site.

collecting health-related data and providing information in response to those data by means of a WWD designed to display interactive information through a connection to the Internet. The present invention may be connected to various HMDs, both medical and exercise-related in nature, and may communicate information via a wireless connection such as a wireless Internet connection.

A major advantage of embodiments of the invention is that the same frees the patient from the constraints of wired systems. The same allows users with consumer “off-the-shelf” wireless devices to significantly extend the range of connectivity over that of wired computer, television, or even wireless telemetry systems.

Quy at 6:5-20.

Third, even if Sun and Quy discloses transmitting PAP treatment efficacy data to a remote internet site, the Examiner suggestion that such data “allows the PAP device to be adjusted automatically,” is insufficient to make out a prima facie case of obviousness based on the combination of Sun and Quy because it focuses on what a POSITA could have done at the time of the invention, not what a POSITA would have done. See *ActiveVideo Networks v. Verizon Communications*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (“It also fails to explain why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does.”).

With regard to the first reason, see the discussion of Section VI.A.1, *supra*.

With regard to the second reason, PO seems to assert that the claim language requires adjusting the one or more PAP device from the remote internet site. Such apparent assertion is narrower than the claim language. As set forth in the NFOA claim rejection, the claim does not recite what adjusts the PAP device, i.e. it does not recite that the remote internet site adjusts the device. The cited portions of the art combination/discussion of claim 1 of the NFOA obviously teach or suggest an electronic component adapted to utilize a cellular network,, e.g. connector 165. The cited portions of the art combination/discussion of claim 1 of the NFOA obviously teach or the connector 165 is adapted to allow the one or more PAP devices to be adjusted automatically “remotely”, i.e. remote from the appliance/cell phone or server, see again, e.g.,

‘012 at, e.g., 6:5-20, with PAP therapy efficacy data. The cited portions of the art combination/discussion of claim 1 of the NFOA obviously teach or suggest that such data is communicated to the patient interface appliance/cell phone That is all the claim requires.

With regard to the third reason, the NFOA’s rejection of claim 3 does not contend “what a POSITA could have done” as asserted. If PO is referring back to the combination of Sun/Axe and Quy as set forth with regard to the rejection of claim 1, e.g., the discussion of the prior art rejection of the second transceiver, such rejection also did not contend “what a POSITA could have done” as asserted.

4. Claim 4¹⁰: Sun Does Not Disclose an Index Based on Both the First Data and the Second Data

On page 16, PO asserts:

Patent Owner respectfully submits that the Examiner’s contention that the parametric data shown in Sun’s FIG. 7E [sic] fails because it is merely sensor data from the PAP device, it is not the first data (*i.e.* “a quantitative measure of symptom severity during use of the PAP device”), let alone an index based on such data.

However, PO’s assertion, to the extent understood due to missing words or word, is deemed not persuasive for the reasons set forth above with regard to Section VI.A.1-2, *supra*. For example, the claims do not require “first data (*i.e.* ‘quantitative measure of symptom severity during use of the PAP device’”), PO’s interpretation of “index” is too narrow/unsupported, and the NFOA rejection did not rely on Sun’s Fig. 7 alone.

Section VI.-B. Ground 2: Claim 27 is Patentable Over Sun in view of Quy and Kumar

¹⁰ I.e. The system of claim 2, wherein the index is based on both the first data and the second data from the one or more PAP device(s).

Since PO asserts claim 27 depends from independent claim 1 and is patentable for at least the same reasons discussed above with respect to Ground 1 on page 16 of the remarks, these assertions are found not persuasive for the same reason as set forth with regard to Section VI.A.1, *supra*.

Section VI.-C. The Art Does Not Teach Amended Claim 1 or New Claims 33

On page 16, PO sets forth “[p]atent [sic] [n]ew [c]laim 33 depends from [c]laim 1 and further recites that ‘the first processor is further adapted for predicting the subject’s symptoms prior to onset, and wherein, in response to predicting the onset of the subject’s symptoms, automatically adjusting the subject’s treatment in real time.’” However, this is not what is recited in added claim 33.

The remainder of the remarks on page 16 with respect to claim 33 have been considered but are deemed moot. A prior art rejection of claim 33 has not been presented. See however the discussion of claim 33 *infra*.

References Asserted as Raising a Substantial New Question (SNQ)

(1) U.S. Patent Application Publication No. 2002/0198473 to Kumar et al. (hereinafter also referred to as Kumar or ‘473 (Exhibit C)), filed March 28, 2002 and published December 26, 2002.

(2) U.S. Patent No. 6,644,311 to Patrick W. Truitt et al. (hereinafter also referred to as Truitt or ‘311 (Exhibit D)), filed December 19, 2001 and issued on November 11, 2003.

(3) International Publication No. 2005/096737 A2 to Farrell et al. (herein after also referred to as Farrell ‘737 or ‘737) (Exhibit O)), filed March 30, 2005 and published October 20, 2005.

(4) U.S. Patent Application Publication No. 2004/0129838 to Lisy et al (hereinafter also referred to as Lisy or ‘838 (Exhibit E)), filed January 3, 2003 and published July 8, 2004.

(5) U.S. Patent Application Publication No. 2002/0022973 to Sun et al. (hereinafter also referred to as Sun or '973 (Exhibit F)), filed March 21, 2001 and published February 21, 2002.

(6) International Publication No. 01/450012 to Quy (herein after also referred to as Quy or '012) (Exhibit H)), filed December 16, 2000 and published June 21, 2001.

(7) U.S. Patent No. 6,167,258 to Robert N. Schmidt et al. (hereinafter also referred to as Schmidt or '258 (Exhibit G)), filed October 9, 1998 and issued on December 26, 2000.

(8) U.S. Patent No. 7,378,008 to John Robert Mumford et al. (hereinafter also referred to as Mumford or '008 (Exhibit I)), filed October 9, 1998 and issued on December 26, 2000.

(9) U.S. Patent No. 5,309,921 to Roger A. Kisner, et al. (hereinafter also referred to as Kisner or '921 (Exhibit J)), filed February 11, 1992 and issued on May 10, 1994.

All of the references identified above and the Request have been reviewed and considered.

Availability of Asserted References as Prior Art

Kumar was published in 2002 and Truitt issued in 2003, each of which predates the earliest possible filing date of the '680 patent, November 4, 2005, by more than one year. Farrell '737 was filed on March 30, 2005 and published October 20, 2005, which predates the earliest possible filing date of the '680 patent. Lisy was published July 8, 2004, which predates the earliest possible filing date of the '921 patent by more than one year. As such, Kumar, Truitt and Lisy, qualify as prior art under 35 USC 102(b) and Farrell '737 qualifies as prior art at least under 35 USC 102(a) and 35 USC 102(e).

Sun published on February 21, 2002, Schmidt issued in 2000 and Quy published on June 21, 2001, all of which predate the earliest possible filing date of the '608 patent by more than one year. As such, Sun, Quy and Schmidt qualify as prior art under 35 USC 102(b).

Mumford was filed May 18, 2005 which predates the earliest possible filing date of the '680 patent. Kisner issued in 1994 which predates the earliest possible filing date of the '680 patent by more than one year. As such, Mumford qualifies as prior art under 35 USC 102(e) and Kisner qualifies as prior art under 35 USC 102(b).

Claim Interpretation

As set forth in MPEP 2240, in making the determination of whether to order reexamination, the Office will determine the proper meaning of the patent claims by giving the claims their broadest reasonable interpretation consistent with the specification (see *In re Yamamoto*, 740 F.2d 1569 (Fed. Cir. 1984)).¹¹

Note Section IX on page 34 of the Request.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

¹¹ Cf. "In a reexamination proceeding involving claims of an expired patent, claim construction pursuant to the principle set forth by the court in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) (words of a claim "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in question at the time of the invention) should be applied since the expired claim are not subject to amendment. See *Ex parte Papst-Motoren*, 1 USPQ2d 1655 (Bd. Pat. App. & Inter. 1986). MPEP 2258.

Claim 33 is rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

Added claim 33 recites “[t]he system in claim 1, wherein the second processor automatically adjusts the subject’s treatment in real time in response to predicting the onset of the subject’s symptoms.” The response at page 9, line 4 relies upon “26:50-27:5” (“Various sleeping disorders have symptoms that can be predicted based on various combinations of physiological signals or data. Various embodiments of the present invention include the approach to identifying these symptoms prior to onset by identifying various characteristic shifts in the power spectrum of the sensors being used to monitor these physiological conditions. This characteristic shift in these signals or data can be identified and used to trigger an actuator on the physical or chemical treatment device(s) to provide for delivery of a certain level of treatment. The various embodiments of the present invention include but are not limited to the following signal-processing techniques that are utilized to predict the onset of these symptoms. These are: (i) the standard deviation technique, (ii) a recursively fit ARMAX system identification model, (iii) the Short-Time Fourier Transform (STFT) technique, and (iv) time-frequency signal analysis with a variety of different 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.”). However

nowhere in this passage is the “second processor” (i.e. the processor” of the “one or more PAP device(s)”) described as automatically adjusting the subject’s treatment in real time in response to predicting the onset of the subject’s symptoms.

Prior Art Rejections

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

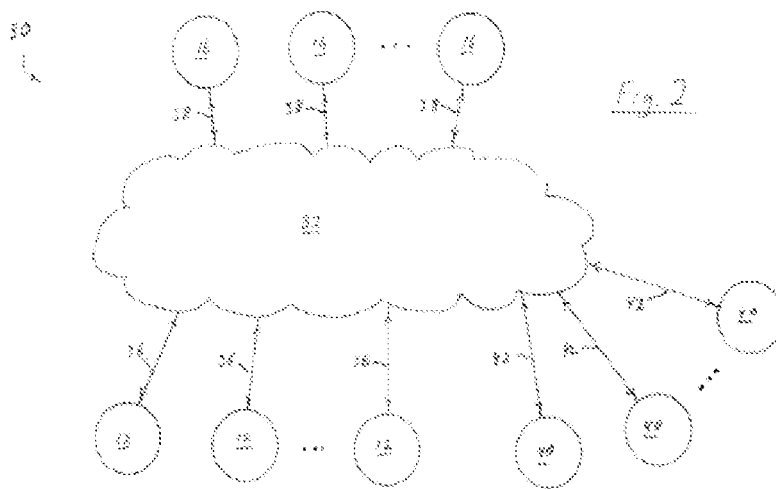
Claims 1-26 and 28-32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0022973 to Sun et al.

(hereinafter also referred to as Sun or '973 (Exhibit F)) in view of International Publication No. 01/450012 to Quy (herein after also referred to as Quy or '012) (Exhibit H)).

Claim 1

See '973 in its' entirety.

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

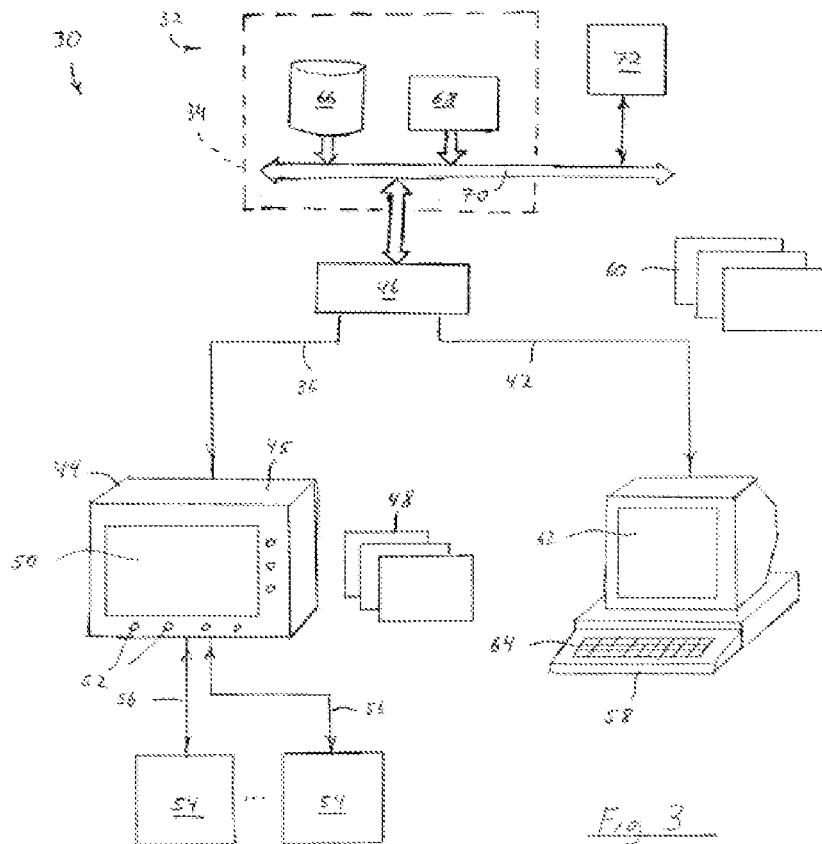


Sun describes system 30 including a medical information management center 32 which is computer-based and capable of storing, collecting, and processing patient medical and biographical information. [0041]. As shown in Fig. 3 (reproduced *infra*) the center 32 is a database and processor hub, e.g. a memory 66 and a microprocessor 68, collectively referred to as server 34, in information management center 32. [0041], [0067]. The information management center 32 is located at a base site and interaction with the base site is achieved using the internet which is accessed via a computer or other internet accessible device. [0042]. The information management center 32 contains information that is collected from a medical device, e.g. CPAP device for sleep apnea treatment, capable of administering medical treatment and/or

monitoring a medical condition and monitoring a patient's use of the device. [0007], [0058]-[0062], [0071] and [0092].

...B. a first non-transitory computer readable medium comprising a first software stored on the non-transitory computer readable medium,
the first software adapted to be executed by a first processor when the first software is downloaded to a cell phone of a subject(s) receiving treatment, the cell phone requiring:
1) at least one first radio frequency wireless transceiver,
2) the first processor,
3) the first software, and
4) a display,...

See '973 at, e.g., Figure 3 (below), elements 44, 50, 36 and 56:



and [0050]-[0057] ("FIG. 3 shows a detailed schematic diagram of medical information management system 30,...In this exemplary embodiment, patient 12 interacts with server 34 via

first communication link 36 using a patient interface appliance 44, which in a preferred embodiment of the present invention, is **a portable, hand-held device** that is capable of periodically establishing the first communication link with the server. More specifically, patient interface appliance 44 preferably **runs a predetermined processing routine** that is **stored** in the unit. Based on this routine, a patient-tailored presentation 48 is presented to the user under the control of the program stored in the appliance. Periodically, patient interface appliance 44 synchronizes with server 34 through a communication network 46, such as a conventional telephone system or cable system commonly used to provide **internet** service to the home. This can be done automatically by the appliance after the patient has provided data into the appliance, after a predetermined amount of data has been loaded into the appliance, or periodically, such as in the middle of the night or other time when the patient is not using the appliance. Once first communication link 36 between patient interface appliance 44 and server 34 is established, **server 34 preferably controls the exchange of information** during this log-on session. In this manner, a patient interacts, at least indirectly, with the information management center and is provided with a patient tailored presentation 48 based on **the reprogrammed routines stored** in the patient appliance. Patient interface appliance 44 includes a housing 45, a **processor 47**, a **memory 49**, a **display 50**, such as an LED or LCD, and at least one input device 52, such as buttons, keys, microphone, touch screen, pen, or mouse, for activating and operating the appliance as well as for using appliance 44 to interact with information management center 32. Housing 45 preferably contains these components as **a small, hand-held, light weight portable unit that can be easily carried. Memory 49 stores programs or commands to be executed by the patient interface appliance, information or indicia to be displayed by the display, and patient data collected by the appliance,**... Patient interface appliance 44 also includes a power

supply (AC, DC, or both) and **a communication terminal or interface 57**, such as modem, **for accessing a communication network 46, which is preferably the internet**, to link the patient interface appliance to the medical information management center. Of course, **memory 49 and processor 47, respectively, store and execute the routines necessary to communicate data over this network**. The present invention further contemplates that patient interface appliance **44 communicates with other medical equipment 54**,...any other medical device or system that is capable of monitoring a physiological condition of a patient. In addition, the present invention contemplates that **patient interface appliance 44 has the capability to interact with medical equipment 54 to receive data indicative of the use of the medical equipment or diagnostic data indicative of the condition of the medical device to alert the patient or others if the monitored parameters, such as operating temperature of the medical device, are not within established thresholds**. To these ends, patient interface appliance 44 includes one or more **medical equipment terminals 55, such as a serial communication port, to communicate with such devices via a medical device communication link 56**. It should be noted that **communication link 56 can be a hardwired or a wireless link, such as an rf or infrared link**. One embodiment of the present invention contemplates that patient interface appliance 44 is a relatively inexpensive piece of hardware that runs a patient interactive routine and accesses the communication network, as well as communicates with other medical equipment, if desired, so that it is easy to use by patients with little or no computer experience. ...In the embodiment described above, patient interface appliance 44 is a limited-use device in that its most basic operation is to run a preprogrammed routine... The present invention contemplates, however, that a patient can use an appropriately configured **computer terminal in place of appliance 44 to provide additional capabilities to the user, such as the ability to run conventional computer**

programs and access the internet in real time. When using a computer terminal in place of patient interface appliance 44, it may be necessary to employ an adapter or other device that allows the conventional computer terminal to communicate with medical devices or systems 54.” (emphasis added)), [0066], [0107]-[0111] (“As noted above, according to one embodiment of the present invention, patient interface appliance 44 runs a preprogrammed processing routine stored in memory 49 for displaying patient-tailored presentation 48 in the form of a series of pages provided on display 50....During this temporary on-line interaction between patient interface appliance 44 and medical information management center 32, the information stored in memory 49 can also be updated by the server. FIG. 8 illustrates an algorithm 228 for operating the patient interface appliance according to the principles of the present invention. This algorithm is stored in memory 49 and executed by processor 47 ... When executed, algorithm begins with a start step 230, and enters a main page display step 232 in which a main page 234 is provided in display 50. See FIG. 7A. Main page 234 is preferably an introductory screen that notifies the user that the unit is operating and presents the user with possible alternative user selectable options for using the patient interface appliance....In an exemplary embodiment of the present invention, main page 234 includes a general information field 236, which includes a text field 237 and a menu field 238 for presenting user selectable options....The information provided in general information field 236, including user selectable options, is generated based in information display commands stored in memory 49,...Of course, the message and user selectable options presented in general information field 236 ...can be periodically altered, for example, from new commands provided by the medical information management center.”) and [0129]-[0133] (“Referring again to FIGS. 3 and 8, in step 286 of FIG. 8, the processor determines whether to establish communication link 38 with medical information management center 32....Once

communication link 36 between patient interface appliance 44 and server 34 is established, server 34 preferably controls the exchange of information during this log-on session...During this on-line interaction, server 34 can download new queries, user selectable options, new advertisements, display information, and so on into memory 49....”).

Therefore, ‘973 describes a patient interface appliance, e.g. a hand-held unit or computer, a processor 47, a display 50, a radio frequency wireless communication link 55/56 and first software stored on a non-transitory computer readable medium i.e. the “predetermined processing routine”, “reprogrammed routines”, “programs or commands to be executed by the patient interface appliance”, “the routines necessary to communicate data over this network”, “an algorithm 228 for operating the patient interface appliance according to the principles of the present invention...stored in memory 49 and executed by processor 47”, “[m]emory 49 stores programs or commands to be executed by the patient interface appliance, information or indicia to be displayed by the display, and patient data collected by the appliance”, downloads and updates.

However, ‘973 1) does not describe the patient interface appliance as being a cell phone of a subject receiving treatment nor the software downloaded to a cell phone of a subject receiving treatment and 2) does not explicitly describe the radio frequency wireless communication link being a rf wireless “transceiver”.

See Quy ‘012 in its’ entirety especially, the abstract, 4:15-22 and 28-34, 5:5-7, 6:5-17, 6:21-7:28, 8:8-31, 10:21-27, 11:16-32, 12:6-25 and 29-31, 13:21-31, 14:2-11, 14:22-16:31, 18:15-25, 20:20-23, 21:18-22, 24:10-25:5 and 25:23-30 and Figures.

Quy '012, like '973, is directed to a wireless health monitoring system for interactively monitoring a disease or health condition of a patient by connecting an internet-enabled wireless web device ("WWD") (12) to a health monitoring device (11) which may be a medical device. Abstract and Figs. 1-4. The system includes a network of medical devices, monitoring devices, and a remote internet site that includes a server. FIG. 3 and 14:22-31. The WWD may be a web/internet-enabled cellular phone or a palm, handheld, or laptop computer or a PDA, equipped with a wireless modem or a hybrid device that combines the functions of a computer, PDA and telephone. 6:21-29. A medical device can be connected to an internet-enabled wireless web device ("WWD") to enable processing of data from the medical device via the internet including review by a physician or other health care professional and to allow the patient to receive guidance displayed on the screen of a web/internet-enabled WWD. 4:30-5:15. Measured data may be transferred to WWD 12 via wireless communication schemes, such as RF including Bluetooth® or 802.11, infrared, optical, microwaves, etc., directly from sensor 24 or from HMD 11. 12:19-20 and 14:2-11.

The patient connects to a specific Internet site and a software program, resident on a remote server located on the Internet, downloads to the WWD an interactive user interface for that patient and an application for the measurement of the physiological data. The software may also be downloaded to the WWD from a personal computer via a synchronization operation in known fashion. 8:8-15. Specifically, to initialize the system, the program starts and a wireless application is loaded into the WWD. The loading of the wireless application may occur via synchronization from a desktop or via downloading from a server over the internet.

A server application may be loaded into an appropriate internet-connected server. Subject data may be loaded into the WWD or into the server. In the latter case, the subject information may later be transferred to the WWD. Subject information may also be transferred to the server from the WWD, as called for by the application. 17:22-31. Server 22 has a base server application 62 with which the same calculates or provides a response based at least in part on data from WHMA 10. Application 62 may include an algorithm 63 for analyzing data from the HMD, and either application 62 or algorithm 63 may optionally access data from an external data source 74 and may further consult an artificial intelligence system. 15:23-29.

With regard to 1) above, a POSITA would have been motivated to substitute a web/internet-enabled cellular phone or hybrid device with such functions for the computer or PDA of '973 in view of the interchangeability of such as taught by '012 for the communication between servers and medical devices in a health monitoring system.

Furthermore, a POSITA would be motivated to include downloading to such cellular phone/hybrid device software/programs/algorithms, e.g. interactive user interface for that patient and an application for the measurement of the physiological data, as taught by '012 with the patient interface appliance of '973 in order to allow the patient interface appliance to interact with the patient, medical equipment and server(s) as described above by '973. To the extent that '973's programming/reprogramming of the patient interface appliance is not interpreted to be downloading to the patient interface appliance, '012 remedies any such perceived deficiency. As such, the proffered modification is merely combining prior art elements ('973's patient interface appliance programming/reprogramming/'012's WWD's initialization/synchronization) according to known methods (using appliance/server/internet) to yield predictable results (operating the patient interface appliance/WWD according to the principles of medical information

management center which is computer-based and capable of storing, collecting, and processing patient medical and biographical information wireless health, a monitoring system for interactively monitoring a disease or health condition of a patient). In other words, the prior art obviously teaches or suggests a cell phone/hybrid cell phone device/patient interface appliance having software downloaded thereto for execution thereby.

With regard to 2), see, e.g., the '680 patent at 25:6-27 ("Optionally, the receiver can further transmit data to another device and/or back. Further optionally, two different receivers can be used, one for receiving transmitted data and another for sending data. For example, with the wireless data acquisition system used in the present invention, the receiver can be a wireless router that establishes a broadband internet connection and transmits the physiological signal to a remote Internet site for analysis, preferably by the subject's physician or another clinician. Other examples of a receiver are a PDA, computer, or cell phone that receives the data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, or cable to a remote processor or remote monitoring site for analysis").

The prior art similarly teaches transmission and reception of data/information between a cell phone/hybrid cell phone device/patient interface appliance and a base station by wireless signal via an antenna and wireless techniques including rf signals. Therefore, the prior art obviously teaches a cell phone/hybrid cell phone device/patient interface appliance which is a rf "transceiver". Furthermore, such cell phone/hybrid device obviously includes components, e.g., an antenna, which enables the functionality of transmission and reception of rf signals. Therefore, the prior art obviously teaches or suggests a rf "transceiver" as claimed.

...C. a second non-transitory computer readable medium comprising at least one second software for a remote internet site and a database, the remote internet site and the database stored on a non-transitory computer readable medium and adapted to:

- 1) be hosted on at least one server, and**
- 2) be used for remote monitoring of multiple subjects receiving PAP therapy;...**

See discussion of preamble above and '973 at, e.g., Fig. 3 above, e.g. a memory 66 and a microprocessor 68, collectively referred to as server 34, in information management center 32. [0041]. See also [0067]-[0068] ("... Memory 66 is any information storage device, such as a hard drive, RAM, or ROM, that is capable of storing information, such as patient biographical information, patient medical information, general medical information, and any other information or data that may be of interest to any party interacting with the information management center. Memory 66 can also contain algorithms for processing the data stored therein, operating microprocessor 68, communicating with other servers, or performing any other tasks commonly preformed [sic] by a microprocessor platform... The patient's medical information includes any information pertaining to the patient's health, such as past medical history, current medical information, e.g., current disease states, diagnoses, physiological parameters or conditions currently being monitored, the results or information gathered from this monitoring, and information regarding the patient's ongoing medical treatments, the treatment plan, prescription, or any combination thereof."), [0070] ("Processor 68 is any conventional processor capable of executing an algorithm, which may be downloaded from a processor memory (not shown), such as a conventional ROM or RAM or from memory 66. A data bus 70 or other suitable communication line allows processor 68 to communicate with memory 66 and other internal or external devices. The present invention contemplates that server 34 communicates with other servers, if necessary, via conventional communication techniques. For example, the present invention contemplates that the bulk of the patient biographical information

and medical information is contained in a small number of servers, which are accessed from other remote servers when a patient, healthcare professional, or third party, accesses the information management system via the remote server. The present invention further contemplates that server 34 is configured to communicate with one or more external devices 72, such as a computer terminal at the server site, a printer, satellite communication link, or any other input/output device.”), [0078]-[0083] (“As noted above, the format or procedure for presenting information between a user and medical information center 32 is dependent upon the type or category of user, i.e., healthcare professional, third party, or patient, accessing the medical information center. FIGS. 5A-5M illustrate an example of a display presentation tailored for use when a healthcare provider interacts with the medical information management system. ... Activating patient management center active field 90 or an active link in that field causes a patient management center page 102 to be displayed, which is used to review the medical or biographical information for each patient being supervised by that healthcare professional, as discussed below with respect to FIG. 5C. ...FIG. 5C illustrates a patient management center page 102 that is accessed via patient management center active field 90 in page 88 of FIG. 5B. Patient management center page 102 serves as a launch point for allowing a healthcare professional to select and review the medical information on each patient that subscribes to the information management system and that is under the supervision of that subscribing healthcare professional. Patient management center page 102 also allows the healthcare professional to provide information to his or her patients and monitor or alter patient's treatment, as discussed in detail below.”), [0085] (“Patient education content manager field 106 includes links 124 that allow the healthcare professional to quickly identify and define groups of patients with common needs and distribute educational material to those groups. For example, the healthcare

professional may be supervising a group of patients suffering from OSA. The patient education content manager field 106 allows the healthcare professional to identify these patients as a group and distribute information on, for example, the latest CPAP devices and mask interfaces to these patients, preferably via e-mail. Links 124 are used to define the groups, the content of the material to be distributed the various groups, and the e-mail address for the patients in the defined groups.”) and [0089] (“FIG. 5F illustrates a patient status page 142 that is displayed when the healthcare professional actuates patient status link 116 in patient observation field 104 of patient management center page 102. Patient status page 142 includes a listing 144 of all of the patients associated with that healthcare professional that are contained in the medical information management system. A "view data" link 145 is provided for each patient included in listing 144. Actuating view data link 145 provides access to the medical information for that patient in the form of a medical data summary page 146 shown in FIG. 5G.”).

...A. one or more PAP device(s);

...wherein the one or more PAP device(s) that is each used for treating the sleeping disorder of the subject(s) or their symptoms, and further comprises:

a blower having an air output,

a sensor for providing a sensor data to determine airflow, the sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of the subject while using the PAP,

a second processor adapted for generating the PAP therapy efficacy¹² data based on a first data and a second data by receiving the sensor data, and calculating both

i) the first data related to a quantitative measure of symptom severity during use of the PAP device and

ii) the second data related to a usage of the PAP device by the subject,

at least one second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data, and

¹² Note the Request, paragraph bridging pages 28-29.

a mask or a nasal cannula; and...

See discussion of the preamble, '973 at, e.g., Figures 2-3 (reproduced above), element 54, and [0054] ("The present invention further contemplates that patient interface appliance 44 communicates with other medical equipment 54, such as a spirometer, scale, glucose monitor, temperature sensor, cardiac monitor, polysomnography system, or any other medical device or system that is capable of monitoring a physiological condition of a patient...patient interface appliance 44 has the capability to interact with medical equipment 54 to receive data indicative of the use of the medical equipment or diagnostic data indicative of the condition of the medical device to alert the patient or others if the monitored parameters, such as operating temperature of the medical device, are not within established thresholds. To these ends, patient interface appliance 44 includes one or more medical equipment terminals 55, such as a serial communication port, to communicate with such devices via a medical device communication link 56. It should be noted that communication link 56 can be a hardwired or a wireless link, such as an rf or infrared link."), [0058]-[0060] ("The present invention further contemplates ... a medical device capable of administering a medical treatment, monitoring a medical condition, or both. For example, the present invention contemplates ... a pressure support device, such as a continuous positive airway pressure (CPAP) device, bi-level pressure support device, auto-titration device, or ventilator, so ... functions as a medical device for administering a pressure support or ventilation therapy to a patient. ...provides variable pressure levels to the patient, either during each respiratory cycle, as done by a ventilator or bi-level pressure support system, or over periods of time, as done by an auto-titration pressure support system or by a CPAP device with a selectable pressure level or a pressure level that can vary in some manner, such as a ramp pressure, which allows the patient to receive a low pressure while trying to fall asleep an

gradually increases....To achieve that auto-titration pressure support, where the pressure level varies with the condition of the patient, for example by increasing the pressure levels if the patient experiences snoring, apneas, or obstructed breathing, the present invention contemplates providing other sensors, such as a microphone, respiratory belt, and oximeter, either alone or in combination with flow and/or pressure sensors 63 and 65, for monitoring the condition of the patient and controlling the pressure support based thereon.”), [0092] (“...In a more sophisticated example, the medical device that the patient has been prescribed, such as a CPAP device, has the ability to monitor the patient's use of the device and report such use directly to the medical information management system without any patient interaction. The compliance data gathered...) and [0061]-[0062] (“Examples of a bi-level pressure support system and the techniques for distinguishing between inspiration and expiration in an a single-limb patient circuit are disclosed in U.S. Pat. Nos. 5,148,802; 5,313,937; 5,433,193; 5,632,269; 5,803,065; and 6,029,664, the contents of which are incorporated herein by reference. Examples of an auto-titration system pressure support system are disclosed in U.S. Pat. Nos. 5,203,343; 5,458,137, and 6,085,747 all to Axe et al. and U.S. Pat. No. 5,645,053, the contents of which are incorporated herein by reference. In addition, to these modes of pressure support, the present invention contemplates that the patient interface appliance can provide other conventional modes of pressure support, such as proportional assist ventilation (PAV.RTM.) and proportional positive airway pressure (PPAP) ventilation. PAV is taught by U.S. Pat. Nos. 5,044,362 and 5,107,830 both to Younes et al., the contents of which are incorporated herein by reference. PPAP ventilation is taught by U.S. Pat. Nos. 5,535,738; 5,794,615, and 6,105,575 all to Estes et al., the contents of which are incorporated herein by reference.”).

Therefore, also see the entirety of, e.g., U.S Patent No. 6,085,747 (e.g., Fig. 1, compressor 43, differential pressure transducer 45, processor 57, mask 39, abstract (“A system including methods and apparatus for treatment of a medical disorder such as obstructive sleep apnea or congestive heart failure. The system involves applying separate and independent gains to flow rates of pressurized gas delivered to a patient during inspiratory and expiratory phases of a respiratory cycle to deliver the pressurized gas in proportion to the respective gains during inspiration and expiration. A base pressure may be applied in addition to the gain-modified pressures and an elevated pressure profile may be employed to assist or control inspiration. The system may be fully automated responsive to feedback provided by a flow sensor that determines the estimated patient flow rate. A leak computer can be included to instantaneously calculate gas leakage from the system. The system may be utilized in connection with conventional continuous positive airway pressure (bi-level PAP) equipment to effect various beneficial treatment applications.”), col. 2, lines 27-57 (“The method and apparatus of the invention provide for the detection and control of sleep disorder breathing in a person. Control of sleep disorder breathing with reduced discomfort due to flow of forced air, is accomplished by selection of pressure for the air flow. Increased pressure is selected upon detection of sleep disorder breathing. Absent occurrence of sleep disorder breathing, the forced air flow is reduced in pressure. For sleep, a patient is fitted with a nasal mask adapted to deliver air from a source of compressed air to the patient's nasal passages. A hose connects the compressed air source and nasal mask. Detection of sleep disorder breathing involves monitoring of face mask pressure and pressure difference (ΔP) between two spaced points along the hose. Specific conditions, including occurrence of apnea, hypopnea and pharyngeal wall vibration are identified. Also detectable are nasal mask problems such as dislodgement of the mask or leakage from the mask. Inhalation and exhalation by the

patient are also detected. Diagnosis of apnea, hypopnea, pharyngeal wall vibration and complete or partial closure of the breathing path is based on measurements of breathing by the patient. Pressure selection is microprocessor controlled and is responsive to detection of specific conditions. Pressure may be adjusted to multiple levels during and following occurrences of sleep disorder breathing. Increased pressure for inhalation, exhalation, or both may be used to suppress sleep disorder breathing, with the pressure level adjusted to achieve suppression of the condition. Mask dislodgement results in reduction of pressure to a minimum level.), col. 3, lines 37-60 (“Referring to FIG. 1, the apparatus will include any type of mask or nostril adapter 39. Mask 39 may be a commercially available product that has two nozzles, each of which fits within a nostril (not shown) of a user. Mask 39 connects to a flexible hose 41 that leads to a low pressure air source such as compressor 43. Mask 39 and hose 41 make up an interface for supplying air under pressure to the user. Compressor 43 draws in ambient air and compresses it to a pressure which can be selected as described below. Increasing the pressure will increase the flow rate of the air through the hose 41 if mask 39 is open to atmosphere. The differential pressure transducer 45 senses the dynamic pressure difference between the output of the compressor 43 and the mask 39. Differential pressure transducer 45 has one sensing tube 46 connected to the interior of mask 39. Another sensing tube 47 connects to the output of compressor 43. Mask sensing tube 46 is downstream from output pressure sensing tube 47. The pressure difference between sensing tubes 46 and 47 corresponds to the quantity of air flow through the hose 41. Normal breathing causes the difference in pressure sensed by the pressure transducer 45 to fluctuate. Pressure transducer 48 measures only the dynamic pressure in the mask 39.”), and col. 4, lines 10-44 (“The microprocessor 57 is programmed to sample the incoming signals from converter 55 at a rate of 4000 times per second and process the sampled

signals at the rate of 10 times per second. For every 400 pressure difference values collected, a mean pressure difference value and a pressure difference standard deviation value are calculated and stored. The mean pressure difference value calculation is, in effect, a low pass filter, whereas the standard deviation calculation is, in effect, a high pass filter. The mean pressure difference values are used to calculate a mean pressure difference base line, which is arbitrarily defined as the signal level dividing inspiration and expiration. If the mean value is larger than the pressure difference base line value by a threshold for more than 15 seconds, the algorithm responds with a 'mask off' signal. Experience has shown that if the mask 39 is removed, the pressure difference becomes very large and will exceed an pressure difference base line value established before the mask was dislodged. The microprocessor 57 algorithm uses the pressure difference standard deviation values to calculate the energy of disturbances in the pressure difference signal greater than an arbitrarily defined threshold. The threshold level is determined according to the following formula: $\text{standard deviation threshold} = (\text{command pressure} - A) * B + C$ where A, B and C are fixed empirical values that set the threshold above the level of disturbances caused by ordinary turbulence in the hose 41. Alternately, the standard deviation threshold values could be adaptive and changed based on past standard deviation values calculated for the person utilizing the mask 39. If the standard deviation value is equal to zero for 10 seconds then the system responds with a 'power off' signal.”)

Therefore, '973/'747 teaches a PAP device, e.g. device 54, used for treating sleeping disorders or symptoms of a subject having a compressor/blower with an output, a sensor internal to the device for measuring air flow, a mask, a processor receiving the sensor data and generating/calculating efficacy data which is based on data related to quantitative symptom

severity data and PAP/mask usage data, e.g. “mask off” data, and an rf frequency bidirectional information transmission/rf link between the device 54 and patient interface appliance 44.

To the extent, ‘973/‘747 does not explicitly teach a “transceiver” for the rf link/transmission, see the discussion above of ‘012 and item (1 with regard to section B. of the claim. In other words, ‘012 also describes the link between the HMD/ventilator and WWD/a cell phone/hybrid cell phone device/patient interface appliance being either wired or wireless and in the case of wireless, e.g., “HMD 160 may have an integral wireless modulator/demodulator disposed within (not shown) . More likely, however, is that HMD 160 has an adaptor 154 connectable thereto which performs these functions. Adaptor 154 may plug into a connector 165 on HMD 160.” Therefore, if not already, a POSITA would be motivated to include a transceiver (e.g. nonintegral or integral modulator/demodulator) as taught by ‘012 with the patient interface appliance/health device of ‘973 in order to allow the patient interface appliance to interact with medical equipment as described above by ‘973. The proffered modification is merely combining prior art elements (‘973’s patient interface appliance/health device communication link /‘012’s WWD/HMD transmission link) according to known methods (using nonintegral/integral transceiver) to yield predictable results (provide wireless rf bidirectional transmission). In other words, the prior art obviously teaches or suggests a health device/PAP device employing a transceiver (e.g. nonintegral or integral modulator/demodulator).

[...B....] **the first software further adapted for:**

i) receiving a PAP therapy efficacy data¹³ or a modified PAP therapy efficacy data based in part on the PAP therapy efficacy data both based on treatment of the subject and its efficacy in whole or in part, and

ii) outputting one or more PAP therapy efficacy measures(s) on the display of the cell phone for viewing by the subject based in whole or in part on the data received by the first software; and

¹³ See again discussion of claim section A. above.

[...C....] the at least one second software for the remote internet site and the database is further adapted to receive the PAP therapy efficacy data, in whole or in part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.¹⁴

See discussion of '937/'747 and '012 above with regard to limitations A.-C. For example, see '973 at, e.g., Figures 2-3, [0027] ("... In addition, the patient interface appliance includes the ability to communicate information from the patient interface appliance to a medical information management center."), [0051] (Periodically, patient interface appliance 44 synchronizes with server 34 through a communication network 46...Once first communication link 36 between patient interface appliance 44 and server 34 is established, server 34 preferably controls the exchange of information during this log-on session. ..."), [0054] "...In addition, the present invention contemplates that patient interface appliance 44 has the capability to interact with medical equipment 54 to receive data indicative of the use of the medical equipment...To these ends, patient interface appliance 44 includes one or more medical equipment terminals 55, such as a serial communication port, to communicate with such devices via a medical device communication link 56. It should be noted that communication link 56 can be a hardwired or a wireless link, such as an rf or infrared link."), [0067]-[0069] ("In the illustrated exemplary embodiment, server 34 in information management center 32 includes a memory 66 and a microprocessor 68. Memory 66 is any information storage device, such as a hard drive, RAM, or ROM, that is capable of storing information, ... patient medical information,...The patient's medical information includes any information pertaining to the patient's health, ... physiological parameters or conditions currently being monitored, the results or information gathered from this monitoring, and information regarding the patient's ongoing medical treatments, the treatment

¹⁴ It is noted that the transmission via the at least one second radio frequency device to the second software is not claimed as being direct transmission, e.g. can include transmission via the structure of A..

plan, prescription, or any combination thereof. This patient biographical and medical information can be provided to information management center 32 in a variety of ways. For example, it can be provided by the patient or it can be provided through the first communication link from a monitoring device being used by the patient...”), [0071] (“Memory 66 and processor 68 cooperate to receive information provided by a patient via the first communication link... and to process this information. This information can then be used to manage the medical condition of the patient. For example, one embodiment of the present invention contemplates that processor 68 review the information received via the first communication link and automatically provide a notification to the patient, healthcare professional, or third party if the information is outside established parameters....In addition, the information management center can be used to prepare a summary of the medical information that its managing and provided this summary to any authorized user. For example, the summary may report on the number of times the patient failed to use their CPAP device....”), [0090]-[0092] (“The illustrated exemplary embodiment of medical data summary page 146 includes a patient information area 148 identifying the patient and a number of areas containing medical information. For example, a vital signs area 150 displays physiological information, which is any information pertaining to the health or medical condition of the patient, such as oxygen saturation, peak flow results, or patient answers to questions regarding his or her health. This information is collected from the patient or from a medical monitoring device used by the patient, such as a spirometer. The present invention contemplates displaying this information in vital signs area graphically. It is to be understood, however, that this information can be displayed as a data chart, as raw data, or in any manner suitable for use by the healthcare professional. The present invention further contemplates that the format for displaying such data in this page can be selected by the user so that he or she is

presented with the information in the manner they prefer. Other information display areas in medical data summary page 146 include a health trend area 152 that displays a trend analysis of the physiological data collected from the patient. This area can indicate, for example, that the patient's weight is increasing, their peak expiratory flow is decreasing, and so on. An alert summary area 154 notifies the healthcare provider if the information or data collected from the patient or from other sources is outside established thresholds. For example, if the patient's peak flow reading falls below a certain level an alert is posed in alert summary area 154. Preferably, the alert would include details about the time the alert occurred and the nature of the alert. A non-compliance area 156 provides information regarding the patient's use (or non-use) of a prescribed or recommended medical treatment... In a more sophisticated example, the medical device that the patient has been prescribed, such as a CPAP device, has the ability to monitor the patient's use of the device and report such use directly to the medical information management system without any patient interaction. The compliance data gathered from the device can be displayed in area 156....”), Fig. 7F, [[0129]-[0130]] (“The present invention further contemplates that the patient can review, at least in a summary form, the information provided by that patient to the patient interface appliance, information collected via a monitoring device, or both. This can be done, for example, by presenting the patient with a personal medical summary option. FIG. 7E illustrates an example of a physiological parameter display page 284 that is provided to the user. This page illustrates the medical data collected over a period of time, which, in this example, is the peak expiratory flow of the patient taken using a spirometer. The medical information is presented in general information field 236 ... This allows the patient to quickly monitor, at least in a general sense, his or her progress to recovery or his or her success in disease management.”), and [0146] (“As noted above, the information or data collected by

patient interface appliance 44 can be downloaded to information management center 32 in a real-time basis, at designated times, when a threshold storage capacity of the appliance is reached, or any combination thereof. Establishing a first communication link with the patient interface appliance can be initiated by the appliance itself, either automatically or following a manually input command from the patient, or by the information management center, assuming that a continuous communication link is maintained between the patient interface appliance and the server.”. See also ‘012 at, e.g., 8:8-31, 12:29-31, 14:7-11 and 18:15-25.

Therefore, the prior art obviously teaches or suggests that PAP therapy efficacy data or a modified PAP therapy efficacy data based in part on the PAP therapy efficacy data which is based on treatment of the subject and its efficacy in whole or in part is received by the software of the cell phone/hybrid cell phone device/patient interface appliance and is also received by the at least one second software for the remote internet site, and the database via the at least one second radio frequency wireless transceiver. Continuing, the prior art also obviously teaches or suggests outputting one or more PAP therapy efficacy measures(s) on the display of the cell phone/hybrid cell phone device/patient interface appliance for viewing by the subject based in whole or in part on the data received by the first software, e.g. graphical representations of monitored medical data collected over a period of time.

Claim 2

The system of claim 1, wherein the one or more PAP therapy efficacy measure(s) includes an index¹⁵.

¹⁵ Note the Request, paragraph bridging pages 80-81.

See the discussion of claim 1, e.g., ‘973 at [0058]-[0062] (and thereby, ‘747) [0129]-[0130] and Figure 7E, e.g. index of sensor measurement, and ‘747 at Tables 1-2 and Figs. 2-8. It is noted that the specifics of “the index” have not been claimed.

Claim 3

The system of claim 2, wherein the one or more PAP device(s) further comprises an electronic component adapted to utilize a cellular network and allow the one or more PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site.

It is noted that what adjusts the PAP is not claimed. See discussion of claim 1, e.g. the cited portions of ‘973, ‘012 and ‘747, e.g., [0054], [0058]-[0062] of ‘973 (and thereby, ‘747) and 6:5 -7:28, 14:2-11, and 24:10-25:7 of ‘012. The prior art obviously teaches or suggests the medical device includes an electronic component adapted to utilize a cellular network, e.g. connector 165, and communicates PAP therapy efficacy data with the patient interface appliance/cell phone and server which PAP therapy efficacy data also allows the PAP device to be adjusted automatically “remotely” from the appliance/cell phone or server, see again, e.g., ‘012 at, e.g., 6:5-20.

Claim 4

The system of claim 2, wherein the index is based on both the first data and the second data from the one or more PAP device(s).

See discussion of claims 1-3, e.g. ‘973 at [0058]-[0062] and [0092] and ‘747 at, e.g., 4:10-44.

Claim 5

The system in claim 4, wherein the PAP device for treating the sleeping disorder of the subject is adjusted based in whole or part on the PAP therapy efficacy data generated by the one or more PAP device(s) and then received by the remote internet site.

See discussion of claims 1-4, e.g. the prior art obviously teaches or suggests the PAP device is adjusted, e.g. automatically, based on the PAP therapy efficacy data generate by the device and such data is also transmitted to/received by the server/remote internet site.

Claim 6

The system in claim 5, wherein the one or more PAP device) [sic] is adjusted automatically with a signal from the remote internet site based on the PAP therapy efficacy data then received by the remote internet site.

It is noted that it is claimed that the PAP is adjusted with a signal from the remote internet site based on the PAP data but such data then being received by the remote internet site. Therefore, as best understood, the PAP device adjustment as claimed in claim 5 is interpreted as now being claimed as an automatic adjustment based on the data and which data is then received by the remote internet site. Accordingly, see the discussion of claim 5.

Claim 7

The system in claim 4, wherein the first software adapted to be executed by the cell phone receives, in whole or part, the PAP therapy efficacy data related to treatment of the subject generated by the one or more PAP device(s) and is then used to retransmit, in whole or part the PAP therapy efficacy data and/or a reprocessed data based in part on the PAP therapy efficacy data related to treatment of the subject to the remote internet site with the at least one first radio frequency wireless transceiver.

See the discussion of claim 1 above, e.g. Fig. 3, links 56 and 36 and at [0053]-[0054], [0069], [0120], and [0146] of '973 and 18:15-28 of '012.

Claim 8

The system in claim 7, wherein the second radio frequency wireless transceiver of the one or more PAP device and the first software adapted to use the at least one first radio frequency wireless transceiver of the cell phone are further adapted to transmit PAP therapy efficacy data and/or a reprocessed data based in part on the PAP therapy efficacy data from the one or more PAP device(s) to the cell phone using a Bluetooth wireless protocol.

It is noted that it that the first transceiver is being claimed as being adapted to transmit data from the PAP device to the cell phone. Therefore, as best understood, the second transceiver as claimed is interpreted as transmitting data to the first transceiver, i.e. the first transceiver receives such data, using a Bluetooth protocol. See the discussion of claims 1, 3 and 7, esp., '973 at, e.g. Fig. 3, elements 54, 56, 44 and '012 at 6:21-7:15.

Claim 9

The system in claim 7, wherein the first software adapted for use with the cell phone is further adapted to be reprogrammed or modified remotely.

See the discussion of claim 1 above, e.g. '973 at, e.g., [0050]-[0051], [0053], [0057], [0108] and [0133].

Claim 10

The system in claim 7, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of a

a standard deviation technique,

a recursively fit ARMAX system identification model,

a short-time Fourier transform technique,

a time-frequency signal analysis with a variety of different kernals [sic], and

a wavelet analysis.

See the discussion of claim 1 above, e.g., the portions of '747 cited, e.g., col. 4, lines 10-44, i.e. a standard deviation technique.

Claim 11

The system of claim 7, wherein the first data of the PAP therapy efficacy data includes specific symptom data related to both obstructive, and central apneas.

See the discussion of claim 1 above, e.g., the portions of '747 specifically cited, e.g., col. 4, lines 10-44. See also col. 4, line 45-col. 8, line 2, Tables 1-2 and Figures 2-8,

Claim 12

The system in claim 4, wherein the first software adapted to be executed by the first processor of the cell phone to receive, in whole or part, the PAP therapy efficacy data generated by the one or more PAP device and/or the modified therapy efficacy data based in part on the PAP therapy efficacy data that is first received at least in part from the PAP device by the remote internet site and then retransmitted to the first software from the remote internet site.

See the discussion of claim 1 above and '973 at, e.g., [0144]-[0145] ("It can be appreciated from the foregoing description of the interaction between information management center 32 and a healthcare professional, third party, or patient, that the information management center has the ability to collect and compile information in an ongoing basis,... However, a more sophisticated embodiment of the present invention contemplates that such information is provided directly to the information management center by the medical device being used by the patient. For example, ... a communication link that allows it to provide the data it collects directly to information management center 32 rather than to patient interface appliance 44.") and [0129]-[0130].

Claim 13

The system in claim 12, wherein the one or more PAP device(s) and the first software adapted for use with the cell phone are further adapted to transmit and receive data based on the PAP therapy efficacy via a cellular network or through the Internet.

See the discussion of claims 1, 3, 7-8 above, e.g. Figs. 2-3 of '973 and the cited portions of '012.

Claim 14

The system in claim 12, wherein the first software adapted for use with the cell phone is further adapted to be reprogrammed or modified remotely.

See the discussion of claim 9 above.

Claim 15

The system in claim 12, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of

a standard deviation technique,

a recursively fit ARMAX system identification model,

a short-time Fourier transform technique,

a time-frequency signal analysis with a variety of different kernals [sic], and

a wavelet analysis.

See the discussion of claim 10 above.

Claim 16

The system of claim 12, wherein the first data of the PAP therapy efficacy data includes specific symptom data related to both obstructive, and central apneas.

See the discussion of claim 11 above.

Claim 17

The system in claim 4, wherein the first software is adapted to be executed by the first processor of the cell phone and the remote internet site both independently receives, in whole or part, the PAP therapy efficacy data generated by the one or more PAP device and/or the modified therapy efficacy data based in part on the PAP therapy efficacy data.

See the discussion of claims 1 and 12 above.

Claim 18

The system in claim 17, the one or more PAP device(s) further comprises an electronic component adapted to transmit the PAP therapy efficacy data to the remote internet site at least in part via a cellular network, and

the second radio frequency wireless transceiver of the one or more PAP device(s) is used to transmit PAP therapy efficacy data of the subject to the first software adapted to use the first radio frequency wireless transceiver of the cell phone using a Blue tooth wireless protocol.

See the discussion of claims 1, 3, 7-8 and 13 above.

Claim 19

The system in claim 17, wherein the first software adapted for use with the cell phone is further adapted to be reprogrammed or modified remotely.

See the discussion of claim 9 above.

Claim 20

The system in claim 17, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of

a standard deviation technique,

a recursively fit ARMAX system identification model,

a short-time Fourier transform technique,

a time-frequency signal analysis with a variety of different kernals [sic], and

a wavelet analysis.

See the discussion of claim 10 above.

Claim 21

The system of claim 17, wherein the one or more PAP device(s) further comprises an electronic component adapted to utilize a cellular network and allow the one or more PAP device [sic] to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site.

See discussion of claim 3 above.

Claim 22

The system of claim 17, wherein the first data of the PAP therapy efficacy data includes specific symptom data related to both obstructive, and central apneas.

See the discussion of claim 11 above.

Claim 23

The system of claim 4, wherein the at least one second software with the remote internet site and the database are adapted to be accessible to a clinician or doctor of the subject for a remote monitoring of the patient and/or their PAP therapy when hosted on the at least one server.

See the discussion of claim 1 above, e.g., '973 at [0063]-[0065], [0067], [0078] and [0090]-[0092].

Claim 24

The system of claim 23, wherein the at least one second software is adapted to perform automatic data analysis for the clinician or doctor for use with the remote monitoring when hosted on the at least one server or with a third processor.

See discussion of claim 24, esp., e.g., '973 at [0067], and [0090]-[0092].

Claim 25

The system of claim 2, wherein the at least one second software with the remote internet site and the database are adapted to be accessible to a clinician or doctor of the subject for a remote monitoring of the patient and/or their PAP therapy when hosted on the at least one server.

See the discussion of claim 23 above.

Claim 26

The system of claim 25, wherein the at least one second software is adapted to perform automatic data analysis for the clinician or doctor for use with the remote monitoring when hosted on the at least one server or with a third processor.

See the discussion of claim 24 above.

Claim 28

The system in claim 1, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to recognize patterns of sleep disorders or therapy for sleep disorders.

It is noted that the claim does not recite the specifics of how the database/data is analyzed to recognize patterns, e.g. by what component of the system. However, see the discussion of claims 1-2, 4, 11, 16, and 22-26 above, e.g., '973 at [0058]-[0062] (and thereby, '747), [0067]-[0068], [0071], [0085], [0090]-[0092], [0095], Figs. 5F-5J, [0129]-[0130] and Fig. 7E, '012 at, e.g., 15:23-16:23 and '747 at, e.g., 6:48-8:2, Tables 1-2 and Figs. 2-8. Accordingly, as best understood, the prior art obviously describes or suggests the database/data being capable of being processed/analyzed, e.g., to recognize trends/patterns of physiological collected data, e.g. of sleep disorders.

Claim 29

The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to train a neural network.

It is noted that the claim does not recite the specifics of the analysis for training nor that a neural network is even part of the system. However, see, e.g., the discussion of claim 28 above. Accordingly, since the prior art obviously describes or suggests the database/data being capable of being processed/analyzed, as best understood, the prior art database/data is obviously also capable of being processed/analyzed as claimed.

Claim 30

The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to correlate more robust data¹⁶ from multiple subjects to teach or train the sensor on the one or more PAP device(s).

It is noted that the claim does not recite the specifics of analysis for teaching or training the sensor. However, see, e.g., the discussion of claim 28 above, e.g. [0085] and [0089].

Accordingly, since the prior art obviously describes or suggests the database/data thereof which includes identifiable/linkable group data/data of multiple patients being capable of being processed/analyzed, as best understood, the prior art database/data is obviously also capable of being processed/analyzed as claimed.

Claim 31

The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed with a relationship algorithm.

See the discussion of claim 28 above, e.g., trend analysis of '973, Tables 1-2 and Figs. 2-8 of '747, '012's analysis/consult using rules based system of AI system.

Claim 32

The system in claim 31, wherein the database with the PAP therapy efficacy data is used with a treatment interface device processor for conducting a titration of a treatment.

See the discussion of claim 1 above, esp. section. A., e.g., the database is used in combination with the components of the titration system of '747 which includes a treatment interface device processor, e.g., transducer 48 and/or circuitry 49 which process signals representing the dynamic pressure in the mask.

¹⁶ It is noted that the claim does not identify the basis for the relative language "more robust".

Claim 27 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0022973 to Sun et al. (hereinafter also referred to as Sun or ‘973 (Exhibit F)) and International Publication No. 01/450012 to Quy (herein after also referred to as Quy or ‘012) (Exhibit H)) as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2002/0198473 to Kumar et al. (hereinafter also referred to as Kumar or ‘473 (Exhibit C)).

Claim 27

The system in claim 1, wherein the remote internet site and/or the database are adapted to be accessible one or more of clinicians, technicians, researchers or doctors for analysis or a remote monitoring of one or more of the subjects in another country.

See the discussion of claim 1, e.g., ‘973 at [0041]-[0042] and ‘012 at 12:13-15 (“Server 17 is in turn connected to the wired, or even a wireless (not shown) Internet 21, which may include the World Wide Web.”), and claims 23-26 above. However, while ‘973 and ‘012 describe a remote internet site and database accessible to patient’s and healthcare professionals via the internet/worldwide web neither ‘973 nor ‘012 explicitly disclose the systems analysis or a remote monitoring of one or more of the subjects in another country by one or more of clinicians, technicians, researchers or doctors. However, see Kumar ‘473 at [‘0014], [0017], [0078], [0181], and [0264]-[0266]. A POSITA would be motivated to utilize the systems analysis/remote monitoring as taught by ‘473 with the prior art internet accessible health monitoring systems, see discussion of claim 1, in order to make treatment available worldwide via the Internet, i.e. to treat patients in another state or country, while simultaneously communicating with them, and viewing their real-time physiological data. To the extent that ‘973/‘012’s internet accessibility is not interpreted to be analysis or a remote monitoring of one or more of the subjects in another

country by one or more of clinicians, technicians, researchers or doctors, ‘473 remedies any such perceived deficiency. As such, the proffered modification is merely combining prior art elements (‘973/‘012’s patient internet accessible health monitoring systems/‘473’s analysis or a remote monitoring of one or more of the subjects in another country by one or more of clinicians, technicians, researchers or doctors) according to known methods (using internet) to yield predictable results (worldwide availability of specialized analysis/monitoring).

Other References Submitted by the Requester

The other rejections proposed by the Requesters are highly material and relevant as they too have been deemed to raise a substantial new question of patentability with respect to the claims. It is noted that while the additional rejections appear to be cumulative at this time, any response to this office action may wish to address those references. Therefore, the claim rejections based upon these references are not made at this time as it would appear to be cumulative to the claim rejections advanced here.

Conclusion

Finality

Patent owner’s amendment filed June 9, 2025 necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

A shortened statutory period for response to this action is set to expire **TWO MONTHS** from the mailing date of this action.

Extensions of time under 37 CFR 1.136(a) do not apply in reexamination

proceedings. The provisions of 37 CFR 1.136 apply only to “an applicant” and not to parties in a reexamination proceeding. Further, in 35 U.S.C. 305 and in 37 CFR 1.550(a), it is required that reexamination proceedings “will be conducted with special dispatch within the Office.”

Extensions of time in reexamination proceedings are provided for in 37 CFR

1.550(c). A request for extension of time must specify the requested period of extension and it must be accompanied by the petition fee set forth in 37 CFR 1.17(g)(1). Any request for an extension in a third party requested ex parte reexamination must be filed on or before the day on which action by the patent owner is due, and the mere filing of a request will not effect any extension of time. A request for an extension of time in a third party requested ex parte reexamination will be granted only for sufficient cause, and for a reasonable time specified. Any request for extension in a patent owner requested ex parte reexamination (including reexamination ordered under 35 U.S.C. 257) for up to two months from the time period set in the Office action must be filed no later than two months from the expiration of the time period set in the Office action. A request for an extension in a patent owner requested ex parte reexamination for more than two months from the time period set in the Office action must be filed on or before the day on which action by the patent owner is due, and the mere filing of a request for an extension for more than two months will not effect the extension. The time for taking action in a patent owner requested ex parte reexamination will not be extended for more than two months from the time period set in the Office action in the absence of sufficient cause or for more than a reasonable time.

The filing of a timely first response to this final rejection will be construed as including a request to extend the shortened statutory period for an additional two months. In no event,

however, will the statutory period for response expire later than SIX MONTHS from the mailing date of the final action. See MPEP § 2265.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to “an applicant” and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings “will be conducted with special dispatch” (37 CFR 1.550(a)). Extension of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a), to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving US Patent No. 11,786,680 throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Amendment in Reexamination Proceedings

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c).

Submissions

Submissions after the second Office action on the merits, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, after final rejection and by 37 CFR 41.33 after appeal, which will be strictly enforced.

After filing of a request for *ex parte* reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. The document must reflect service or the document may be refused consideration by the Office. See 37 CFR 1.550(f).

All correspondence relating to this *ex parte* reexamination proceeding may be submitted via:

By Mail to: Mail Stop *Ex Parte* Reexam
 Central Reexamination Unit
 Commissioner for Patents
 United States Patent & Trademark Office
 P.O. Box 1450
 Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

Art Unit: 3992

By hand: Customer Service Window
Knox Building
501 Dulany Street
Alexandria, VA 22314

For Patent Center transmissions, 37 CFR 1.8(a)(1)(i)(C) and (ii) states that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if (a) it is transmitted via the Office's electronic filing system in accordance with 37 CFR 1.6(a)(4), and (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

Any inquiry concerning this communication should be directed to the Central Reexamination Unit at telephone number 571-272-7705.

Other useful telephone numbers: Reexamination Practice (571) 272-7703.

/Karin Reichle/
Primary Examiner
Art Unit 3992

Conferees:

/Cameron Saadat/
Primary Examiner, Art Unit 3992

/H.B.P/
Hetul Patel
Supervisory Patent Reexamination Specialist, Art Unit 3992