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Cleveland, OH 44103

EXAMINER

REICHLE, KARIN M

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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.



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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

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***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)).

Order Granting Request For Ex Parte Reexamination	Control No. 90/019,705	Patent Under Reexamination 11786680	
	Examiner Karin M Reichle	Art Unit 3992	AIA (FITF) Status No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 10/17/2024 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☐ PTO/SB/08, c) ☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

/Karin Reichle/ Primary Examiner, Art Unit 3992	/J.W./ Primary Examiner, Art Unit 3992	
cc:Requester (if third party requester)		

DECISION ON REQUEST FOR *EX PARTE* REEXAMINATION

Third Party Requester (TPR) submitted a request for reexamination of claims 1-32 of US Patent No. 11,786,680 (hereinafter also referred to as ‘680 or Kayyali ‘680) on October 17, 2024. A substantial new question of patentability affecting claims 1-32 of ‘680 is raised by the request for *ex parte* reexamination. Accordingly, claims 1-32 of ‘680 will be reexamined.

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

In order to insure full consideration of any amendments, affidavits or declarations or other documents as evidence of patentability, such documents must be submitted in response to the first Office action on the merits (which does not result in a close of prosecution). 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.

Waiver of Right to File Patent Owner Statement

In a reexamination proceeding, Patent Owner may waive the right under 37 C.F.R. 1.530 to file a Patent Owner Statement. The document needs to contain a statement that Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement and proof of service in the manner provided by 37 C.F.R. 1.248, if the request for reexamination was made by a third party requester, see 37 C.F.R 1.550(f).

Patent Owner **did not waive** the right under 37 C.F.R. 1.530 to file a Patent Owner Statement.

Service of Papers

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).

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.

(10) Japanese Patent Publication No, P2002-291889A to the inventor Shinichi Toge (hereinafter also referred to as Toge or '889 (Exhibit K)), filed March 29, 2001 and published on October 8, 2002.

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

Other

On pages 9-11, the Request sets forth:

Requester further notes that, besides the prior art references listed above, additional references are cited in the attached Form PTO/S8/08a¹ and as identified in the table below. **While these additional referenced [sic] are not relied upon explicitly as combinations that raise a SNQP,** they are believed to be pertinent to the patentability of the claims whose reexamination is requested herein and to substantiate the level of understanding of a POSTTA. Accordingly, copies of these additional references are enclosed herewith for the Examiner's consideration.
(Emphasis added.)

Proposed Grounds of Rejection of Claims 1-32 of US. Pat. No. 11,786,680

Ground 1: Claims 1-9, 11-14, 16-19, and 21-32 are obvious over Kumar, Truitt and '737 Farrell.

Ground 2: Claims 10, 15 and 20 are obvious over Kumar, Truitt, '737 Farrell and Lisy.

Ground 3: Claims 1-9, 11-14, 16-19, and 21-32 are obvious over Sun, Quy and Schmidt.

Ground 4: Claims 10, 15 and 20 are obvious over Sun, Quy, Schmidt and Lisy.

Ground 5: Claims 1-9, 12-14, 17-19, and 23-32 are obvious over Mumford and Quy.

Ground 6: Claims 10, 15, and 20 are obvious over Mumford, Chey and Kisner.

Ground 7: Claims 1-32 are obvious over "Toge in view of various references".

¹ No Form PTO/S8/08a accompanied the Request.

Patent Prosecution History

16/599,410 Prosecution (Exhibit B)

The '680 patent was originally filed as U.S. Application No. 16/599, 410 (herein after also referred to as the '410 application) on October 11, 2019, containing claims 1-20. The '410 application was a continuation of U.S. Patent Application Serial No. 15/355,189 filed on November 18, 2016 and issued as U.S. Patent No. 10,543,328 on January 28, 2020, which was a continuation of U.S. Patent Application Serial No. 13/975,792 filed on August 26, 2013 and issued as U.S. Patent No. 9,533,114 on January 3, 2019, which was a continuation of U.S. Patent Application Serial No. 11/880,046 filed on July 19, 2007 and issued as U.S. Patent No. 8,545,416 on October 1, 2013, which was a continuation-in-part of U.S. Patent Application Serial No. 11/266,899 filed on November 4, 2005 and issued as U.S. Patent no. 8,172,766 on May 8, 2012. A preliminary amendment was filed on November 29, 2021. The specification was amended to cross-reference International Application No. WO 2019161314A, original claims 1-20 were cancelled and claims 21-40 were added.

A first non-final office action issued on September 27, 2022 with various claim objections and rejections under 35 USC 101, 112, 102, and 103. EX. B, 139-161. In addition, it was noted that at least claim 28 did not have support in the '898 Application and therefore, at least claim 28 had a priority date of July 19, 2007, which is the filing date of the '046 Application. *Id.*, 141-142. Specifically, claims 21-26, 30-32, and 36-40 were rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Farrell et al., U.S. Patent Application Publication no. 2007/0161913 A1 ("Farrell"). See Exhibit L. Claims 27 and 29 were rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Farrell, as applied to claims 24 and 25, respectively,

above, and further in view of Hedner et al., U.S. Patent Application Publication No. 2008/0257349 A1 (“Hedner”).

Farrell ‘913 (Exhibit L) is the US Patent Application Publication of US Patent Application No. 10/598,914 (now US Patent No. 7,878,198 (Exhibit OTH-9)) which ‘914 application was the National Stage of PCT/US2005/010663 which published as WO2005/096737 (Exhibit O) now being asserted by the Request.

In response, claims 21-40 were substantially amended and claims 41-52 were added. EX. B, 110-132.

A Final Office Action issued on May 22, 2023 indicating the claims contained subject matter that was allowable over the cited art; however, the claims remained objected to and rejected under 35 USC 101 and 112.

Following an interview on August 10, 2023, a response after final was filed on August 11, 2023, including amendments to the claims that substantially paralleled those discussed during the August 10, 2023 interview.. The response merely noted that agreement was reached during the aforementioned interview.

A Notice of Allowance issued on September 5, 2023.

The Notice of Allowance included reasons for allowance which set forth:

As to Claims 21-52, neither Farrell, U.S. Patent Application Publication No. 2007/0161913 A1 (“Farrell”), Hedner et al., U.S. Patent Application Publication No. 2008/0257349 A1 (“Hedner”), Pirzada, U.S. Patent Application Publication No. 2007/0155208 A1 (“Pirzada”), nor the prior art of record teaches the sleeping disorder treatment system of base claim 21, including the following, in combination with all other limitations of the base claim:

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 [sic] by a first processor when the first software is downloaded to a cell phone [sic] 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,
the first software further adapted for:
i) receiving 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, 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

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;

...

a second processor adapted for generating the PAP therapy efficacy 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,

...

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.

The '680 Patent issued on September 6, 2025 with the only independent claim, claim 21, renumbered as claim 1.

As such it appears from the record that the technical features missing from the prior art at the time of allowance of the claims 1-32 of the '608 Patent are, "in combination with other limitations of the base claim"²:

² Claim 1 also claims "[a] A system for remote internet server-based diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment comprising

A. one or more PAP device(s);

[1] [A. one or more PAP device(s);

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

a second processor adapted for generating the PAP therapy efficacy 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...]

[2] ...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 execute 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.**

[3] ...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.**

... wherein the one or more PAP devices) 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,

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

a mask or a nasal cannula: and....”

- [4] ...the first software further adapted for:
- i) receiving 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, 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.

[5] ...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.

Substantial New Question Of Patentability

For a substantial new question of patentability (SNQ) to be present, it is only necessary that: (A) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and (B) the same question of patentability as to the claim has not been decided by the Office in a previous examination or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim. *See* MPEP §2242.

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).

Note Section IX on page 34 of the Request.

Analysis

Issue 1

The request alleges that the technological teachings of Kumar, Truitt, and Farrell '737, alone or in combination with Lisy raise a substantial new question (SNQ) of patentability regarding claims 1-32 of the '680 patent, as follows:

A. The request alleges that the technological teachings of Kumar, Truitt, and Farrell '737 raise an SNQ with respect to claims 1-9, 11-14, 16-19, and 21-32 of the '680 patent (SNQ 1).

B. The request alleges that the technological teachings of Kumar, Truitt, Farrell '737 and Lisy raise an SNQ with respect to claims 10, 15 and 20 are of the '680 patent (SNQ 2).

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 (a) and 35 USC 102(e).

None of Kumar, Truitt, and Lisy were of record during prosecution of the '680 patent and are therefore new art. As discussed above, Farrell '913 (Exhibit L) was applied and discussed during prosecution and such is the US Patent Application Publication of US Patent Application No. 10/598,914 (now US Patent No. 7,878,198 (Exhibit OTH-9)) which '914 application was the

National Stage of PCT/US2005/010663 published as WO2005/096737 (Exhibit O) now being asserted. As such, Farrell '737 is being viewed as "old art". MPEP 2242 states:

"for example, a substantial new question of patentability may be based solely on old art where the old art is being presented viewed in a new light, or in a different way, as compared with its use in the earlier examination(s), in view of a material new argument or interpretation presented in the request."

In this instance, the Request asserts Farrell '737 in combination with Kumar and Truitt or Kumar, Truitt and Lisy which combinations of prior art were never previously asserted. As such, Farrell '737 is being viewed in a new light.

Accordingly, Farrell '737 is not precluded from raising a substantial new question of patentability as presented.

See, e.g., pages 37-62 and Claim Chart 1 of the Request.

It is agreed that the technological teachings of Kumar, Truitt, and Farrell '737 raise an SNQ with respect to claims 1-9, 11-14, 16-19, and 21-32 of the '680 patent.

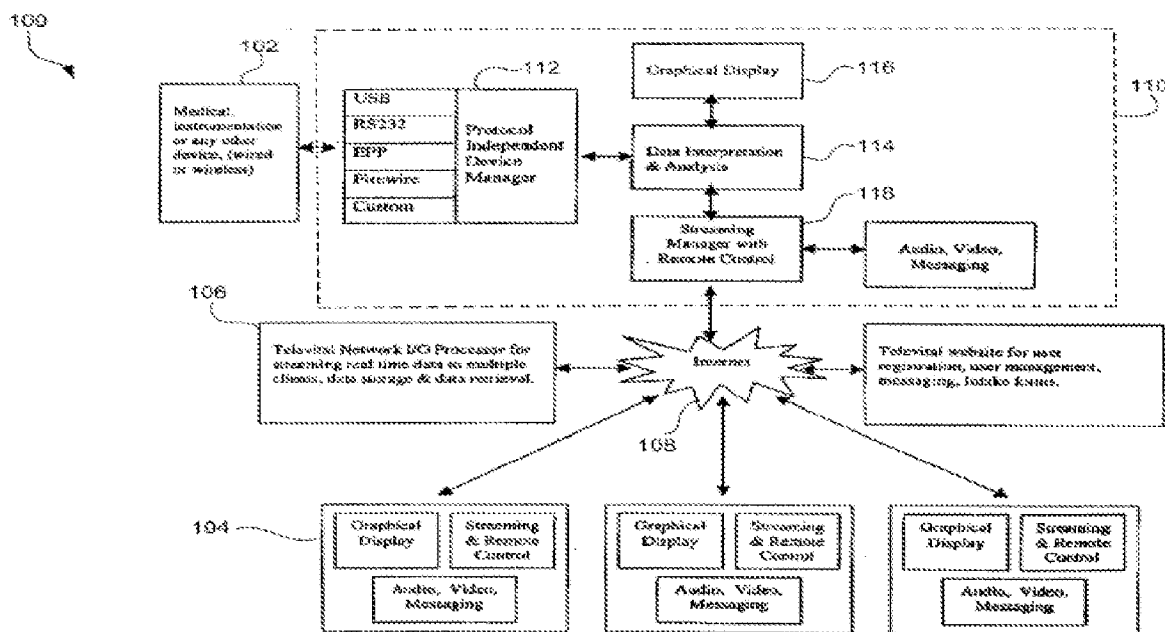


Fig. 1A

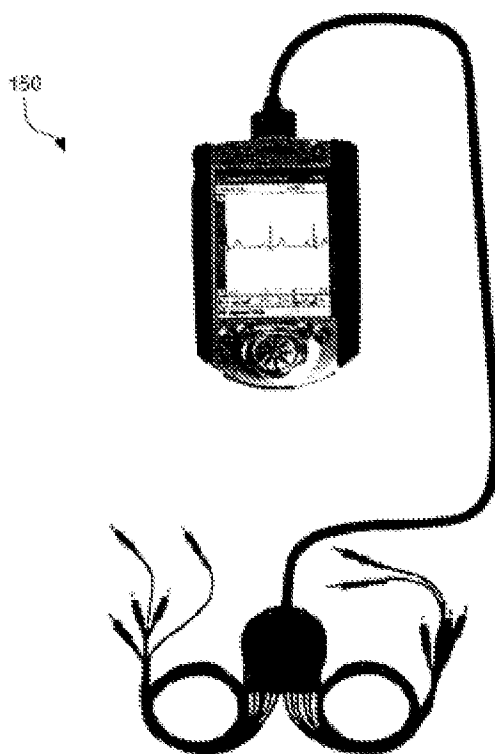


Fig. 1B

Kumar is directed to a “System and Method for Real-Time Monitoring, Assessment, Analysis, Retrieval, and Storage of Physiological Data over a Wide Area Network.” Ex C, Title. See also [0002], [0010], [0018]. As shown above in Figs. 1A and B, the system includes one or more patient-side devices 102 for collecting data from a patient/client, one or more provider-side devices 104, and an engine implemented on a central server 106. [0067]. See also [0069], [0011], [0072]. The central server 106 is connected to a wide area network (WAN) 108 such as the Internet and provides communication between the patient-side devices with the provider-side devices. [0067]. The patient-side device 102 may also be connected via a computing device 110, such as a computer, handheld devices, wireless telephones to the WAN. [0072], [0013]. See also Fig. 1B (showing an example of a wireless pocket PC with display). [0022]. The computing device may also be “built-in” to the patient side device. *Id.* Similarly, the provider-side device can be any type of computing device, such as a computer, PDA, wireless telephone, etc. [0072]. In one embodiment, the provider’s computing device (such as a PDA or telephone) has a wireless connection to the WAN so that, even though the doctor is not at a hospital or his office, he may still be consulted remotely without the need to rush to the hospital, *Id.*

On the patient-side, a device manager 112 running on the computing device establishes a two-way communication with a vast array of client-side devices, including medical and/or biofeedback devices that can be wired or wireless.” *Id.* As shown in Fig. 1A, data interpretation and analysis module 114 is also on the patient-side and is used to interpret the data stream from the client-side device, perform mathematical analysis on the data using FFT, DFT, etc., and generate statistics. [0075]. The data may be displayed graphically on the display module 116. *Id.*

The patient-side device and/or the computing device coupled to the patient-side device can send a request to the engine and the engine will send the appropriate plug-in which allows

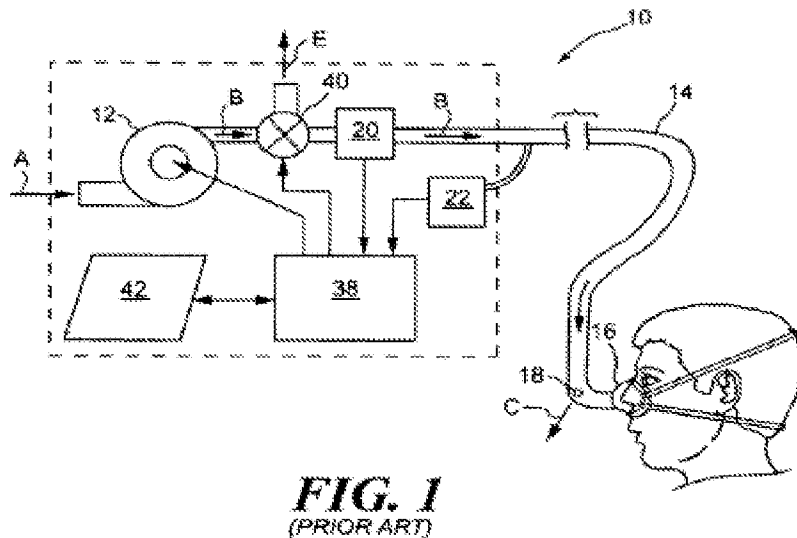
the computing device to communicate with the patient-side device and thus, supports both plug-and-play web device drivers and customized graphical user interfaces (GUIs) for the various devices. [0018], [0074]. This can also apply to the provider-side device. [0074]. In addition, the engine may configure the devices to transfer the data directly from one device to the other, may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device, or may store the data for later transmission to the provider-side device, etc. [0081], [0083]. The invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium. [0087].

By receiving data from the patient-side device, a provider is able to monitor the patient's physiology for research, keep track of documentation, perform analysis, manage and maintain records, diagnose the patient, and provide treatment in real-time to the patient, etc. [0078]. The internet-based monitoring and assessment system can be adapted to many applications for monitoring various medical conditions. [0173]. This includes applications directed to sleep apnea-hypopnea syndrome characterized by repetitive episodes of upper airway obstruction that occurs during sleep as well as partial reduction of airflow and provide remote, in-home and online live monitoring for sleep apnea-hypopnea syndrome. [0239]-[0241].

As such, it appears that the technological teachings of Kumar teach key features identified in [1]-[5] above that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the '680 patent.

Truitt is directed to a pressure support system, e.g. a continuous positive airway pressure (CPAP) device to supply a constant positive pressure to the airway of a patient to treat

obstructive sleep apnea (OSA) as well as other disorders. 1:24-43. Truitt describes a “prior art” CPAP device shown below:



As disclosed in Fig. 1 and described in the accompanying specification, a conventional pressure support system 10 includes a blower that receives a supply of gas from a gas source, such as ambient atmosphere and a patient circuit 14, which is typically a flexible conduit that delivers the elevated pressure breathing gas to the airway of the patient via a patient interface device 16 coupled to the other end. 1:44-55. The blower and the mask deliver elevated pressure to treat sleep apnea and other sleep disorders. *Id.* The conventional PAP device also includes a flow sensor 20, 32', pressure sensor 22, 32, or both internal to the PAP that monitor the flow and/or pressure of gas passing in patient circuit 14 and determine the volume of gas passing through the patient circuit from the flow information. 1:44-2:4. The signal from flow sensor 20 is provided to a controller 38. 2:37-40. The controller 38 receives information from flow sensor 20 and/or pressure sensor 22 to control the pressure or flow of gas provided to the patient, monitor the condition of the patient, and monitor the usage of the pressure support device (patient compliance). 2:1-11. See also 2:38-42. The processor also uses the output of flow sensor 32' for

calculating the flow and/or volume of gas passing through conduit 56.” 6:46-48. The system also includes an input/output device 42, such as a keypad, buttons, lights, LED or LCD display, and/or an audio device, in order to enter information and commands to the pressure support system such as the maximum and minimum pressures and pressure change in an auto-titration system and to display information. 3:12-20.

Similarly, Farrell’737 is directed to methods and apparatus for treating and monitoring sleep disordered breathing (“SDB”). 1:7-9. It is described that the most common form of sleep disordered breathing is obstructive sleep apnea (“OSA”) and that because the symptoms of sleep apnea present themselves as a result of a precursor, SDB has become the general term used to describe any disease state that manifests apneas and/or hypopneas during sleep 1:16-18. Further, the most common treatment of SDB is to administer continuous positive airway pressure (CPAP). 1:22-23.

Fig. 1 of Farrell ‘737 is reproduced below:

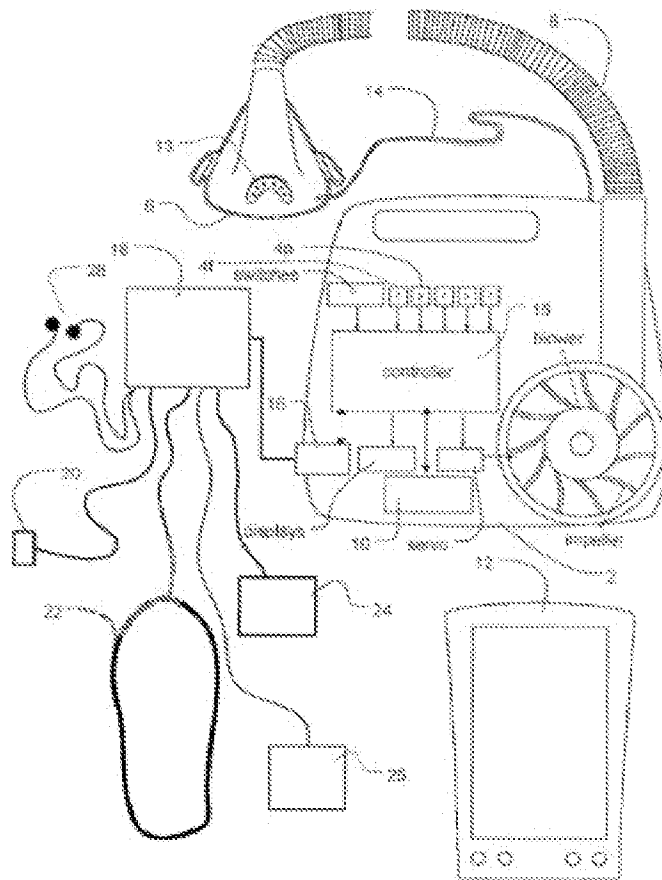


FIG. 1

The pressure delivery device of Fig. 1 may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6. 5:2-4. A controller 15 or processor is configured and adapted to implement the methodology described and may include integrated chips, a memory and/or other instruction or data storage medium. 5:20-23. The controller can be used for many different pressure treatment therapies simply by adjusting the pressure delivery equation that is used to set the speed of the blower or to manipulate the venting with the release valve. 5:24-27.

The disclosed CPAP device further includes a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12. The apparatus may further include an additional interface 16 for connection to additional diagnosis or patient information gathering devices. 5:28-31. As an example, the CPAP device can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication or it may interface with a network for transmission between the devices such that if, using such a device or system, a physician may, for example, remotely monitor, analyze, or record the status or data history of a patient. 6:23-27. Further, remote devices may send and receive from the apparatus any desired information or information may even be transmitted from the apparatus to a database of one or more patients. 6:22-29.

With respect to monitoring of sleep disordered breathing and related information, it is described the device provides efficacy tracking by detecting and recording or scoring SDB events or related information or indices over time, for example, by tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring. 7:35-8:24. Similarly, pressure and/or flow versus time data may also be recorded for analysis. In so doing, the device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting. *Id.* Finally it is described that methods for detecting and recording such information are known in the art. *Id.*

As such, it appears that the technological teachings of Truitt and Farrell '737 also teach key features identified above in at least Technical Features [1] and [4]-[5] that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the '680.

Therefore, the combined teachings of Kumar, Truitt, and Farrell '737 teach key features missing at the time of allowance. Since the teachings of the Kumar, Truitt, and Farrell '737 are directly related to the subject matter considered as the basis for allowability of patent claims 1-9, 11-14, 16-19, and 21-32 of the '680 patent, a reasonable examiner would consider the evaluation Kumar, Truitt, and Farrell '737, to be important in determining the patentability of claims 1-32. As such, the teachings of the Kumar, Truitt, and Farrell '737 are deemed to raise an SNQ on claims 1-9, 11-14, 16-19, and 21-32 of the '680 patent.

The request applies Lisy to dependent claims 10, 15 and 20. Since the teachings of Kumar, Truitt, and Farrell '737 raise an SNQ on the independent claim, the references also raise an SNQ on the dependent claims. As such, Lisy raises an SNQ on claims 10, 15 and 20 through dependency.

Issue 2

The request alleges that the technological teachings of Sun, Quy and Schmidt, alone or in combination with Lisy raise a substantial new question (SNQ) of patentability regarding claims 1-32 of the '680 patent, as follows:

A. The request alleges that the technological teachings of Sun, Quy and Schmidt raise an SNQ with respect to claims 1-9, 11-14, 16-19, and 21-32 of the '680 patent (SNQ 3).

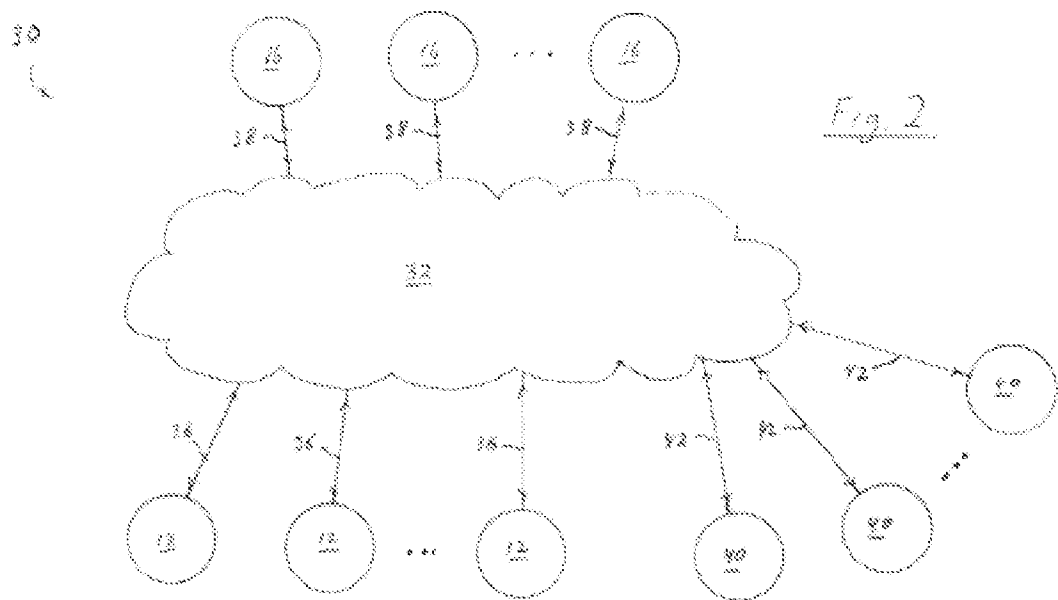
B. The request alleges that the technological teachings of Sun, Quy and Schmidt and Lisy raise an SNQ with respect to claims 10, 15, and 20 of the '680 patent (SNQ 4).

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 as well as Lisy, discussed above, qualify as prior art under 35 USC 102(b).

Neither Quay or Lisy were of record during prosecution of the '680 patent and are therefore, new art. Both Sun and Schmidt were cited but not applied or discussed during prosecution. They were also never considered in combination with Quay and Lisy. As such, both Sun and Schmidt are being viewed in a new light.

See, e.g., pages 62-90 and Claim Charts 2 of the Request.

It is agreed that the technological teachings of Sun, Quay and Schmidt raise an SNQ with respect to claims 1-9, 11-14, 16-19, and 21-32 of the '680 patent.



Sun describes a medical information management center which is computer-based and capable of storing, collecting, and processing patient medical and biographical information. [0041]. As shown above in Fig. 1, a database and processor hub, collectively referred to as server 34, in information management center 32 includes a memory 66 and a microprocessor 68. [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]. Each patient 12 interacts with server 34 via a first communication link 36 using a patient interface appliance 44, a healthcare professional 16 interacts with management center 32 via a second communication link 38 which enables the healthcare professional to review the patient medical information, update the information and provide recommendations to the patient. [0043], [0045], and [0050].

Patient interface appliance 44 is a portable, hand-held device that is capable of periodically establishing the first communication link with the server and runs a predetermined processing routine that is stored in the unit. [0050] Based upon this routine, a patient-tailored presentation 48 is provided to the user under the control of the program stored in the appliance. *Id.* Since patient interface appliance 44 is a small, handheld, light weight portable unit it can be easily carried and includes a housing 45, a processor 47, a memory 49, a display 50 and at least one input device 52. [0052].

Patient interface appliance 44 communicates with any medical device or system that is capable of monitoring a physiological condition of a patient and receiving data indicative of the use of the medical equipment or diagnostic data indicative of the condition of the medical device in order to alert the patient or others if the monitored parameters are not within established thresholds and to do so via a wireless link. [0054]. The appliance itself maybe a medical device. [0058]. It is contemplated that the functions of the patient interface appliances can be incorporated into a pressure support device, such as a continuous positive airway pressure (CPAP) device bi-level pressure support device, auto-titration device, or ventilator, so that the patient interface device also functions as a medical device for administering a pressure support or ventilation therapy to a patient.” *Id.*, Fig. 4.

As such, it appears that the technological teachings of Sun teach key features identified in Technical Features [1]-[5] above that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the '680 patent.

Quy 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. Figs. 1-4. The system includes a network of medical devices, monitoring devices, and a remote internet site that includes a server. FIG. 3, 14:22-31. The WWD may be a web/internet-enabled cellular phone, 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") for 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. 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 or 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.

Schmidt relates generally to a wireless data acquisition system for data communication that may be adapted for different applications by software programming. 1:15-20. The programmable wireless data acquisition system includes a signal processing module that has a microprocessor that controls the operation of the signal processing module. Abstract. The signal processing module is capable of receiving multiple external inputs and generating and transmitting a radio frequency signal encoded with data corresponding to the inputs for wireless transmission to a distributed network, including a base station. *Id.* Figs. 1-2.

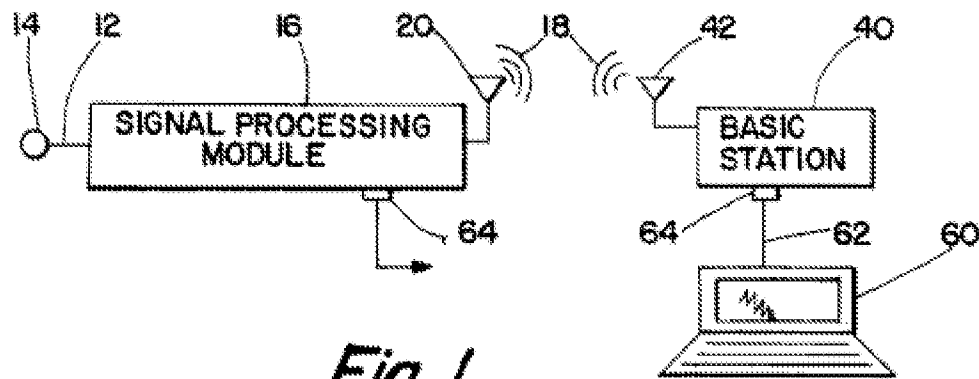


Fig. 1

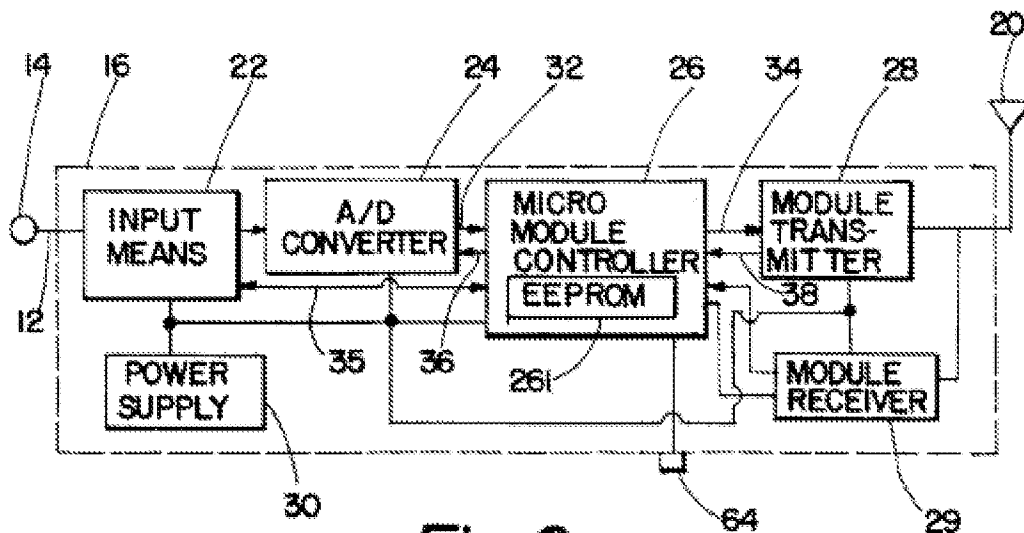


Fig. 2

The disclosed system processes signals from air flow and respiration sensors. The processing module 16 wirelessly transmits data to base station 40 via bidirectional transceiver. The base station 40 receives the radio frequency signal 18 through base antenna 42, demodulates the radio frequency signal 18, and decodes the data. The signal processing module 16 includes a module microcontroller 26 with a nonvolatile memory, advantageously, an EEPROM 261, a module transmitter 28 and a module receiver 29. 4:63-8:8. It is also noted that the '680 Patent includes the entire Detailed Description from Schmidt, 4:63 to 14:54 and Figures 1-6.

As such, it appears that the technological teachings Quay and Schmidt further teach key features identified in Technical Feature [1]-[5] above that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the '680 patent

Therefore, the combined teachings of Sun, Quay and Schmidt also teach key features missing at the time of allowance. Since the teachings of the Sun, Quay and Schmidt are directly related to the subject matter considered as the basis for allowability of patent claims 1-9, 11-14, 16-19, and 21-32 of the '680 patent, a reasonable examiner would consider the evaluation Sun, Quay and Schmidt, to be important in determining the patentability of claims 1-32. As such, the teachings of the Sun, Quay and Schmidt are deemed to raise an SNQ on claims 1-9, 11-14, 16-19, and 21-32 of the '680 patent.

The request applies Lisy to dependent claims 10, 15 and 26. Since the teachings of Sun, Quay and Schmidt raise an SNQ on the independent claim, the references also raise an SNQ on the dependent claims. As such, Lisy raises an SNQ on claims 10, 15 and 26 through dependency.

Issue 3

The request alleges that the technological teachings of Mumford and Quay, alone or in combination with Lisy raise a substantial new question (SNQ) of patentability regarding claims 1-32 of the '680 patent, as follows:

A. The request alleges that the technological teachings of Mumford and Quay raise an SNQ with respect to claims 1-9, 12-14, 17-19, and 23-32 of the '680 patent (SNQ 5).

B. The request alleges that the technological teachings of Mumford, Quay and Kisner, raise an SNQ with respect to claims 10, 15 and 20 of the '680 patent (SNQ 6).

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 Quay, see discussion above, and Kisner qualify as prior art under 35 USC 102(b).

Neither of Quay nor Kisner were of record during prosecution of the '680 patent and are therefore, new art. Mumford was of record during prosecution of the '680 patent, but was never cited or applied. It was also never considered in combination with Quay and Kisner. As such, Mumford is being viewed in a new light.

See pages 90-107 and Claim Chart 3 of the Request.

It is agreed that the technological teachings of Mumford, and Quay raise an SNQ with respect to claims 1-9, 12-14, 17-19, and 23-32 of the '680 patent.

Mumford is generally directed to a system and method for monitoring and measuring physiological signals that are communicated to a monitoring unit which, in association with a CPAP device, serves to determine the efficacy of the CPAP treatment and to vary operational parameters of the treatment. Abstract.

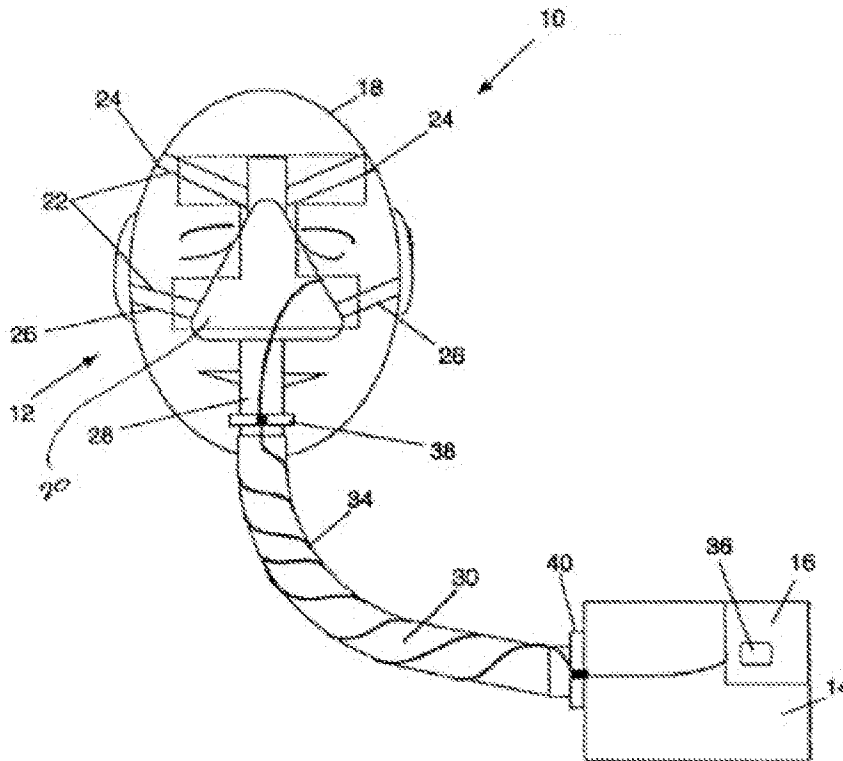


Figure 1

As shown in Figure 1, a mask assembly with integrated sensors senses the efficacy of treatment of medical conditions, such as obstructive sleep apnea during treatment with continuous positive airway pressure. 2:66-3:2. The sensors may include at least one of a blood oximetry sensor, a body position sensor and a pressure sensor. 7:30-33. The breathing rate of the wearer derived using a pressure transducer 316 is used to provide an indication of apnea and hypopnea events. 12:42-47. The mask is connected to a CPAP device 14 with an associated monitoring unit 16 which processes the physiological information according to a sleep efficacy algorithm. 7:34-37. The monitoring unit 16 may be separate from the CPAP device 14. See 6:63-7:10, 7:34-57.

Mumford also discloses a remote processing unit, 414, 514, which can be connected to the monitoring unit 16 via cable 34 and several interfaces for providing an electrical connection with the integrated sensors on the mask assembly 412. See Fig. 5a-b. 12:62-13:33. The functionality of the remote processing unit can also be similarly done by the monitoring unit 16. 13:65-14:2. The remote processing unit 414 may also perform the sleep efficacy algorithm 36 which can be stored on the memory unit 432. 14: 19-21. The control unit 426 directs the activity of the remote processing unit 414 and processes each of the signals provided by the sensors. The control unit 426 may be a digital signal processor. 13:25-28.

The sleep efficacy algorithm 36 may use standard techniques, as is commonly known to those skilled in the art, to process the physiological signals, determine the quality of sleep and generate the control signal. 7:51-57. The sleep efficacy algorithm 36 may identify sleep stages and generate the sleep profile information based on the physiological information sensed from the wearer 18. *Id.* The sleep profile includes the quality of the patient's sleep, the efficacy of the CPAP device 14, and compliance data. 7:34-46. Accordingly, the remote processing unit 414 may determine the sleep profile information for the wearer 18, generate the control signal to improve the sleep quality experienced by the wearer 18 and send the control signal to the CPAP device 14 to augment the pressure that is delivered to the nasal mask 20. 14:19-26. The sleep efficacy algorithm 36 may also use the sleep profile information to vary the CPAP titration pressure depending on the sleep stage and physicians may use the profile information to improve the quality of care and allow them to objectively assess the efficacy of treatment and monitor changes to therapy. 16:8-21.

Additionally, such sleep profile information may be transmitted to a caregiver through a wire connection to a computer. Wireless transmission may also be used. The wireless communication unit 516 runs a suitable wireless protocol such as the BLUETOOTH™ protocol which is suitable for short-range communication. For longer-range communication, the wireless communication unit 516 may employ another communications protocol such as CDMA. 14:26-40. Fig 5b, 15:13-29, Fig. 6.

As such, it appears that the technological teachings of Mumford show key features identified in Technical Features [1] and [4]-[5] above that were missing from the prior art at the time of allowance of claims 1-4, 6-8, 10-13, 15, and 16 of the '680 patent.

See the discussion of Quy with regard to Issue 2 above.

Therefore, the combined teachings of Mumford, and Quy teach key features missing at the time of allowance. Since the teachings of the Mumford, and Quy directly related to the subject matter considered as the basis for allowability of patent claims 1-9, 12-14, 17-19, and 23-32 of the '680 patent, a reasonable examiner would consider the evaluation Mumford, and Quy to be important in determining the patentability of claims 1-32. As such, the teachings of the Mumford and Quy are deemed to raise an SNQ on claims 1-9, 12-14, 17-19, and 23-32 of the '680 patent.

The request applies Kisner to dependent claims 10, 15 and 20. Since the teachings of Mumford and Quy raise an SNQ on the independent claims, the references also raise an SNQ on the dependent claim. As such, Kisner raises a SNQ on claims 5, 9, and 14 through dependency.

Issue 4

The request alleges that the technological teachings of the Toge, and “various references” raise a substantial new question (SNQ) of patentability regarding claims 1-32 of the ‘680 patent.

On pages 2-4, 5 and 9 of the Request, Japanese Patent Publication No, P2002-291889A to the inventor Shinichi Toge (hereinafter also referred to as Toge or ‘889 (Exhibit K)) is identified as one of the “material, non-cumulative prior art references [which] raise a substantial new question of patentability (“SNQ”) concerning all claims of the “680 Patent, copies of which are attached hereto and listed in an accompanying Form PTO/SB/08a”. Specifically, Japanese Patent Publication No, P2002-291889A was identified as raising SNQ 7, i.e. “Obviousness: Toge in view of various references”. Continuing, the Request asserted “[a] copy of a certified translation of Toge” was “attached as Ex. K”. However:

- No form PTO/SB/08a accompanied the Request.
- A copy of Japanese Patent Publication No, P2002-291889A was not attached to the Request.
- The translation copy purported to be an English translation of Japanese Patent Publication No, P2002-291889A attached as Ex. K is not certified.

Furthermore, with regard to the “various references”, the listing on page 4 lists a number of “SNQP 7 References”, i.e. Lankford, Farrell ‘913, Rasid, ‘345 Berthon-Jones, ‘129 Berthon-Jones, Hansen and Kumar. See also Claim Chart 4. However, Lankford, Farrell ‘913, Rasid, ‘345 Berthon-Jones and ‘129 Berthon-Jones are not discussed on pages 7-9 as one of the 10 prior art references for which reexamination is requested. In fact, Lankford, Farrell ‘913, Rasid, ‘345

Berthon-Jones, and ‘129 Berthon-Jones appear on pages 9-10 of the Request in a table listing of references noted by the request as follows:

Requester further notes that, besides the prior art references listed above, additional references are cited in the attached Form PTO/S8/08a and as identified in the table below. **While these additional references are not relied upon explicitly as combinations that raise a SNQP**, they are believed to be pertinent to the patentability of the claims whose reexamination is requested therein and to substantiate the level of understanding of a POSTTA. Accordingly, copies of these additional references are enclosed herewith for the Examiner’s consideration.

(Emphasis added.)

Page 107 of the request further sets forth:

Requestor notes that the Toge reference, which is relied on in this SNQP as the primary reference, is discussed in detail supra, §X. **For the sake of simplicity, as CHART-4 is replete with details including much of the same information presented above in an alternative combination**, a full analysis is not provided herein.

(Emphasis added.)

Finally, on pages 34-37, X. STATEMENT IDENTIFYING EACH SUBSTANTIAL NEW QUESTION OF PATENTABILITY (37 C.F.R. §1.510), and A. Obviousness Considerations for the Challenged Claims, 1. Overall Reasons to Combine, the Request only discusses Toge, Truitt and Schmidt generally with respect to the state of the art in 2005.

Therefore, either in view of the lack of a certified English translation of Japanese Patent Publication No, P2002-291889A and/or the lack of clarity as to the “SNQ 7” as presented by the Request with regard to such Japanese Patent Publication No, P2002-291889A, i.e. Japanese Patent Publication No, P2002-291889A alone, Toge with Lankford, Farrell ‘913, Rasid, ‘345 Berthon-Jones, ‘129 Berthon-Jones, Hansen and Kumar, Toge with only Hansen and Kumar,

Toge with Truitt and Schmidt, a reasonable examiner would not consider the evaluation of Toge and “various references” as asserted to be important in determining the patentability of claims 1-32. Therefore, it is not agreed that the technological teachings of Toge, and “various references” as asserted by the Request raise an SNQ with respect to claims 1-32 of the ‘680 patent.

35 USC 325(d)

A review of the post grant history of the underlying ‘680 patent indicates that there have been no other Office post grant challenges made to the patent (Reexamination Proceedings or *Inter Partes* Review, Post Grant Review, Covered Business Methods trials). Accordingly, a discretionary denial of reexamination pursuant to 35 USC 325(d) is not applicable.

Conclusion

Accordingly, as a substantial new question of patentability is present, reexamination is granted, see MPEP 2242. Claims 1-32 will be reexamined.

Correspondence

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

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