IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of Hani Kayyali *et al.*	§	Attorney Docket: 227745.010200-R680
U.S. Patent No. 11,786,680	§	Customer No.: 35893
Issue Date: October 17, 2023	§	
Filing Date: October 11, 2019	§	
For: INTEGRATED DIAGNOSTIC AND THERAPEUTIC SYSTEM AND METHOD FOR IMPROVING TREATMENT OF SUBJECT WITH COMPLEX AND CENTRAL SLEEP APNEA	§	

REQUEST FOR *EX PARTE* REEXAMINATION OF U.S. PATENT 11,786,680

Mail Stop "*Ex Parte* Reexam"
Attn: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

ResMed Corp. (hereinafter "the Requester") hereby requests *ex parte* reexamination under 35 U.S.C. §§ 301-307 and 37 C.F.R. §§ 1.510-1.570 of United States Patent No. 11,786,680 B1 (EX. A, "the '680 Patent"),[1] which issued on October 17, 2023 to Hani Kayyali et al. from an application filed on October 11, 2019. The '680 Patent has not yet expired and is therefore still in force.

As set forth in detail below, ResMed submits that each prior art reference discussed below is analogous art to the '680 Patent as they pertain to telemedicine devices for patient treatment and communication with healthcare providers. The prior art describes hardware and software solutions for administering patient treatment, particularly addressing sleep disorders and conditions, i.e., sleep apnea, and facilitating communication with healthcare providers and improving overall

[1] The prosecution history for the '680 Patent is included herein as Exhibit B.

treatment. These solutions described in these prior art references are known to one skilled in the art well before they are identified as alleged inventions of the '680 Patent. For the reasons below, the identified prior art references raise substantial new questions of patentability for the claims of the '680 Patent.

I. STANDARDS FOR INITIATING EX PARTE REEXAMINATION AT THE USPTO

Under 35 U.S.C. §302, an order for reexamination of a patent is granted by the United States Patent and Trademark Office ("the Office") if a substantial new question of patentability affecting any of the claims of the patent is raised by the requester. According to MPEP §2242(I), a prior art reference presents a substantial new question of patentability when there is a substantial likelihood that a reasonable examiner would consider the reference important in deciding whether a claim is patentable. While a substantial *new* question of patentability does not arise when "*the same* question of patentability has already been decided," *id.* (emphasis added), a substantial new question of patentability may still arise from "old" references. *Id.* §2242(II)(A). For example, a request may raise a substantial new question of patentability when it casts old references in a new light or presents them in a way that previously escaped review. *Id.*; *see also* §2216.

II. REQUIREMENTS UNDER 37 C.F.R. § 1.510

This request satisfies the requirements of 37 C.F.R. § 1.510, as follows:

A. Reexamination Fee (37 C.F.R. § 1.510(a))

Requester submits herewith the required fee under 37 C.F.R. § 1.20(c)(1). If any additional fees are due and/or a refund is made, the Commissioner is hereby authorized to debit/deposit additional funds from/to Deposit Account No. 501561.

B. Claims for which Reexamination is Requested (37 C.F.R. § 1.510(b)(2))

Requester respectfully requests *ex parte* reexamination under 35 U.S.C. §§ 301-307 and 37 C.F.R. §§ 1.510-1.570 of Claims 1-32 of the '680 Patent, and issuance of a reexamination

certificate canceling those claims. The following material, non-cumulative prior art references raise a substantial new question of patentability ("SNQP") concerning all claims of the '680 Patent, copies of which are attached hereto and listed in an accompanying Form PTO/SB/08a.

Reference	Abbreviation and Exhibit Number	Publication/Issue Date	Previously Cited	Previously Applied in a Rejection
U.S. Publication No. 2002/0198473 to Kumar et al.	Kumar EX. C	December 26, 2002	No	No
U.S. Patent No. 6,644,311 to Patrick W. Truitt et al.	Truitt EX. D	November 11, 2003	No	No
U.S. Publication No. 2004/0129838 to Lisy et al.	Lisy EX. E	July 8, 2004	No	No
U.S. Publication No. 2002/0022973 to Sun et al.	Sun EX. F	February 21, 2002	Yes	No
U.S. Patent No. 6,167,258 to Robert N. Schmidt et al.	Schmidt EX. G	December 26, 2000	No	No
W.O. Publication No. 01/45014 to Quy	Quy EX. H	June 21, 2001	No	No
U.S. Patent No. 7,575,005 to John Robert Mumford et al.	Mumford EX. I	August 18, 2009	Yes	No
U.S. Patent No. 5,309,921 to Roger A. Kisner, et al.	Kisner EX. J	May 10, 1994	No	No
JP Patent No. 2002291889 to Toge	Toge EX. K	October 8, 2002	No	No
WO 2005/096737A2 (Farrell et al.)	'737 Farrell EX. O *also* OTH-6	October 10, 2002	Yes	No

With respect SNQP 7, the following listing is provided:

SNQP 7 References	Abbreviation and Exhibit Number	Publication/ Issue Date/Filing Date
JP Patent No. 2002291889 to Toge	Toge EX. K	2002
Lankford, D. A., Ph.D., *Wireless CPAP Patient Monitoring: Accuracy Study,* Telemedicine Jr. v. 10, no. 2 (2004).	Lankford EX. OTH-1	2003
U.S. Publication No. 2007/0161913 (Farrell et al.)	'913 Farrell EX. L	2004
Mohd Fadlee A. Rasid and Bryan Woodward, Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks," IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005	Rasid EX. OTH-13	2005
U.S. Patent No. 5,704,345 (Berthon-Jones et al.)	'345 Berthon-Jones EX. OTH-18	1998
U.S. Patent No. 6,152,129 (Berthon-Jones)	'129 Berthon-Jones EX. M	2000
U.S. Publication No. 2003/0065536 (Hansen et al.)	Hansen EX. N	2003
U.S. Publication No. 2002/0198473 to Kumar et al.	Kumar EX. C	2002

Pursuant to 37 C.F.R. § 1.510(b)(3) and (4), Requester includes copies of the '680 Patent and each patent and printed publication presenting a substantial new question of patentability for the challenged claims.

Further, pursuant to 37 C.F.R. §1.510(b)(1), Requester identifies the following combinations that raise an SNQP concerning each claim of the '680 Patent.

SNQP No.	Claims	Basis for Rejection
1	1-9, 11-14, 16-19, and 21-32	Obviousness: Kumar, Truitt and '737 Farrell
2	10, 15 and 20	Obviousness: Kumar, Truitt, '737 Farrell and Lisy
3	1-9, 11-14, 16-19, and 21-32	Obviousness: Sun, Quy and Schmidt
4	10, 15 and 20	Obviousness: Sun, Quy, Schmidt and Lisy
5	1-9, 12-14, 17-19, and 23-32	Obviousness: Mumford and Quy
6	10, 15, and 20	Obviousness: Mumford, Quy and Kisner
7	1-32	Obviousness: Toge in view of various references

C. Certificate of Service (37 C.F.R. § 1.510(b)(5))

Requester accompanies this request with a certification that the patent owner (i.e., Cleveland Medical Devices Inc., (hereinafter "CleveMed") has been served with this request in its entirety at the address provided for in 37 C.F.R. § 1.33(c). The certificate indicates the name and address of the party served. Requester has also served courtesy copies on CleveMed's counsel-of-record.

D. Certification Regarding Statutory Estoppel Provisions (37 C.F.R. § 1.510(b)(6)) and 35 U.S.C § 325(d)

Requester certifies that the statutory estoppel provisions of both inter partes review (35 U.S.C. § 315(e)(1)) and post grant review (35 U.S.C. § 325(e)(1)) do not bar or prohibit Requester from requesting *ex parte* reexamination of the '680 Patent.

The Federal Circuit's decision in *In re Vivint, Inc.*, 14 F.4th 1342 (Fed. Cir. 2021) does not apply to this Request should Patent Owner argue for a denial under §325(d). In *Vivint*, unlike here, the Requestor engaged in "serial" filings by submitting a reexam request after filing a series of IPR petitions, the last of which the Board deemed an "undesirable, incremental" attack on the

Patent Owner and denied the petition. *Id.* at 1346. Yet, after that denial, the Requestor filed a reexam request that ultimately resulted in cancellation of the challenged claims. On review, the Federal Circuit reversed the CRU's decision about reexam, finding that the request, which mirrored the denied IPR petition, was an abusive filing. The Federal Circuit reasoned that the reexam "copied, word-for-word, two grounds from the [denied petition], the very petition deemed 'a case of undesirable, incremental petitioning.'" *Id.* at 1353.

In contrast, this Request involves no evidence of "serial" filing or harassment. It raises substantial new questions of patentability based on new information that the Office has not previously addressed. The Request addresses specific prior art disclosures and fills a gap not previously considered. Therefore, unlike *Vivint*, this Request does not constitute "undesirable, incremental petitioning" and should not be denied under § 325(d) based on the *Vivint*.

III. RESERVATION OF RIGHTS

As indicated above, *ex parte* reexamination is requested of all claims (i.e., Claims 1-32). Requester reserves all rights and defenses available including, without limitation, defenses as to invalidity, unenforceability, and non-infringement regarding the '680 Patent. Further, for the purposes of this Request, the Office should construe the claims of the '680 Patent by applying the "broadest reasonable interpretation" during reexamination. *See* MPEP §2258. This interpretation should control regardless of how a court may interpret the claims. *See* MPEP §2286 (explaining that "because of the different standards of proof and claim interpretation employed by the District Courts and the Office," the Office makes its own independent interpretation). Accordingly, any interpretation or construction of the claims presented for reexamination in this request, either implicitly or explicitly, should not be viewed as constituting, in whole or part, Requester's own interpretation or construction of such claims. Requester expressly reserves the right to explain,

however appropriate, its own interpretation or construction, which may differ, in whole or part, from that reflected herein, in this or an alternate proceeding.

IV. LEVEL AND PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") would have had a bachelor's degree in mechanical engineering, electrical engineering, computer science or an equivalent field and two years of industry experience working with diagnostic sensor systems and networked data systems, where an increase in experience could compensate for less education, and vice-versa. A POSITA would have worked with professionals having specialized training in related disciplines such as clinical use and operation of sleep disordered breathing treatment devices. The patent owner has previously agreed to this definition of a POSITA in the related IPR2023-00565, Patent Owner's Response, p. 8.

V. CITATION OF PRIOR ART

Reexamination is requested in light of the following prior art references:

1. U.S. Publication No. 2002/0198473 to Kumar et al. ("Kumar"). The application for Kumar was filed on March 28, 2002, and published on December 26, 2002, making it prior art to the '680 Patent under 35 U.S.C. §102(b). Kumar was not cited as a reference in the prosecution of the '680 Patent. A copy of Kumar is attached as EX. C.

2. U.S. Patent No. 6,644,311 to Patrick W. Truitt et al. ("Truitt"). The application for Truitt was filed on December 19, 2001, and the patent issued on November 11, 2003, making it prior art to the '680 Patent under 35 U.S.C. §102(b). Truitt was not cited as a reference in the prosecution of the '680 Patent. A copy of Truitt is attached as EX. D.

3. U.S. Publication No. 2004/0129838 to Lisy et al. ("Lisy"). The application for Lisy was filed on January 3, 2003, and the patent issued on July 8, 2004, making it prior art to

the '680 Patent under 35 U.S.C. §102(b). Lisy was not cited as a reference in the prosecution of the '680 Patent. A copy of Lisy is attached as EX. E.

4. U.S. Publication No. 2002/0022973 to Sun et al. ("Sun"). The application for Sun was filed on March 21, 2001, and published on February 21, 2002, making it prior art to the '680 Patent under 35 U.S.C. §102(b). Sun was cited as a reference in the prosecution of the '680 Patent, but importantly it was not relied upon in any rejection. A copy of Sun is attached as EX. F.

5. U.S. Patent No. 6,167,258 to Robert N. Schmidt et al. ("Schmidt"). The application for Schmidt was filed on October 9, 1998, and the patent issued on December 26, 2000, making it prior art to the '680 Patent under 35 U.S.C. §102(b). Schmidt was not cited as a reference in the prosecution of the '680 Patent. A copy of Schmidt is attached as EX. G.

6. W.O. Publication No. 01/450012 to Quy ("Quy"). The application for Quy was filed on December 16, 2000, making it prior art to the '680 Patent under 35 U.S.C. §102(b). Quy was not cited as a reference in the prosecution of the '680 Patent. A copy of Quy is attached as EX. H.

7. U.S. Patent No. 7,575,005 to John Robert Mumford et al. The application for Mumford was filed on May 18, 2005 and claims priority to U.S. Provisional Applications 60/571,890; 60/571,944; 60/571,942, each of which was filed on May 18, 2004, and the patent published on August 18, 2009, making it prior art to the '680 Patent under 35 U.S.C. §102(e). While Mumford was cited as a reference in the prosecution of the '680 Patent, it was not relied upon in any of the rejections. A copy of Mumford is attached as EX. I.

8. U.S. Patent No. 5,309,921 to Roger A. Kisner, et al. ("Kisner"). The application for Kisner was filed on February 11, 1992, and the patent issued on May 10, 1994, making it

prior art to the '680 Patent under 35 U.S.C. §102(b). Kisner was not cited as a reference in the prosecution of the '680 Patent. A copy of Kisner is attached as EX. J.

9. JP Patent Publication No. 2002291889 to Toge ("Toge"). The application for Toge was filed on March 29, 2001, and was published on October 8, 2002, making it prior art to the '680 Patent under 35 U.S.C. §102(b). Toge was not cited as a reference in the prosecution of the '680 Patent. A copy of a certified translation of Toge is attached as EX. K.

10. WO Publication No. 2005/096737A2 to Farrell et al. ("Farrell"). The application for Farrell was filed on March 31, 2004, making it prior art to the '680 Patent under 35 U.S.C. §102(a) and (e). While '737 Farrell was cited as a reference in the prosecution of the '680 Patent, it was not relied upon in any of the rejections. A copy of '737 Farrell is attached as EX. O.

Requester further notes that, besides the prior art references listed above, additional references are cited in the attached Form PTO/SB/08a and as identified in the table below. While these additional referenced 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 POSITA. Accordingly, copies of these additional references are enclosed herewith for the Examiner's consideration.

Other (OTH) References	Abbreviation and Exhibit Number	Publication/ Issue Date/Filing Date
Lankford, D. A., Ph.D., *Wireless CPAP Patient Monitoring: Accuracy Study,* Telemedicine Jr. v. 10, no. 2 (2004).	Lankford EX. OTH-1	2003
Bluetooth Ver.1.0B (Parts A and B) (November 1999).	BT V.1. EX. OTH-2	1999
U.S. Patent Application Publication 2002/0165462A1	Westbrook EX. OTH-3	2002

Other (OTH) References	Abbreviation and Exhibit Number	Publication/ Issue Date/Filing Date
Guilleminault, et al., *Clinical Overview of the Sleep Apnea Syndromes, Sleep Apnea Syndromes* (1978), pp.1-12.	Guilleminault-1978 EX. OTH-4	1978
"Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research: The Report of an American Academy of Sleep Medicine Task Force," SLEEP Vol. 22, No. 5 (1999), pp.667-689.	Chicago Criteria EX. OTH-5	1999
WO 2005/096737A2 (Farrell et al.)	'737 Farrell EX. OTH-6	2005
U.S. Patent No. 10,076,269 Prosecution History	'269 PH EX. OTH-7	
Guilleminault, et al., *Obstructive sleep apnea syndromes*, Med. Clin. N.Am. Vol. 88, No. 3 (May 1, 2004), pp.611-630.	Guilleminault-2004 EX. OTH-8	2004
U.S. Patent No. 7,878,198 (Farrell)	Farrell-198 EX. OTH-9	2005
U.S. Patent No. 7,438,747 (Gliner)	Gliner EX. OTH-10	2005
U. S. Patent No. 5,987,519 (Peifer)	Peifer EX. OTH-11	1999
Jasemian and Arendt Nielsen, Evaluation of realtime, remote monitoring telemedicine system using the Bluetooth protocol and a mobile phone network, Journal of Telemedicine and Telecare 2005, Vol. 11, Issue 5	Jasemian EX. OTH-12	2005
Mohd Fadlee A. Rasid and Bryan Woodward, Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks," IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005	Rasid EX. OTH-13	2005
U.S. Patent Publication No. 2002/0165462 (Kocinski)	Kocinski EX. OTH-14	2002

Other (OTH) References	Abbreviation and Exhibit Number	Publication/ Issue Date/Filing Date
Paradiso, et al., *Wearable Health Care System for Vital Signs Monitoring*, 4th Annual IEEE Conf. on Information Technology Applications in Biomedicine, 2003	Paradiso EX. OTH-15	2003
US Patent No. 4,944,310 (Sullivan)	'310 Sullivan EX. OTH-16	1990
US Patent No. 5,245,995 (Sullivan)	'995 Sullivan EX. OTH-17	1993
U.S. Patent No. 5,704,345 (Berthon-Jones)	'345 Berthon-Jones EX. OTH-18	1998
WO 04/032719A2 (Burton et al.)	Burton EX. OTH-19	2004
U.S. Patent Publication No. 2003/0236450 (Kocinski)	Kocinski EX. OTH-20	2003

VI. RELATED COURT AND ADMINISTRATIVE PROCEEDINGS

A. Related District Court Proceedings

To expedite processing of this Request, the Requester notes that the '680 Patent is asserted in the following lawsuit that may affect or be affected by a decision in this proceeding: *ResMed Corp. v. Cleveland Medical Devices, Inc.*, case no. 23-cv-0111, currently pending before the United States District Court for the Northern District of Ohio (hereinafter "the Ohio Litigation"). Also asserted in the Ohio Litigation are other related patents as identified below.

In addition to the Ohio Litigation, CleveMed filed another case against ResMed, *Cleveland Medical Devices, Inc. v. ResMed Inc.*, 1-22-cv-00794, currently pending in the United States District Court for the District of Delaware (hereafter "the Delaware Litigation"). In total,

Patent Owner asserts 13 patents against ResMed in these two separate lawsuits. The 13 asserted patents generally fall into two groups:

Group 1: CleveMed asserts six "PAP" patents (Nos. 10,076,269; 11,602,284; 11,375,921; **11,786,680**; 11,857,333; 11,872,029), all of which are continuations or continuations-in-part of U.S. Patent App. No. 11/266,899 and purportedly are directed to positive airway pressure (PAP) sleep disorder treatment systems. CleveMed accuses various ResMed products of infringing the PAP patents.

The '269 Patent is asserted in the Delaware Litigation, while the rest of the PAP patents are asserted in the Ohio Litigation.

Group 2: CleveMed asserts seven "HST" patents (Nos. 10,426,399; 10,925,535; 11,064,937; 10,028,698; 11,202,603; 11,234,637; 11,690,512) from multiple patent families. The HST patent claims are directed to systems for remote or at-home sleep analysis. CleveMed accuses various ResMed products of infringing the HST patents in the various litigations.

The '512 patent is asserted in the Ohio Litigation, while the rest of the HST patents are asserted in the Delaware Litigation.

For the reasons discussed herein, the Requester respectfully submits that the cited prior art references render claims 1-32 of the '680 Patent unpatentable in view of the knowledge of a POSITA and raise substantial new questions of the patentability impacting the claims under 37 C.F.R. §1.510(B)(2). The Requester requests reexamination of the claims by the Office for the resolution of these questions.

B. Related Post-Grant Review Proceedings

Further, the Requester notes various other proceedings, involving post-grant petitions filed by Requester, are currently pending before the Office as identified below.

1. PGR2024-00012 for U.S. Patent No. 11,602,284 ("the '284 patent")

The '284 patent is the subject of a Post-Grant Review ("PGR") petition filed in the Office by Requester, identified as PGR2024-00012. The Petition is currently denied institution on procedural grounds relating to whether the '284 patent is a pre-AIA patent or an AIA-eligible patent. Petitioner filed a request for rehearing, which remains pending.

2. IPR2023-00565 for U.S. Patent No. 10,076,269 ("the '269 patent")

The related '269 patent is the subject of an *inter partes* review ("IPR") petition, namely IPR2023-00565, filed by ResMed (hereinafter "the '269 patent IPR"). On May 6, 2024, the PTAB issued its decision to institute review of the '269 patent IPR for claims 1-20 ("the challenged claims of the '269 patent IPR"). In particular, the PTAB Institution Decision reasoned that claims of the '269 patent were shown to be obvious over various prior art combinations, including that independent Claim 15 was obvious over Kocinski (U.S. Patent Publication No. 2002/0165462) (EX. OTH-14) in view of the '737 Farrell (WO 2005/096737A2) (EX. O), and Bluetooth (Bluetooth Ver.1.0B (Parts A and B) (November 1999) EX. OTH-2 (BT V.1)) (hereafter "Kocinski, '737 Farrell, and Bluetooth combination"). The PTAB also instituted the '269 patent IPR on the grounds that claims 16-20, which depend from Claim 15 were obvious, and therefore unpatentable, over the same combination, or the same combination with the addition of one or more of EX. OTH-8 (Guilleminault-2004), EX. OTH-3 Westbrook (U.S. Patent Publication No. 2002/0165462), or EX. OTH-15 (Paradiso).

Exemplary Claim 15 of the '269 patent, which shares features with Claim 1 of the '680 patent, is reproduced below.

> 15. A positive airway pressure (PAP) sleep disorder treatment system comprising:
>
> a PAP device with an enclosure further comprising:
>
> a blower having an air output,

> an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data;
>
> a processor adapted for receiving the airflow sensor data, and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device;
>
> a mask or a nasal cannula;
>
> a first radio frequency wireless module transceiver and
>
> a base station, cellular phone, or PDA;
>
> the first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and the data of usage to the base station, cellular phone or PDA;
>
> the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display,
>
> the base station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.

Claim 15, '269 Patent.

For example, during prosecution of claim 1 of the related '921 patent, Patent Owner explained that the above claim 15 of the '269 patent was very similar to then pending claim 1 of the '921 patent, in arguing for allowance. Patent Owner stated, with respect to the '921 patent that "Claim 1 has been modified and Amended to be similar to previously allow[sic] Claim 15 in its direct parent case Appln. Ser. No. 13/440,116, which issued as U.S. Pat. No. 10,076,269," and further noted that "Claims 4-6, 8-13, and 15-22 were patterned after Claims 16-20 in the patent[sic] case." EX. B, '921 Patent File History, Corrected Amendment dated October 15,

2021 at 12. Patent Owner explained that the "main difference between the claim allowed in the parent case and that currently being prosecuted in the instant case is that we are claiming the software instead of the base station, cellular phone or PDA, but the software is subject to being used with a base station, cellular phone or PDA, which has all the limitations of those claimed in the parent case. The same data is being transferred as in the parent case but refer to it as *'data related to the subject's treatment and its efficacy'* for display to the subject and their care providers." EX. B, '921 Patent File History, Corrected Amendment dated October 15, 2021 at 12 (emphasis in original). Patent Owner acknowledged the likelihood of an obviousness type double patenting rejection and indicated a willingness to file a terminal disclaimer to obviate such a rejection. EX. B, '921 Patent File History, Corrected Amendment dated October 15, 2021 at 12. Generally, Patent Owner acknowledged during prosecution that the claims of the '921 Patent are not patentably distinct by way of features from those of the '269 patent, currently under review by the PTAB. The '921 and '269 patent claims discussed above, share similar features recited in the claims of the '680 patent.

In light of the above, the combination of Kocinski, '737 Farrell, and Bluetooth combination, upon which the PTAB instituted review of Claim 15 of the '269 patent and its dependents, would also be relevant to present a substantial new question of patentability with regard to features of at least Claim 1 of the '680 patent and its dependents.

3. Request of *Ex Parte* Reexamination for U.S. Patent No. 11,375,921 ("the '921 patent")

An *ex parte* reexamination request was filed October 11, 2024. The request remains pending. There is not yet an associated application number to the reexamination, consistent with MPEP 2232.01 acknowledging "about a ten (10) day lag between filing and data entry into the database." For ease of cross-reference, Requester proposed the following substantial new questions of patentability for the '921 patent:

SNQP No.	Claims	Basis for Rejection
1	1-4, 6-8, 10-13, 15 and 16	Obviousness: Truitt, Giuffrida and Lisy
2	1-4, 6-8, 10-13, 15 and 16	Obviousness: Truitt, Schmidt and Lisy
3	5, 9 and 14	Obviousness: Truitt, Giuffrida, Lisy and Burton
4	5, 9 and 14	Obviousness: Truitt, Schmidt, Lisy and Burton
5	1-4, 7, 8, 11-13, and 16	Obviousness: Mumford, Genger and Kisner
6	1-4, 6-8, 10-13, 15, and 16	Obviousness: Mumford, Toge and Kisner
7	5, 9 and 14	Obviousness: Mumford, Genger, Kisner and Burton
8	5, 9 and 14	Obviousness: Mumford, Toge, Kisner and Burton
9	1-16	Obviousness: Toge and Various Cited Art

VII. OVERVIEW OF THE STATE OF THE ART AND THE UNDERSTANDING OF A POSITA

The '680 Patent ultimately alleges priority to November 4, 2005 ("Alleged Priority Date"), which is before March 16, 2013, so pre-AIA 35 U.S.C. §§102, 103 may apply.

Generally, the claims of the '680 Patent recite features directed to an internet-server based system for remotely monitoring a positive airway pressure (PAP) device used to treat sleep disorders. The '680 Patent acknowledges that prior art PAP devices were understood to adjust positive airway pressure flow, as measured by sensors, for the purpose of alleviating sleep disorder symptoms experienced by a patient during sleep. EX. A, 2:19-39. Treatment-related information is recited to be displayed.

As of the Alleged Priority Date, a POSITA would have known and generally understood the following and explained in detailed sections below: (1) the degree of severity of sleeping

disorders may be analyzed and classified using criteria which include measurement of airflow; (2) sleeping disorders in a patient may be diagnosed using polysomnography equipment including airflow sensors; (3) some sleeping disorders in the patient may be treated using a PAP device and a mask to provide a supply of air at positive pressure to the patient; (4) advanced PAP devices used to treat a patient with a sleep disorder include sensors to measure airflow and a controller to automatically adjust a treatment pressure of air provided to the patient, based on airflow measurement; and (5) patients may be remotely monitored, with adjustments to treatment provided back to the patient location, over a communication network (e.g., "telemedicine").

A. Classification of Sleeping Disorders Was Known

As of the Alleged Priority Date, POSITA knew that obstructive sleep apnea is a condition characterized by repetitive obstruction of the upper airway often resulting in oxygen desaturation and arousals from sleep. "Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research: The Report of an American Academy of Sleep Medicine Task Force," SLEEP Vol. 22, No. 5 (1999), p. 667, EX. OTH-5 (Chicago Criteria), at 667. POSITA understood definitions of the following respiratory events: apneas and hypopneas, and respiratory effort-related arousals ("RERA"). POSITA understood that an index of respiratory events, the apnea hypopnea index ("AHI"), could be used to classify the severity of a patient's condition.

As of the Alleged Priority Date, POSITA knew that an apnea was a complete cessation of airflow, and that a hypopnea was a reduction in airflow. POSITA knew that an obstructive apnea/hypopnea event was an event which, of following criteria, fulfilled criterion 1 or 2, and criterion 3:

1. A clear decrease (>50%) from baseline in the amplitude of a valid measure of breathing during sleep.

2. A clear amplitude reduction of a validated measure of breathing during sleep that does not reach the above criterion but is associated with either an oxygen desaturation of >3% or an arousal.

3. The event lasts 10 seconds or longer.

As of the Alleged Priority Date, POSITA knew that a respiratory effort-related arousal ("RERA") event was an event which fulfilled both of the following criteria:

1. Pattern of progressively more negative esophageal pressure, terminated by a sudden change in pressure to a less negative level and an arousal

2. The event lasts 10 seconds or longer.

See "Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research: The Report of an American Academy of Sleep Medicine Task Force," SLEEP Vol. 22, No. 5 (1999), pp.669-70, EX. OTH-5 (Chicago Criteria), at 669-70.

As of the Alleged Priority Date, POSITA knew and understood that the diagnostic criteria for obstructive sleep apnea would include a patient demonstrating five or more obstructed breathing events per hour during sleep when subject to overnight monitoring, and that these events may include any combination of obstructive apneas/hypopneas or respiratory effort related arousals. Furthermore, POSITA knew of the number of obstructed breathing events per hour during sleep as the Apnea Hypopnea Index ("AHI"). Furthermore, POSITA knew that an AHI of 5 to 15 events was "mild," that an AHI of 15 to 30 events was "moderate" and that an AHI of greater than 30 events was "severe." *See* "Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research: The Report of an American Academy of Sleep Medicine Task Force," SLEEP Vol. 22, No. 5 (1999), p.670, EX. OTH-5 (Chicago Criteria), at 670.

As of the Alleged Priority Date, POSITA knew and understood that the Sleep Apnea Definitions Task Force of the American Academy of Sleep Medicine had established in 1999 definitional criteria ("the Chicago Criteria") for scoring respiratory events, including apnea (both obstructive and central), Respiratory Effort Related Arousal ("RERA"), determining an Apnea-Hypopnea Index ("AHI"), and a Respiratory Disturbance Index ("RDI"). EX. OTH-5 (Chicago Criteria), pp.670 (AHI), 677 (generally), 678 (RERA).

"Apnea" was also understood to describe the cessation of airflow at the nostrils and mouth lasting a predetermined time. *See* Guilleminault, et al., *Clinical Overview of the Sleep Apnea Syndromes, Sleep Apnea Syndromes* (1978), pp.1-12, EX. OTH-4 (Guilleminault-1978), 2.

AHI includes the recording of apnea and hypopnea events, and a POSITA would have known that AHI, like apneas and hypopneas, can be measured and/or derived from sensor data involving understood aspects of patient breathing volume and/or blood oxygen saturation. The Chicago Criteria identified known sensors for detecting relevant information to classify the above events, including airflow sensors, pressure sensors, thermal sensors, piezo sensors and strain gauges, oximetry sensors, and respiratory inductance plethosymnography. EX. OTH-5 (Chicago Criteria), 675-680, 684.

B. The Diagnosis of Sleeping Disorders Using Polysomnography Was Known

POSITA knew and understood that sleeping disorders such as sleep apnea were known to be diagnosed using physiological evaluation by polysomnography. EX. A ('680 Patent), 1:41-56.

Polysomnography was known to involve connecting sensors to the patient, the sensors including nasal cannula to measure airflow, pulse photoplethesmography to measure oxygen saturation, and sensors to measure eye movement ("EOG"), brain function ("EEG") and heart function ("ECG"). EX. OTH-3 (Westbrook) at [0010].

C. Treatment of Sleeping Disorders Using a PAP Device Was Known to POSITA

The use of nasal continuous positive airway pressure ("CPAP") to treat obstructive sleep apnea was known to POSITA prior to the Alleged Priority Date. One form of CPAP device known to POSITA for treating obstructive sleep apnea comprised a blower, a length of tubing and a face mask. EX. OTH-16 ('310 Sullivan) (1990). It was known to POSITA to adjust a treatment pressure using the apparatus to suit a particular patient, for example with a pressure in the range of 4 to 15 cm H20 above atmospheric pressure. *Id.* at 2:46-54.

To provide for sleep disorder treatment, devices are understood to use positive air pressure, often called "PAP" devices that may use various algorithm controls depending on the desired operational characteristics, with PAP devices in different forms having been developed prior to 2005. EX. OTH-8 (Guilleminault-2004) at 2.

D. Advanced Automatic PAP Devices Were Known to Treat Sleep Disorders

More advanced devices and methods for monitoring breathing during sleep, for control of CPAP treatment and preventing of apnea were known to POSITA prior to the Alleged Priority Date. A feedback-controlled CPAP system in which a patient's respiratory system is monitored, and a processor responsive to the monitoring controls the CPAP pressure according to patient requirements to prevent apneic episodes was known to POSITA. *See* EX. OTH-17 ('995 Sullivan).

Automatically adjusting PAP devices for treating sleep disorders, produced by the major manufacturers ResMed ("the ResMed AutoSet devices"), were known to POSITA by the Alleged Priority Date. The ResMed AutoSet devices were known to practice technology disclosed in ResMed U.S. Patent 5,704,345 ('345 Berthon-Jones), EX. OTH-18, published 6 January 1998, prior to the Alleged Priority Date.

As known to POSITA prior to the Alleged Priority Date, a device in accordance with Berthon-Jones comprises a mask, a servo-controlled blower, pressure sensor, a flow sensor and a controller. A respiratory airflow signal created by the flow sensor is analyzed by the controller. The controller calculates—based on the airflow signal—a breathing index, and an obstruction index, and determines whether to commence, increase or decrease CPAP pressure which is provided by the blower.

As known to POSITA prior to the Alleged Priority Date, an advanced automatically adjusting PAP device includes a processor which performs a number of processing functions upon the signals which it receives from sensors. EX. OTH-18 at 8:24-25 ('345 Berthon-Jones).

As known to POSITA prior to the Alleged Priority Date, an advanced automatically adjusting PAP device filters data from sensors, for example, using a low-pass filter of an air flow signal, or a bandpass filter of a flow signal. *See* EX. OTH-18, col. 8 ('345 Berthon-Jones). Furthermore, it was known for moving averages to be calculated, for example a moving average variance of an air flow signal. *See* EX. OTH-18, cols. 9-10 ('345 Berthon-Jones). Furthermore, it was known to calculate an index value from a root mean square (RMS) deviation. *See* EX. OTH-18, col. 3 ('345 Berthon-Jones).

Furthermore, the '680 Patent acknowledges that prior art PAP devices were understood to measure patient parameters using sensors and adjust pressure automatically for the purpose of alleviating sleep disorder symptoms experienced by a patient during sleep. EX. A, 2:12-39 ('680 patent).

E. Use of Wireless and Internet Technology to Transmit and Receive Clinical Data Among Devices Via Telemedicine, Including a PAP Device, Was Known to POSITA

The practice of using telecommunications technology to enhance medical care remotely was known prior to November 2005. As discussed below, telemedicine was understood to be

useful for providing remote healthcare and ascertain compliance in circumstances, using well-known communication platforms adapted for healthcare delivery models. EX. H, Abstract (Quy) (describing "a method and apparatus for wireless health monitory system for interactively monitoring a disease or health condition of a patient (38) by connecting an internet-enabled wireless Web device ('WWD') (12) to a health monitoring device 11 (which may be a medical device ...."). Generally, prior to 2005, personal computers were adapted to transmit and exchange various types of information. This information exchange became more pervasive by way of the internet. The evolution of these network-based exchanges, individually and collectively, provided a foundation for the evolution of telemedicine. The advent of the World Wide Web and advances in digital technology further provided for the expansion of telemedicine, including video consultations, electronic medical records, remote diagnostics, collection of data, and reporting of compliance data. *See, e.g.*, Paradiso, et al., *Wearable Health Care System for Vital Signs Monitoring*, 4th Annual IEEE Conf. on Information Technology Applications in Biomedicine, 2003, at 283 EX. OTH-15 (Paradiso) ("An overview of the technology in WEALTHY ... [with] the main phases of the process shown, namely: sensing pre-processing, transmission, processing and data management."); *see also* EX. OTH-11, Abstract (Peifer, US Patent No. 5,987,519) (1999) (describing "a packet-based telemedicine system for communicating video, voice and medical data between a central monitoring station and a patient monitoring station which is remotely-located with respect to the central monitoring station ..." including "medical measurement data").

By way of example, a claim presented in a 2001 international publication illustrates the general building blocks of a telemedicine system generally applicable to the claims of the '680 Patent, the claim describing a health sensing device for the patient (HMD-health monitoring

device), patient health data, a separate wireless web gateway (WWD-wireless web device), and a remote server directed to a health provider, as illustrated below:

> 1. A ***wireless health-monitoring system for monitoring a state or condition of a patient***, comprising:
>
> An ***internet-enabled wireless web device***, the internet-enabled wireless web device including a first communications port having a generic input/output port and a second communications port having a circuit for wireless communications with a network, the internet-enabled wireless web device configured to store:
>
> a ***health parameter***, the health parameter corresponding to a state or condition of a patient and ***determined by a health parameter determining means***:
>
> A ***device application***; and
>
> a ***user interface***; and
>
> ***A server application***, residing on a computer readable medium and disposed on a server in communication with the wireless network, for causing the server to:
>
> Receive the determined health parameter;
>
> Calculate a response based in part on the determined health parameter; and
>
> Provide the response to the internet-enabled wireless web device.

EX. H, p. 27, Claim 1 (Quy) (emphasis added).

As a further example, prior to 2005, because of the rise of broadband internet and wireless communication, the concept of telemedicine implementing wireless data exchanges was understood within the relationship of healthcare providers and patients. EX. H, Abstract (Quy) (describing "the WWD (12) may be wirelessly connected (16) to the health-monitoring device, such as via an infrared or radio frequency connection, including using protocols such as Bluetooth or 802.11."). By way of illustration, prior to 2005, many types of portable devices with wireless Bluetooth capabilities, provided for exchanging information using bidirectional radio transceivers, and were known and understood by a POSITA. Prior to 2005, "[t]he Bluetooth

transceiver is operating in the 2.4 GHz ISM band," and the use and requirements of Bluetooth are well-known to a POSITA. Bluetooth Ver.1.0B (Parts A and B) (November 1999) EX. OTH-2 (BT V.1), p.18; *see* also p.41 ("Bluetooth is a short-range radio link…."); *see also* Jasemian and Arendt Nielsen, Evaluation of realtime, remote monitoring telemedicine system using the Bluetooth protocol and a mobile phone network, Journal of Telemedicine and Telecare 2005, Vol. 11, Issue 5, at 256, EX. OTH-12 (Jasemian) at 256 (describing a developed "realtime wireless telemedicine system … that uses the Bluetooth protocol and the general packet radio service for mobile phones" to transmit collected biometric sensor data to a central monitoring station); Mohd Fadlee A. Rasid and Bryan Woodward, Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks," IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005, at 35, EX. OTH-13 (Rasid) at 35 (describing telemedicine service via a Bluetooth enabled patient unit that transmits sensor data to a GPRS enabled mobile phone, which transmits the data to a hospital server for access via a local area network or a physician's mobile phone).

POSITA understood, in the telemedicine context, that a patient-local device (WWD), interacting with a patient-treatment device, could connect to a remote server providing a convenient way to promote interactions between the patient-local device and a remote health care provider to transfer data involving a patient's monitored condition to a patient-treatment device. The patient-local device was also described to receive software downloaded from a server configured to interact with any number of patient-treatment devices. For example, it was understood that:

> In a method according to an embodiment of the invention, the ***patient connects to a specific Internet 10 site*** and a software program, resident on a remote server located on the Internet, ***downloads 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 15 via a synchronization operation in known fashion. The ***software provides a personalized display for the user and configures the WWD to control and monitor devices*** connected via a generic input/output port to the WWD.

EX. H, at 8:8-18 (Quy) (emphasis added).

Telemedicine was further understood to be adapted to provide for managing a wide range of disorders and diseases, offering in-home treatments that enhanced accessibility and convenience for patients, including, for example, patients suffering from respiratory disorders such as sleep disorders. In particular, telemedicine allowed for remote monitoring of physiological conditions and providing for the sharing of patient and therapy data with healthcare providers. EX. H, Abstract (Quy) (describing that "health related data is transmitted from the WWD (12) to a server (37) using standard internet protocols … [and] [t]he server (37) calculates a response … and may further provide for review by a physician …."). The data was understood to include diagnostic parameters and parameters related to the severity of the subject's condition, which could be used to address a patient's sleep disorder. A POSITA understood how to provide better-defined personalized action plans addressing a patient's condition even when not in the direct presence of a medical provider. EX. H, 1:25-31 (Quy) (explaining "health-monitoring of persons where measured or input health data is communicated by a wireless device to and from a software application … running on a server and where the same may be studied and processed by the software application, a health professional, or the subject.") A POSITA understood that the data may include data that could be monitored and shared, concerning diagnostic parameters and parameters related to the severity of the subject's condition, whereby a telemedicine system could be reasonably understood to address patient disorders, including sleep disorder aspects experienced by the patient, using well-known patient treatment devices. EX. H, Abstract (Quy).

It was also known to use telehealth systems like those discussed above with in-home treatment devices for sleep disordered breathing disorders, such as sleep apnea. For example, Dr. Lankford described a wireless CPAP monitoring study in 2004 that involved collecting and wirelessly transmitting information such as mask-on duration and AHI from the CPAP device to a secure web server at a remote location. *See* Lankford, D. A., Ph.D., Wireless CPAP Patient Monitoring: Accuracy Study, Telemedicine Jr. v. 10, no. 2 (2004) at Abstract, p. 164, EX. OTH-1 (Lankford). As another example, US 2003/0236450 ("Kocinski") describes a "data collection and processing system" that includes a "CPAP apparatus [] programmed to periodically transfer data to a central database server" that can be accessed "over the Internet." EX. OTH-20, (Kocinski) at Abstract. Kocinski teaches that the "medical professional can access the database server over the internet to obtain information on patient compliance and, preferably, other information, such as a patient's response to CPAP treatments." EX. OTH-20 Kocinski, ¶9 (*see also* 12, 28, 45, 49, FIGs. 1, 10). As another example, WO 04/032719A2 to David Burton et al. ("Burton") describes a CPAP system that can monitor "SBD-related (sleep breathing disorder) signals during a subject's sleep" and send "reports" via "W-LAN and even Bluetooth. EX. OTH-19 at 8:28-9:1, 19:24-28 (Burton).

POSITA understood that a telemedicine system was adaptable and whereby the features of the system could be applied to various treatment devices. POSITA also understood that treatment devices included types of devices directed to sleep disorders, with different parameters understood to be used to address aspects of the patient's condition and consider the appropriate treatment.

In view of the above, and more generally directed to aspects of sleep disorders within a telemedicine platform for addressing sleep disorders, a POSITA understood that various types of data could be measured and collected related to the patient's condition during sleep, which could

also be used to consider a level of severity of the sleep disorder, whereby a level of severity may be indicated by an index of various sleep disorder events including apneas.

F. Pre-2005, Telemedicine Was Understood to Use Sensors, Including Sensors Useful for Addressing Sleep Disorders

A POSITA understood that sensors were useful for measuring conditions of a patient, and the Challenged Patent explains that "sensors that are used with various embodiments of the present invention are described herein but can also be any of those known to those skilled in the art for the applications of this method." EX. A ('680 Patent), 14:58-61. For example,

> The diagnostic part of the system or device can use various sensors for measuring the subject's respirations, cardiac signals, brain wave signals, blood gases, EMG, EOG, airway pressure, and the like. Any sensor that can or has been used with a full polysomnogram (PSG) may likewise be used alone or in combination with other sensors. Sensors for measuring the subject's brain wave signals include EEG electrodes and the like. Sensors for measuring the subject's respirations or oxygen levels include sensors to measure airflow, respiratory effort, oxygenation and ventilation, and the like.

EX. A ('680 Patent), 3:28-38. "Measurement of oxygenation and ventilation is preferably measured by pulse oximetry, transcutaneous oxygen monitoring, transcutaneous carbon dioxide monitoring, expired end carbon dioxide monitoring, and the like." EX. A ('680 Patent), 3:48-51; *see also* 16:61-65.

By way of example, the prior art to Schmidt describes a wireless physiological data acquisition system that gathers patient data through various sensors, including SpO2 sensors, PO2 sensors (partial pressure of oxygen dissolved in blood), PCO2 sensors (partial pressure of CO2 in blood), "air flow" sensors, and "respiration" sensors, to supply data to signal processing module 16, which then wirelessly transmits the data to base station 40 via bidirectional transceivers. EX. F (Schmidt), 5:32-38; Fig. 1, *compare with* EX. A ('680 patent), 40:45-51.

Schmidt describes a process that "adapts the signal processing module in response to variation in the range, character and type of the physiological signal such that the adaptation

occurs during signal processing module operation." *See* EX. F (Schmidt), 4:7-22; 14:40-54; EX. A ('680 patent), 49:56-59. Schmidt further describes how the system and processing features are "adapted for different applications by software programming" (EX. F (Schmidt), 1:15-20) including a "biomedical environment" (*id.*, 8:32-33; 6:28-35) and, further, as a "universal platform design [that] can be utilized for all applications." *Id.*, 6:40-41; 7:16-20.[2] In comparison to Schmidt, the '680 patent also explains that "[t]he treatment device can be any device known to those skilled in the art. The treatment device can either physically or chemically treat the subject's sleeping disorder. An example of physically treating the subject's sleeping disorder would be a device to provide positive airway pressure to a subject." EX. A ('680 Patent), 4:47-52; *see also* 14:11-13 ("positive airway pressure (PAP) and continuous positive airway pressure (CPAP) treatment for sleep apneas.").

And the '680 Patent further acknowledges that "[t]he ***treatment device can be any device known to those skilled in the art***. The treatment device can either physically or chemically treat the subject's sleeping disorder. An example of physically treating the subject's sleeping disorder would be a device to provide position airway pressure to a subject. The treatment device can either be a traditional PAP or CPAP, or can include various devices for chemical or medical treatment of the subject." EX. A, ('680 patent), 4:47-54 (emphasis added).

G. The Term "Efficacy"

Prior to the earliest possible priority date of the Challenged Patent, a POSITA understood at least the following with respect to symptoms and "efficacy."

> A patient monitoring unit 200 may additionally or alternatively comprise one or more devices for ***facilitating characterization, assessment, and/or evaluation of particular symptoms and/or***

[2] Schmidt shares an inventor (Robert Schmidt) with the '680 Patent, who is a Patent Practitioner identified in the PTO's Correspondence Address records for the Challenged Patent and the Schmidt reference. Figures 1-6 of the '680 Patent, along with a significant portion of the description, were copied from Schmidt.

> ***patient performance*** relative to one or more behaviors, tasks, and/or tests. Such devices may comprise, for example, motion sensors; accelerometers; force, torque, and/ or strain sensors and/or gauges; and/or other devices. The ***collection of information indicative of the efficacy and/or efficiency*** of neural stimulation may aid in selecting, ***defining, modifying, updating, and/or adjusting one or more portions of a treatment program.***

EX. OTH-10 at 9:50-60 (Gliner et al.) (2005) (emphasis added).

By way of example, US 7,878,198 ("Farrell-198") describes common treatment of sleep disordered breathing by CPAP devices, including a number of commercially available devices for treatment of obstructive sleep apnea and other respiratory sleep disorders. EX-9 (Farrell-198), 1:18-67. Farrell further describes that such treatment devices can provide "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." EX-9 (Farrell-198), 6:5-11. Farrell-198 recognized that "[m]ethods for detecting and recording such information are known in the art, and may be implemented as described in U.S. Pat. No. 5,704,345," where one example is where the "device may record AHI (apnea hypopnea index) over time or during particular time periods …." EX-9 (Farrell-198), 6:17-19. Farrell-198 similarly recognized that "[t]hose skilled in the art will recognize other methods or modifications for detecting sleep disordered breathing information such as hypopnea or apneas and determining an AHI over time or within time periods." *Id.* 6:37-41. Similarly, Dr. Lankford, in discussing a wireless CPAP monitoring study in 2004, described that "[f]ourteen subjects used a flow generator that collected additional efficacy data such as apnea-hypopnea index" and wirelessly transmitting "compliance and efficacy data …." EX. OTH-1 (Lankford), Abstract. Lankford also describes that "therapeutic data collected by the CPAP units, such as time, median leak, and the apnea-hypopnea index … are potentially available to evaluate therapeutic efficacy …." *Id.* at 163. Lankford also describes

a ResMed AutoSet T Flow Generator that "collects usage/compliance data as well as therapeutic data that measures efficacy." *Id.* at 164. "Efficacy measures included indices of mask leak, along with the apnea–hypopnea index, among others." *Id.* at 166.

VIII. SUMMARY OF THE '680 PATENT

A. Brief Description of the '680 Patent

The '680 Patent is directed to a system for "Integrated Diagnostic And Therapeutic System And Method For Improving Treatment Of Subject With Complex And Central Sleep Apnea." *See* '680 Patent, Title. The '680 Patent claims, among other things, a system for remote internet server-based diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment, and transmitting data among the PAP device, a cell phone, and a remote internet site.

Despite PO's statements about prior art, commenting that "more advanced PAP devices automatically adjust the gas pressure based on sensors built into the device. The sensors measure gas flow, pressure, or other fluid characteristics in the device or its mask, and adjust the delivered pressure based on various algorithms known in the art. These auto-PAP devices rely on the single, physiological variable (the measured or estimated fluid characteristics) to predict or detect an apnea event." (EX. A, 2:32-39), the '680 Patent purports to describe adjusting a treatment device based on sensor feedback. *Id.*, 2:53-67.

The '680 Patent issued from the following chain of applications:

Appl. No.	Filing Date	Application Type	Issued as:
15/355,189	November 18, 2016	CON	10,543,328
13/975,792	August 26, 2013	CON	9,533,114

Appl. No.	Filing Date	Application Type	Issued as:
11/880,046	July 19, 2007	CIP	8,545,416
11/266,899	November 4, 2005	CON	8,172,766

B. '680 Patent Specification

1. '680 Patent Copies Descriptions of Prior Art

a. Airflow Sensors and Sensor Data

As noted above, at least six columns of text found in the '680 Patent specification—spanning 40:9 to 46:9—represents a copy of at least portions of the Detailed Description of Schmidt. EX. F (Schmidt).[3] The '680 Patent further copies each of Schmidt's Figures 1-6. Schmidt discloses sensors, as copied in the '680 Patent, an "air flow" sensor to supply data to signal processing module 16 for conditioning and processing. EX. G (Schmidt), 4:7-22; 14:40-54; EX. A ('680 Patent), 16:66-17:10. The processing module 16 wirelessly transmits data to base station 40 via bidirectional transceivers (*id.*, 5:32-38; Fig. 1), as in the '680 Patent (40:18-20; Fig. 1).

2. The Claimed Inventions are only Directed to Known Treatment Devices, Sensors, and Data Processing Algorithms

As above, the '680 Patent is not directed to a new sleep disorder treatment device. Instead, "[t]he treatment device can be any device known to those skilled in the art." EX. A, 4:47-67.

[3] Schmidt was not identified to the '680 Patent's Examiner. The Schmidt Patent shares an inventor (Schmidt) with the '680 Patent, and that same person appears to be a Patent Practitioner identified in the PTO's Correspondence Address records for the '680 Patent and the Schmidt prior art patent.

As above, the '680 Patent is not directed to a new type of sensor. "sensors that are used with various embodiments of the present invention are described herein but can also be any of those known to those skilled in the art for the applications of this method. The collected physiological, kinetic, and environmental signals can be obtained by any method known in the art." EX. A, 14:58-63. "The diagnostic part of the system of device can use various sensors for measuring the subject's brain wave signals, respirations and the like. … Sensors for measuring the subject's respirations or oxygen levels include sensors to measure airflow, respiratory effort, oxygenation and ventilation, and the like." *Id.*, 3:28-51.

Further, the '680 Patent is not directed to any new data analysis algorithm. "Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms." EX. A, 26:42-45. The '680 Patent confirms that data processing algorithms "would also include other on-line signal processing algorithms known to those skill in the art, such as wavelet analysis…." *Id.*, 26:67-27:2. The "signal-processing techniques" disclosed at 26:42-28:48 are verbatim from paragraphs 40-45 of Lisy, EX. E.

C. The '680 Patent Prosecution History

As noted above, the '680 Patent was filed as the '410 Application, now U.S. 11,786,680. EX. A. The '410 Application is a continuation of the '189 Application, now U.S. 10,543,328, which is a continuation of the '792 Application, now U.S. 9,533,144, which is a continuation of the '046 Application, now U.S. 8,545,416, which is a continuation in part of the '899 Application, now U.S. 8,172,766. *Id.*

On November 29, 2021, the Applicant filed a preliminary amendment in which, among other things, canceled all the originally filed claims 1-20 and introduced new claims 21-40. The

preliminary amendment fails to provide any citation to the application as filed for support and does not provide a statement that no new matter has been added.

During prosecution, the examiner issued the first office action on September 27, 2022, issuing various claim objections and rejected each of the pending claims as either non-patentable subject matter, anticipated, or obvious under 35 U.S.C. §§ 101, 102, and 103, respectively. EX. B, 139-161. In addition, the examiner noted that at least claim 28 did not have support in the '899 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.

In response, the Applicant responded with substantial amendments to the claims and arguments over the various rejections, the cited art, and objections. EX. B, 110-132. The Applicant responded to the priority date issues raised by the examiner with an amendment to claim 28 and alleged that the claims, as filed in the November 29, 2021 preliminary amendment, are entitled to a November 4, 2005 priority date, without providing citation to those portions of the '899 Application to support the priority statement. The Applicant's response does not provide citation to the Application as filed for support or provide a statement that no new matter was added. *Id.*

In response, the Examiner issued a Final Office Action on May 22, 2023. In the Final Office Action, the claims were indicated to contain subject matter that was allowable over the cited art; however, the claims remained objected to and rejected under §§101 and 112. *Id.* 67-78. On August 10, 2023, an interview was conducted to discuss proposed amendments to overcome the pending objections and rejections of the Final Office Action. *Id.* 57-65.

The Applicant then filed a response, after final, including amendments to the claims that substantially paralleled those discussed during the August 10, 2023 interview. *Id.* 45-54. The response merely notes that agreement was reached during the aforementioned interview and did not present substantive arguments. *Id.*

On September 5, 2023, the Examiner issued a notice of allowance, formally entering the amendments from the after final response dated August 11, 2023. *Id.* 14-22. On September 6, 2023, the Applicant paid the issue fee and the '680 Patent issued on October 17, 2023.

IX. CLAIM CONSTRUCTION

No claim term needs formal construction for purposes of evaluating the prior art in this Petition. Petitioner reserves the right to propose formal constructions in other forums where disputed issues may differ, or in response to PO's arguments in this proceeding.

X. STATEMENT IDENTIFYING EACH SUBSTANTIAL NEW QUESTION OF PATENTABILITY (37 C.F.R. § 1.510(B)(1))

Each of the above patents and publications are prior art to the '680 Patent and the grounds of rejection outlined in this Request raise substantial new questions of patentability (SNQPs) because the references used to establish these grounds provide new teachings not previously considered in the proposed combinations by the Office. None of the references used to establish the grounds for rejection in this Request, nor the grounds themselves, were substantively advanced by the Examiner during prosecution of the '680 Patent. Each of the grounds included in this Request, however, disclose the teachings identified by the Examiner in the Notice of Allowance as reasons for allowing the claims.

For reasons summarized below and explained in further detail within the entirety of this Request, the consideration of each of: (1) Kumar in combination with Truitt and '737 Farrell; (2) Kumar in combination of Truitt, '737 Farrell and Lisy; (3) Sun in combination with Quy and Schmidt; (4) Sun in combination with Quy, Schmidt and Lisy; (5) Mumford in combination with Quy; (6) Mumford in combination with Quy and Kisner, and (7) Toge in view of various references present an SNQP of patentability for claims 1-32 of the '680 Patent.

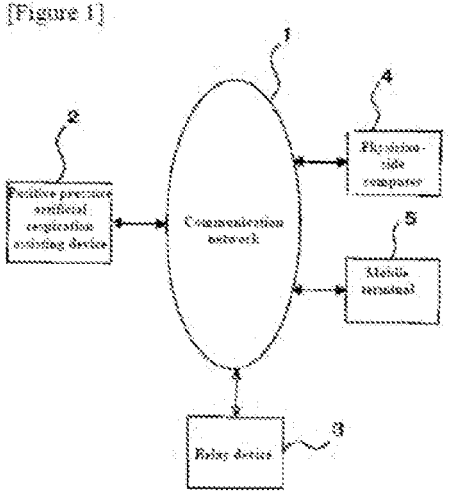
Below are the rejections proposed in support of the unpatentability of claims 1-32 of the '680 Patent.

A. Obviousness Considerations for the Challenged Claims

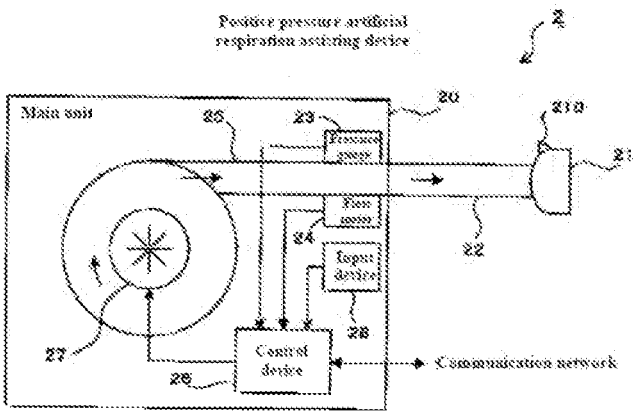
1. Overall Reasons to Combine

The '680 Patent merely describes the well-established concept of telemedicine, which involves extending medical practice beyond traditional in-person patient/physician interaction. This concept was known before 2005. For example, Toge, published October 8, 2002 (EX. K), illustrates and explains that "[h]ome medical devices may be provided to patients receiving treatment or care at home." EX. K (Toge), ¶[0002]. Specifically, "Figure 1 is a block diagram illustrating the overall configuration of a remote medical (telemedicine) system according to the present invention." EX. K (Toge), ¶ [0008]. As illustrated below, Toge describes the main components of a telemedicine system utilizing a PAP device.

[Figure 1]



[Figure 2]



EX. K (Toge), Figs. 1 and 2.

The '680 Patent does not describe anything different, novel, or non-obvious in this regard, as it describes only conventional CPAP equipment used to treat sleep disorders. For example, the '680 Patent does not disclose a new sleep disorder treatment device. Instead, the '680 Patent acknowledges that "[m]ethods of determining airflow or air pressure from sensors

placed in or on a PAP or CPAP device are generally known in the art, and any such method is appropriate for the present invention." EX. A ('680 Patent), 17:6-10; *see also* 17:58-61 (same). In addition, years earlier, Toge had, as shown above, already described a "telemedicine system comprises a positive pressure artificial respiration ... and physician-side terminal devices, ... all connected to communication network ...." EX. K (Toge), ¶ [0008].

By 2005, as Toge illustrates above, a POSITA understood the use of control systems with processing and memory capabilities, as well as data analysis algorithms, to analyze the data collected from the sensors and quantify the severity of the subject's sleeping disorder. Additionally, control systems with integrated wireless communication capabilities for transmitting and receiving data to and from remote devices, including a cell phone, were also well known to a POSITA by 2005. When providing treatment to patients with disorders, including sleep disorders, a POSITA recognizes the benefits of using sensors to monitor patient responses to treatment by collecting and analyzing the data associated with the patient's physiological condition.

A POSITA also recognizes the benefit of providing monitored treatment in-home, away from clinicians, to facilitate patient compliance as well as overall treatment progress. Thus, a POSITA would be motivated to provide a system that operates remotely from a clinician, using known control and communication systems integrated with existing CPAP devices and sensors. This system would accurately quantify the severity of the patient's sleep disorder via in-home control/monitoring and wirelessly transmit information to a clinician for remote analysis or other purposes. The overall system would integrate wireless communication capabilities with processing, memory, data analysis algorithms, and display features for a clinician on the receiving end to analyze and view the received information. By 2005, implementing this system

would have taken no more than routine skill—combining conventional components, each operating as expected—and would have been at least obvious to try.

A POSITA would have been motivated to combine well-known control and communication systems with existing CPAP devices and sensors to facilitate remote clinician assessment and monitoring. This approach offers the advantages of improving sleep disorder treatment at a lower cost, quantifying the impact of the disorder over time, increasing the treatment oversight, and reducing the need for in-person consultations. It would have required routine skill to provide such a treatment system, which includes sensors with data collection and communication techniques for both on-location and remote location consideration of treatment outcomes over time. At the very least, it would have been obvious to try.

The challenged claims would have been obvious for the following reasons: A POSITA, considering a traditional CPAP system such as that described in Truitt, using sensors to monitor and treat the patient's sleep disorder, would have recognized how to incorporate the communication capabilities of Schmidt to deliver sensor data. This integrated system would enhance patient sleep disorder treatment by using a CPAP machine with sensors to measure diagnostic parameters, a control system to monitor, collect and assess the measured parameters of a subject's treatment for sleep disorder, and an integrated communication ability to remotely communicate the treatment data to an off-site clinician for further monitoring and analysis.

XI. '680 PATENT (37 C.F.R. § 1.510(B)(2))

A. SNQP 1: Claims 1-9, 11-14, 16-19 and 21-32 are unpatentable over Kumar in view of Truitt and '737 Farrell under 35 U.S.C. §103(a)

For the reasons discussed below, it is respectfully submitted that claims 1-9, 11-14, 16-19 and 21-32 are obvious over Kumar in view of Truitt and '737 Farrell under 35 U.S.C. §103. *See* EX. C (Kumar), EX. D (Truitt) and EX. OTH-9 ('737 Farrell). A claim chart attached as an exhibit and identified as CHART-1 provides prior art disclosure against the limitations for each claim

addressed in this SNQP, with more particularized detail below explaining the prior art disclosures against certain features.

Specifically, Kumar (i.e., the primary reference) was not applied during any prior examination of the '410 Application/'680 Patent, and its teachings, when combined with those of Truitt, present a substantial new question of patentability because the combined teachings of these references were not considered by the Examiner during prosecution of the claims of the '410 Application. Had the teachings of this prior art been considered, the Examiner would not have allowed the claims thereof that correspond to claims 1-9, 11-14, 16-19 and 21-32 of the '680 Patent.

To facilitate consideration and discussion, Claim 1, the only independent claim of the '680 Patent, is reproduced below:

> 1. 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);
>
> B. a first non-transitory computer readable medium comprising a first software stored on the first 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, the first software further adapted for:
>
> ii) 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;

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 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

a mask or a nasal cannula; and

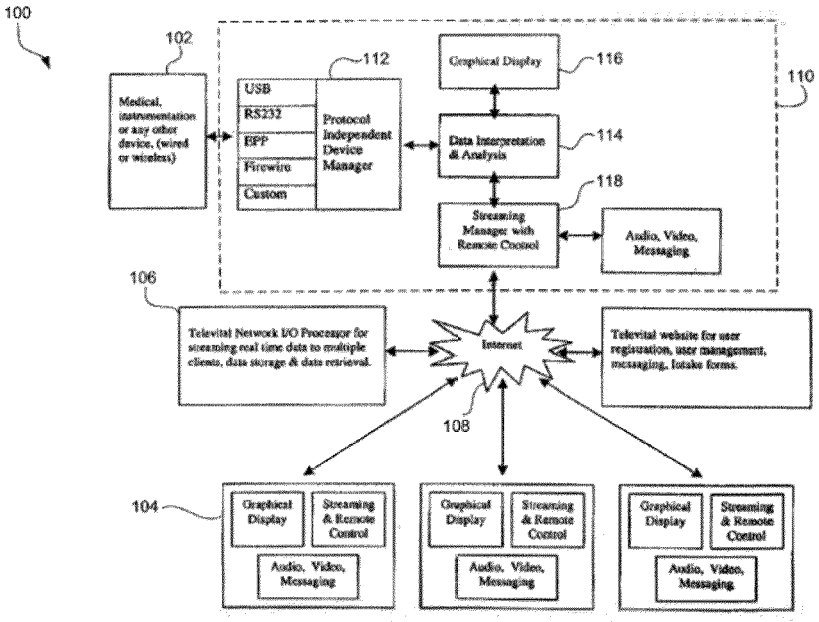
the at least one second software for the remote internet site and the database is further adapted to receive the PAP therapy efficacy data, in whole or in part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.

EX. A ('680 Patent), Claim 1. Kumar in view of Truitt and '737 Farrell disclose all of these limitations.

1. Kumar discloses the recited "internet server-based diagnostic monitoring" system for "sleep disorder treatment"

The claims of the '680 Patent are all generally directed to "a system for remote internet server-based diagnostic monitoring" with one or more PAP devices used for treating sleep disorder. The claimed system recites the various components and functions of the system.

Similarly, Kumar is directed to "System and Method for Real-Time Monitoring, Assessment, Analysis, Retrieval, and Storage of Physiological Data over a Wide Area Network." Ex. C (Kumar), Title. Kumar teaches a system and method for "networked-based monitoring of physiological data" involving "at least one patient-side device [that] collects physiological data from a patient" and a "provider-side device [that] receives the data … via a wide area network." Kumar, *Abstract*, ¶ [0002]; ¶ [0012] ("connection of multiple patient-side devices provider-side devices, and engines."); ¶ [0069] (same). Kumar further states that the "patient side device is located with a patient and can be any device that gathers physiological data from the patient," including "breathing patterns," *id.* ¶ [0071], used for applications in treating "[s]leep apnea-hypopnea" and "upper airway obstructions." *Id.*, ¶ [240]; *see also* ¶ [0078] ("By receiving data from the patient-side device, a provider is able to monitor the patient's physiology for … providing treatment in real-time to the patient."). The "provider" includes "a medical provider such as a doctor, nurse, etc., but also includes any recipient of the data, whether affiliated with health care or not." *Id.*, ¶ [0071]. The general architecture of the Kumar system is shown in Figure 1 reproduced below.



EX. C (Kumar), Fig. 1A. As shown, 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." *Id.*, ¶ [0067]. Kumar states that the disclosed 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. *Id.*, ¶ [0067]. The patient-side device may also be connected to "a computing device 110, such as a computer, handheld devices…, wireless telephone..." *Id.*, ¶ [0072]. The computer device may also be "built-in" to the patient side device. Similarly, the "provider-side device can be any type of computing devices, such as a computer, PDA, wireless telephone, etc. 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.*; Fig. 1B.

On the patient-side, a "device manager 112 running on the computer 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. 1, 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. The data may be displayed graphically on the display module 116." *Id.*, ¶ [0075]. Kumar states that its "invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium." *Id.*, ¶[0087]. Kumar further states that 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." *Id.*, ¶ [0018]; *see also* Fig. 1B (showing an example of a wireless pocket PC). The software downloaded to the computing device, such as a wireless telephone, supports "both plug-and-play web device drivers and customized graphical user interfaces (GUIs) for the various devices." *Id.*

A POSITA would understand that the wireless telephone disclosed in Kumar includes a cellular phone with a wireless transceiver. Kumar further discloses that the software on the wireless phone receives the collected physiological data captured by the patient-side device and displays the data for viewing by the patient on the wireless phone. While Kumar does not explicitly disclose downloading viewing software onto the storage medium of the wireless phone, Kumar discloses downloading other software, i.e., "appropriate plug-ins which allows the computing device to communicate with the patient-side device," including "customized graphical user interfaces (GUIs)." *Id.*, ¶ [0018]. It would have been understood by a POSITA that the disclosed software for the wireless phone in Kumar is "adapted to be executed by" the wireless phone processor and may be downloaded, particularly in view of Kumar's disclosure of downloading other software to the wireless phone to facilitate communication between the wireless phone and the patient device.

Thus, as disclosed, Kumar's internet-based monitoring system has one or more patient-side devices for collecting physiological data including breathing data. A POSITA would understand that the patient-side device is connected to a wireless phone having a processor, downloadable software may be stored on a computer readable storage medium, with the wireless phone including a display, and that downloadable software could display patient data, including the received physiological data, via the display, as recited by the features of Claim 1 of the '680 Patent.

Kumar further states that "[b]y receiving data from the patient-side device, a provider is able to monitor the patient's physiology for research, keeping track of documentation, performing analysis, managing and maintain records, diagnosing the patient, providing treatment in real-time to the patient, etc." EX.C (Kumar), ¶ [0078]. In addition, Kumar discloses that "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, may store the data for later transmission to the provider-side device, etc." *Id.*, ¶ [0081]. Thus, a POSITA would recognize that the disclosed provider-side devices implemented on a central server 106 include least one computer with a database located at a remote internet site that could be used to receive "in whole or in part" the data generated by the patient-side devices and monitor such devices in real-time, as recited by Claim 1 of the '680 Patent.

2. Kumar in view of Truitt and '737 Farrell renders obvious the recited internet server-based monitoring and assessment system with one or more PAP devices for sleep disorder treatment recited in Claim 1

a. Motivation to combine Kumar, Truitt and '737 Farrell

As noted, Kumar discloses that "the patient-side device is located with the patient/client and gathers physiological data from the patient/client." Kumar, ¶ [0013]. Kumar further states that the described internet-based monitoring and assessment system "can be adapted to many applications… for monitoring various medical conditions." *Id.* at ¶ [0173]. As a non-exhaustive

example of applications for its system, Kumar describes an applications directed to sleep apnea-hypopnea syndrome—"characterized by repetitive episodes of upper airway obstruction that occurs during sleep" and "partial reduction of airflow"—and explains that its system allows "remote," "in-home" and online "live monitoring" for sleep apnea-hypopnea syndrome. *Id.*, ¶ [0239-4.] While Kumar does not explicitly disclose the details of patient-side device used for sleep disorder applications, it states that its internet-based system "allows remote monitoring of such devices by providing in-home monitoring…." *Id.*

By 2005, a POSITA would recognize positive airway pressure (PAP) devices as commonly used to treat sleep disorders as a "patient side" device and these PAP devices "gather physiological data" addressing sleep disorders, including aspects of sleep apnea disclosed in Kumar. A POSITA would also know the components of a PAP device, examples of which are shown in EX. D (Truitt) and EX. OTH-9 ('737 Farrell). *See also* EX. A ('680 Patent), 17:7-10 ("Methods of determining airflow or air pressure from sensors in or on a PAP or CPAP device are generally known in the art, and any such method is appropriate for the present invention.").

Like Kumar, Truitt explains using collected breathing data for patient compliance—a goal readily understood by one of ordinary skill in the art. EX. D (Truitt), 2:5-10 ("The information from flow sensor 20 … is used, for example, to … monitor the usage of the pressure support device (patient compliance), or any combination thereof."). Similarly, '737 Farrell also teaches "methods and apparatus for treating and monitoring sleep disordered breathing ("SDB") in patients…" EX. OTH-9 ('737 Farrell), 1:7-9; 7:35-8:24 ("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."). A POSITA would have understood how to evaluate patient compliance as well as improve a doctor's ability to remotely monitor progress and adjust treatment for a patient using in-home medical devices associated with an integrated system. Toge at 1-2.

Kumar discloses an internet-based distributed network of monitoring devices, including cell phones having a radio frequency wireless transceiver, a processor, software for displaying data, and a display. Like the patient-side device of Kumar, the PAP devices disclosed in Truitt and '737 Farrell also include a processor. Further, Kumar, Truitt and '737 Farrell are all in the same field of endeavor—in home medical devices for treating disorders. Thus, a POSITA would recognize the benefit of integrating the Truitt PAP devices as the patient-side device in the disclosed Kumar system as it would have been obvious to equip the PAP device disclosed in Truitt and with a wireless communication described by Kumar for the patient side device used in treating sleep disorders as shown in '737 Farrell— 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 25 transmission between the devices." *Id.*, 6:23-25. This integration would enhance patient compliance and eliminate the need for face-to-face visits while allowing treatments to be provided and modified, without requiring a patient to travel to a medical provider. This approach would also reduce the necessity for a provider to be available during limited office hours at a specific location. Further, the combined system would improve how a third party, such as an insurance provider, could evaluate whether treatment is being administered as prescribed, to address a patient's sleep disorder. Kumar, ¶ [0078] ("The present invention also allows for daily or periodic monitoring of patients without the need for the patient to travel to the provider's location.")

Given the foregoing teachings of Kumar, in view of Truitt and '737 Farrell, a POSITA would be motivated to combine Kumar with Truitt and '737 Farrell as it would simply be combining similar elements—sensors, processors and wireless communication—each adapted for use as intended—receive sensor data, monitor usage and adjust treatment and transmit the collected information to a remote location—to yield predicable results—improving patient compliance and overall treatment.

b. Kumar in view of Truitt and '737 Farrell discloses an internet server-based monitoring and assessment system for one or more PAP devices

Truitt discloses that CPAP devices are well known "to treat obstructive sleep apnea (OSA) as well as other disorders." EX. D (Truitt), 1:26-30. For example, Truitt discloses "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." *Id.*, 1:24-30. Truitt describes a "prior art" CPAP device, which is shown in Fig. 1 and reproduced below:

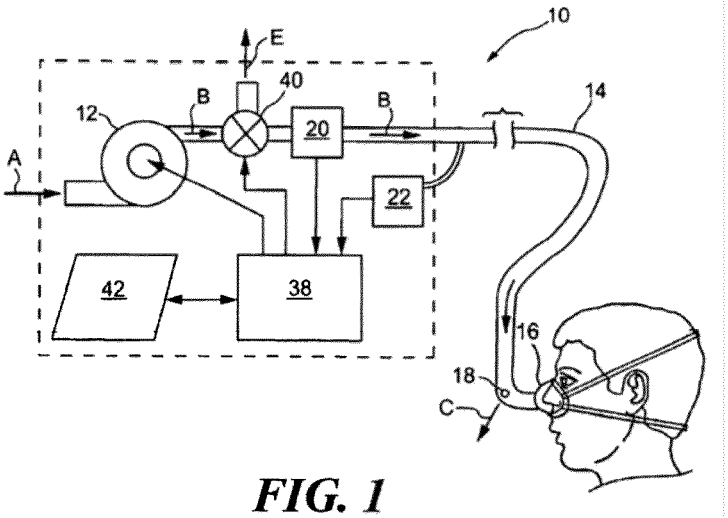


FIG. 1
(PRIOR ART)

Id., FIG. 1. As disclosed in Fig. 1 and the accompanying specification, Truitt shows "a conventional pressure support system 10" with "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." Truitt, 1:44-55 (emphasis added); FIG. 1. As shown and disclosed in Truitt, the blower and the masks deliver elevated pressure to treat sleep apnea and other sleep disorders. *Id.*

The conventional PAP device shown in Fig. 1 of Truitt also includes "a flow sensor 20, pressure sensor 22 or both that monitor the flow and/or pressure of gas passing in patient circuit

14," internal to the PAP device and are used "to determine the volume of gas passing through the patient circuit." *Id.*, 2:1-4. It would have been obvious to a POSITA that Truitt teaches "a sensor" that is "internal to the PAP device" and determines airflow "for measuring or deriving the respiratory airflow of the subject while using the PAP." Similarly, Kumar discloses that the sensors of its disclosed patient-side devices "are coupled to a medical and/or biofeedback patient-side device that is in wireless or wired communication with a computing device." EX. C(Kumar), ¶ [0089]. Thus, Kumar in view of Truitt discloses the feature of having a sensor internal to a PAP device that provides airflow sensor data, as recited by Claim 1 of the '680 Patent.

As with the data interpretation and analysis module 114 used to interpret the data stream from the client-side devices disclosed in Kumar, Truitt discloses a "first processor" of the PAP device that "receives sensor data," as recited in Claim 1 of the '680 Patent. With reference to Fig. 2, reproduced below, Truitt discloses that "[t]he signal from flow sensor 20… is provided to a controller 38…" EX. D (Truitt), 2:37-40 (emphasis added). Based on the above, a POSITA would understand that the Truitt PAP device includes a processor to receive data via an airflow sensor.

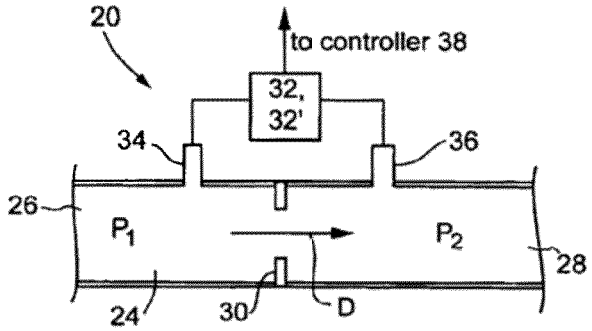


FIG 2
(PRIOR ART)

Truitt further states that 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***, ***monitor the usage*** of the pressure support device (patient compliance),

or any combination thereof." Truitt, 2:1-11 (emphasis added); *see also* 2:38-42 (same). The processor also uses "[t]he output of flow sensor 32' … for ***calculating*** the flow and/or volume of gas passing through conduit 56." *Id.*, 6:46-48 (emphasis added).

The Truitt processor further adjusts "***the pressure provided to the patient changes based on the detected conditions of the patient***, such as whether the patient is snoring or experiencing an apnea, hypopnea or upper airway resistance. This typically is referred to as an auto-titration mode of pressure support because ***the pressure support system automatically attempts to titrate the pressure support to suit the needs of the patient***." Truitt 1:34-43 (emphasis added). In particular:

> ***Controller 38 receives the signals output from sensors 20*** and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof in a feedback fashion based on these received signals. For example, in a simple CPAP device, ***controller 38 monitors the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level***.
>
> ***
>
> In the auto-titration mode of pressure support, ***where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient***, these pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc. ***The pressure and/or flow is then controlled to counteract or prevent these conditions***.

Id., 2:57-3:11. Truitt also teaches "an input/output device 42, such as a keypad, buttons, lights, LED or LCD display, and/or an audio device, [] used to enter information and commands to the pressure support system and to display information…" *Id.*, 3:12-15. The input device is "used to enter the … maximum and minimum pressures and pressure change in an auto-titration system." *Id.*, 3:19-20.

Similarly, '737 Farrell is directed to "methods and apparatus for treating and monitoring sleep disordered breathing ("SDB")…" EX. OTH-9 ('737 Farrell), 1:7-9. '737 Farrell explains

that "[t]he most common form of sleep disordered breathing is obstructive sleep apnea ("OSA") and that "[b]ecause 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." *Id.*, 1:16-18. Further, "[t]he most common treatment of SDB is to administer continues positive airway pressure (CPAP)." *Id.*, 1:22-23. Referring to Fig. 1 of '737 Farrell, a copy of which is reproduced below, '737 Farrell teaches a "pressure delivery device that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6." *Id.*, 5:2-4.

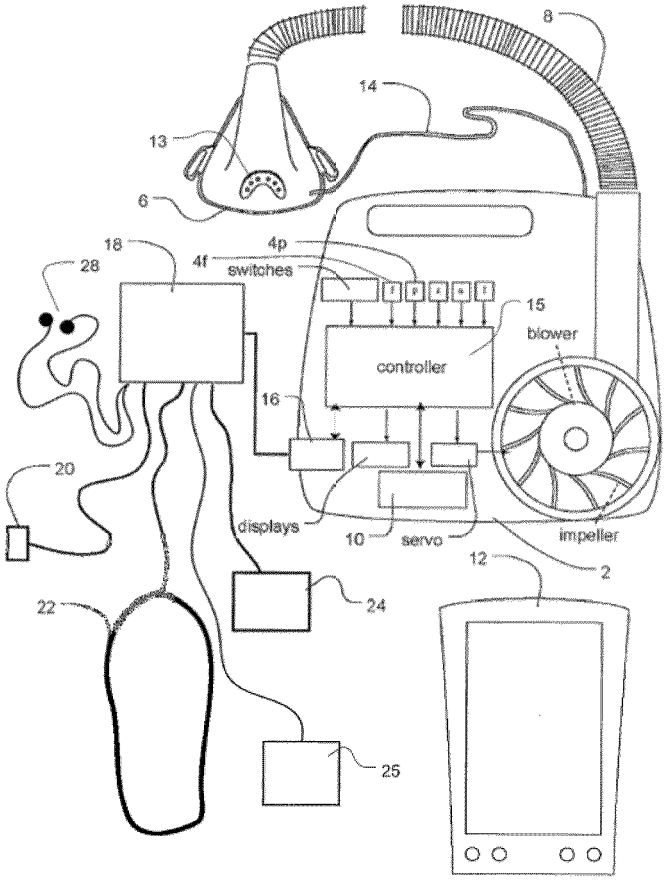


FIG. 1

Id., FIG. 1. '737 Farrell further teaches "[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." *Id.*, 5:20-23. The disclosed 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." *Id.*, 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 30 communication with other devices or computers such as hand-held display and control devices 12. The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices." *Id.*, 5:28-31. As an example, '737 teaches that 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 25 transmission between the devices" and that using "such a device or system, a physician may, for example, remotely monitor, analyze, or record the status or data history of a patient." *Id.*, 6:23-27. Further, "information may even be transmitted from the apparatus to a database of one or more patients." *Id.*, 6:22-29.

With respect to monitoring of sleep disordered breathing and related information, '737 Farrell teaches:

> Preferably, the device provides ***efficacy tracking*** by detecting and recording or scoring SDB events or related information or indices overtime, for example, by tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring.
>
> ***
>
> 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. Methods for detecting and recording such

> information are known in the art, and may be implemented as described in U.S. Patent 5,704,345. For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc.
>
> ***
>
> Those skilled in the art will recognize other methods or modifications for detecting sleep disordered breathing information such as hypopneas or apneas and determining an AHI over time or within time periods.

Farrell-737, 7:35-8:24.

Patent Owner stated in discussing the specification of the '284 Patent, which overlaps with the '680 Patent, that "[a] skilled artisan would know that apnea and hypopnea events, which are indicated based on breathing metrics, represent data of severity of the patient's sleep disorder symptoms." *See* PGR2024-00012, POPR at 19. Patent Owner also asserted that a POSITA would understand symptom severity data "calculated from data collected while patient is undergoing treatment" to be equivalent to data related to treatment efficacy. *Id.* at 9, 12. Further, "[e]fficacy, in the context of OSA, reflects the ability of treatment to prevent the occurrence of obstructive breathing events during periods when treatment is being physically applied." *Id.* at 13.

As disclosed, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "a second processor adapted for generating the PAP therapy efficacy data based on … and calculating ... the first data related to a quantitative measure of symptom severity … and … the second data related to a usage of the PAP device by the subject," as recited in Claim 1.

Further, Kumar discloses a wireless patient-side device for gathering physiological data from the patient. EX. C (Kumar), ¶ [0071]; Fig. 1 (102 "Medical instrumentation or any other device, (wired or wireless)). Likewise, '737 Farrell also states that "the apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication or it may interface with a network for transmission between the devices." EX, OTH-9 ('737 Farrell), 6:23-

25. Thus, Kumar in view of Truitt teaches or suggests the feature of "at least one second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data," as recited in Claim 1 of the '680 Patent.

3. Kumar in view of Truitt and '737 Farrell teaches or suggests an "index," as recited in claims 2 and 4

As discussed in connection with Claim 1 above, the discussion of which is incorporated here by reference in its entirety, the processor disclosed in Truitt "monitors the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion" to "counteract apneas or hypopneas." Truitt 2:57-3:11. A POSITA would understand from the teachings of Truitt—where a processor in a PAP device continues to monitor signal data relating to the respirator airflow and pressure provided to the patient and adjust the pressure and flow provided to the patient based on the monitored data to "counteract" the detected apnea or hypopnea—that the processor determines the treatment provided to the patient and adjusts the treatment based on the detected level of airflow necessary to mitigate the patient's detected disorder.

Similarly, '737 Farrell teaches a CPAP processor that provides "efficacy tracking by detecting and recording SDB [sleep disordered breathing] events or related information or indices over time, for example, by tracking or detecting central apnea, obstructive apneas, hypopneas, partial obstructions" and that "[t]hose skilled in the art will recognize other methods or modifications for detecting sleep disordered breathing information such as hypopneas or apneas and determining an AHI [apnea hypopnea index] over time or within time periods." EX. OTH-9 ('737 Farrell), 7:35-8:24.

Moreover, in the Patent Owner's Preliminary Response for the '284 PGR, Patent Owner explains that it was known to utilize an index in the context of treatment therapy. *See* PGR2024-00012, POPR at 1 (patent owner arguing that "index of treatment efficacy ... referring to indices

that measures the efficacy of therapies."). Patent Owner further describes that "an index of treatment efficacy is just another term for the level of severity of a patient's symptoms determined while the patient is being treated." *Id*. at 13; *see also id*. at 1 (the "resulting level of severity" from "***determining the level of severity*** of the subject's sleeping disorder or symptoms while simultaneously ***applying treatment***" is an "index of treatment efficacy.")

Thus, as disclosed and consistent with Patent Owner's statements, Kumar in view of Truitt teaches or suggests the feature of a "PAP therapy measure(s) includes an index," as recited in Claim 2 and "wherein the index" is based on the collected data "related to the quantitative measure of symptom severity" and "usage" of the PAP device, as recited in Claim 4 of the '680 Patent.

4. Adjusting PAP devices would have been obvious to a POSITA in view of Kumar, Truitt and '737 Farrell, as recited in claims 3, 5, 6, 9, 14, 19 and 21

As discussed above with respect Claim 1, the discussion of which is incorporated here in its entirety, the PAP device processor adjusts "***the pressure provided to the patient changes based on the detected conditions of the patient***," and "***automatically attempts to titrate the pressure support to suit the needs of the patient***." EX. D (Truitt), 1:34-43 (emphasis added). Similarly, Kumar discloses that the "devices on the patient/client and/or provider sides may allow for various forms of bidirectional communication" and "the provider may remotely control the client-side devices," including "start[ing] these devices remotely to read the data periodically or whenever needed." EX. C (Kumar), [0015]; Fig. 1 (showing provider-side devices each having "remote control" capabilities."); Claim 14 (claiming a system "wherein the provider is allowed to remotely control the at least one patient-side device."); Claim 22 (same). Kumar further states that "using optional remote control features built in to the system, remote providers can control the software on the patient's end." *Id*., ¶ [0080]; *see also* ¶ [0085]. '737 Farrell also

teaches "a device or system, a physician may, for example, remotely monitor, analyze, or record the status or data history of a patient." *Id.*, 6:23-27.

Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of PAP device "comprises an electronic component adapted to utilize a cellular network and allow the … PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remoted internet site," as recited in claims 3 and 21 of the '680 Patent.

In addition, Kumar states that using the internet, "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, may store the data for later transmission to the provider-side devices, etc." *Id.*, ¶ [0081]. Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "the PAP device … adjusted based … on the PAP therapy data … received by the remote internet site," as recited in Claim 5 or "adjusted automatically," as recited in Claim 6 of the '680 Patent.

Kumar also discloses downloading plug-ins from the provider-side devices to the patient-side devices via the internet to facilitate communication between the patient- and provider- side devices. *Id.*, ¶ [0018]. In addition, "updates to the software are done by simply running the latest software from a website" *id.*, ¶ [0086] and providing "immediate software upgrades without the software distribution through CDs." *Id.*, ¶ [0217]. Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "the first software … with the cell phone is … reprogramed or modified remotely," as recited in claims 9, 14, and 19 of the '680 Patent.

5. Independently receiving and retransmitting data would have been obvious to a POSITA in view of Kumar, Truitt and '737 Farrell, as recited in claims 7, 12, 13 and 17

Kumar states that the disclosed "patient-side device can include, for example medical and/or biofeedback device that communications through a serial, parallel, wireless or customized

interface" and "may then be connected via a computing device" or "[a]lternative[ly], the patient-side device may have a built-in computing device." EX. C (Kumar), ¶ [0013]; ¶ [0072]. Kumar also discloses a "protocol independent device manager 112 running on the computer device establishes a two-way communication with a vast array of client-side devices, including but not limited to medical and/or biofeedback devices, … data acquisition units, etc." *Id.* ¶ [0072]. Further, Kumar discloses that "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, may store the data for later transmission to the provider-side devices, etc." *Id.*, ¶ [0011]; ¶ [0081]. '737 Farrell also states that using "such a device or system, a physician may, for example, remotely monitor, analyze, or record the status or data history of a patient." *Id.*, 6:23-27. Further, "information may even be transmitted from the apparatus to a database of one or more patients." *Id.*, 6:28-29.

A POSITA would understand Kumar in view of Truitt and '737 Farrell to teach two-way communication and the collected data from the PAP device can be wirelessly transmitted and retransmitted to and/or from each of the patient-side, provider-side and central server devices and vice versa. Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "the first software … receives … the PAP therapy efficacy data … and … then used to retransmit … the PAP therapy efficacy data … to the remote internet site with the … wireless transceiver" (as recited in Claim 7) or "PAP therapy efficacy data … first received … from the PAP device by the remote internet site and then retransmitted to the first software from the remote internet site" (as recited in Claim 12) and "via a cellular network or through the Internet" (Claim 13). Similarly, Kumar in view of Truitt teaches or suggests the feature of "the first software … and the remote internet site both independently receives… the PAP therapy efficacy data…," as recited in Claim 17 of the '680 Patent.

6. An Internet-based monitoring system for addressing sleep apnea would have been obvious to a POSITA in view of Kumar, Truitt and '737 Farrell, as recited in Claims 11, 16 and 22

As discussed above, the combination of Kumar and Truitt disclose a system for addressing sleep disorders including sleep apnea. *See* supra XI, A. 2; *see also, e.g.,* Kumar, ¶¶ [0239-241]; Truitt, 1:26-30 (discloses that CPAP devices are well known "to treat obstructive sleep apnea (OSA) as well as other disorders."). Truitt also discloses that "it is known to use 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." Truitt, 1:27-30. Truitt further discloses that airflow sensors "are used to snoring, apneas, hypopneas, etc.," and the pressure for the PAP device is then "controlled to counteract or prevent these conditions." *Id.*, 3:4-11. Similarly, '737 Farrell is directed to "methods and apparatus for treating and monitoring sleep disordered breathing ("SDB")…" EX. OTH-9 ('737 Farrell), 1:7-9. '737 Farrell explains that "[t]he most common form of sleep disordered breathing is obstructive sleep apnea ("OSA") and that "[b]ecause 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." *Id.*, 1:16-18. A POSITA recognizes sleep apnea disorder—includes different types of apneas. Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "data of the PAP therapy efficacy data includes … data related to both obstructive, and central apneas," as recited in claims 11, 16 and 22.

7. Using Bluetooth would have been obvious in view of Kumar, Truitt and '737 Farrell, as recited in claims 8 and 18

Based at least in part on Fig. 1 of Kumar, the communication link between the patient-side device, i.e., the "medical instrumentation" 102 for collecting the physiological data, and the computing device 110, is described to be "wireless." Kumar, Fig. 1; *see also Id.*, ¶ [0071]. A POSITA would have understood the different technologies suitable to support the suggested

wireless communication between devices, including the use of Bluetooth technology. By 2005, Bluetooth technology was commonly understood by a POSITA as a known technology supporting wireless device communications, and it would have been understood to be a suitable method to provide for wireless communications between the patient-side device and the computing device disclosed in Kumar. Similarly, '737 Farrell teaches that the disclosed 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 25 transmission between the devices." EX. OTH-9, 6:22-25. Thus, Kumar in view of Truitt and '737 Farrell, and the knowledge of a POSITA, teaches or suggests the feature of "using a Bluetooth wireless protocol," as recited in claims 8 and 18. Bluetooth Ver.1.0B (Parts A and B) (November 1999) EX. OTH-2 (BT V.1), p.18; *see* also p.41 ("Bluetooth is a short-range radio link….").

8. Kumar in view of Truitt renders obvious an internet based system for use by clinicians involving remote monitoring as recited in claims 23, 25 and 27

Kumar discloses a "networked-based monitoring of physiological data" involving "at least one patient-side device [that] collects physiological data from a patient" and a "provider-side device [that] receives the data … via a wide area network." Kumar, *Abstract,* ¶ [0002]; ¶ [0012] ("connection of multiple patient-side devices provider-side devices, and engines."). Kumar further discloses that the devices on the "provider-side" are intended for "a medical provider such as a doctor, nurse, etc." *Id.*, ¶ [0071]. Kumar also states that "remote client module (not shown) allows remote hosts to view the data being streamed in real time. The remote client module is described to control the software being run on the patient and/or provider end. Multiple remote client modules can run concurrently, allowing multiple remote providers to view data form one device." *Id.*, ¶ [0085]. Kumar further describes that "[b]y receiving data from the patient-side device, a provider is able to monitor the patient's physiology for research, keeping

track of documentation, performing analysis, managing and maintain records, diagnosing the patient, providing treatment in real-time to the patient, etc." *Id.*, ¶ [0014]. Similarly, '737 Farrell teaches that "with such a device or system , a physician may, for example, remotely monitor, analyze or record the status or data history of a patient. For example , remote devices may send to or retrieve from the apparatus any desired cardiovascular or other information." EX. OTH-9, 6:25-28.

Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "at least one second software with the remote internet site and the database are …accessible to a clinician or doctor … for a remote monitoring…," as recited in claims 23 and 25 of the '680 Patent.

Kumar further describes that its internet-based monitoring system can be used even "when a patient or provider is in or on an airplane or ship, or when the patient or provider is located in a different part of the world." EX. C (Kumar), ¶ [0078]. Kumar explains, as an example of using the disclosed system, facilitating "an anesthesiologist in the United States can remotely assist a surgeon performing surgery in Ecuador." *Id.*, ¶ [0266]. Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "remote monitoring of … subjects in another country," as recited in Claim 27 of the '680 Patent.

9. Automatic data analysis is obvious in view of Kumar, Truitt and '737 Farrell, as recited in claims 24 and 26

In addition to receiving and collecting physiological data from the patient-side devices Kumar further states that "[a]lerts may be sent upon occurrence of an event recognized in the data. For example, based on real-time streaming of vital patient information" software on the remote server "may be tailored to forward proper responses to the patient." EX. C (Kumar), ¶ [0088]. The disclosed internet-based "communication modes described above may be set up to allow for rapid communications to the patient or provider in an emergency situation." Id.; see also ¶ [0077] (disclosed system "can be supported by threshold and alarm controls…"). Similarly, '737 Farrell

teaches that "with such a device or system, a physician may, for example, remotely monitor, ***analyze*** or record the status or data history of a patient. For example, remote devices may send to or retrieve from the apparatus any desired cardiovascular or other information." EX. OTH-9, 6:25-28 (emphasis added); *see also* 7:35-8:24. Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "second software … adapted to perform automatic data analysis … for use with the remote monitoring …," as recited in claims 24 and 26 of the '680 Patent.

10. Kumar in view of Truitt and '737 Farrell renders obvious data analysis recited in claims 28-31 of the '680 Patent

Kumar discloses that software on the central server "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, may store the data for later transmission to the provider-side devices, etc." *Id.*, ¶ [0081]. The "storage of the data allows for the creation of statistical databases, including development of a database of biomedical test results…" *Id.*, ¶ [0083]. Kumar further describes that the patient-side device gathers physiological data include "breathing pattern," *id.*, ¶ [0071], and as discussed above, Kumar discloses using its system to treat "[s]leep apnea-hypopnea syndrome." *Id.* at ¶ [00249-40]. With respect to the data stored on the central server, Kumar further states that its "system may also track trends during the recording, and using artificial intelligence, predict future behaviors and physiological responses based on the habits of the particular client…" *Id.*, ¶ [0084]. Likewise, "device manufacturers can monitor, via the WAN, how the device is being used, and analyze any problems or limitations experienced by the providers. This will allow for the improved development software and hardware based on real time feedback received from providers." *Id.*, ¶ [0249]. A POSITA would therefore have understood that hardware on the patient-side devices include sensors may be used to collect physiological data via the application of the Kumar device. Further, Farrell-737 discloses:

> 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. Methods for detecting and recording such information are known in the art, and may be implemented as described in U.S. Patent 5,704,345. For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc…Those skilled in the art will recognize other methods or modifications for detecting sleep disordered breathing information such as hypopneas or apneas and determining an AHI over time or within time periods."

Farrell-737, 7:35-8:24.

Thus, Kumar in view of Truitt and '737 Farrell teaches or suggests the feature of "PAP therapy efficacy data … adapted to be analyzed to recognize patterns" (as recited in Claim 28), "train a neural network" (as recited in Claim 29), "correlate more robust data from multiple subjects to teach or train sensors…" (as recited in Claim 30), and "analyzed with a relationship algorithm" (as recited in Claim 31).

11. Titration Treatment is obvious in view of Kumar, Truitt and '737 Farrell as recited in Claim 32

As discussed above with respect Claim 1, the discussion of which is hereby incorporated by reference in its entirety, the processor adjusts "***the pressure provided to the patient changes based on the detected conditions of the patient***," and "***automatically attempts to titrate the pressure support to suit the needs of the patient***." EX. D (Truitt), 1:34-43 (emphasis added); *see also* Truitt, 3:4-8 (Truitt also discloses that the PAP system has an "auto titration mode of pressure support, where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient, these pressure and flow sensors…"). Kumar shows a "protocol independent device manager 112 running on the computer device establishes a two-way communication with a vast array of client-side devices, including but not limited to medical and/or biofeedback devices, … data acquisition units, etc." EX. C (Kumar), ¶ [0072]. A POSITA would

understand that the database on Kumar's central stores data concerning PAP therapy is used with a processor to automatically adjust treatment by controlling the software of the PAP device. Thus, Kumar in view of Truitt teaches or suggests the feature of "PAP therapy efficacy data … adapted with a treatment interface device processor for conducting a titration of a treatment," as recited in Claim 32 of the '680 Patent.

B. SNQP 2: Claims 10, 15 and 20 are unpatentable over Kumar in view of Truitt, Schmidt, '737 Farrell and Lisy under 35 U.S.C. §103(a)

Based on SNQP 1, Kumar in view of Truitt discloses each of the recited elements of Claim 1 of the '680 Patent, the description of which is hereby incorporated by reference in its entirety. A claim chart attached as an exhibit and identified as CHART-1 provides prior art disclosure against the limitations for each claim addressed in this SNQP, with more particularized detail below explaining the prior art disclosures against certain features.

All of the patient-side device disclosed in Kumar and the PAP of Truitt and '737 Farrell involve collecting physiological, i.e., breathing, data from the patient and processing that data. Truitt further states that 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***, ***monitor the usage*** of the pressure support device (patient compliance), or any combination thereof." Truitt, 2:1-11 (emphasis added); *see also 2*:38-42 (same). The processor also uses "[t]he output of flow sensor 32′ … for ***calculating*** the flow and/or volume of gas passing through conduit 56." *Id*., 6:46-48 (emphasis added). While Kumar, Truitt and '737 Farrell are silent with respect to the specific function used to process the sensor signals, a POSITA would have understood the different methods by which sensor data may processed, including the known data processing techniques described by Lisy. *See, e.g.,* EX. E (Lisy).

Lisy discloses "various embodiments of … signal-processing techniques that are utilized to predict the onset of flow separation. These are: (i) ***the standard deviation technique, (ii) a***

recursively fit ARMAX system identification model, (iii) the Short-Time Fourier Transform (SFFT) technique, and (iv) time-frequency signal analysis with a variety of different kernels." Lisy, ¶ 40 (emphasis added). Lisy further states that "[t]he 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. *Id.* (emphasis added). To address data indicating flow separation,

Lisy describes using different signal processing techniques for generating data. The data processing features described in Lisy disclose the recited alternative features recited in claims 5, 10, and 10 of the '680 patent. As described above, the '680 Patent includes verbatim disclosures from paragraphs 40-45 of Lisy, which further supports the obvious combination of Lisy with the teachings of Kumar and Truitt—prior art directed monitoring systems for sleep disorders. *See* EX. A ('680 Patent), 26:52-28:40.

As above, a POSITA understood that there are different methods to process signals for a sensor, and it was known to adapt a processor receiving data from an airflow sensor, such as that associated with the Truitt PAP device, based on the processing techniques suggested by Lisy, including a wavelet analysis, to enhance measured sensor data. A POSITA would have therefore understood how to adapt, based on the Lisy data processing techniques, the Truitt PAP device whereby data is transmitted for further monitoring and analysis by a medical practitioner at a remote location, as suggested by Kumar. Thus, Kumar, in view of Truitt and Lisy, teaches or suggests the features recited by dependent claims 10, 15 and 20 of the '680 Patent.

C. SNQP 3: Claims 1-9, 11-14, 16-19, and 21-32 are unpatentable over Sun in view of Quy and Schmidt under 35 U.S.C. §103(a)

For the reasons discussed below, it is respectfully submitted that claims 1-9, 11-14, 16-19 and 21-32 are obvious over Sun in view of Schmidt under 35 U.S.C. §103. A claim chart attached

as an exhibit and identified as CHART-2 provides prior art disclosure against the limitations for each claim addressed in this SNQP, with more particularized detail below explaining the prior art disclosures against certain features.

Specifically, Sun (i.e., the primary reference) was not applied during any prior examination of the '410 Application/'680 Patent, and its teachings, when combined with those of Quy and Schmidt, present a substantial new question of patentability because the combined teachings of these references were not considered by the Examiner during prosecution of the claims of the '410 Application. Had the teachings of this prior art been considered, the Examiner would not have allowed the claims thereof that correspond to claims 1-9, 11-14, 16-19 and 21-32 of the '680 Patent.

To facilitate consideration and discussion, Claim 1, the only independent claim of the '680 Patent, is reproduced below:

> 1. 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);
>
> B. a first non-transitory computer readable medium comprising a first software stored on the first 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, the first software further adapted for:
>
> ii) 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; 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 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

a mask or a nasal cannula; and

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.

Sun in view of Schmidt discloses all of these limitations.

1. Sun discloses the claimed "internet server-based diagnostic monitoring" system for use with or more PAP devices for "sleep disorder treatment."

The claims of the '680 Patent are all generally directed to "a system for remote internet server-based diagnostic monitoring" with one or more PAP devices used for treating sleep disorders. The claimed system recites the various components and functions of the system.

Similarly, Sun generally relates to a medical information management system "that stores and manages patient information and [] enables a patient, a healthcare provider, and an authorized third party…, to access that patients' medical information." Sun, ¶ [0003]. Sun states that "[t]elemedicine is an increasingly popular technique that allows a health professional, such as doctor or nurse, to monitor the condition of a patient outside the hospital or doctor's office." *Id.*, ¶ [0013]. Sun notes patient compliance as one of the challenges with at-home treatments. *Id.*, ¶ [0007]. As an example, Sun explains that "a patient suffering from obstructive sleep appeal (OSA) is typically prescribed a pressure support therapy, such as a continuous positive airway pressure (CPAP) treatment, that is to be used nightly" and "[t]he challenge exists in ensuring that the patient uses this CPAP treatment each night." *Id.*

To overcome this and other challenges, Sun teaches an internet-based system for telemedicine "in which a number of patients 12 communicates with an information management system 32" and "healthcare professionals 16, such as doctors, nurses, specialists, therapists, lab technicians and other professionals involved in the field of healthcare." Sun, ¶ [0013]. An example of the disclosed system in Sun is shown schematically in Fig. 2 reproduced below:

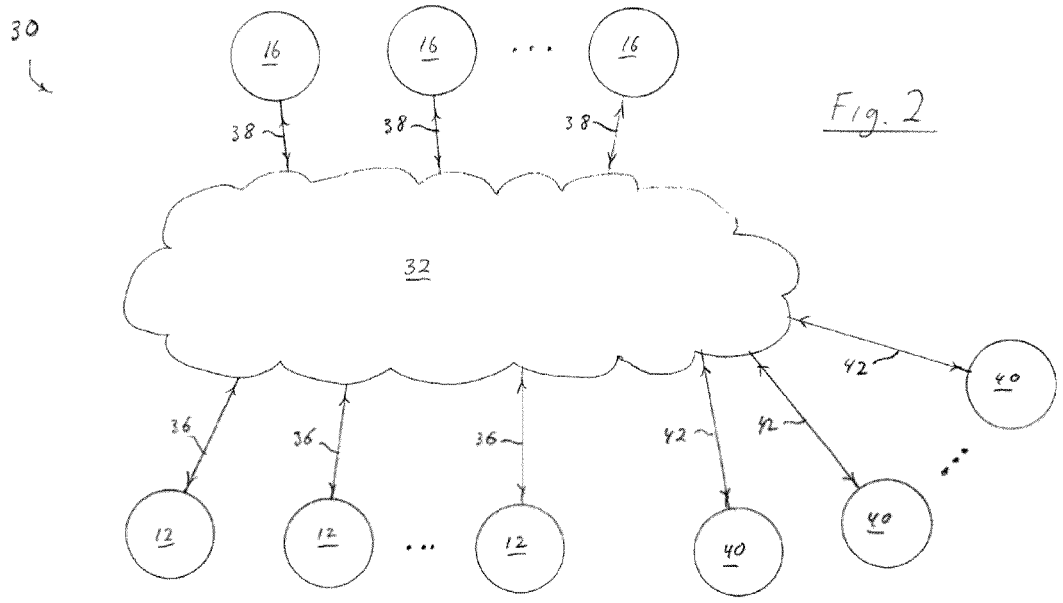


Fig. 2

Sun, Fig. 2; *see also* ¶¶ [0013-15], [0041-45]. Sun explains that the information management center is "computer based" and "capable of storing, collecting, and processing patient medical and biographical information." *Id.*, ¶ [0041]. It further includes "a database and processor hub, collectively referred to as server 34." *Id.*, ¶ [0041]. In addition,

> 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, 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 performed by a microprocessor platform.

Sun, ¶ [0067].

The information management center 32 disclosed in Sun "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." *Id.*, ¶ [0042]. As shown and explained, "each patient 12 … interacts with server 34 via a first communication link 36." *Id.*, ¶ [0043]. Likewise, "each healthcare professional 16 … interacts with management 32 via a second communication link 38," which enables "the healthcare profession to review the patient medical information, update the information… and provide recommendations to the patient." *Id.*, ¶ [0045]. The medical information management system also allows others to remotely "[m]onitor the ongoing treatment of a patient by reviewing that patient's medical information, even if the third party is hundreds or thousands of miles from the patient." *Id.*, ¶ [0046].

Sun discloses an embodiment in which the "patient interacts with server 34 via first communication link 36 using a patient interface appliance 44." *Id.*, ¶ [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" that provides "a patient-tailored presentation 48 … to the user under the control of the program stored in the appliance." *Id.*, ¶ [0051]. A POSITA would understand from this teaching that the portable handheld device includes software stored in its memory for the processors to control the device.

"Patient interface appliance 44 includes a housing 45, a processor 47, a memory 49, a display 50, … and at least one input device 52." *Id.*, ¶[0052]. Further "[h]ousing 45 preferably contains these components as a small, handheld, light weight portable unit that can be easily carried." *Id.* A POSITA would recognize that by at least 2005, the disclosed wireless and portable patient interface appliance disclosed in Sun may include other well-known devices such a cellphone. Indeed, in the Patent Owner's Preliminary Response for the '284 PGR, Patent Owner explained that a "remote communication systems is 'a computer or processor, which receives the data transmission and displays the data or records it on some recording medium" and characterized

such devices as including "for example, a cell phone." *See* PGR2024-00012, POPR at 20. A POSITA would recognize, as confirmed by Patent Owner, that the description of a portable computing device suggests a cellphone.

In view of the teachings of Sun, a POSITA would further understand that the disclosed remote wireless portable patient interface appliance suggests a cell phone that would include a processor, memory, display, and a wireless transceiver, where the processor has software downloaded to the memory of the cellphone and is capable of receiving therapy data for display on its display, based on the generalized descriptions and known features set forth for the portable patient interface appliance.

Sun also discloses that the "patient interface appliance 44 communicates with … other medical device or system that is capable of monitoring a physiological condition of a patient" by "receiving 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… are not within established thresholds" and to do so via a "wireless link." *Id.*, ¶ [0054]. Sun identifies a CPAP device as an example of a medical equipment device and further disclose as an alternative "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.*, ¶ [0058].

Fig. 4 of Sun, reproduced below, "illustrates the patient interface appliance having the additional features of a pressure support system." *Id.*, ¶ [0059].

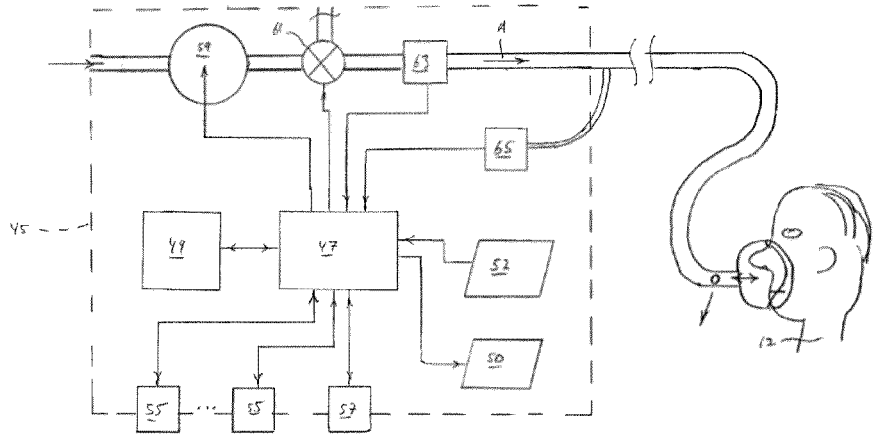


Fig. 4

Id., FIG. 4. As shown, a CPAP includes:

> 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, 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.

Id., ¶ [0059]. The CPAP device also includes a mask for delivering the airflow to the patient. *Id.*, Fig. 4.

Sun further discloses and illustrates in Fig. 4 the CPAP device with "a flow sensor 63 and or pressure sensor 65, for monitoring the flow and/or pressure of the breathing gas delivered to the patient." *Id.*, ¶ [0060]. These sensors are used "for monitoring the condition of the patient and controlling the pressure support based thereon." *Id.* Sun further states that "[i]n 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." *Id.*, ¶ [0092]. A POSITA would understand from Sun that the disclosed medical information management system includes CPAP devices with a blower, a mask, internal sensors for measuring airflow during use of the CPAP device. A POSITA would further understand from Sun that the disclosed CPAP device would further include the known features of a processor, memory and wireless transceiver, with the processor adapted to monitor and control the pressure support based on the condition of the patient, and further wirelessly transmit information for use with a medical information management system, such that the management system may provide for adjustments in automatic fashion. ¶¶ [0060], [0092]; *see also* Fig. 4.

Sun incorporates by reference, descriptions for other CPAP devices that disclose "bi-level pressure support" and a "technique for distinguishing between inspiration and expiration in an [] single-limb patient circuit" as well as "other conventional modes of pressure support, such as proportional assist ventilation (PAV®) and proportional positive airway pressure (PAP) ventilation." *Id.*, ¶¶ [0061-0062]. Specifically, Sun specifies that its descriptions include U.S. Patent No. 5,458,137, titled "Method and Apparatus for Controlling Sleep Disorder Breathing," issued to Axe et al. on October 17, 1995 ("Axe"), whereby the contents of which is incorporated by reference. Axe, as incorporated, is generally directed to a method and apparatus "for controlling sleep disorder breathing, particularly one utilizing positive air pressure supplied to a person's breathing passages." Axe, 1:15-18. Axe further discloses that by monitoring pressure differences in the PAP device, the device provides "[d]iagnosis of apnea, hypopnea … based on measurements of breathing by the patient." *Id.*, 2:40-50. Further, a microprocessor controls the air pressure provided to the patient in "response to detection of specific conditions," and the air pressure of the CPAP "may be adjusted to multiple levels during and following occurrences of sleep disorder

breathing" with "[i]ncreased 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." *Id*., 2:52-58.

Based on the above, a POSITA would understand that Sun discloses a remote internet server-based diagnostic monitoring system, is hosted on at least one server and is capable of wirelessly monitoring one or more CPAP devices by receiving data indicative of the use of various CPAP devices, directed to aspects of sleep disorder treatment, including the condition of the patient and the patient's usage of a treatment CPAP device.

2. Sun in view of Quy and Schmidt renders obvious an internet-based monitoring and assessment system for a PAP device with integrated wireless communication capabilities to remotely transmit treatment data

a. Motivation to combine Sun, Quy and Schmidt

Sun discloses an internet-based monitoring system that wirelessly receives data from PAP devices to be considered by a healthcare professional and other third parties "for monitoring the flow and/or pressure of the breathing gas delivered to the patient" and "the condition of the patient" as well as "controlling the pressure support" provided to the patient. *See, e.g*., Sun, ¶ [0060].

Similar to Sun, Quy is generally directed to an internet-based monitoring system. For example, Quy discloses "a wireless health monitoring system for interactively monitoring a disease or health condition of a patient (38) by connecting an internet-enabled wireless web device ("WWD") (12) to a health monitoring device (11) which may be a medical device." EX. H, Abstract. Quy explains that the system provides "a full-feature health-monitoring system that may wirelessly connect to a back-end server application via the internet. The invention allows wireless access to and from a wide variety of present medical or health-related instruments and

devices, while maintaining the capability of connecting to future such devices." *Id.* 4:15-22. *See, infra* §XI.D.2, addressing Quy.

Similar to Sun, Quy describes a system that includes a network of medical devices, monitoring devices, and a remote internet site that includes a server. As a first instance, Quy teaches that a cell phone, or "the WWD may be a hybrid device that combines the functions of a computer, PDA and telephone." *Id.* 6:27-29. Quy explains that the WWD can include a number of different wireless technologies including "infrared (IR), microwaves, radio frequency (RF), e.g., Bluetooth® or 802.11 protocols, optical techniques including lasers, and other such techniques may be used." *Id.* 7:10-16. Quy discloses a cell phone, and a POSITA would further understand that Quy further suggests a non-transitory computer readable medium, whereby the cell phone would include a radio frequency wireless transceiver, a processor, software, and a display.

Similar to Sun, Quy teaches a server-based health monitoring system connected via the internet. For example, Quy describes a system that includes a server node 18 in a network that functions to collate data from a number of medical devices and connected WWDs. Quy states, "Referring to FIG. 3, WHMA 10 is shown communicating wirelessly with the Internet. In doing so, WHMA 10 generally sends a wireless signal to a base station 14 (in known fashion) that is connected to a server 18 that is in signal communication (in known fashion) with the internet. Server 18 communicates via a protocol (in known fashion) to Internet 20, which also communicates via a protocol (in known fashion) to a server 22 running an application 62. Server 22 may be accessed (in known fashion) by a client computer 44 through a connection 64." *Id.* 14:22-31.

Further, Quy teaches that a medical device can be connected to an internet-enabled wireless web device ("WWD") for "processing 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…" *Id.* 4:30-5:15. Quy further indicates that the "WWD is a web-enabled cellular phone." *Id.*, 6:22.

It would have been obvious to implement the patient interface device of Sun using the web-enabled cellular phone of Quy, because the cellular phone embodies the physical characteristics preferred by Sun in that it is a "small, hand-held, light weight portable unit that can be easily carried," in an "off-the-shelf" device already used by consumers. It could also "significantly extend the range of connectivity." *Id.*, 6:15-20; 3:30-34.

Based on the above, Sun and Quy are both directed to methods and systems for network connected patient monitoring, including a first software downloaded on a cell phone and a second non-transitory computer readable medium for a remote internet site and date base. A POSITA would have understood that each is in the same field of endeavor and are each directed to the same general problem and solution of enhancing the treatment of patients through the use of telemedicine. Further, a POSITA would have recognized that the combination of Sun, Quy and Schmidt address the same underlying goal of providing for adaptable telehealth medicine networks to improve patient treatment while also addressing how to determine patient compliance with treatment recommendations, utilizing methods of transferring data between a patient location and a medical facility. Moreover, a POSITA would have reason to combine the above prior art identified above for the following reasons:

1) Sun discloses that it is beneficial to transmit sleep profile information to caregivers, physicians, or industry members.

2) Quy teaches that distribution of patient data to remote medical providers "allows wireless access to and from a wide variety of present medical or health-related instruments and devices, while maintaining the capability of connecting to future such devices." EX. H, 4:19-22.

3) In an article entitled Wireless CPAP Patient Monitoring: Accuracy Study by Dr. Lankford ("Lankford"), Lankford discusses a study in which the accuracy and reproducibility of subject CPAP data was wirelessly transmitted to a remote site. Lankford, 163. Lankford further explains that "Potential benefits of this technology include advanced compliance and efficacy along with a potential reduction in health-care costs." *Id.*, Abstract.

Sun and Quy do not detail data acquisition from the disclosed air and pressure sensors in the CPAP device by the processor to generate data from the signals received. Prior to 2005, as explained more particularly below, a POSITA understood that data acquisition can be accomplished by software operating on the processor to acquire data from sensors signals in a CPAP device and to use the collected data to monitor the CPAP usage and to wirelessly transmit the collected data. A POSITA would have known the details of such data acquisition, as described by Schmidt, explained in further detail below.

Indeed, by 2005, to promote the efficiencies of telemedicine and improve patient treatment, a POSITA would have understood the benefits of combining the CPAP data acquisition teachings of Schmidt and the use of sensors and a processor of a CPAP device disclosed in Sun, whereby the sensor signals are converted into data. The data may be used to monitor and control the CPAP usage as well as having the data being wirelessly transmitted to an integrated medical information system via the internet for further monitoring by healthcare providers.

Schmidt relates generally to a "wireless data acquisition system for data communication… that may be adapted for different applications by software programming." EX. G (Schmidt), 1:15-20. Schmidt discloses a programmable wireless data acquisition system with a signal processing module that has a microprocessor that controls the operation of the signal processing module. *Id.*, 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." *Id.* Schmidt further discloses processing the sensor signals into data for wireless transmission to a distributed network, including a base station. *Id.*, Abstract; Fig. 1.

Like the CPAP devices in Sun, Schmidt discloses the use of "air flow" and respiration sensors and further describes supplying sensor signals to the signal processing module for conditioning and processing where the "module microcontroller [dynamically] adapts the signal processing module in response to variation in the range, character and type of the physiological signal such that the adaptation occurs during signal processing module operation." *Id.*, 4:7-22; 14:40-54.

The '680 Patent includes the entire Detailed Description from Schmidt, 14 columns, spanning 4:63 to 14:54 and each of Schmidt's Figures 1-6. Because both Schmidt and Sun are each directed to monitoring systems for patient treatment, a POSITA would have understood how to adapt the various features of each to provide for an improved system having the combined features of an internet based medical information system for wirelessly connecting patients using CPAP devices with healthcare providers—leveraging the data acquisition system of Schmidt—to remotely "monitor[] the condition of the patient and control[] the pressure support" with the CPAP devices as disclosed in Sun.

A POSITA understood the benefit of providing such treatment in-home, away from clinicians, to facilitate patient compliance as well as overall treatment progress as suggested by Sun. Thus, a POSITA had reasons to provide for a system that operates remotely from a clinician, utilizing known control and communication systems integrated with existing CPAP devices and sensors. This improved system, provides for the capability of improved patient treatment and further allows for the remote adjustment of treatment without requiring in-person consultation with a patient, while also documenting usage compliance in accordance with

medical recommendations to address changes in patient symptoms. The improved system would monitor the patient's usage and the severity of the patient's disorder and wirelessly transmit the treatment information to a clinician for remote analysis or other purposes.

Based on the understood objectives of telemedicine known to POSITA and disclosed in Sun, Quy and Schmidt similarly suggests that its system "provides a single device for measuring such widely disparate signal types and presents distinct economic advantages, especially to small enterprises such as a medical clinic located in a rural area, which would be empowered by this invention to conduct tests which would otherwise have required patient travel to a large medical center, with all the attendant cost thereof." EX. G (Schmidt), 5:52-6:35.

A POSITA understood, based on the teachings of Sun in view of Quy and Schmidt, that data may be acquired for such a system via the sensors of the treatment PAP device of Sun, whereby the integrated wireless communication capabilities provide for the transmission of the treatment data wirelessly to clinicians. A POSITA understood that the combination of Sun and Schmidt would simply involve combining similar features and components—sensors, processors and known CPAP devices—for receiving data from the sensors and determine the severity of the patient's symptoms, including the usage of the device. The combined sleep disorder treatment platform could include wireless communication capabilities to transmit information to a remote location to for consideration of treatment outcome and/or patient compliance. The combined treatment system involves using each of the known elements according to its known purpose in accordance with the disclosed methods to yield predicable results—to improve patient compliance and evaluate overall treatment outcomes to provide for improved patient monitoring without in-person consultation. This would enhance patient compliance determinations and realize the benefits of telemedicine known in the art, improving the overall treatment of sleep disorders treated with PAP systems, as suggested by Sun.

b. Sun in view of Quy and Schmidt discloses an internet-based monitoring and assessment system for one or more PAP devices

Schmidt discloses a "programmable wireless data acquisition system" with "a signal processing module comprising a module microcontroller having a memory." EX. G (Schmidt), 2:7-10. The disclosed system processes signals including sensors signals from the "air flow and respiration" sensors. *Id.*, 4:14-18. Similar to the CPAP of Sun, the processing module 16 wirelessly transmits data to base station 40 via bidirectional transceiver. *Id.*, 5:32-38; Fig. 1. Also, like Sun, Schmidt states that the disclosed data acquisition system is designed to "be adapted for different applications by software programmed." *Id.* 1:15-20.

Like the medical equipment 54, i.e., the CPAP device, disclosed in Sun, Schmidt discloses wireless transmission of the processed sensor data with reference to Fig. 1, reproduced below:

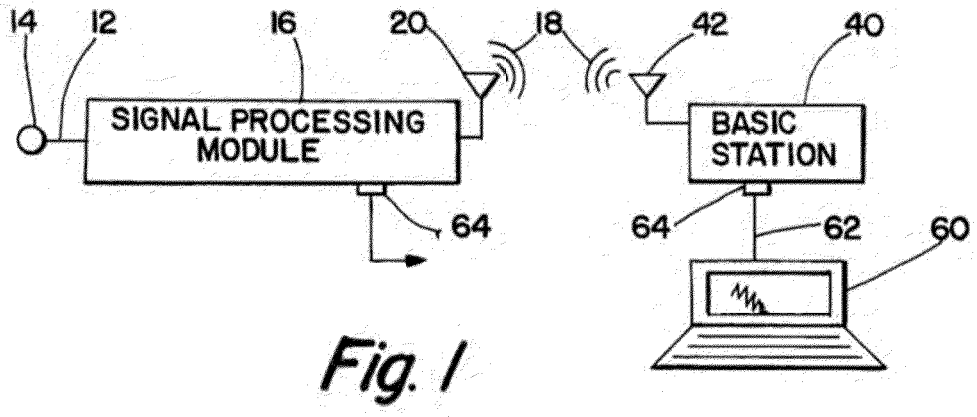


Fig. 1

As shown, "input 12 from sensor 14 is inputted to signal processing module 16." *Id.* 4:65-67. "The signal processing module 16 transmits the signal 18 by wireless means to base station 40," which is shown in Fig. 1 as radio frequency (RF)." *Id.*, 5:5-6. The base station 40 receives the radio frequency signal 18 through base antenna 42, demodulates the radio frequency signal 18, and decodes the data." *Id.* 5:10-12. Thus, similar to the teachings of Sun, a POSITA would

understand that the Schmidt system teaches a processor that processes airflow sensor signals and wirelessly transmits the data to a remote base station, to receive the processed data.

With respect to the signal processing module, Schmidt illustrates in FIG. 2, reproduced below, "a block diagram of the signal processing module 16 with the sensor 14 and the module antenna 20." *Id.*, 5:52-54.

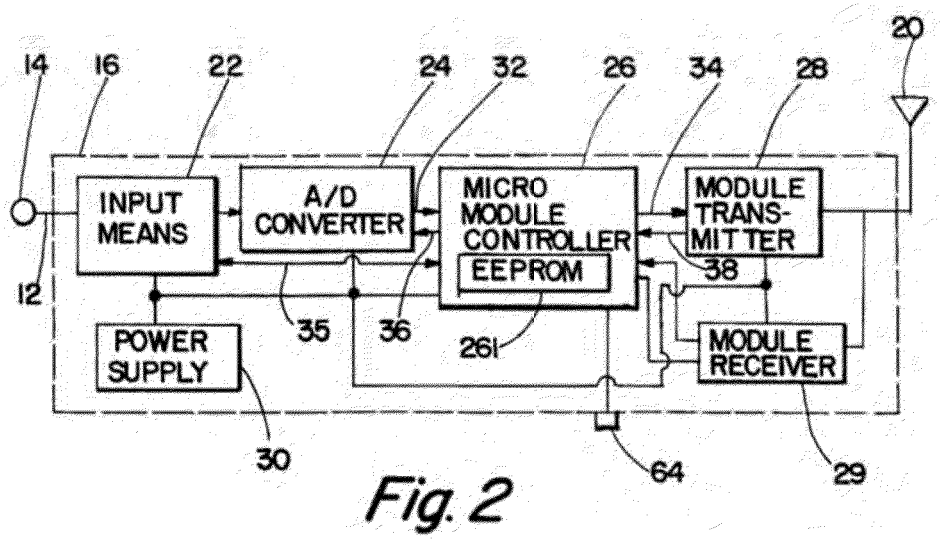


Fig. 2

Id., FIG 2. Schmidt describes:

> The signal processing module 16 comprises input means 22, analog-to-digital (A/D) means 24, a module microcontroller 26 with a nonvolatile memory, advantageously, an EEPROM 261, a module transmitter 28, a module receiver 29 and a module power supply 30.
>
> ***
>
> A module power supply 30 provides electrical power to the signal processing module 16 which includes the input means 22, A/D means 24, module microcontroller 26 module transmitter 28 and module receiver 29."
>
> ***
>
> The input means 22 is adjustable either under control of the module microcontroller 26 or by means of individually populatable components based upon the specific external input 12 characteristics and range enabling the input means 22 to accept that specific external input 12.

Id. 5:54-6:5; *see also* 7:4-10. Further, "[i]f the input characteristics change the programing and/or components change accordingly" and can accommodate different applications including "measurements of vital signs such as … respiration rate." *Id.*, 6:9-21. Schmidt also discloses that the "module microcontroller 26 can be programmed to control the input means 22 and the A/D means 24 to provide specific number of external inputs 132, sampling rate, filtering gain." *Id.*, 6:56-59.

Schmidt further discloses that the "signal processing module 16 is capable of accepting multiple external inputs 12 from multiple sensors 14" and "generates a signal 18 encoded with data corresponding to the external input 12" for wireless transmission to the base station 40. *Id.*, 4:66-5:7. In particular, "signal processing module 16 is variably configurable through software programming … to receive external inputs 12 having different characteristics and range and to provide variable sampling rate, filtering and gain of the external inputs based upon such characteristics and range and/or the specific application" and can be reconfigured "for varying signal characteristic." *Id.*, 8:23-37. Schmidt also discloses that "[f]or maximum flexibility, [] reconfiguration can be carried out during a series of measurements" and "to accept an external input 12 of larger amplitude, or a different frequency range, where signal characteristics change significantly during the course of a series of measurements." *Id.*, 8:38-8:47. Thus, Sun in view of Schmidt describes a CPAP device with software on the processor adapted to receive signals from the air flow sensors and process the signals into data for use to control and monitor the airflow and pressure of the CPAP device.

Here, as disclosed, the processor in the CPAP device monitors the flow and air pressure delivered to the patient via the flow and pressure sensors and is further used "for monitoring the condition of the patient and controlling the pressure support based thereon." *Id.*, ¶ [0060]. As detailed in Axe, the description of which has been incorporated in Sun, the disclosed CPAP devices

treat sleep disorders using a microprocessor to control the delivery of air pressure in "response to detection of specific conditions" and "may be adjusted to multiple levels during and following occurrences of sleep disorder breathing" with "[i]ncreased 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." *Id.*, 2:52-58.

Thus, based on the teachings of Sun in view of Quy and Schmidt, it would have been obvious to a POSITA to incorporate the programmable software for the processor in the disclosed CPAP device of Sun to acquire the data from the airflow sensors, as described in Schmidt, and use the collected data to monitor CPAP usage, control airflow and adjust the pressure support provided to the patient depending the condition of the patient to treat a sleep disorder, as disclosed in Sun. A POSITA would further understand that in monitoring the usage of the CPAP device and the condition of the patient based on the sensor data, the software on the processor calculates data related to the patient's treatment and the patient's usage of the device.

Indeed, in the Patent Owner Preliminary Response for the '284 PGR, Patent Owner stated that "by collecting and processing respiratory airflow, the PAP device calculates sleep disordered breathing episodes such as apnea events, which a skilled artisan understands is used along with the data of usage to determine sleep apnea indices/level of severity of sleep disordered breathing," and calculating "data collected while the patient is undergoing treatment" is equivalent to data related to treatment efficacy. *See* PGR2024-00012, POPR at 9 and 12.

Thus, Sun in view of Quy and Schmidt teaches or suggests the feature of "a second processor adapted for generating the PAP therapy efficacy data based … and calculating ... the first data related to a quantitative measure of symptom severity … and … the second data related to a usage of the PAP device by the subject" as recited in independent Claim 1.

3. Sun in view of Quy and Schmidt discloses therapy efficacy measures that include an "index," as recited in claims 2 and 4

Sun teaches a CPAP device that monitors the condition of the patient and controls the pressure provided by the CPAP device based on the monitored patient condition. *Id.*, ¶ [0060]. Sun states that "[i]n 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." *Id.*, ¶ [0092]. Sun, as incorporating the disclosure of Axe, further teaches a microprocessor that controls the air pressure of the CPAP in "response to detection of specific conditions," and the air pressure "may be adjusted to multiple levels during and following occurrences of sleep disorder breathing" with "[i]ncreased 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." *Id.*, 2:52-58.

The combination of Sun, and the incorporated disclosure of Axe, with Quy and Schmidt, describes that the disclosed CPAP processor has software that monitors, adjusts, and readjusts the air pressure, i.e., treatment, delivered to the patient to address the sleep disorder events such as apneas. A POSITA would understand from the teachings of Sun and Schmidt—where a processor in a PAP device continues to monitor signal data relating to the respirator airflow and pressure provided to the patient and adjust and readjusts the pressure and flow provided to the patient based on the monitored data to "suppress" the detected apnea or hypopnea—that the processor detects and records the treatment and related information necessary to mitigate the patient's detected disorder over time and determines the effectiveness of the treatment.

Patent Owner explained that it is known to utilize an index in the context of treatment therapy and that an "index of treatment efficacy ... refer[s] to indices that measure the efficacy of therapies." *See* PGR2024-00012, POPR at 1 (internal quotations omitted). Patent Owner further

provides that "an index of treatment efficacy is just another term for the level of severity of a patient's symptoms determined while the patient is being treated." *Id.* at 13; *see also Id.* at 1 (the "resulting level of severity" from "***determining the level of severity*** of the subject's sleeping disorder or symptoms while simultaneously ***applying treatment***" is an "index of treatment efficacy."

Thus, as disclosed and consistent with Patent Owner's statements, Sun in view of Quy and Schmidt teaches or suggests the feature of a "PAP therapy measure(s) includes an index," as recited in Claim 2 and "wherein the index" is based on the collected data "related to the quantitative measure of symptom severity" and "usage" of the PAP device, as recited in Claim 4 of the '680 Patent.

4. Remotely Adjusting and Reprogramming the PAP devices would have obvious to a POSITA in view of Sun, Quy and Schmidt as recited in claims 3, 5, 6, 9, 14, 19 and 21

Sun teaches that "healthcare professionals 16, such as doctors, nurses, specialists, therapists, lab technicians and other professionals involved in the field of healthcare," can "interact with information management System 14, for example, to review the collected patient information, add or modify patient information, change or modify medical treatments provided to the patient, or a combination of these functions." *Id.*, ¶ [0015]. Sun also discloses that the processor of the remote server "review[s] the information received via the first communication link and automatically provide[s] a notification to the patient … if the information is outside established parameters," which includes "providing an alarm." Sun, ¶ [0071].

Thus, Sun in view of Quy and Schmidt teaches or suggests the feature of PAP device "comprises an electronic component adapted to utilize a cellular network and allow the … PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site," as recited in claims 3 and 21 of the '680 Patent. Based on the above, Sun in view of

Quy and Schmidt also teaches or suggests the feature of "the PAP device … adjusted based … on the PAP therapy data … received by the remote internet site," as recited in Claim 5 or "adjusted automatically," as recited in Claim 6 of the '680 Patent.

Quy additionally teaches that the WWD ("cell phone") downloads software, either locally or remotely stored, e.g., "the patient connects to a specific Internet 10 site and a software program, resident on a remote server located on the Internet, downloads 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." *Id.* 8:8-15. The combination of Sun, Quy and Schmidt discloses the first software adapted for use with the cell phone is further adapted to be reprogrammed or modified remotely. For example, Quy teaches "To initialize the system, the program starts and a wireless application is loaded into the WWD." *Id.* 17:22-23. The combination results in a first software that can be modified remotely due to the wireless downloading of the new programing. Thus, Sun in view of Quy and Schmidt teaches or suggests the feature of "the first software … with the cell phone is … reprogrammed or modified remotely," as recited in claims 9, 14 and 19 of the '680 Patent.

5. Independently receiving and retransmitting data would have been obvious to a POSITA in view of Sun, Quy and Schmidt as recited in claims 7, 12, 13 and 17

Sun teaches an internet-based system for telemedicine "in which a number of patients 12 communicates with an information management system 32" and "healthcare professionals 16, such as doctors, nurses, specialists, therapists, lab technicians and other professionals involved in the field of healthcare." Sun, ¶ [0013]. Sun also teaches that "each patient 12 … interacts with server 34 via a first communication link 36." *Id.*, ¶ [0043]. Likewise, "each healthcare professional 16 … interacts with management 32 via a second communication link 38," which

enables "the healthcare profession to review the patient medical information, update the information… and provide recommendations to the patient." *Id.*, ¶ [0045]. The medical information management system also allows others to remotely "[m]onitor the ongoing treatment of a patient by reviewing that patient's medical information, even if the third party is hundreds or thousands of miles from the patient." *Id.*, ¶ [0046]. A POSITA would understand from Sun and Schmidt to teach two-way communication and that the collected data from the PAP device can be wirelessly transmitted and retransmitted to and/or from each of the patient, healthcare professionals and server and vice versa.

Thus, Sun in view of Quy and Schmidt teaches or suggests the feature of "the first software … receives … the PAP therapy efficacy data … and … retransmit … the PAP therapy efficacy data … to the remote internet site with the … wireless transceiver" (as recited in Claim 7) or "first received … from the PAP device by the remote internet site and then retransmitted to the first software from the remote internet site" (as recited in Claim 12) and "via a cellular network or through the Internet" (Claim 13). Similarly, Sun in view of Quy and Schmidt teaches or suggests the feature of "the first software … and the remote internet site both independently receives… the PAP therapy efficacy data…," as recited in Claim 17 of the '680 Patent.

6. An Internet-based and monitoring and assessment system with data related to apnea would have been obvious to a POSITA in view of Sun, Quy and Schmidt as recited in claims 11, 16 and 22

As discussed above, Sun describes the use of its CPAP device for treating patients suffering from obstructive sleep apnea (OSA). Sun, ¶¶ [0007], [0059-62]; Fig. 4. A POSITA recognizes sleep disorder and in particular sleep apnea includes different types of apneas. Thus, Sun in view of Quy and Schmidt teaches or suggests the feature of "data of the PAP therapy efficacy data includes … data related to both obstructive, and central apneas," as recited in claims 11, 16 and 22.

7. Using Bluetooth would have been obvious in view of Sun, Quy and Schmidt, as recited in claims 8 and 18.

Referring back to Fig. 1 of Sun and the accompanying disclosures, "[c]ommunication links 18 between patients 12 healthcare professionals 16, and information management system 14 are establish using any conventional communication technique or protocol…" Sun, ¶ [0015]. Further, for communication between the patient interface appliance and the medical equipment terminals, where the data relating to the monitored physiological conditions of the patient is transferred, Sun discloses a communication link that includes "a wireless link, such as an RF or infrared link." Sun, ¶ [0054]. Similarly, Quy discloses sending of sensed medical data from a sensor, to a cell phone, then to a server, and various combinations thereof using cellular and BLUETOOTH protocols. *See* EX. H (Quy), 13:32 – 14:11. Thus, Sun in view of Quy and Schmidt teaches or suggests the feature of "using a Bluetooth wireless protocol," as recited in claims 8 and 18. *See, e.g.,* Bluetooth Ver.1.0B (Parts A and B) (November 1999) EX. OTH-2 (BT V.1), p.18; *see* also p.41 ("Bluetooth is a short-range radio link….").

8. Sun in view of Quy and Schmidt renders obvious an internet base monitoring and assessment system for use with clinicians for remote monitoring as recited in claims 23, 25 and 27

Sun states that "[t]elemedicine is an increasingly popular technique that allows a health professional, such as doctor or nurse, to monitor the condition of a patient outside the hospital or doctor's office," i.e., remotely. Sun, ¶ [0013]; Claim 5 ("information management center includes means for … performing a monitoring function."); claims 14, 36, and 52 (same). Sun teaches an internet-based system for telemedicine "in which a number of patients 12 communicates with an information management system 32" and "healthcare professionals 16, such as doctors, nurses, specialists, therapists, lab technicians and other professionals involved in the field of healthcare." Sun, Fig. 2; *see also* ¶¶ [0013-15], [0041-45]. Sun also discloses that the processor of the remote server "review the information received via the first communication link and automatically provide

a notification to the patient … if the information is outside established parameters," which includes "providing an alarm." Sun, ¶ [0071].

Thus, Sun in view of Schmidt teaches or suggests the feature of "at least one second software with the remote internet site and the database are …accessible to a clinician or doctor … for a remote monitoring…," as recited in claims 23 and 25.

Sun also teaches that the disclosed medical information management system is accessible by clinicians via the internet. A POSITA would understand generally that such access would be available across the world wherever the internet is accessible. Thus, a POSITA would have understood that the remote monitoring, as taught and further suggested by Sun in view of Schmidt, allows clinician to monitor one or more patients located in another country. Specifically, Sun teaches that remote access via the internet-accessible system allows access by others that are "hundreds or thousands of miles from the patient." Sun, ¶ [0046]. Thus, Sun in view of Schmidt teaches or suggests the feature of "remote monitoring of … subjects in another country," as recited in Claim 27 of the '680 Patent.

9. A Remote Server that automatically Analyzes Data would have been obvious to a POSITA in view of Sun, Quy and Schmidt as recited in claims 24 and 26

In addition to receiving and collecting physiological data from the patient interface appliance, Sun further states that the processor on the server of the information management system "review[s] the information received via the first communication link and automatically provide a notification to the patient, healthcare … if the information is outside established parameters." Sun, ¶ [0071]; Claim 3 ("means for automatically providing a notification to at least one of a patient… responsive to … the patient information falling outside a predetermined threshold."); Claims 12 (same). Thus, Sun in view of Schmidt teaches or suggests the feature of

"second software … adapted to perform automatic data analysis … for use with the remote monitoring …," as recited in claims 24 and 26.

10. Sun in view of Quy and Schmidt renders claims 28-31 obvious

Quy discloses:

> a method according to an embodiment of the invention, the patient connects to a specific Internet 10 site and a software program, resident on a remote server located on the Internet, . . . software, as well as inputs from the patient or other inputs, can control the manner, content, and display of information presented to the patient, and measured or input data can be stored for review by a health care provider or by a software algorithm or application. The algorithm may be of varying complexity, from a simple program that merely acknowledges receipt of information to ***an artificial intelligence algorithm, such as an expert system, collaborative filtering system, rules based system, case-based reasoning system, or other such artificial intelligence application***.

EX. H (Quy), 8:8-31 (emphasis added). Quy also discloses that "[a]pplication 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 76***." *Id*. 15:25-29 (emphasis added). A POSITA, based on Quy, would understand that the data recorded, transmitted, and stored in the server 22 of Quy could be processed and analyzed using various known artificial intelligence processing methods.

A POSITA, based on the teachings of Sun in view of Quy and Schmidt, would understand that the data recorded, transmitted, and stored in a remote server, as suggested by Sun and Quy, could be assessed using known artificial intelligence processing methods. Thus, Sun in view of Schmidt and Quy teaches or suggests the feature of "PAP therapy efficacy data … adapted to be analyzed to recognize patterns" (as recited in Claim 28), "train a neural network" (as recited in Claim 29), "correlate more robust data from multiple subjects to teach or train sensors…" (as recited in Claim 30), and "analyzed with a relationship algorithm" (as recited in Claim 31).

11. Titration Treatment is Obvious in view of Sun, Quy and Schmidt as recited in Claim 32

As discussed above, *supra* §XI.B.1, Sun discloses "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." Sun, ¶ [0058]. Thus, Sun in view of Schmidt and Quy teaches or suggests the feature of "PAP therapy efficacy data … adapted with a treatment interface device processor for conducting a titration of a treatment," as recited in Claim 32 of the '680 Patent.

D. SNQP 4: Claims 10, 15 and 20 are unpatentable over Sun in view of Quy, Schmidt and Lisy under 35 U.S.C. §103(a)

Similar to SNQP 3, Sun in view of Schmidt discloses all of the claimed elements for Claim 1 of the '680 Patent, the discussion of which is hereby incorporated by reference in its entirety. A claim chart attached as an exhibit and identified as CHART-2 provides citations to the prior art as applied against the limitations for each claim addressed in this SNQP, with more particularized detail below explaining the prior art disclosures against certain features.

Sun in view of Quy and Schmidt discloses the use of sensors to collect data relating to a patient's usage of a CPAP device and data related to the severity of the patient's disorder. Schmidt describes a wireless data acquisition system, for example, sensor data, and describes processing a sensor signal via an analog-to-digital converter 24 which "conditions it." *Id.*, 6:47-49. Schmidt also describes a controllable A/D converter to provide a specific sampling rate, filtering and gain. *Id.*, 6:56-59. Schmidt suggests use of a filter to "reject offset voltages in an AC-coupled application, or to reject extremely high frequencies which fall well beyond the frequency band of interest, or a combination of the two." *Id.*, 9:67-10:4. AC coupling filter 225 is

also suggested (*id.*, 10:32-52), as is an antialias filter 226 for lowpass filtering "to guard against false signals caused by aliasing between external input 12 content and sampling rate of downstream sampling functions such as multiplexing and analog-to-digital conversion." *Id.*, 10:53-57.

While Schmidt discloses various signal processing techniques, a POSITA would understand that other techniques may be employed to adapt the sensor data of Sun and Schmidt, including those techniques addressed in Lisy. For example, Lisy discloses "various embodiments of … signal-processing techniques that are utilized to predict the onset of flow separation. These are: (i) ***the standard deviation technique, (ii) a recursively fit ARMAX system identification model, (iii) the Short-Time Fourier Transform (SFFT) technique, and (iv) time-frequency signal analysis with a variety of different kernels***." EX. E (Lisy), ¶ 40 (emphasis added). Lisy further states that "[t]he 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. *Id.* (emphasis added). Lisy discloses exemplary signal processing techniques as recited in claims 10, 15 and 20. As noted above, the '680 Patent includes verbatim disclosures from paragraphs 40-45 of Lisy. *See* EX. A ('680 Patent), 26:52-28:40.

A POSITA understood that there are different methods to process signals for a sensor, and it was known to adapt a processor receiving data from an airflow sensor, such as that associated with Sun, in view of Schmidt, based on the processing techniques suggested by Lisy, including wavelet analysis to enhance measures sensor data. A POSITA would have therefore understood how to adapt, based on the Lisy data processing techniques, to the Sun PAP device whereby data is transmitted for further monitoring and analysis by a medical practitioner at a

remote location, as suggested by Sun. Thus, Sun in view of Schmidt and Lisy teaches or suggests the features recited in claims 10, 15 and 20 of the '680 Patent.

E. SNQP 5: Claims 1-9, 12-14, 17-19, and 23-32 are Unpatentable over Mumford in view of Quy under 35 U.S.C. §103(a)

For the reasons discussed below, it is respectfully submitted that claims 1-9, 12-14, 17-19, and 23-32 are obvious based on Mumford in view of Quy under 35 U.S.C. §103. A claim chart attached as an exhibit and identified as CHART-3 provides prior art disclosure against the limitations for each claim addressed in this SNQP, with more particularized detail below explaining the prior art disclosures against certain features.

Specifically, since Mumford (i.e., the primary reference) was not applied during any prior examination of the '410 Application/'680 Patent, its teachings, when combined with those of Quy, presents a substantial new question of patentability because the combined teachings of these references were not considered by the Examiner during prosecution of the claims of the '410 Application. Had the teachings of this prior art been considered, the Examiner would not have allowed the claims thereof that correspond to claims 1-9, 12-14, 17-19 and 23-32 of the '680 Patent.

1. Mumford Discloses The Claimed Remote Internet Server-Based Diagnostic Monitoring With One Or More Positive Airway Pressure (PAP) Device(s)

The independent claim, Claim 1 of the '680 Patent is directed to a system for remote internet server-based diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment. To facilitate consideration and discussion, relevant claim elements for the system from Claim 1 are reproduced below.

> Claim 1. A system for remote internet server-based diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder comprising:
>
> A. one or more PAP device(s);

B. . . . a cell phone of a subject(s) receiving treatment, the cell phone requiring:

1) at least one first radio frequency wireless transceiver,

***

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:

***

2) be used for remote monitoring of multiple subjects receiving PAP therapy;

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 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

a mask or a nasal cannula; and

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.

Mumford discloses all of these limitations. Mumford is titled, "Mask Assembly with Integrated Sensors," and 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." EX. I (Mumford), Abstract.

As background, Mumford states,

> Arousals due to upper airway resistance may be detected from a shift in frequency of the patient's EEG and/or EOG as well as a decrease in blood oxygen levels. The monitoring unit includes an algorithm that detects the arousals and sleep stages, and uses the physiological information to automatically adjust the delivered respiratory gas pressure to the CPAP device wearer based on the physiological information. The algorithm can also use the physiological information to determine the effectiveness of the treatment.

Id. 23-25.

To improve "effectiveness of the treatment," as performed in the context of telemedicine, Mumford describes a system including one or more network connected PAP devices. In an embodiment, Mumford discloses a plurality of PAP devices. Mumford discloses a cell phone having at least one first radio frequency wireless transceiver, 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. For example, Mumford discloses a remote processing unit as part of a CPAP system, *see Id.* 2:66 – 3:2. Mumford explains that the system can include a connection from the CPAP system 10 that can be connected to a phone. *Id.* 15:25-29. Moreover, Mumford discloses "the sleep profile information may be transmitted to a caregiver through a wire connection to a computer. Wireless transmission may also be used." *Id.* 14:26-29. For example, Mumford discloses the processing

unit 414 can include for "longer-range communication, the wireless communication unit 516 may employ another communications protocol such as CDMA." *Id.* 14:38-40. The remote processing unit 414 determines the sleep profile information for the user. *Id.* 14:19-31. The sleep profile includes the quality of the patient's sleep, the efficacy of the CPAP device 14, and compliance data. *Id.* 7:34-46. Thus, the sleep profile information includes the efficacy of the subject using a PAP device, data of severity of sleep disorder symptoms of the subject, e.g., the quality of the patient's sleep, and data of usage of the PAP device by the subject, e.g. the compliance data, where the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject are both calculated by the PAP device. Moreover, the system of Mumford discloses transmitting the aforementioned data from the PAP devices to a phone or external data point. Therefore, Mumford discloses a:

> cell phone requiring: . . . [a] 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]
>
> one or more PAP device(s) . . . 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. . .

Further, Mumford discloses a remote internet site, the remote internet site adapted "be used for remote monitoring of multiple subjects receiving PAP therapy." As explained above, Mumford discloses transmitting the sleep profile information to a caregiver, which is a remote site and the aforementioned data can be sent wirelessly via BLUETOOTH or CDMA cellphone signals.

Mumford discloses a "remote processing unit 414 may also perform the sleep efficacy algorithm 36 which can be stored on the memory unit 432. 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. In addition, the sleep profile information may be transmitted to a caregiver through a wire connection to a computer." *Id*. 14:19-28. Mumford explains that while a remote processing unit 414 is described, a remote processing unit 414 can replace the monitoring unit 16 within the CPAP unit 14.

Thus, Mumford discloses that telemedicine connected CPAP devices, e.g., CPAP devices, are well known in the art, for example "[w]hen an individual is diagnosed with OSA [obstructive sleep apnea], the individual may be prescribed a therapeutic regime involving the use of a Continuous Positive Airway Pressure (CPAP) device." Mumford (EX. I), 1:47-55.

Mumford's PAP device is a CPAP system 10 which is disclosed to include an enclosure, as shown in FIG. 1, below. The CPAP system 10 of Mumford additionally includes a blower having an air output, e.g., the connector 40. For example, Mumford discloses "mask assembly 12 also includes a gas inlet 28 for receiving air, or another Suitable gas such as pure oxygen, from the CPAP device 14 via a hose 30. *Id.*, 7:4-7.

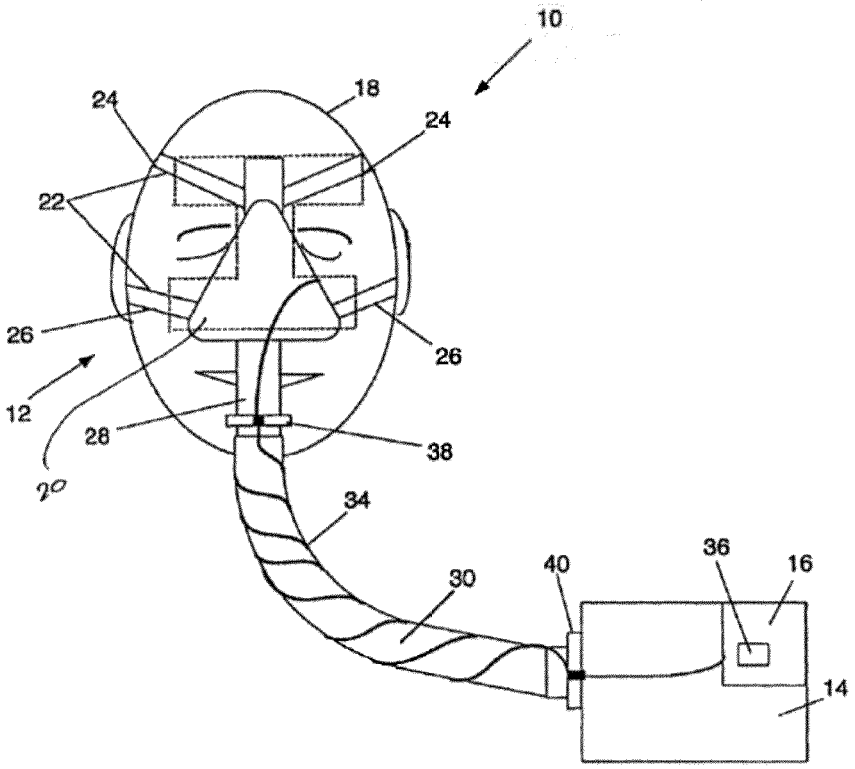


Figure 1

Mumford discloses that the CPAP system 10 includes an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data. Of note, in the currently pending IPR2023-00565 involving the related '269 Patent, the Patent Owner states, "CleveMed agrees with Petitioner that an airflow sensor located at the patient's mask is external to the CPAP machine because that is the only conclusion that is consistent with the plain meaning of the claim language and the intrinsic record." *See* IPR2023-00565, Patent Owner's Response p. 14. Here, independent claim 1 of the '680 Patent recites that the PAP device includes "a mask or nasal cannula." Mumford teaches or suggests the feature of a "PAP device(s) that is . . . used for treating the sleeping disorder of the subject(s) or their symptoms, and further comprises . . . a sensor for providing 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. . . [and] a mask or nasal canula," as recited in independent claim 1. Moreover, it is well within the ordinary skill in the art to place an airflow sensor anywhere within the flow path of the fluid for measurement, here air, as a matter of simple rearrangement of parts. *See e.g.,* Truitt discussed *supra*. For example, '737 Farrell teaches "Optionally, a flow sensor 4 f and/or pressure sensor 4 p may also be utilized in which case mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal F(t)." '737 Farrell, 5:2-19. As shown in FIG. 1 of '737 Farrell, the flow sensor 4f is disposed within an enclosure of the blower 2. A POSITA would have understood that placing the flow sensor 4f within the enclosure is a matter of simple rearrangement of parts and can allow for the sensor to be fixed with respect to the blower itself.

For example, Mumford discloses a pressure transducer, e.g. 316, which "is used to detect the pressure within the cavity of the nasal mask 20 from which the breathing rate of the wearer 18 can be derived." EX. I (Mumford), 12: 42-47 and 13:7-11. The pressure transducer 316 is in electrical connection with the processing unit 414. *Id.* 13:12-22. Mumford's remote processing unit 414 determines the sleep profile information for the user based, in part, on data received from the pressure transducer. *Id.* 14:19-31. Mumford's sleep profile teaches or suggests "the sleep profile information may include data, Such as a test score, related to efficacy and compliance)." *Id.* 7:34-46. All of this serves the goal of addressing sleep disorders using known telemedicine techniques.

In addition, Mumford discloses a 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." To improve "effectiveness of the treatment," Mumford describes the CPAP system as including a "remote processing unit 414 may also perform the sleep efficacy algorithm 36 which can be stored on the

memory unit 432. 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. In addition, the sleep profile information may be transmitted to a caregiver through a wire connection to a computer." *Id.* 14:19-28. Mumford explains that while the remote processing unit 414 is discussed, the remote processing unit 414 can replace the monitoring unit 16 within the CPAP unit 14. Further, Mumford discloses "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." *Id.*, 13:25-28.

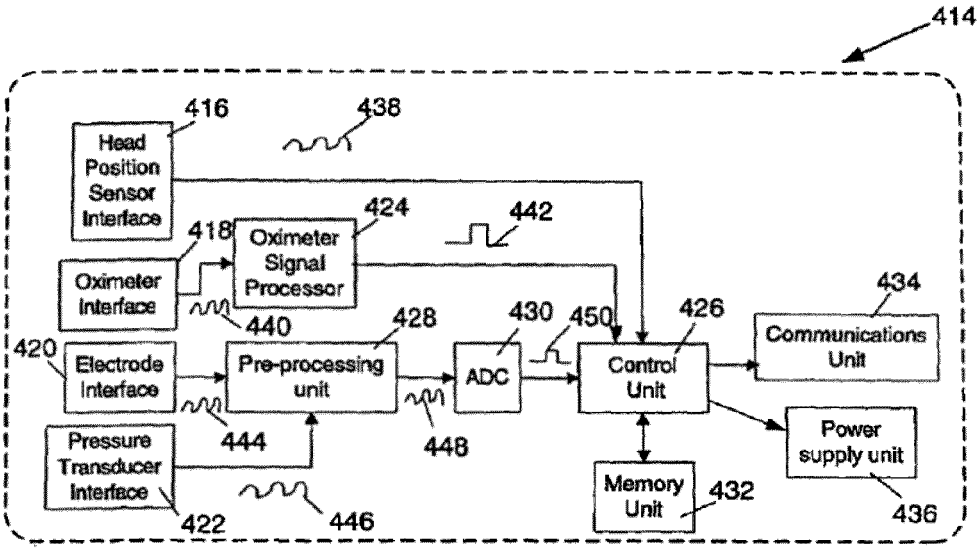


Figure 5b

EX. I (Mumford), Fig. 5b.

The CPAP system 10 of Mumford includes a mask or nasal canula, for example the mask assembly 12 illustrated in FIG. 1, above. The mask in combination with the blower are adapted for physically treating a subject's sleeping disorder symptoms.

Mumford discloses sending data from the CPAP system 10 to a network accessible by a physician, but is silent with respect to a software stored on a non-transitory computer readable

medium and executable by a cell phone having a processor, the software adapted to be used with and to display the data related to the subject's treatment and the treatment's efficacy to the subject or a care provider.

2. Mumford in view of Quy renders obvious a telehealth network including a PAP device, a cellphone, and a server, having software to use and display data from the PAP device

Quy is an International Publication of PCT Application No. PCT/US00/34159 having an earliest effective filing date of December 17, 1999. Quy is generally directed to methods and systems including "a wireless health monitoring system for interactively monitoring a disease or health condition of a patient (38) by connecting an internet-enabled wireless web device ("WWD") (12) to a health monitoring device (11) which may be a medical device." EX. H (Quy), Abstract. Quy explains that the system provides, "a full-feature health-monitoring system that may wirelessly connect to a back-end server application via the internet. The invention allows wireless access to and from a wide variety of present medical or health-related instruments and devices, while maintaining the capability of connecting to future such devices." *Id.* 4:15-22. To facilitate consideration and discussion, relevant claim elements for the system from Claim 1 are reproduced below.

Claim 1. A system for remote internet server-based diagnostic monitoring . . .

* * *

> B. a first non-transitory computer readable medium comprising a first software stored on the first 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,

> 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;

* * *

Quy's system includes a network of internet connected medical devices, monitoring cellphones, and a remote internet site including a server. As a first node, Quy teaches that a cell phone, or "the WWD may be a hybrid device that combines the functions of a computer, PDA and telephone." *Id.* 6:27-29. Quy explains that the WWD can include a number of different wireless technologies including "infrared (IR), microwaves, radio frequency (RF), e.g., Bluetooth® or 802.11 protocols, optical techniques including lasers, and other such techniques may be used." *Id.* 7:10-16. Therefore, Quy discloses "a first non-transitory computer readable medium comprising a first software stored on the first 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," as recited in claim 1 of the '680 Patent.

Quy additionally teaches that the WWD ("cell phone") downloads software, either locally or remotely stored, e.g., "the patient connects to a specific Internet 10 site and a software program,

resident on a remote server located on the Internet, downloads 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." *Id.* 8:8-15. Quy explains that this software can be used to display and monitor the connected health devices.

Another aspect to Quy's system includes a server node 18 in the network that functions to collate data from a number of discrete medical devices and WWD. Quy states, "Referring to FIG. 3, WHMA 10 is shown communicating wirelessly with the Internet. In doing so, WHMA 10 generally sends a wireless signal to a base station 14 (in known fashion) that is connected to a server 18 that is in signal communication (in known fashion) with the internet. Server 18 communicates via a protocol (in known fashion) to Internet 20, which also communicates via a protocol (in known fashion) to a server 22 running 30 an application 62. Server 22 may be accessed (in known fashion) by a client computer 44 through a connection 64." *Id.* 14:22-31.

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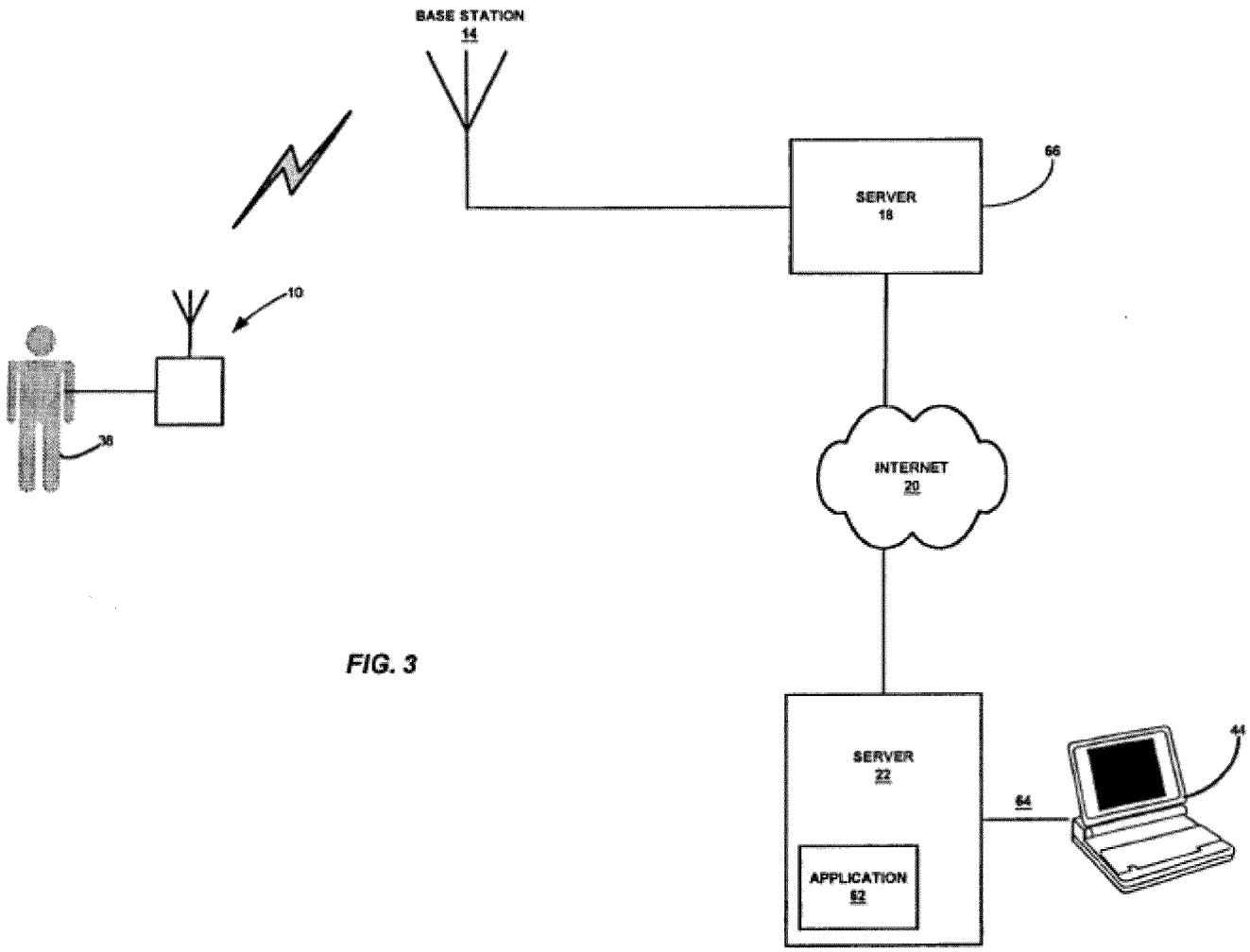


FIG. 3

As such, Quy both teaches and suggests a method and system for network connected patient monitoring including a first software downloaded on a cell phone and a second non-transitory computer readable medium for a remote internet site and date base. Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of invention, to include the cell phone and server of Quy in the system of Mumford as this combination would achieve the underlying desire of the industry at the time of invention to create adaptable telehealth medicine networks to ensure increased compliance of treatment by the patients, improve the effectiveness of a given treatment, and easily transfer data between the patient's home and the medical facilities. Moreover,

a POSITA would be motivated to combine the references as outlined above for the following reasons:

1) Mumford discloses that it is beneficial to transmit sleep profile information to caregivers, physicians, or industry members.

2) Quy teaches that distribution of "health related data," Quy, Abstract, to remote medical providers "allows wireless access to and from a wide variety of present medical or health-related instruments and devices, while maintaining the capability of connecting to future such devices." Quy, 4:19-22.

3) In an article entitled Wireless CPAP Patient Monitoring: Accuracy Study by Dr. Lankford ("Lankford"), Lankford discusses a study in which the accuracy and reproducibility of subject CPAP data was wirelessly transmitted to a remote site. Lankford, 163. Lankford explains that "Potential benefits of this technology include advanced compliance and efficacy along with a potential reduction in health-care costs." *Id.*, Abstract.

Thus a POSITA would have been motivated to combine Mumford with Quy to enable ease of transmission of medical data between nodes in a distributed network of patients and medical providers, e.g., to and from a smart phone, which were increasingly being used in the medical industry to advance patient compliance and efficacy, in addition to reducing health-care costs.

3. Claims 2-9, 12-14, 17-19, and 23-32 are obvious over Mumford in view of Quy under 35 U.S.C. § 103(a)

Mumford teaches or suggests the system, as explained above, including that the PAP therapy efficacy measure(s) includes an index. Of note, the '680 Patent explains "that an observed data set acquired in real-time from a subject. This data set is further compared, in real time, with one or more reference data sets which characterize distinct physiological states. The comparison yields an index . . ." '680 Patent 59:51-55. Mumford explains that 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. 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." Mumford (EX. I), 7:51-57. Therefore, Mumford discloses the PAP therapy efficacy measure(s) includes an index.

The combination of Mumford and Quy disclose a CPAP system including an electronic component utilizing a cellular network to allow the PAP device to be adjusted remotely by the remote internet site. Mumford explains that using the collected and analyzed data can result in a PAP device that can generate a control signal. For example, Mumford discloses the processing unit 414 can include "the BLUETOOTH™ protocol which is suitable for short-range communication longer-range communication, the wireless communication unit 516 may employ another communications protocol such as CDMA." *Id.*, 14:35-40. Mumford additionally discloses that the PAP device "allow[s] the one or more PAP device to be adjusted remotely based on the PAP therapy efficacy data", as recited in at least dependent claim 2. For example, Mumford explains, "[i]n an alternative, the remote processing unit 414 may also perform the sleep efficacy algorithm 36 which can be stored on the memory unit 432." *Id.*, 14:19-21. Mumford further discloses "[t]he sleep efficacy algorithm 36 may also use the sleep profile information to vary the CPAP titration pressure depending on the sleep stage." *Id.*, 16:4-13. Similarly, Quy discloses a "physician, accessing server application 62, may in turn send detailed care plans to a caregiver via connection 72. The received data may be analyzed using algorithm 63, external data source 74, and AI system 76." Quy (EX. H) 17:10-15. 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." *Id.* 14:19-26.

In addition, Mumford discloses a CPAP unit including a "remote processing unit 414 may also perform the sleep efficacy algorithm 36 which can be stored on the memory unit 432. 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." Mumford, 14:19-28. Mumford explains that "[t]he sleep efficacy algorithm 36 may also use the sleep profile information to vary the CPAP titration pressure depending on the sleep stage. . . When combined with an automated sleep efficacy algorithm that performs sleep staging and pressure control, the mask assembly of the invention provides a quick, convenient means for monitoring and improving the sleep profile of the wearer 18. The sleep profile information can be used by physicians to improve the quality of care and allow them to objectively assess the efficacy of treatment and monitor changes to therapy." *Id.*, 16:8-21. Thus, the combination of Mumford and Quy disclose 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.

The combination of Mumford and Quy teaches or suggests 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. Mumford discloses transmitting the sleep profile information to physicians to allow them to objectively assess the efficacy of treatment and monitor changes to the CPAP therapy. Mumford (EX. I) 16:18-21. Quy discloses sending of sensor-based

medical data to a cell phone, then to a server, including various combinations of wireless transmission of data using cellular and BLUETOOTH protocols. *See* Quy (EX. H) 13:32 – 14:11.

The combination of Mumford and Quy additionally discloses the first software adapted for use with the cell phone is further adapted to be reprogrammed or modified remotely. For example, Quy teaches "To initialize the system, the program starts and a wireless application is loaded into the WWD." *Id.* 17:22-23. Thus, the combination results in a first software that can be modified remotely due to the wireless downloading of the new programing.

In addition, the combination of Mumford and Quy teaches or suggests the first data of the PAP therapy efficacy data includes specific symptom data related to both obstructive and central apneas, including Mumford disclosing measuring the breathing rates of the patient. *See* Mumford (EX. I), 12:42-47.

Moreover, the combination of Mumford and Quy disclose data, stored on a server as discussed above, that is adapted to be a) analyzed to recognize patterns of sleep disorders, b) analyzed to train a neural network, c) analyzed to correlate more robust data from multiple subjects to teach or train the sensor on the one or more PAP devices, d) analyze with a relationship algorithm, and e) used with a treatment interface device processor for conducting a titration of a treatment. For example, Quy discloses "a method according to an embodiment of the invention, the patient connects to a specific Internet 10 site and a software program, resident on a remote server located on the Internet, . . . software, as well as inputs from the patient or other inputs, can control the manner, content, and display of information presented to the patient, and measured or input data can be stored for review by a health care provider or by a software algorithm or application. The algorithm may be of varying complexity, from a simple program that merely acknowledges receipt of information to ***an artificial intelligence algorithm, such as an expert system, collaborative filtering system, rules based system, case-based reasoning system, or other***

such artificial intelligence application." Quy (EX. H), 8:8-31 (emphasis added). Quy additionally teaches, "[a]pplication 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 76***." *Id.* 15:25-29 (emphasis added). A POSITA looking to the teachings of Quy would understand that the data recorded, transmitted, and stored in the server 22 of Quy could thus be analyzed using any known artificial intelligence processing methods.

Thus, claims 2-9, 12-14, 17-19, and 23-32 are additionally rendered obvious over the combination of Mumford and Quy.

Claims 1-9, 12-14, 17-19, and 23-32 of the '680 Patent are therefore rendered obvious by the combination of Mumford in view of Quy with exemplary disclosures shown in the Claim Charts, attached.

F. SNQP 6: Claims 10, 15, and 20 are Unpatentable Over the Combination of Mumford and Quy in View of Kisner

A claim chart attached as an exhibit and identified as CHART-3 provides prior art disclosure against the limitations for each claim addressed in this SNQP, with more particularized detail below explaining the prior art disclosures against certain features.

The combination of Mumford and Quy generally disclose pre-processing data received from sensors. For example, Mumford explains "The remote processing unit 414 further includes a preprocessing unit 428 that is connected to the electrode interface 420 and an analog-to-digital converter (ADC) 430 that is connected between the pre-processing unit 428 and the control unit 426." Mumford at 13:33-36. However, Mumford is silent with respect to the specific function used by the preprocessing unit 428. Kisner, however, teaches and suggests known signal processing of breathing parameters including wavelet analysis, "Breathing parameters are extracted from true

component signals 108 using wavelet analysis or similar means at 112 to generate signal 116." EX. J (Kisner), 13:36-53.

It would have been obvious to modify Mumford with the specific wavelet analysis of Kisner in order to generate usable data for analysis by a medical practitioner, or other such professional, and as Kisner teaches, wavelet analysis of the sensor data can be used "to determine if an alarm or other desired output condition exists which is expressed and communicated by signal 122." Id. 13:51-53.

Therefore, the combination of Mumford, Quy, and Kisner renders dependent claim 10, as well as dependent claims 15 and 20, obvious and unpatentable.

G. SNQP 7: Claims 1-32 are Unpatentable Over a Combination of Toge and Various Cited Art

A Claim Chart attached as an exhibit and identified as CHART-4 provides prior art disclosure against the limitations for each claim addressed in this SNQP, with particularized detail explaining the prior art disclosures against certain features.

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.

Thus, Requestor submits that as Toge generally discloses a PAP device as recited in at least the independent claims, as explained in detail in CHART-4, Toge, and the associated secondary references, render each and every limitation of claims 1-32 obvious and are therefore unpatentable.

XII. CONCLUSION

For the reasons discussed hereinabove, a substantial new question as to the patentability of at least one claim (e.g., claims 1-32) of the '680 patent has been established which was not raised

in any previous examination. Accordingly, it is respectfully requested that an order for reexamination of all of the claims of the '680 Patent be issued.

The enclosed Request for Ex Parte Reexamination Request Transmittal Form authorizes the Commissioner to charge the fee as set forth in 37 C.F.R. §1.20(c)(2) to Deposit Account No. 502678. If any additional fees are due in connection with the submission of this Request, the Commissioner is hereby authorized to charge them to Deposit Account No. 502678.

Respectfully submitted,

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