

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<i>In re</i> patent of Hani Kayyali <i>et al.</i>	§	Attorney Docket: 227745.010200-R921
U.S. Patent No. 11,375,921	§	Customer No.: 35893
Issue Date: July 5, 2022	§	
Filing Date: August 8, 2018	§	
For: DEVICES AND METHODS	§	
FOR SLEEP DISORDER	§	
DIAGNOSIS AND		
TREATMENT		

**REQUEST FOR *EX PARTE* REEXAMINATION OF
U.S. PATENT 11,375,921**

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. 11,375,921 B1 (EX. A, “the ‘921 Patent”),¹ which issued on July 5, 2022, to Hani Kayyali et al. from an application filed on August 8, 2018. The ‘921 Patent has not yet expired and is therefore still in force.

As set forth in detail below, ResMed submits that each of the prior art references discussed below is analogous art to the ‘921 Patent, and 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, and facilitating communication with healthcare providers to improve

¹ The prosecution history for the ‘921 Patent is included herein as Exhibit B.

overall treatment. These solutions described in these prior art references were known to one skilled in the art well before they were identified as alleged inventions of the '921 Patent.

For the reasons below, the identified prior art references raise substantial new questions of patentability for the claims of the '921 Patent and granting of the request for reexamination is hereby requested.

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 1-16 of the '921 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 '921 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. Patent No. 6,644,311 to Patrick W. Truitt et al.	Truitt EX. C	November 11, 2003	No	No
U.S. Patent No. 8,187,209 to Joseph Giuffrida	Giuffrida EX. D	May 29, 2012	No	No
U.S. Publication No. 2004/0129838 to Lisy et al.	Lisy EX. E	July 8, 2004	No	No
U.S. Patent No. 6,167,258 to Robert N. Schmidt et al.	Schmidt EX. F	December 26, 2000	No	No
U.S. Patent No. 7,575,005 to John Robert Mumford et al.	Mumford EX. G	August 18, 2009	Yes	No
W.O. 02/078775A2 of Genger et al. (Certified Translation)	Genger EX. H	October 10, 2002	No	No
U.S. Patent No. 5,309,921 to Roger A. Kisner, et al.	Kisner EX. I	May 10, 1994	No	No
JP Patent No. 2002291889 to Toge	Toge EX. J	October 8, 2002	No	No

Reference	Abbreviation and Exhibit Number	Publication/Issue Date	Previously Cited	Previously Applied in a Rejection
W.O. 04/032719A2 to David Burton et al.	Burton EX. K	April 22, 2004	Yes ²	No

With respect SNQP 9, the following listing is provided:

SNQP 9 References	Abbreviation and Exhibit Number	Publication/Issue Date/Filing Date
JP Patent No. 2002291889 to Toge	Toge EX. J	2002
Lankford, D. A., Ph.D., <i>Wireless CPAP Patient Monitoring: Accuracy Study</i> , Telemedicine Jr. v. 10, no. 2 (2004).	Lankford EX. OTH-1	2003
WO 2005/096737A2 (Farrell et al.)	'737 Farrell EX. OTH-6	2005
U.S. Publication No. 2007/0161913 (Farrell et al.)	'913 Farrell EX. L	2007
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 No. 5,704,345 (Berthon-Jones et al.)	'345 Berthon-Jones EX. OTH-18	1998

² Cited in the '921 Patent as US8,069,852.

SNQP 9 References	Abbreviation and Exhibit Number	Publication/ Issue Date/Filing Date
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

Pursuant to 37 C.F.R. § 1.510(b)(3) and (4), Requester includes copies of the '921 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 '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
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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 ‘921 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 decision in the 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 1-16). Requester reserves all rights and defenses available including, without limitation, defenses as to invalidity, unenforceability, and non-infringement regarding the ‘921 Patent. Further, for the purposes of this Request, the Office should construe the claims of the ‘921 Patent by applying the “broadest reasonable interpretation consistent with the specification” 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 including 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. 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 '921 Patent under 35 U.S.C. §102(b). Truitt was not cited as a reference in the prosecution of the '921 Patent. A copy of Truitt is attached as EX. C.
2. U.S. Patent No. 8,187,209 to Joseph Giuffrida ("Giuffrida"). The application for Giuffrida was filed on March 17, 2005, and the patent issued on March 29, 2012, making it prior art to the '921 Patent under 35 U.S.C. §102(e). Giuffrida was not cited as a reference in the prosecution of the '921 Patent. A copy of Giuffrida 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 '921 Patent under 35 U.S.C. §102(b). Lisy was not cited as a reference in the prosecution of the '921 Patent. A copy of Lisy is attached as EX. E.
4. 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 '921 Patent under 35 U.S.C. §102(b). Schmidt was not cited as a reference in the prosecution of the '921 Patent. A copy of Schmidt is attached as EX. F.

5. 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 '921 Patent under 35 U.S.C. §102(e). While Mumford was cited as a reference in the prosecution of the '921 Patent, it was not relied upon in any of the rejections. A copy of Mumford is attached as EX. G.

6. W.O. 02/078775A2 of Genger et al. (Certified Translation) ("Genger"). The application for Genger was filed on April 2, 2002, and the application published on October 10, 2002, making it prior art to the '921 Patent under 35 U.S.C. §102(b). Genger was not cited as a reference in the prosecution of the '921 Patent. A copy of Genger is attached as EX. H.

7. 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 '921 Patent under 35 U.S.C. §102(b). Kisner was not cited as a reference in the prosecution of the '921 Patent. A copy of Kisner is attached as EX. I.

8. 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 '921 Patent under 35 U.S.C. §102(b). Toge was not cited as a reference in the prosecution of the '921 Patent. A copy of Toge is attached as EX. J.

9. W.O. 04/032719A2 to David Burton et al. ("Burton"). The application for Burton was filed on October 9, 2003, and published on April 22, 2004, making it prior art to the '921 Patent under 35 U.S.C. §102(b). Burton was cited as U.S. 8,069,852 in the prosecution of the

'921 Patent, but importantly was not relied upon in any rejection. A copy of Burton is attached as EX. K.

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., <i>Wireless CPAP Patient Monitoring: Accuracy Study</i> , 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
Guilleminault, et al., <i>Clinical Overview of the Sleep Apnea Syndromes</i> , <i>Sleep Apnea Syndromes</i> (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," <i>SLEEP</i> 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	

Other (OTH) References	Abbreviation and Exhibit Number	Publication/ Issue Date/Filing Date
Guilleminault, et al., <i>Obstructive sleep apnea syndromes</i> , 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	2005
Paradiso, et al., <i>Wearable Health Care System for Vital Signs Monitoring</i> , 4 th 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	1998

Other (OTH) References	Abbreviation and Exhibit Number	Publication/ Issue Date/Filing Date
	EX. OTH-18	
WO 0145014 A1 (Quy)	Quy EX. OTH-19	2001

VI. RELATED COURT AND ADMINISTRATIVE PROCEEDINGS

A. Related District Court Proceedings

To expedite processing of this Request, the Requester notes that the '921 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 the Claims 1-16 of the '921 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 the ‘269 patent IPR on the grounds that claims 1-20 (“the challenged claims of the ‘269 patent IPR”) were obvious and unpatentable. In particular, the PTAB Institution Decision determined that claims of the ‘269 patent were 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. OTH-6) , 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, is reproduced below for illustration purposes, recites various, similar features.

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.

During prosecution of claim 1 of the '921 patent, Patent Owner explained that the above claim 15 of the '269 patent was very similar to then pending claim 1 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.

In light of the above, Requestor submits that 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 presents a substantial new question of patentability with regard to at least claim 1 of the '921 patent and its dependents.

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

The '921 Patent ultimately alleges priority to November 4, 2005 (before March 16, 2013), so pre-AIA 35 U.S.C. §§102, 103 may apply.

An object of the invention of the '921 Patent is said to be to provide a system and method of treatment which analyzes a subject's sleeping disorder or symptoms and adjusts a treatment device based, in part, on this analysis. ('921 Patent, column 2, lines 33-37). Generally, the claims of the '921 Patent are directed to a sleeping disorder treatment system for a subject, the system comprising a positive airway pressure ('PAP') device, a mask or cannula, a sensor, a processor and a remote internet site.

The '921 Patent ultimately alleges priority to November 4, 2005 ('Alleged Priority Date'). Since the Alleged Priority Date may be before March 16, 2013, pre-AIA 35 U.S.C. §§102, 103 may apply.

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 ('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. AHI, as argued by Patent Owner, reflects “an indicator of the level of severity of a patient’s sleep disordered breathing....” U.S. Patent No. 10,076,269 Prosecution History, EX. OTH-7. 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. ‘921 Patent, 1:35-46. The ‘921 Patent acknowledges that sleep disorders had been diagnosed using objective physiological evaluations such as “polysomnography to evaluate the patient[’]s sleep architecture (e.g., obtaining respiratory disturbance index to diagnose sleep apnea) followed by an all day test such as the Multiple Sleep Latency Test (MSLT) or its modified version, Maintenance of Wakefulness Test (MWT).” *Id.*, 1:40-56.

Polysomnography was known to involve connecting sensors to the patient, the sensors including nasal cannula to measure airflow, pulse photoplethysmography to measure oxygen saturation, and sensors to measure eye movement (“EOG”), brain function (“EEG”) and heart function (“ECG”). EX. OTH-3 Westbrook (U.S. Patent Publication No. 2002/0165462) 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 H₂O above atmospheric pressure. EX. OTH-16 (‘310 Sullivan) (1990) 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), 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 (U.S. Patent No. 5,245,995) (‘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. (Berthon-Jones, column 8). Furthermore, it was known for moving averages to be calculated, for example a moving average variance of an air flow signal (Berthon-Jones, columns 9-10). Furthermore, it was known to calculate an index value from a root mean square (RMS) deviation. (Berthon-Jones, columns 3).

Furthermore, the '921 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, 2:12-22.

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. OTH-19, 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. OTH-19, 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. OTH-19, 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).

In the telemedicine context, a patient-local device (WWD), interacting with a patient-treatment device, was understood to connect to a remote server that provided a convenient way to promote interactions between the patient-local device and a remote health care provider to transfer data about a patient's monitored condition via 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. OTH-19, 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 has allowed for remote monitoring of physiological

conditions and providing for the sharing of patient and therapy data with healthcare providers. EX. OTH-19, 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. OTH-19, 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. OTH-19, 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-14, (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-14 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. K at 8:28-9:1, 19:24-28 (Burton).

With the understanding that a telemedicine system was understood to be adaptable and applied to treatment devices, it was also known to provide devices directed to types of 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

Sensors were generally understood by a POSITA to be useful for measuring conditions of a patient, and the Challenged Patent explains that “[s]ensors which can be used are known to those skilled in the art.” EX. A (’921 Patent), 6:10-11. For example, “[t]he diagnostic part of the system or 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.*, 3:8-15. “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.” *Id.*, 3:25-28; *see also* 7:40-43.

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. (*id.*, 5:32-38; Fig. 1), *compare with* ’921 Patent (9:26-32).

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 (’921 Patent), 18:36-50. 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.^{3 4} In comparison to Schmidt, the ’921 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

³ Schmidt was not disclosed to the examiner during prosecution. It shares an inventor (Robert Schmidt) with the ’921 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 ’921, along with a significant portion of the description, were copied from Schmidt.

⁴ Figure 7 of the ’921 Patent depicts as described, a “conventional pressure support system” (22:47-48), whereby only Figure 8, at best, could be purportedly illustrating new subject matter. Truitt was not identified by Patent Owner during the prosecution of the ’921 Patent.

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 ('921 Patent), 3:48-53; *see also* 4:1-3 ("a continuous positive airway pressure (CPAP) device [is] for treating the subject's sleep apnea"); 2:18-19 (aka "continuous positive gas pressure" devices). A "conventional" CPAP device 310 (Figure 7) is acknowledged as including "a pressure generator 312, a blower, a piston or bellows, that receives a supply of gas from a gas source, such as ambient atmosphere ... or pressurized gas tanks ... [and] a flexible conduit [that] delivers the elevated pressure breathing gas to the airway of the subject." *Id.*, 22:47-56.

And the '921 Patent further acknowledges that "[p]hysical and chemical methods to treat sleeping disorders are *known to those skilled in the art*. ... Physical methods to therapeutically treat sleeping disorders and symptoms of these disorders include [CPAP], electrical stimulation of the muscles and nerves, and the like. Chemical methods to therapeutically treat sleeping disorders and symptoms while less common include various pharmaceutical agents with various delivery techniques including oral delivery, injection, transdermal delivery, injection with a controlled pump, inhalation therapy and the like." *Id.*, 22:13-28 (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 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).

Efficacy in the context of sleep disordered breathing treatments was also known in the art. For 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 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 ’921 PATENT

A. Brief Description of the ’921 Patent

The ’921 Patent is directed to a system for “Sleep Disorder Diagnosis and Treatment.” *See* ’921 Patent, Title. The ’921 Patent claims, among other things, a positive airway pressure (PAP) sleep disorder treatment system directed to the patient’s treatment and the treatment’s efficacy based on the “severity” of a patient’s sleep disorder and transmitting data among: 1) the PAP device; 2) a base station, cell phone or PDA; and 3) a remote internet site. While the title of the ’921 Patent includes both diagnosis and treatment, the claims recite nothing of diagnosis.

Despite acknowledging that prior art CPAP devices already used feedback sensors to adjust operation, the ’921 Patent nonetheless purports to describe its alleged invention as adjusting a treatment device based on sensor feedback. EX. A, 2:34-37 (“... an object of the present invention to provide a system and method of treatment, which analyzes a subject’s sleeping disorder or symptoms and adjusts a treatment device based, in part, on this analysis...”) as compared with *Id.*, 2:16-20 (“devices have been developed that adjust this continuous positive gas pressure through sensors built into the device...”).

The ’921 Patent issued from the following chain of applications:

Appl. No.	Filing Date	Application Type	Issued as:
13/3440,116	April 5, 2012	CON	10,076,269
11/266,899	November 4, 2005	CON	8,172,766

The following chain of applications claim priority to the '921 Patent:

Appl. No.	Filing Date	Application Type	Issued as:
17/825,266	May 26, 2022	CON	11,602,284
18/195,277	February 3, 2023	CON	11,872,029

B. '921 Patent Specification

1. '921 Patent Copies Descriptions of Prior Art

a. '921 Patent Copies a "Prior Art" "Conventional" PAP System

It should be understood that Figure 7 of the '921 Patent and corresponding description (22:45-23:17) are copied from Figure 1 of Truitt (labeled "Prior Art") and its accompanying text in the "Background of the Invention" section at 1:45-2:10. EX. C (Truitt).⁵ Nonetheless, the '921 Patent refers to the PAP device in Figure 7 as an "embodiment," *see, e.g.*, Ex. A ('921 Patent), 22:41-45, and describes a flow sensor internal to the PAP device and using information from that flow sensor to control or monitor the usage of the PAP device—all of which were copied from

⁵ Figure 7 of the '921 Patent depicts a "conventional pressure support system" (22:53-62) leaving only Figure 8 to depict purportedly new subject matter.

Truitt.⁶ *Compare* EX. A ('921 Patent), 22:45-23:17 *with* EX. C (Truitt), 1:45-2:10. Truitt was not identified by Patent Owner during the prosecution of the '921 Patent.

b. Data Acquisition from Airflow Sensors

Further, approximately ten columns of text found in the '921 Patent—spanning 4:63 to 14:54—are a copy of the entire Detailed Description of Schmidt. EX. F (Schmidt).⁷ The '921 Patent further copies each of Schmidt's Figures 1-6. Schmidt discloses, as copied by the '921 Patent, an “air flow” sensor to supply data to signal processing module 16 for conditioning and processing. EX. F (Schmidt), 4:7-22; 14:40-54; EX. A ('921 Patent), 18:46-60. The Schmidt processing module 16 wirelessly transmits data to base station 40 via bidirectional transceivers (*id.*, 5:32-38; Fig. 1), as copied by the '921 Patent (9:26-32; Fig. 1). Schmidt was not disclosed to the examiner during prosecution.

Other prior art was also copied verbatim into the '921 patent, including for example Giuffrida, EX. D (*compare* EX. A, 19:12-45 *with* EX. D, 13:5-36) and Lisy, EX. E (*compare* EX. A, 20:11-21:67 *with* EX. E ¶¶40-45).

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

As above, the '921 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 3:56-61; 2:25-29.

⁶ The identification and discussion herein of disclosures of the prior art copied into the '921 patent in connection with the '921 patent claims should not be considered an admission that similar disclosures in the '921 patent provide written description support for the claims.

⁷ Schmidt shares an inventor (Robert Schmidt) with the '921 Patent, who is a Patent Practitioner identified in the PTO's Correspondence Address records for the '921 Patent and the Schmidt reference.

As above, the '921 Patent is not directed to a new type of sensor. "Sensors which can be used are known to those skilled in the art." EX. A, 6:21-22. "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.*, 3:17-23.

Further, the '921 Patent is not directed to any new data analysis or processing algorithm. Instead, it acknowledges that "[v]arious 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, 20:11-14. The '921 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.*, 20:36-41. The "signal-processing techniques" of independent claims 1, 7, and 12, disclosed at 20:21-22:8, are copied verbatim from paragraph 40 of Lisy, EX. E.

C. The '921 Patent Prosecution History

As noted above, the '921 Patent was filed as the '963 Application, as a continuation of the '116 Application, now U.S. 10,076,269, which is a continuation of the '899 Application, now U.S. 8,172,766.

During prosecution, the examiner issued the first office action on February 16, 2021, objecting and rejecting the pending claims as either anticipated or obvious under 35 U.S.C. §102 and 103, respectively. EX. B, 268-290. The Applicant responded with substantial amendments to the claims and arguments over the cited art and objections. EX. B, 254-267. The amendments to the claims failed to underline the added texts (e.g., "a PAP device") and strike through removed

texts (e.g., “of the level of”). Additionally, 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 Notice of Non-Compliant Amendment asserting that all of the then pending claims were restricted by original presentation, finding a substantial burden on the Examiner to search for a patentably distinct device. *Id.*, 244-248. The Examiner conducted an interview on August 19, 2021, and no agreement was reached. *Id.* 243. The Applicant followed with another response dated October 15, 2021, providing amendments to the originally filed claims and arguments traversing the restriction by original presentation and the rejections and objections of the first office action of February 16, 2021. *Id.* 223-238. Again, the amendments to the claims were not proper in form, e.g., failing to show deleted claim elements via strikethrough. Thus, the record appears unclear as to all the changes to the claims from filing through allowance of the Application.

The Examiner issued a final office action on January 21, 2022, rejecting the claims under 35 U.S.C. §§101, 112, 102, and 103, and indicating that then pending claims 18-20 would be allowable if rewritten to overcome the §§101 and 112 rejections. *Id.* 187-218. In an after final response, the Applicant incorporated the noted allowable subject matter of claims 18-20 (notably, without alerting the examiner to the existence of Lisy or that the “allowable” subject matter had been copied from the same) into each of the three then pending independent claims. *Id.* 173-184.

On May 23, 2022, the Examiner issued a notice of allowance and an examiner’s amendment. *Id.* 9-27. As noted in the interview summary, the examiner’s amendment was made to correct informalities and other grammatical errors in the claims. *Id.* 184. On May 26, 2022, the Applicant paid the issue fee and the ‘921 Patent issued on June 15, 2022.

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))

All the patents and publications identified in Section V "Citation of Prior Art" are prior art to the '921 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, is substantively advanced by the Examiner during prosecution of the '921 Patent. Each of the grounds included in this Request discloses 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, each of: 1) Truitt in combination with Giuffrida and Lisy; 2) Truitt in combination with Schmidt and Lisy; 3) Truitt in combination with Giuffrida, Lisy, and Burton; 4) Truitt in combination with Schmidt, Lisy, and Burton; 5) Mumford in combination with Genger and Kisner; 6) Mumford in combination with Toge and Kisner; 7) Mumford in combination with Genger, Kisner, and Burton; 8) Mumford in combination with Toge, Kisner, and Burton; and 9) Toge with various cited art present a substantial new question of patentability for claims 1-16 of the '921 Patent.

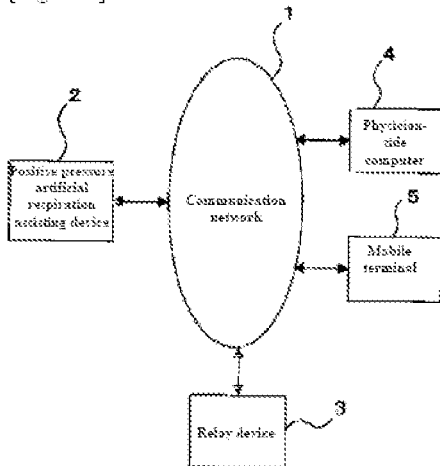
Below are the rejections proposed in support of the unpatentability of Claims 1-16 of the '921 Patent.

A. Obviousness Considerations for the Challenged Claims

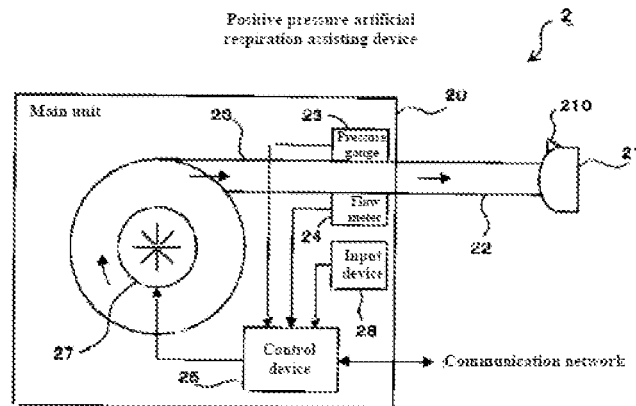
1. Overall Reasons to Combine

The '921 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. J), illustrates and explains that “[h]ome medical devices may be provided to patients receiving treatment or care at home.” Toge, ¶[0002]. Specifically, “Figure 1 is a block diagram illustrating the overall configuration of a remote medical (telemedicine) system according to the present invention.” Toge, ¶ [0008]. As illustrated below, Toge describes the main components of a telemedicine system utilizing a PAP device.

[Figure 1]



[Figure 2]



Toge, EX. J, Figs. 1 and 2

The '921 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 '921 Patent does not disclose a new sleep disorder treatment device. Instead, it concedes that Fig. 7 of its specification, a “device of the present invention,” is a “conventional”

CPAP device with “various sensors... for measuring the subject’s respirations or oxygen levels ... and ventilation.” ’921 Patent, 3:9-15. In addition to Truitt having already disclosed the identical figure and description, 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” Toge (EX. J) at ¶ [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 expand the diagnosis by sending the sensor data to a non-local clinician. 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. DETAILED EXPLANATION OF EACH PROPOSED REJECTION OF THE '921 PATENT (37 C.F.R. § 1.510(B)(2))

A. SNQP 1: Claims 1-4, 6-8, 10-13, 15 and 16 are unpatentable over Truitt in view of Giuffrida and Lisy under 35 U.S.C. §103(a)

For the reasons discussed below, it is respectfully submitted that Claims 1-4, 7-13 and 16 are obvious over Truitt in view of Giuffrida, and further in view of Lisy under 35 U.S.C. §103. 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, Truitt (i.e., the primary reference) was not applied during any prior examination of the '963 Application/'921 Patent, and its teachings, when combined with those of Giuffrida and Lisy, 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 '963 Application. Had the teachings of this prior art been considered, the Examiner would not have allowed the claims that correspond to Claims 1-4, 6-8, 10-13 and 16 of the '921 Patent.

1. Truitt discloses the claimed positive airway pressure system for sleep disorder treatment

The independent claims, Claims 1, 7 and 12, of the '921 Patent are all directed to a positive airway pressure (PAP) sleep disorder system with integrated airflow sensor and processor to monitor a patient's usage and adjust the airflow to provide treatment based on the condition of the patient. To facilitate consideration and discussion, relevant claim elements for the PAP device from Claim 1 of the '921 Patent are reproduced below, and the following discussion is also applicable to Claims 7 and 12.

Claim 1. A sleeping disorder treatment system comprising:

a PAP device configured to be a single enclosure, the PAP device comprising:

a blower having an air output;

an airflow sensor internal to the PAP device and adapted for measuring the respiratory airflow of a subject while using the PAP device;

a first processor adapted for generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping 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;

wherein the airflow sensor and the first processor are adapted for measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment and further providing for a data related the subject's treatment and the treatment's efficacy;

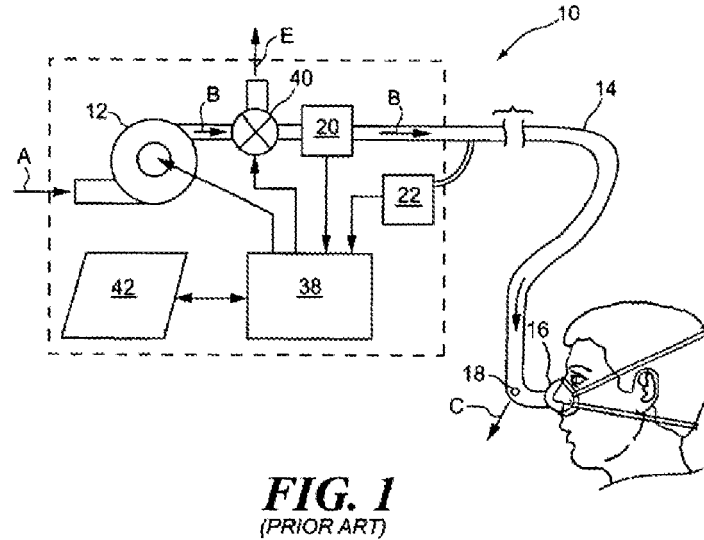
wherein the blower, and the mask or the nasal cannula are adapted for physically or chemically treating a subject's sleeping disorder symptoms,

wherein the first processor is configured to adjust or re-adjust the blower using, in part, the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment;

Truitt discloses each of these limitations.

Truitt discloses that PAP devices are well known "to treat obstructive sleep apnea (OSA) as well as other disorders." 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.” Truitt, 1:24-30. Truitt describes and shows a “prior art” CPAP device in Fig. 1, reproduced below:



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; FIG. 1. As noted above, *see supra* VII, B, 1, a, the '921 Patent includes Fig. 1 and the accompanying text from Truitt in their entirety. *See, e.g.,* Truitt, Fig. 1 (above), 1:45-2:10 and compare with Fig. 7 (reproduced below) and 22:45-23:17 of '921 Patent.

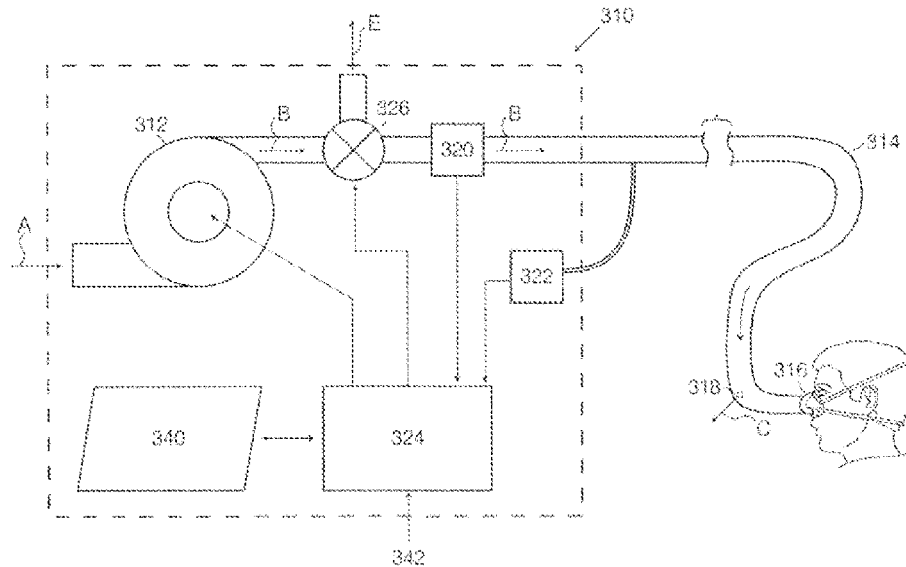


Fig. 7

'921 Patent, Fig. 7. Moreover, where Truitt describes the shown PAP device as “prior art,” the '921 Patent describes the reproduced PAP as one “embodiment” of the alleged invention. *See* '921 Patent, 22:41-45.

As shown and disclosed in Truitt, the blower and the mask deliver elevated pressure to treat sleep apnea and other sleep disorders. Truitt, 1:44-50. Referring to the conventional “prior art” PAP device shown in Fig. 1, Truitt also shows “a flow sensor 20, pressure sensor 22 ... 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.

Truitt further discloses a “first processor” in the PAP device for outputting “data related to the subject’s treatment and the treatment’s efficacy,” as claimed in the independent claims of the '921 Patent. With reference to Fig. 2, reproduced below, Truitt discloses that “[t]he signal from flow sensor 20... is provided to a controller 38 where it is used ... to control the pressure or flow of gas provided to the patient or monitor the patient’s usage of the medical device.” Truitt, 2:37-42 (emphasis added).

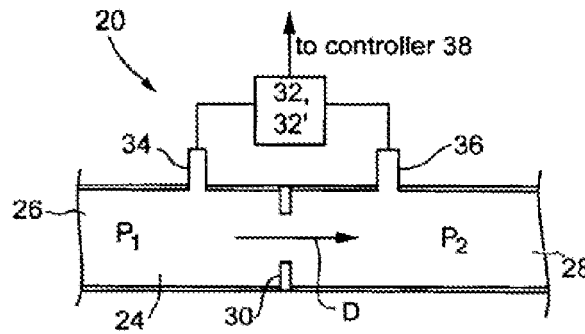


FIG 2
(PRIOR ART)

Id. Fig. 2. 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). Thus, a POSITA would readily recognize Truitt’s PAP device as including a processor that receives data from the airflow sensors and controls.

Truitt further states that the disclosed processor and the airflow sensors adjusts “**the pressure provided to the patient [] 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.***

Truitt 2:57-3:11 (emphasis added). 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.

Patent Owner conceded in discussing the specification of the '284 Patent, which is common to the '921 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 further 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 in Truitt, in monitoring the condition of the patient based on the signals from the airflow sensors, i.e., “the pressure or flow of breathing gas delivered to the patient,” to detect whether the patient is “experiencing apneas, hypopneas or upper airway resistance,” a POSITA would understand that the processor of the Truitt PAP device generates and outputs data based on the pressure and flow of breathing gas from the sensor signals over time—i.e.,

“data related to the subject’s treatment and the treatment’s efficacy”—and determines whether adjustments, if any, to the pressure and flow of the breathing air to the patient is needed to counteract apneas or hypopneas—i.e., calculate “quantified symptom data of the severity of the subject’s sleeping disorder symptoms” and “data of usage” of the PAP device.

Truitt also discloses that during treatment, the processor of the PAP device continues “in a feedback fashion” to monitor “the flow of breathing gas and the pressure level” provided to the patient and adjusts the flow “based on the conditions of the patient” to counteract or prevent “apneas, hypopneas. A POSITA would recognize that as the processor in Truitt’s PAP device continues to collect and process the respirator airflow and pressure provided to the patient and make adjustments, the processor determines the level of severity, i.e., calculates an “index of a subject’s symptoms measured during use of the PAP device.”

Patent Owner’s Preliminary Response for the ’284 PGR also concedes 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. Patent Owner further agrees 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.”).

In light of the teachings in Truitt and the knowledge of a POSITA, and as Patent Owner concedes, a POSITA would understand Truitt’s processor: 1) receives sensor data from the airflow sensor; 2) generates and outputs “data related to the subject’s treatment and the treatment’s efficacy”—i.e., data relating to the pressure or gas flow provided to the patient; 3)

calculates the “quantified symptom data of the severity of the sleep disorder symptom and/or an index of a subject’s symptoms” and “data of usage of the PAP device”—i.e., monitor the pressure and air flow provided to the patient and determine the level of severity based on the airflow and pressure data collected; and 4) “adjust or re-adjust the blower using, in part, the data of the quantitative output of the level of severity of the subject’s sleeping disorder symptoms during treatment”—i.e., change the airflow and pressure provided to the patient to counteract apneas and hypopneas, as recited in Claim 1 of the ’921 Patent.

2. Truitt in view of Giuffrida renders obvious a PAP device with integrated wireless communication capabilities to remotely transmit treatment data

a. Motivation to combine Truitt and Giuffrida

Truitt does not expressly disclose wireless communication of the treatment data. However, as described above, by 2005, a POSITA would be familiar with the benefits of telemedicine and its application to various at home medical devices to treat different disorders. Improving patient-doctor communication, during which the doctor is informed and able to monitor the patient’s usage, treatment provided, and the overall outcome of an at-home treatment device is also commonly recognized as a benefit of telemedicine by those skilled in the art. *See, e.g.,* Toge at 1-2.

Truitt explains using the collected data to monitor the condition of the patient and improve patient compliance—a goal readily understood by one of ordinary skill in the art. 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.”). A POSITA would further know the various approaches already developed by at least 2005 to evaluate

patient compliance and to improve the doctor's ability to remotely monitor the condition and progress of the patient and adjust the treatment of the in-home medical devices. Toge at 1-2.

As the PAP device disclosed in Truitt already includes a processor, a POSITA would readily recognize the benefit of integrating a wireless communication chip, as shown in Giuffrida, to transmit data to a remote clinician and/or treatment clinic. Indeed, it would have been obvious to integrate a system like Giuffrida—in the same field of endeavor, at-home treatment devices for health disorders as Truitt—with a distributed network of monitoring devices, including cell phones with a radio frequency wireless transceiver, a processor, software for displaying data, and a display. Giuffrida is also directed to “measuring the severity of a subject's symptoms.” Giuffrida, Abstract. This obvious integration enhances patient compliance, eliminates the need for face-to-face visits, allows treatment to be provided and modified without requiring the patient to travel to the medical provider and reduces the necessity for the provider to be available for office hours. Additionally, it improves how a third party, such as an insurance provider, can verify that the patient is complying with the treatment as prescribed, thereby addressing the patient's sleep disorder symptoms.

It would have been obvious to one skilled in the art to combine the PAP device of Truitt and send the data related to the subject's at-home treatment and the treatment's efficacy remotely as shown in Giuffrida. Thus, connecting patients using PAP devices wirelessly to health care providers, as taught in Truitt in view of Giuffrida, meets the objectives of telemedicine well-known to the POSITA.

b. Giuffrida discloses the claimed “software” for a “second processor” and “remote internet site”

The independent claims of the ‘921 Patent all require a “software” for a “second processor” to display the received data and “a remote internet site.” In particular, as an example in Claim 1 of the ‘921 Patent,

a software stored on a non-transitory computer readable medium and executable by a second 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 by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display; and

a remote internet site, the remote internet site adapted to receive the data relate to the subject’s treatment and the treatment’s efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

wherein the software is further adapted to retransmit a data related to the subject’s treatment and the treatment’s efficacy received by the software from the first radio frequency wireless transceiver of the PAP device, in whole or part, to the remote internet site, and

Giuffrida discloses at least all these limitations.

Giuffrida is titled “Movement Disorder Monitoring System and Method,” and is generally directed to a patient monitoring and treatment system involving wireless communications that provide for a method for monitoring and “measuring the severity of a subject’s movement disorder,” EX. C, 1:14-15. Similar to Truitt, the Giuffrida system is described as “a treatment delivery system that can monitor symptoms in subject [sec] and deliver treatment in response to those symptoms.” *Id.*, 2:58-60. The Giuffrida system provides “information to be analyzed as needed by the clinician... in real-time, ... allows for home monitoring of symptoms ... and provides remote access to the clinician or physician,” *Id.*,

Abstract; *see also Id.* 2:43-46 (“provide continuous information to be analyzed as needed by the clinician.”). It also features “real-time clinical video feedback.” *Id.*, 2:35-36. Giuffrida also discloses a “drug delivery treatment system for dosing a subject in response to the increased severity of a subject’s symptoms.” *Id.* at 4:43-45. In the context of disorder treatments and pharmaceutical interventions, Giuffrida states that “[t]he efficacy of these intervention is often judged by the interventions ability to alleviate patient symptoms and improve their quality of life.” *Id.* at 23-25. Thus, in addition to physically treating a subject’s disorder symptoms, the Giuffrida’s system is also adapted for chemically treating a subject’s disorder symptoms.

Like Truitt, Giuffrida discloses the use of “a first sensor ... and a second sensor ... wherein the severity of the subject’s movement disorder is calculated based in part on the signals of the first and second sensors.” *Id.* at 3:14-21. Giuffrida also shows the disorder treatment device to “accurately quantify symptoms,” *id.*, 3:3-5, with “at least one processor for receiving the signal and calculating the severity of the subject’s movement disorder in real-time.” *Id.* at 3:35-37; *see also Id.*, 8:10-16 (“microprocessor 70 for detecting ... signals.”).

Among the other electronic components disclosed, the Giuffrida system also discloses electronic components with “nonvolatile rewritable memory.” *Id.*, 9:18-19. The disclosed Giuffrida system also includes “transmitting wirelessly a signal” measured from the sensors, “receiving the wirelessly transmitted signal; and scoring the severity of a subject’s movement disorder based in part on the wirelessly transmitted signal.” *Id.* at 3:22-29. Giuffrida further shows “recording [] data to memory on the device, downloading that data to a computer at a later time and calculating the severity of the subject’s movement disorder.” *Id.* at 3:43-45. The disclosed Giuffrida system provides “analysis in real-time, that allows for home monitoring of symptoms in subjects with these movement disorders to capture the complex fluctuation patterns

of the disease over the course of days, weeks or months, that maximizes subject safety, and that provides *remote access to the clinician or physician.*” Giuffrida, 1:14-18.

Giuffrida discloses “remote communication station of various embodiments,” including “any device known to receive RF transmissions used by those skilled in the art to receive transmissions of data.” Giuffrida, 13:5-8; *see also* 10:53-54 (“Preferably the circuitry of the one or more electronic components includes an RF transmitted.”); 11:3-8 (“Optionally, the radio transmission of the present invention may use frequency-selective antennas for separating the transmission and receiving bands...”); 12:38-44 (disclosing “RF link utilizes a two-way (bi-directional) data transmission” to increase data safety.) The remote communication of Giuffrida is also used “for relaying the transmission” for “re-processing the transmission, and “relaying it to another remote communication station, a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combination of these devices.” *Id.* at 13: 8-16. Giuffrida also describes communication stations that can “transmit data both to another device and/or back,” *id.* 13:16-18, and with “RF link utilize[ing] a two-way (bi-directional) data transmission” to increase data safety. 12:38-44.

Giuffrida further discloses various examples of communication devices, including:

the remote communication system of the present invention can be a wireless router, which establishes a broadband Internet connection and *transmits the physiological signal to a remote Internet site* for analysis, preferably by the subject’s physician. Another example is where the remote communication system is a *PDA, computer or cellphone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines or cable* to a remote site for analysis. Another example is where the remote communication system is a computer or processor, which receives the data transmission and *displays the data* or records it on some recording medium, which *can be displayed or transferred for analysis* at a later time.

Id. at 13:20-36. (emphasis added). The identical disclosure is also found in the ‘921 Patent. *See*, ‘921 Patent, 19:12-45.

Further, in the Patent Owner’s Preliminary Response for the ’284 PGR, Patent Owner contends that this same excerpt copied from Giuffrida discloses “software downloadable on a cell phone for displaying data, such as an index of treatment efficacy,” and that such data “may include first and second indices that calculated over different periods of usage of the PAP device, assess the efficacy of treatment over time.” *See* PGR2024-00012, POPR at 20-21. As Giuffrida teaches and as Patent Owner concedes, a POSITA understands that the disclosed processor in the remote cell phone receives the data and “re-processes” or “displays the data” via the software stored and executed on a computer readable medium on the cell phone. That Giuffrida is directed to a movement disorder but explicitly teaches providing the subject’s treatment in real-time to a clinician would suggest to POSITA to use the system for other health disorders suitable for in-house treatment to improve the overall level of care and treatment to the patient.

Given the foregoing teachings of Truitt and Giuffrida, a POSITA would be motivated to combine the PAP device of Truitt with integrated wireless communication capabilities to transmit the treatment data wirelessly to clinicians as suggested by Giuffrida because doing so would facilitate patient compliance and realize the benefits of telemedicine well-known in the art—particularly relevant for sleep disorders treated with PAP devices, as disclosed in Truitt. A POSITA would further be motivated to combine Truitt with Giuffrida as it would simply be combining similar elements—sensors, processors receiving data from the sensors, calculating the severity of the patient’s symptoms and usage of the device, and wirelessly transmitting information to a remote location to monitor patient compliance. Doing so is merely using each of these known elements according to its known and disclosed method to yield predictable

results—to improve patient compliance and overall treatment efficacy. Such a combination would have been merely an occurrence in the ordinary course without any innovation.

Thus, it would have been obvious to a POSITA that Truitt in view of Giuffrida discloses a system having a PAP device with “a first radio frequency wireless transceiver” for transmitting data related to the patient’s treatment and the treatment’s efficacy from the PAP device to a remote device—e.g., a cell phone or PDA or a remote Internet Site—where the remote device having “a processor,” “a software stored on a non-transitory computer readable medium,” “a second radio frequency wireless transceiver” and “a display for receiving and displaying data related to the patient’s treatment and the treatment’s efficacy and to further retransmit the data to other remote sites, as required by Claim 1, 7 and 12 of the ‘921 Patent.

3. Processing Sensor Signals as Disclosed in Lisy would have been obvious to a POSITA in view of Truitt and Giuffrida

Both Truitt and Giuffrida teach processors that receive and process signals from sensors to measure and collect usage data and to calculate severity of the subject’s sleeping disorder symptoms. Truitt explicitly teaches the use of airflow sensors and that “[t]he signal from flow sensor 20... is provided to a controller 38...” Truitt, 2:37-40 (emphasis added). Giuffrida discloses that “the signals are converted to a digital form. This can be achieved with an electronic component or processing chip through the use of an ADC.” Giuffrida, 9:30-33. However, the combination of Truitt and Giuffrida is silent with respect to the specific function used to process the sensor signals claimed in the independent claims of the ’931 patent. Lisy, however, teaches:

wherein the sensor data from the sensors is processed by the first processor using one or more of the signal processing techniques from the group consisting of *a standard deviation technique, a recursively fit ARMAX system identification model, a short-time*

fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

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 the identical exemplary signal processing techniques taught as claimed in claim 1 and in the ’921 Patent. Indeed, as noted above, the ’921 Patent includes verbatim disclosures from paragraphs 40-45 of Lisy. *See* ’921 Patent, 20:11- 21:67.

It would have been obvious to a POSITA that there are many ways to process sensor signals and to process the signals from the airflow sensors of the Truitt PAP device with the specific wavelet analysis of Lisy to generate usable data from the Truitt PAP device and transmit that data for further monitoring and analysis by a medical practitioner at a remote location, as Giuffrida teaches. Therefore, the combination of Truitt, Giuffrida and Lisy renders independent claim 1 unpatentable as obvious under 35 U.S.C. §103. As Giuffrida expressly teaches transmitting data to multiple locations within the medical telecommunication network, *see, e.g.*, Giuffrida 13:8-16 (“re-processing the transmission, and “relaying it to another remote communication station, a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combination of these devices.”), claims 7 and 12 are likewise obvious over the combination of Truitt, Giuffrida and Lisy.

Thus, Claims 1, 7 and 12 are rendered obvious by the combination of Truitt in view of Giuffrida and Lisy.

4. Claims 2-4, 6, 8, 10, 11, 13, 15 and 16 are obvious over Truitt in view of Giuffrida in view of Lisy under 35 U.S.C. § 103(a)

As discussed above, Truitt discloses a PAP device with 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.” Truitt 2:57-3:11 (emphasis added). Likewise, the Giuffrida system provides “information to be analyzed ... [to] provide analysis in real-time...” Giuffrida. Abstract. Giuffrida also describes using the remote communication system for “relaying the transmission” for “re-processing the transmission and “then relaying it to another remote communication station,” *id.* at 13: 8-16, with “RF link utilize[ing] a two-way (bi-directional) data transmission” to increase data safety. *Id.*, 12:38-44. Giuffrida also discloses that the electrical components include “arrangement [that] allows for reprogramming...” *Id.*, 10:43-44. Thus, Truitt in view of Giuffrida and Lisy renders obvious Claims 2, 3, 6, 10, 11, 15 and 16.

Giuffrida also describes using the “commercially available chip (blue tooth technology)” that will not only “greatly reduce the size of the device, but the transceiver capabilities will allow two-way communications...” *Id.*, 16:1-6. Thus, Truitt in view of Giuffrida and Lisy renders obvious Claims 4 and 13.

Likewise, as already discussed above, Truitt in view of Giuffrida discloses a PAP device that transmit data related to the subject’s treatment and the treatment’s efficacy to “*a remote Internet site*” and “a PDA, computer or cellphone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines or cable to a remote site for analysis.” Giuffrida, 13:20-36. Thus, Truitt in view of Giuffrida and Lisy renders Claim 8 obvious.

B. SNQP 2: Claims 1-4, 6-8, 10-13, 15 and 16 are unpatentable over Truitt in view of Schmidt and Lisy under 35 U.S.C. §103(a)

As with SNQP 1, Truitt discloses all of the claimed elements for the independent Claims 1, 7 and 12 of the '921 Patent relating to the PAP device, the discussion 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.

1. Truitt in view of Schmidt renders obvious a PAP device with integrated wireless communication capabilities to remotely transmit treatment data

a. Motivation to combine Truitt and Schmidt

Truitt does not expressly disclose wireless communication using the PAP device. With respect to the discussion above for Truitt and Giuffrida, *see* X, A, the discussion of which is incorporated by reference in its entirety here, that by 2005, it would have been obvious to a POSITA to combine the PAP device of Truitt with integrated wireless communication capabilities to send data related to the subject's at-home treatment and the treatment's efficacy to a remote location. Schmidt discloses a programmable wireless data acquisition system with a signal processing module to process the sensor data for transmission to a distributed network of monitoring devices, including base stations with radio frequency wireless transceiver, a processor, software for displaying data, and a display. *See*, Schmidt, Abstract; Fig. 1.

Like Truitt, Schmidt discloses "air flow" and respiration sensors to supply sensor data to the signal processing module for conditioning and processing where the "module microcontroller [which 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.” *See* Schmidt, 4:7-22; 14:40-54. As both Truitt and Schmidt teach the same solutions to address the same technical issue, a POSITA would have found it obvious to look to Schmidt for additional solutions for use with the same technical issue, i.e., wirelessly send the data from the PAP device of Truitt. The fact that Patent Owner combined the identical teachings of Truitt and Schmidt by copying parts from both of them into the ‘921 Patent is further support that it would have been obvious for a POSITA to combine the teachings of Truitt and Schmidt: as already discussed in Sections VII, B, 1, above, the ‘921 Patent copies the entire Detailed Description from Schmidt (14 columns, spanning 4:63 to 14:54 and each of Schmidt’s Figures 1-6), and copies Fig. 7 of the ‘921 Patent from Fig. 1 of Truitt.

b. Schmidt discloses the claimed “software” for a “second processor” and “remote internet site.”

The independent claims of the ‘921 Patent all recite a “software” for a “second processor” to display the received data and “a remote internet site.” In particular, as an example, Claim 1 requires:

a software stored on a non-transitory computer readable medium and executable by a second 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 by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display; and

a remote internet site, the remote internet site adapted to receive the data relate to the subject’s treatment and the treatment’s efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

wherein the software is further adapted to retransmit a data related to the subject’s treatment and the treatment’s efficacy received by the software from the first radio frequency wireless transceiver of the PAP device, in whole or part, to the remote internet site, and

Schmidt discloses all these limitations.

Schmidt discloses a “programmable wireless data acquisition system, comprising a signal processing module comprising a module microcontroller having a memory.” Schmidt, 2:7-10. As noted, the signals include sensors signals from the “air flow and respiration” sensors. *Id.*, 4:14-18. The processing module 16 wirelessly transmits data to base station 40 via bidirectional transceiver. *Id.*, 5:32-38; Fig. 1. Schmidt states that the disclosed data acquisition system is designed to “be adapted for different applications by software programmed,” *id.*, 1:15-20, and as a “universal platform design [that] can be utilized for all applications.” *Id.*, 6:40-41; 7:16-20.

With respect to the signal processing module, Schmidt shows with reference to 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.

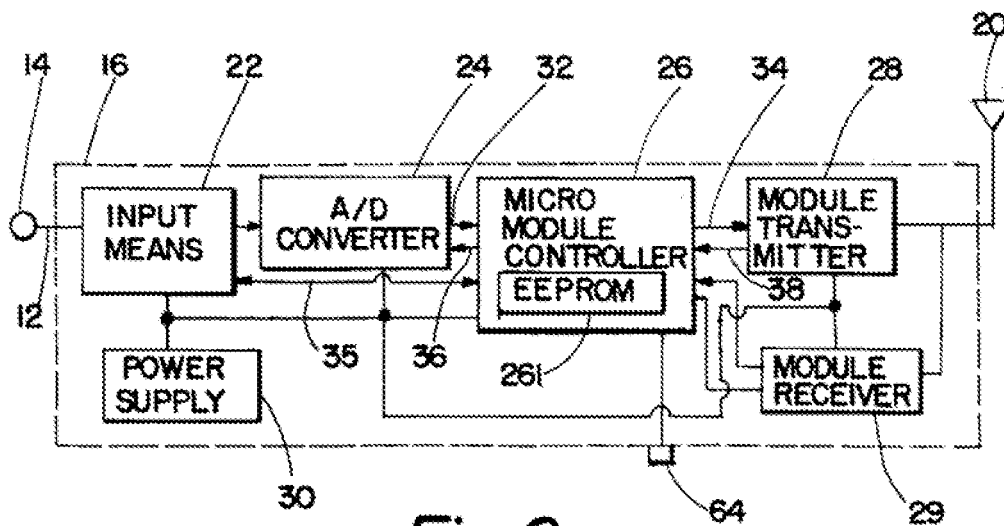


Fig. 2

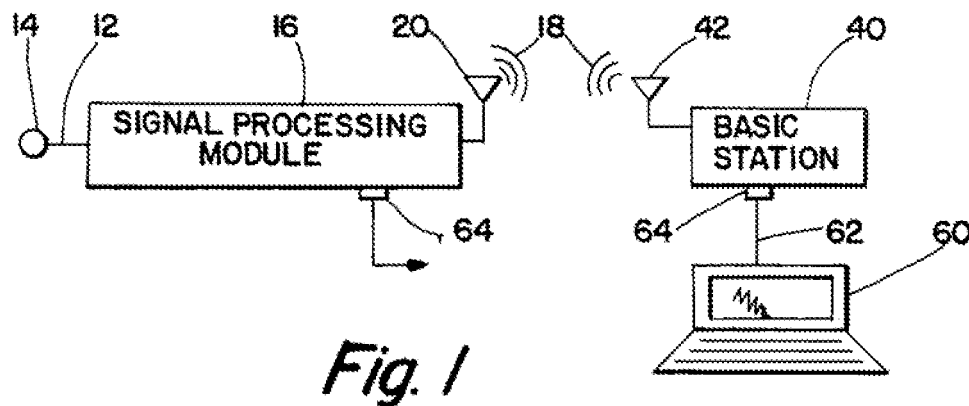
Schmidt further describes:

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.”

Id. 5:54-67; *see also* 7:4-10. Schmidt further discloses that 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.*, 6:1-5.

Schmidt discloses wireless transmission of the processed sensor data with reference to Fig. 1, reproduced below:



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. The “base station 40” is further shown to include a “personal

computer” having a display with “programming means 60, shown in Fig. 1 as a personal computer, contains software which is used to program the signal processing module 16 and the base station 40.” *Id.*, 5:18-21. Thus, a POSITA would understand that the Schmidt system teaches a processor that processes airflow sensor signals and wirelessly transmits the data to a base station, equipped with antenna to receive the processed data, and a personal computer with software and memory to process the received data for further processing and display.

Schmidt also discloses that “*the signal processing module 16 and the base station 40 can be programed* by connecting a data interface cable 62 between it and an external programming means 60 or *by radio frequency (or other type) of signals transmitted between a base station 40 to the signal processing module 16 or another base station 40.*” *Id.*, 5:26-32 (emphasis added). In addition, “RF signals... can be both transmitted and received by both signal processing module 16 and base station 40.” *Id.*, 5:32-34. As shown, the personal computer “can monitor, analyze can display the data in addition to its programing functions.” *Id.*, 5:40-43. Thus, it would have been obvious to a POSITA that sensor data—i.e., data relating to the subject’s treatment and the treatment’s efficacy, as taught in Truitt and Schmidt, is transmitted and retransmitted wirelessly to a network of other devices, each of which includes its antenna, software and processor to further process and display and retransmit the received data as disclosed in Schmidt.

Here, consistent with objectives of telemedicine known to POSITA, *see, e.g.*, Section VI, Schmidt discloses 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.” Schmidt, 5:52-6:35.

Thus, it would have been obvious to a POSITA that Truitt in view of Schmidt discloses a system having a PAP device with “a first radio frequency wireless transceiver” for transmitting data related to the patient’s treatment and the treatment’s efficacy from the PAP device to a base station having “a processor,” “a software stored on a non-transitory computer readable medium,” “a second radio frequency wireless transceiver” and “a display” for receiving and displaying data related to the patient’s treatment and the treatment’s efficacy and to further retransmit the data to other remote sites, as required by Claims 1, 7 and 12 of the ‘921 Patent.

Given the foregoing teachings of Truitt and Schmidt, a POSITA would be motivated to equipped the PAP device of Truitt with integrated wireless communication capabilities to transmit the treatment data wirelessly to clinicians as suggested by Schmidt because doing so would facilitate patient compliance and realize the benefits of telemedicine well-known in the art—particularly relevant for sleep disorders treated with PAP systems, as disclosed in Truitt. A POSITA would further be motivated to combine Truitt with Schmidt as it would simply be combining similar elements: sensors, processors receiving data from the sensors, calculating the severity of the patient’s symptoms and usage of the device, and wirelessly transmitting information to a remote location to monitor patient compliance. Doing so is merely using each of these known elements according to its known and disclosed method to yield predictable results—to improve patient compliance and overall treatment efficacy. Such a combination would have been merely an occurrence in the ordinary course without any innovation.

Thus, it would have been obvious to a POSITA that Truitt in view of Schmidt discloses a system having a PAP device with “a first radio frequency wireless transceiver” for transmitting

data related to the patient's treatment and the treatment's efficacy from the PAP device to a remote device—e.g., a cell phone or PDA or a remote Internet Site—where the remote device having “a processor,” “a software stored on a non-transitory computer readable medium,” “a second radio frequency wireless transceiver” and “a display for receiving and displaying data related to the patient's treatment and the treatment's efficacy and to further retransmit the data to other remote sites, as required by Claim 1, 7 and 12 of the '921 Patent.

2. Processing Sensor Signals as Disclosed in Lisy would have been obvious to a POSITA in view of Truitt and Schmidt

Both Truitt and Schmidt teach processors that receive and process signals from sensors to measure and collect usage data and to calculate quantified symptom data of the severity of the subject's sleeping disorder symptoms. Truitt explicitly teaches the use of airflow sensors and that “[t]he signal from flow sensor 20... is provided to a controller 38...” Truitt, 2:37-40 (emphasis added). Schmidt discloses a wireless data acquisition system for acquiring, for example airflow sensor data, and describes processing the sensor signal via an analog-to-digital converter 24 which “conditions” the sensor signal. *Id.*, 6:47-49. Schmidt also describes a controllable A/D converter “to provide a specific number of external inputs [], 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. The combination of Truitt and Schmidt is silent with respect to the specific function used to process the sensor signals claimed in the independent claims of the '931 patent. Lisy, however, teaches:

wherein the sensor data from the sensors is processed by the first processor using one or more of the signal processing techniques from the group consisting of *a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernels*, and **a wavelet analysis**.

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 the identical exemplary signal processing techniques taught as claimed in claim 1 and in the ’921 Patent. Indeed, as noted above, the ’921 Patent includes verbatim disclosures from paragraphs 40-45 of Lisy. *See* ’921 Patent, 20:11- 21:67.

It would have been obvious to a POSITA that there are many ways to process sensor signals and to process the signals from the airflow sensors of the Truitt PAP device with the specific wavelet analysis of Lisy to generate usable data from the Truitt PAP device and transmit that data for further monitoring and analysis by a medical practitioner at a remote location, as Giuffrida teaches. Therefore, the combination of Truitt, Schmidt and Lisy renders independent claim 1 unpatentable as obvious under 35 U.S.C. §103. As Schmidt expressly teaches transmitting data to multiple locations, within the medical telecommunication network, *see, e.g.,* Schmidt, 5:26-33 (“...signals transmitted between a base station 40 to the signal processing module 16 or to another base station 40”), claims 7 and 12 are likewise obvious over the combination of Truitt, Schmidt and Lisy.

Thus, Claims 1, 7 and 12 are rendered obvious by the combination of Truitt in view of Schmidt and Lisy.

3. Claims 2-4, 6, 8, 10, 11, 13, 15 and 16 are obvious over Truitt in view of Schmidt in view of Lisy under 35 U.S.C. § 103(a)

As discussed above, Truitt discloses a PAP device with 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.” Truitt 2:57-3:11 (emphasis added). Schmidt likewise discloses “input means 22 is adjustable []under control of the module microcontroller 26.” Schmidt, 5:4-6. Schmidt further states that “the module receiver 29 in the signal processing module 16 receives RF signals from the base station 40. The signals from the base station 40 can be used to operate and control the signal processing 16 by programming and reprogramming the module microprocessor 26 and EEPROM 261 therein.” *Id.*, 8:4-8. In addition, Schmidt discloses that “[f]or maximum flexibility, such reconfiguration can be carried out during a series of measurements by means of the wireless link which is understood in this context to be bidirectional.” Schmidt, 8:38-41. Thus, Truitt in view of Schmidt and Lisy renders obvious Claims 2, 3, 6, 10, 11, 15 and 16.

Schmidt discloses the use of RF wireless data acquisition systems and states that “[o]ther data transmission means, such as infrared, optical or any means which does not require a mechanical connection is understood to offer similar advantages as RF transmission.” Schmidt, 1:67-2:3. By 2005, it would have been well-known to a POSITA that Schmidt suggests the use commercially available Bluetooth technology. Thus, Truitt in view of Schmidt and Lisy renders obvious Claims 4 and 13.

Likewise, as already discussed above, *see, e.g.* X, B, Truitt in view of Schmidt discloses a PAP device that transmits data related to the subject’s treatment and the treatment’s efficacy to “*a base station*” where “software which is used to program the signal processing module 16 and the base station 40 through data interface cable 62.” Schmidt, 5:18-21. Moreover, “[t]he same

data interface cable 62 or two different interface cables 62 can be used, one for the base station 40 and one for the signal processing module 16” and “the signal processing module 16 and the base station 40 can be programmed by connecting a data interface cable 62 between it and an external programming means 60 ... or to another base station 40.” Schmidt, 5: 24-34. Thus, Truitt in view of Giuffrida and Lisy renders Claim 8 obvious.

C. SNQP 3: Claims 5, 9, and 14 are Unpatentable Over the Combination of Truitt, Giuffrida and Lisy under 35 U.S.C. §103(a)

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, as noted above, the combination of Truitt, Giuffrida and Lisy disclose the limitations of Claims 5, 9, and 14. However, the combination is silent as to the type of index of the subject’s symptoms and, more specifically, that the index is a respiratory disturbance index. Burton, in the same field of endeavor—of monitoring and interpreting physiological signals and spontaneous breathing events, (*see* Abstract)—discloses the recited feature of “automatically adjust the therapeutic treatment based on at least one index or derived data set wherein the index or derived data set can include the following: . . . Respiratory Disturbance Index.” Burton (EX. K) 14:54 – 15:48. It would have been obvious to a POSITA, at the time of invention, to calculate the respiratory disturbance index of Burton for use in the system taught by Truitt in view of Giuffrida and Lisy, e.g., to automatically adjust the therapeutic treatment, as suggested by Burton.

D. SNQP 4: Claims 5, 9, and 14 are Unpatentable Over the Combination of Truitt, Schmidt and Lisy in View of Burton under 35 U.S.C. §103(a)

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, as noted above, the combination of Truitt, Schmidt and Lisy disclose the limitations of Claims 5, 9, and 14. However, the combination is silent as to the type of index of the subject's symptoms and, more specifically, that the index is a respiratory disturbance index. Burton, in the same field of endeavor—of monitoring and interpreting physiological signals and spontaneous breathing events, (*see* Abstract)—discloses the recited feature of “automatically adjust the therapeutic treatment based on at least one index or derived data set wherein the index or derived data set can include the following: . . . Respiratory Disturbance Index.” Burton (EX. K) 14:54 – 15:48. It would have been obvious to a POSITA, at the time of invention, to calculate the respiratory disturbance index of Burton in the system taught by Truitt in view of Schmidt and Lisy to, e.g., automatically adjust the therapeutic treatment, as suggested by Burton.

E. SNQP 5: Claims 1-4, 7, 8, 11-13, and 16 are Unpatentable over Mumford in view of Genger in view of Kisner under 35 U.S.C. §103(a)

For the reasons discussed below, it is respectfully submitted that Claims 1-4, 7, 8, 11-13, and 16 are obvious in view of the Mumford in view of Genger in view of Kisner 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, since Mumford (i.e., the primary reference) was not applied during any prior examination of the '963 Application/'921 Patent, its teachings, when combined with those of

Genger and Kisner, 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 '963 Application. Had the teachings of this prior art been considered, the Examiner would not have allowed the claims thereof that correspond to Claims 1-16 of the '921 Patent.

1. Mumford Discloses The Claimed PAP System For Sleep Disorder Treatment

The independent claims, Claims 1, 7 and 12, of the '921 Patent are all directed to a PAP sleep disorder system with integrated airflow sensor and processor to monitor patient's usage and adjust airflow to provide treatment based on the condition of the patient. To facilitate consideration and discussion, relevant claim elements for the PAP from Claim 1 is reproduced below with discussion that follows also applicable to Claims 7 and 12.

Claim 1. A sleeping disorder treatment system comprising:

a PAP device configured to be a single enclosure, the PAP device comprising:

a blower having an air output;

an airflow sensor internal to the PAP device and adapted for measuring the respiratory airflow of a subject while using the PAP device;

a first processor adapted for generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping 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 first radio frequency wireless transceiver;

a mask or a nasal cannula;

wherein the airflow sensor and the first processor are adapted for measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a

treatment and further providing for a data related the subject's treatment and the treatment's efficacy;

wherein the blower, and the mask or the nasal cannula are adapted for physically or chemically treating a subject's sleeping disorder symptoms,

wherein the first processor is configured to adjust or re-adjust the blower using, in part, the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment;

a remote internet site, the remote internet site adapted to receive the data relate to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

Mumford, Claim 1.

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." Mumford (EX. G), 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 PAP 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 PAP 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 PAP unit 14.

Thus, Mumford discloses that telemedicine connected PAP devices, e.g., PAP 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. G), 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 PAP 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.

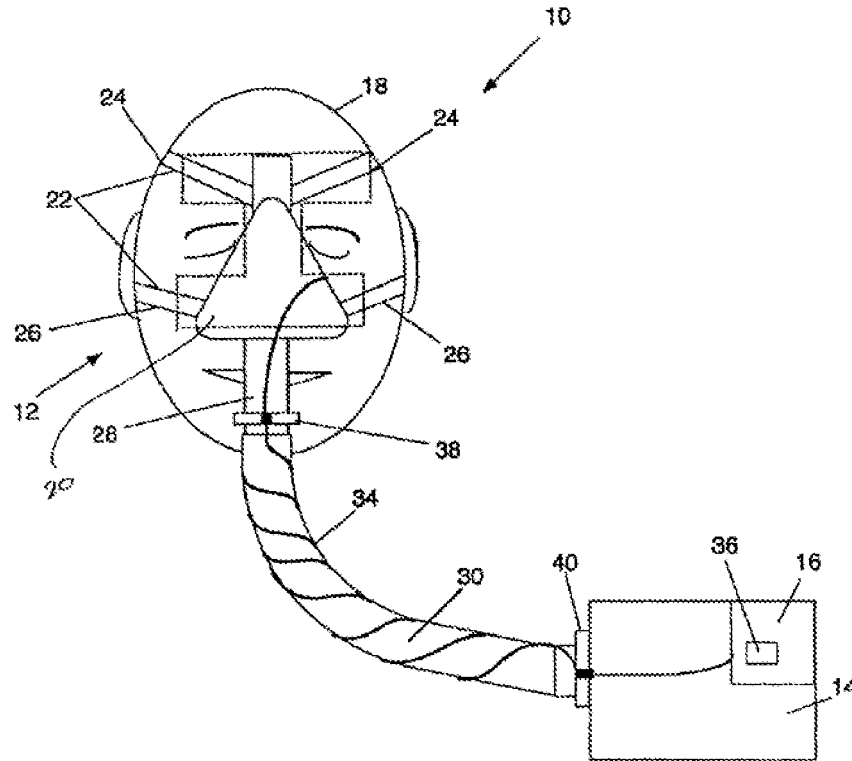


Figure 1

Id.

Mumford goes on to disclose that the PAP 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 IPR proceeding regarding the '269 Patent (IPR2023-00565), 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 '921 Patent, as allowed, requires that the PAP device includes "a mask or nasal cannula." As the mask forms part of the claimed PAP device, an airflow sensor internal to the mask would therefore read on 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, 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.

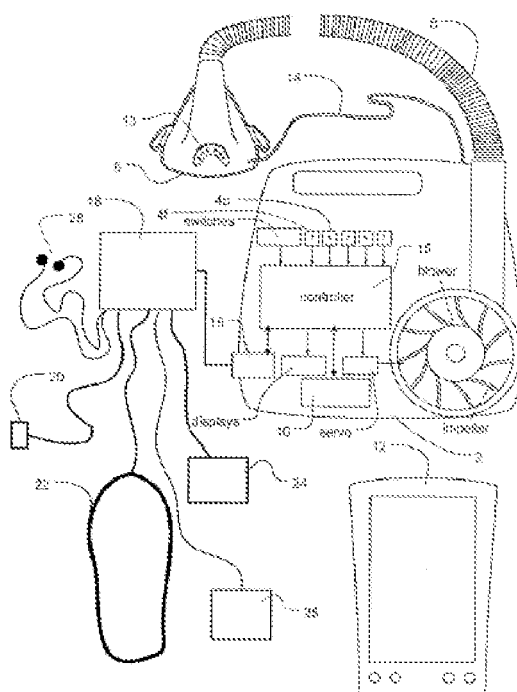


FIG. 1

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. G 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. The sleep profile includes the quality of the patient's sleep, the efficacy of the CPAP device 14, and is able to provide compliance data. *Id.* 7:34-46. All of this serves the goal of addressing sleep disorders using known telemedicine techniques.

In addition, Mumford discloses a (first) processor adapted for generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving the airflow sensor data, for calculating both the quantified symptom data of the severity of the sleeping 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 and a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment and further providing for a data related the subject's treatment and the treatment's efficacy, as recited in independent claim 1. 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.

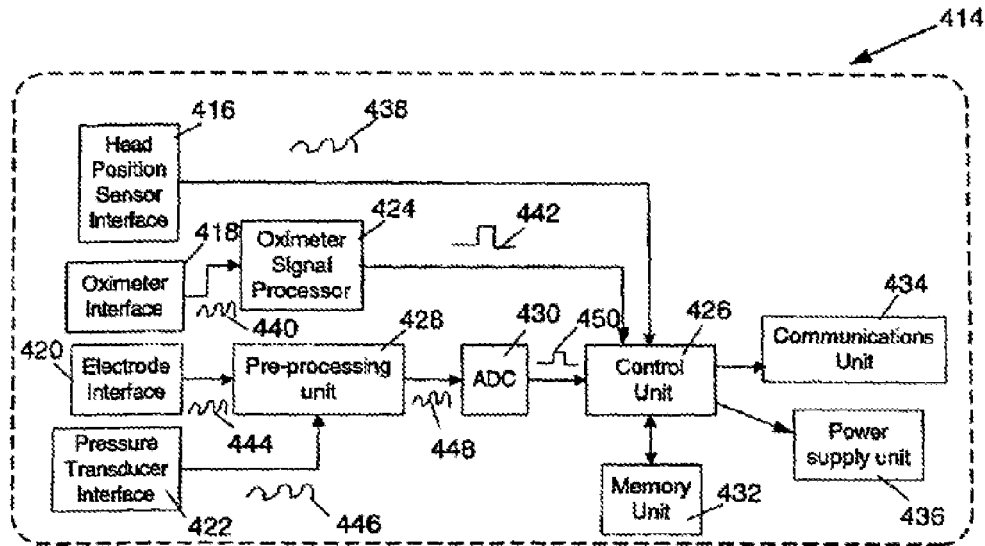


Figure 5b

Id.

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 goes on to disclose that the remote processing unit additionally includes at least one first radio frequency wireless transceiver, the first radio frequency wireless transceiver is adapted for transmitting the data related to the subject's treatment and the treatment's efficacy. For example, 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 “related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping 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,” as recited in independent claim 1.

Further, Mumford discloses a remote internet site, the remote internet site adapted to receive the data related to the subject's treatment and the treatment's efficacy via the first radio frequency wireless transceiver. As explained above, Mumford discloses transmitting the sleep profile information to a caregiver, which is equivalent to a remote internet site and the aforementioned data can be sent wirelessly via BLUETOOTH or CDMA cellphone signals. To further explain, because Mumford discloses sharing sleep profile information with a caregiver's computer, via remote transmission of that data, then the data presented on the caregiver's computer can be understood to be a remote website, given the broadest reasonable interpretation of the term.

Mumford additionally discloses that the first processor is configured to adjust the blower in part based on the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment. For example, Mumford explains, “In an alternative, the 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.**” *Id.* 14:19-26.

Mumford discloses sending data from the CPAP system 10 to a physician, but is silent with respect to a software stored on a non-transitory computer readable medium and executable by a second 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 by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display.

2. Mumford in view of Genger renders obvious a telehealth network including a PAP device and a network attached device having software to use and display data from the PAP device

Genger, in the same field of endeavor of CPAP treatment devices, teaches and suggests at least:

1. A sleep disorder treatment system comprising:

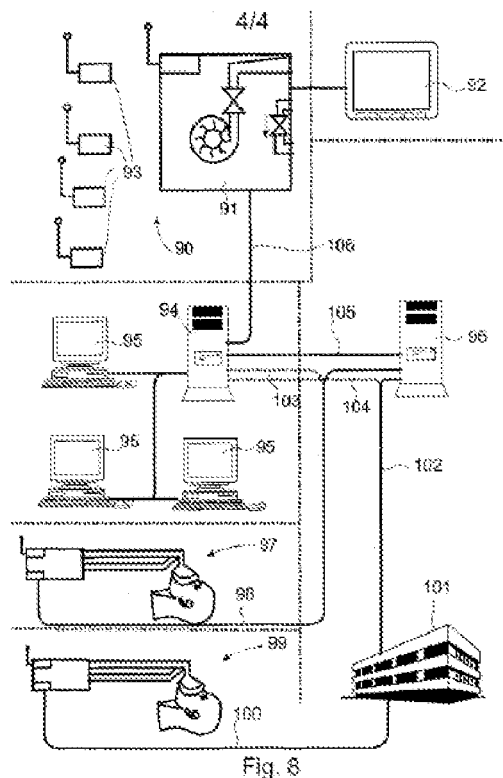
a software stored on a non-transitory computer readable medium and executable by a second processor, the software adapted to be used with and to display the data related to the subject's treatment and the treatment's efficacy to the subject or a care provider by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display; and

a remote internet site, the remote internet site adapted to receive the data relate to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the first radio frequency wireless transceiver,

wherein the software is further adapted to retransmit a data related to the subject's treatment and the treatment's efficacy received by the software from the first radio frequency wireless transceiver of the PAP device, in whole or part, to the remote internet site, and

Genger is directed to systems and methods for “Radio Module, Respirator And Monitoring Device Therefor; Therapeutic Device For Carrying Out CPAP Treatment And

Monitoring Device Therefor, Systems And Methods.” Genger (EX. H), Title. Genger discloses a PAP sleep disorder treatment system. Genger’s “invention relates in particular to CPAP (continuous positive airway pressure; see *Id.* 1:274) treatment devices, which communicate, in a wireless manner, with sensor units and monitoring devices, to radio modules that are suitable for use in the medical field, to respiratory devices, which likewise communicate, in a wireless manner, with sensor units and monitoring devices and to an intelligent networking of treatment rooms in a hospital, of a hospital network, of national organizations, of medical establishments and also of domestic environments.” *Id.* Abstract. In an embodiment, Genger discloses a combined hospital and private home network for data sharing, as shown in FIG. 8, reproduced below. *Id.* 10:11-12.



Id.

Genger equates the various computing devices shown in FIG. 8, stating that “PCs are manufactured in large quantities and are therefore inexpensive. Smaller devices, such as palmtops or organizers, are also increasingly being used, also with integrated cell phones.” *Id.* 7:6-8. Genger discloses that in the context of FIG. 8, “[t]he modems may be connected to the server 96 via connection 98 or to the medical and health care supplier 101 via connection 100, via 25 the conventional telephone network or via mobile phone networks, as explained above in connection with Fig. 2.” *Id.* 17:23-26. Genger’s modems are capable of receiving and transmitting pre-processed data from ventilators, or CPAP devices, 97, 99 to medical staff, physicians, and health care suppliers for **display** to the necessary parties.

Notably, Genger’s network contemplates a plurality of devices (94, 95, 96, 101) that are able to share “trend data, stored on the server 94, may be forwarded to the national server 96 via the connection 105, in order to make the patient data centrally available to other hospitals, for example at the vacation destination, or to physicians in different practices. To ensure the confidentiality of the data, connection 105 and the other connections 98, 100, 102, 103 and 104 are secure connections.” *Id.* 18:12-16. Thus, Genger discloses, teaches, and explicitly suggests distributing data between the nodes on the network, e.g., from a cell phone or a PDA to a PAP device or a remote internet site, and back again to one of a cell phone, or a PDA.

Genger goes on to explain that “the measurement data of other treatment and diagnostic devices can also be made available on a national basis, in order to save money by avoiding duplicate examinations. . . Finally, the data may be stored anonymously on the national server 96. This enables also smaller hospitals to access extensive (anonymized) patient data, and thus increases the attractiveness of small hospitals 25 for young physicians.” *Id.* 18:18-25. As such, Genger teaches:

- 1) “the software is further adapted to retransmit a data related to the subject's treatment and the treatment's efficacy received by the software from the first radio frequency wireless transceiver of the PAP device, in whole or part, to the remote internet site,” as recited in independent claim 1;
- 2) “the software is further adapted to receive, in whole or part, the data related to the subject's treatment and the treatment's efficacy generated by the PAP device that is first received by then retransmitted from the remote internet site,” as recited in independent claim 7; and
- 3) “both the software and the remote internet site independently receive, in whole or part, the data related to the subject's treatment and the treatment's efficacy generated by the PAP device,” as recited in independent claim 12.

It would have been obvious to a POSITA, at the time of invention, to include the cell phones, or PDAs, including at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, the display of Genger and the data transfer paths enumerated above 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 and easily transferred 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) Genger teaches that distribution of data to remote medical providers can prevent the need for duplication of sleep studies or examinations, and smaller devices, such as palmtops or organizers, are also increasingly being used, also with integrated cell phones.

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 goes on to explain 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 Genger with Mumford to enable ease of transmission of medical data between nodes in a distributed network of patients and medical providers, e.g., to a smart phone, which were increasingly being used in the medical industry to advance patient compliance and efficacy, in addition to a reduction in health-care costs.

3. Mumford in view of Genger in view of Kisner renders obvious a PAP device that uses wavelet analysis

The combination of Mumford and Genger 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:

1. A sleep disorder treatment system comprising:

wherein the sensor data from the sensors is processed by the first processor using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and **a wavelet analysis**.

Kisner teaches that known signal processing of breathing parameters include wavelet analysis, “Breathing parameters are extracted from true component signals 108 using wavelet analysis or similar means at 112 to generate signal 116.” Kisner (EX. I) 13:36-53.

It would have been obvious to a POSITA 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, Genger, and Kisner renders independent claim 1 unpatentable as obvious under 35 U.S.C. §103. Moreover, independent claims 7 and 12 are similarly rendered obvious under substantially the same grounds. As Genger expressly teaches transmitting sensor data to multiple nodes within the medical telecommunication network, as well as from node to node, claims 7 and 12 are likewise obvious over the combination of Mumford, Genger, and Kisner.

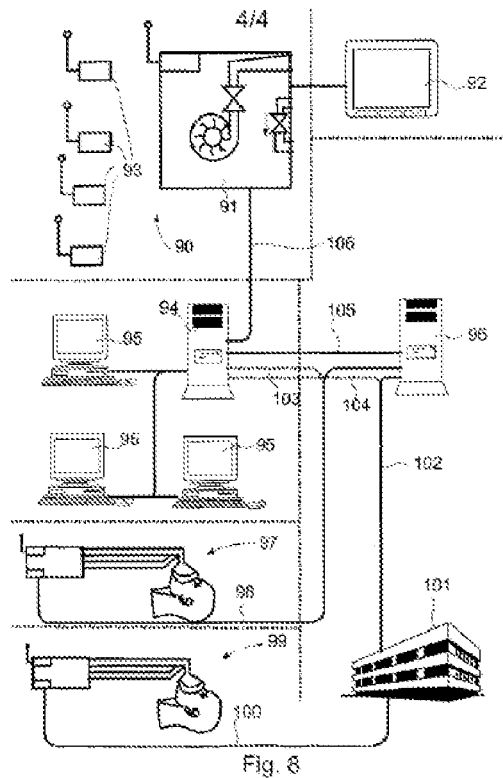
4. Claims 2-4, 8, 11, 13, and 16 are obvious over Mumford in view of Genger in view of Kisner under 35 U.S.C. § 103(a)

Mumford discloses the system, as explained above, including 1) the first radio frequency wireless transceiver of the PAP device and the software adapted to use second radio frequency wireless transceiver of the base station, cellular phone or PDA to transmit the data related to treatment between each other using Bluetooth wireless protocol and 2) the PAP device and the

remote internet site as well as the remote internet site and the software adapted for the base station, cellular phone or PDA transmit the data related to the subject's treatment and the treatment's efficacy via cell towers or cable.

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.” Mumford (EX. G), 14:35-40. 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.” *Id.*, 14:19-28. Mumford goes on to explain, “The 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 Genger discloses that the CPAP system allows for remote internet sites to communicate with the second software on the CPAP device to modify the second software with changes to the therapy of the device based on the data of severity of symptoms and/or the recited “index.”

The combination of Mumford and Genger teaches or suggests that the remote internet site, here for example, Genger discloses a combined hospital and private home network for data sharing, as shown in FIG. 8, reproduced below. Genger (EX. H) 10:11-12. Remote internet site on device 94 includes a plurality of monitors 95 for displaying the index or data of usage by a clinician. In addition, 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. G) 16:18-21.



Thus, claims 2-4 are additionally rendered obvious over the combination of Mumford, Genger, and Kisner. Similarly, claims 8, 11, 13, and 16 are obvious over the same combination.

Claims 1-4, 7, 8, 11-13 and 16 of the '921 Patent are rendered obvious by the combination of Mumford in view of Genger and Kisner with exemplary disclosures shown in the Claim Charts, attached.

F. SNQP 6: Claims 1-4, 6-8, 10-13, 15, and 16 are Unpatentable as obvious over Mumford in view of Toge in view of Kisner under 35 U.S.C. § 103(a)

1. Claim 1 is obvious over Mumford in view of Toge in view of Kisner

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, since the combination of Mumford and Kisner discloses the limitations of at least independent claim 1, as outlined *supra* in XI.E.1. However, as noted above, Mumford discloses sending data from the CPAP system 10 to a physician, but is silent with respect to a software stored on a non-transitory computer readable medium and executable by a second 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 by using a base station, a cell phone or a PDA, each comprising a second radio frequency wireless transceiver, the second processor and a display.

Toge, in the same field of endeavor of CPAP treatment devices, discloses “remote monitoring of the condition of a patient or the condition of a positive pressure artificial respiration assist device when the device is in use.” Toge (EX. J) ¶[0005]. Toge goes on to explain that various nodes within the telehealth network include a relay device. For example, “the relay device receives the treatment data transmitted from the positive pressure artificial respiration assist device and transmits all or a part of the received treatment data to the doctor’s terminal device via the communications network, and the doctor’s terminal device receives all or a part of the treatment data transmitted from the relay device.” *Id.* ¶[0006].

Toge teaches that medical professionals can make use of portable terminals that are in communication with the medical device and the portable terminal includes a mobile phone, a PHS, a PDA, and the like. *Id.* ¶[0019]. As such, Toge teaches:

- 1) “the software is further adapted to retransmit a data related to the subject's treatment and the treatment's efficacy received by the software from the first radio frequency wireless transceiver of the PAP device, in whole or part, to the remote internet site,” as recited in independent claim 1;
- 2) “the software is further adapted to receive, in whole or part, the data related to the subject's treatment and the treatment's efficacy generated by the PAP device that is first received by then retransmitted from the remote internet site,” as recited in independent claim 7; and
- 3) “both the software and the remote internet site independently receive, in whole or part, the data related to the subject's treatment and the treatment's efficacy generated by the PAP device,” as recited in independent claim 12.

Therefore, it would have been obvious to a POSITA, at the time of invention, to include the cell phones, PDAs, or a base station, including at least one radio frequency wireless transceiver, the processor, the software when downloaded and a display of Toge 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 and easily transferred 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.

2) Toge teaches that “[b]y transmitting this ventilation volume Fa in almost real time or at regular time intervals (for example, one hour), a doctor at a remote hospital, etc. can learn the condition of the patient when using the positive pressure artificial respiration assistance device 2.” *Id.* ¶[0039]. In addition, Toge discloses that “[b]y transmitting operational status in real time, doctors can respond to patient emergencies. . . If the oxygen saturation level falls below 90%, for example, the doctor can take emergency measures from the remote doctor's computer 4 or mobile terminal 5, such as resetting the prescribed pressure higher, operating the positive pressure artificial respiration assist device 2 so that it is used in combination with an oxygen concentrator, or increasing the flow rate from an oxygen concentrator that is being used in combination.” *Id.* ¶¶[0046]-[0047].

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 cite. Lankford, 163. Lankford goes on to explain 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 Toge with Mumford to enable ease of transmission of medical data between nodes in a distributed network of patients and medical providers, e.g., to a smart phone, which were increasingly being used in the medical industry to advance patient compliance and efficacy, in addition to a reduction in health-care costs.

Therefore, the combination of Mumford, Toge, and Kisner renders independent claim 1 unpatentable as obvious under 35 U.S.C. §103. Moreover, independent claims 7 and 12 are similarly rendered obvious under substantially the same grounds. Claims 7 and 12 are likewise obvious over the combination of Mumford, Toge, and Kisner, because Toge expressly teaches transmitting sensor data to multiple nodes within the medical telecommunication network, as well as from node to node.

2. Claims 2-4, 6, 8, 10, 11, 13, 15, and 16 are obvious over the combination of Mumford, Toge, and Kisner

The combination of Mumford, Toge, and Kisner disclose the limitations of claims 2-4, 6, 8, 10, 11, 13, 15, and 16. As noted above, for a detailed mapping of each claim to the prior art, see the Claim Chart.

For example, with respect to claim 6, the combination of Mumford, Toge, and Kisner teaches exchanging information between various nodes of a telehealth network, as explained above. Moreover, Toge teaches remote reprogramming of a node's software. For example, "setting[s] can be made by an input terminal carried by the doctor and separable from the main unit 20, or . . . the setting can be made via the communication network 1 by the doctor's computer 4 or mobile terminal 5." Toge ¶[0027].

Claims 1-4, 6-8, 10-13, 15 and 16 of the '921 Patent are rendered obvious by the combination of Mumford in view of Toge and Kisner with exemplary disclosures shown in the attached Claim Chart.

G. SNQP 7: Claims 5, 9, and 14 are Unpatentable Over the Combination of Mumford, Genger or Toge, and Kisner in View of Burton

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, since the combination of Mumford, Genger, and Kisner disclose the limitations of claims 5, 9, and 14 but are silent as to the index of the subject's symptoms is a respiratory disturbance index. Burton, in the same field of endeavor, of monitoring and interpreting physiological signals and spontaneous breathing events, (Abstract), discloses "automatically adjust the therapeutic treatment based on at least one index or derived data set wherein the index or derived data set can include the following: . . . Respiratory Disturbance Index." Burton (EX. K) 21:4 – 22:21. It would have been obvious to a POSITA, at the time of invention, to use the respiratory disturbance index of Burton in the system of Mumford in order to automatically adjust the therapeutic treatment, as suggested by Burton.

Claims 9 and 14 parallel claim 5, but depend from independent claims 7 and 12, respectively, and are unpatentable for the same reason as claim 5.

H. SNQP 8: Claims 5, 9, and 14 are Unpatentable Over the Combination of Mumford, Toge, and Kisner in View of Burton

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 particularized detail explaining the prior art disclosures against certain features.

Specifically, the combination of Mumford, Toge, and Kisner disclose the limitations of claims 5, 9, and 14 but are silent as to the index of the subject's symptoms is a respiratory disturbance index. Burton, in the same field of endeavor, of monitoring and interpreting

physiological signals and spontaneous breathing events, (Abstract), discloses “automatically adjust the therapeutic treatment based on at least one index or derived data set wherein the index or derived data set can include the following: . . . Respiratory Disturbance Index.” Burton (EX. K) 21:4 – 22:21. It would have been obvious to one of ordinary skill in the art, at the time of invention, to use the respiratory disturbance index of Burton in the system of Mumford in order to automatically adjust the therapeutic treatment, as suggested by Burton.

Claims 9 and 14 parallel claim 5, but depend from independent claims 7 and 12, respectively, and are unpatentable for the same reason as claim 5.

I. SNQP 9: Claims 1-16 are Unpatentable Over a Combination of Toge and Various Cited Art

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 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*, §XI.F. For the sake of simplicity, as CHART-3 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-3, Toge, and the associated secondary references, render each and every limitation of claims 1-16 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 1-16) of the ‘921 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 '921 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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