

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	App. of Kayyali et al.	)	
		)	
Serial No.:	18/510,801	)	
		)	Art Unit: 3791
Filed:	November 16, 2023	)	
		)	Docket No.: CMD-135
For:	Devices and methods for	)	
	sleep disorder diagnosis	)	
	and treatment	)	
		)	
Examiner:	Navin Natnithithadha	)	
		)	

August 28, 2024

AMENDMENT

Commissioner of Patents and Trademarks
Alexandria, VA 22313

This Amendment is responsive to an Office Action dated May 30, 2024. The Applicants submit that the Amendment is timely and no extension of time is needed. The following amendments and remarks are respectfully submitted.

IN THE SPECIFICATION:

Please amend page 1, lines 6-16 to read:

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application Serial No. 18/105,277, which was filed February 4, 2023, issued as U.S. Patent No. 11,872,029 on January 16, 2024, and which is a continuation of U.S. Patent Application Serial No. 17/825,266, which was filed on May 26, 2022, issued as U.S. Patent No. 11,602,284 on March 14, 2023, and which is a continuation of U.S. Patent Application Serial No. 16/057,963, which was filed on August 8, 2018, issued as U.S. Patent No. 11,375,921 on July 5, 2022, and which is a continuation of U.S. Patent Application Serial No. 13/440,116, which was filed on April 5, 2012, issued as U.S. Patent No. 10,076,269 on September 18, 2018, and which is a continuation of U.S. Patent Application Serial No. 11/266,899, which was filed on November 4, 2005, and issued as U.S. Patent No. 8,172,766 on May 8, 2012. The specifications and drawings of each of the above patents and applications are hereby incorporated by reference in their entirety.

IN THE CLAIMS:

Please amend claim 20 as follows:

1. (original) A positive airway pressure (PAP) sleep disorder treatment system comprising:

a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone a treatment efficacy of the subject using a PAP device, the treatment efficacy based in whole or in part on a data based on one or more measure(s) of the treatment efficacy received by the first software, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, and a display;

the PAP device with an enclosure further comprising:

a blower having an air output within the enclosure,
an airflow sensor being any type of sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP device and outputting airflow sensor data,
a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating the one or more measures of the treatment efficacy comprising:

- i) the data of a severity of the sleep disorder symptoms of the subject,
- ii) the data of usage of the PAP device by the subject, and/or
- iii) the index based in whole or in part on either i) or ii) or both i) and ii),

a mask or a nasal cannula connected to the enclosure, and
at least one second radio frequency wireless transceiver within the enclosure, the at least one second radio frequency wireless transceiver adapted for transmitting a PAP data based in whole or part on at least one of the one or more measures of treatment efficacy calculated by the second processor; and

a remote internet site, the remote internet site adapted for receiving the PAP data or data based on the at least one of the one or more treatment efficacy measures, related to the subject's treatment and the treatment's efficacy in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.

2. (original) The system of Claim 1, wherein the remote internet site is adapted to be hosted on a remote communication system with a third processor and a recording medium for reprocessing, storing and/or outputting data received from the first and/or second radio frequency wireless transceiver in whole or part, and to further output the reprocessed and/or the outputted data.

3. (original) The system of Claim 2, wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol.

4. (original) The system of Claim 2, wherein the at least one second radio frequency wireless transceiver is adapted to transmit the data to the remote internet site in whole or in part via cell towers.

5. (original) The system of Claim 4, wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol.

6. (original) The system of Claim 4, the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is adapted for calculating the data in whole or in part, wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site.

7. (original) The system of Claim 5, the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second

software which is adapted for calculating the data in whole or in part, wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site.

8. (original) The system of Claim 1, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data received by the remote internet site.

9. (original) The system of Claim 1, wherein the first software is adapted to be reprogrammed or modified remotely.

10. (original) The system of Claim 2, wherein the airflow sensor data is processed by the second processor, at least in part using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

11. (original) The system of Claim 4, wherein the airflow sensor data is processed by the second processor, at least in part using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

12. (original) The system of Claim 2, wherein the remote internet site is adapted to retransmit the data to the first radio frequency wireless transceiver on the cell phone, in whole or in part, of i) and ii), or i), ii), and iii) related to the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device.

13. (original) The system of Claim 4, wherein the remote internet site is adapted to retransmit to the first radio frequency wireless transceiver on the cell phone the data, in whole or in part, the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device.
14. (original) The system of Claim 2, wherein the PAP device further comprises an adaptive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.
15. (original) The system of Claim 14, wherein the PAP device further comprises an adaptive predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.
16. (original) The system of Claim 2, wherein the remote communication system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer and/or a second display for review by a clinician to determine the treatment efficacy.
17. (original) The system of Claim 13, wherein the remote communication system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer and/or a second display for review by a clinician to determine the treatment efficacy.
18. (original) The system in Claim 2, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.
19. (original) The system in Claim 10, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.
20. (currently amended) A positive airway pressure (PAP) sleep disorder treatment system comprising:

a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone a treatment efficacy of the subject using a PAP device, the treatment efficacy based in whole or in part on a data based on one or more measure(s) of the treatment efficacy received by the first software, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, and a display;

the PAP device with an enclosure further comprising:

- a blower having an air output within the enclosure,
- an airflow sensor being any type of sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP device and outputting airflow sensor data,
- a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating the one or more measures of the treatment efficacy comprising:
 - i) the data of a severity of the sleep disorder symptoms of the subject,
 - ii) the data of usage of the PAP device by the subject, and/or
 - iii) the index based in whole or in part on either i) or ii) or both i) and ii),
- a mask or a nasal cannula connected to the enclosure, and
- at least one second radio frequency wireless transceiver within the enclosure, the at least one second radio frequency wireless transceiver adapted for transmitting a PAP data based in whole or part on at least one of the one or more measures of treatment efficacy calculated by the second processor;

the non-transitory computer readable medium or a second non-transitory computer readable medium comprising a second software adapted to be executable the first processor on the cell phone or a third processor on a portable, wearable patient data acquisition device comprising a pulse oximeter and an accelerometer the portable, wearable patient data acquisition device adapted to wore on the subject's finger to collect additional physiological data from the subject while using the PAP device for combining with the data collected by the PAP, the second software further

adapted to forward the additional physiological data to combine with the data from the PAP device to determine the treatment efficacy of the subject using the PAP device; and

a remote internet site, the remote internet site adapted for receiving the PAP data or data based on the at least one of the one or more treatment efficacy measures, related to the subject's treatment and the treatment's efficacy in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver, and the additional physiological data collected with the portable, wearable patient acquisition device.

REMARKS

In the Office Action of May 30, 2024, claims 1-20 were rejected. Claim 20 and the specification are herein amended. The Applicants believe these amendments place this application in condition for allowance.

Restriction Requirement

The Applicants thank the Examiner for reversing the restriction requirement as requested by the Applicants.

Obviousness Type Double Patenting

The Applicants submit that the above claims 1-20 are similar in scope to the claims allowed over this very same art in the parent case in U.S. Patent No. 11,872,029 and have voluntarily filed a terminal disclaimer with respect to the parent case.

Claim Rejections – 35 U.S.C. § 103

To provide legal context as well as an analytical framework for the remarks that follow, the Applicant wishes at the outset to respectfully point out that obviousness under 35 U.S.C. § 103(a) is a question of law based on underlying findings of fact, and that the Examiner bears the initial burden of factually supporting any conclusion of obviousness by establishing a *prima facie* case based on the facts. *See* MPEP 2142. Additionally, if the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* To provide the proper factual support for an assertion of *prima facie* obviousness the Examiner must perform the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966). These factual inquiries include (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) determining the level of ordinary skill in the art at the time of the claimed invention. *Graham* also indicates that “secondary considerations” such as commercial success, long-felt but unsolved needs, failure of others and unexpected results may be considered in determining obviousness. Importantly, “the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis.” MPEP 2141(II) (emphasis added).

Against this backdrop it becomes clear that if the Examiner errs in performing any of the *Graham* factual inquiries, the Examiner cannot be deemed to have established a *prima facie* case of obviousness since such a conclusion would be unsupported by the factual foundation required by *Graham*. Examples of the Examiner committing error in performing the *Graham* factual inquiries include, among other things, failure to appreciate the differences between the claimed invention and the prior art (leading to a flawed conclusion under the second *Graham* factor), as well as a failure to determine the level of ordinary skill in the art (resulting in failure based on the third *Graham* factor).

With specific regard to the Examiner's obligation under the third *Graham* factor to determine the level of ordinary skill in the art at the time of the claimed invention, the Applicant would direct particular attention to the requirement that “[a]ny obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill.” *See* MPEP 2141(II)(C) (emphasis added).

In addition, it is important to recognize that merely setting forth what the Examiner believes the level of ordinary skill should be or merely making the blanket assertion that the level of ordinary skill in the pertinent art is set forth in the references is insufficient to meet the Examiner's burden under the third *Graham* factor and 35 U.S.C. § 103(a) if the Examiner is relying on a combination of references to demonstrate obviousness. This is because in addition to providing an “indication of the level of ordinary skill,” *MPEP 2141(II)(C)*, the Examiner must also provide an explanation of how and why the person of ordinary skill in the art at the time of the invention would have deemed it obvious to select and combine various references relied upon by the Examiner in such a way as to render the claimed invention obvious. *See In re Vaidyanathan*, Appeal No. 2009-1404, Fed. Cir., May 19, 2010 (nonprecedential) (faulting both the BPAI and Examiner for failing to provide “any evidentiary support or reasoning for why a person of ordinary skill in the field of the invention would have deemed it obvious to select and combine various steps from different references, in the manner of the applicant” and further noting that *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) “did not remove the need to anchor the analysis [of obviousness] in explanation of how a person of ordinary skill would select and apply the teachings of the references”).

Thus, in order for the Examiner to properly establish a *prima facie* case of obviousness the Examiner must first make the factual inquiries required by *Graham* and, if relying on a

combination of references, must further provide some motivation to combine the references from the perspective of one of ordinary skill in the art. If the Examiner falls short in meeting any of these requirements then the Examiner has failed to establish a *prima facie* case and the applicant is entitled to the patent. See *In re Glaug*, 283 F.3d 1335 at 1338 (Fed. Cir. 2002) (“If the PTO fails to meet this burden [to establish a *prima facie* case], then the applicant is entitled to the patent”). As stated in the United States Patent and Trademark Office’s own rules, “[a] *prima facie* case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable under the *preponderance of evidence*, burden-of-proof standard...” See 37 C.F.R. § 1.56(b)(2)(ii) (emphasis added). Further, refusal to issue the patent in the face of failure to properly establish a *prima facie* case of obviousness or some other proper grounds for rejection places the Examiner and the USPTO in controversion of 35 U.S.C. § 131, which dictates that if after examination “it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor” (emphasis added).

In all of the above, the Applicants wish to emphasize the high bar to which the Examiner is held during the examination process and hereby respectfully request that in the ongoing prosecution of the present application that the Examiner provide explicit and detailed analysis of any grounds of rejection relied upon. See, e.g., *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (“[an obviousness] analysis should be made explicit,” citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

Claims 1, 2, 4, 6-9 and 12-19 were rejected under pre-AIA 35 U.S.C. §103(a) as being unpatentable over Farrell et al., U.S. Pat. Appln. Pub. No. 2007/0161913 (“Farrell”), in view of Geva et al., U.S. Appln. Pub. No. 2007/0155208 (“Geva”). The Applicants traverse.

Farrell teaches a method and apparatus for monitoring *the cardiovascular condition of patients with sleep disordered breathing*. More specifically the Abstract points out:

A method for relating to each other cardiovascular and sleep disordered breathing conditions of a patient. The patients heart rate and/or detailed echocardiogram data is monitored and recorded continuously or periodically together with sleep disordered breathing information on similar timescales. Changes in the patient's heart rate associated with changes in sleep disordered breathing can then be observed. More specifically, positive airway pressure at therapeutic levels for treatment of sleep disordered breathing is applied while events associated with the

treatment of the patients sleep disordered breathing are detected and recorded. At the same time, information concerning the cardiovascular condition of the patient is stored and the stored information concerning the cardiovascular condition of the patient and the recorded events associated with the treatment of the patient's sleep disordered breathing are related to each other.

In fact, the invention in Farrell is described as "a combination of products, services and business pathways for providing care of SDB and CVD co-morbid patients", see Farrell para. [0019].

With respect to the application of Farrell, first the Applicants would point out, the present invention claims " a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone an index of treatment efficacy of the subject using a PAP device, the index based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, and a display".

The Examiner admits this is not taught by Farrell.

The present invention further claims "an airflow sensor being any type of sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data".

Importantly it should be noted that the apparatus in Farrell the Examiner alleges teaches the claim limitations of the present invention with an enclosure further comprising a blower having an air output, an airflow sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data, a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based on either i) or ii) or both i) and ii), and at least one second radio frequency wireless transceiver, the at least one second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor as claimed requires significantly more sensors to make such determinations. Further please importantly note for instance, one skilled in the art would understand the teaching in Farrell does not disclose a airflow sensor internal to the PAP enclosure. Instead Farrell discloses that not only the pressure

4p or flow sensor 4f taught in Farrell teach that mask flow may be measured using these sensors, para. 24, external to the PAP enclosure. Farrell also teaches a plethora of other sensors that are used to understand sleep disordered breathing (SDB) including but not limited to a sense tube 14 (also not internal to the PAP device) used to measure these pressure levels in the mask, a pulse oximeter 20 and respiratory movement sensors 22 such as a chest band to acquire sleep disorder breathing measurements such as for as for example in paras. [0049, 0066, and 0067] of Farrell, see below for those quoted teachings. Farrell simply does not teach internal airflow sensors in the PAP's enclosure. The present invention on the other hand clearly claims a different PAP device than Farrell teaches for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device by the subject. Farrell in para. 28 makes it clear that the apparatus is understood to be the combination of devices and/or computers to accomplish the goals of the invention (obviously including the multitude of sensors outlined in Farrell). Those goals are described in para. 11 of Farrell and are centered around early treatment and diagnosis of cardiovascular disease (CVD) and the ability to solve the lack of understanding of the mechanics of CVD when combined with the comorbidity of SDB.

In addition, the present invention further claims a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based on either i) or ii) or both i) and ii).

Para. [0049] of Farrell teaches "cardiovascular related treatment or diagnostic *devices* may be implemented to query for or ***measure SDB related information for the purpose of detecting SDB*** or otherwise determining a relationship between the cardiovascular condition of the patient and SDB." Emphasis added.

Para. [0066] of Farrell goes on to teach that "***[s]uch data may be combined with other sleep disordered breathing data recorded by the device, for example, an AHI***, if the device is configured to record such data and may be included in the message or warning to the physician or user." Emphasis added. Referring to the other diagnostic devices.

In addition in para. [0067] Farrell teaches "***[s]imilarly, other cardiovascular related treatment or diagnostic device may be configured or programmed to make an assessment for SDB related information of the patient***, for example, a blood pressure monitor, heart rate monitor, oximetry monitor, Holter Monitor or other ECG device or cardiac event monitor,

automated tape measure, automated scale device for weight, treadmill device, blood analyzer device, cardiac output analyzer device. VO2 max data device, peripheral arterial tone device etc." In other words, other devices [and their processors] may be used to make this assessment, and clearly .

Farrell does not describe a second processor within the enclosure, to provide for AHI and SDB measurements but indicates these may be performed on a variety of processors and devices.

Just as importantly, Farrell does not teach the limitations of the present invention of a remote internet site, the remote internet site adapted to receive the data of the severity of the symptoms of the subject, the data of usage and/or the index of the PAP device by the subject both related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver as claimed. First nowhere in Farrell is a remote internet site described, and further in para. 47 of Farrell relied on by the Examiner it is clear that Farrell teaches not only periodically accessing the data but that the data may be accessed *directly* clearly by the physician or clinician getting the apparatus (equipment) returned and looking at the display on the PAP, or alternatively remotely over a secure electronic network to a database – this clearly is not the internet in that no one skilled in the art would describe the internet as a secure electronic network. One skilled in the art rather would interpret this teaching as requiring a pager or some other form of secure connection at the time of the present invention.

Finally Farrell makes clear that the hand held display and control device 12 such as the Palm Pilot, Farrell para. [0012], is used by a physician to remotely monitor, analyze and record, and change remotely the patient's "desired cardiovascular" information, Farrell para. [0028]. The hand held devices can also be programmed to provide the 1) physician with the re-imburement pathways identifying the steps they must take, 2) to provide the physician with a ready references to the appropriate billing codes, and 3) to allow highly skilled physicians "such as a cardiologist" the ability to delegate responsibilities to their staff, Farrell para. [0070].

With respect to Geva, the Abstract in states the following:

Methods and systems that (a) adaptively segment a raw data stream(s) of different type biomedical signals; (b) assign attribute values to each segment; (c) determine an attribute domain based on a point corresponding to said segment attribute value; (d) generate a cluster set(s) in said attribute domain that includes a

combination of points; (e) obtain a probability of order of appearance of each cluster point, according to its property value, (f) use said probability to update each point's property value; (g) repeat (d) through (f) while varying combinations of points in clusters according to their most updated property values and points derived from additional raw data stream adaptive segmentations, (h) associate at least one updated cluster with a normal/abnormal physiological state based on reference clusters in said domain; and (i) obtain the change probability between normal/abnormal physiological states using said probability of the order of appearance.

Clearly Geva describes a "self-adaptive system for the analysis of biomedical signals of a patient". The use of this system with a CPAP is just one of many preferred embodiments of Geva.

The Examiner quotes from Geva in an attempt to show the teaching of the limitations of the software used in the present invention adapted for use with a cellular phone for displaying and for viewing by the subject an index of treatment efficacy to the patient by stating that in Geva the "cellular phone 3002 contains software, the task of which is to carry out a preliminary classification process of the signals, i.e., for identify typical and irregular shapes in these signals, and transmit the latter signals to a cellular base-station 3004, in which a dedicated server 3005 resides." Para. [00294]

First, the Examiner confuses the preferred embodiment shown in FIG. 30 of Geva with another totally different preferred embodiment shown in FIG. 31 of Geva and as such he uses these embodiments interchangeably. In FIG. 30, Geva demonstrates a cellular phone based remote monitoring system, which includes electrodes being placed onto a monitored person. These electrodes are for example ECG and EEG electrodes where the electrodes contain transmitters for transmitting their wireless communication to the cellular phone. It is the cellular phone that does the signal analysis to identify features in these signals, and these signals are then transmitted to a cellular phone base station (not the internet) with a dedicated server which does the full evaluation of the received signals. There is no teaching of a remote internet site as claimed with the specific capabilities as with the present invention.

In fact with the preferred embodiment described in FIG. 30 of Geva it further states "[w]hen a decision is made in server 3005, regarding heartbeat (or heartbeat rate) disorder, and problematic segments (i.e., of the types described above), the corresponding data is transmitted from base-station 3004 to clinician's cellular phone 3006, and displayed on its

display in the form of a graph or otherwise, Geva para. [0294]. Geva goes on to say that "[t]here are several drugs that only qualified physician can authorize their usage. However, a qualified physician is rarely present at a scene wherein a person urgently needs such a drug, and a considerable amount of time may be lost until the person is brought to such qualified physician", Geva para. [0295]. Geva still further goes on to say this allows "paramedical staff to administer drugs to a person while taking orders from a physician that is located far away from the paramedical staff. According to the invention, upon arrival at a scene, wherein a person is found to be in medical critical situation, an, e.g., ambulance staff attaches electrodes to the person, and the relevant data is received by a physician's cellular phone, essentially as described above", see Geva para. [0296].

Geva describes a separate system for monitoring signals of a patient using a CPAP system, in FIG. 31 and its description. FIG. 31 describes a CPAP system where in the patient's mask 3101 that an electrode 3102 is mounted in such a way that it transmits 3105 signals to ASS & Respiratory system 3103 (which is clearly a system separate from the CPAP system), which processes the signal. "Whenever required, system 3103 sends a signal to CPAP system, for causing it to change the pressure of the air that is provided to mask 3101", see Geva para. [0298].

Geva goes on to point out that "[c]onventional CPAP systems...have several drawbacks: (1) apnea events may return whenever the CPAP is used improperly, which is normally the case because conventional CPAP systems are poorly controlled, or not controlled at all, by physiological feedback. Therefore, these systems output a constant continuous pressure, or vary the pressure to coincide with the person's breathing pattern, or start with low pressure, after which the pressure is gradually increased....From technical point of view conventional CPAP systems are inefficient, because they supply, at different periods, air that is not beneficial to the patient". Geva para. [0299]

Clearly, the ASS & Respiratory system 3103 is not contained within the CPAP enclosure in Geva since it sends a signal to the CPAP system, see Geva para. [0298]. Also clearly, the ASS & Respiratory system 3103 utilizes an electrode 3102 to allow it to control the CPAP. Finally, Geva does not teach using a cellular phone to provide an index of therapy efficacy to the patient. Clearly Geva does not use a cellular phone with its ASS & Respiratory system 3103 to control the CPAP or report therapy efficacy in any way to the physician.

Both Farrell and Geva describe electrode sensors not airflow sensors. Both the electrode sensors in Farrell and Geva are external to the PAP enclosure. Neither, Farrell nor Geva teach of a remote internet site as claimed, a first software to display therapy efficacy data of a patient receiving PAP therapy to the patient, a PAP system where an air flow sensor within the PAP enclosure is used along with a second process within the PAP enclosure to determine therapy efficacy data for the patient, nor any other features of the claimed invention.

With respect to Claim 2, Farrell does not teach or disclose wherein the remote internet site is adapted to be hosted on a remote communication system with a third processor and a recording medium for reprocessing, storing and/or outputting data received from the first and/or second radio frequency transceiver in whole or part, and to further output the reprocessed and/or the outputted data as claimed. The Examiner cites to Farrell para. [0042] for this teaching, which one skilled in the art would understand does not teach the limitations of Claim 2. Farrell para. [0042] is a remote *device* not internet site configured to "receive information relating to cardiovascular information for the patient". In addition there is no indicating the *device* not internet site contains a third processor and a recording medium for reprocessing, storing and/or outputting data received from the first and/or second radio frequency transceiver, and further that can output reprocessed and/or outputted data as claim.

With respect to Claim 4, Geva does not teach or disclose wherein the at least one radio frequency wireless transceiver is adapted to transmit the data to the remote internet site in whole or in part via cell towers. The Examiner cites to Geva's ECG/EEG electrode system for checking on a patient heart rate/cardiac issues that transmits ECG data from an emergency responder's cellular phone to a physician's cellular phone so the physician can instruct the emergency responder as to their next steps with respect to providing medication to the patient and monitoring its effects. This has nothing to do with transmitting therapy efficacy data from the PAP in whole or in part over cell towers to a remote internet site where it is accessible to the patient's professional care providers as claimed.

With respect to Claims 6, 7 and 19, Farrell does not teach or disclose a PAP device comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is adapted for calculating the data in whole or in part, wherein the PAP is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site as claimed. The

Examiner cites to Farrell paras. [0028], [0042] and [0047]. First there is no teaching that the PAP device in Farrell contains software, second there is no teaching that the PAP device in Farrell even contains a processor within the enclosure to calculate therapy efficacy, and finally there is no indication that the software in Farrell can be reprogrammed from a remote internet site.

With respect to Claim 8, Farrell does not teach wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on data received at the remote internet site as claimed. Farrell teaches that the PAP may be automatically adjusted by determination of SDB events. However, Farrell teaches that these SBD events may be calculated by auxiliary devices. Farrell does not teach sending data to a remote internet site of therapy efficacy. While Farrell does teach that the treatment program of the patient can be changed remotely in para. 28, it doesn't describe how and certainly could be changed remotely by merely calling the patient and certainly Claim 8 is not inherently adjusted according to its limitations.

With respect to Claim 9, Farrell does not teach or disclose wherein the first software is adapted to be reprogrammed or modified remotely. Farrell does not describe a software to be installed and executed on a cell phone let alone where it can be remotely reprogrammed or modified.

With respect to Claims 12 and 13, Farrell does not teach or disclose wherein the remote internet site is adapted to retransmit the data to the first radio frequency wireless transceiver on the cell phone, in whole or in part, of i) and ii), or i), ii), and iii) related to the data of the subject's treatment and the treatment efficacy calculated and transmitted by the PAP device as claimed. The Examiner cites to Farrell para. [0047] for this teaching. However, Farrell teaches that cardiovascular and SBD information may be periodically remotely transferred to the physician or accessed directly through displays on the device. Farrell does not teach of a remote internet site. Farrell's teaching in para. [0047] further has nothing to do with retransmitting the data to a cell phone of the patient for their visualization.

With respect to Claims 14 and 15, Farrell does not teach or disclose wherein the PAP device further comprises an adaptive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor as claimed. The Examiner claims Farrell para. [0005] establishes this teaching, however, there is no indication that

the teaching represents a extended horizon, adaptive, predictive controller nor that the flow of the blower is adjusted in part on the severity of symptoms calculated by the second processor nor is this inherent in the teachings of Farrell.

With respect to Claims 16 and 17, Farrell does not teach or disclose wherein the remote communication system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer and/or a second display for review by a clinician to determine the treatment efficacy as claimed. The Applicants incorporate their above comments and submit Farrell does not teach of a remote communications station to output efficacy treatment information received by a remote internet site.

With respect to Claims 18 and 19, Farrell does not teach or disclose wherein the second processor of the PAP is configured to distinguish between and calculate both obstructive apneas and central apneas of the subject during a treatment with the PAP device. Given that Farrell treats the device as the Palm Pilot, and various other devices described in the disclosure of Farrell it is unclear whether Farrell makes this calculation and distinction with the PAP device let alone a processor on the PAP device. Certainly this is not inherent from this teaching.

The Farrell reference and the Geva references are non-analogous art to the present invention - particularly given the Examiner's reliance on the preferred embodiment shown in Geva FIG. 30 for a heart rate monitor. Furthermore, in an attempt to explain the purported combination of these references, the Examiner States that "it would be obvious for one of ordinary skill in the art at the time of the present application to modify Farrell's "hand-held display and control devices 12" to be a "cellular phone 3002" as taught by Geva, and use Farrell's software", because it is merely substituting one know portable device for another to yield predictable results. This simply isn't the case. The hand held display and control devices in Farrell are devices for the physicians. The software in Farrell is not software for implementation on a patient's cell phone so the patients can follow the course of their treatment as with the present invention.

Furthermore, since these diverse references do not establish on their face the level of skill of a person in the art then the Examiner must either define such himself or cite to that which defines the level of skill in the art. As such, a person having ordinary skill in the art would find no motivation in any of the references to combine them, and would understand that such combination would fail to teach all the limitations of the present claims. Further, the Examiner

fails to provide any valid reasoning or support for the conclusory statement of what a person of skill in the art would have found obvious at the time the invention was made. Further still, the Examiner has failed to explicitly define or establish the level of ordinary skill in the art, and neither reference adequately provides the level implicitly. Additionally under a proper Graham analysis numerous questions remain unasked, and unanswered, as to what the level of ordinary skill in the art is, and why a person having ordinary skill in the art would find it obvious to combine these references. For example, what are the scope and content of the Farrell and Geva references? What are the similarities between the claimed invention and Farrell and Geva? What are the differences? What exactly is the level of ordinary skill in the art, and why is that pertinent to the problem at hand? Instead, the Examiner relies upon a conclusory statement purporting to explain what a person of ordinary skill in the art would understand, without providing the required factual reasoning behind his flawed conclusion. As noted above, the Examiner has the burden of providing evidence to support his analysis of the Graham factors, but has failed to do so. The Applicants therefore again respectfully request the Examiner provide an explicit statement as to what the level of ordinary skill in the art is, or what in the references points to the level of ordinary skill in the art. The Applicants further suggest that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the Examiner, and requested that he therefore submit an affidavit detailing as specifically as possible the personal knowledge upon which his rejection is based. *See* 37 C.F.R. § 1.104(d) (2). The Examiner noted that it appears the above arguments did not reference any particular claim limitation, but instead merely address the construction of the rejection.

Given the above comments the Applicants urge withdrawal of this rejection.

Claims 3 and 5 were rejected under pre-AIA 35 U.S.C. §103(a) as being unpatentable over Farrell et al., U.S. Pat. Appln. Pub. No. 2007/0161913 (“Farrell”), as applied to claims 2 and 4, respectively above, further in view of Hedner et al., U.S. Pat. Pub. Appln. No. 2008/0257349 (“Hedner”). The Applicants traverse.

The Applicants incorporate by reference their above comments.

Claim 20 was rejected under pre-AIA 35 U.S.C. §103(a) as being unpatentable over Farrell et al., U.S. Pat. Appln. Pub. No. 2007/0161913 ("Farrell"), in view of Lee et al., U.S. Pat. Pub. No. 2005/0061323 ("Lee"), and further in view of Geva et al., U.S. Appln. Pub. No. 2007/0155208 ("Geva"). The Applicants traverse.

The Applicants incorporate by reference their above comments.

CONCLUSION

The Applicants urge issuance of this Application given the above amendments place this Application in condition for allowance.

Respectfully submitted,

8/28/2024
Dated _____

/Brian Kolkowski/

Brian M. Kolkowski
Reg. No.: 36,847
Attorney for the Applicants
Cleveland Medical Devices Inc.
4415 Euclid Ave., Suite 500
Cleveland, Ohio 44103
(216) 649-0376
Fax: (216) 649-0397
E-mail: bkolkowski@clevemed.com