UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ResMed Inc.,
Petitioner,

v.

New York University,
Patent Owner,

Case No. IPR2022-00990

PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 9,533,115

Claims 1, 3-6, 9-12, 14-24, 26-29

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1027	ResMed, "AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1," (1999)

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1028	ResMed, "Auotset T, Optimal Therapy for your OSA Patients," (2000)
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1036	V. Hoffstein, et al., "Treatment of Obstructive Sleep Apnea with Nasal Continuous Positive Airway Pressure," Am. Rev. Respir. Dis. (1992)
1037	R. Berry, et al., "The Use of Auto-Titrating Continuous Positive Airway Pressure Treatment of Adult Obstructive Sleep Apnea," (2002)

I. INTRODUCTION

ResMed Inc. ("ResMed" or "Petitioner") respectfully requests *inter partes* review of claims 1, 3-6, 9-12, 14-24, 26-29 of U.S. Patent No. 9,533,115 (EX1001, "'115 Patent").

The '115 Patent relates to positive airway pressure (PAP) systems to address sleep apnea. In 1981, Professor Colin Sullivan and his colleagues at the University of Sydney were the first to treat sleep apnea using PAP systems, which became "the standard of care" by 2003. EX1001, 1:60-63. Applying air pressure to keep a patient's airway open, these PAP machines improve sleep quality for patients with snoring or other breathing problems during sleep. Patients, however, often struggle to use PAP systems because of the discomfort caused by the high pressure while awake. The '115 Patent seeks to address this problem by automatically increasing the pressure when the patient is asleep and decreasing the pressure when the patient is awake. But this feature was by no means inventive in August 2003—the claimed priority date for the '115 Patent.

By the early 1990s, Professor Sullivan and his colleagues had already developed and tested a self-setting PAP machine that "would aid compliance by allowing a minimal awake pressure." EX1012, 1. Indeed, in 1993, Dr. David Rapoport himself (the inventor of the '115 Patent) "had to compliment [them] (as [h]e did 10 years ago Colin) for being involved in it … a few months ahead of the

rest of us." *Id.*, 3. Consequently, by 2003, Professor Sullivan and his colleagues had already published numerous references disclosing this feature. This prior art includes WO 01/05460 (EX1006, "Sullivan460"), which discloses "a first mode for use when the patient is awake, and a second mode for use when the patient is asleep" to provide "minimally intrusive air and pressure delivery to the patient, and hence is more comfortable." EX1006, 6:30-34. The Examiner did not consider Sullivan460 when allowing the '115 Patent.

Accordingly, ResMed respectfully requests the Board institute review and find all challenged claims of the '115 Patent unpatentable.

II. MANDATORY NOTICES

A. Real Party-in-Interest

The real party-in-interest is ResMed Inc.

B. Related Matters

U.S. Patent Office records indicate that the '115 Patent is assigned to New York University ("PO"), which is currently asserting the '115 Patent in the following concurrent litigation filed on June 2, 2021: *New York University v. ResMed Inc.*, 1:21-cv-00813-JPM (D. Del.).

Petitioner has filed, at substantially the same time that this Petition was filed, petitions for *inter partes* review against related family members U.S. Patent No.

6,988,994, U.S. Patent No. 9,108,009, U.S. Patent No. 9,168,344, U.S. Patent No. 9,427,539, U.S. Patent No. 9,867,955, and U.S. Patent No. 10,384,024.

C. Notice of Counsel and Service Information

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A Power of Attorney is being filed concurrently with this Petition in accordance with 37 C.F.R. § 42.10(b). Petitioner consents to electronic service.

D. Fee for *Inter Partes* Review

The Director is authorized to charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Account No. 60-4184.

E. Certification of Grounds for Standing

Petitioner certifies pursuant to 37 C.F.R. § 42.104(a) that the '115 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the ground identified in this Petition.

III. IDENTIFICATION OF CHALLENGES (37 C.F.R. § 42.104(B))

Ground 1: Claims 1, 3-6, 9-12, 14-18, 20-24, and 26-29 are obvious under 35 U.S.C. § 103 over Sullivan995[1] in view of Sullivan460[2].

[1] U.S. Patent No. 5,245,995 (EX1005, "Sullivan995") is §§ 102 (a), (b), and (e) prior art.

[2] PCT Publication No. WO 01/05460 (EX1006, "Sullivan460") is §§ 102 (a) and (b) prior art.

Ground 2: Claim 19 is obvious under 35 U.S.C. § 103 over Sullivan995 in view of Sullivan460 and Matthews[3].

Ground 3: Claims 1, 3-6, 9-12, 14-24, and 26-29 are obvious under 35 U.S.C. § 103 over Rapoport502[4] in view of Sullivan460.

Ground 4: Claim 19 is obvious under 35 U.S.C. § 103 over Rapoport502 in view of Sullivan460 and Matthews.

IV. BACKGROUND

A. Overview of the Technology

1. PAP Machines

"Obstructive sleep apnea syndrome (OSAS) is a well recognized disorder… [and] one of the most common causes of excessive daytime somnolence." EX1001, 1:31-33. OSAS "is characterized by an intermittent obstruction of [a patient's] upper airway occurring during sleep." *Id.*, 1:37-40. "The obstruction results in a spectrum of respiratory disturbances ranging from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring)." *Id.*, 1:40-44. Because apnea, hypopnea, and heavy snoring produces decreased blood

[3] U.S. Patent No. 7,168,429 (EX1007, "Matthews") is §§ 102 (a) and (e) prior art.

[4] U.S. Patent No. 5,490,502 (EX1008, "Rapoport502") is §§ 102 (a) and (b) prior art.

oxygenation, they "are recognised [] causes of sleep disruption and risk factors in certain types of heart disease." EX1013, 1:27-28, 1:43-45; *see also* Behbehani ¶¶32-33.

Positive airway pressure (PAP) therapy has been "the mainstay of treatment" since Dr. Colin Sullivan, Dr. Michael Berthon-Jones, and their colleagues first applied it to treat OSAS in 1981. EX1001, 1:60-2:10; EX1014, 1 (citing EX1015). "[T]he upper airway during sleep mimics the behavior of a collapsible tube." EX1014, 1. To prevent this collapse, positive airway pressure can oppose the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). *Id.*; *see also* Behbehani ¶¶34-37.

Generally, a prescription and patient training for PAP therapy is "performed in, or directly under, the supervision of the sleep disorders laboratory." *Id.*, 5. After a full night of observation in the laboratory, a physician prescribes a therapeutic pressure for the patient and PAP machine for home use. But, as PAP therapy research developed, the industry began examining a variable approach that "would improve on, and possibly do away with, the one-size-fits-all pressure determination night." EX1012, 1; Behbehani ¶38.

By 1993, Dr. Sullivan, Dr. Berthon-Jones, and their colleagues had developed a self-setting continuous positive airway pressure (CPAP) machine that "adjusts CPAP pressure on a minute-by-minute basis according to the degree of upper airway

obstruction." *Id.*, 1. This approach had several advantages including "aid[ing] compliance by allowing a minimal awake pressure." *Id.* "The major limitation of CPAP therapy relates to discomfort or other factors leading to incomplete compliance with the necessary use of the device." EX1014, 5; EX1016, 1 ("Patients often complain of side effects caused by NCPAP treatment, including nasal congestion, dry mouth, difficulty exhaling, and nocturnal awakenings."). By the mid-1990s, it was well-recognized that lowering the pressure when the patient is awake would increase compliance. *See* EX1012, 4 ("lower pressure … will be more comfortable for the patient, particularly when they are awake, which may result in a higher compliance and better CPAP therapy than may result from a very high pressure"). As Dr. Berthon-Jones explained, "patients feel uncomfortable at high CPAP pressures," and will "object violently to [high pressure] while they are wide awake trying to go to sleep on an ordinary night." *Id.*; *see also* Behbehani ¶¶39-42.

Consequently, automatically adjusting PAP machines became common, particularly those that "while the subject is awake…automatically adjust the degree of assistance to maintaining at least a specified minimum ventilation." EX1017, Abstract. By 2003, machines for delivering PAP therapy were on the market that included one or more sensors and a central processing unit that could detect breathing patterns and increase and decrease pressure as appropriate based on those breathing patterns. Ex. 1035, 2; Ex. 1037, 2, *see also* Behbehani Decl. ¶¶47-48.

2. Sleep and Breathing Patterns

"Sleep is not a simple linear process whereby an individual enters into stage I non-REM sleep at the beginning of the night, progresses through to stage IV sleep, enters REM sleep, and then wakes up in the morning." EX1021, 1. "Rather, repeated episodes of non-REM and REM sleep alternate cyclically through the night." *Id.* "Frequently, a patient awakens during a period of extended sleep for any number of reasons," although "the time require for a patient to fall back to sleep once awakened is less than that initially required." EX1022, 16:39-42. The typical sleep pattern in a young adult is shown below. Behbehani ¶¶49-50.

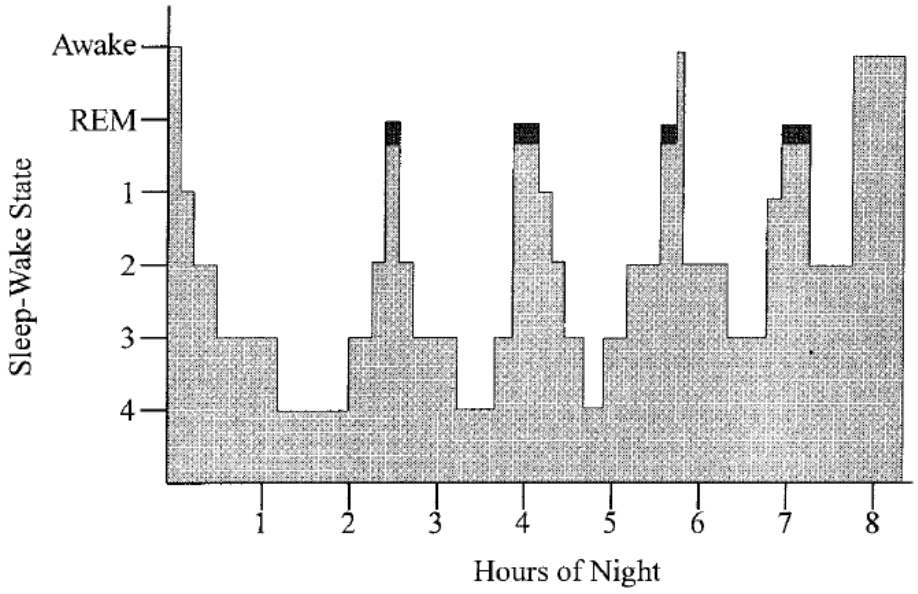


FIG. 2.

EX1021, Fig. 2

At different sleep-wake states, an individual will exhibit different breathing patterns. "[O]verall tidal volume and respiratory rate are stable in non-REM sleep but are characteristically irregular in REM sleep." EX1021, 8. Importantly, "postural muscle tone is highest in wakefulness, decreased in non-REM sleep, and minimal or absent in REM sleep with the exception of occasional muscle twitches." EX1021, 5. Consequently, "during sleep, loss of muscle tone results in variable narrowing of the upper airway during inspiration, with consequent flow limitation." EX1023, 1; EX1021, 5 ("The reduction in pharyngeal muscle tone in sleep leads to upper airway narrowing or even complete collapse in sleep producing snoring and episodes of obstructive sleep apnea (Fig. 6B), which is an absence of effective breathing due to an airway obstruction."); Behbehani ¶¶51-52.

Thus, for decades, breathing patterns have been used to indicate the sleep-wake state of a patient, particularly in the awake state, the non-REM sleep state (stable breathing), REM state (unstable breathing), and disordered sleep state. *See, e.g.*, EX1023, 3 ("Two hundred fifty respiratory cycles were randomly selected. They were observed in different sleep stages [stage 1, stage 2, stage 3/4, and rapid eye movement (REM) sleep] and during wakefulness."); EX1024, 2 ("Dynamic compliance, airflow resistance, and breathing pattern variables were calculated for at least 20 consecutive breaths during one period each of wakefulness, stage 2 sleep, and REM sleep."). These analyzed breathing patterns include those from nocturnal

panic (or as coined in the '994 Patent, "troubled wakefulness"), where an individual "wak[es] from sleep in a state of panic," typically accompanied by "breathing irregularities." EX1025, 1, 10; Behbehani ¶¶53-54.

B. '115 Patent

The '115 Patent describes a well-known system and method for treating OSAS with CPAP therapy by delivering a flow of breathable gas to a patient's airways. EX1001, Abstract, Fig. 1, 2:62-3:20. The patent describes Figure 1 (reproduced below) as illustrating an embodiment of "the present invention," yet admits the components in the figure are conventional and operate in a conventional way.

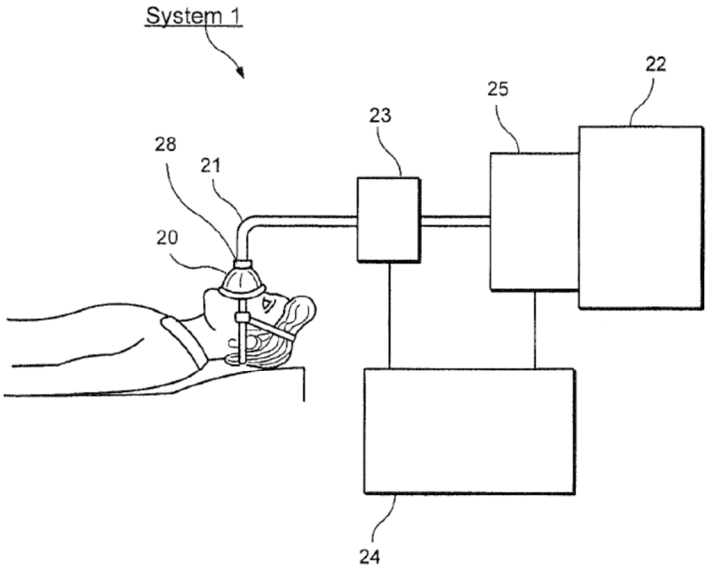
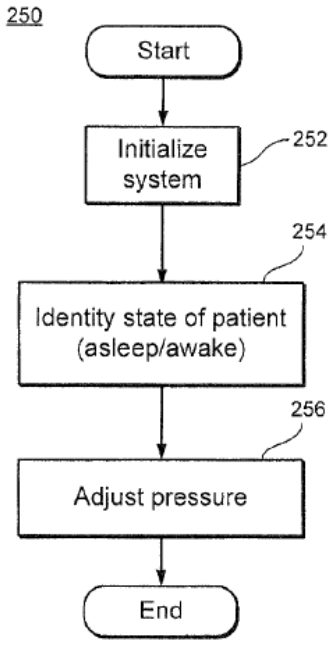


FIG. 1

A patient wears "a mask 20 which is connected via a tube 21 to receive airflow having a particular pressure from a flow generator 22" where the amount of pressure is determined with "any conventional PAP [positive airway pressure] therapy methods." *Id.* 3:54-61. "Conventional flow sensors 23…detect the rate of airflow to/from patent [sic] and/or a pressure supplied to the patent [sic] by the generator 22," and send signals to the processing arrangement 24, which "outputs a signal to a conventional flow control device 25" to control the pressure. *Id.* 3:63-4:4.

The patent attempts to address limitations of "[s]ome conventional PAP systems [that] utilize algorithms which continuously and automatically titrate the applied pressure." *Id.*, 2:50-51. Delivering high pressure airflow to the patient causes discomfort when the patient is awake and is therefore desirable "only when the patient is asleep." *Id.*, 2:35-37. To remedy the patient's discomfort, the patent describes the processing arrangement 24 as "mak[ing] a determination as to a current state of the patient" (*id.*, 4:26-30) and "adjust[ing] the pressure supplied to the patient based on the state." *Id.*, 8:50-52). Specifically, the processing arrangement 24 "reduce[s] the applied pressure" when the patient is awakened and "instruct[s] the flow control device 25 to elevate the pressure" when the patient falls asleep. *Id.*, 5:1-3, 6:11-14. Figure 10 (reproduced below) illustrates this feature.



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C. Challenged Claims

The challenged claims are entitled to an effective filing date of no earlier than August 14, 2003.[5]

The '115 Patent has 30 claims, 4 independent claims and 26 dependent claims. Independent claims 1, 15 and 27 recite nearly identical systems, including:

(1) a flow generator

(2) a flow sensor; and

[5] Petitioner does not concede that any challenged claim is entitled to this priority date. For the purpose of this Petition, it is unnecessary to break the priority chain to a later date.

(3) a hardware processor that:

(i) determines whether to alter pressure, and

(ii) increases pressure when the patient transitions to sleep, where an indication of transition includes a regularity of breathing.

Independent claims 15 and 27 also recite that the indication of transition includes a regular period of obstructions.

Independent claim 21 is a method claim reciting 5 steps:

(1) supplying a flow of breathable gases using a flow generator;

(2) measuring breathing patterns data using a flow sensor;

(3) determining breathing patterns using a processor;

(4) applying no pressure or low pressure when the patient is awake; and

(5) increasing pressure when the patient transitions to sleep.

D. Prosecution History

The applicant obtained allowance of the ’115 Patent by filing a terminal disclaimer to address a double patenting rejection by the Examiner based on the parent of the ’115 Patent—U.S. Patent No. 9,427,539. EX1002, 136-138. The Examiner issued a notice of allowance with no other rejections. *Id.*, 153-155.

V. OVERVIEW OF THE PRIOR ART

A. Sullivan995 (EX1005)

Sullivan995 discloses each limitation of the independent claims except it does not expressly disclose determining the patient is in an asleep state. Sullivan995 discloses a CPAP system that delivers a controllable airway pressure to a patient's airway passages. EX1005, Fig. 3, Abstract, 1:32-36, 2:15-19, 9:57-58. A CPAP nose mask covers the patient's nose and creates an "enclosed airway" that forms a flow path for breathable gas to be inhaled and exhaled by the patient. *Id.*, Figs. 1A, 1B, 8:47-59.

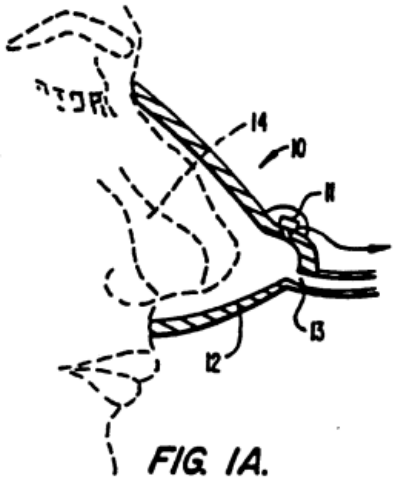


FIG. 1A.

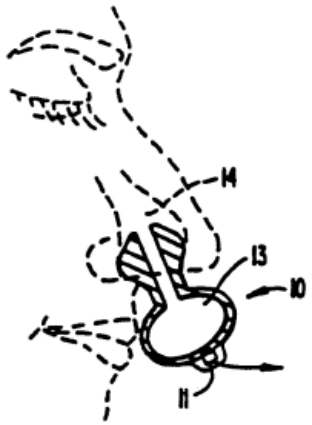


FIG. 1B.

Positioned within that enclosed airway is a microphone 11 (a differential pressure sensor) that senses various flow characteristics of the breathable gas, including exhaled air flow volume, inhaled air flow volume, breathing rate, breathing patterns, exhaled air flow rate, inhaled air flow rate, and/or indicators of snoring. *Id.*, 17:4-

12, 12:54-66, 18:47-66, 18:27-31, 4:28-45, 6:54-66, 13:10-33, 13:65-14:16, 14:45-67, Abstract.

As depicted in Figure 3, an amplifier/filter/processor unit 26 and speed control unit 23 are connected to the microphone 11 and receive and process the flow data obtained from the microphone 11. *Id.*, 10:3-6, 11:55-62.

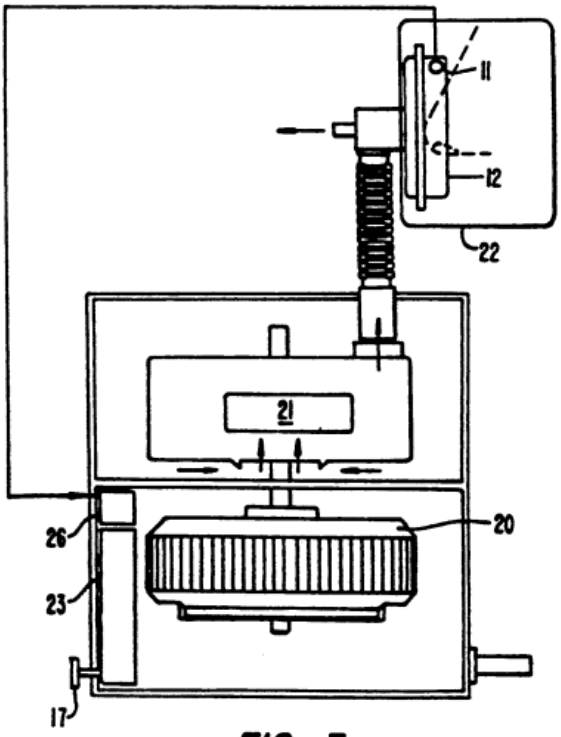


FIG. 3

Figure 12 of Sullivan995 also depicts a computing system that receives and processes various breathing pattern data (e.g., snore, flow rate, volume, breathing rate) from an amplifier/filter/processor combination that provide the data based on a signal from the pressure sensor. *Id.*, 17:6-12.

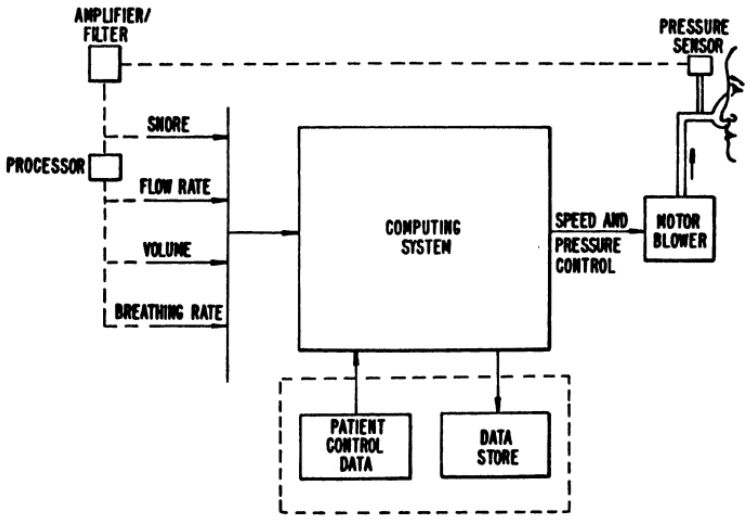


FIG. 12.

The output of the amplifier/filter/processor and speed control unit in Figure 3, and of the computing system in Figure 12 is a control signal that signals whether to "increase[] the speed of the electronic motor 20," which "increases the blower speed," thereby "increas[ing] the output air pressure of the blower 21." *Id.*, 9:58-64, 10:6-12, 10:55-58.

For example, when a snore is detected by the microphone 11, the processor 26 increases the blower speed, which increases the air pressure in the flow path of breathable gas delivered to the patient. *Id.*, 10:40-46, 10:10-12.

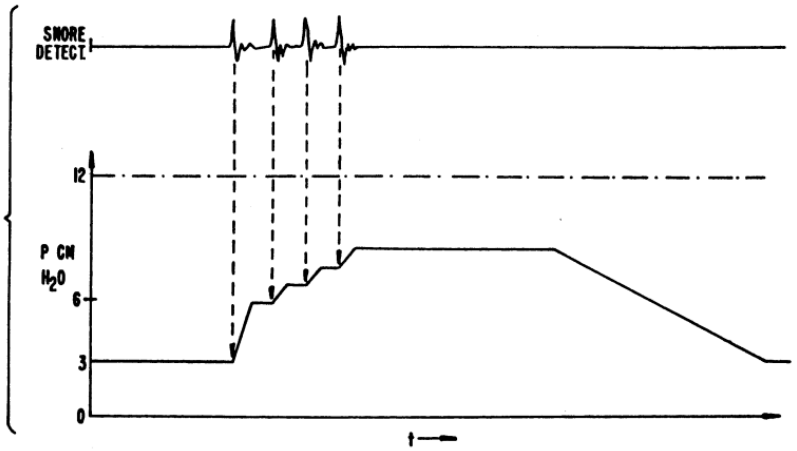


FIG. 13.

Figure 13 of Sulllivan995 depicts an incremental pressure increase for each detected snore and pressure decrease in the absence of snores. *Id.*, 18:6-18, 10:31-37, 15:18-24. Because the patient only snores when asleep, Sullivan995 only increases the pressure when the patient has fallen asleep. Similarly, Sullivan995 also describes increasing treatment pressure upon detection of other abnormal breathing patterns that occur while in a sleep state, such as apneas or hypopneas. *Id.*, 6:40-66, 15:34-64, 16:17-22, 16:51-59. Specifically, if the patient's air flow rate drops below a baseline, Sullivan995 increases the pressure. *Id.*, 6:41-57, Figs. 10-12.

B. Sullivan460 (EX1006)

Sullivan460 discloses the asleep state limitation not expressly disclosed in Sullivan995. Sullivan460 shares the same inventor as Sullivan995 and incorporates Sullivan995 by reference, stating Sullivan995 describes ResMed's AutoSet product: "the flow rate measurement means and the treatment means may be constructed

together as part of one apparatus, such as the AutoSet product from ResMed described in US Patent No 5245995 [Sullivan995], the contents of which are incorporated herein by reference." EX1006, 6:22-29.

Like Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep. *Id.*, 6:17-29, 7:3-12, 10:9-33, 11:10-13, cls. 22-28, 43-46, Figs. 2-4. Sullivan460 also discloses that the system selects between an "awake" mode and an "asleep" mode, and applies high pressure in the "asleep" mode and low pressure in the "awake" mode. *Id.*, 6:30-7:22, 14:7-36.

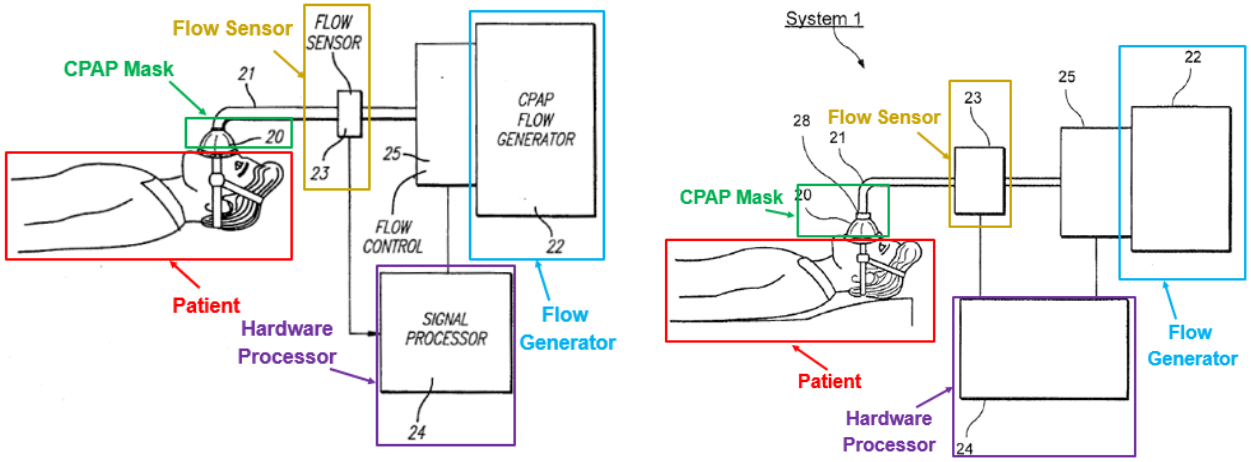
Specifically, Sullivan460 selects between an "awake" mode and an "asleep" mode, and applies high pressure in the "asleep" mode and low pressure in the "awake" mode. *Id.* When the flow rate increases above a certain level, the controller determines the patient is in an awake state and switches the CPAP system into a first mode in which a reduced air pressure is applied to the patient's airways. *Id.*, 10:21-25, 14:7-36. Likewise, when interruptions 10 are detected in the patient's breathing patterns, or a reduced average airflow indicates the patient is asleep, Sullivan460's controller 100 determines the patient is in an asleep state and switches the CPAP system into a second mode in which an increased air pressure is applied to the patient's airways, to eliminate the patient's upper airway flow limitation. *Id.*, 10:3-16.

C. Matthews (EX1007)

Matthews is a PAP system that "optimizes the pressure delivered to the patient to treat … disordered breathing while minimizing the delivered pressure for patient comfort." EX1007, Abstract. "When a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic," (*Id.*, 21:37-39), and Matthews "interrupt[s] the auto-CPAP controller if the patient's breathing pattern becomes too variable." *Id.*, 21:39-41.

D. Rapoport502 (EX1008)

As discussed, the '115 Patent uses conventional hardware components for PAP machines. *See* Section IV.B. Indeed, Rapoport502 (published nearly a decade before the '115 Patent by the same inventor) discloses nearly identical hardware, including a conventional flow generator, flow sensor, and processor. EX1008, Fig. 9.



Rapoport502, Fig. 9 **'115 Patent, Fig. 1**

The processor determines whether a flow limitation (obstruction) has occurred based on the data from the flow sensors, and "the pressure setting is raised, lowered or maintained" accordingly. EX1008, Abstract.

VI. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") in 2003 would have had at least a bachelor's degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience. Additional experience could substitute for less education, and additional education could likewise substitute for less experience. Behbehani Decl. ¶86.

This Petition does not turn on this precise definition, and the challenged claims would be unpatentable from the perspective of any reasonable person of ordinary skill in the art at the relevant time. Behbehani Decl. ¶87.

VII. CLAIM CONSTRUCTION

The Board construes the claims "using the same claim construction standard that would be used" in district courts. 37 C.F.R. §42.100(b). This Petition establishes the prior art meets each of the claim limitations under any reasonable construction.[6]

[6] Petitioner reserves the right to argue alternative constructions in other proceedings, including that the claims are indefinite where such a defense is available.

A. "troubled wakefulness" (claim 19)

This term to a POSITA in the context of the '024 Patent means "state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable." Behbehani Decl. ¶90. This term is not an industry standard term and was coined in the '024 Patent. *Id.,* ¶91. As such, the construction is derived directly from the specification, which describes "troubled wakefulness" as a state "in which the breathing pattern is characterized by irregularity variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient's airflow tracing indicating that the patient is awake and either anxious or uncomfortable." EX1001, 4:59-64, Fig. 7. The specification further confirms that "Patient's discomfort during wakefulness is often associated with changes from a regular breathing pattern … and frequently occur when the patient is distressed by the PAP system." *Id.*, 2:40-47.

VIII. GROUND 1: SULLIVAN995 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1, 3-6, 9-12, 14-18, 20-24, 26-29

A. Motivation to Combine

It would have been obvious to a POSITA to modify the hardware processor in Sullivan995 to determine that an indication of the patient's breathing patterns representative of a change from an awake state to an asleep state has occurred, and in response to that determination, increases a pressure supplied to the patient, as taught in Sullivan460. Behbehani Decl. ¶93. A POSITA would have been motivated

to implement this modification to cause Sullivan995's CPAP system to apply a lower pressure or higher pressure upon detecting the patient's awake state or asleep state, respectively.

First, a POSITA would have recognized the advantages of using the same CPAP system to treat both sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught in Sullivan460. EX1006, 7:3-12; Behbehani Decl. ¶95. An upper airway flow limitation characterized by at least one decrease in upper airway inspiratory flow rate, followed by at least one increase in flow rate, is indicative of pre-eclampsia (and not observed in typical snoring), and could be treated with the modified system. *See* EX1006, Fig. 1, 6:22-29, 9:31-10:6; Behbehani Decl. ¶96. Women with sleep apnea are at higher risk for pre-eclampsia, and each of pre-eclampsia, snoring, and apnea involve hypertension, high blood pressure, and obstructions during sleep. *See* EX1006, 1:5-8, 4:33-34, 5:29-6:2. The modification to Sullivan995's CPAP system would allow for detection of inaudible low frequency vibrations, including those associated with pre-eclampsia, so that the patient may be treated with high pressure. *See* EX1006, 2:19-22, 4:33-34, 6:3-34, 9:31-10:6. Sullivan995 even suggests that such modifications would be desirable, as its CPAP system is not limited to treating apnea and snoring, but also apply to other upper airway disorders, which the POSITA would have understood to include vibrations related to pre-eclampsia. EX1005, 1:14-31, 4:36-45.

Second, a POSITA would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment. The modified CPAP system would apply a low pressure upon wake-up, adding to patient comfort and decreasing the likelihood the patient will remove the mask due to uncomfortably high pressure. Sullivan995 strongly suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period). EX1005, 10:13-46, 14:45-64. Moreover, as Sullivan995 explains, prior to Sullivan995, therapy pressure was often delivered at levels higher than necessary for substantial periods, causing discomfort (4:20-24), and Sullivan995 partially solves the problem by reducing the pressure at the beginning of therapy, when the patient connects herself to the CPAP system. Behbehani Decl. ¶100.

B. Reasonable Expectation of Success

The POSITA would have had a reasonable expectation of success in making the modification to Sullivan995. Behbehani Decl. ¶101.

First, Sullivan460 explicitly recognizes the combination of Sullivan995 with the teachings in Sullivan460. Behbehani Decl. ¶102. Sullivan460 expressly states that Sullivan995 may be modified to include features of Sullivan460, such as "sens[ing] an upper airway flow limitation characterised by at least one decrease in

upper airway inspiratory flow rate followed by at least one increase in flow rate." EX1006, 6:22-29. As Sullivan460 discloses in further embodiments, a sleep sensor detects "reduced average airflow in the patient's upper airway" to detect the sleep state and a higher average airflow to detect the awake state, and switching between different pressure delivery depending on which state is determined. *Id.*, 6:22-7:22, cls. 22-28, 43-47. Therefore, a POSITA, upon reading the teachings of Sullivan995 and Sullivan460, would have had a reasonable expectation of success in performing this modification because Sullivan460 already describes Sullivan995 as being used to sense flow limitations, and Sullivan460 further explains that flow data may be used to determine an awake/sleep state. Behbehani Decl. ¶104.

Second, Sullivan995 and Sullivan460 are analogous art. Behbehani Decl. ¶105. Both references describe CPAP systems that include flow sensors and flow generators. Like Sullivan995, Sullivan460 discloses a flow rate measurement means 70 (Fig. 2) located in the flow path for detecting the rate at which the patient breathes. EX1006, 10:10-12. The flow rate measurement means or sensor 70 detects "interruptions" 10 (Fig 1) within the patient's breathing cycle. The "interruptions" are superimposed at the peak of each cycle and indicate upper airway flow limitation in the patient. *Id.*, 9:31-34. Also similar to Sullivan995, when Sullivan460 senses interruptions 10 in the patient's "breathing patterns" or determines the patient is asleep, a controller 100 activates a switch 110, which activates the nCPAP apparatus

90 to supply air to the patient 30 at a higher pressure, to ameliorate or eliminate the patient's upper airway flow limitation. *Id.*, 10:3-16.

Given the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.

C. Independent Claims 1, 15, 27

1. Preamble

To the extent the preamble is limiting, Sullivan995 discloses a CPAP system[7] (*a positive airway pressure system*) which "deliver[s] appropriate airway pressure" to the patient's airway passages (*for delivery of a flow of breathable gas*). EX1005, Fig. 3, Abstract, 1:33-36, 2:15-19, 9:57-58. As a POSITA would have understood, CPAP delivers "positive" airway pressure relative to atmospheric pressure (*a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure*). Behbehani Decl. ¶108.

[7] Sullivan995 refers to the same CPAP system of components as a CPAP apparatus, device, system, and unit. EX1005, 2:15-19, 9:57-66, 11:44-47, 11:55-58, 14:30-32, 14:38-48, 14:61-64, 16:60-63. Petitioner refers to each of these as the CPAP system.

Sullivan995's CPAP system includes a nose mask 12 "fluidly sealable to the [patient's] nasal air passages" and is "for delivery of air to the patient's nasal passages" (*a flow of breathable gas…delivered to an entrance of a patient's airways*). EX1005, cl. 6, 5:12-34, 10:67-11:4, 11:23-43. This is *in order to assist in treating a sleeping disorder in a patient* by providing air pressure at a certain level to "prevent the onset of apnea" (*sleeping disorder*) in the patient. *Id.*, 10:31-35, 1:20-31, 11:15-20; *see also* 1:32-48 (CPAP is used to "treat[] the occurrence of obstructive sleep apnea" and "is effective in treating central and mixed apnea"); Behbehani Decl. ¶110.

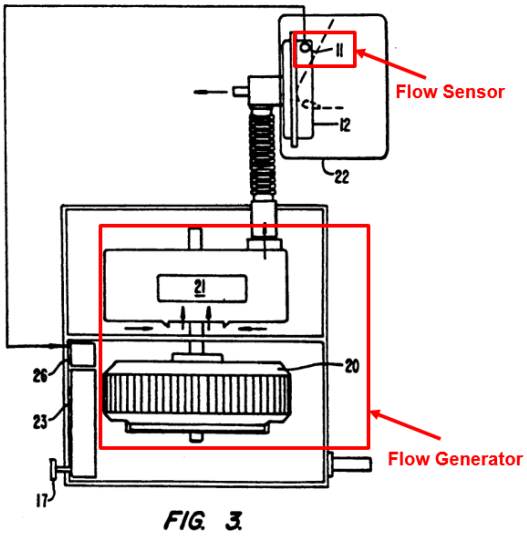
2. 1[a]/15[a]/27[a]: flow generator

Sullivan995 discloses this limitation. Behbehani Decl. ¶111. Sullivan995's CPAP system includes a motor 20 with a variable speed that drives a blower 21 (*flow generator*). EX1005, 9:57-64. The blower 21 *generates a flow of breathable gases to be supplied to a patient* by providing pressurized air to the patient. *Id.*, 9:60-64 ("[A]n increase in motor speed also increases the blower speed which in turn increases the output air pressure of the blower 21."); Behbehani Decl. ¶111.

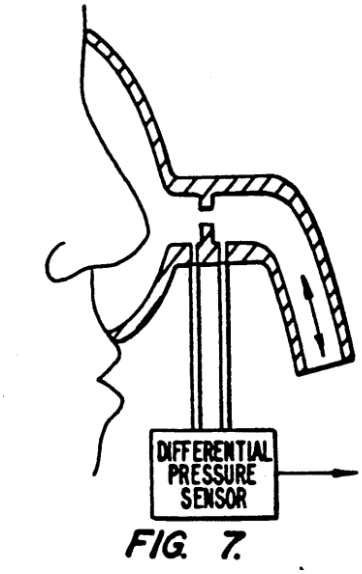
3. 1[b]/15[b]/27[b]: flow sensor

Sullivan995's CPAP system includes a differential pressure sensor, e.g., microphone 11 (*flow sensor*). EX1005, Figs. 3, 7, 9:64-66 (the snoring detection means 22 is a pressure detection means and microphone 11 is a ***differential pressure***

sensor."); Behbehani Decl. ¶112. The microphone "consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the ***rate of breathing***, inhaled air flow or inhaled ***air flow rate***." *Id.*, 3:21-30 (emphasis added); *see also id.*, Abstract.



EX1005, Fig. 3



EX1005, Fig. 7

The microphone 11 (*flow sensor*) performs a "form of measurement" (*measuring data*) by "detecting snoring sounds" and "other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate" (*indicative of the patient's breathing patterns*). EX1005, 3:21-33; *see also id.*, 11:5-20, 15:56-64 (describing, with reference to Figure 3, detecting "a snore, or snore patterns or abnormal breathing pattern"); Behbehani Decl. ¶114.

Shown below side-by-side, Figures 2A and 9 depict the patient's breathing patterns (*indicative of the patient's breathing patterns*) measured by the microphone 11 without and with, respectively, delivery of air flow from the CPAP system.

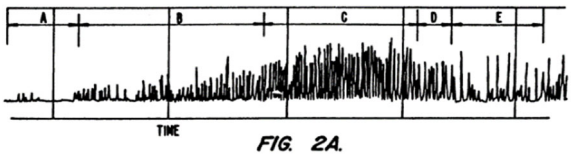


FIG. 2A.

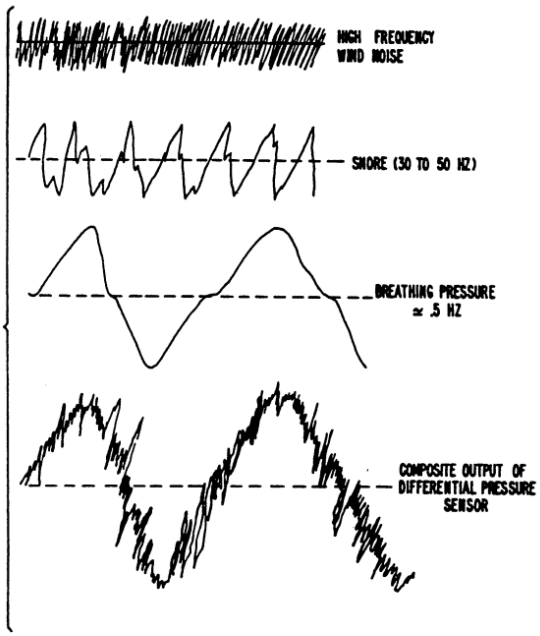


FIG. 9.

EX1005, Fig. 2A **EX1005, Fig. 9**

Further, Sullivan995's sensors are "continuously sensing the patient'breathing [sic] patterns" including "an exhaled air flow volume, an inhaled air flow volume, breathing rate, an exhaled air flow rate, or an inhaled air flow rate." EX1005, 18:27-31, 18:50-53. Each of these metrics relates to the gas flow delivered to the patient and is *data indicative of the patient's breathing patterns.* Behbehani Decl. ¶117.

4. 1[c1]/15[c1]/27[c1]: hardware processor

The combination of an amplifier/filter/processor unit 26[8] and speed control unit 23[9] (depicted in Figure 3 and described in part as the computing system in Figure 12) is *a hardware processor.* The microphone 11 (*flow sensor*) provides its measured data to processor unit 26, which means the *hardware processor receives the measured data corresponding to the flow of breathing gases from the flow sensor*. EX1005, 10:3-6 ("[e]lectrical impulses are fed from said microphone 11 to an amplifier/filter/processor unit 26"); *see also id.,* 10:37-66 (describing the processor unit 26 receiving an electronic signal from the microphone 11 and detecting snores), 11:55-62.

[8] Sullivan995 refers to the same processor unit 26 as an amplifier/filter/processor unit 26, amplifier/filter/processor 26, and processor 26. EX1005, 10:40-46, 10:55-58, 11:58-62, 14:50-55, 15:27-33, 15:59-64. For ease of reference, Petitioner refers to each as processor unit 26.

[9] Sullivan995 refers to the same speed control unit 23 as an electronic speed control unit 23, a speed control unit 23, a feedback speed controller 23, and a speed controller 23. EX1005, 9:59-60, 10:14-16, 11:63-64, 14:40-41, 15:1-3. For ease of reference, Petitioner refers to each as the speed control unit 23.

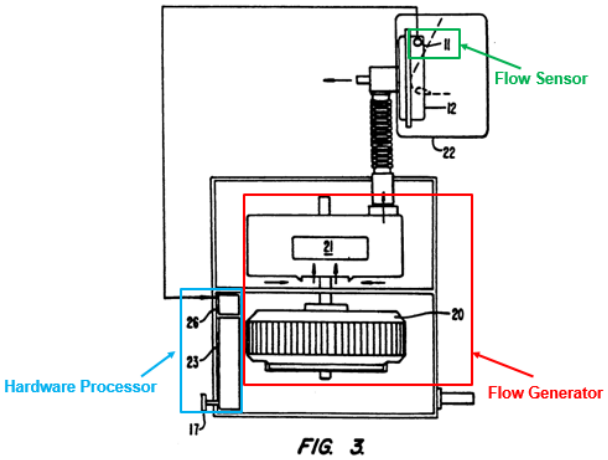


FIG. 3

Therefore, the processor unit 26 is part of a hardware processor that receives the measured data corresponding to the flow of breathable gases from the flow sensor.

Moreover, as Sullivan995's CPAP system in Figure 4 (and therefore in Figure 3 as well) includes the feedback speed controller 23 illustrated in Figure 12 in block form and includes a computing system. *Id.*, 17:3-6

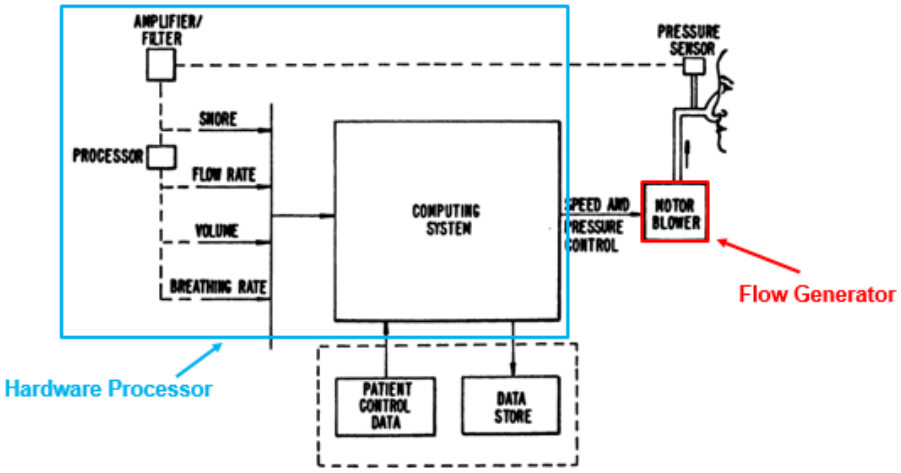


FIG. 12

Sullivan995 states "[t]he electrical signals from the pressure transducer are amplified and filtered to provide pressure waves of the desired frequencies indicative of

snoring and breathing [that are] further processed to generate signals indicative of flow rate, volume and breathing rate." EX1005, 17:6-12 (referencing Figure 12). These amplification, filtering, and processing steps would have been performed by the processor unit 26 (included in the *hardware processor*). Accordingly, Sullivan995's *hardware processor receives the measured data corresponding to the flow of breathable gases from the flow sensor*.

Sullivan995 further describes various *breathing patterns* for the patient. Referencing Figure 4, Sullivan995's *hardware processor* includes the processor unit 26, "which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern." EX1005, 11:55-62. In generating this control signal, the processor unit 26 (included in the *hardware processor*) therefore *analyzes the data for an indication of the patient's breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.

The computing system (including processing unit 26 and speed controller 23) "analyses and records signals from the pressure sensor," and analyzes "the sound and breathing patterns" to record "indexes such as the number of apneic episodes, the number of hypopneas, their duration, etc." *Id.*, 12:67-13:8 (referencing Figure 12). Therefore, the computing system is part of the *hardware processor* and *analyzes the data for the indication of the patient's breathing patterns.*

5. 1[c2]/15[c2]/27[c2]: determines whether to alter pressure

In response to the electrical signal generated when snoring sounds occur, a motor speed control means "increases the speed of the electronic motor 20," which "increases the blower speed," thereby "increas[ing] the output air pressure of the blower 21" (*flow generator*). *Id.*, 9:58-64, 10:6-12; *see also id.*, 10:40-46 (describing the processor 26 "increasing the blower speed in incremental steps each time a snore is detected by the microphone 11"); *id.* 10:55-58 (explaining that the increase in motor speed is done "via the processor 26"); *id.* 10:10-12 ("the output pressure of the CPAP unit increases in response to detection of snoring"). The motor speed control means in Sullivan995 is the same as the speed control unit 23 because it controls the speed of the motor and is therefore part of the *hardware processor*. *Id.*, 9:58-64; Behbehani Decl. ¶126. Similarly, "in the absence of an electronic signal from the microphone 11," meaning the patient is not snoring, Sullivan995's processor unit 26 "achieve[s]" a decrease in CPAP pressure by "continuously gradually reducing the blower speed over a period of time." EX1005, 10:37-46; Behbehani Decl. ¶126. Increasing or decreasing the blower speed results is an *alter[ing] [of] the pressure supplied by* the blower (*flow generator*) *to the airway of the patient* and is based on "when snoring sounds occur." Behbehani Decl. ¶¶126-127.

The determination to increase the output air pressure in Sullivan995 is made when "respond[ing] to a snore, or a snore ***pattern***," and is therefore made *based, at least in part, on the indication of the patient's breathing patterns.* EX1005, 10:55-58. Moreover, by describing the speed control unit using the signal from the processor unit 26 to determine whether to increase or decrease the pressure, Sullivan995's *hardware processor* performs the *determin[ation] [of] whether to alter the pressure supplied by the flow generator to the airway of the patient*. *See also*, *supra*, Sections VIII.C.3 and VIII.C.4 (describing *the determined breathing patterns of the patient*).

6. 1[c3]/15[c4]/27[c4]: increases pressure when patient transitions to sleep

Sullivan995 discloses the hardware processor automatically increases the pressure supplied by the flow generator to the airway of the patient when the hardware processor determines that an indication of a change to an asleep state has occurred. Behbehani Decl. ¶139. Specifically, "the output pressure of the CPAP unit increases in response to detection of snoring." *Id*., 10:10-16, Fig. 3; *see also* 14:17-20, Fig. 13. Also, the pressure is decreased "if an extended period of snore free breathing occurs" by "automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected." *Id*., 10:31-46; *see also id*. 10:47-61 (the CPAP pressure increases "via the processor 26," in response to the "snore, or snore pattern."), Fig. 13.

Although the patient is awake when he "connects himself to the CPAP unit" when "[t]he CPAP pressure is initially at a minimum operating value" (*id.*, 10:47-58, 12:35-40), Sullivan995 does not explicitly disclose that the increase occurs *when the hardware processor determines that an indication of a change from an awake state* has occurred. Behbehani Decl. ¶144. However, this limitation would have been obvious from Sullivan995 in view of Sullivan460. *Id*.

a) Teachings of Sullivan460 on determining awake state

Sullivan460 incorporates Sullivan995 by reference and refers to Sullivan995 as describing a "flow rate measurement means and [a] treatment means [as being] constructed together as part of one apparatus." EX1006, 6:22-29. Like Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep. *Id.*, 6:17-29, 7:3-12, 10:9-33, 11:10-12, cls. 22-28, 43-46, and Figs. 2-4; Behbehani Decl. ¶76.

Sullivan460 discloses *determin[ing] that the patient is in an awake state* by describing embodiments in which "a sleep sensor [] senses whether or not the patient is asleep" by determining "when there is a reduced average airflow in the patient's upper airway." EX1006, 7:3-7, 7:10-12, 7:17-19; Behbehani Decl. ¶¶76, 103. According to Sullivan460, "a switching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second

mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46. Because Sullivan460 only enters the higher-pressure second mode when the patient is asleep, Sullivan460 discloses *increasing the pressure supplied to the airway of the patient when the hardware processor determines that an indication of a change from an awake state*. Behbehani Decl. ¶¶76, 145.

b) Motivation to Combine and Reasonable Expectation of Success

See Section XIII.A and XIII.B.

7. 1[c4]/15[c3]/27[c3]: indication of transition includes a regularity of breathing or a regular period of obstructions

Sullivan995 discloses *an indication of transition includes a regular period of obstructions*, by detecting a "sequence of snores" and generating a signal so that the speed control unit 23 increases the speed of the fan motor and the output pressure is increased. EX1005, 10:13-28, 14:17-20, 14:56-15:15, Fig. 13. Sullivan995 expressly illustrates that four (4) snores (*a regular period of obstructions*) are detected. *Id.*, Fig. 13, 8:36-44, 14:48-15:15. Sullivan995 also discloses detection of a *regular period of obstructions* as "abnormal breathing patterns" (*id.*, 18:9-15, 18:35-42), detecting a "snore pattern" or "snore patterns" (*id.* 10:55-58, 7:1-8, 6:20-24), detecting "breathing patterns" (*id.* 14:61-64), detecting "snoring patterns" and "apneas" (*id.* 4:28-45), detecting "patterns" indicating snoring or breathing disorders

(*id.* 7:29-41), indexing detected "hypopneas" and "the number of apneic episodes" (*id.* 12:67-13:9), and depicting multiple closely spaced obstructions (*id,* Figs. 2A and 9). Moreover, Sullivan995 describes determining "flow rate," "breathing rate," "time interval," and "volume" data to detect sleep apnea or hypopneas (*see, e.g., id.,* parts D and E of Fig. 2A). *Id.*, Fig. 12, 6:40-68, 15:34-64, 17:3-27. The purpose in Sullivan995 of detecting these *regular periods of obstructions* is to increase pressure to treat sleeping disorders. Behbehani Decl. ¶154. Therefore, detecting any of these *regular periods of obstructions* in Sullivan995 means that *the patient's breathing pattern* indicates a *change* or *transition from an awake state to an asleep state*.

Sullivan995 also discloses a *regularity of breathing* in an asleep state. Specifically, Sullivan995 describes that the waveforms in Figure 2A depict various patient states (identified by the letters across the top of the chart) with normal breathing (part A), soft to moderate snoring (part B), constant loud snoring (part C), a pre-apneic pattern indicative of obstructive hypopnea (part D), and periods of silence punctuated by snoring, which is indicative of sleep apnea (part E). EX1005, 9:16-32; Behbehani Decl. ¶149. Part A of Figure 2A shows "normal breathing" and is therefore *a regularity of breathing*. Behbehani Decl. ¶149. This is consistent with the knowledge of a POSITA that *a regularity of breathing* can be used to indicate that the patient has transitioned to a sleep state. *See* Ex. 1034 at 5:34-35 ("When a

patient is asleep his respiration becomes stable, this is used to detect the instant when the patient falls asleep."). Behbehani Decl. ¶150.

To the extent that Sullivan995 does not expressly state that this *regularity of breathing* is an *indication* of a *change* or *transition from an awake state to an asleep state*, this would have been obvious from Sullivan995 in view of Sullivan460. Behbehani Decl. ¶155.

a) Teachings of Sullivan460 on transition between awake and asleep

In Sullivan460, a switching means receives a signal from the sleep sensor, and "causes the treatment means to switch from one treatment mode to the other treatment mode." EX1006, Cl. 27. In other words, the treatment mode is switched "upon determining whether the patient is asleep or awake, including a *transition[] between an awake state and an asleep state*. *Id.*, Cls. 44-45.

Sullivan460's sleep sensor also detects *a regular period of obstructions*. The flow rate measurement means 70 detects multiple "interruptions," which Fig. 1 depicts, and are a *regular period of obstructions*. EX1006, 10:12-16. Sullivan460's claim 1 specifies a sensor that detects at least one interruption cycle and claim 2 specifies that detection of a plurality of interruption cycles, either of which are detectable only with a *regular period of obstructions*. *See also id.*, claims 22, 25-27. Further, Sullivan460 detects the occurrence of "two or more interruption cycles" (which are regularly-spaced obstructions) in the upper inspiratory flow rate and the

treatment means treats the airway limitation on the detection of said at least two interruption cycles. *Id.*, 3:20-23. Thus, the sleep detection technique in Sullivan460 (which may also be used in the modified device as explained above) is also based on detection of a *regular period of obstructions*, and means that *the patient has transitioned between an awake state and to an asleep state*.

b) Motivation to Combine and Reasonable Expectation of Success

See Sections VIII.A and VIII.B. It would have been further obvious to use the teachings of Sullivan995 or Sullivan460's detection of a *combination of obstructions* to *determine[] the patient has transitioned between an awake state and an asleep state*, as taught by Sullivan460's "sleep sensor" and "switching means." A POSITA would have recognized that verifying a sleep state would have avoided false positives that would occur when only a single obstruction is detected. As indicated in figures of both Sullivan995 and Sullivan460 (EX1005, Figs. 2, 9, 13; EX1006, Fig. 1), such obstructions (e.g., snores, apneas, hypopneas, or other flow limitations) typically occur in groups during sleep. Behbehani Decl. ¶163. Both Sullivan995 and Sullivan460 suggest using multiple obstructions as a trigger for treatment. EX1006, 3:20-23 (triggering treatment upon detection of "at least two or more interruption cycles [obstructions] in the upper inspiratory flow rate", which is an indication of sleep); EX1005, 10:13-30, 14:65-15:17 (triggering treatment upon detection of a "sequence of snores"); Behbehani Decl. ¶164. Therefore, the modification is a

combination of known prior art elements according to known methods and known techniques to yield predictable results, involves a simple substitution of one known element for another to obtain predictable results, and involves use of a known technique to improve a similar device in the same way. Behbehani Decl. ¶165

D. Dependent Claims 3-6, 9-12, 14, 16-18, 20, 28-29[10]

1. Claim 3, 17: regular period are three or more obstructions

Sullivan995 alone discloses this limitation or renders this limitation obvious in view of Sullivan460 or the knowledge of a POSITA Each of Sullivan995 and Sullivan460 expressly discloses that four (4) snores are detected. *Id.*, Figs. 2A (section E), 13, 8:36-44, 9:16-32, 14:48-15:15; EX1006 Fig. 1, 3:1-3, 3:20-23, 5:7-9, 9:31-36, cls. 2, 33; Behbehani Decl. ¶¶76, 166-167. Further, as the POSITA would have understood, obstructions tend to occur in a cyclical, periodic pattern. *See* EX1005, Figs. 2A, 9, 13; Ex. 1006, Fig. 1. Detecting only two obstructions is insufficient to determine whether there is a cyclical or periodic pattern, because there is only a single spacing between two obstructions. This means that detection of only two obstructions provides no insight into whether the obstructions are cyclical or periodic. Behbehani Decl. ¶¶168-71.

[10] All dependent claims incorporate the analysis of the claims from which they depend.

2. Claim 4: obstructions are apneas

Sullivan995 alone discloses this limitation, or renders obvious this limitation in view the knowledge of a POSITA. The *obstructions* in Sullivan995 referenced in 1[c4]/15[c3]/27[c3] include *apneas*. *See* EX1005, 4:28-45 (detecting "apneas"), 13:4-9 (indexing "the number of apneic episodes); *see* Section VIII.C.7. Specifically, the *obstructions* in Fig. 2A are "indicative of sleep apnea, with periods of airway occlusion which terminate with one or more loud breathing sounds followed by further occlusions" and are therefore *apneas. Id.*, 13:55-59; Behbehani Decl. ¶172.

To the extent that Sullivan995 does not expressly disclose this limitation, this would have been obvious to a POSITA. Apneas indicate a sleep state and should be treated with increased pressure, as taught by Sullivan995. Behbehani Decl. ¶173. Snores do not always precede apneas, such that detecting apneas would have been particularly desirable. Behbehani Decl. ¶173.

3. Claim 5: obstructions are hypopneas.

Sullivan995 alone discloses this limitation, or renders obvious this limitation in view the knowledge of a POSITA. The *obstructions* in Sullivan995 referenced in in 1[c4]/15[c3]/27[c3] include *hypopneas*. EX1005, 13:4-9 (indexing detected "hypopneas"). Specifically, the *obstructions* in Section D of Fig. 2A are "indicative of obstructive hypopnea, a condition in which the breath-by-breath intensity

decreases progressively, and then increases" and "is a 'pre-apneic' pattern." *Id.*, 13:46-54; *see also id.*, 13:4-8 and 14:17-32 (describing the computing system of Fig. 13 as diagnosing "hypopnea" and processing "the number of hypopneas"). Moreover, Sullivan995 describes determining "flow rate," "breathing rate," "time interval," and "volume" data to detect sleep apnea or hypopneas (*see, e.g.,* parts D and E of Fig. 2A). *Id.*, Fig. 12, 6:40-68, 15:34-64, 17:3-27; Behbehani Decl. ¶174.

To the extent that Sullivan995 does not expressly disclose this limitation, this would have been obvious to a POSITA. Hypopneas indicate a sleep state and should be treated with increased pressure, as taught by Sullivan995. Behbehani Decl. ¶175. Snores do not always precede hypopneas, such that detecting hypopneas would have been particularly desirable. Behbehani Decl. ¶176.

4. Claim 6: obstructions are elevated upper airway resistance

Sullivan995 discloses this limitation. The *obstructions* in Sullivan995 referenced in 1[c4]/15[c3]/27[c3] include *elevated upper airway resistance*. Behbehani Decl. ¶177. Sullivan995 states "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-16; *see also id.,* 10:47-61 (the CPAP pressure increases "via the processor 26," which is part of the *hardware processor*, in response to the "snore, or snore pattern"); *see* Section VIII.C.4 (Ground 1, 1[c1]/15[c1]/27[c1]. Moreover, Figure 13 depicts how the

Figure 12 computing system (included in the *hardware processor*) increases pressure based on the snoring detection. *Id.*, 14:17-20.

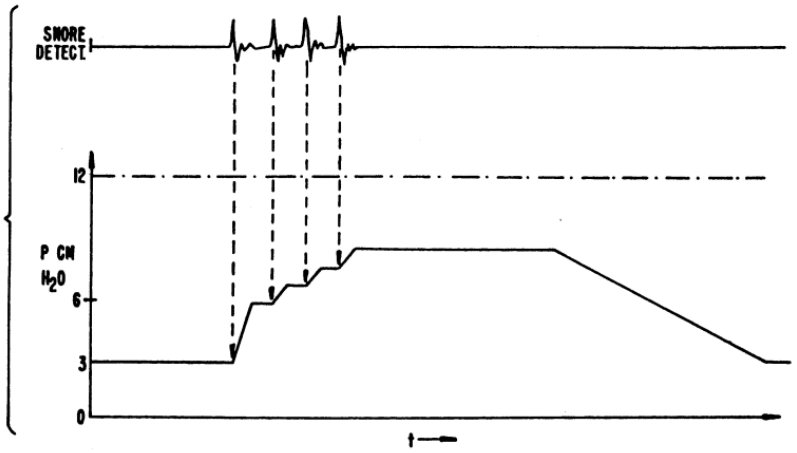


FIG. 13.

As Sullivan995 describes, "snoring is caused by vibration of the soft palate [and] is therefore indicative of an unstable airway and… is a warning signal of the imminence of upper airway occlusion." *Id.*, 10:16-21, 15:3-8. Moreover, a "decreasing intensity of the snoring occurs when the upper airway is almost, but not entirely, sucked closed by strong inspiratory efforts." *Id.*, 9:21-26, 13:50-53. As would have understood from Sullivan995's teachings of snoring as indicating an "unstable airway," an "imminence of upper airway occlusion," and a nearly closed "upper airway," the snoring in Sullivan995 is *an elevated upper airway resistance.* Behbehani Decl. ¶181.

5. Claim 9, 18: when breathing pattern indicative of elevated upper airway resistance, hardware processor increases pressure

Sullivan995 alone discloses this limitation, or renders this limitation obvious in view of Sullivan460. As discussed in 1[c3]/15[c4]/27[c4], the *hardware processor* in Sullivan995 *increase the pressure applied to the airway of the patient* when the *hardware processor* determines that the patient's breathing patterns are indicative of a regular period of obstruction. *See* Section VIII.C.6 (Ground 2, 1[c3]/15[c4]/27[c4]. Further, as discussed for claim 6, these obstructions include *breathing patterns indicative of the patient experiencing an elevated upper airway resistance*. *See* Section VIII.D.4 (Ground 1, Claim 6); Behbehani Decl. ¶¶182-84.

To the extent Sullivan995 does not explicitly describe this limitation, it would have been obvious from Sullivan995 in view of Sullivan460. Specifically, the CPAP system in Sullivan460, upon detecting the patient is asleep "when there is a reduced average airflow in the patient's upper airway" (*the patient is experiencing an elevated upper airway resistance*), increases the CPAP pressure (*increases the pressure applied to the airway of the patient*). *See* EX1006, 6:17-29, 7:3-19, 10:9-33, 11:10-12, claims 22-28, 43-46, Figs. 2-4, *see also* EX1005, Fig. 8.; Behbehani Decl. ¶185.

6. Claim 10: when breathing pattern indicative of hypopnea event, hardware processor increases pressure

Sullivan995 discloses this limitation. As discussed in 1[c3]/15[c4]/27[c4], the *hardware processor* in Sullivan995 *increases the pressure applied to the airway of the patient* when the *hardware processor* determines that the patient's breathing patterns are indicative of a regular period of obstruction. *See* Section VIII.C.6 (Ground 1, 1[c3]/15[c4]/27[c4]). Further, as discussed for claims 6, these obstructions include *hypopneas*. *See* Section VIII.D.3 (Ground 1, Claim 6).

7. Claim 11: when breathing pattern indicative of apnea event, hardware processor increases pressure

Sullivan995 discloses this limitation. As discussed in 1[c3]/15[c4]/27[c4], the *hardware processor* in Sullivan995 *increases the pressure applied to the airway of the patient* when the *hardware processor* determines that the patient's breathing patterns are indicative of a regular period of obstruction. *See* Section VIII.C.6 (Ground 1, 1[c3]/15[c4]/27[c4]). Further, as discussed for claim 4, these obstructions include *apneas*. *See* Section VIII.D.2 (Ground 1, Claim 4).

8. Claim 12: when breathing pattern indicative of transition to awake from asleep, hardware processor lowers pressure

Sullivan995 in view of Sullivan460 renders obvious this limitation. Sullivan995's processor unit 26 and/or the speed control unit 23 (parts of the *hardware processor*) reduces pressure "if an extended period of snore free breathing occurs" by "automatically reducing the CPAP pressure at a gradual rate as long as

snoring is not detected." EX1005, 10:31-46; *see* Section VIII.C.4 (Ground 1, 1[c1]/15[c1]/27[c1]).

Although Sullivan995 does not explicitly disclose *a breathing pattern indication of a transition to an awake state*, this is taught by Sullivan460. Sullivan460 discloses a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19; *see* Section VIII.C.6 (Ground 1, 1[c3]/15[c4]/27[c4]). "[S]witching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. *Id.*, 6:30-7:12, cls. 22-28, 43-46. This means that *when* the patient *has transitioned to an awake state from an asleep state*, Sullivan460 *lowers the pressure applied to the airway of the patient*. Behbehani Decl. ¶189.

It would have been obvious to a POSITA to modify Sullivan995 so that when the hardware processor in Sullivan995 determines that the patient has transitioned to an awake state from an asleep state, the hardware processor lowers the pressure applied to the airway of the patient, as taught in Sullivan460, for the same reasons as explained for 1[c3]/15[c4]/27[c4]. *See* Section VIII.C.6 (Ground 1, 1[c3]/15[c4]/27[c4]). As the POSITA would have recognized from the teachings of

Sullivan995 and Sullivan460, a lower pressure is desirable when the patient is awake because it ensures the patient is comfortable and reduces the likelihood the patient will remove the mask. Behbehani Decl. ¶190.

9. Claim 14, 20, 28: pressure increased using ramp procedure

As Sullivan995 depicts in Figure 13, *the pressure is increased* incrementally with each snore that is detected. EX1005, 14:17-20. The incremental increase depicted in Figure 13 is *using a ramp system* because the incremental increases occur at different times, upon detection of each snore. Behbehani Decl. ¶191; *see also* EX1005, Figs. 4-6, 11:55-12:26 (discussing "a ramp generator" and "obtain[ing] a ramp voltage" to gradually increase the motor speed over time).

10. Claim 16: obstructions are apneas, hypopneas, or elevated airway resistance

As discussed for claims 4-6, Sullivan995 discloses this limitation. *See* Sections VIII.D.2-4.

11. Claim 29: hardware processor further increases pressure when one or more obstructions detected

Sullivan995 discloses increasing pressure when periods of airway occlusion terminate with one or more loud breathing sounds followed by further occlusions." *Id.*, 9:16-32; Behbehani Decl. ¶193.

E. Independent Claim 21

1. Preamble

To the extent limiting, Sullivan995 discloses the preamble. *See* Section VIII.C.1 (Ground 1, 1[preamble]/15[preamble]/27[preamble]); Behbehani Decl. ¶194.

2. 21[a]: supplying breathable gases using a flow generator to produce positive pressure

Sullivan995 discloses this limitation. *See* Sections VIII.C.1 (Ground 1, 1[preamble]/15[preamble]/27[preamble]) and VIII.C.2 (Ground 1, 1[a]/15[a]/27[a]); Behbehani Decl. ¶195.

3. 21[b]: measuring data using a sensor

Sullivan995 discloses this limitation. *See* Section VIII.C.2 (Ground 1, 1[b]/15[b]/27[b]); Behbehani Decl. ¶196.

4. 21[c]: determining using hardware processor breathing patterns including a regularity of breathing or regular period indicative of asleep state

Sullivan995 discloses this limitation. *See* Sections VIII.C.4 (Ground 1, 1[c1]/15[c1]/27[c1]) and VIII.C.7 (Ground 1, 1[c4]/15[c3]/27[c3]); Behbehani Decl. ¶197.

5. 21[d]: applying no pressure or low pressure when patient awake

As explained above, Sullivan995's *hardware processor* reduces pressure "if an extended period of snore free breathing occurs" by "automatically reducing the

CPAP pressure at a gradual rate as long as snoring is not detected." EX1005, 10:31-46; *see* Sections VIII.C.6 and VIII.D.8. This means the blower 21 (*flow generator*) in Sullivan995 *appl[ies] a lower pressure* in the absence of snoring.

To the extent that Sullivan995 does not expressly disclose this limitation, it would have been obvious in view of Sullivan460 for the reasons explained above. *See* Sections VIII.C.6 and VIII.D.8.

6. 21[e]: increasing applied pressure when patient has transitioned from awake to asleep

Sullivan995 discloses this limitation. *See* Section VIII.C.6 (Ground 1, 1[c3]/15[c4]/27[c4]); Behbehani Decl. ¶201.

F. Dependent Claims 22-24, 26

1. Claim 22: obstructions are apneas, hypopneas, or elevated airway resistance

As discussed for claims 4-6, Sullivan995 discloses this limitation. *See* Sections VIII.D.2-4; Behbehani Decl. ¶202.

2. Claim 23: regular period are comprises at least three obstructions

Sullivan995 discloses this limitation. *See* Section VIII.D.1 (Ground 1, Claims 3, 17); Behbehani Decl. ¶203.

3. Claim 24: increasing pressure when patient is asleep and obstruction is detected

Sullivan995 discloses this limitation. Figure 13 of Sullivan995 incrementally increases pressure for each of four periodic snores. EX1005, 14:17-20; *see* Section VIII.C.6 (Ground 1, 1[c3]/15[c4]/27[c4]).

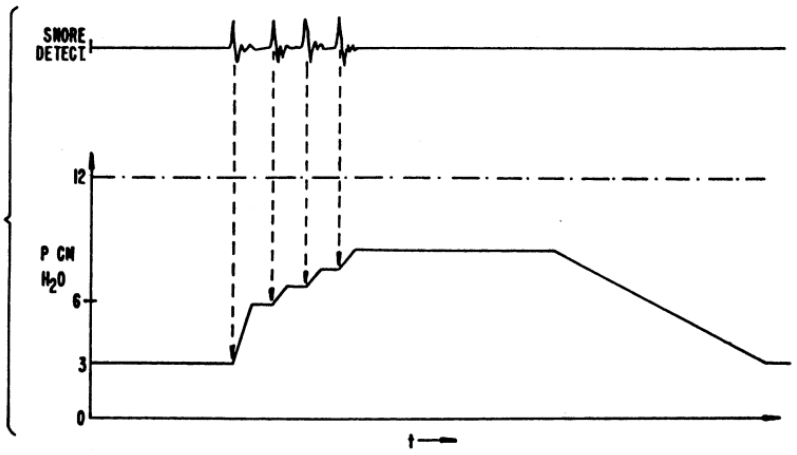


FIG. 13.

Upon detection of the first snore, the pressure is increased from 3 to 6 cm H_20, and upon detection of each of the second, third, and fourth snores, the pressure is increased incrementally by 1 cm H_20. *Id.*, 10:13-30, 10:40-46, 10:47-61, 11:8-20; Fig. 13. Thus, Sullivan995 discloses *increasing* from a *previously provided pressure* (e.g., 6, 7, or 8 cm H_20, which were provided upon detection of the first, second, or third snores respectively, and any of which is a *previously provided pressure*) *supplied to a patient when the patient is in an asleep state and an obstruction* (snore) *is detected*. Behbehani Decl. ¶¶205-206.

4. Claim 26: pressure increased using ramp procedure

Sullivan995 discloses this limitation. *See* Section VIII.D.9 (Ground 1, Claims 14, 20, 28).

IX. GROUND 2: SULLIVAN995 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIM 19

A. Motivation to Combine

It would have been obvious to a POSITA to modify the system of Sullivan995 and Sullivan460 in view of Matthews so that the *hardware processor* in Sullivan995 determines when the patient transitions to a *troubled wakefulness state*. A POSITA would have recognized the advantages of detecting different awake states, including a distressed state (*troubled wakefulness*) in which the patient has breathing that becomes "erratic," as taught in Matthews. Behbehani Decl. ¶209. The modification to Sullivan995 and Sullivan460's CPAP system would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort. Sullivan995 is already concerned with the patient's comfort, and already discloses it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible. EX1005, 2:31-39.

B. A POSITA Would Have Had a Reasonable Expectation of Success

Sullivan995, Sullivan460, and Matthews are analogous art and describe CPAP systems with flow sensors and generators. Like Sullivan995 and Sullivan460, Matthews discloses a "flow sensor 46 that measures a rate at which the breathing

gas flows within patient circuit 34." EX1007, 7:11-14. The data from the flow sensor are monitored to control the pressure. *Id.*, 8:54-9:15. Sullivan460 discloses lowering the pressure upon detecting an awake state (EX1006, 6:30-7:19, cls. 22-28, 43-46), and the POSITA would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient. Behbehani Decl. ¶211.

The modification is a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way. Behbehani Decl. ¶212.

C. Dependent Claim 19

This limitation would have been obvious in further view of Matthews. Behbehani Decl. ¶213. Similar to Sullivan995 and Sullivan460, Matthews discloses a pressure support system to treat disordered breathing by optimizing the pressure delivered to the patient. EX1007, Abstract. In Matthews, the pressure support system monitors the flow of gas in a patient's airway and controls the pressure of the flow based on the gas flow. *Id.*, cl. 1. Matthews also discloses an *awake state is a troubled wakefulness state* by describing "[w]hen a patient is awake…or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable." *Id.*, 21:34-44; *see also id.* 21:63-22:1. Matthews's description of erratic breathing when the

patient is awake and in distress is consistent with the '115 Patent's description of *troubled wakefulness* as "awake and anxious or distressed" (EX1001, 4:54-55 with "erratic" breathing (*id.* 4:54-66).

X. GROUND 3: RAPOPORT502 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1, 3-6, 9-12, 14-18, 20-24, 26-29

A. Motivation to Combine

It would have been obvious to a POSITA to modify the hardware processor in Rapoport502 to determine that an indication of the patient's breathing patterns representative of a change from an awake state to an asleep state has occurred, and in response to that determination, increases a pressure supplied to the patient, as taught in Sullivan460. Behbehani Decl. ¶219.

First, the POSITA would have recognized that the advantages of using the same PAP system to treat both sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught in Sullivan460. EX1006, 7:3-12; Behbehani Decl. ¶221. An upper airway flow limitation characterized by at least one decrease in upper airway inspiratory flow rate, followed by at least one increase in flow rate, is indicative of pre-eclampsia (and not observed in typical snoring), and could be treated with the modified system. *See id.*, Fig. 1, 6:22-29, 9:31-10:7; Behbehani Decl. ¶222. Women with sleep apnea are at higher risk for pre-eclampsia, and each of pre-eclampsia, snoring, and apnea involve hypertension, high blood pressure, and obstructions during sleep. *See id.*, 1:5-8, 4:33-34, 5:29-6:2. The modification to

Rapoport502's PAP system would allow for detection of inaudible low frequency vibrations, including those associated with pre-eclampsia, so that the patient may be treated with high pressure. *See id.*, 2:19-22, 4:33-34, 6:3-7:2, 9:31-10:6. Rapoport502 even suggests that such modifications would be desirable, as it acknowledges that obstructive sleep apnea syndrome (OSAS) is not limited to any particular disorder, but rather "is associated with all conditions in which there is anatomic or functional narrowing of the patient's upper airway, and is characterized by an intermittent obstruction of the upper airway occurring during sleep," which the POSITA would have understood to include vibrations related to pre-eclampsia. EX1008, 1:29-33; Behbehani Decl. ¶224.

Second, a POSITA would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment. Behbehani Decl. ¶225. Both Dr. Rapoport and Dr. Sullivan recognized that a major limitation with CPAP therapy was noncompliance due to discomfort. EX1014, 5. Both also recognized that lowering pressure when the patient is in an awake state could improve compliance. EX1015, 5. As explained above, the modified CPAP system would apply a low pressure whenever the sensor detects that the patient is awake. Reverting to a low pressure upon wake-up would add to patient

comfort and decrease the likelihood the patient will remove the mask due to uncomfortably high pressure. Behbehani Decl. ¶225.

B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in making the modification to Rapoport502. Behbehani Decl. ¶226.

First, Rapoport502 and Sullivan460 are analogous art. Behbehani Decl. ¶227. Both references describe CPAP systems that include flow sensors and flow generators. Like Rapoport502, Sullivan460 discloses a flow rate measurement means 70 (Figure 2) located in the flow path for detecting the rate at which the patient breathes. EX1006, 10:10-12. The flow rate measurement means or sensor 70 detects "interruptions" 10 (Fig 1) within the patient's breathing cycle. The "interruptions" are superimposed at the peak of each cycle and indicate upper airway flow limitation in the patient. *Id.*, 9:31-34. Also similar to Rapoport502, when Sullivan460 senses interruptions 10 in the patient's "breathing patterns" or determines the patient is asleep, a controller 100 activates a switch 110, which activates the nCPAP apparatus 90 to supply air to the patient 30 at a higher pressure, to ameliorate or eliminate the patient's upper airway flow limitation. *Id.*, 10:3-16.

Second, Dr. Rapoport was familiar with Dr. Sullivan's work, and acknowledged that Dr. Sullivan and his colleagues were "a few months ahead of the rest of us." EX1012, 3; Behbehani Decl. ¶228. A POSITA improving CPAP

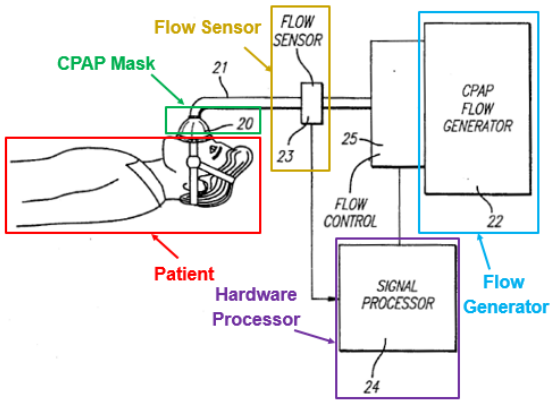
machines would have naturally looked at the pioneer in CPAP machines for algorithms for different air pressure settings that could improve compliance. *Id*. In fact, Dr. Rapoport repeatedly cites to Dr. Sullivan's work in his own published papers. EX1014, 7-8.

Given that the proposed modification involves a simple change in a programming algorithm, it is nothing more than a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way. Behbehani Decl. ¶229.

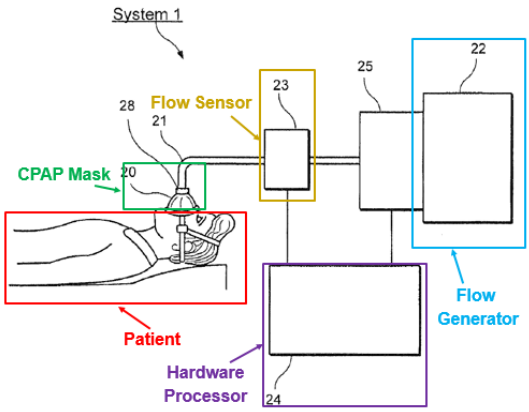
C. Independent Claims 1, 15, 27

1. Preamble

To the extent the preamble is limiting, Rapoport502 discloses a continuous *positive airway pressure system* in the same manner as the '115 Patent. *See* EX1008, 1:16-21 (describing the CPAP system is "for adjusting the positive airway pressure of a patient to an optimum value in the treatment of obstructive sleep apnea."), Fig. 9; Behbehani Decl. ¶230. A POSITA would have understood that the air supplied to the patient is at *a positive treatment pressure with respect to ambient air pressure*. Behbehani Decl. ¶108.



Rapoport502, Fig. 9 (annotated)



'115 Patent, Fig. 1 (annotated)

2. 1[a]/15[a]/27[a]

Rapoport502's CPAP system includes a *flow generator* 22 (blue), which *supplies* air to the *patient* (red) via a patient worn CPAP mask 20 (green). EX1008, 5:51-53 ("a CPAP mask 20 is connected via tube 21 to receive air from a CPAP flow generator 22"), Fig. 9; *see also* Section X.C.1.

3. 1[b]/15[b]/27[b]

Rapoport502's "conventional flow sensor 23…provide[s] an electric output signal corresponding to the waveform of the airflow in the tube 21. This signal is applied to a signal processor 24, which detects the existence in the waveforms of conditions that indicate flow limitation." *Id.*, 5:56-61. The conventional flow sensor 23 is a *flow sensor measuring data* corresponding to the "air through the flow sensor," and the measured data is in the form of a waveform *indicative of the patient's breathing patterns* analyzed by the processor 24. *Id.*, 3:23-36; Behbehani

Decl. ¶233. Further, Figures 1-5 illustrate exemplary waveforms of airflow between the patient and the flow generator at various pressures that the sensor 23 would output, and shows the gradual onset of a sleep disorder with the change of the patient's breathing patterns. EX1008, 4:47-5:50, Figs. 1-5; Behbehani Decl. ¶233.

4. 1[c1]/15[c1]/27[c1]

Rapoport502's CPAP system includes a signal processor 24 (purple) corresponding to a *hardware processor*. *See* Section X.C.1. The '115 Patent illustrates the processing arrangement 24 as a "black box" but does not disclose what constitutes the processing arrangement 24. *See id.* (illustrating '115 patent Fig. 1); Behbehani Decl. ¶234. Rapoport502 illustrates the signal processor 24 connected in the same manner, and further uses the term "signal processor" which had a well-understood structure akin to an arrangement of elements that performs processing. Behbehani Decl. ¶234.

Both the '115 Patent and Rapoport502 describe the processing arrangement 24 and signal processor 24, respectively, functionally in terms of the information that it receives and analyzes, and the control of pressure in the CPAP system based on that analysis. *Compare* EX1001, 3:67-4:9, 4:15-34, 5:42-6:1-54 *with* EX1008, 5:56-63 (describing waveforms received and analyzed and the output to control other components of the CPAP system), EX1008, 6:1-55 (disclosing the decision flow of the signal processor 24 in relation to Fig. 10); Behbehani Decl. ¶235.

Further, the signal processor 24 receives the measured data corresponding to the flow of breathable gases from the flow sensor.

The processor 24 *analyzes the data to determine the patient's breathing patterns* by "detect[ing] the existence in the waveforms [supplied by the flow generator 23] of conditions that indicate flow limitation" of the patient. EX1008, 5:59-61; Behbehani Decl. ¶237. Figures 1-5 illustrate exemplary breathing pattern waveforms that are analyzed by the signal processor 24 and depict the gradual onset of a sleep disorder with the change of the patient's breathing patterns. EX1008, 4:47-5:50, Figs. 1-5; Behbehani Decl. ¶237.

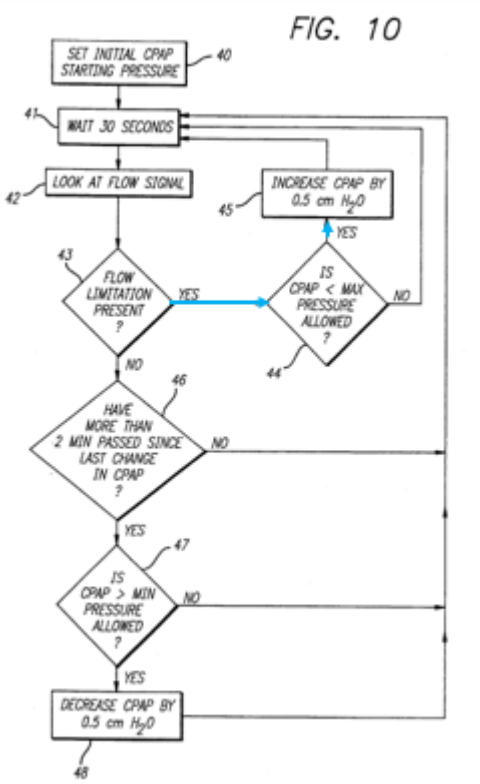
5. 1[c2]/15[c2]/27[c2]

Further to the analysis *on the determined breathing patterns of the patient* (*see* Section X.C.4 (Ground 3, 1[c1]/15[c1]/27[c1]), "[t]he signal processor 24 outputs a signal to a conventional flow control 25 for controlling the pressure applied by the flow generator to the tube 21." EX1008, 5:61-63. Correspondingly, Figure 10 describes processor 24's decision flow *whether to alter a pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient*. Behbehani Decl. ¶238. For example, "[i]f it is determined [by the processor 24] that flow limitation has occurred (step 43) and that the CPAP pressure is less than the maximum allowed (step 44), then the CPAP

pressure is increased" with the control signal output of the processor 24. EX1008, 6:9-13; Behbehani Decl. ¶238.

6. 1[c3]/15[c4]/27[c4]

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani Decl. ¶¶239-44. Rapoport502 discloses the hardware processor automatically increases the pressure supplied by the flow generator to the airway of the patient when the hardware processor determines that an indication of a change to an asleep state has occurred by determining a flow limitation state for the patient, as seen by Figure 10. EX1008, Fig. 10 (reproduced below); Behbehani Decl. ¶240.



EX1008, Fig. 10 (annotated)

Figure 10 represents Rapoport502's "automatic adjustment mode" effectuated by the *hardware processor* in which "several input parameters…are used in the determination of the action to be taken" including applying a delay before onset of a pressure increase to the patient. EX1008, 7:6-8. As seen in (blue), the signal processor 24 determines "YES" for a flow limitation (Step 43), it applies *a pressure increase to the patient* of 0.5 cm H_20 (Step 45) provided that the current CPAP pressure is less than the maximum allowed (Step 44). *Id.*, 6:9-13; Behbehani Decl. ¶241.

While Rapoport502 increases pressure in response to flow limitations, Rapoport502 does not expressly disclose a pressure increase in response to *determin[ing] that the patient is in an awake state*. However, this limitation would have been obvious in view of Sullivan460. Behbehani Decl. ¶244.

a) Teachings of Sullivan460

Sullivan460 discloses *determin[ing] that the patient is in an awake state*. *See* Section VIII.C.6.a) (Ground 1, 1[c3]/15[c4]/27[c4], discussing Sullivan460).

b) Motivation to Combine and Reasonable Expectation of Success

See Section X.A and X.B (Ground 3, Motivation to Combine and Reasonable Expectation of Success).

7. 1[c4]/15[c3]/27[c3]

Rapoport502 renders obvious this limitation in view of Sullivan460. Behbehani Decl. ¶247. Rapoport502 discloses *a regularity of breathing*. Specifically, Rapoport502 describes, as shown in Figure 1 (reproduced below), a "normal" waveform "corresponding to apnea free inspiration." EX1008, 4:57-59, Figs. 1, 8. Further, Rapoport502 compares the inspiratory flow waveform with a pure sine wave which is a regularly repeating waveform to determine if it reveals flow limitation (i.e., an obstruction). Behbehani Decl. ¶248; *see also* EX1008, claim 15(c).

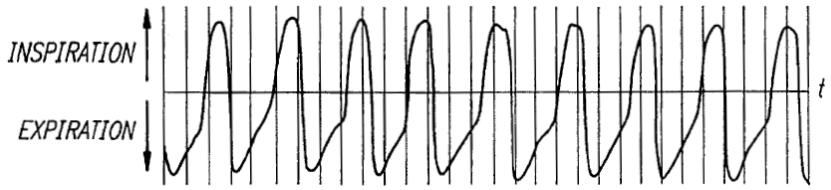


FIG. 1
AIRFLOW TO AND
FROM CPAP GENERATOR

This is consistent with the knowledge of a POSITA that *a regularity of breathing* can be used to indicate that the patient has transitioned to a sleep state. *See* Ex. 1034 at 5:34-35 ("When a patient is asleep his respiration becomes stable, this is used to detect the instant when the patient falls asleep."); Behbehani Decl. ¶249.

Rapoport502 further discloses *a regular period of obstructions*. EX1008, 4:66-5:12, Figs. 2-5, 2:55-59. Rapoport502 also teaches that the patient breathing

patterns shown in Figs 1-5 can be analyzed for "harmonics of cyclic rate of the waveform." *Id.*, 6:441-49; *see also id.* 7:24-28. Rapoport502 teaches that by considering the existence of "flow and pressure waveforms and position signal, in time-correlated sequence" (*Id.*, 14:21-25), one can detect *a regular period of obstructions*. Moreover, Rapoport502 explains that "[a]s part of the decision process, the system calculates a time weighted majority function (MF) from the flow limitation parameter values for a certain number of previous breaths, e.g., three, five or ten breaths depending on the type of current breath*." Id*., 10:61-66; Behbehani Decl. ¶250.

To the extent that Rapoport502 does not expressly state that *this regularity of breathing* or *regular period of obstructions* is an indication of a *change* or *transition from an awake state to an asleep state*, this would have been obvious from Rapoport502 in view of Sullivan460. Behbehani Decl. ¶251.

a) Teachings of Sullivan460

Sullivan460 discloses this limitation. *See* Section VIII.C.7.a) (Ground 1, 1[c4]/15[c3]/27[c3], discussing Sullivan460).

b) Motivation to Combine and Reasonable Expectation of Success

See Section X.A and X.B (Ground 3, Motivation to Combine and Reasonable Expectation of Success).

D. Dependent Claims 3-6, 9-12, 14, 16-18, 20, 28-29

1. Claims 3, 17

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA discloses this limitation. *See* Section VIII.D.1 (Ground 1, Claims 3, 17, discussing Sullivan460 and knowledge of POSITA); Behbehani Decl. ¶254.

2. Claim 4

Rapoport502 discloses that *obstructions are apneas*. EX1008, 1:29-36 ("[Obstructive sleep apnea syndrome]…is characterized by an intermittent *obstruction* of the upper airway occurring during sleep. The *obstruction* results in a spectrum of respiratory disturbances [including]…the total absence of airflow (*apnea*)…") (emphasis added); Behbehani Decl. ¶255.

3. Claim 5

Rapoport502 discloses that *obstructions are hyponeas*. EX1008, 1:29-36 ("[Obstructive sleep apnea syndrome]…is characterized by an intermittent *obstruction* of the upper airway occurring during sleep. The *obstruction* results in a spectrum of respiratory disturbances [including]… significant obstruction with or without reduced airflow (*hypopnea* and snoring)…") (emphasis added); Behbehani Decl. ¶256.

4. Claim 6

Rapoport502's detected flow limitation occurs *during an asleep state* when *the patient is experiencing elevated upper airway resistance*. *See* Sections X.D.2-3

(describing apneas and hypopneas as obstructions of the upper airway occurring during sleep); Behbehani Decl. ¶257.

5. Claim 9, 18

As discussed for 1[c3]/15[c4]27[c4] and claim 6, these obstructions include *breathing patterns indicative of the patient experiencing an elevated upper airway resistance*. *See* Sections X.C.6 and X.D.4. When the signal processor 24 (*hardware processor*) determines "YES" for a flow limitation (Step 43), it *increases pressure applied to airway of patient* by 0.5 cm H_20 (Step 45). EX1008, 6:9-13, Fig. 10; Behbehani Decl. ¶256.

6. Claim 10

As discussed in 1[c3]/15[c4]/27[c4], the *hardware processor* in Rapoport502 *increases the pressure applied to the airway of the patient* when the *hardware processor* determines that the patient's breathing patterns are indicative of a regular period of obstruction. *See* Section X.C.6. Further, as discussed for claims 6, these obstructions include *hypopneas*. *See* Section X.D.3.

7. Claim 11

As discussed in 1[c3]/15[c4]/27[c4], the *hardware processor* in Rapoport502 *increases the pressure applied to the airway of the patient* when the *hardware processor* determines that the patient's breathing patterns are indicative of a regular period of obstruction. *See* Section X.C.6. Further, as discussed for claim 4, these obstructions include *apneas*. *See* Section X.D.2.

8. Claim 12

Rapoport502's signal processor 24 (*hardware processor*) detects a patient transitioning between a flow limitation state and a no flow limitation state, and *lowers pressure applied to airway of patient* by 0.5 cm H_20 (Step 48) when it determines a "NO" flow limitation state (step 43) and the CPAP pressure is greater than the minimum pressure allowed (Step 47). EX1008, 6:17-29.

Rapoport502 does not expressly disclose *a breathing pattern indicative of a transition to an awake state*, this is taught by Sullivan460. Behbehani Decl. ¶264. Sullivan460 discloses a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19; *see* Section VIII.C.6.a) "[A] switching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46. This means that *when* the patient *has transitioned to an awake state from an asleep state*, Sullivan460 *lowers the pressure applied to the airway of the patient*. Behbehani Decl. ¶265.

It would have been obvious to a POSITA to modify Rapoport502 so that *when the hardware processor* in Rapoport502 *determines that the patient has transitioned to an awake state* (when there is no flow limitation) *from an asleep state* (when there

is a flow limitation)*, the hardware processor lowers the pressure applied to the airway of the patient*, as taught in Sullivan460, for the same reasons as explained above. As the POSITA would have recognized from the teachings of Rapoport502 and Sullivan460, a lower pressure is desirable when the patient is awake because it ensures the patient is comfortable and reduces the likelihood the patient will remove the mask. Behbehani Decl. ¶266.

9. Claim 14, 20, 28

"[T]he controlled positive *pressure* could be changed" (*increased*, *see* Section X.C.6 (is limitation. See Sections)) "automatically via an automated system, either in response to feedback control or *using* pre-set *ramps* or steps in the controlled positive pressure throughout the night (in laboratory or at home)." EX1008, 13:37-41 (emphasis added). Also, Rapoport502 discloses "a slope parameter [of the ramp], e.g., 0.1 cm per two seconds." EX1008, 11:44-46. A POSITA would understand to increase the pressure using the ramp system disclosed by Rapoport502. Behbehani Decl. ¶267.

10. Claim 16

As discussed for claims 4-6, Rapoport502 discloses this limitation. *See* Sections X.D.2-4 (Ground 3, Claims-4-6).

11. Claim 29

Rapoport502 discloses this limitation. Behbehani Decl. ¶269. As previously explained (*see* Section X.C.6.), Figure 10 represents Rapoport502's "automatic

adjustment mode" effectuated by the hardware processor in which "several input parameters…are used in the determination of the action to be taken" including applying a delay before onset of a pressure increase to the patient. Ex. 1008 at 7:6-8; *see* Section X.C.6; Behbehani Decl. ¶269.

As seen in (blue), the signal processor 24 determines "YES" for a flow limitation (Step 43), it applies a pressure increase to the patient of 0.5 cm H20 (Step 45) provided that the current CPAP pressure is less than the maximum allowed (Step 44) (*the hardware processor further increases pressure when one or more obstructions is detected during an asleep state*). Ex. 1008 at 6:9-13; Behbehani Decl. ¶270.

E. Independent Claim 21

1. Preamble

To the extent limiting, Rapoport502 discloses the preamble. *See* Section X.C.1 (Ground 3, 1[preamble]/15[preamble]/27[preamble]); Behbehani Decl. ¶¶271.

2. 21[a]

Rapoport502 discloses this limitation. *See* Sections X.C.1 (Ground 3 1[preamble]/15[preamble]/27[preamble]) and X.C.2 (Ground 3, 1[a]/15[a]/27[a]).

3. 21[b]

Rapoport502 discloses this limitation. *See* Section X.C.2 (Ground 3, 1[b]/15[b]/27[b]).

4. 21[c]

Rapoport502 in view of Sullivan460 renders obvious this limitation. *See* Sections X.C.4 (Ground 3, 1[c1]/15[c1]/27[c1]) and X.C.7 (Ground 3, 1[c4]/15[c3]/27[c3]).

5. 21[d]

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani Decl. ¶275. As explained for claim 12, Rapoport502's *hardware processor* decreases pressure if a flow limitation or other change in CPAP does not occur within a certain amount of time. *See* Section X.D.8 (Ground 3, Claim 12). This means the *flow generator* in Rapoport502 *appl[ies] a lower pressure* in the absence of snoring. As explained in Sections X.D.8 and X.D.8, the modified CPAP system would apply a low pressure *when* the sensor detects that *the patient is in an awake state*, which would add to patient comfort and decrease the likelihood the patient will remove the mask due to uncomfortably high pressure. *See* Sections X.D.8 and X.D.8 (Ground 3, Motivation to Combine and Reasonable Expectation of Success); Behbehani Decl. ¶¶275-76.

6. 21[e]

Rapoport502 in view of Sullivan460 discloses this limitation. *See* Section X.C.6 (Ground 3, 1[c3]/15[c4]/27[c4]).

F. Dependent Claims 22-24, 26

1. Claim 22

As discussed for claims 4-6, Rapoport502 discloses this limitation. *See* Sections X.D.2-4 (Ground 3, Claims 4-6).

2. Claim 23

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA renders obvious this limitation. *See* Section X.D.1 (Ground 3, Claims 3 and 17).

3. Claim 24

Rapoport502 discloses this limitation. Behbehani Decl. ¶280. As explained for 1[c3]/15[c4]/27[c4], Rapoport502 increases pressure when a flow limitation occurs and the patient is necessarily asleep. *See* Section X.C.6 (Ground 3, 1[c3]/15[c4]/27[c4]).

4. Claim 26

Rapoport502 discloses this limitation. *See* Section X.D.9 (Ground 3, Claims 14, 20, 28).

XI. GROUND 4: RAPOPORT502 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIM 19

A. Motivation to Combine

It would have been obvious to a POSITA to modify the system of Rapoport502 and Sullivan460 in view of Matthews so that the *hardware processor* in Rapoport502 determines that the *awake state* is a *troubled wakefulness state*.

A POSITA would have recognized the advantages of detecting different awake states, including a distressed state (*troubled wakefulness*) in which the patient has breathing that becomes "erratic," as taught in Matthews. Rapoport502 acknowledges that "[i]ncreasing the comfort of the system, which is partially determined by minimizing the necessary nasal pressure, has been a major goal of research aimed at improving patient compliance with therapy." EX1008, 1:60-64. Rather than wait until more than two minutes have passed since the last change in CPAP (step 46), the POSITA would have been motivated to decrease CPAP when *troubled wakefulness* is determined, as taught by Matthews. The modification to Rapoport502 and Sullivan460's CPAP system would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort by waiting as much as two minutes.

The modification would have been a natural extension of Rapoport502's air pressure adjustment approach. "The air pressure setting is raised, lowered or maintained depending on whether flow limitation has been detected and on the previous actions taken by the system." EX1008, 3:18-21. Rapoport502 already adjusts the air pressure based on flow limitation states. *Id.*, Fig. 10. Adding a *troubled wakefulness* based on data from the flow sensors would have made the system even more effective. Behbehani Decl. ¶285.

B. Reasonable Expectation of Success

Rapoport502, Sullivan460, and Matthews are analogous art and describe CPAP systems with flow sensors and generators. Like Rapoport502 and Sullivan460, Matthews discloses a "flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34." Ex., 1007, 7:11-14. The flow sensor data are monitored to control the pressure delivered to the patient. *Id.*, 8:54-9:15. Sullivan460 discloses lowering the pressure upon detecting an awake state (6:28-7:19, cls. 22-28, 43-46), and the POSITA would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient.

Modifying the CPAP system of Rapoport502 and Sullivan460 would have been as simple as adding another decision point in the algorithm. Specifically, because the flow sensors provided data to determine flow limitations, the algorithm shown in Figure 10 could simply be modified to add "Erratic Breathing Present" between step 43 and step 46. If yes, continue to step 47, and if no, continue step 46. Behbehani Decl. ¶288.

Given that the proposed modification involves a simple change in a programming algorithm, it is nothing more than a combination of known prior art elements according to known methods and known techniques to yield predictable

results, and involves use of a known technique to improve a similar device in the same way. Behbehani Decl. ¶289.

C. Dependent Claim 19

Sullivan995 in view of Matthews renders this limitation obvious. Specifically Matthews discloses *a troubled wakefulness state*. *See* Section IX.C (Ground 2, Claim 19); Behbehani Decl. ¶¶290-91.

XII. SECONDARY CONSIDERATIONS

There are no secondary considerations known to Petitioner that affect—let alone overcome—this strong case of obviousness. Should PO proffer any relevant evidence of secondary considerations in its preliminary response, Petitioner will seek leave to reply.

XIII. THE BOARD SHOULD REACH THE MERITS OF THIS PETITION

A. Institution is appropriate under § 325(d)

Institution is appropriate under § 325(d) because substantially the same art and arguments have never been presented to or considered by the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinishche Geräte GmBH*, IPR2019-01469, Paper 6 at 6-11 (Feb. 13, 2020) (precedential) (describing two-part framework based on the *Becton, Dickinson* factors). Specifically, none of the asserted references was considered during prosecution.

B. Institution is appropriate under § 314(a)

A trial date has not yet issued in the parallel litigation. Thus, the *Fintiv* factors cannot be fully evaluated at this stage. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (Mar. 20, 2020). To the extent these facts change, Petitioner will seek leave for reply. Regardless, the efficiency and fairness considerations discussed in *Fintiv* weigh strongly in favor of institution given the infancy and minimal investment in the parallel litigation.

XIV. CONCLUSION

For these reasons, Petitioner respectfully requests *inter partes* review of claims 1, 3-6, 9-12, 14-24, 26-29 of the '115 Patent.

Respectfully submitted,

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Claim Listing (Appendix)

1. A positive airway pressure system which delivers of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure to an entrance of a patient's airways in order to assist in treating a sleeping disorder, the positive airway pressure system comprising:

   [a] a flow generator which generates a flow of breathable gases to be supplied to a patient;

   [b] a flow sensor measuring data indicative of the patient's breathing patterns; and

   [c1] at least one hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data, [c2] the hardware processor determines whether to alter the pressure supplied by the flow generator to the airway of the patient based, at least in part, on the indication of the patient's breathing patterns, [c3] wherein the hardware processor automatically increases a pressure supplied to the patient when the hardware processor determines that an indication of the patient's breathing patterns representative of a change from an awake state to an asleep state has occurred, [c4] the indication of the patient's breathing patterns representative of a change from an awake state to an asleep state including at least one of a regularity of breathing or a regular period of obstructions.

3. The system of claim 1, wherein the regular period of obstructions are three or more obstructions.

4. The system of claim 3, wherein the obstructions are apneas.

5. The system of claim 3, wherein the obstructions are hypopneas.

6. The system of claim 3, wherein the obstructions are elevated upper airway resistance.

9. The system of claim 1, wherein when the hardware processor determines during an asleep state that the patient is experiencing a breathing pattern indicative of an elevated upper airway resistance, the hardware processor increases the pressure applied to the airway of the patient.

10. The system of claim 1, wherein when the hardware processor determines during an asleep state that the patient is experiencing a breathing pattern indicative of a hypopnea event, the hardware processor increases the pressure applied to the airway of the patient.

11. The system of claim 1, wherein when the hardware processor determines during an asleep state that the patient is experiencing a breathing pattern indicative of an apnea event, the hardware processor increases the pressure applied to the airway of the patient.

12. The system of claim 1, wherein when the hardware processor determines that the patient is experiencing a breathing pattern indicative of a transition to an awake state from an asleep state, the hardware processor lowers the pressure applied to the airway of the patient.

14. The system of claim 1, wherein the pressure is increased using a ramp procedure.

15. A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's airways in order to assist in treating a sleeping disorder, the positive airway pressure system comprising:

[a] a flow generator which generates a flow of breathable gases to be supplied to a patient;

[b] a flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and

[c1] a hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data for an indication of the patient's breathing patterns, [c2] the hardware processor determines whether to alter a pressure supplied by the flow generator to the airway of the patient based, at least in part, on the indication of the patient's breathing patterns, [c3] wherein the hardware processor analyzes the indication of the patient's breathing patterns for a pattern indicative of a transition between an awake state and an asleep state, wherein the pattern indicative of a transition between an awake state and an asleep state is at least one of a regularity of breathing or a regular period of obstructions, [c4] wherein when the hardware processor determines a pattern indicative of a transition between an awake state and an asleep state has occurred, the

hardware processor increases the pressure supplied by the flow generator to the airway of the patient.

16. The system of claim 15, wherein the obstructions are one or more of apneas, hypopneas or elevated upper airway resistance.

17. The system of claim 15, wherein the regular period of obstructions are three or more obstructions.

18. The system of claim 15, wherein when the hardware processor determines during an asleep state that the indication of the patient's breathing patterns is indicative of the patient experiencing an elevated upper airway resistance, the hardware processor increases the pressure applied to the airway of the patient.

19. The system of claim 15, wherein the awake state is a troubled wakefulness state.

20. The system of claim 15, wherein the pressure is increased using a ramp procedure.

21. A method for treatment of a sleeping disorder in a patient using a positive airway pressure delivery system that delivers a flow of breathable gases at a positive treatment pressure with respect to ambient air pressure, the flow of breathable gases being delivered to an airway of a patient, the method comprising:

[a] supplying a flow of breathable gases to an airway of a patient using a flow generator which generates a flow of gases to produce a positive pressure at or above a pressure at ambient air pressure;

[b] measuring, using a sensor, data indicative of the patient's breathing patterns;

[c] determining, using a hardware processor, one or more indications of the patient's breathing patterns based on the data indicative of the patient's breathing patterns, the indications including a regularity of breathing or a regular period of obstructions indicative of an asleep state;

[d] applying no pressure or a low pressure, using the flow generator, when the patient is in an awake state; and

[e] increasing an applied pressure to an elevated pressure when the hardware processor determines that the patient has transitioned from the awake state to

the asleep state based on the one or more indications of the patient's breathing patterns.

22. The method of claim 21, wherein the obstructions include at least one or more of an apnea, hypopnea or elevated upper airway resistance.

23. The method of claim 21, wherein a regular period of obstructions comprises at least three obstructions.

24. The method of claim 21, further comprising:

increasing a previously provided pressure supplied to a patient when the patient is in an asleep state and an obstruction is detected in the one or more indications of the patient's breathing patterns.

26. The method of claim 21, further comprising:

ramping the applied pressure when the applied pressure is increased.

27. A positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure delivered to an entrance of a patient's airways in order to assist in treating a sleeping disorder, the positive airway pressure system comprising:

[a] a flow generator which generates a flow of breathable gases to be supplied to a patient;

[b] a flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and

[c1] a hardware processor which receives the measured data corresponding to the flow of breathable gases from the flow sensor and analyzes the data to determine the patient's breathing patterns, [c2] the hardware processor also determines whether to alter a pressure supplied by the flow generator to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, [c3] wherein the hardware processor analyzes the breathing patterns for indications of a transition between an awake state and an asleep state, the indications being a regularity of breathing, [c4] wherein when the hardware processor determines a regularity of breathing has occurred, the hardware processor increases the pressure supplied by the flow generator to the airway of the patient.

28. The system of claim 27, wherein increasing the pressure is performed by a ramping procedure.

29. The system of claim 27, wherein the hardware processor further increases pressure when one or more obstructions is detected during an asleep state.

CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

Under 37 C.F.R. § 42.24(b)(1), the undersigned certifies that the foregoing Petition contains 13,190 words, excluding table of contents, mandatory notices under § 42.8, and a certificate of service or word count, as measured by the word-processing system used to prepare this paper. 37 CFR. § 42.24(a)(1).

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CERTIFICATE OF SERVICE

The undersigned certifies that a complete copy of this Petition for *Inter Partes* Review of U.S. Patent No. 9,533,115 and all Exhibits and other documents filed together with this Petition were served on the official correspondence address for the patent shown in PAIR via STANDARD OVERNIGHT FEDERAL EXPRESS next business day delivery on June 1, 2022:

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