UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ResMed Inc.,

Petitioner,

v.

New York University,
Patent Owner,

Case No. IPR2022-00992

PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 10,384,024

Claims 1-14

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EXHIBIT LIST

Exhibit	Description
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1002	Prosecution History of U.S. Patent No. 10,384,024 ("'024 FH")
1003	Declaration of Dr. Khosrow Behbehani ("Behbehani")
1004	*Curriculum Vitae* of Dr. Khosrow Behbehani ("Behbehani CV")
1005	U.S. Patent No. 5,245,995 to Sullivan et al. ("Sullivan995")
1006	WO 01/05460 to Sullivan ("Sullivan460")
1007	U.S. Patent No. 7,168,429 to Matthews et al. ("Matthews")
1008	U.S. Patent No. 5,490,502 to Rapoport et al. ("Rapoport502")
1009	Reserved
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1012	M. Berthon-Jones, "Feasibility of a Self-Setting CPAP Machine," *Sleep* 16:S120-123 (1993) ("Berthon-Jones 1993")
1013	U.S. Patent No. 5,704,345 to Berthon-Jones ("Berthon-Jones345")
1014	D. Rapoport, "Methods to Stabilize the Upper Airway Using Positive Pressure," *Sleep* 19(9):S123-S130 ("Rapoport 1996")
1015	C. Sullivan, "Reversal of Obstructive Sleep Apnea by Continuous Positive Airway Pressure Applied through the Nares," *Lancet* 1981:1862-5 ("Sullivan 1981")
1016	M. Pressman et al., "Ramp Abuse: A Novel Form of Patient Noncompliance to Administration of Nasal Continuous Positive Airway Pressure for Treatment of Obstructive Sleep Apnea," Am. J of Respiratory and Critical Care Med., Vol. 151, 1632-1634 (1995)

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1017	U.S. Patent No. 6,484,719 to Berthon-Jones ("Berthon-Jones719")
1018	Reserved
1019	Reserved
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1021	S. Thompson et al., "Sleep as a Teaching Tool for Integrating Physiology and Motor Control," *Advances in Physiology Education* (June 2001)
1022	Reserved
1023	R. Tamisier et al., "Characterization of pharyngeal resistance during sleep in a spectrum of sleep-disordered breathing," *J Appl Physiol* 89:120-130, 2000 ("Tamisier")
1024	D. Hudgel et al., "Mechanics of the respiratory system and breathing pattern during sleep in normal humans," *The American Physiology Society* (1984)
1025	M. Craske, "Nocturnal Panic," American Psychological Association 153 (1997)
1026	Teschler, H., et al., "Automated Continuous Positive Airway Pressure Titration for Obstructive Sleep Apnea Syndrome," Am. J. Respir. Crit. Care Med. 54:734-740 (1996)
1027	ResMed, "AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1," (1999)
1028	ResMed, "Auotset T, Optimal Therapy for your OSA Patients," (2000)
1029	Sunrise Medical, "DeVillibis, AutoAdjust, LT Nasal CPAP System Instructions Guide Model 8054," (1999)
1030	Respironics, "Introducing the REMstar Auto. A simply smarter Smart

Exhibit	Description
	CPAP*"* (2002)
1031	ResMed Origins, downloaded from https://document.resmed.com/en-us/documents/articles/resmed-origins.pdf on May 3, 2022.
1032	U.S. Patent No. 7,966,061 to Al-Abed, et al. ("Al-Abed")
1033	Reserved
1034	WO 03/075991 to Delache ("Delache")
1035	F. Roux, et al., "Continuous Positive Airway Pressure: New Generations," Clinics in Chest Medicine (2003)
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 1-14 of U.S. Patent No. 10,384,024 (EX1001, "'024 Patent") and a finding that all challenged claims of the '024 Patent are unpatentable.

Patients often struggle to use positive airway pressure (PAP) systems because the high pressure treatment causes discomfort. The '024 Patent addresses this by decreasing pressure when the patient is awake. But many references, including WO 01/05460 (EX1006, "Sullivan460"), disclosed this feature well before the '024 Patent priority date.

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 '024 Patent is assigned to New York University ("PO"), which is currently asserting the '024 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. 9,533,115 and U.S. Patent No. 9,867,955.

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 '024 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

Ground 1: Claims 1-5, 7-14 are obvious under 35 U.S.C. § 103 over Sullivan995[1] in view of Sullivan460[2].

Ground 2: Claim 6 is obvious under 35 U.S.C. § 103 over Sullivan995 in view of Sullivan460 and Matthews[3].

Ground 3: Claims 1-5, 7-14 are obvious under 35 U.S.C. § 103 over Rapoport502[4] in view of Sullivan460.

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1 U.S. Patent No. 5,245,995 to Sullivan et al. (EX1005, "Sullivan995").

2 PCT Publication No. WO 01/05460 (EX1006, "Sullivan460").

3 U.S. Patent No. 7,168,429 to Matthews et al. (EX1007, "Matthews").

Ground 4: Claim 6 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), a well-recognized disorder, "is characterized by an intermittent obstruction of [a patient's] upper airway occurring during sleep." EX1001, 1:35-38. The obstructions range "from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring)." *Id.*, 1:38-342. Because apnea, hypopnea, and heavy snoring produces decreased blood oxygenation, they "are recognised [] causes of sleep disruption and risk factors in certain types of heart disease." EX1013, 1:27-28, 1:43-48; *see also* Behbehani ¶¶32-33.

Positive airway pressure (PAP) therapy has been "the mainstay of treatment" since Professor Colin Sullivan, Dr. Michael Berthon-Jones, and their colleagues first applied it to treat OSAS in 1981. EX1001, 1:58-2:2; EX1014, 1 (citing EX1015). To prevent collapse of the upper airway during sleep, PAP opposes the force created during inspiration (*i.e.*, inhalation) and the gravitational effects on the

[4] U.S. Patent No. 5,490,502 to Rapoport et al. (EX1008, "Rapoport").

tongue during expiration (*i.e.*, exhalation). EX1014, 1; *see also* Behbehani ¶¶33-37.

Generally, a prescription and patient training for PAP therapy is "performed in, or directly under, the supervision of the sleep disorders laboratory." EX1014, 5. After a full night of observation in the laboratory, a physician will prescribe 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, Professor 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" and further provided a "minimal awake pressure." EX1012, 1. However, "[t]he major limitation of CPAP therapy relates to discomfort or other factors…." EX1014, 5; EX1016, 1 (other side effects include "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*., 4; *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 processing unit that could detect breathing patterns and adjust pressure as appropriate based on those breathing patterns. Ex. 1035, 2; EX1037, 2; *see also* Behbehani ¶¶43-48.

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.

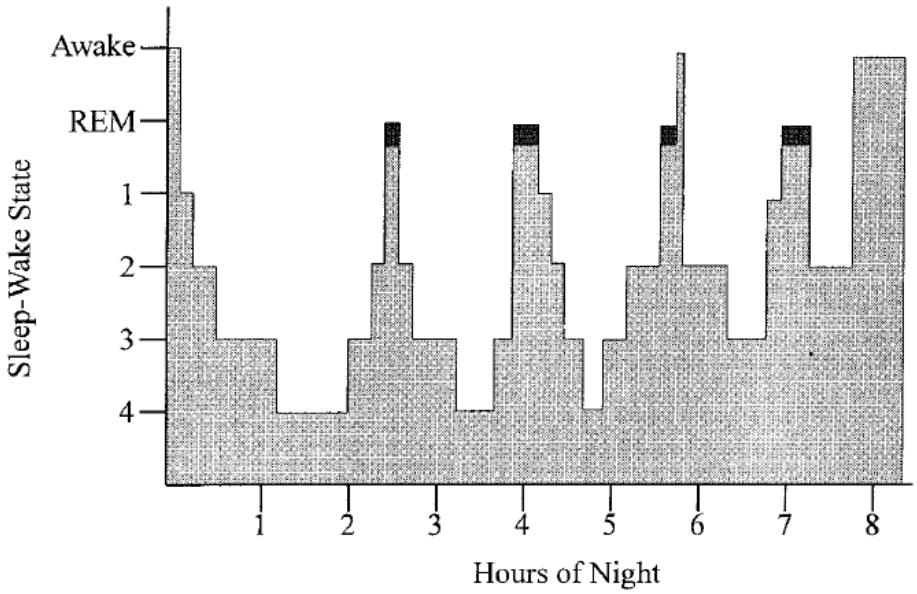


FIG. 2.

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 absent in REM sleep with the exception 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. The '024 Patent

The '024 Patent describes a well-known system and method for treating a sleeping disorder with CPAP therapy. EX1001, Abstract, Fig. 1, 2:60-3:18. Figure 1 (reproduced below) illustrates conventional components operating conventionally.

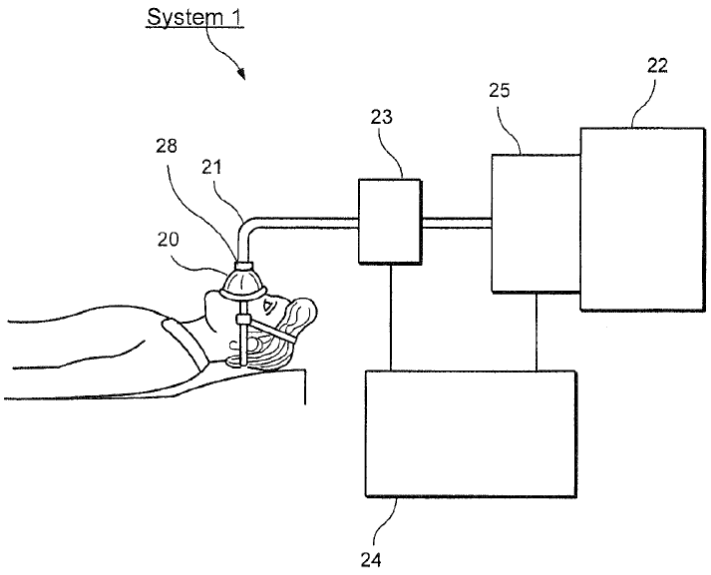


FIG. 1

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.* 3:52-56. "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.* 3:61-4:2.

The patent attempts to address limitations of "[s]ome conventional PAP systems [that] utilize algorithms which continuously and automatically titrate the applied pressure." *Id.*, 2:48-49. 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.*, 2:33-35. 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.*, 4:24-28) and "adjust[ing] the pressure" to correspond to the patient's current state (*id.*, 8:48-50). 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.*, 4:66-5:1, 6:9-12. This allegedly inventive feature is reflected in Figure 10 below.

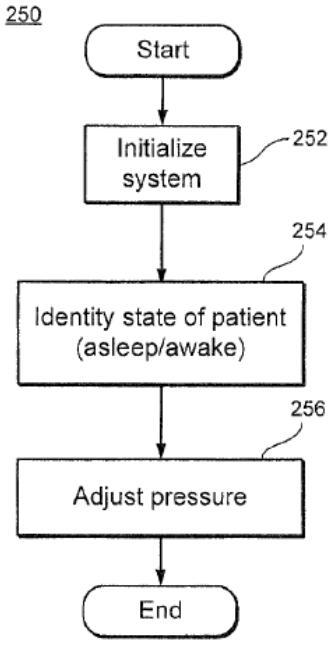


FIG. 10

C. The Challenged Claims

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

The '024 Patent has 14 claims, 1 independent claim and 13 dependent claims. Independent claim 1 recites:

(1) a flow generator;

(2) a flow sensor;

(3) a processing arrangement that automatically delays a pressure increase until the patient is in an asleep state.

D. Prosecution History

The applicant obtained allowance of the '024 Patent by filing a terminal disclaimer, "disclaiming the terminal portion of any patent granted on th[e] application which would extend beyond the expiration date of U.S. Patent No. 9,108,009 B2." EX1002, 127, 138.

On November 19, 2018, the Examiner provisionally rejected claims 23-36 on "the ground of nonstatutory double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 9,108,009 B2." *Id.*, 95-96. The Examiner continued,

[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.

"Claims 23-36 would be allowable if a terminal disclaimer in compliance with CFR 1.321(c) or 1.321(d) is timely filed to overcome the provision rejection based on a nonstatutory obviousness-type double patenting ground." EX1002, 96. The Applicant responded March 19, 2019 by filing a "Terminal Disclaimer to Obviate a Double Patenting Rejection over a 'Prior Art' Patent." EX1002, 127. The Examiner reviewed and allowed claims 23-26 based on the terminal disclaimer. *Id*., 137.

V. OVERVIEW OF THE PRIOR ART

A. Sullivan995 (EX1005)

Sullivan995 discloses a CPAP system, such as shown by Figures 1A and 1b (reproduced below). EX1005, Figs. 1A, 1b, 3, Abstract, 1:33-36, 2:15-20, 9:57-58.

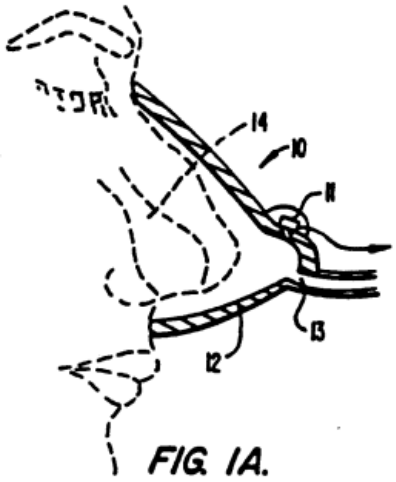


FIG. 1A.

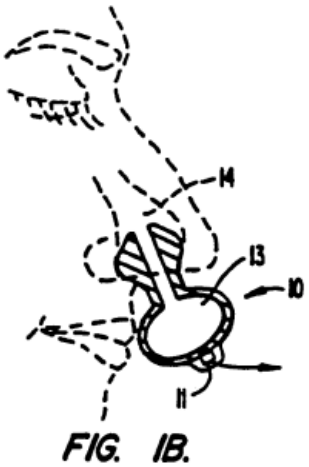


FIG. 1B.

Sullivan995 positions a microphone 11 (a differential pressure sensor) within the enclosed airway of the CPAP system for sensing various flow characteristics of the

breathable gas, including exhaled and inhaled air flow volume, breathing rate and patterns, exhaled and inhaled air flow rates 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.

Figure 3 below shows amplifier/filter/processor unit 26 and speed control unit 23 connected to microphone 11 and that processes flow data from the microphone 11. *Id.*, 10:3-6, 11:55-62, Fig. 3.

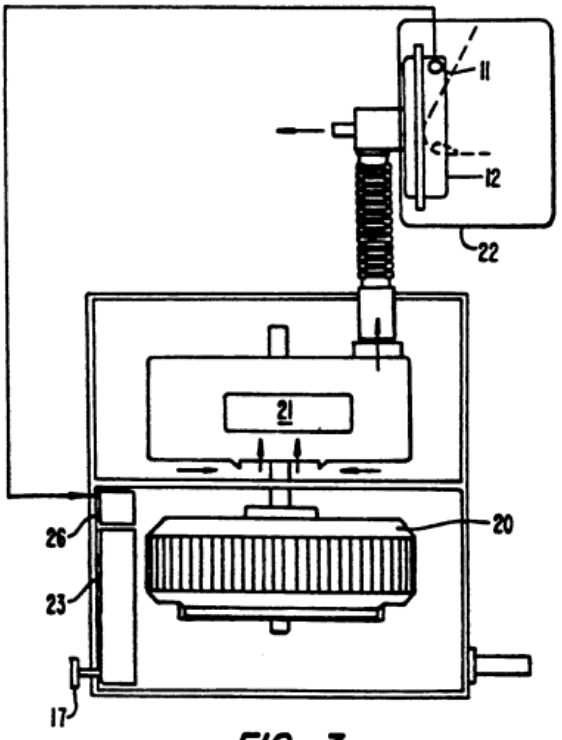


FIG. 3.

As seen in Figure 12 below, a computing system processes various breathing pattern data (e.g., snore, flow rate, volume, breathing rate) from the amplifier/filter/processor combination as in Figure 3. *Id.*, 17:6-13.

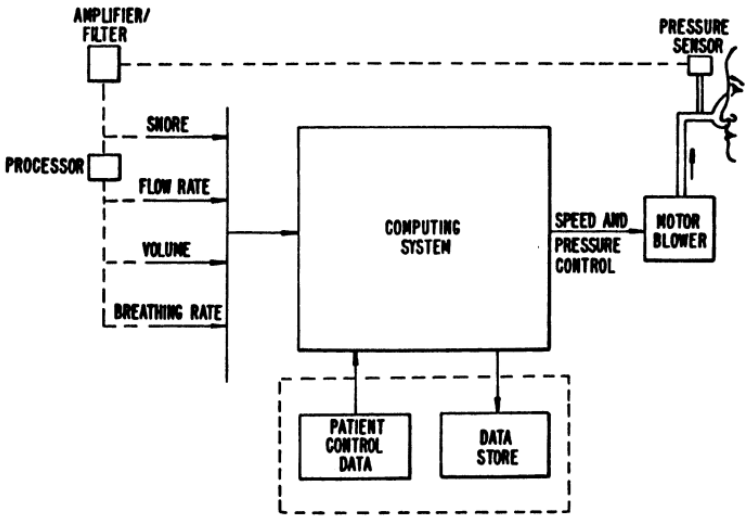


FIG. 12.

Accordingly, these outputs are 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.

Because the patient only snores when asleep, Sullivan995 increases the pressure when the patient has fallen asleep. Further, Sullivan995 increases pressure upon detection of other abnormal breathing patterns that occur while in a sleep state, such as apneas or hypopneas. *Id.*, 6:41-68, 15:34-68, 16:17-22, 16:51-59.

B. Sullivan460 (EX1006)

Sullivan460 is by the same inventor as Sullivan995 and incorporates Sullivan995 by reference, stating Sullivan995 describes ResMed's AutoSet product. EX1006, 6:22-29. 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.

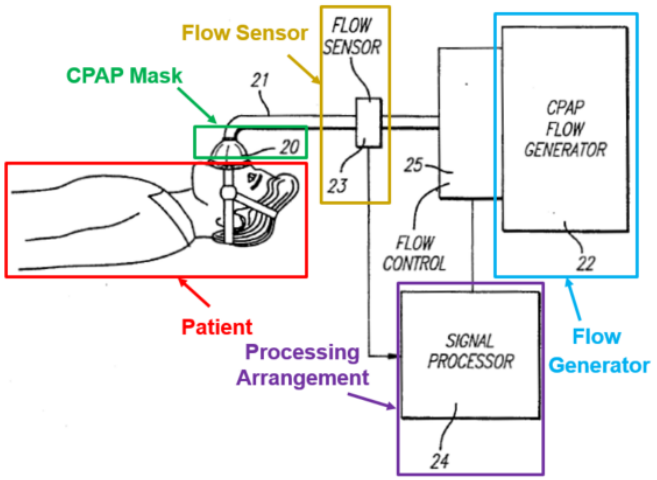
Specifically, Sullivan460 selects between an "awake" mode and an "asleep" mode, and applies high pressure in the "asleep" mode and low pressure in the "awake" mode. *Id.*, 6:30-7:22, 14:7-36, cls. 22-31. When the flow rate increases above a threshold, controller 100 determines the patient is in an awake state and switches the CPAP system into the "awake" mode. *Id.*, 10:21-25, 14:7-36, cls. 22-31. When the system detects interruptions 10, or a reduced average airflow indicating that the patient is asleep, controller 100 determines the patient is in an asleep state and switches the CPAP system into an "asleep" mode, to eliminate the patient's upper airway flow limitation. *Id.*, 10:3-16.

C. Matthews (EX1007)

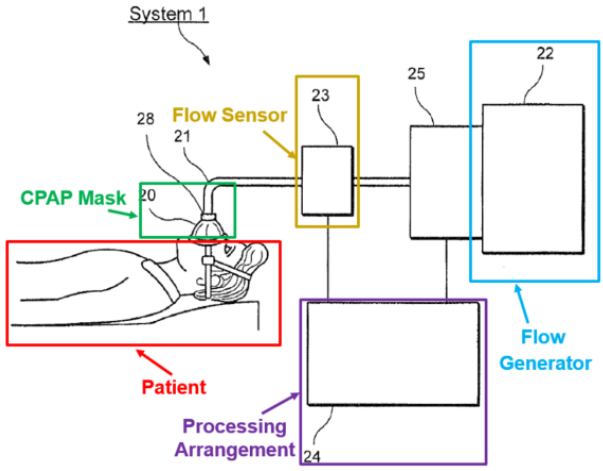
Matthews is a PAP system that "optimizes the pressure delivered to the patient to treat … disordered breathing while minimizing the delivered pressure for patient comfort." EX1007, Abstract. "When a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic," (*Id.*, 21:37-39),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

D. Rapoport502 (EX1008)

Rapoport502 (published nearly a decade before the '024 Patent) is by the same inventor as the '024 Patent and discloses nearly identical hardware. EX1008, Fig. 9.



Rapoport502, Fig. 9



'024 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 ¶87.

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 ¶88.

VII. CLAIM CONSTRUCTION

A. "troubled wakefulness" (claim 6)

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 ¶91. This term is not an industry standard term and was coined in the '024 Patent. *Id.,* ¶92. 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 "[p]atient'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 1-5, 7-14

A. Motivation to Combine

It would have been obvious to a POSITA to modify Sullivan995 so that the *processing arrangement in Sullivan995 determines that the patient is in an awake state, and in response, automatically delays the onset of a pressure increase to the patient*, as taught in Sullivan460. Behbehani ¶¶94-103. 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.

A POSITA would have recognized the advantages of using the same CPAP system to treat sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught in Sullivan460. EX1006, 7:3-12; Behbehani ¶96. 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 ¶97. 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, 6:3-7-2, 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, including pre-eclampsia. EX1005, 1:14-31, 4:36-45.

A POSITA would have recognized that the modification is advantageous. It improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks. 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. Sullivan995 suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (e.g., including 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 (*id.,* 4:21-25), and Sullivan995 partially solves the problem by reducing the pressure at the beginning of therapy. Behbehani ¶99.

B. A POSITA Would Have a Reasonable Expectation of Success

Sullivan460 explicitly recognizes the combination of Sullivan995 with the teachings in Sullivan460. Behbehani ¶101. 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, 6:26-29. As Sullivan460 also discloses, 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 adjusting pressure depending on the state. EX1006, 6:22-7:22, cls. 22-28, 43-47. A POSITA, informed by 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 ¶¶100, 102.

Sullivan995 and Sullivan460 are analogous art. Behbehani ¶102. Both describe CPAP systems that include flow sensors and 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 techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.

C. Independent Claim 1

1. Preamble: *"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 in a patient, the positive airway pressure system comprising:"*

To the extent the preamble is limiting, Sullivan995 discloses this limitation. Behbehani ¶¶104-106. Sullivan995 discloses a CPAP system[6] (*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,

[6] 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.

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 ¶¶104.

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 ¶106.

2. 1[a]: *"a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient;"*

Sullivan995 discloses this limitation. Behbehani ¶¶107-108. Sullivan995's CPAP system includes a variable speed motor 20 that drives a blower 21 (*flow generator*). EX1005, 9:57-64. The blower 21 *supplies a positive treatment pressure 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 ¶107-108.

3. 1[b]: *"a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing pattern; and"*

Sullivan995 discloses this limitation. Behbehani ¶¶109-120. Sullivan995's CPAP system includes a differential pressure sensor, e.g., microphone 11 (*flow sensor*). EX1005, Fig. 3, 9:64-66 (the snoring detection means 22 is a pressure detection means and microphone 11 is a ***differential pressure sensor***."); Behbehani ¶¶109-110. 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.

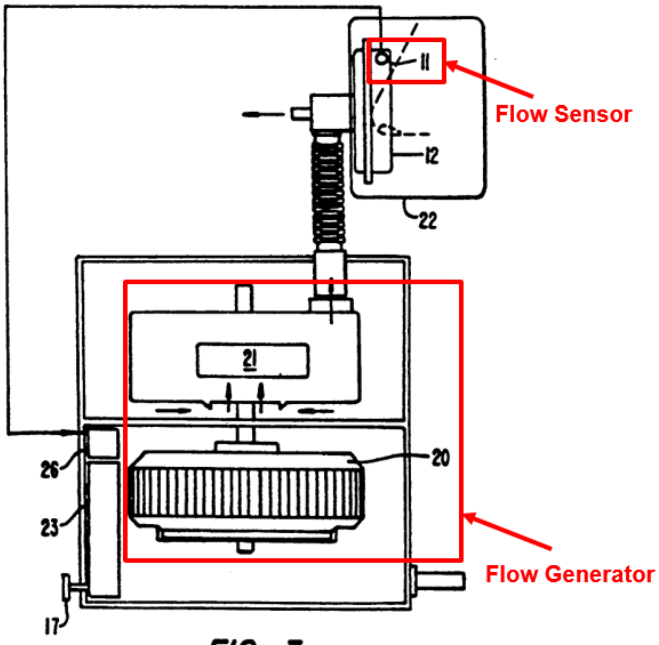


FIG. 3.

EX1005, Fig. 3

To determine the differential pressure used to calculate air flow rate, the *flow sensor* is inside the mask (*located in a flow path of the positive treatment pressure flow of breathable gases*) as depicted in Figure 3. Behbehani ¶¶110-111.

Sullivan995 expressly teaches multiple places where snoring detection means 22 (and therefore microphone 11) can be located, including *located in a flow path of the positive treatment pressure flow of breathable gases*. Snoring detection means 22 of Figure 3 may be "conveniently in the form of the previously described device 10" as shown in Figures 1A, 1b, 2A, and 2b. EX1005, 10:1-3.

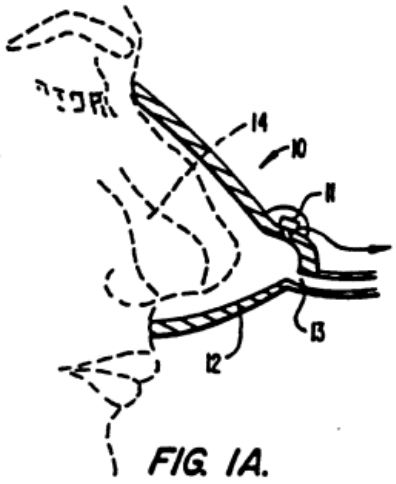


FIG. 1A.

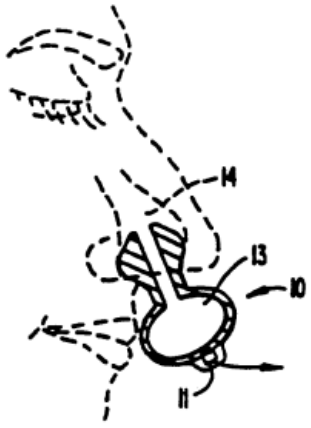


FIG. 1B.

Figure 1A depicts the microphone 11 (*flow sensor*) located "in sound communication with the container 12 of [the] nose mask." *Id.*, 8:47-49. Sullivan995 discloses an "enclosed airway," which "extends from the source of snoring sounds …through the nasal passages 14 and out of the opening 13 in the nasal mask." *Id.*, 8:49-59. That enclosed airway includes air "being inhaled by the patient" that "enters the nasal passageways" and therefore forms a *flow path of the positive treatment pressure flow of breathable gases*. *Id.*; Behbehani ¶111. The microphone 11 "is ideally located to take advantage of the natural stethoscope formed by the enclosed airway," which means it is *located in [that] flow path*. EX1005, 8:49-59. Similarly, Figure 1b depicts the microphone 11 as being "located within, or attached externally of, a nasal prong device" (*id.*, 8:59-61), which also discloses the microphone 11 (*flow sensor*) is *located in a flow path of the positive treatment pressure flow of breathable gases*. Behbehani ¶113.

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, 3:21-30; *see also id.*, 11:5-20, 15:56-64 (describing, with reference to Figure 3, detecting "a snore, or snoring patterns or abnormal breathing pattern"); Behbehani ¶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. The patterns in Figure 9 show a "high frequency wind noise," meaning the CPAP system is actively delivering a *flow of breathable gases directed to the patient*. EX1005, 13:10-21.

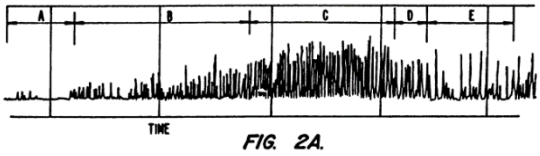


FIG. 2A.

EX1005, Fig. 2A

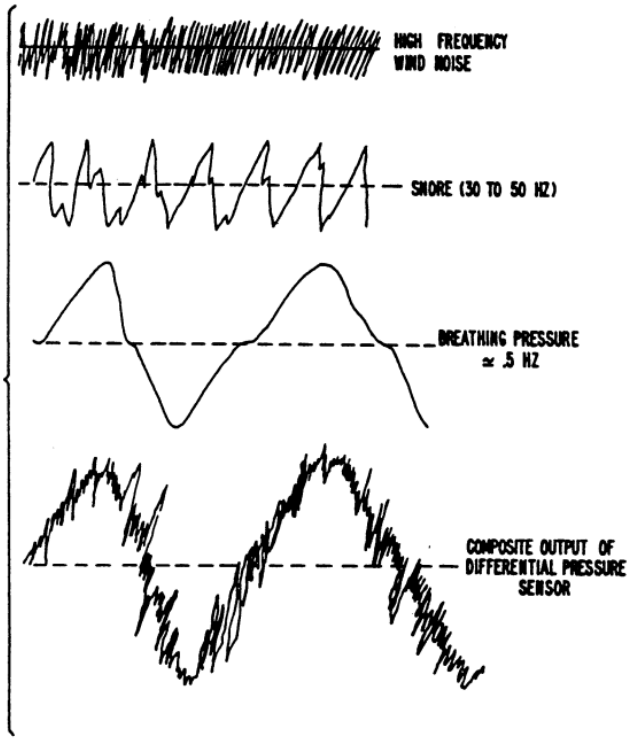


FIG. 9.

EX1005, Fig. 9

Further, Sullivan995's sensors are "continuously sensing the patient'breathing [sic] patterns" (*id.*, 18:27-31) including "an exhaled air flow volume, an inhaled air flow volume, breathing rate, an exhaled air flow rate, or an inhaled air flow rate." *Id.*, 18:50-53. Each of these metrics relates to the gas flow delivered to the patient and is *data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns.* Behbehani ¶109-118.

4. 1[c]: *"a processing arrangement 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,"*

Sullivan995 discloses this limitation. Behbehani ¶¶121-126. The combination of an amplifier/filter/processor unit 26[7] and speed control unit 23[8] (depicted in Figure 3 and described in part as the computing system in Figure 12) is *a processing arrangement.* The microphone 11 (*flow sensor*) provides its *measured data* to processor unit 26. 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.

[7] Sullivan995 refers to the same processor unit 26 as an amplifier/filter/processor unit 26, amplifier/filter/processor 26, and processor 26. EX1005, 10:3-6 10:41-46, 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.

[8] 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.

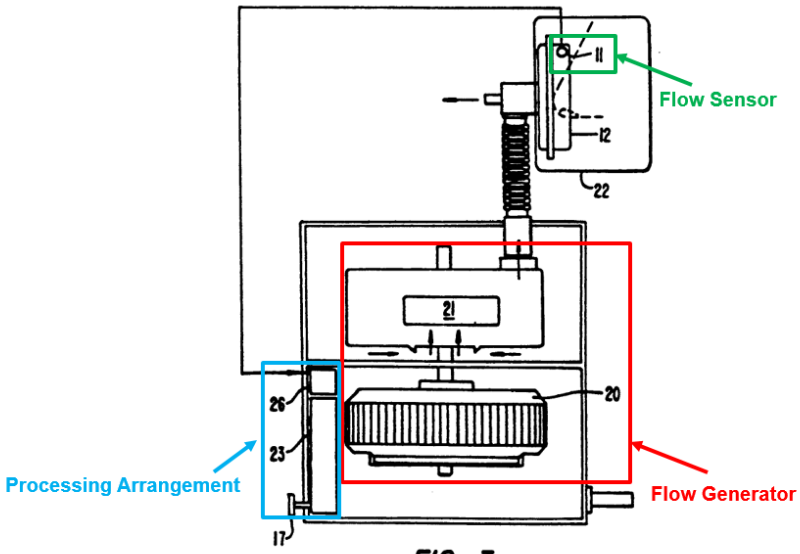


FIG. 3.

Therefore, the processor unit 26 is part of a *processing arrangement 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. EX1005, 17:3-4.

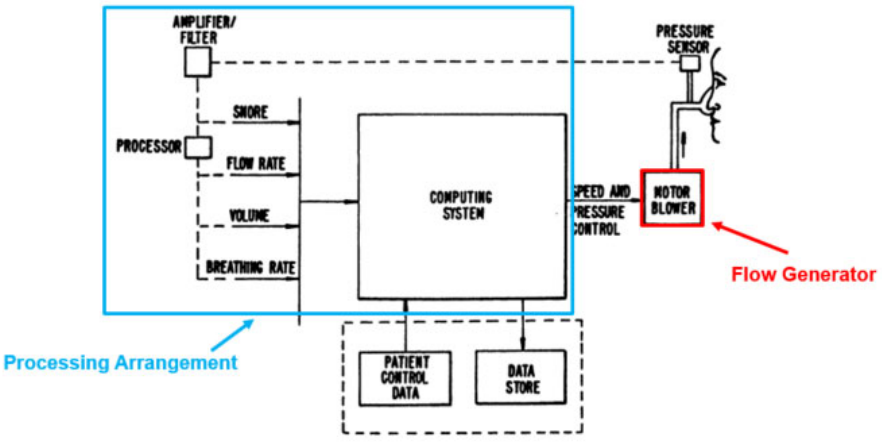


FIG. 12.

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 *processing arrangement*). Accordingly, Sullivan995's *processing arrangement receives the measured data corresponding to the flow of breathable gases from the flow sensor*.

Sullivan995 describes various *breathing patterns* for the patient. Referencing Figure 4, Sullivan995's *processing arrangement* 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 *processing arrangement*) therefore *analyzes the data [from the flow sensor] to determine 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 *processing arrangement* and *analyzes the data [from the flow sensor] to determine the patient's breathing patterns.*

5. 1[d]: *"the processing arrangement also determines whether to alter the 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,"*

Sullivan995 discloses this limitation. Behbehani ¶127. As explained for 1[b] and 1[c], Sullivan995 describes various *breathing patterns* for the patient. Referencing Figure 4, Sullivan995's *processing arrangement* 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 *processing arrangement*) therefore *analyzes the data [from the flow sensor] to determine the patient's breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.

As Sullivan995 describes with reference to Figure 12, 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.

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.* 10:40-48 (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 *processing arrangement*. *Id.*, 9:58-64; Behbehani ¶128. 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 ¶128. 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 ¶¶128-129.

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 determined breathing patterns of the patient. EX1005, 10:55-58. (emphasis added). 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 describes a *processing arrangement that determines whether to alter the 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. See also* Sections VIII.C.3 and VIII.C.4.

6. 1[e]: *"wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is an awake state,"*

Sullivan995 renders this limitation obvious either alone or in view of Sullivan460. Behbehani ¶140. Sullivan995 discloses *the processing arrangement automatically delays the onset of a pressure increase to the patient* until a snore is detected, meaning the patient has fallen asleep. Specifically, "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-12, 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*., 10:31-47; *see also* Fig. 13. Put simply, because the pressure is reduced automatically in the absence of snoring and is increased in response to snore detection, the *processing arrangement automatically delays the onset of a patient increase to the patient*

until snoring is detected. *See also id.* 10:47-61 (it is only "some time after going to sleep [when] the patient's body relaxes, [and] the airway start[s] to become unstable and the patient start[s] to snore," and the CPAP pressure increases "via the processor 26," in response to the "snore, or snore pattern."). 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), Sullivan995 does not explicitly disclose that the delay occurs *when the processing arrangement determines that the patient is in an awake state*. Behbehani ¶144. However, this limitation would have been obvious from Sullivan995 in view of Sullivan460. Behbehani ¶144.

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 ¶145.

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 ¶146. 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 *automatically delay[ing] the onset of a pressure increase to the patient* upon a *determin[ation] that the patient is in an awake state*. Behbehani ¶146.

b) Motivation to Combine and Reasonable Expectation of Success

See Sections VIII.A and VIII.B.

7. 1[f]: *"wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state."*

Sullivan995 alone or in view of Sullivan460 discloses this limitation. Behbehani ¶148. Sullivan995 delays the onset of a pressure increase to the patient until after a snore is detected. EX1005, 10:10-61, 14:17-20, Fig. 13; *see also, supra*, Section VIII.C.5. As a POSITA would have readily understood, because the patient only begins snoring after *the patient is in an asleep state*, this means that Sullivan995

ensures *the delay lasts at least until the processing arrangement determines that the patient is in an asleep state*. Behbehani ¶148.

To the extent this limitation is not explicitly disclosed in Sullivan995, the modified CPAP system taught by Sullivan995 in view of Sullivan460 would have rendered this limitation obvious.

a) Teachings of Sullivan460 on delay until asleep

Sullivan460 discloses a sleep detection technique based on detection of "reduced average airflow," and it would have been obvious to use Sullivan460's sleep detection technique with the modified CPAP system for detecting an asleep state for the reasons explained herein. *See* Sections VIII.A and VIII.B. Sullivan460's awake/asleep determination technique based on "reduced average airflow" would have been easily used in Sullivan995's CPAP system, especially given Sullivan995's use of a flow sensor to sense and analyze air flow rate. EX1005, Figs. 10-12, 6:54-68; Behbehani ¶150.

The modified CPAP system "is an improvement over the prior art because as soon as the patient goes to sleep…, the second treatment mode [increased pressure] is activated." EX1006, 7:10-12. Therefore, the modified CPAP system changes from a low pressure to a higher pressure when an asleep state is detected, meaning that *the delay lasts at least until the processing arrangement determines that the patient is in an asleep state*. *Id.*, 6:30-7:22, 10:7-16, 14:7-36, cls. 22-31.

b) Motivation to Combine and Reasonable Expectation of Success

See Section VIII.A and VIII.B.

In addition, the POSITA would have recognized that the modification would have resulted in higher therapeutic pressure being permitted as soon as the patient goes to sleep. This is an advantage because without such sleep detection, the CPAP system may begin activating the higher pressure either (1) too early, so that the higher pressure is activated when the patient is still awake and causes discomfort, or (2) too late, so that the higher pressure is activated well after the patient has fallen asleep and may have already experienced apneic episodes at the lower pressure. Behbehani ¶153. Sullivan460 solved that problem, which would have been a significant benefit for a patient using Sullivan995's CPAP system. Behbehani ¶154.

D. Dependent Claims 2-5, 7-14[9]

1. Claim 2: the processing arrangement determines during an asleep state that the patient is experiencing an elevated upper airway resistance, the processing arrangement increases the pressure applied to the airway patient.

Sullivan995 discloses this limitation. Behbehani ¶¶155-158. Sullivan995 states "the output pressure of the CPAP unit increases in response to detection of

[9] All dependent claims incorporate the analysis of the claims upon which they depends on.

snoring." EX1005, 10:10-12; *see also id.,* 10:47-61 (the CPAP pressure increases "via the processor 26," which is part of the *processing arrangement*, in response to the "snore, or snore pattern"); *see* Section X.C.1. Moreover, Figure 13 depicts how the Figure 12 computing system (included in the *processing arrangement*) increases pressure based on the snoring detection. *Id.*, 14:17-20.

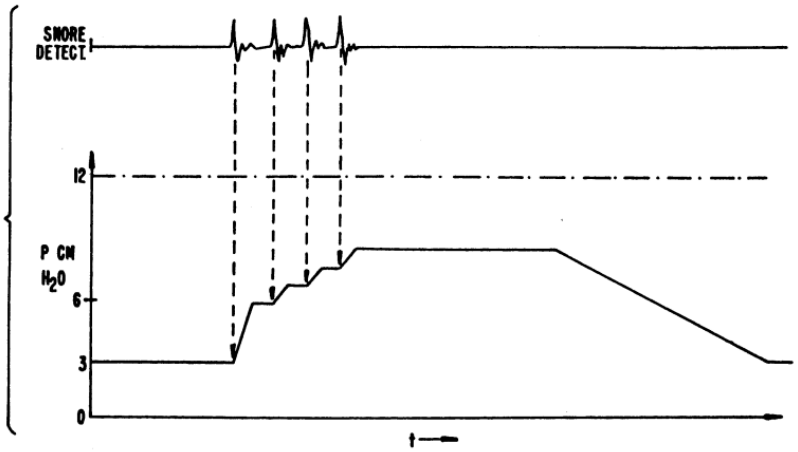


FIG. 13.

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 means *the patient is experiencing an elevated upper airway pressure. Id.*, 15:3-8; Behbehani ¶156.

As Sullivan995 further explains, the processor unit 26 (part of the *processing arrangement*) or computing system (part of the *processing arrangement*) increases the CPAP pressure in response to the snore (EX1005, 10:47-61), which means *the processing arrangement increases the pressure applied to the airway of the patient*, and that this happens *when the processing arrangement determines during an asleep state that the patient is experiencing an elevated upper airway resistance.* Behbehani ¶157.

Similarly, Sullivan460's CPAP system, 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, cls. 22-28, 43-46, Figs. 2-4.

2. **Claim 3:** the processing arrangement determines during an asleep state that the patient is experiencing a hypopnea event, the processing arrangement increases the pressure applied to the airway of the patient.

Sullivan995's *processing arrangement* detects obstructions *during an asleep state*, and those obstructions are hypopneas and therefore include *a hypopnea event.* To treat the obstruction (a *hypopnea event*), Sullivan995's *processing arrangement* increases the CPAP pressure *when* the *hypopnea event* occurs, which

increases the pressure applied to the airway of the patient. EX1005, 12:67-13:9, 13:46-54, 14:17-32, Figs. 2A, 12, 13; Behbehani ¶159..

3. **Claim 4:** the processing arrangement determines during an asleep state that the patient is experiencing an apnea event, the processing arrangement increases the pressure applied to the airway of the patient.

Sullivan995's *processing arrangement* detects obstructions *during an asleep state*, and those obstructions are apneas and therefore include *an apnea event.* Behbehani ¶160. To treat the obstruction (an *apnea event*), Sullivan995's *processing arrangement* increases the CPAP pressure *when* the *apnea event* occurs, which *increases the pressure applied to the airway of the patient*. EX1005, 4:28-45, 12:67-13:9, 13:55-59, Figs. 2A, 12; *see* Section VIII.D.3.

4. **Claim 5:** the processing arrangement determines that the patient has transitioned to an awake state from an asleep state, the processing arrangement lowers the pressure applied to the airway of the patient.

Sullivan995 renders this limitation obvious either alone or in view of Sullivan460. Behbehani ¶¶161-165. Sullivan995's processor unit 26 and/or the speed control unit 23 (parts of the *processing arrangement*) automatically reduce 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.

Although Sullivan995 does not explicitly disclose determining that *the patient has transitioned 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. "[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 ¶¶162-163.

It would have been obvious to a POSITA to modify Sullivan995 so that *when the processing arrangement* in Sullivan995 *determines that the patient has transitioned to an awake state from an asleep state, the processing arrangement lowers the pressure applied to the airway of the patient*, as taught in Sullivan460, for the same reasons as explained for 1[e]. *See* Section VIII.C.6; Behbehani ¶164. 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 ¶165.

5. Claim 7: the pressure is increased using a ramp system.

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 ¶166; *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).

6. Claim 8: the processing arrangement determines that the patient is in an asleep state when the breathing pattern is a period of regular breathing.

Sullivan995 discloses this limitation, or renders this limitation obvious in view of Sullivan460. Behbehani ¶¶167-177. Sullivan995 *determines that the patient is in an asleep state when the breathing pattern is a period of regular breathing*. Behbehani ¶¶167-170. Sullivan995 describes the ability to identify various breathing patterns associated with sleep. *Id.* ¶167. For example, Sullivan995 states that "Part A of FIG. *2a* is indicative of normal breathing, part B indicates soft to moderate snoring, part C shows constant loud snoring and part E shows periods of silence punctuated by snoring." *Id.* 13:43-46, Fig 1A (emphasis in original) Additionally, Sullivan995 expressly illustrates an example where four (4) snores are detected. *Id.*, Fig. 13, 8:36-44, 14:48-15:15. Sullivan995 also discloses detection of "abnormal breathing patterns" (*id.*, 18:9-15, 18:35-43),

detecting a "snore pattern" or "snore patterns" (*id.* 10:55-58, 7:1-8, 6:20-31), 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. Sullivan995 therefore discloses the ability to identify normal breathing patterns during sleep and discloses a system where the *processing arrangement determines that the patient is in an asleep state when the breathing pattern is a period of regular breathing*. Behbehani ¶¶167, 170.

To the extent that Sullivan995 does not expressly state that *a sleep state determination is made based on a period of regular breathing*, this would have been obvious from Sullivan995 in view of Sullivan460.

a) Teachings of Sullivan460 on transition between awake and asleep

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," which would include a *transition[] between an awake state and an asleep state. Id.*, Cls. 44-45.

Sullivan460's sleep sensor also detects *breathing patterns*. The flow rate measurement means 70 detects multiple "interruptions," which Fig. 1 depicts, and are an example of a breathing pattern. EX1006, 10:12-16. Sullivan460 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 combination 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 breathing patterns, 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 (Ground 1, Motivation to Combine and Reasonable Expectation of Success). It would have been further obvious to use the teachings of Sullivan995 or Sullivan460's detection of a *breathing patterns* 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), and such obstructions (e.g., snores, apneas, hypopneas, or other flow limitations) typically occur in groups during sleep. Behbehani ¶177. 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"). 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 ¶177.

7. Claim 9: the processing arrangement determines that the patient is in an asleep state when the breathing pattern indicates a pattern hypopnea events.

Sullivan995 discloses the ability to identify various breathing patterns associated with sleep, including those patterns associated with hypopnea events. *See* Section VIII.D.6 (Ground 1, Claim 8); Behbehani ¶¶178-183.

8. Claim 10: the processing arrangement determines that the patient is in an asleep state when the breathing pattern indicates a pattern of obstructive apnea events.

Sullivan995 discloses the ability to identify various breathing patterns associated with sleep, including those patterns associated with apnea events. *See* Section VIII.D.6 (Ground 1, Claim 8); Behbehani ¶184.

9. Claim 11: the pattern of apnea events is at least three obstructive apnea events.

Sullivan995 discloses this limitation or renders obvious this limitation in view of Sullivan460 or the knowledge of one skilled in the art. Behbehani ¶185. Figure 13 of Sullivan995 depicts a set of four snores, which are *at least three obstructive apnea events.* Moreover, Figure 2A depicts *at least three obstructive apnea events* in Section E. EX1005, 9:16-32. This is also consistent with Sullivan995's teaching of providing treatment upon detecting a "sequence of snores," "breathing patterns," and "snore patterns."

Figure 1 of Sullivan460 depicts *at least three obstructive apnea events* in the form of an "interruption 10" for each cycle. EX1006, 9:31-36. Sullivan460 also describes "treat[ing] the airway limitation on detection of said at least two interruption cycles." *Id.*, 3:20-23; *see also* 3:1-3, 5:7-9, cls. 2, 33.

To the extent that neither Sullivan995 nor Sullivan460 expressly disclose this limitation, this would have been obvious to a POSITA. As the POSITA would have recognized, detecting two obstructions is more susceptible to errors and false

positives than detection of *at least three obstructive apnea events*. Behbehani ¶188. Furthermore, as the obstructions tend to occur in a cyclical, periodic pattern (*see* EX1005, Figs. 2A, 9, and 13 and EX1006, Fig. 1), the POSITA would have known to detect at least three obstructive apnea events in order to characterize the periodicity of that pattern. Behbehani ¶190. Specifically, there is only one spacing between two obstructions, which means that detecting only two obstructions does not provide any insight into whether the obstructions are cyclical or periodic. In contrast, *at least three obstructive apnea events* involves at least two spacings, which informs whether the obstructions are occurring in a cyclical or periodic pattern and indicates the patient is asleep. As the POSITA would have recognized, such detection is only possible with *at least three obstructive apnea events.* Behbehani ¶191. Such an implementation is therefore 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.

The *obstructions* in Sullivan995 referenced in 1[f] and claim 3 include *apneas*. *See* EX1005, 4:28-45 (detecting "apneas"), 13:4-9 (indexing "the number of apneic episodes). 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 ¶191.

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 ¶192. Snores do not always precede apneas, such that detecting apneas would have been particularly desirable. Behbehani ¶192. The purpose of detecting Sullivan995's "snore," "flow rate," "breathing rate" or "time interval," and "volume" data is to detect breathing patterns having apneas, and upon detection of the apneas, treat them by increasing pressure. EX1005, 4:36-5:11, 6:54-68, 10:13-30, 14:65-15:17, 17:9-27. The POSITA would have recognized that detecting *at least three obstructive apnea events* would have been a good technique for verifying a sleep state, and would avoid false positives that may occur when only one or two apneas are detected. Behbehani ¶192. A minimum number (3) of *apneas* would have been obvious because, as explained for claim 2, the analysis of which is incorporated herein, *apneas* occur in a cyclical or periodic pattern, and such detection is only possible with *at least three obstructive apnea events.* Behbehani ¶193.

10. Claim 12: the processing arrangement determines during an asleep state that the patient is experiencing an apnea event, the processing arrangement increases the pressure applied to the airway of the patient.

Sullivan995 discloses this limitation. Behbehani ¶194. As explained for claims 1 and 4, Sullivan995's *processing arrangement* detects obstructions *during an asleep state*, and those obstructions are apneas and therefore include *an apnea event.* To treat the obstruction (an *apnea event*), Sullivan995's *processing arrangement* increases the CPAP pressure *when* the *apnea event* occurs, which *increases the pressure applied to the airway of the patient*. EX1005, 4:28-45, 12:67-13:9, 13:55-59, Figs. 2A, 12.

11. Claim 13: the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state and is experiencing an apnea event, the processing arrangement automatically increases the pressure to a treatment pressure.

Sullivan995 discloses this limitation or renders obvious this limitation in view of Sullivan460. Behbehani ¶¶195-203. Sullivan995 describes a system that determines that the patient is in an asleep state when the breathing pattern indicates a pattern of obstructive hypopnea events/indicates a pattern of obstructive apnea.

As Sullivan995 further explains, the processor unit 26 (part of the *processing arrangement*) or computing system (part of the *processing arrangement*) increases the CPAP pressure in response to the snore (EX1005,

10:47-61), which means *the processing arrangement increases the pressure to a treatment pressure.* Behbehani ¶¶196-197.

In other words, to treat the obstruction, Sullivan995's *processing arrangement* increases the CPAP pressure *when* the apnea *event* occurs, which *increases the pressure to a treatment pressure*. EX1005, 12:67-13:9, 13:46-54, 14:17-32, Figs. 2A, 12, 13.

> **12. Claim 14:** the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state and is experiencing elevated upper airway resistance, the processing arrangement automatically increases the pressure to at least a first treatment.

Sullivan995 discloses this limitation or renders obvious this limitation in view of Sullivan460. Behbehani ¶¶204-208. 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 *processing arrangement*, in response to the "snore, or snore pattern"). Moreover, Figure 13 depicts how the Figure 12 computing system (included in the *processing arrangement*) increases pressure based on the snoring detection. *Id.*, 14:17-20.

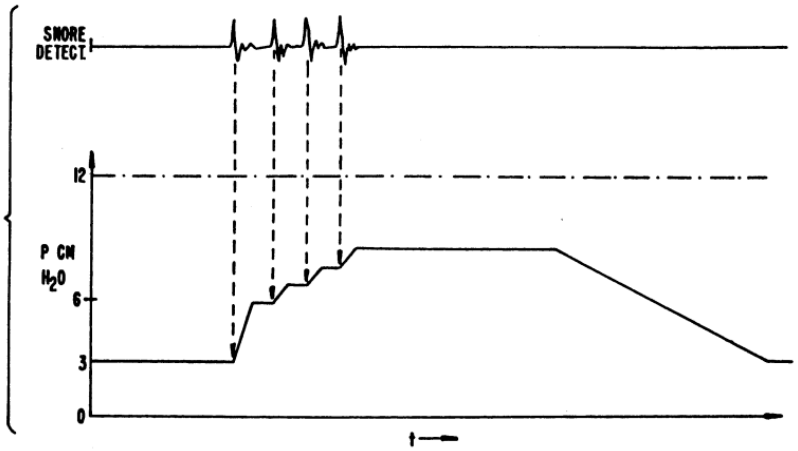


FIG. 13.

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 been 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 means *the patient is experiencing an elevated upper airway pressure.* Behbehani ¶206.

As Sullivan995 further explains, the processor unit 26 (part of the *processing arrangement*) or computing system (part of the *processing arrangement*) increases the CPAP pressure in response to the snore (EX1005, 10:47-61), which means *the processing arrangement increases the pressure*

applied to the airway of the patient, and that this happens *when the processing arrangement determines during an asleep state that the patient is experiencing an elevated upper airway resistance.* Behbehani ¶207.

Sullivan460's CPAP system, 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, cls. 22-28, 43-46, Figs. 2-4.

IX. GROUND 2: SULLIVAN995 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIM 6

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 *awake state is a troubled wakefulness state.* Behbehani ¶¶209-213. The POSITA would have been motivated to implement this modification to cause Sullivan995's modified CPAP system to *lower[] the pressure* upon detecting the patient's *troubled wakefulness* state. Behbehani ¶¶209-210.

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 ¶210. 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. 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." Ex., 1007, 7:11-16. 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 ¶¶211-212.

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 ¶213.

C. Dependent Claim 6

This limitation would have been obvious from the teachings of Sullivan995 in view of Sullivan460 and Matthews. Behbehani ¶¶214-218. To the extent *the awake state is a troubled wakefulness state* would not have been obvious from Sullivan995 in view of Sullivan460, this limitation would have been obvious in further view of Matthews. Behbehani ¶214. Similar to Sullivan995 and Sullivan460, Matthews describes a CPAP system that detects and analyzes breathing patterns and supplies pressurized air to a patient based on the breathing pattern to support and treat breathing disorders. EX1007, 1:15-22, 21:45-57.

Matthews discloses *determining whether a breathing pattern is indicative of a troubled wakefulness state*. Behbehani ¶215. As discussed above, the troubled wakefulness state is denoted by a breathing pattern "characterized by irregular[] 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; *see also* Section VII.A (Claim Construction, "troubled wakefulness"). The erratic nature of a troubled wakefulness state is demonstrated in Figure 7, particularly when contrasted with a regular sleep pattern demonstrated in Figure 4:

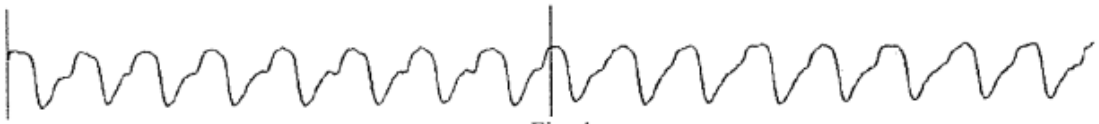


Fig. 4

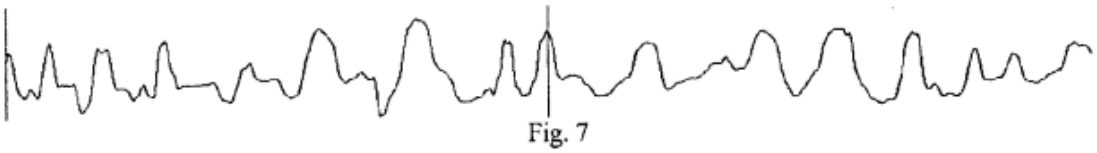


Fig. 7

EX1001, Figures 4, 7.

Matthews recognizes that "[w]hen a patient is awake…or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable." EX1007, 21:37-40. To address potential instability, Matthews discloses "a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing." *Id.*, 40:25-30. The breathing control layer "performs statistical analysis on the scatter of the trended weighted peak flow data to detect unstable breathing patterns or abrupt changes in patient response," similar to those found in Figure 7. Matthews's disclosure of monitoring and detecting erratic or irregular breathing, meets the *determining whether a breathing pattern is indicative of a troubled wakefulness state* claim limitation. Behbehani ¶¶217-218.

X. GROUND 3: RAPOPORT502 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1-5, 7-14

A. Motivation to Combine

It would have been obvious to a POSITA to modify the *processing arrangement* in Rapoport502 so that it *determines that the patient is in an awake state*, and in response to that determination, *automatically delays the onset of a pressure increase to the patient*, as taught in Sullivan460. Behbehani ¶¶219-225.

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. EX1006., 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 ¶220.

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. Behbehani ¶221. 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 ¶221.

B. A POSITA Would Have Had Reasonable Expectation of Success

Rapoport502 and Sullivan460 are analogous art. Behbehani ¶223. Both describe CPAP systems with flow sensors and 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 CPAP 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.

Dr. Rapoport knew Dr. Sullivan's work, and said it was "a few months ahead of the rest of us." EX1012, 3; Behbehani ¶224. A POSITA improving CPAP machines would have looked at the pioneer in CPAP machines for algorithms for different air pressure settings that could improve compliance. Behbehani ¶224. Further, Dr. Rapoport repeatedly cited Dr. Sullivan's work. EX1014, 7-8.

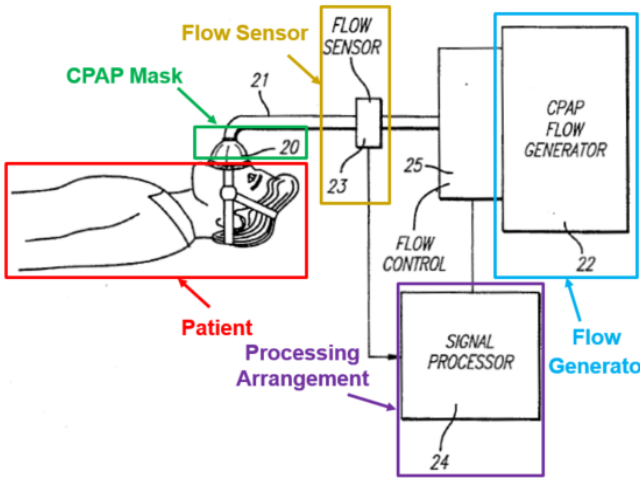
Given that the proposed modification involves a simple change in a programming algorithm, it is nothing more than a combination of known prior art

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 ¶225.

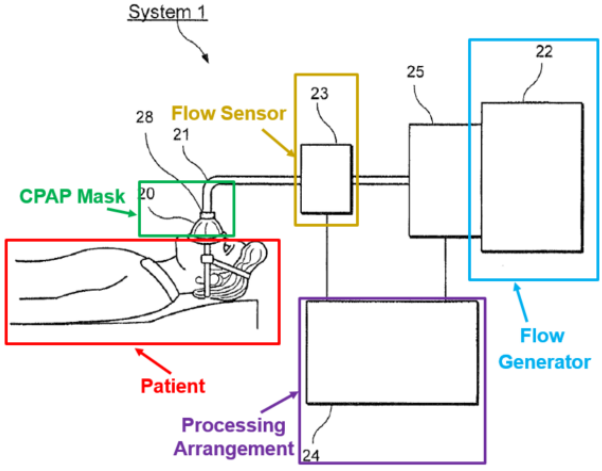
C. Independent Claim 1

1. Preamble

To the extent the preamble is limiting, Rapoport502 discloses a continuous *positive airway pressure system* in the same manner as the '024 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 ¶¶226-227.



Rapoport502, Fig. 9 (annotated)



'024 Patent, Fig. 1 (annotated)

2. 1[a]

Rapoport502 discloses this limitation. Behbehani ¶228. 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. A POSITA would have understood that the air supplied to the patient is *a positive airway pressure to assist in treating a sleeping disorder*. Behbehani ¶228.

3. 1[b]

Rapoport502 discloses this limitation. Behbehani ¶¶229-231. Rapoport502's CPAP system includes a conventional *flow sensor* 21 (brown) "coupled to the tube 21," which defines the *flow path of the positive treatment pressure flow of breathable gases* from the flow generator 22 to the patient worn CPAP mask 20. EX1008, Fig. 9; *see also* Section X.C.1. The flow sensor 21 to be *in* the flow path. Behbehani ¶230. Specifically, Rapoport502 discloses that "the blower [i.e., flow generator 22] ***supplies air through the flow sensor*** to the patient via a hose and nasal coupling" of the CPAP mask 20 and further illustrates the flow sensor being in the flow path in the same manner as the '024 Patent. EX1008, 3:22-28 (emphasis added); Behbehani ¶¶229-32.

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." EX1008, 5:56-61. The conventional flow

sensor 23 *measures 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.*, 3:22-28; Behbehani ¶231. 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 ¶231.

4. 1[c]

Rapoport502 discloses this limitation. Behbehani ¶¶232-236. Rapoport502's CPAP system includes a signal processor 24 (purple) corresponding to a *processing arrangement*. *See* Section X.C.1. The '024 Patent illustrates the processing arrangement 24 as a "black box" but does not disclose what constitutes the processing arrangement 24. *See id.* (illustrating '024 patent Fig. 1); Behbehani ¶233. 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 ¶¶232-33.

Both the '024 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, 3:60-64, 4:14-28, 5:48-54 *with* EX1008, 5:56-63 (describing waveforms received and analyzed and the output to control other components of the CPAP system), *id.,* 6:1-55 (disclosing the decision flow of the signal processor 24 in relation to Fig. 10); Behbehani ¶234.

Further, the signal processor 24 receives the measured data corresponding to the flow of breathable gases from the flow sensor. *See* Section X.C.4. 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 ¶236. 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 ¶236.

5. 1[d]

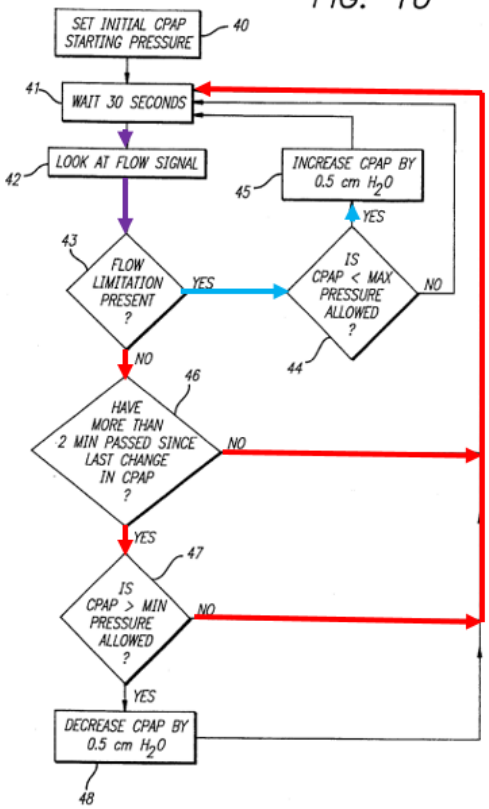
Rapoport502 discloses this limitation. Behbehani ¶237. "The signal processor 24 outputs a signal to a conventional flow control 25 for controlling the pressure applied by the flow generator to the tube 21." EX1008, 5:61-63. Correspondingly, Figure 10 describes processor 24's decision flow *whether to alter the 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 ¶237.

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 ¶237.

6. 1[e]

Rapoport502 renders this limitation obvious in view of Sullivan460. Behbehani ¶¶238-243. Rapoport502 discloses *the processing arrangement automatically delays* by at least 30 seconds *the onset of a pressure increase to the patient* relative to determining a flow limitation state for the patient, as seen by Figure10. EX1008, Fig. 10 (reproduced below); *see also* Behbehani ¶¶238-240.

FIG. 10



EX1008, Fig. 10 (annotated)

Figure 10 represents Rapoport502's "automatic adjustment mode" effectuated by the *processing arrangement* 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 (red), after the determination of a "NO" flow limitation (step 43), if the signal processor 24 determines that 2 minutes have not passed since the last pressure change (Step 46) or the CPAP pressure is not greater than the minimum pressure allowed (Step 47), the signal processor 24 returns to Step 41 and *automatically delays* by at least 30 seconds a change in pressure. *Id.*, 6:17-29. As seen in (blue), after completion of the delay and 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.

While Rapoport502 automatically delays the onset of a pressure increase relative to flow limitations, Rapoport502 does not expressly disclose delaying the onset of a pressure increase relative to *determin[ing] that the patient is in an awake state*. However, this limitation would have been obvious in view of Sullivan460. Behbehani ¶241.

a) Teachings of Sullivan460

Sullivan460 discloses automatically delay[ing] the onset of a pressure increase to the patient upon determin[ing] that the patient is in an awake state. *See* Section VIII.C.6.a) (Ground 1, 1[e], 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[f]

Rapoport502 renders this limitation obvious in view of Sullivan460. Behbehani ¶¶244-248. Rapoport502's 30-second *delay* (Step 41) *lasts at least until the processing arrangement determines that the patient* is in a flow limitation state. As indicated in (purple), the *delay lasts at least* for 30 seconds *until* the signal processor 24 analyzes and determines the presence of a flow limitation (Step 43), at which time, pressure is increased. *See* Section X.C.6 (describing blue path). If there is no flow limitation, the *delay* continues for another 30 seconds. *See id.* (describing red path).

Rapoport502 inherently discloses that the signal processor 24 *determines that the patient is in an asleep state* because a flow limitation can only occur during an asleep state. Behbehani ¶245; *Sony Corp. v. MPHJ Tech. Investments LLC*, IPR2013-00302, Paper 52 (Nov. 19, 2014) (functionality disclosed if necessarily present in reference). In other words, the positive determination of a

flow limitation at Step 43 necessarily means that the signal processor 24 *determines that the patient is in an asleep state. See id*.

While Rapoport502 does not expressly disclose delaying at least until the signal processor 24 *determines that the patient is in an asleep state*, this limitation would have been obvious in view of Sullivan460 as well. Behbehani ¶246.

a) Teachings of Sullivan460

Sullivan460 discloses this limitation. *See* Section VIII.C.7.a) (Ground 1, 1[f], discussing Sullivan460).

b) Motivation to Combine and Reasonable and Expectation of Success

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

D. Dependent Claims 2-5, 7-14

1. Claim 2

Rapoport502 discloses this limitation. Behbehani ¶249. Rapoport502 discloses that *obstructions are elevated upper airway resistance*. 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)…"), Fig. 10 (showing detection of flow limitation); Behbehani ¶249.

2. Claim 3

Rapoport502 discloses this limitation. Behbehani ¶250.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 ¶250.

3. Claim 4

Rapoport502 discloses this limitation. Behbehani ¶251. 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 ¶251.

4. Claim 5

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani ¶¶252-255. Rapoport502's signal processor 24 (*processing arrangement*) detects a patient transitioning between a state associated with a flow limitation and a different state associated with no flow limitation. Based on this detection, the signal processor 24 *lowers pressure applied to airway of patient* by

0.5 cm H_20 (at step 48) when it determines a "NO" flow limitation state (at step 43) and the CPAP pressure is greater than the minimum pressure allowed (at step 47). EX1008, 6:17-29.

Although Rapoport502 does not explicitly disclose lowering pressure upon detection of an awake state, this is disclosed in Sullivan460. Sullivan460's CPAP system includes a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19. As Sullivan460 further explains, "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. As the POSITA would have readily understood, 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 ¶254.

It would have been obvious to a POSITA to modify Rapoport502 so that *when the processing arrangement* 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 processing arrangement lowers the pressure applied to the airway of the patient*, as taught in Sullivan460, for the same

reasons as explained above. The POSITA would have recognized from the teachings of Rapoport502 and Sullivan460 that a lower pressure is desirable when the patient is awake. Applying a lower pressure when the patient is awake ensures the patient is comfortable and reduces the likelihood the patient will remove the mask, thereby increasing compliance with CPAP treatment. *See also* Sections X.A (Ground 3, Motivation to Combine) and X.B (Ground 3, Reasonable Likelihood of Success).

5. Claim 7

Rapoport502 discloses this limitation. Behbehani ¶256. In Rapoport502's CPAP system, "the controlled positive *pressure* could be changed" "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. Moreover, Rapoport502's CPAP system makes use of "a slope parameter [of the ramp], e.g., 0.1 cm per two seconds." EX1008, 11:44-46. A POSITA would have understood to increase the pressure using such a ramp system as disclosed in Rapoport502. Behbehani ¶256.

6. Claim 8

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA discloses this limitation. Behbehani ¶¶257-259. Rapoport502's *processing arrangement* analyzes flow limitation data from the flow sensors. Moreover, as I

have already explained in my analysis of limitations 1[d] and 1[e] for this ground (*see* Sections X.C.5 and X.C.6), Rapoport502 also detects *the patient's breathing patterns*. The waveforms show a change in the breathing patterns of the patient that indicate a gradual onset of a sleeping disorder as the applied pressure was varied. EX1008, 4:47-5:50, Figs. 1-5. A POSITA would have understood the period of breathing prior to the onset of a sleeping disorder to be *a period of regular breathing*. Behbehani ¶258. To the extent Rapoport502 does not explicitly disclose this limitation, a POSITA would have found this limitation obvious by combining the teachings of Rapoport502 with Sullivan460, as explained for 1[e] for this ground. *See* Section X.C.6 (Ground 3, 1[e]).

7. Claim 9

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA discloses this limitation. Behbehani ¶¶260-263. Rapoport502's *processing arrangement* analyzes flow limitation data from the flow sensors. Moreover, as I have already explained in my analysis of limitations 1[d] and 1[e] for this ground (*see* Sections X.C.5 and X.C.6), Rapoport502 also detects flow limitations in *the patient's breathing patterns*. Because flow limitations are detected, this means the *sleep state of a patient* is an asleep state. Further, as explained above, Rapoport502 is configured to identify based on breathing patterns when a patient is experiencing an hypopnea event. *See* Section X.D.2 (Ground 3, Claim 3). To the extent

Rapoport502 does not explicitly disclose this limitation, a POSITA would have found this limitation obvious by combining the teachings of Rapoport502 with Sullivan460, as explained for 1[e] for this ground. *See* Section X.C.6 (Ground 3, 1[e]).

8. Claim 10

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA discloses this limitation. Behbehani ¶¶264-67. Rapoport502's *processing arrangement* analyzes flow limitation data from the flow sensors. Moreover, as I have already explained in my analysis of limitations 1[d] and 1[e] for this ground (*see* Sections X.C.5 and X.C.6), Rapoport502 also detects flow limitations in *the patient's breathing patterns*. Because flow limitations are detected, this means the *sleep state of a patient* is an asleep state. Further, as explained above, Rapoport502 is configured to identify based on breathing patterns when a patient is experiencing an apnea event. *See* Section X.D.3 (Ground 3, Claim 4). To the extent Rapoport502 does not explicitly disclose this limitation, a POSITA would have found this limitation obvious by combining the teachings of Rapoport502 with Sullivan460, as explained for 1[e] for this ground. *See* Section X.C.6 (Ground 3, 1[e]).

9. Claim 11

Rapoport502 discloses this limitation. Behbehani ¶¶268-269. Rapoport502 raises the controlled positive pressure upon the detection of one or two apnea obstructions. EX1008, 11:35-39 ("If two apneas of a duration of ten seconds or longer occur within one minute, then the controlled positive pressure is raised. If one long apnea having a duration of twenty seconds or longer occurs, then the controlled positive pressure is raised.").

A POSITA would have readily understood that apneas indicate a sleep state and should be treated with increased pressure, as taught by Rapoport502. Behbehani ¶269. The POSITA would have recognized that detecting *three or more apneas* would have been a good technique for verifying a sleep state, and would avoid false positives that may occur when only one or two apneas are detected as disclosed by Rapoport502. *Id*.

10. Claim 12

Rapoport502 discloses this limitation. Behbehani ¶270. Rapoport502's signal processor 24 (*processing arrangement*) determines "YES" for a flow limitation (at step 43), the signal processor 24 *increases pressure applied to airway of patient* by 0.5 cm H_20 (at step 45). Ex. 1008 at 6:9-13, Fig. 10; *see also* Section X.C.6 (Ground 3, 1[e]). A POSITA would have understood that Rapoport502's determination of a flow limitation occurs *during an asleep state* when *the patient is*

experiencing a hypopnea event/apnea event/elevated upper airway resistance. *See* Sections X.D.1- 3 (Ground 3, Claims 2-4, describing Rapoport502's disclosure of apneas and hypopneas as obstructions).

11. Claim 13

Rapoport502 discloses this limitation for the same reasons that I have already explained in Sections X.D.1 and X.D.3 (Ground 3, Claims 2 and 4); Section X.D.10 (Ground 3, Claim 12). Claims 13 differs from claim 12 by reciting an *apnea event* instead of a hypopnea event. Behbehani ¶271.

12. Claim 14

Rapoport502 discloses this limitation. *See* Sections X.D.1 and X.D.2 (Ground 1, Claims 2 and 3); Section X.D.10 (Ground 3, Claim 12). Claims 14 differs from claim 12 by reciting an *elevated upper airway resistance* instead of a hypopnea event. Behbehani ¶272.

XI. GROUND 4: RAPOPORT502 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIM 6

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 *processing arrangement* in Rapoport502 *delay[s] the onset of a pressure increase* when the patient has a *troubled wakefulness state* and to *lower[] the pressure* when the patient transitions to a *troubled wakefulness state*. Behbehani ¶¶273-280. The

POSITA would have been motivated to implement this modification to cause Rapoport502's modified CPAP system to, *lower[] the pressure* upon detecting the patient's *troubled wakefulness* state. Behbehani ¶¶273-276.

First, 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 ¶274. 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 system could also 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. Behbehani ¶275.

Second, the modification would have been a logical extension of Rapoport502's air pressure adjustment approach. Behbehani ¶276. "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. EX1008, Fig. 10; Behbehani ¶276.

B. Reasonable Expectation of Success

The POSITA would have had a reasonable expectation of success in making the modification to Rapoport502 and Sullivan460's CPAP system. Behbehani ¶277-280.

First, Rapoport502, Sullivan460, and Matthews are analogous art. Behbehani ¶278. All references describe CPAP systems with flow sensors and flow 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, 7:12-16. The data from the flow sensor are monitored and used to determine how to control the pressure delivered to the patient. *Id.*, 8:54-9:15. Sullivan460 already 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.

Second, modifying the CPAP system of Rapoport502 and Sullivan460 would have been as simple as adding another decision point in the algorithm. Behbehani ¶279. Specifically, because the flow sensors already 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 ¶279.

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 ¶280.

C. Dependent Claim 6

Rapoport502 and Sullivan460 in view of Matthews discloses this limitation. Behbehani ¶281. A POSITA would have modified the system of Rapoport502 and Sullivan460 to lower pressure when the *processing arrangement* determines that the patient is in a *troubled wakefulness state*, as taught by Matthews. *See* Section IX.C (describing Matthews).

XII. SECONDARY CONSIDERATIONS

There are no known secondary considerations. Should PO argue secondary considerations, 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.

Respectfully submitted,

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Claims Listing (Appendix)

1. 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 in a patient, the positive airway pressure system comprising:

   [a] a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient;

   [b] a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and

   [c] a processing arrangement 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, [d] the processing arrangement also determines whether to alter the 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, [e] wherein the processing arrangement automatically delays the onset of a pressure increase to the patient when the processing arrangement determines that the patient is in an awake state, wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state.

2. The system of claim 1, wherein when the processing arrangement determines during an asleep state that the patient is experiencing an elevated upper airway resistance, the processing arrangement increases the pressure applied to the airway of the patient.

3. The system of claim 1, wherein when the processing arrangement determines during an asleep state that the patient is experiencing a hypopnea event, the processing arrangement increases the pressure applied to the airway of the patient.

4. The system of claim 1, wherein when the processing arrangement determines during an asleep state that the patient is experiencing an apnea event, the processing arrangement increases the pressure applied to the airway of the patient.

5. The system of claim 1, wherein when the processing arrangement determines that the patient has transitioned to an awake state from an asleep state, the processing arrangement lowers the pressure applied to the airway of the patient.

6. The system of claim 5, wherein the awake state is a troubled wakefulness state.

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

8. The system of claim 1, wherein the processing arrangement determines that the patient is in an asleep state when the breathing pattern is a period of regular breathing.

9. The system of claim 1, wherein the processing arrangement determines that the patient is in an asleep state when the breathing pattern indicates a pattern of hypopnea events.

10. The system of claim 1, wherein the processing arrangement determines that the patient is in an asleep state when the breathing pattern indicates a pattern of obstructive apnea events.

11. The system of claim 10, wherein the pattern of apnea events is at least three obstructive apnea events.

12. The system of claim 1, wherein when the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state and is experiencing a hypopnea event, the processing arrangement automatically increases the pressure to a treatment pressure.

13. The system of claim 1, wherein when the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state and is experiencing an apnea event, the processing arrangement automatically increases the pressure to a treatment pressure.

14. The system of claim 1, wherein when the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state and is experiencing elevated upper airway resistance, the processing

arrangement automatically increases the pressure to at least a first treatment pressure.

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 13,970 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. 10,384,024 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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