UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ResMed Inc.
Petitioner

v.

New York University
Patent Owner

Case No. IPR2022-00988

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,108,009

Claims 1-30

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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)
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1035	F. Roux, et al., "Continuous Positive Airway Pressure: New Generations," Clinics in Chest Medicine (2003)
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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. ("Petitioner") respectfully requests *inter partes* review of claims 1-30 of U.S. Patent No. 9,108,009 (EX1001, "'009 Patent") and a finding that all challenged claims of the '009 Patent are unpatentable.

Patients often struggle to use positive airway pressure (PAP) systems because the high pressure treatment causes discomfort. The '009 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 '009 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 '009 Patent is assigned to New York University ("PO"), which is currently asserting the '009 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. 9,168,344, U.S. Patent No. 9,427,539, U.S. Patent No. 9,533,115, U.S. Patent No. 9,867,955, and U.S. Patent No. 10,384,024.

C. Notice of Counsel and Service Information

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

D. Fee for Inter Partes Review

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

E. Certification of Grounds for Standing

Petitioner certifies pursuant to 37 C.F.R. § 42.104(a) that the '009 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 1-11, 13-21, 23-28, and 30 are obvious under 35 U.S.C. § 103 over Sullivan995[1] in view of Sullivan460[2].

Ground 2: Claims 12, 22, and 29 are obvious under 35 U.S.C. § 103 over Sullivan995 in view of Sullivan460 and Matthews[3].

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

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

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

Ground 3: Claims 1-11, 13-21, 23-28, and 30 are obvious under 35 U.S.C. § 103 over Rapoport502[4] in view of Sullivan460.

Ground 4: Claims 12, 22, and 29 are obvious under 35 U.S.C. § 103 over Rapoport502 in view of Sullivan460 and Matthews.

IV. BACKGROUND

A. Overview of the Technology

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, 1:31-32. The obstructions range "from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring)." *Id.*, 1:32-36. They decrease blood oxygenation as well, and elevate "risk factors in certain types of heart disease." EX1013, 1:27-28, 1:42-45; EX1007, 1:35-48; *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, 1:52-2:2; EX1014, 1 (citing EX1015). To prevent collapse of the upper airway during sleep, PAP opposes the

[4] U.S. Patent No. 5,490,502 (EX1008, "Rapoport502502") is §§ 102 (a) and (b) prior art.

force created during inspiration (*i.e*., inhalation) and the gravitational effects on the tongue during expiration (*i.e.*, exhalation). EX1014, 1; *see also* Behbehani ¶¶33-38.

"The 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 1993, Dr. Berthon-Jones and others 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. 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"); Behbehani ¶¶39-41.

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 pressure]." EX1017, Abstract; *see also* Behbehani ¶¶42-48.

B. '009 Patent

The '009 Patent describes a well-known approach for treating OSAS with CPAP therapy. EX1001, Abstract, Fig. 1, 3:47-4:7. Figure 1 illustrates conventional components operating conventionally.

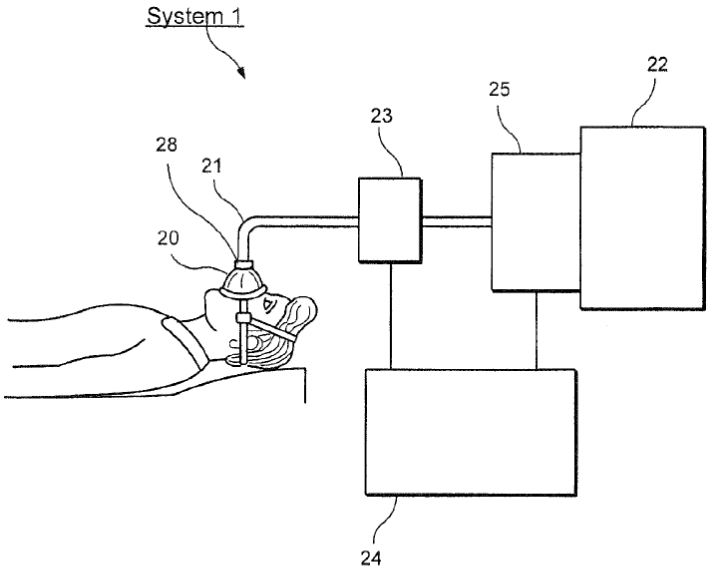
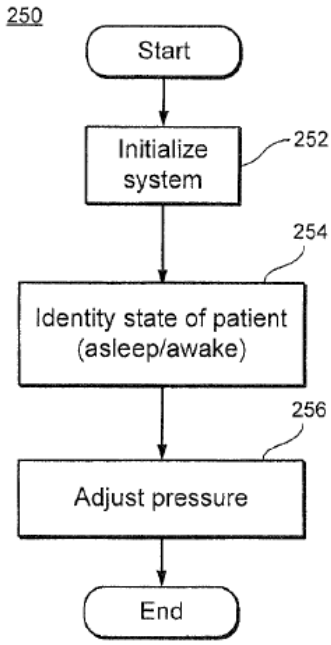


FIG. 1

A patient wears "a mask 20…to receive airflow having a particular pressure from a flow generator 22" where the pressure is determined with "any conventional PAP [positive airway pressure] therapy methods." *Id.* 3:48-54. "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.* 3:55-64.

To purportedly remedy the patient's discomfort caused by high pressure when the patient is awake, the patent describes the processing arrangement 24 as "mak[ing] a determination as to a current state of the patient" (*id.*, 4:19-23) and "adjust[ing] the pressure to correspond to the patient's current state" (*id.*, 5:55-57). Figure 10 illustrates this feature.



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C. Challenged Claims

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

[5] Petitioner does not concede this priority date and breaking the priority chain is unnecessary for this petition.

The ’009 Patent has 30 claims, 3 independent claims and 27 dependent claims. Independent claims 1 and 14 recite nearly identical systems and are addressed together herein.

D. Prosecution History

The applicant obtained allowance of the ’009 Patent by arguing that detecting an awake state was novel despite having admitted the contrary during the prosecution of the ’009 Patent parent—U.S. Patent No. 9,168,344 (“’344 Patent”).

During the ’344 Patent prosecution and in response to a rejection based on U.S. Patent No. 6,397,845 to Burton (EX1010, “Burton845”), the applicant argued that “Burton[845] merely refers to ***detection of wakefulness*** [an awake state] and makes no disclosure of a troubled wakefulness state.” EX1009, 402 (emphasis added). The Examiner found this argument “persuasive,” and the claims of the ’344 Patent (which were narrowed to cover troubled wakefulness) were eventually allowed. *Id.* 424-25, 468.

During prosecution of the ’009 Patent, the applicant addressed a different rejection with another unrelated Burton patent—U.S. Patent No. 8,069,852 (EX1011 “Burton852”). The applicant argued more broadly that Burton852 does not disclose detecting an awake state.[6] EX1002, 136 (“Burton[852]’s explicit use of the term ‘arousal’…is not within the scope of the claimed term of ‘awake state.’”).

[6] The applicant failed to identify Burton845.

The Examiner found the lack of detecting an awake state "persuasive" and eventually allowed the claims of the '009 Patent.

V. THE PRIOR ART

A. Sullivan995 (EX1005)

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

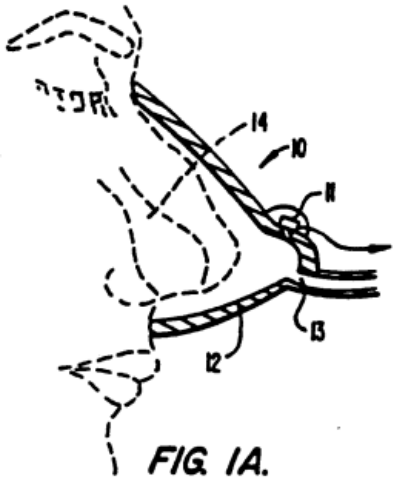


FIG. 1A.

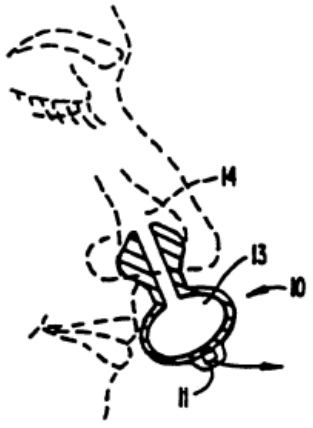


FIG. 1B.

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, 18:27-32, 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.

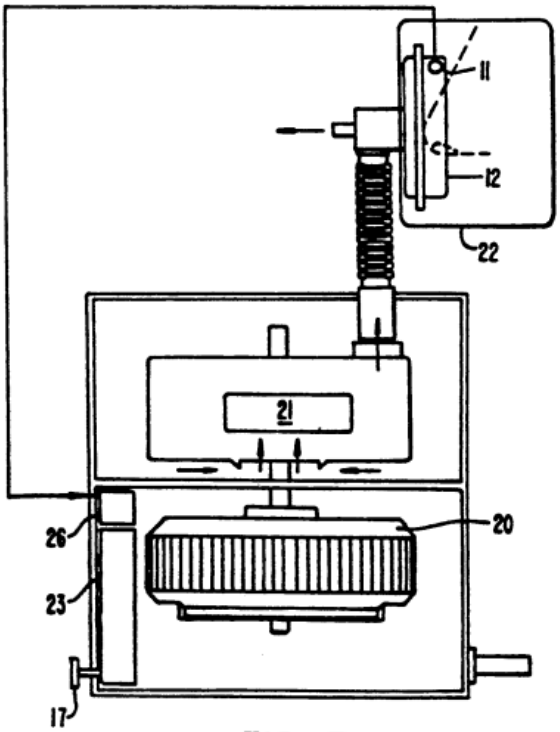


FIG. 3.

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.*, 17:6-12.

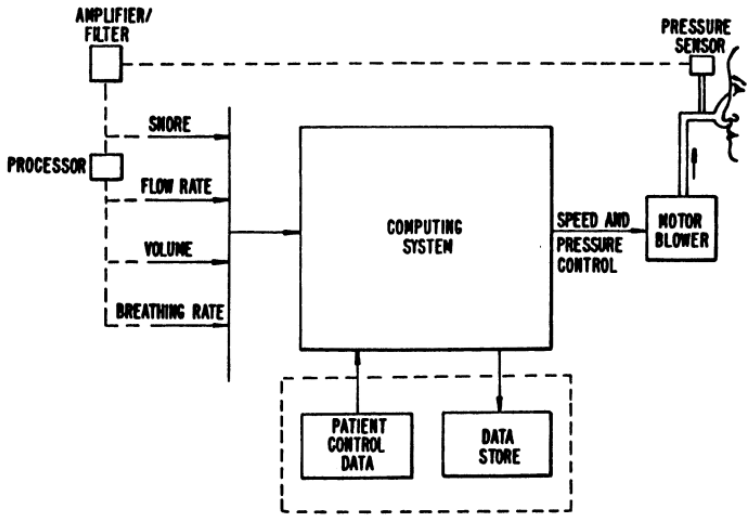


FIG. 12.

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 snores, apneas, hypopneas, and other abnormal breathing patterns occur when the patient is asleep, Sullivan995 increases the pressure when the patient has fallen asleep. *Id.*, 6:40-68, 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.

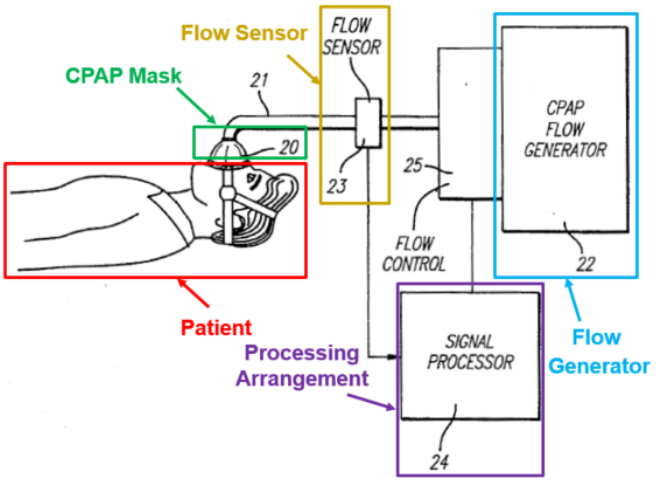
Specifically, Sullivan460 selects between an "awake" mode and an "asleep" mode, and applies high pressure in the "asleep" mode and low pressure in the "awake" mode. Id., 6:30-7:22, 14:7-36. When the flow rate increases above a threshold, controller 100 determines the patient is in an awake state and switches the CPAP system into the "awake" mode. Id., 10:21-25, 14:7-36. 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)

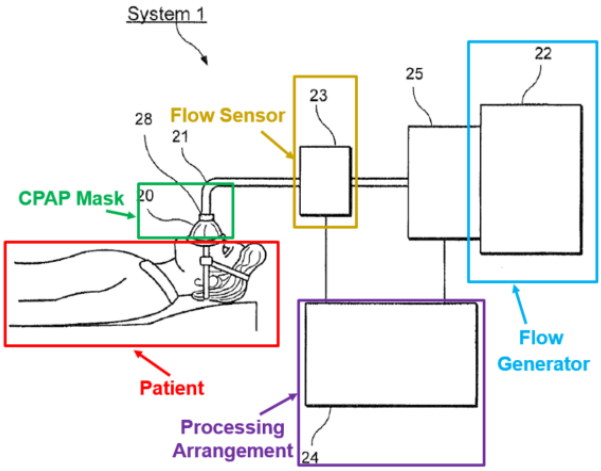
Matthews is a PAP system that "optimizes the pressure delivered to the patient to treat … disordered breathing while minimizing the delivered pressure for patient comfort." EX1007, Abstract. "When a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic," (*Id.*, 21:37-39) , 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 '009 Patent) is by the same inventor as the '009 Patent and discloses nearly identical hardware. EX1008, Fig. 9.



Rapoport502, Fig. 9



'009 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 ¶81.

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 ¶82.

VII. CLAIM CONSTRUCTION

The Board construes the claims "using the same claim construction standard that would be used" in district courts. 37 C.F.R. §42.100(b). This Petition establishes the prior art meets each of the claim limitations under any reasonable construction.[7]

VIII. GROUND 1: SULLIVAN995 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1-11, 13-21, 23-28, 30

A. Motivation to Combine

It would have been obvious to a POSITA to modify the processing arrangement in Sullivan995 to determine[] that the patient is in an awake state, and in response, automatically delay[] the onset of a pressure increase to the patient, as taught in Sullivan460. Behbehani ¶85. A POSITA would have been motivated to implement this modification for the following reasons.

First, 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 ¶¶87-89. 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

[7] Petitioner reserves the right to argue alternative constructions in other proceedings, including indefiniteness.

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 ¶88. 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* EX1005, 1:20-31, 10:21-23, 15:8-10; 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.

Second, a POSITA would have recognized that the modification improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks. Behbehani ¶90. 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. Id. 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 (4:23-24), and Sullivan995 partially solves the problem by reducing the pressure at the beginning of therapy. Behbehani ¶90.

B. Reasonable Expectation of Success

Sullivan460 explicitly recognizes the combination of Sullivan995 with the teachings in Sullivan460. Behbehani ¶91. Sullivan460 expressly states that Sullivan995 may be modified to include features of Sullivan460, such as "sens[ing] an upper airway flow limitation characterised by at least one decrease in upper airway inspiratory flow rate followed by at least one increase in flow rate." EX1006, 6:22-29. As Sullivan460 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 ¶92.

Sullivan995 and Sullivan460 are also analogous art. *Id.* ¶93. 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. Behbehani ¶94.

C. Independent Claims 1, 14

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 a CPAP system[8] (*a positive airway pressure system*) which "deliver[s] appropriate airway pressure" to the patient's airway passages (*for delivery of a flow of breathable gas*). EX1005, Fig. 3, Abstract, 1:33-36, 2:15-19, 9:57-58. As a POSITA would have understood, CPAP delivers "positive" airway pressure relative to atmospheric pressure (*a flow of breathable gas at a positive treatment pressure with respect to ambient air pressure*). Behbehani ¶95.

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*

[8] Sullivan995 refers to a CPAP apparatus, device, system, and unit for the same CPAP components. 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.

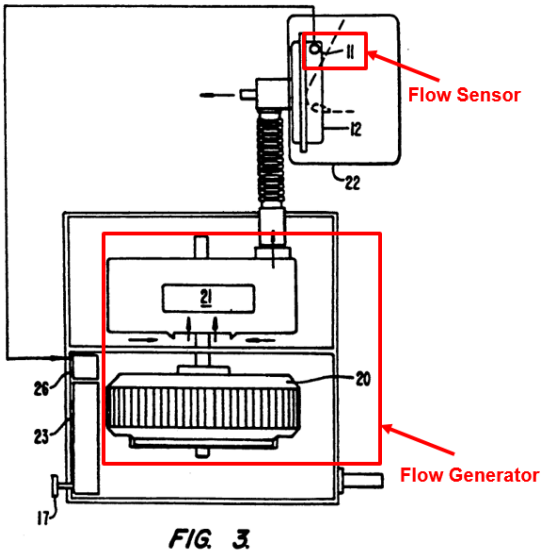
treating a sleeping disorder in a patient by providing air pressure at a certain level to "prevent the onset of apnea" (*sleeping disorder*) in the patient. *Id.*, 10:31-35, 1:20-31, 11:15-20; *see also* 1:32-48 (CPAP is used to "treat[] the occurrence of obstructive sleep apnea"); Behbehani ¶¶96-97.

2. 1[a]/14[a]: *"a flow generator which supplies a positive treatment pressure flow of breathable gases to be supplied to a patient;"*

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.*, 9:60-63 ("[A]n increase in motor speed also increases the blower speed which in turn increases the output air pressure of the blower 21."); Behbehani ¶98.

3. 1[b]/14[b]: *"a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases;"*

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 ¶¶99-100. 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; *see also* Abstract.



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 Figures 3 and 7. Behbehani ¶¶101-103.

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.

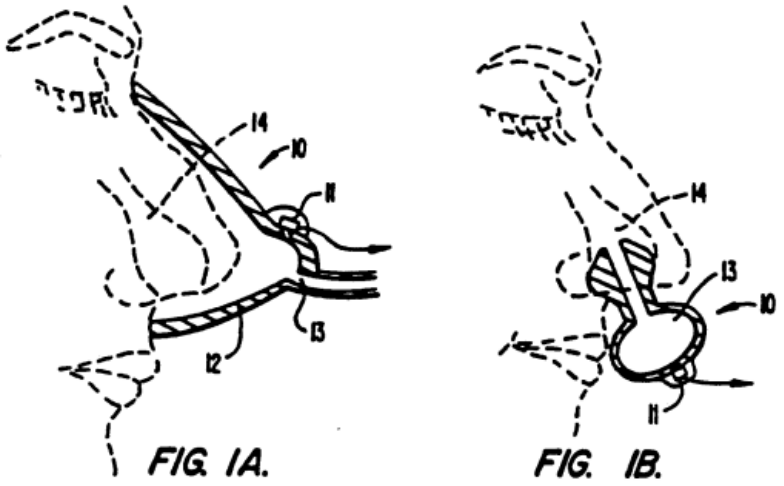


Figure 1A depicts the microphone 11 (*flow sensor*) located "in sound communication with the container 12 of [the] nose mask." *Id.*, 8:47-49. Sullivan995 discloses an "enclosed airway," which "extends from the source of snoring sounds …through the nasal passages 14 and out of the opening 13 in the nasal 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*. The microphone 11 A"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 ¶103.

4. 1[c]/14[c]: *"the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns"*

The microphone 11 (*flow sensor*) performs a "form of measurement" (*measuring* data) by "detecting snoring sounds" and "other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate" (*indicative of the patient's breathing patterns*). EX1005, 3:21-33 ; *see also id.*, 11:5-20, 15:56-64 (describing, with reference to Figure 3, detecting "a snore, or snoring patterns or abnormal breathing pattern"); Behbehani ¶104.

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.

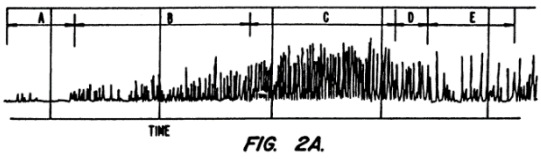


FIG. 2A.

EX1005, Fig. 2A

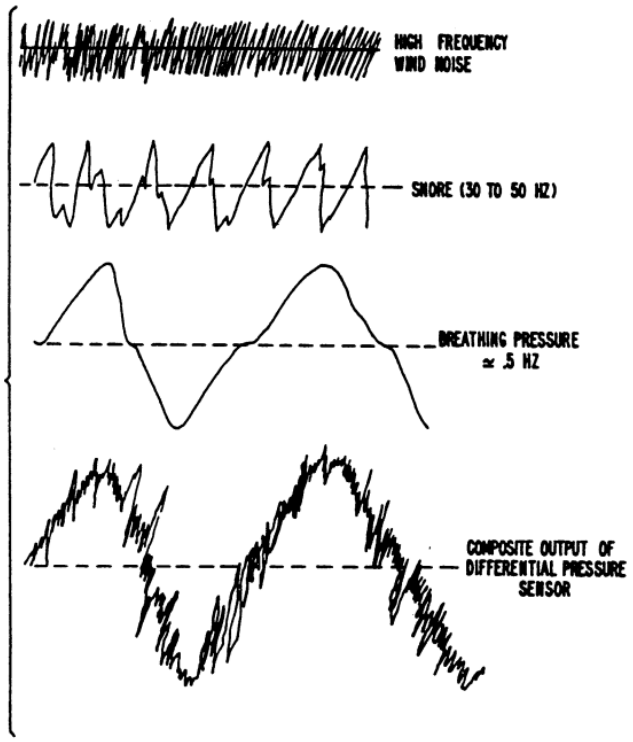


FIG. 9.

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 ¶¶105-109.

5. 1[d1]/14[d1]: *"a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and"*

The combination of an amplifier/filter/processor unit 26[9] and speed control unit 23[10] (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.

[9] Sullivan995 refers to the same processor unit 26 as an amplifier/filter/processor unit 26, amplifier/filter/processor 26, and processor 26. EX1005, 10:, 10:41-42, 10:56, 11:59, 14:51-52, 15:28-29, 15:61. For ease of reference, Petitioner refers to each as processor unit 26.

[10] 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, 10:15, 11:63-64, 14:40-41, 15:2-3. For ease of reference, Petitioner refers to each as the speed control unit 23.

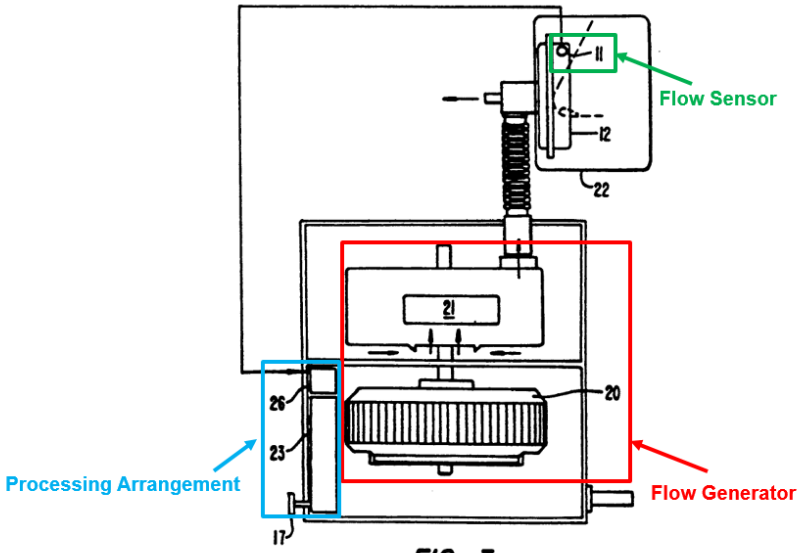


FIG. 3.

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. Behbehani ¶110.

Moreover, Sullivan995's CPAP system in Figure 4 (and therefore also in Figure 3) includes the feedback speed controller 23, which is illustrated in Figure 12 in block form with a computing system. EX1005, 17:3-4; Behbehani ¶112.

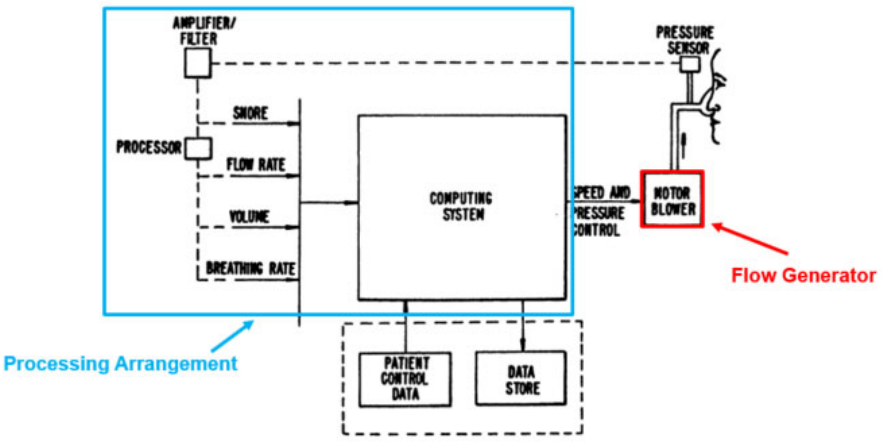


FIG. 12.

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*. Behbehani ¶112.

6. 1[d2]/14[d2]: *"[the processing arrangement] analyzes the data to determine the patient's breathing patterns,"*

As explained for 1[c] and 1[d1], 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. Behbehani ¶113.

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.* Behbehani ¶114.

7. 1[d3]/14[d3]: *"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"*

In response to the electrical signal generated when snoring sounds occur, a motor speed control means "increases the speed of the electronic motor 20," which "increases the blower speed," thereby "increas[ing] the output air pressure of the blower 21" (*flow generator*). *Id.*, 9:58-64, 10:6-12; *see also id.*, 10:40-46 (describing the processor 26 "increasing the blower speed in incremental steps each time a snore is detected by the microphone 11"), *id.* 10:55-58 (explaining that the increase in motor speed is done "via the processor 26"), *id.* 10:10-12 ("the output pressure of the CPAP unit increases in response to detection of snoring"). The motor speed control means in Sullivan995 is the same as the speed control unit 23 because it controls the speed of the motor and is therefore part of the *processing*

arrangement. *Id.*, 9:58-64; Behbehani ¶¶115-16. 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. 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 ¶117.

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. Moreover, by describing the speed control unit using the signal from the processor unit 26 to determine whether to increase or decrease the pressure, Sullivan995's *processing arrangement* performs the *determin[ation] [of] whether to alter the pressure supplied by the flow generator to the airway of the patient*. *See also*, *supra*, Sections VIII.C.4 and VIII.C.6 (describing *the determined breathing patterns of the patient*). Behbehani ¶¶118-127.

8. 1[e1]/14[e1]: *"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,"*

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. Behbehani ¶¶128-30. Specifically, "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-16, Fig. 3, *see also* 14:17-20, Fig. 13. Also, the pressure is decreased "if an extended period of snore free breathing occurs" by "automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected." *Id*., 10:31-46; *see also* 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 pressure 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. However, this limitation would have been obvious from Sullivan995 in view of Sullivan460. Behbehani ¶¶131-32.

a) Teachings of Sullivan460 on determining awake state

Sullivan460 incorporates Sullivan995 by reference and states that its "flow rate measurement means and [] treatment means may be constructed together as part of one apparatus [with Sullivan995]." 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 ¶133.

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 ¶134. According to Sullivan460, "a switching means 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 ¶134.

b) Motivation to Combine and Reasonable Expectation of Success

Sullivan460 indicates that the disclosed system can be implemented as part of one apparatus with the teachings of Sullivan995. Behbehani ¶135; *see also* Section VIII.A and VIII.B.

9. 1[e2]/14[e2]: *"wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state"*

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.8. 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 ¶136.

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. Behbehani ¶137.

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, supra*, Section VIII.C.8 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 ¶138.

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, 10:8-16, 14:7-36; Behbehani ¶139.

b) Motivation to Combine and Reasonable Expectation of Success

See Section VIII.A and VIII.B. Further, 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 ¶¶140-41. Sullivan460 solved that problem, which would have been a significant benefit for a patient using Sullivan995's CPAP system. *Id.* ¶142.

10. 1[f]/14[f]: *"wherein the processing arrangement determines the patient has transitioned between an awake state and an asleep state when [a combination of obstructions]/[three or more obstruction] are detected."*

Sullivan995 discloses *a combination of obstructions* and *three or more obstructions are detected* by teaching when a "sequence of snores is detected," a signal is generated so that the speed control unit 23 increases the speed of the fan motor and the output pressure is increased. EX1005, 10:13-28, 14:17-20, 14:56-15:15, Fig. 13. Sullivan995 expressly illustrates that four (4) snores (*combination of obstructions*) are detected. *Id.*, Fig. 13, 8:36-44, 14:48-15:15. Sullivan995 also discloses detection of a *combination of obstructions* as "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. The purpose in Sullivan995 of detecting these *combination[s] of obstructions* is to increase pressure to treat sleeping disorders. Therefore, detecting any of these *combination[s] of obstructions* in Sullivan995 means that *the patient has transitioned between an awake state and an asleep state*. Behbehani ¶¶143-45.

To the extent that Sullivan995 does not expressly disclose a transition from and to an awake state, this would have been obvious from Sullivan995 in view of Sullivan460. Behbehani ¶146.

a) Teachings of Sullivan460 on transition between awake and asleep when obstructions detected.

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 *a combination of obstructions*. The flow rate measurement means 70 detects multiple "interruptions," which Fig. 1 depicts, and are a *combination of obstructions*. 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.*, cls. 22, 25-27. Further, Sullivan460 detects the occurrence of "two or more interruption cycles" (which are regularly-spaced obstructions) in the upper inspiratory flow rate and the treatment means treats the airway limitation on the detection of said at least two interruption cycles. *Id.*, 3:20-23. Thus, the sleep detection technique in Sullivan460 (which may also be used in the modified device as explained above) is also based on detection of a *combination of obstructions*, and means that *the patient has transitioned between an awake state and to an asleep state*. Behbehani ¶¶147-48.

b) Motivation to Combine and Reasonable Expectation of Success

See Section VIII.A and VIII.B. It would have been further obvious to use the teachings of Sullivan995 or Sullivan460's detection of a *combination of obstructions* to *determine[] the patient has transitioned between an awake state and an asleep state*, as taught by Sullivan460's "sleep sensor" and "switching means." A POSITA would have recognized that verifying a sleep state would have

avoided false positives that would occur when only a single obstruction is detected. As indicated in figures of both Sullivan995 and Sullivan460 (EX1005, Figs. 2, 9, 13; EX1006, Fig. 1), and such obstructions (e.g., snores, apneas, hypopneas, or other flow limitations) typically occur in groups during sleep. Behbehani ¶¶149-50. 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 indication of sleep); EX1005, 10:13-30, 14:65-15:17 (triggering treatment upon detection of "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 ¶151.

D. Dependent Claims 2-11, 13, 15-21, 23[11]

1. **Claim 2:** combination of obstructions are regular period of obstructions

Figure 13 of Sullivan995 depicts a "sequence of snores," which is a *combination of obstructions*. EX1005, 14:65-15:1; *see also* Section VIII.C.10. The

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

four snores in Figure 13 are spaced evenly apart in time and therefore are *a regular period of obstructions.* Behbehani ¶152. As another example, Section E in Figure 2A depicts "periods of silence punctuated by snoring" and "periods of airway occlusion which terminate with one or more loud breathing sounds followed by further occlusions," which are another *regular period of obstructions*. EX1005, 9:16-32; Behbehani ¶152.

For Sullivan460, the multiple "interruptions" correspond to a *combination of obstructions*. *See* Section VIII.C.10. Those "interruptions" are "superimposed at the peak 20 of each cycle [and] are indicative of an upper airway flow limitation." EX1006, 9:31-36, Fig. 1. Because they occur at the "peak 20 of each cycle" where the cycles are regularly spaced apart, Sullivan460's "interruptions" are *a regular period of obstructions*. Behbehani ¶153. As Sullivan460 further explains, the advantage of generating an "output signal representative of the breathing cycle is that the airway vibrations indicative of an upper airway flow limitation can be time-locked to the breathing cycle" such that "peaks in the signal occur during inspiration or expiration," which "provides confirmation that the signal being received is in fact due to airway vibrations." *Id.*, 8:1-6. By describing the signal peaks as being "time-locked" to the breathing cycle and occurring during a specific portion of the breathing cycle, Sullivan460 discloses that the *combination of obstructions are a regular period of obstructions*. Behbehani ¶153.

To the extent that neither Sullivan995 nor Sullivan460 expressly disclose this limitation, it would have been obvious to a POSITA to design the sensor to detect sleep upon detection of a regular period of "two or more" obstructions (e.g., snores, airway limitation, apneas, hypopneas, or other interruptions). *See* EX1006, 3:20-23 ("treat[ing] the airway limitation on detection of said at least two interruption cycles," which are *a regular period of obstructions*). A POSITA would have recognized detecting only a single obstruction or a non-cyclic series of obstructions would result in false positives, as the patient may not have actually transitioned to an asleep state. Behbehani ¶154. In contrast, detecting a *regular period of obstructions* to verify a sleep state would have been desirable because it results in fewer false positives, and would have been obvious. As depicted in the figures of both Sullivan995 and Sullivan460, such obstructions typically occur in *regular period[s]*, and the POSITA would have found it obvious to detect the *regular period of obstructions* to *determine[] the patient has transitioned between an awake state and an asleep state*. Behbehani ¶155.

2. Claim 3: *combination of obstructions are three or more obstructions*

Figure 13 of Sullivan995 depicts a set of four snores, which are *three or more obstructions. See* Section VIII.C.10. Moreover, Figure 2A depicts *three or more obstructions* 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." *See* Section VIII.C.10; Behbehani ¶156.

Figure 1 of Sullivan460 depicts *three or more obstructions* 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; Behbehani ¶157.

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 *three or more obstructions*. Behbehani ¶158. 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 obstructions in order to characterize the periodicity of that pattern. Behbehani ¶159. 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, *three or more obstructions* 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 explained for claim 2, determining a transition between an awake state

and an asleep state upon detecting *a regular period of obstructions* would have been obvious. *See* Section VIII.D.1 As the POSITA would have recognized, such detection is only possible with *three or more obstructions.* Behbehani ¶160. 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. *Id.* ¶161.

3. Claim 4, 6, 16: *obstructions are apneas*

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); *see* Section VIII.C.10. 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 ¶162.

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 ¶163. Snores do not always precede apneas, such that detecting apneas would have been particularly desirable. *Id*. 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 *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. Behbehani ¶164. 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 *three or more apneas. Id.*

4. Claim 5, 15: *obstructions are hypopneas*

The *obstructions* in Sullivan995 referenced in 1[f] include *hypopneas*. EX1005, 13:4-9 (indexing detected "hypopneas"). Specifically, the *obstructions* in Section D of Fig. 2A are "indicative of obstructive hypopnea, a condition in which the breath-by-breath intensity decreases progressively, and then increases" and "is a 'pre-apneic' pattern." *Id.*, 13:46-54; *see also id.*, 13:4-8 and 14:17-32 (describing the computing system of Fig. 13 as diagnosing "hypopnea" and processing "the number of hypopneas"). Moreover, Sullivan995 describes determining "flow rate," "breathing rate," "time interval," and "volume" data to detect sleep apnea or hypopneas (*see, e.g.,* Sections D and E of Fig. 2A). *Id.*, Fig. 12, 6:40-68, 15:34-64, 17:3-27; Behbehani ¶165.

To the extent that Sullivan995 does not expressly disclose this limitation, this would have been obvious to a POSITA. Hypopneas indicate a sleep state and should be treated with increased pressure, as taught by Sullivan995. Behbehani ¶166. Snores do not always precede hypopneas, such that detecting hypopneas would have been particularly desirable. Behbehani ¶167. The purpose of detecting Sullivan995's "snore," "flow rate," "breathing rate" or "time interval," and/or "volume" data is to detect breathing patterns having hypopneas, and upon detection of the hypopneas, treat them by increasing pressure. EX1005, 4:36-5:11, 6:54-68, 10:13-30, 14:65-15:17, 17:9-27..

5. Claim 7: *regular period of obstructions comprises at least three apneas*

As explained for claims 4, 6, and 16, *apneas* occur in a cyclical or periodic pattern, and detection of a *regular period of obstructions* when those *obstructions* are *apneas* is only possible with three or more *apneas. See* Section VIII.D.3; Behbehani ¶168.

6. Claim 8, 18: *when processing arrangement determines during asleep state that patient is experiencing elevated upper airway resistance, increases pressure applied to airway of patient*

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"); *see* Section VIII.C.8.

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; Behbehani ¶169.

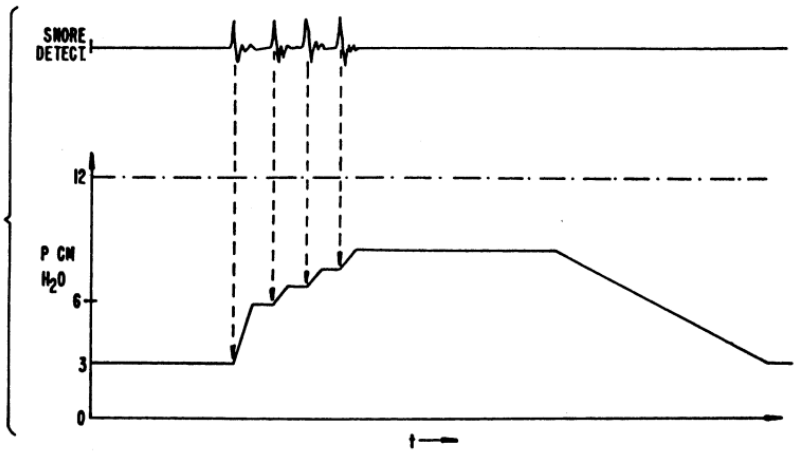


FIG. 13.

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.* Behbehani ¶170.

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 ¶171.

Similarly, as indicated in 1[e1]/14[e1], 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; *see* Section VIII.C.8; Behbehani ¶172.

7. Claim 9, 19: *when processing arrangement determines during asleep state that patient is experiencing hypopnea event, increases the pressure applied to airway of patient*

As explained for claims 1 and 5, 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; *see* Section VIII.C and VIII.D.4; Behbehani ¶173.

8. Claim 10, 20: *wherein when processing arrangement determines during asleep state that patient is experiencing apnea event, increases pressure applied to airway of patient*

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; *see* Sections VIII.C and VIII.D.3; Behbehani ¶174.

9. Claim 11, 21: *when processing arrangement determines that patient has transitioned to awake state from asleep state, lowers pressure applied to airway of patient*

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; *see* Section VIII.C.8; Behbehani ¶175.

Although Sullivan995 does not explicitly disclose that the processing arrangement determines that the patient has *transitioned to an awake state*, it would

have been obvious in view of Sullivan460. Sullivan460 discloses a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19; *see* Section VIII.C.8. "[S]witching means 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 ¶176.

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[e1]/14[e1]. *See* Section VIII.C.8. 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 ¶177. ,

10. Claim 13, 23: *pressure is increased using 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 ¶178; *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).

E. Independent Claim 24

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

To the extent limiting, Sullivan995 discloses the preamble. Behbehani ¶178. Sullivan995 discloses the recited *positive airway pressure delivery system*. *See* Section VIII.C.1. Sullivan995's *positive airway pressure delivery system* employs a method for "treatment of partial or complete upper airway occlusion" such as "snoring and sleep apnea" which is a *method for treatment of a sleeping disorder.* EX1005, 1:14-18, 1:20-24; Behbehani ¶179.

2. 24[a]: *"supplying, using a flow generator which generates a flow of gases to produce a positive pressure at or above a pressure at ambient air pressure, a flow of breathable gases to an airway of a patient;"*

Sullivan995 discloses this limitation. *See* Sections VIII.C.1 and VIII.C.2.

3. 24[b]: *"measuring, using a sensor, data indicative of the patient's breathing patterns;"*

Sullivan995 discloses this limitation. *See* Sections VIII.C.3 and VIII.C.4.

4. 24[c]: *"determining, using a processing arrangement, an indication of the patient's breathing patterns based on the data indicative of the patient's breathing patterns;"*

As explained above, Sullivan995's *processing arrangement* analyzes "the sound and breathing patterns" (*the data indicative of the patient's breathing patterns*) to record "indexes such as the number of apneic episodes, the number of hypopneas, their duration, etc." (*an indication of the patient's breathing patterns*). EX1005, 12:67-13:8; *see* Sections VIII.C.5 and VIII.C.6; Behbehani ¶182.

5. 24[d]: *"analyzing, using the processing arrangement, the indication of the patient's breathing patterns to determine the sleep state of a patient;"*

As explained above, Sullivan995's *processing arrangement* analyzes "indexes such as the number of apneic episodes, the number of hypopneas, their duration, etc." (*the indication of the patient's breathing patterns*) to determine whether apneic episodes or hypopneas have occurred. *See* Section VIII.C.6. These particular *breathing patterns* only occur when the *sleep state of a patient* is an

asleep state. EX1005, 12:67-13:8. Further, as explained above, Sullivan995 detects snores in *the patient's breathing patterns*. *See* Section VIII.C.8 and VIII.C.9; Behbehani ¶¶183-84.

6. 24[e]: *"increasing a pressure of the flow of breathable gases, using the flow generator, to an airway of a patient when the patient is in an asleep state and an elevated upper airway resistance is detected;"*

As explained above, Sullivan995's *processing arrangement* causes "the output pressure of the CPAP unit [to] increase[] in response to detection of snoring." EX1005, 10:10-16, Fig. 3; *see* Section VIII.C.8. The CPAP system in Sullivan995 includes a blower 21 (*flow generator*) that provides pressurized air to the patient, and therefore a *pressure of flow of breathable gases to an airway of the patient*. *See* Sections VIII.C.2 and VIII.C.3. Because the patient only begins snoring after the *patient is in an asleep state*, this means that Sullivan995 ensures the pressure is increased *when the patient is in an asleep state*. Sullivan995 explains that snoring "is characterized by partial occlusion [of the upper airway passage during sleep]" and therefore represents *an elevated upper airway resistance is detected*. *Id.* 1:22-24; *see also* Section VIII.D.6; Behbehani ¶¶185-86.

7. 24[f]: *"applying a lower pressure, using the flow generator, when the processing arrangement determines the patient is in an awake state based on the indication of the patient's breathing patterns; and"*

As explained above, Sullivan995's *processing arrangement* automatically reduces pressure "if an extended period of snore free breathing occurs" by "automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected." EX1005, 10:31-46; *see* Sections VIII.C.8 and VIII.D.9. This means the blower 21 (*flow generator*) in Sullivan995 *appl[ies] a lower pressure* in the absence of snoring. Behbehani ¶187.

Although Sullivan995 does not expressly disclose this limitation, it would have been obvious in view of Sullivan460 for the reasons explained above. *See* Sections VIII.C.8 and VIII.D.9; Behbehani ¶188.

8. 24[g]: *"increasing an applied pressure to an elevated pressure when the processing arrangement determines that the patient transitions from the awake state to the asleep state based on the indication of the patient's breathing patterns, wherein the indication of the patient's breathing patterns is a pattern of at least three obstructions."*

Sullivan995 discloses this limitation. *See* Section VIII.C.10.

F. Dependent Claims 25-28, 30

1. Claim 25: *obstructions are apneas*

Sullivan995 discloses this limitation. *See* Section VIII.D.3.

2. Claim 26: *obstructions are hypopneas*

Sullivan995 discloses this limitation. *See* Section VIII.D.4.

3. Claim 27: *pattern is regular period of three or more obstructions*

Sullivan995 discloses this limitation. *See* Sections VIII.D.1 and VIII.D.2.

4. Claim 28*: increasing pressure when the patient is asleep and obstruction detected*

Figure 13 of Sullivan995 incrementally increases pressure for each of four periodic snores. EX1005, 14:17-22; *see* Section VIII.C.8; Behbehani ¶193.

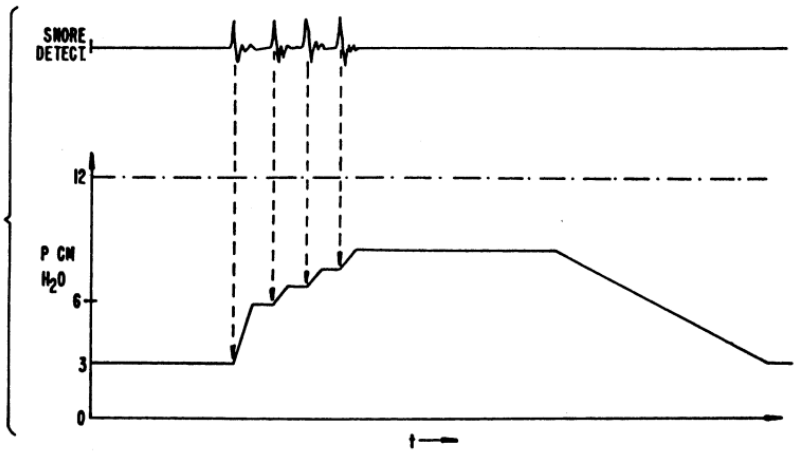


FIG. 13.

Upon detection of the first snore, the pressure is increased from 3 to 6 cm H_20, and upon detection of each of the second, third, and fourth snores, the pressure is increased incrementally by 1 cm H_20. *Id.*, 10:13-30, 10:40-46, 10:47-61, 11:8-20, Fig. 13. Thus, Sullivan995 discloses *increasing* from a *previously provided pressure* (e.g., 6, 7, or 8 cm H_20, which were provided upon detection of the first, second, or third snores respectively, and any of which is a *previously provided*

pressure) *supplied to a patient when the patient is in an asleep state and an obstruction* (snore) *is detected*. Behbehani ¶194.

5. Claim 30: *automatically ramping without manual initiation*

As explained above, Figure 13 of Sullivan995 depicts incrementally increasing the pressure with each snore using a ramp system. EX1005, 14:17-20; *see Section* VIII.D.10. As Sullivan995 expressly states, the pressure begins at a low level and is "automatically increased after a selectable period of time." *Id.*, 12:35-40. Because the pressure is "automatically increased," this means Sullivan995 *ramp[s] the applied pressure* by *automatically ramping the applied pressure without requiring a manual initiation from a user*. Behbehani ¶195.

IX. GROUND 2: SULLIVAN995 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIMS 12, 22, 29

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 *processing arrangement* in Sullivan995 *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*. 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 ¶196.

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 ¶197. The modification to Sullivan995 and Sullivan460's CPAP system would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort. Sullivan995 is already concerned with the patient's comfort, and already discloses it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible. EX1005, 2:31-39.

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

Sullivan995, Sullivan460, and Matthews are analogous art and describe CPAP systems with flow sensors and generators. Like Sullivan995 and Sullivan460, Matthews discloses a "flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34." 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 ¶¶198-99.

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 ¶200.

C. Dependent Claims 12, 22

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 ¶¶201-202. Similar to Sullivan995 and Sullivan460, Matthews discloses a pressure support system to treat disordered breathing by optimizing the pressure delivered to the patient. EX1007, Abstract. In Matthews, the pressure support system monitors the flow of gas in a patient's airway and controls the pressure of the flow based on the gas flow. *Id.*, cl. 1. Matthews also discloses an *awake state is a troubled wakefulness state* by describing "[w]hen a patient is awake… or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable." *Id.*, 21:34-44; *see also id.* 21:63-22:1. Matthews's description of erratic breathing when the patient is awake and in distress is consistent with the '009 Patent's description of *troubled wakefulness* as "awake and anxious or distressed" (EX1001, 4:47-48) with "erratic" breathing (*id.* 4:47-59). In Matthews, when such a state is detected, Matthews

"interrupt[s] the operation of the auto-CPAP controller," and to "decrease[] the pressure delivered to the patient." EX1007, 21:57-61, 23:67-24:1.

D. Dependent Claim 29

Matthews discloses this limitation. Behbehani ¶203. Matthews teaches "interrupt[ing] the operation of the auto-CPAP controller" when erratic breathing (*troubled wakefulness state*) is detected, and to "decrease[] the pressure delivered to the patient." EX1007, 21:57-61, 23:67-24:1; Behbehani ¶¶203-206.

X. GROUND 3: RAPOPORT502 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1-11, 13-21, 23-28, 30

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. *See* Section VIII.A for the discussion of Sullivan460; Behbehani ¶207.

The modification to Rapoport502's PAP system would allow for detection of inaudible low frequency vibrations, including those associated with pre-eclampsia, so that the patient may be treated with high pressure. *See* EX1008, 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 ¶208.

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 ¶209. 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 ¶209.

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

Rapoport502 and Sullivan460 are analogous art. Behbehani ¶210. 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.*, 10:4-16.

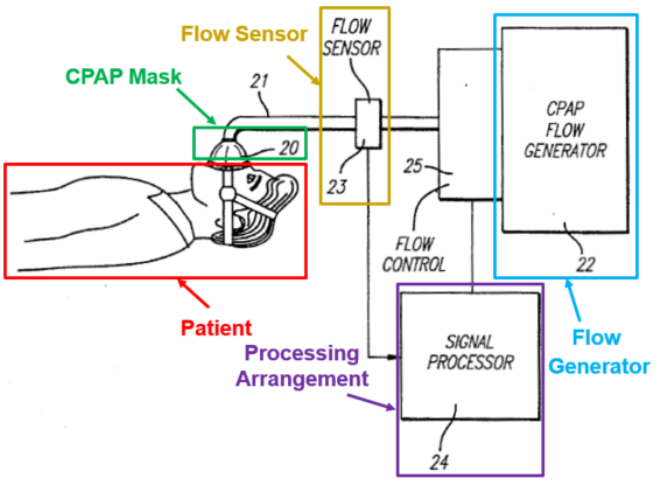
Dr. Rapoport knew Dr. Sullivan's work, and praised it as "a few months ahead of the rest of us." EX1012, 3; Behbehani ¶212. A POSITA improving CPAP machines would have looked at the pioneer in CPAP machines for algorithms for different air pressure settings that could improve compliance. Behbehani ¶212. 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 ¶213.

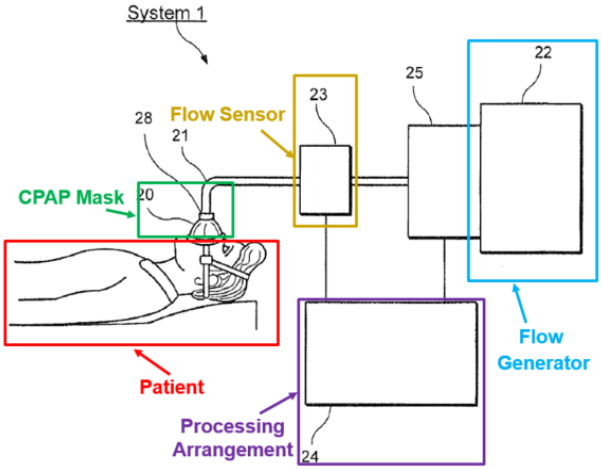
C. Independent Claims 1, 14

1. Preamble

To the extent the preamble is limiting, Rapoport502 discloses a continuous *positive airway pressure system* in the same manner as the '009 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 ¶214.



Rapoport502, Fig. 9 (annotated)



'009 Patent, Fig. 1 (annotated)

2. 1[a]/14[a]

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

understood that the air supplied to the patient is *a positive treatment pressure flow of breathable gases*. Behbehani ¶215.

3. 1[b]/14[b]

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. A POSITA would have understood the flow sensor 21 to be *in* the flow path. Behbehani ¶217. 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 '009 Patent. EX1008, 3:22-28 (emphasis added).

4. 1[c]/14[c]

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.*, 3:24-26; Behbehani ¶218. 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 ¶218.

5. 1[d1]/14[d1]

Rapoport502's CPAP system includes a signal processor 24 (purple) corresponding to a *processing arrangement*. *See* Section X.C.1. The '009 Patent illustrates the processing arrangement 24 as a "black box" but does not disclose what constitutes the processing arrangement 24. *See id.* (illustrating '009 patent Fig. 1); Behbehani ¶219. 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 ¶219.

Both the '009 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, 3:59-64, 4:14-27, 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 ¶220.

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.

6. 1[d2]/14[d2]

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 ¶222. 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 ¶222.

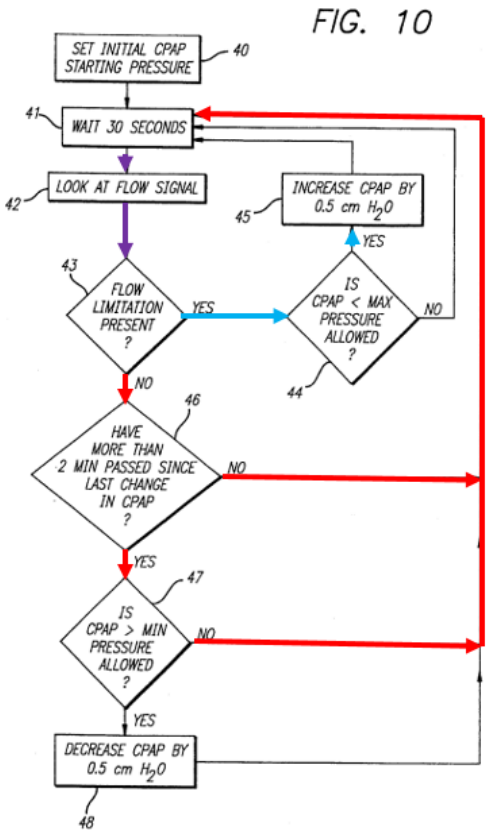
7. 1[d3]/14[d3]

Further to the analysis *on the determined breathing patterns of the patient* (*see* Section X.C.6), "[t]he signal processor 24 outputs a signal to a conventional flow control 25 for controlling the pressure applied by the flow generator to the tube 21." EX1008, 5:61-63. Correspondingly, Figure 10 describes processor 24's decision flow *whether to alter 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 ¶223. 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 ¶223.

8. 1[e1]/14[e1]

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); Behbehani ¶224.



EX1008, Fig. 10 (annotated)

Figure 10 represents Rapoport'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; Behbehani ¶¶225-26.

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 ¶¶225-27.

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.8.a).

b) Motivation to Combine and Reasonable Expectation of Success

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

9. 1[e2]/[e2]

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.8 (describing blue path). If there is no flow limitation, the *delay* continues for another 30 seconds. *See id.* (describing red path). Behbehani ¶230.

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 ¶231; *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.* Behbehani ¶231

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 ¶232.

a) Teachings of Sullivan460

Sullivan460 discloses this limitation. *See* Section VIII.C.9.a).

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).

10. 1[f]/14[f]

To the extent that Rapoport502 does not expressly state that the processing arrangement determines the patient has transitioned between an awake state and an asleep state when a combination of obstructions are detected, this would have been obvious from Rapoport502 in view of Sullivan460. Behbehani ¶236.

a) Teachings of Sullivan460

Sullivan460 discloses this limitation. *See* Section VIII.C.9.a).

b) Motivation to Combine and Reasonable Expectation of Success

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

D. Dependent Claims 2-11, 13, 15-21, 23

1. Claim 2

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA discloses this limitation. *See* Section VIII.D.1 (discussing Sullivan460 and knowledge of POSITA).

2. Claim 3

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA discloses this limitation. *See* Section VIII.D.2 (discussing Sullivan460 and knowledge of POSITA).

3. Claim 4, 6, 16

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 ¶241.

4. Claim 5, 15

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 ¶242.

5. Claim 7

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."); Behbehani ¶243.

A POSITA would have readily understood that apneas indicate a sleep state and should be treated with increased pressure, as taught by Rapoport502. 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. Behbehani ¶244.

6. Claim 8, 18

When the signal processor 24 (*processing arrangement*) determines "YES" for a flow limitation (Step 43), it *increases pressure applied to airway of patient* by 0.5 cm H_20 (Step 45). EX1008, 6:9-13, Fig. 10. Rapoport502s's detected flow limitation occurs *during an asleep state* when *the patient is experiencing elevated upper airway resistance*. *See* Sections X.D.3 and X.D.4 (describing apneas and

hypopneas as obstructions of the upper airway occurring during sleep); Behbehani ¶245.

7. Claim 9, 19

Claims 9 and 19 differ from claims 8 and 18 by reciting a *hypopnea event* instead of an elevated upper airway resistance. Rapoport502 discloses this limitation. *See* Section X.D.4 (discussing Rapoport502's disclosure of a hypopnea event as an elevated upper airway resistance condition); *see also* Section X.D.6 (discussing Rapoport502's disclosure of claims 8 and 18); Behbehani ¶246.

8. Claim 10, 20

Claims 10 and 20 differ from claims 8 and 18 by reciting an *apnea event* instead of an elevated upper airway resistance. Rapoport502 discloses this limitation. *See* Section X.D.3 (discussing Rapoport502's disclosure of an apnea event as an elevated upper airway resistance condition); *see also* Section X.D.6 (discussing Rapoport502's disclosure of claims 8 and 18); Behbehani ¶247.

9. Claim 11, 21

Rapoport502's signal processor 24 (*processing arrangement*) detects a patient transitioning between a flow limitation state and a no flow limitation state, and *lowers pressure applied to airway of patient* by 0.5 cm H_20 (Step 48) when it determines a "NO" flow limitation state (step 43) and the CPAP pressure is greater than the minimum pressure allowed (Step 47). EX1008, 6:17-29; Behbehani ¶248.

Rapoport502 does not expressly disclose the patient is in an awake state when there is no flow limitation present, but Rapoport502 inherently discloses the patient is asleep when the patient has a flow limitation (*see* Section X.C.9). It would have been obvious in view of Sullivan460 to determine an awake state. Behbehani ¶249.

Sullivan460 discloses a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19; *see Section* VIII.C.8.a). "[A] switching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46. This means that *when* the patient *has transitioned to an awake state from an asleep state*, Sullivan460 *lowers the pressure applied to the airway of the patient*. Behbehani ¶250.

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. Behbehani ¶251. As the POSITA would have

recognized from the teachings of Rapoport502 and Sullivan460, a lower pressure is desirable when the patient is awake because it ensures the patient is comfortable and reduces the likelihood the patient will remove the mask. Behbehani ¶252.

10. Claim 13, 23

"[T]he controlled positive *pressure* could be changed" (*increased*, *see* Section X.C.8) "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; Behbehani ¶253. Also, Rapoport502 discloses "a slope parameter [of the ramp], e.g., 0.1 cm per two seconds." EX1008, 11:44-46. A POSITA would understand to increase the pressure using the ramp system disclosed by Rapoport502. Behbehani ¶254.

E. Independent Claim 24

1. Preamble

To the extent limiting, Rapoport502 discloses the preamble. *See* Section X.C.1 (Ground 3, 1[preamble]/14[preamble]).

2. 24[a]

Rapoport502 discloses this limitation. *See* Sections X.C.1 and X.C.2 (Ground 3, 1[preamble]/14[preamble] and 1[a]/14[a]).

3. 24[b]

Rapoport502 discloses this limitation. *See* Sections X.C.3 and X.C.4 (Ground 3, 1[b]/14[b] and 1[c]/14[c]).

4. 24[c]

Rapoport502 discloses this limitation. *See* X.C.5 and X.C.6 (Ground 3, 1[d1]/14[d1] and 1[d2]/14[d2]).

5. 24[d]

Rapoport502 discloses this limitation. Behbehani ¶¶259-60. As explained for 1[d2]/14[d2], Rapoport502's *processing arrangement* analyzes flow limitation data from the flow sensors. *See* Section X.C.6. Further, Rapoport502 detects flow limitations in *the patient's breathing patterns*. *See* Sections X.C.8 and X.C.9.

6. 24[e]

Rapoport502 discloses this limitation. Behbehani ¶261. Sullivan995's *processing arrangement* causes pressure to increase when a flow limitation is detected. *See* Section X.C.8. The PAP system in Rapoport502 includes a *flow generator* that provides pressurized air to the patient, and therefore a *pressure of flow of breathable gases to an airway of the patient*. *See* Sections X.C.2 and X.C.3. Because the patient only begins snoring after the *patient is in an asleep state*, this means that Rapoport502 ensures the pressure is increased *when the patient is in an asleep state*. *See* Section X.D.6 (Ground 3, Claims 8, 18).

7. 24[f]

Rapoport502 in view of Sullivan460 discloses this limitation. Behbehani ¶262. Rapoport502's *processing arrangement* automatically decreases pressure if a flow limitation or other change in CPAP does not occur within a certain amount of time. *See* Sections X.C.8. This means the *flow generator* in Rapoport502 *appl[ies] a lower pressure* in the absence of snoring. Although Rapoport502 does not disclose *an awake state*, this limitation would have been obvious from Rapoport502 in view of Sullivan460. *See* Section X.D.9; Behbehani ¶262.

8. 24[g]

Rapoport502 discloses this limitation. *See* Sections VIII.C.10.

F. Dependent Claims 25-28, 30

1. Claim 25

Rapoport502 discloses this limitation. *See* Section X.D.3.

2. Claim 26

Rapoport502 discloses this limitation. *See* Section X.D.4.

3. Claim 27

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA discloses this limitation. *See* Sections X.D.1 and X.D.2.

4. Claim 28

As explained for 1[e1]/14[e1], Rapoport502 increases pressure when a flow limitation and the patient is necessarily asleep. *See* Section X.C.8.

5. Claim 30

Rapoport502 discloses this limitation. *See* EX1008, 13:37-43 ("using pre-set ramps or steps in the controlled positive pressure throughout the night"); Behbehani ¶269.

XI. GROUND 4: RAPOPORT502 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIMS 12, 22, 29

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*. 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 ¶¶270-71.

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. 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,

1:60-63. 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 ¶272.

Second, the modification would have been a logical extension of Rapoport502's air pressure adjustment approach. "The air pressure setting is raised, lowered or maintained depending on whether flow limitation has been detected and on the previous actions taken by the system." EX1008, 3:18-21. Rapoport502 already adjusts the air pressure based on flow limitation states. EX1008, Fig. 10. Adding a *troubled wakefulness* based on data from the flow sensors would have made the system even more effective. Behbehani ¶273.

B. A POSITA Would Have a Reasonable Expectation of Success

Rapoport502, Sullivan460, and Matthews are analogous art and describe CPAP systems with flow sensors and generators. Behbehani ¶¶274-75. Like Rapoport502 and Sullivan460, Matthews discloses a "flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34." EX1007, 7:11-16. The flow sensor data are monitored to control the pressure delivered to the patient. *Id.*, 8:54-9:15. Sullivan460 discloses lowering the pressure upon detecting an

awake state (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 ¶275.

Modifying the CPAP system of Rapoport502 and Sullivan460 would have been as simple as adding another decision point in the algorithm. Specifically, because the flow sensors provided data to determine flow limitations, the algorithm shown in Figure 10 could simply be modified to add "Erratic Breathing Present" between step 43 and step 46. If yes, continue to step 47, and if no, continue step 46. Behbehani ¶276.

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 ¶277.

C. Dependent Claims 12, 22, 29

Rapoport502 and Sullivan460 in view of Matthews discloses this limitation. Specifically, Matthews discloses the limitations of these claims. *See* Section IX.C (Ground 2, Claims 12, 22) and Section IX.D (Ground 2, Claims 29); Behbehani ¶278. 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. Behbehani ¶278.

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

A. Institution is appropriate under § 325(d)

Institution is appropriate 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 *Becton, Dickinson* factors). Specifically, no 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.

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 patients 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, [c] the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patients breathing patterns; and

   [d1] 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, [d2] 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, [e1] 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, [e2] wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state, [f] wherein the processing arrangement determines the patient has transitioned between an awake state and an asleep state when a combination of obstructions are detected.

2. The system of claim 1, wherein the combination of obstructions are a regular period of obstructions.

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

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

5. The system of claim 1, wherein the obstructions are hypopneas.

6. The system of claim 1, wherein the obstructions are apneas.

7. The system of claim 2, wherein the regular period of obstructions comprises at least three apneas.

8. 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.

9. 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.

10. 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.

11. 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.

12. The system of claim 11, wherein the awake state is a troubled wakefulness state.

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

14. 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 patients 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, [c] the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patients breathing patterns; and

[d1] 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, [d2] 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, [e1] 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, [e2] wherein the delay lasts at least until the processing arrangement determines that the patient is in an asleep state, [f] wherein the processing arrangement determines the patient has transitioned between an awake state and an asleep state when three or more obstructions are detected.

15. The system of claim 14, wherein the obstructions are hypopneas.

16. The system of claim 14, wherein the obstructions are apneas.

17. The system of claim 14, wherein the three or more obstructions are a regular period of three or more obstructions.

18. The system of claim 14, 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.

19. The system of claim 14, 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.

20. The system of claim 14, 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.

21. The system of claim 14, 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.

22. The system of claim 14, wherein the awake state is a troubled wakefulness state.

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

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

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

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

[c] determining, using a processing arrangement, an indication of the patient's breathing patterns based on the data indicative of the patient's breathing patterns;

[d] analyzing, using the processing arrangement, the indication of the patient's breathing patterns to determine the sleep state of a patient;

[e] increasing a pressure of the flow of breathable gases, using the flow generator, to an airway of a patient when the patient is in an asleep state and an elevated upper airway resistance is detected;

[f] applying a lower pressure, using the flow generator, when the processing arrangement determines the patient is in an awake state based on the indication of the patients breathing patterns; and

[g] increasing an applied pressure to an elevated pressure when the processing arrangement determines that the patient transitions from the awake state to the asleep state based on the indication of the patient's breathing patterns, wherein the indication of the patient's breathing patterns is a pattern of at least three obstructions.

25. The method of claim 24, wherein the obstructions include at least one apnea.

26. The method of claim 24, wherein the obstructions include at least one hypopnea.

27. The method of claim 24, wherein pattern of at least three obstructions are a regular period of three or more obstructions.

28. The method of claim 24, further comprising increasing a previously provided pressure supplied to a patient when the patient is in an asleep state and an obstruction is detected.

29. The method of claim 24, wherein applying a lower pressure when the patient is in an awake state comprises applying a lower pressure when the patient is in a troubled wakefulness state.

30. The method of claim 24, wherein ramping the applied pressure comprises automatically ramping the applied pressure without requiring a manual initiation from a user.

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 13,894 words, excluding table of contents, mandatory notices under § 42.8, and a certificate of service or word count, as measured by the word-processing system used to prepare this paper. 37 CFR. § 42.24(a)(1).

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CERTIFICATE OF SERVICE

The undersigned certifies that a complete copy of this Petition for *Inter Partes* Review of U.S. Patent No. 9,108,009 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 May 31, 2022:

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