UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ResMed Inc.,
Petitioner,

v.

New York University,
Patent Owner,

Case No. IPR2022-00991

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,867,955

Claims 1-6, 8, 11-12, 16-26 and 30-31

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1013	U.S. Patent No. 5,704,345 to Berthon-Jones ("Berthon-Jones345")
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1016	M. Pressman et al., "Ramp Abuse: A Novel Form of Patient Noncompliance to Administration of Nasal Continuous Positive Airway Pressure for Treatment of Obstructive Sleep Apnea," Am. J of Respiratory and Critical Care Med., Vol. 151, 1632-1634 (1995) ("Pressman 1995")).
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1029	Sunrise Medical, "DeVillibis, AutoAdjust, LT Nasal CPAP System Instructions Guide Model 8054," (1999)
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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. ("ResMed" or "Petitioner") respectfully requests *inter partes* review of claims 1-6, 8, 11-12, 16-26, 30 of U.S. Patent No. 9,867,955 (EX1001, "'955 Patent") and a finding that all challenged claims of the '955 Patent are unpatentable.

Patients often struggle to use positive airway pressure (PAP) systems because the high pressure treatment causes discomfort. The '955 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 '955 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 '955 Patent is assigned to New York University ("PO"), which is currently asserting the '955 Patent in the following concurrent litigation filed on June 2, 2021: *New York University v. ResMed Inc*., 1:21-cv-00813-JPM (D. Del.).

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

6,988,994, U.S. Patent No. 9,108,009, U.S. Patent No. 9,168,344, U.S. Patent No. 9,427,539, U.S. Patent No. 9,533,115, and U.S. Patent No. 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 (37 C.F.R. § 42.104(B))

Ground 1: Claims 1-5, 8, 11-12, 16-22, 24-26 and 30-31 are obvious under 35 U.S.C. § 103 over Sullivan995[1] in view of Sullivan460[2].

Ground 2: Claims 6 and 23 are obvious under 35 U.S.C. § 103 over Sullivan995 in view of Sullivan460 and Matthews[3].

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

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

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

Ground 3: Claims 1-5, 8, 11-12, 16-22, 24-26 and 30-31 are obvious under 35 U.S.C. § 103 over Rapoport502[4] in view of Sullivan460.

Ground 4: Claims 6 and 23 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) is a well recognized disorder…[and] one of the most common causes of excessive daytime somnolence." EX1001, 1:25-27. OSAS "is characterized by an intermittent obstruction of [a patient's] upper airway occurring during sleep." EX1001, 1:31-34. "The obstruction results in a spectrum of respiratory disturbances ranging from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring)." EX1001, 1:34-38. Because apnea, hypopnea, and heavy snoring produces decreased blood oxygenation, they "are recognised [] causes of sleep disruption and risk factors in certain types of heart disease." EX1013, 1:27-30, 1:43-45; *see also* Behbehani ¶¶32-33.

Positive airway pressure (PAP) therapy has been "the mainstay of treatment" for OSAS since its introduction by Professor Colin Sullivan, Dr. Michael Berthon-Jones, and their colleagues in 1981. EX1001, 1:64-2:4; EX1014, 1 (citing

[4] U.S. Patent No. 5,490,502 to Rapoport et al. (EX1008, "Rapoport502").

EX1015). "[T]he upper airway during sleep mimics the behavior of a collapsible tube." EX1014, 1. To prevent this collapse, positive airway pressure can oppose the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). *Id.*; *see also* Behbehani ¶¶33-37.

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

By 1993, Dr. Sullivan, Dr. Berthon-Jones, and their colleagues had developed a self-setting continuous positive airway pressure (CPAP) machine that "adjusts CPAP pressure on a minute-by-minute basis according to the degree of upper airway obstruction." *Id.*, 1. This approach had several advantages including "aid[ing] compliance by allowing a minimal awake pressure." *Id.* "The major limitation of CPAP therapy relates to discomfort or other factors leading to incomplete compliance with the necessary use of the device." EX1014, 5; EX1016, 1 ("Patients often complain of side effects caused by NCPAP treatment, including nasal congestion, dry mouth, difficulty exhaling, and nocturnal awakenings."). By

the mid-1990s, it was well-recognized that lowering the pressure when the patient is awake could increase compliance. *See* EX1012, 4 ("lower pressure … will be more comfortable for the patient, particularly when they are awake, which may result in a higher compliance and better CPAP therapy than may result from a very high pressure"). As Dr. Berthon-Jones explained, "patients feel uncomfortable at high CPAP pressures," and will "object violently to [high pressure] while they are wide awake trying to go to sleep on an ordinary night." EX1012, 4; *see also* 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." EX1017, Abstract. By 2003, machines for delivering PAP therapy were on the market that included one or more sensors and a processing unit that could detect breathing patterns and adjust pressure as appropriate based on those breathing patterns. EX1035, 2; EX1037, 2, *see also* Behbehani ¶¶42-47.

B. The '955 Patent

The '955 Patent describes a well-known system and method for treating a sleeping disorder by delivering a flow of breathable gas to a patient's airways. EX1001, Abstract, Fig. 1, 2:58-3:16. The patent describes Figure 1 (reproduced

below) as illustrating an embodiment of "the present invention," yet admits the components in the figure are conventional and operate in a conventional way.

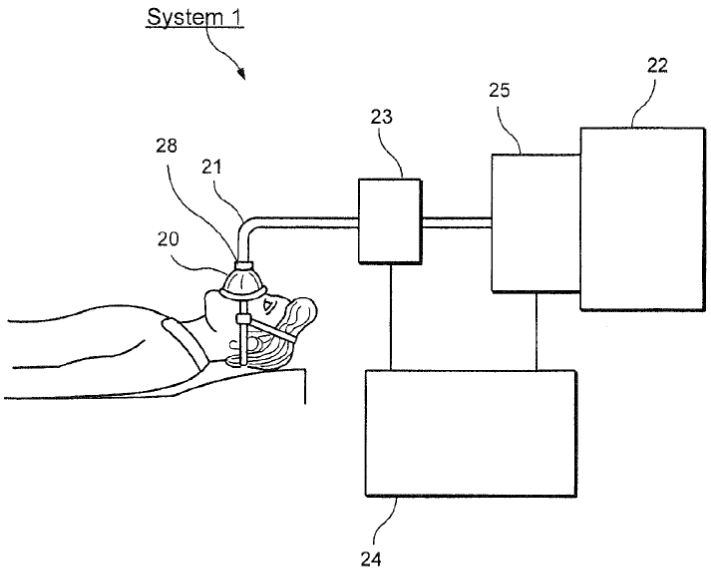
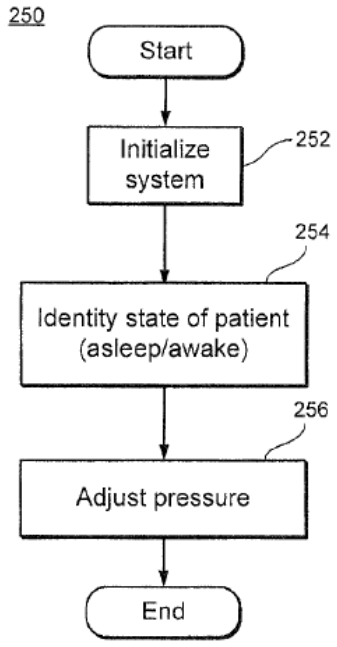


FIG. 1

A patient wears "a mask 20 which is connected via a tube 21 to receive airflow having a particular pressure from a flow generator 22" where the amount of pressure is determined with "any conventional PAP [positive airway pressure] therapy methods." *Id.* 3:56-57. "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.* 3:59-67.

The patent attempts to address limitations of "[s]ome conventional PAP systems [that] utilize algorithms which continuously and automatically titrate the applied pressure." *Id.*, 2:46-47. Delivering high pressure airflow to the patient causes discomfort when the patient is awake and is therefore desirable "only when the patient is asleep." *Id.*, 2:26-32. To remedy the patient's discomfort, the patient describes the processing arrangement 24 as "mak[ing] a determination as to a current state of the patient" (*id.*, 4:22-26) and "adjust[ing] the pressure to correspond to the patient's current state" (*id.*, 5:58-60). Specifically, the processing arrangement 24 "reduce[s] the applied pressure" when the patient is awakened and "instruct[s] the flow control device 25 to elevate the pressure" when the patient falls asleep. *Id.*, 5:60-64, 6:7-10. This allegedly inventive feature is reflected in Figure 10 below.



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C. The Challenged Claims

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

The '955 Patent has 31 claims, 2 independent claims and 29 dependent claims. Independent claim 1 recites:

(1) a positive airway pressure system for delivery of a flow of breathable gas at a positive treatment pressure;

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

(2) a flow generator;

(3) a flow sensor; and

(4) a processing arrangement that (i) receives the measured data corresponding to the flow of breathable gases from the flow sensor (ii) analyzes the data to determine the patient's breathing patterns and (iii) automatically controls the flow generator to increases pressure using a ramp system.

Independent claim 19 recites a similar system as a 7-step method.

D. Prosecution History

The applicant only obtained allowance of the '955 Patent because the Examiner found that the prior art of record did not teach an "awake state." EX1002, 150-54. But the Examiner did not consider Sullivan460 during the prosecution of the '955 Patent.

V. OVERVIEW OF THE PRIOR ART

A. Sullivan995 (EX1005)

U.S. Patent No. 5,245,995 to Sullivan et al. ("Sullivan995"), filed May 27, 1992 and published on September 21, 1993, is prior art under 35 U.S.C. §§ 102 (a), (b), and (e). Sullivan995 discloses each limitation of the independent claims except it does not expressly disclose determining the patient is in an asleep state.

Sullivan995 discloses a "continuous positive airway pressure (CPAP)" system that delivers a controllable airway pressure to a patient's airway passages.

EX1005, Fig. 3, Abstract, 1:33-36, 2:15-20, 9:57-58. A CPAP nose mask covers the patient's nose and creates an "enclosed airway" that forms a flow path for breathable gas to be inhaled and exhaled by the patient. *Id.*, Figs. 1A, 1B, 8:47-59.

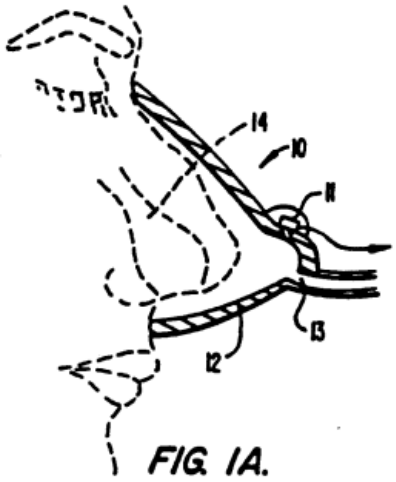


FIG. 1A.

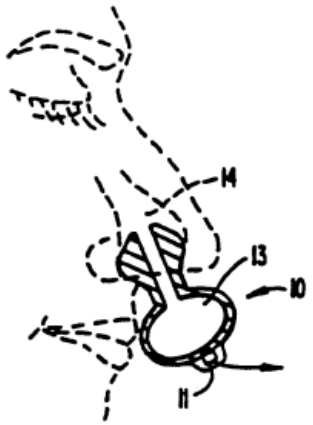


FIG. 1B.

Positioned within that enclosed airway is a microphone 11 (a differential pressure sensor) that senses various flow characteristics of the breathable gas, including exhaled air flow volume, inhaled air flow volume, breathing rate, breathing patterns, exhaled air flow rate, inhaled air flow rate, and/or indicators of snoring. *Id.*, 17:4-12, 12:54-66, 18:47-66, 18:27-31, 4:28-45, 6:54-65, 13:10-33, 13:65-14:16, 14:45-67, Abstract.

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

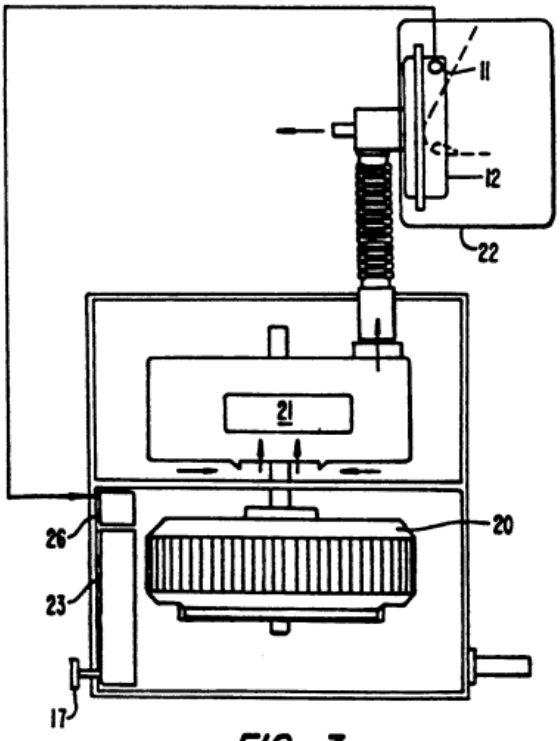


FIG. 3.

Figure 12 of Sullivan995 also depicts a computing system that receives and processes various breathing pattern data (e.g., snore, flow rate, volume, breathing rate) from an amplifier/filter/processor combination that provide the data based on a signal from the pressure sensor. *Id.*, 17:6-13.

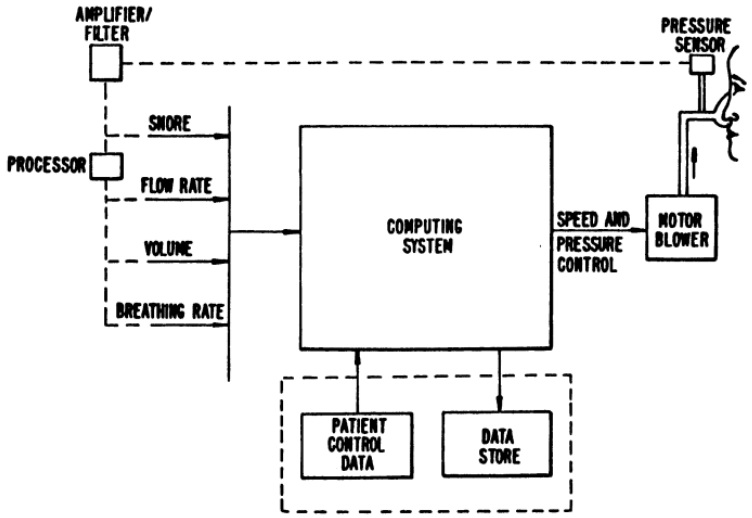


FIG. 12.

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

For example, when a snore is detected by the microphone 11, the processor 26 increases the blower speed, which increases the air pressure in the flow path of breathable gas delivered to the patient. *Id.*, 10:41-46, 10:10-12.

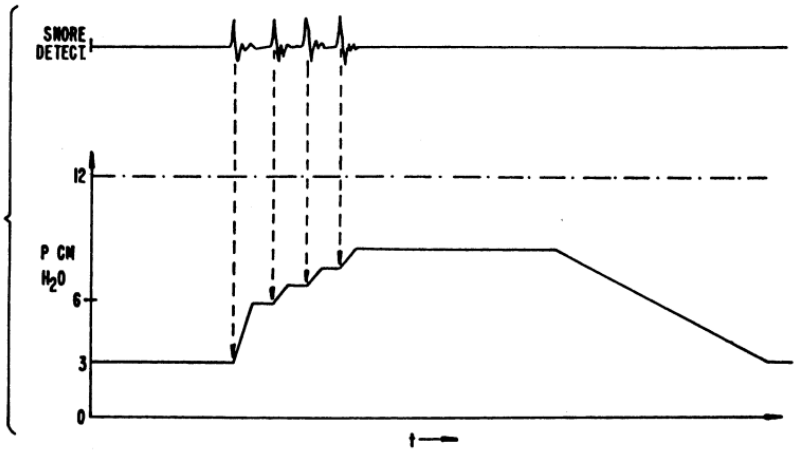


FIG. 13.

Figure 13 of Sulllivan995 depicts an incremental pressure increase for each detected snore and pressure decrease in the absence of snores. *Id.*, 18:6-18, 10:31-37, 15:18-23. Because the patient only snores when asleep, Sullivan995 only increases the pressure when the patient has fallen asleep. Similarly, Sullivan995 also describes increasing treatment pressure upon detection of other abnormal breathing patterns that occur while in a sleep state, such as apneas or hypopneas. *Id.*, 6:40-67, 15:34-65, 16:17-22, 16:51-59. Specifically, if the patient's air flow rate drops below a baseline, Sullivan995 increases the pressure. *Id.*, 6:41-57, Figs. 10-12.

B. Sullivan460 (EX1006)

PCT Application Publication No. WO 01/05460 to Sullivan et al. ("Sullivan460"), filed April 26, 2000 and published on January 25, 2001, is prior

art under 35 U.S.C. §§ 102 (a) and (b). Sullivan460 discloses the "determines the patient is in an asleep state" limitation not expressly disclosed in Sullivan995.

Sullivan460 is a PCT application by the same inventor as Sullivan995 and incorporates Sullivan995 by reference, stating Sullivan995 describes ResMed's AutoSet product: "the flow rate measurement means and the treatment means may be constructed together as part of one apparatus, such as the AutoSet product from ResMed described in US Patent No 5245995 [Sullivan995], the contents of which are incorporated by reference." EX1006, 6:22-29.

Like Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep. *Id.*, 6:17-29, 7:3-12, 10:9-33, 11:10-12, cls. 22-28, 43-46, Figs. 2-4. Sullivan460 also discloses that the system selects between an "awake" mode and an "asleep" mode, and applies high pressure in the "asleep" mode and low pressure in the "awake" mode. *Id.*, 6:30-7:22, 14:7-36, cls. 22-31.

Specifically, a central controller 100 receives signals and breathing patterns signals from the flow rate measurement means 70. *Id.*, 10:4-6. When the flow rate increases above a certain level, the controller determines the patient is in an awake state and switches the CPAP system into a first mode in which a reduced air pressure is applied to the patient's airways. *Id.*, 10:21-25, 14:7-36, cls. 22-31. Likewise, when interruptions 10 are detected in the patient's breathing patterns, or

a reduced average airflow indicates the patient is asleep, the controller determines the patient has an asleep state and switches the CPAP system into a second mode in which an increased air pressure is applied to the patient's airways, to eliminate the patient's upper airway flow limitation. *Id.*, 10:3-16.

C. Matthews (EX1007)

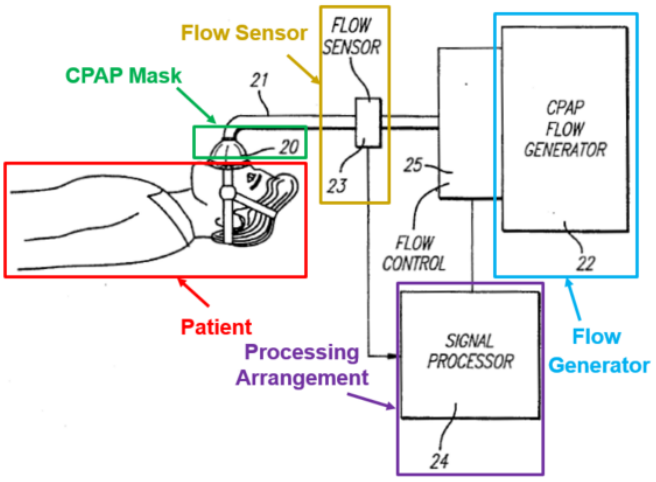
U.S. Patent No. 7,168,429 to Matthews et al. ("Matthews"), filed on October 10, 2002 and published on June 19, 2003, is prior art under 35 U.S.C. §§ 102 (a) and (e). Matthews discloses the troubled wakefulness state of claims 12, 22, and 29.

Matthews is a positive airway pressure system that "optimizes the pressure delivered to the patient to treat … disordered breathing while minimizing the delivered pressure for patient comfort." EX1007, Abstract. Specifically, "[w]hen a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic." *Id.*, 21:37-39. In such event, the Matthews system will "interrupt the auto-CPAP controller if the patient's breathing pattern becomes too variable." *Id.*, 21:39-41.

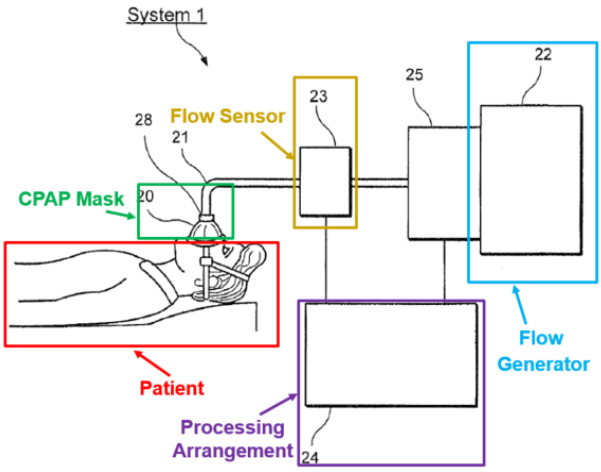
D. Rapoport502 (EX1008)

U.S. Patent No. 5,490,502 to Rapoport ("Rapoport502"), filed May 20, 1994 and published on February 13, 1996, is prior art under 35 U.S.C. §§ 102 (a) and (b). As discussed, the '955 Patent uses conventional hardware components for PAP machines. *See* Section IV.B. Indeed, Rapoport502 (published nearly a decade

before the '009 Patent) discloses nearly identical hardware, including a conventional flow generator, flow sensor, and processor. EX1008, Fig. 9.



Rapoport502, Fig. 9



'955 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 ¶84.

This Petition does not turn on this precise definition, and the challenged claim would be unpatentable from the perspective of any reasonable person of ordinary skill in the art at the relevant time. Behbehani ¶85.

VII. CLAIM CONSTRUCTION

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

A. "troubled wakefulness" (claim 6 and 23)

This term to a POSITA in the context of the '024 Patent means "state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable." Behbehani Decl. ¶91. This term is not an industry standard term and was coined in the '024 Patent. *Id.,* ¶92. As such, the construction is derived directly from the specification, which describes "troubled wakefulness" as a state "in which the breathing pattern is characterized by irregularity variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient's airflow tracing indicating that the patient is

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

awake and either anxious or uncomfortable." EX1001, 4:59-64, Fig. 7. The specification further confirms that "Patient's discomfort during wakefulness is often associated with changes from a regular breathing pattern … and frequently occur when the patient is distressed by the PAP system." *Id.*, 2:40-47.

VIII. GROUND 1: SULLIVAN995 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1-5, 8, 11-12, 16-22, 24-26 AND 30-31

A. Motivation to Combine

It would have been obvious to a POSITA to modify Sullivan995 so that the *processing arrangement* in Sullivan995 applies *a lesser pressure when the patient is in an awake state*, and *determines that the patient has transitioned between at least an awake state and an asleep state*, as taught in Sullivan460. Behbehani ¶91. A POSITA would have been motivated to implement this modification to cause Sullivan995's CPAP system to apply a lower pressure upon detecting the patient's awake state.

First, a POSITA would have recognized the advantages of using the same CPAP system to treat both sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught in Sullivan460. EX1006, 7:3-12; Behbehani ¶93. An upper airway flow limitation characterized by at least one decrease in upper airway inspiratory flow rate, followed by at least one increase in flow rate, is indicative of pre-eclampsia (and not observed in typical snoring), and could be treated with the modified system. *See* EX1006, Fig. 1, 6:22-29, 9:31-10:7; Behbehani ¶94. Women

with sleep apnea are at higher risk for pre-eclampsia, and each of pre-eclampsia, snoring, and apnea involve hypertension, high blood pressure, and obstructions during sleep. *See*; EX1006, 1:5-8, 4:33-34, 5:29-36. 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, 6:3-35, 9:31-10:6. Sullivan995 even suggests that such modifications would be desirable, as its CPAP system is not limited to treating apnea and snoring, but also apply to other upper airway disorders, which the POSITA would have understood to include vibrations related to pre-eclampsia. EX1005, 1:14-31, 4:36-45.

Second, a POSITA would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment. 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. Sullivan995 strongly suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period). EX1005, 10:13-46, 14:45-64.

Moreover, as Sullivan995 explains, prior to Sullivan995, therapy pressure was often delivered at levels higher than necessary for substantial periods, causing discomfort (*id.,* 4:21-25), and Sullivan995 partially solves the problem by reducing the pressure at the beginning of therapy, when the patient connects herself to the CPAP system. Behbehani ¶96.

B. Reasonable Expectation of Success

The POSITA would have had a reasonable expectation of success in making the modification to Sullivan995. Behbehani ¶97.

First, Sullivan460 explicitly recognizes the combination of Sullivan995 with the teachings in Sullivan460. Behbehani ¶98. Sullivan460 expressly states that Sullivan995 may be modified to include features of Sullivan460, such as "sens[ing] 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." EX1006, 6:26-29. As Sullivan460 discloses in further embodiments, a sleep sensor detects "reduced average airflow in the patient's upper airway" to detect the sleep state and a higher average airflow to detect the awake state, and switching between different pressure delivery depending on which state is determined. EX1006, 6:22-7:22, cls. 22-28, 43-47. Therefore, a POSITA, upon reading the teachings of Sullivan995 and Sullivan460, would have had a reasonable expectation of success in performing this modification because Sullivan460 already describes Sullivan995

as being used to sense flow limitations, and Sullivan460 further explains that flow data may be used to determine an awake/sleep state. Behbehani ¶98.

Second, Sullivan995 and Sullivan460 are analogous art. Behbehani ¶99. Both references describe CPAP systems that include flow sensors and flow generators. Like Sullivan995, Sullivan460 discloses a flow rate measurement means 70 (Fig. 2) located in the flow path for detecting the rate at which the patient breathes. Sullivan460 at 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. EX1006, 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. EX1006, 10:3-16.

Given the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way. Behbehani ¶100.

C. Independent Claim 1

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

To the extent limiting, Sullivan995 discloses a "continuous positive airway pressure (CPAP)" system[7] which is *a positive airway pressure system*. EX1005, Fig. 3, Abstract, 1:33-36, 2:15-19, 9:57-58. Sullivan995's CPAP system "deliver[s] appropriate airway pressure" to the patient's airway passages and is therefore *for delivery of a flow of breathable gas*. *Id.*, 2:15-16. As a POSITA would have understood, CPAP delivers "positive" airway pressure relative to atmospheric pressure, so that the breathable gas delivered by Sullivan995's CPAP system is *at a positive treatment pressure with respect to ambient air pressure.* Behbehani ¶ 101.

As shown in Figure 3 (reproduced below), the CPAP system of Sullivan995 includes a nose mask 12 or nasal prongs that are "fluidly sealable to the nasal air passages of a patient" and are "for delivery of air to the patient's nasal passages,"

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

meaning the CPAP system delivers the elevated air pressure *to an entrance of a patient's airways*. EX1005, cl. 6, 5:12-34, 11:1-4, 11:23-43.

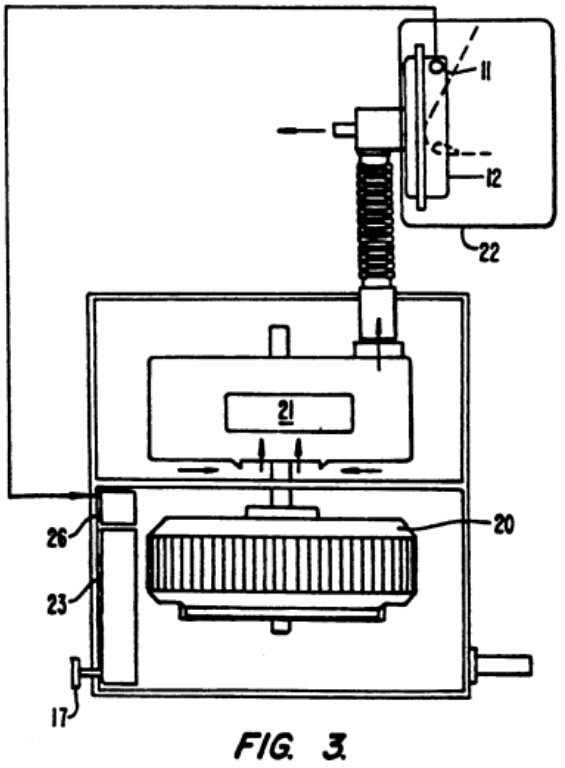


FIG. 3.

EX1005, Fig. 3

Sullivan995's CPAP system delivers the breathable gas *in order to assist in treating a sleeping disorder in a patient* by providing air pressure at a certain level to "prevent the onset of apnea" in the patient, where Sullivan995 characterizes sleep apnea as a complete occlusion of the upper airway passage during sleep, which is a *sleeping disorder*. *Id.*, 10:31-35, 1:20-31, 11:15-20; *see also* 1:32-48 (explaining that CPAP is used to "treat[] the occurrence of obstructive sleep apnea" and "is effective in treating central and mixed apnea"); Behbehani ¶103.

2. 1[a]: *"a flow generator which supplies a positive treatment pressure flow of breathable gases to the entrance of a tube, the tube directing the flow of breathable gases to the airway of a patient to provide the patient with the positive treatment pressure flow of breathable gases;"*

Sullivan995 discloses this limitation. Behbehani ¶104. Sullivan995's CPAP system includes a motor 20 with a variable speed that drives a blower 21 (*flow generator*). EX1005, 9:57-64. The blower 21 *supplies a positive treatment pressure flow of breathable gases* by providing pressurized air to the patient. *Id.*, 9:60-64 ("[A]n increase in motor speed also increases the blower speed which in turn increases the output air pressure of the blower 21."); Behbehani ¶104.

As shown in Figure 3, blower 21 supplies pressurized air through an air line (*to the entrance of a tube*). The air line connects from blower 21 to the nose piece. EX1005, 7:13-25, 7:29-41, Fig. 3. A POSITA would understand that the connection of the air line (*tube*) from blower 21 to the nose piece is *directing the flow of breathable gases to the airway of a patient to provide the patient with the positive treatment pressure flow of breathable gases.* Behbehani ¶106.

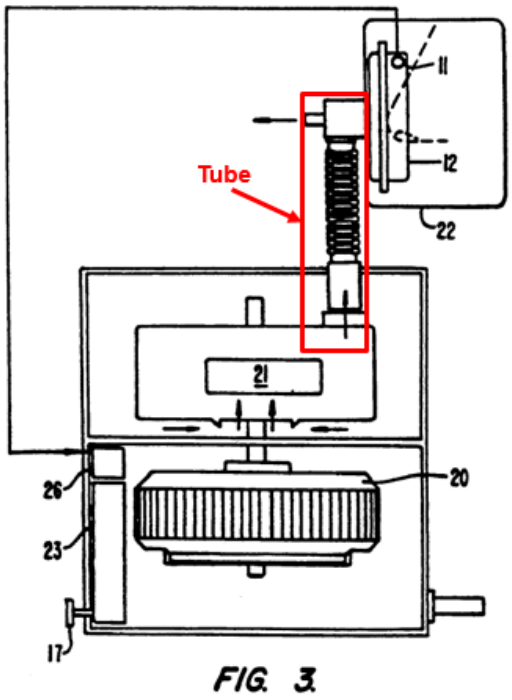
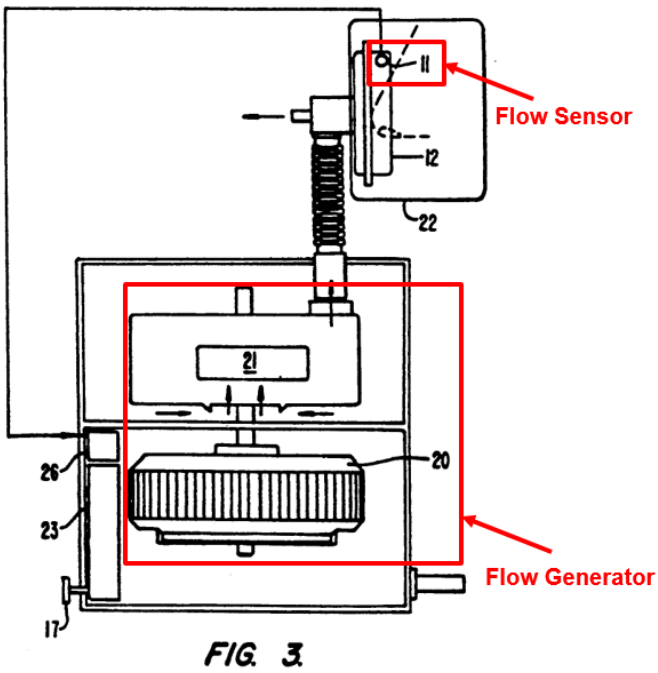


FIG. 3

EX1005, Fig. 3 (annotated)

3. **1[b]:** *"a flow sensor located in a flow path of the positive treatment pressure flow of breathable gases, the flow sensor measuring data corresponding to the flow of breathable gases directed to the patient and indicative of the patient's breathing patterns; and"* Sullivan995 discloses this limitation. Behbehani ¶107. Sullivan995's CPAP system includes a differential pressure sensor (microphone 11), which is a *flow sensor*. EX1005, Fig. 3, 9:64-66; Behbehani ¶107. As shown in Figure 3 (reproduced below), "the snoring detection means 22 is a pressure detection means and microphone 11 is a ***differential pressure sensor***." EX1005, 9:66-10:1. Sullivan995 explains that the microphone is a sound transducer that "consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the ***rate of breathing***,

inhaled air flow or inhaled ***air flow rate***." *Id.*, 3:21-30 (emphasis added); *see also id.*, Abstract. This is consistent with the '009 Patent's description of "[c]onventional flow sensors 23" as "detect[ing] the ***rate of airflow*** to/from patent [sic] and/or a ***pressure*** supplied to the patent [sic]." EX1001, 3:59-61 (emphasis added).



EX1005, Fig. 3

As depicted in Figure 3, microphone 11 is located within the snoring detection means 22, and is therefore *located in a flow path of the positive treatment pressure flow of breathable gases*. EX1005, 8:52-57; Behbehani ¶109. Sullivan995 generally explains: "The breathing rate or interruption of breathing, the air flow

rate during inhalation/exhalation and the beginning/end points of the breathing cycle are derived from the very low frequency pressure wave after further sampling or processing." *Id.*, 5:65-6:1. To determine the differential pressure used to calculate air flow rate, the pressure sensor is placed in the flow path (inside the mask) as depicted in Figure 3. Behbehani ¶109.

Further, Sullivan995 expressly teaches that there are 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*. Sullivan995 states that the 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.

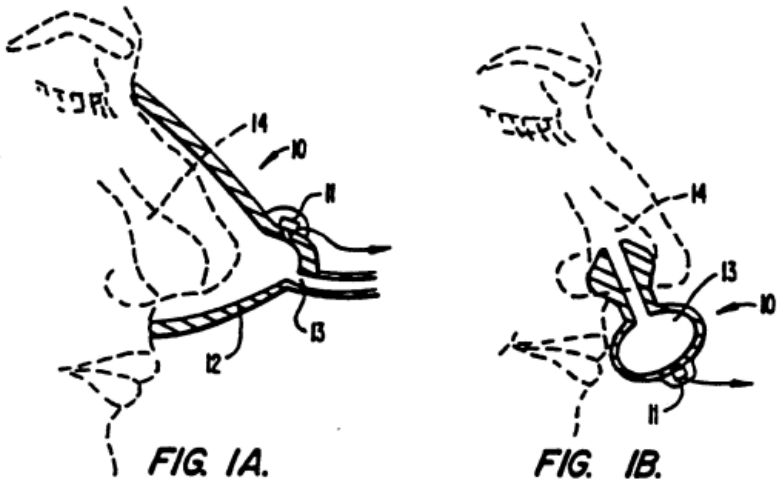


Figure 1A depicts the microphone 11 (*flow sensor*) as being located "in sound communication with the container 12 of [the] nose mask." *Id.*, 8:47-49. Sullivan995

discloses an "enclosed airway," which "extends from the source of snoring sounds within the patient's body, through the nasal passages 14 and out of the opening 13 in the nasal mask." *Id.*, 8:49-59. That enclosed airway includes air "being inhaled by the patient" that "enters the nasal passageways" and therefore forms a *flow path of the positive treatment pressure flow of breathable gases*. *Id.*; Behbehani ¶111. The microphone 11 of Figure 1A "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, 8:52-59. 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 ¶111.

Sullivan995 discloses this limitation. Behbehani ¶111. As Sullivan995 explains, the microphone 11 (*flow sensor*) performs a "form of measurement" by "detecting snoring sounds" and "other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate." EX1005, 3:26-33. By measuring snoring sounds, breathing rate, inhaled air flow or inhaled air flow rate, Sullivan995's microphone 11 (*flow sensor*) *measur[es] data* that is *indicative of the patient's breathing patterns*. *See also id.*, 11:5-20 (describing, with reference to Figure 3, detecting "a snore, or snoring patterns or abnormal breathing pattern"); Behbehani ¶112.

For example, the waveforms in Figures 2A and 9 depict the data *indicative of the patient's breathing patterns* that is measured by the microphone 11, and reflect "pressure waves of interest indicative of snoring and breathing." EX1005, 8:23-28; Behbehani ¶113.

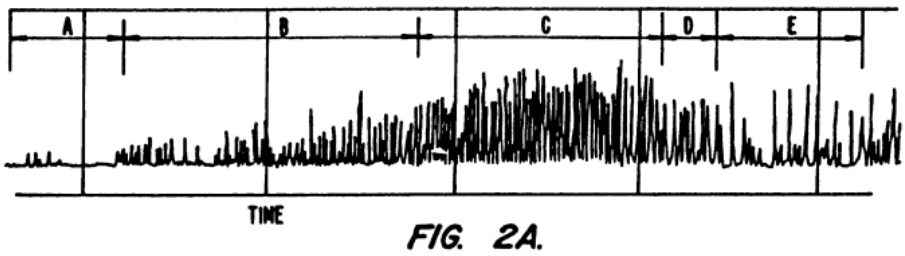


FIG. 2A.

EX1005, Fig. 2A

Specifically, the waveforms in Figure 2A depict normal breathing (part A), soft to moderate snoring (part B), constant loud snoring (part C), a pre-apneic pattern indicative of obstructive hypopnea (part D), and periods of silence punctuated by snoring, which is indicative of sleep apnea (part E). EX1005, 9:16-32; Behbehani ¶114.

While Figure 2A depicts the patient's breathing patterns without delivery of any air flow from the CPAP system, Figure 9 depicts the patient's breathing patterns when the air blower of the CPAP system is generating "high frequency wind noise," meaning the CPAP system is actively delivering a *flow of breathable gases directed to the patient*. EX1005, 13:10-21.

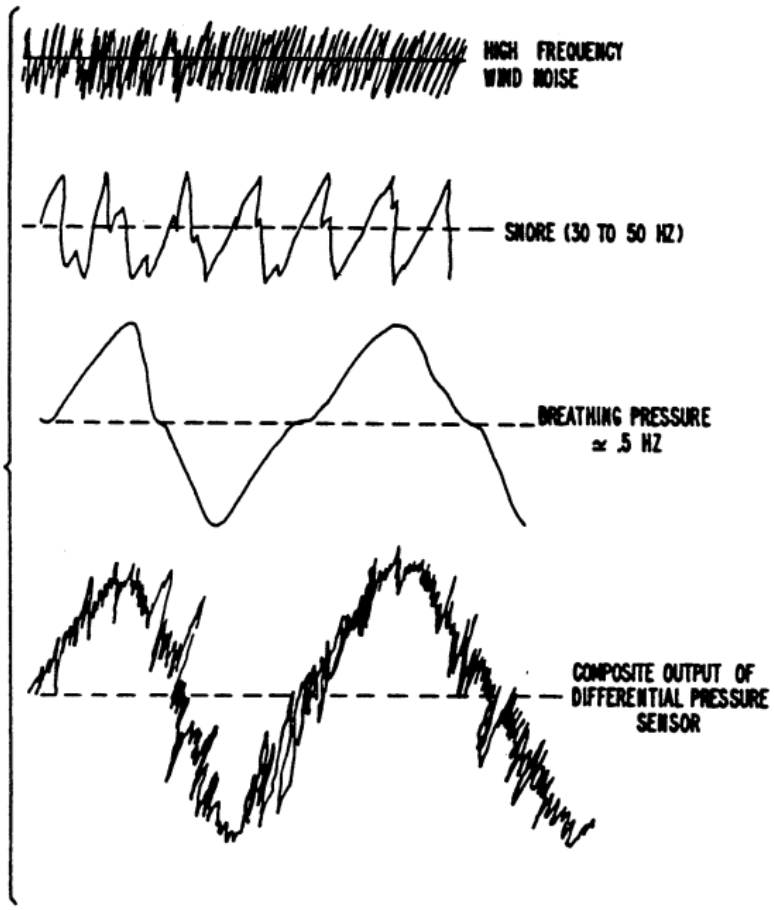


FIG. 9.

EX1005, Fig. 9

Further, in reciting sensors in its claims, Sullivan995 states that the sensors are "continuously sensing the patient'breathing [sic] patterns" (*id.*, 18:27-31) that sense data 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. For example, Figure 8 "shows the volume of air inhaled (or exhaled) by the patient with each breath as determined by the volume integrator from the breathing signal filtered from the pressure sensors." *Id.*, 13:65-68. Part A of Figure 8 shows "normal breathing," and Part B shows "shallow breathing or hyperventilation." *Id.*, 13:68-14:2. The "decreasing pattern of air volume inspired by the patient can be indicative of the imminent onset of apnea" (*id.*, 14:2-5) and therefore meets this limitation. Behbehani ¶117. As further examples, Figures 10-12 depict various data, including "flow rate", "snore", "volume", and "breathing rate" from the pressure sensor, each of which also meets this limitation. Behbehani ¶118.

4. 1[c1]: *"a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor,"*

Sullivan995 discloses this limitation. Behbehani ¶119. The combination of an amplifier/filter/processor unit 26[8] with a speed control unit 23[9] depicted in

[8] Sullivan995 refers to the same processor unit 26 as an amplifier/filter/processor unit 26, amplifier/filter/processor 26, and processor 26. EX1005, 10:3-6, 10:41-46, 10:55-58, 11:58-62, 14:50-55, 15:27-33, 15:59-61. For ease of reference, Petitioner refers to each as processor unit 26.

[9] Sullivan995 refers to the same speed control unit 23 as an electronic speed control unit 23, a speed control unit 23, a feedback speed controller 23, and a speed

Figure 3 and described in part as the computing system in Figure 12 is *a processing arrangement.* As Sullivan995 describes, 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). Additionally, in relation to Figure 4, which depicts the circuitry of the CPAP system in Figure 3 in block form, Sullivan995 states "[t]he electrical signals of the microphone 11 are sent to a Filter/Amplifier/Processor 26 which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern." *Id.*, 11:55-62.

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controller 23. EX1005, 9:59-60, 10:14-16, 11:63-64, 14:40-41, 15:1-3. For ease of reference, Petitioner refers to each as the speed control unit 23.

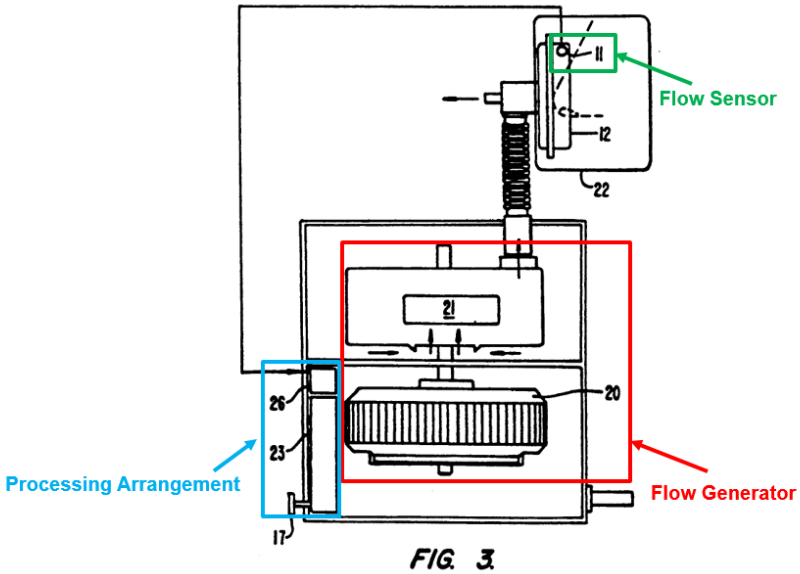


FIG. 3

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

Moreover, as Sullivan995 explains, the circuitry of the CPAP system in Figure 4 (and therefore in Figure 3 as well) includes the feedback speed controller 23 illustrated in Figure 12 in block form and includes a computing system. EX1005, 17:3-4.

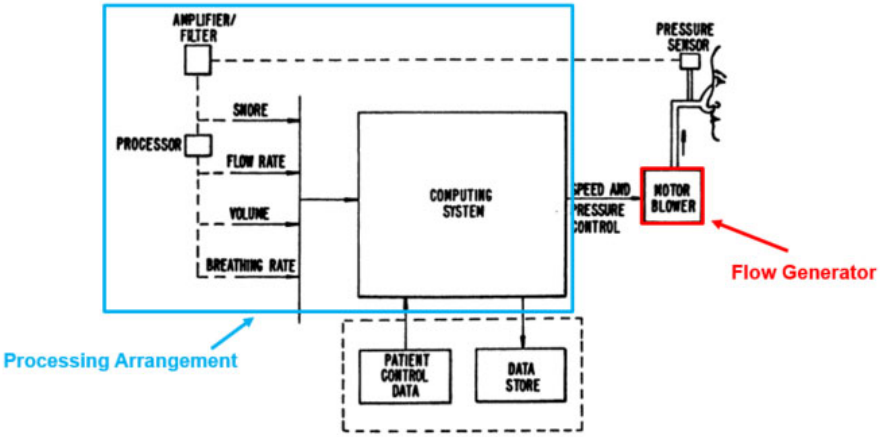


FIG. 12.

In describing Figure 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. The pressure wave indicative of breathing is further processed to generate signals indicative of flow rate, volume and breathing rate." EX1005, 17:6-12. These amplification, filtering, and processing steps would have been performed by the amplifier/filter/processor depicted in Figure 12 and would have been included as part of the amplifier/filter/processor unit 26 (included in the *processing arrangement*) of Figures 3 and 4. Accordingly, Sullivan995's *processing arrangement receives the measured data corresponding to the flow of breathable gases from the flow sensor*.

5. 1[c2]: *"[the processing arrangement] analyzes the data to determine the patients breathing patterns,"*

Sullivan995 discloses this limitation. Behbehani ¶123. As explained for 1[b] and 1[c1], Sullivan995 describes various *breathing patterns* for the patient.

Referencing Figure 4, Sullivan995's *processing arrangement* includes the processor unit 26, "which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern." EX1005, 11:55-62. In generating this control signal, the processor unit 26 (included in the *processing arrangement*) therefore *analyzes the data [from the flow sensor] to determine the patient's breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.

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

6. 1[c3]: *"the processing arrangement also determines whether to alter the pressure supplied to the airway of the patient based, at least in part, of the determined breathing patterns of the patient,"*

Sullivan995 discloses this limitation. Behbehani ¶125. 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.*, 9:60-64, 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 ¶126. Similarly, "in the absence of an electronic signal from the microphone 11," meaning the patient is not snoring, Sullivan995's processor unit 26 "achieve[s]" a decrease in CPAP pressure by "continuously gradually reducing the blower speed over a period of time." EX1005, 10:37-46; Behbehani ¶126. Increasing or decreasing the blower speed results is an *alter[ing] [of] the pressure supplied by* the blower (*flow generator*) *to the airway of the patient* and is based on "when snoring sounds occur." Behbehani ¶126.

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.3 and VIII.C.5 (describing *the determined breathing patterns of the patient*).

7. 1[d1]: *"wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and;"*

Sullivan995 discloses this limitation. Behbehani ¶138. As Sullivan995 explains for Figure 3, "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-12. A POSITA would understand that the detection of snoring indicates that the patient is in an asleep state. *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."); Behbehani ¶139.

Moreover, as explained for 1[c1], the *processing arrangement* includes the computing system depicted in Figure 12. Figure 13 (reproduced below) depicts an example of how that computing system increases pressure based on the snoring detection. *Id*., 14:17-20.

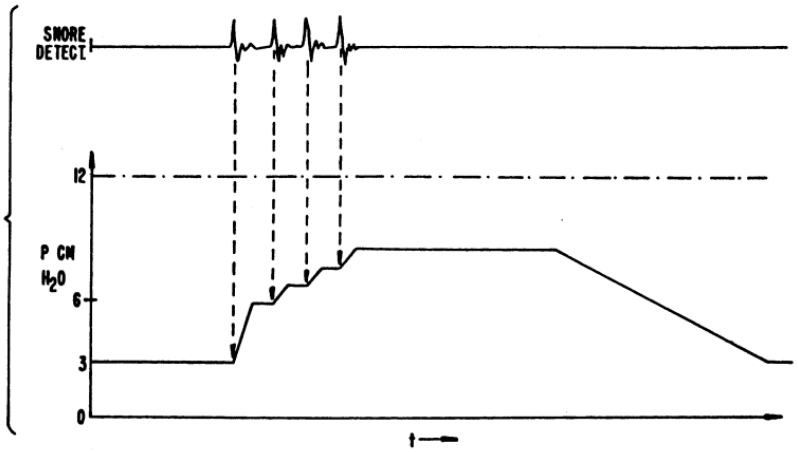


FIG. 13.

EX1005, Fig. 13

As depicted in Figure 13, the computing system maintains a constant pressure until the first snore is detected. In response to that first snore, and each subsequent snore, the computing system increases the pressure. Behbehani ¶141.

8. 1[d2]: *"[the processing arrangement applies] a lesser positive treatment pressure in an awake state"*

Sullivan995 in view of Sullivan460 renders obvious this limitation. Behbehani ¶142. As explained for 1[d1], Sullivan995 increases pressure to the patient when a snore is detected. EX1005, 10:10-12, 14:17-20, Fig. 13. Although Sullivan995 does not explicitly disclose that *a lesser positive treatment pressure* is applied *in an awake state*, this is taught by Sullivan460. Behbehani ¶¶143-45.

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 ¶146

a) Teachings of Sullivan460 on lesser pressure when awake.

Sullivan460 discloses "sleep sensor [that] is adapted to register that the patient is asleep when there is a reduced average airflow in the patient's upper airway." EX1006, 7:17-19. Sullivan460 further discloses "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. *Id.*, 6:30-7:12, cls. 22-28, 43-46. This means that Sullivan460 applies *a lesser positive treatment pressure* when the processing arrangement determines the patient *is in an awake state*. Behbehani ¶¶147-48.

b) Motivation to Combine and Reasonable Expectation of Success

See Section VIII.A (Ground 1, Motivation to Combine) and VIII.B (Ground 1, Reasonable Expectation of Success).

9. 1[e1]: *"wherein the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state"*

Sullivan995 in view of Sullivan460 renders obvious this limitation. Behbehani ¶¶150-52. Specifically, "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-12, Fig. 3; *see also* 14:17-20, Fig. 13. Also, the pressure is decreased "if an extended period of snore free breathing occurs" by "automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected." *Id*., 10:31-46; *see also id.* 10:47-61 (the CPAP pressure increases "via the processor 26," in response to the "snore, or snore pattern."), Fig. 13.

Although the patient is awake when he "connects himself to the CPAP unit" when "[t]he CPAP pressure is initially at a minimum operating value" (*id.*, 10:48-57), Sullivan995 does not explicitly disclose that the increase occurs when *the processing arrangement determines that the patient has transitioned between at least an awake state and an asleep state* has occurred. Behbehani ¶152. However, this limitation would have been obvious from Sullivan995 in view of Sullivan460. *Id*.

a) Teachings of Sullivan460 on determining awake state

Sullivan460 incorporates Sullivan995 by reference and refers to Sullivan995 as describing a "flow rate measurement means and [a] treatment means [as being]

constructed together as part of one apparatus." EX1006, 6:22-29. Like Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep. *Id.*, 6:17-29, 7:3-12, 10:9-33, 11:10-13, cls. 22-28, 43-46, and Figs. 2-4.

Sullivan460 discloses *determin[ing] that the patient has transitioned between at least an awake state and an asleep 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 ¶152. According to Sullivan460, "a switching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46.

b) Motivation to Combine and Reasonable Expectation of Success

See Section VIII.A(Ground 1, Motivation to Combine) and VIII.B (Ground 1, Reasonable Expectation of Success).

10. 1[e2]: *"the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system."*

Sullivan995 discloses this limitation. Behbehani ¶153. As Sullivan995 depicts in Figure 13, the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube incrementally with each snore that is detected. EX1005, 14:17-20. As a POSITA would have readily recognized, 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 ¶155; *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).

D. Dependent Claims 2-5, 8, 11-12, 16-18[10]

1. Claim 2: determines during asleep state that patient is experiencing elevated upper airway resistance based and increases pressure

Sullivan995 discloses this limitation. Behbehani ¶156. Sullivan995 states "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-12; *see also id.,* 10:47-61 (the CPAP pressure increases "via the processor 26," which is part of the *processing arrangement*, in response to

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

the "snore, or snore pattern"); *see* Section VIII.C.4. Moreover, Figure 13 depicts how the Figure 12 computing system (included in the *processing arrangement*) increases pressure based on the snoring detection. *Id.*, 14:17-20.

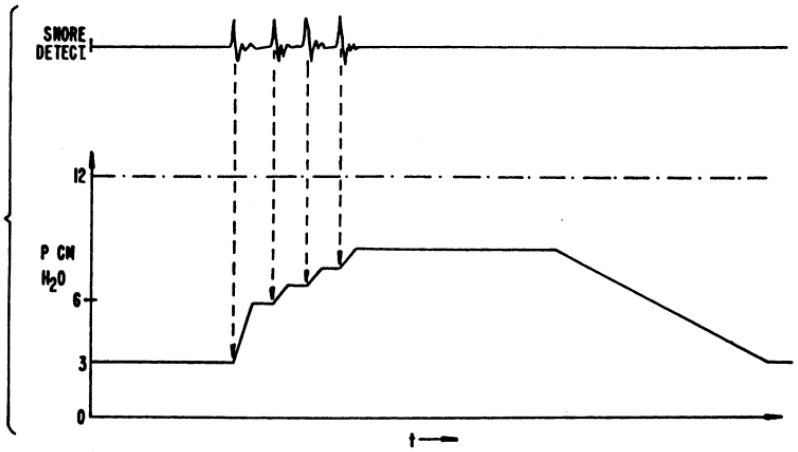


FIG. 13.

As Sullivan995 describes, "snoring is caused by vibration of the soft palate [and] is therefore indicative of an unstable airway and… is a warning signal of the imminence of upper airway occlusion." *Id.*, 10:16-21, 15:3-8. Moreover, a "decreasing intensity of the snoring occurs when the upper airway is almost, but not entirely, sucked closed by strong inspiratory efforts." *Id.*, 9:21-26, 13:50-53. As would have understood from Sullivan995's teachings of snoring as indicating an "unstable airway," an "imminence of upper airway occlusion," and a nearly closed "upper airway," the snoring in Sullivan995 is *an elevated upper airway pressure.* Behbehani ¶157.

2. Claim 3: determines during asleep state that the patient is experiencing hypopnea event and increases pressure

Sullivan995 alone or in view of the knowledge of a POSITA renders obvious this limitation. Behbehani ¶160. The waveforms in section D of Fig. 2A are "indicative of obstructive hypopnea, a condition in which the breath-by-breath intensity decreases progressively, and then increases" and "is a 'pre-apneic' pattern." *Id.*, 13:46-54; *see also id.*, 13:4-8 and 14:17-32 (describing the computing system of Fig. 13 as diagnosing "hypopnea" and processing "the number of hypopneas"). Moreover, Sullivan995 describes determining "flow rate," "breathing rate," "time interval," and "volume" data to detect sleep apnea or hypopneas (*see, e.g.,* parts D and E of Fig. 2A). *Id.*, Fig. 12, 6:40-68, 15:34-64, 17:3-27; Behbehani ¶162.

To the extent that Sullivan995 does not expressly disclose this limitation, this would have been obvious to a POSITA. Hypopneas is a disordered breathing pattern and should be treated with increased pressure, as taught by Sullivan995. Behbehani ¶164. Snores do not always precede hypopneas, such that detecting hypopneas would have been particularly desirable. Behbehani ¶165.

3. Claim 4: determines during asleep state that patient is experiencing apnea event and increases pressure

Sullivan995 discloses this limitation. Behbehani ¶166. The waveforms 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 ¶166.

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 ¶167. Snores do not always precede apneas, such that detecting apneas would have been particularly desirable. *Id*.

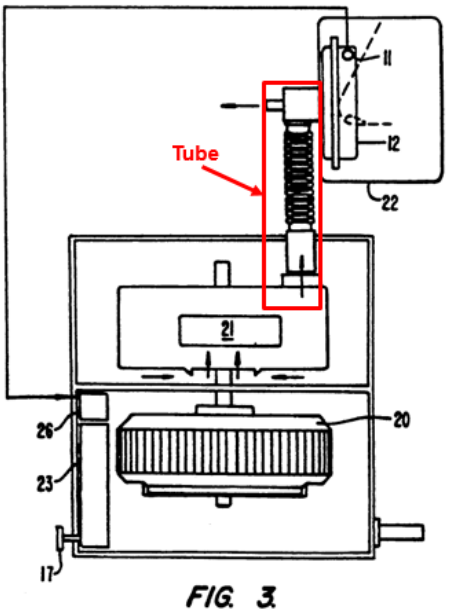
4. Claim 5: determines that patient has transitioned to an awake state and lowers pressure

Sullivan995 in view of Sullivan460 renders obvious this limitation. *See* Section VIII.C.8 (Ground 1, 1[d2]). Sullivan460 discloses "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." EX1006, 6:30-7:12, cls. 22-28, 43-46. Because the switching means can switch between the two modes, a POSITA would understand that Sullivan460 also teaches that the *processing arrangement lowers the positive treatment pressure* when it *determines that the patient has transition to an awake state from an asleep state based on the determined patient's breathing patterns.*

5. Claim 8: mask connected to patient end of tube placed on face of patient and covering at least mouth or nose of patient

Sullivan995 discloses this limitation. Behbehani ¶170. Sullivan995 discloses that there is the air line that connected to a nose piece. *See e.g.,* EX1005, 7:13-25; *see also* Fig. 3.



EX1005, Fig. 3 (annotated)

As shown in Figures 1A and 1B (reproduced below), the CPAP system of Sullivan995 includes a nose mask 12 or nasal prongs that are "fluidly sealable to the nasal air passages of a patient" and are "for delivery of air to the patient's nasal passages." EX1005, Figs. 1A, 1B, 5:12-21, 8:58-60; Behbehani ¶172.

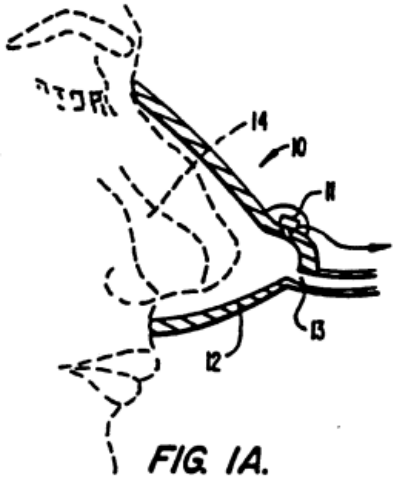


FIG. 1A.

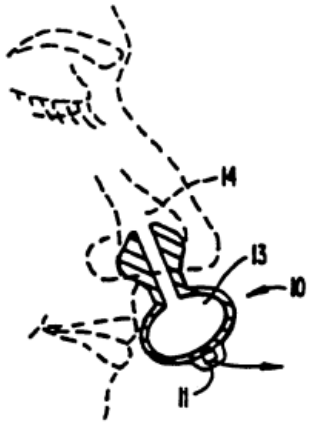


FIG. 1B.

Sullivan995 therefore discloses a mask connected to a patient end of the tube and placed on a face of the patient and covering at least one of the mouth and the nose of the patient. Behbehani ¶173.

6. Claim 11: flow sensor external to flow generator

Sullivan995 discloses this limitation. Behbehani ¶174. As shown in Figure 3, microphone 11 (*flow sensor*) is external to blower 21 (*flow generator*).

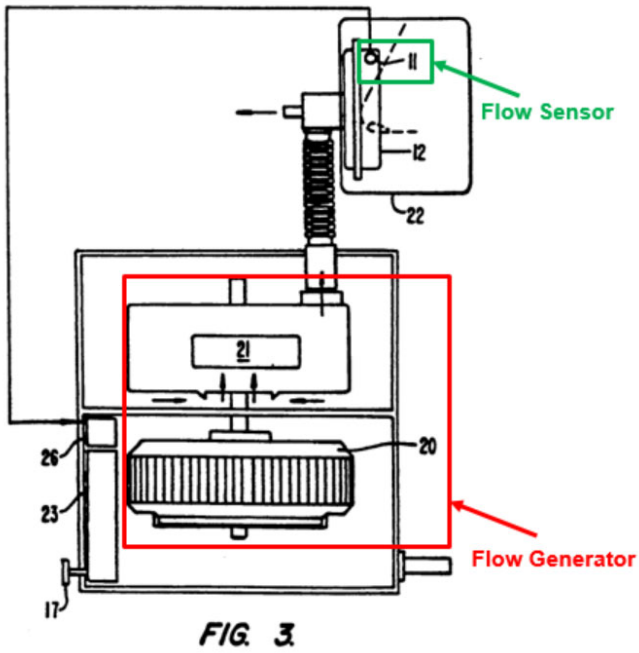


FIG. 3

EX1005, Fig. 3 (annotated)

7. **Claim 12:** determines that the patient is asleep state when breathing pattern is period of regular breathing

Sullivan995 alone or in view of the knowledge of a POSITA renders obvious a *period of regular breathing* in an *asleep state*. Behbehani ¶¶176-78. Specifically, Sullivan995 describes that the waveforms in Figure 2A depict various patient states (identified by the letters across the top of the chart) with normal breathing (part A), soft to moderate snoring (part B), constant loud snoring (part C), a pre-apneic pattern indicative of obstructive hypopnea (part D), and periods of silence punctuated by snoring, which is indicative of sleep apnea (part E). EX1005, 9:16-32; Behbehani ¶177. Part A of Figure 2A shows "normal breathing" and is therefore *a regularity of breathing*. *Id*.

To the extent that Sullivan995 does not explicitly disclose a *period of regular breathing*, this was known to a POSITA. *See, e.g.,* EX1034, 5:26-28 ("When a patient is asleep his respiration becomes stable, this is used to detect the instant when the patient falls asleep."); EX1020, [0050] ("Fig. 4a shows that in a normal respiratory effort waveform 43, the inspiratory peaks 45 a-d are of approximately the same amplitude. By comparison in Fig. 4b, in a waveform 47 the inspiratory peaks 50 a-d become significantly greater in amplitude at the onset of obstructive apnea than the immediately preceding inspiratory peak 52."); Behbehani ¶178.

8. Claim 16: when patient has transitioned between at least awake state and asleep state and experiencing hypopnea event, automatically increases pressure

Sullivan995 in view of Sullivan460 renders obvious this limitation. Behbehani ¶179. As explained for claim 3, Sullivan995's *processing arrangement* determines *during an asleep state that the patient is experiencing a hypopnea event based on the determined patient's breathing pattern and increases the positive treatment pressure*. *See* Section VIII.D.2. Although Sullivan995 does not explicitly disclose that this occurs when *a patient has transitioned between at least awake state and asleep state*, this is taught by Sullivan460. Sullivan460 discloses "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." *Id.*, 6:30-7:12, cls. 22-28, 43-46. Because the switching means can switch between the two modes, a POSITA would understand that Sullivan460 also teaches increasing pressure when there is a transition. Behbehani ¶179. This pressure increase occurs automatically because it is done without any human intervention. Behbehani ¶¶139, 179.

9. Claim 17: when patient has transitioned between at least awake state and asleep state and experiencing apnea event, automatically increases pressure

Sullivan995 in view of Sullivan460 renders obvious this limitation. Behbehani ¶180. As explained for claim 4, Sullivan995's *processing arrangement* determines *during an asleep state that the patient is experiencing a hypopnea event based on the determined patient's breathing pattern and increases the positive treatment pressure*. *See* Section VIII.D.3. Although Sullivan995 does not explicitly disclose that this occurs when *a patient has transitioned between at least awake state and asleep state*, this is taught by Sullivan460. *See* Section VIII.D.8 (Ground 1, Claim 16, discussing Sullivan460).

10. Claim 18: when patient has transitioned between at least awake state and asleep state and experiencing elevated upper airway resistance event, automatically increases pressure

Sullivan995 in view of Sullivan460 renders obvious this limitation. Behbehani ¶181. As explained for claim 2, Sullivan995's *processing arrangement*

determines *during an asleep state that the patient is experiencing a hypopnea event based on the determined patient's breathing pattern and increases the positive treatment pressure*. *See* Section VIII.D.2. Although Sullivan995 does not explicitly disclose that this occurs when *a patient has transitioned between at least awake state and asleep state*, this is taught by Sullivan460. *See* Section VIII.D.8 (Ground 1, Claim 16, discussing Sullivan460).

E. Independent Claim 19

1. Preamble: *"A method for treatment of a sleeping disorder in a patient using a positive airway pressure delivery system that delivers a flow 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:"*

Sullivan995 discloses this limitation. *See* Sections VIII.C.1(Ground 1, 1[preamble]); Behbehani ¶185.

2. 19[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 or breathable gases to an airway of a patient;"*

Sullivan995 discloses this limitation. *See* Sections VIII.C.1 (Ground 1, 1[preamble]) and VIII.C.2 (Ground 1, 1[a]). As a POSITA would have understood, that it is blower 21 (*flow generator*) of Sullivan995's CPAP system that delivers "positive" airway pressure relative to atmospheric pressure, so that blower 21 *generates a flow of gases to produce a positive pressure at or above a pressure at*

ambient air pressure, a flow or breathable gases to an airway of a patient. Behbehani ¶188.

3. 19[b]: *"measuring, using a sensor, data indicative of the patient's breathing patterns;"*

Sullivan995 discloses this limitation. *See* Sections VIII.C.3 (Ground 1, 1[c]); Behbehani ¶189.

4. 19[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;"*

Sullivan995 discloses this limitation. Behbehani ¶190. 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, 13:4-8.

5. 19[d]: *"analyzing, using the processing arrangement, the indication of the patient's breathing patterns to determine the sleep state of a patient;"*

Sullivan995 discloses this limitation. Behbehani ¶¶193-96. 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. These particular *breathing patterns* only occur when the *sleep state of a patient* is an asleep state. EX1005, 13:4-8. Further, Sullivan995 detects snores in

the patient's breathing patterns, meaning the *sleep state of a patient* is an asleep state. *Id.*, 10:10-61, 14:17-20, Fig. 13. Therefore, Sullivan995 discloses this limitation.

To the extent Sullivan995 does not disclose this limitation, it would have been obvious to combine the teachings of Sullivan995 with Sullivan460, for the same reasons as explained for 1[d2], to *determine the sleep state of the patient* by *analyzing the indication of the patient's breathing patterns*. Specifically, Sullivan460 discloses "a sleep sensor [] senses whether or not the patient is asleep" by analyzing the patient's breathing patterns to determine "when there is a reduced average airflow in the patient's upper airway." EX1006, 7:3-7, 7:10-12, 7:17-19.

6. 19[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;"*

Sullivan995 discloses this limitation. *See* Section VIII.D.1 (Ground 1, Claim 2).

7. 19[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"*

Sullivan995 in view of Sullivan460 renders obvious this limitation. *See* Section VIII.C.8 (Ground 1, 1[d2]).

8. 19[g]: *"the processor determines that the patient has transitioned between at least an awake state and an asleep*

> *state, the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system."*

Sullivan995 in view of Sullivan460 renders obvious this limitation. *See* Sections VIII.C.9 (Ground 1, 1[e1]) and VIII.C.10 (Ground 1, 1[e2]).

F. Dependent Claims 20-22, 24-26, 30-31

1. Claim 20: increasing previously provided pressure supplied to patient when patient is asleep and hypopnea detected

Sullivan995 discloses this limitation. *See* Section VIII.D.2 (Ground 1, Claim 3); Behbehani ¶202.

2. Claim 21: increasing previously provided pressure supplied to patient when patient is asleep and apnea detected

Sullivan995 discloses this limitation. *See* Section VIII.D.3 (Ground 1, Claims 4); Behbehani ¶203.

3. Claim 22: increasing previously provided pressure supplied to patient when patient is asleep and elevated upper airway resistance detected

Sullivan995 discloses this limitation. *See* Section VIII.D.1 (Ground 1, Claim 2); Behbehani ¶204.

4. Claim 24: ramping applied pressure comprises automatically ramping applied pressure without manual initiation from user

Sullivan995 discloses this limitation. Behbehani ¶205. A POSITA would have understood that the incremental increase depicted in Figure 13 occurs upon detection of each snore, meaning that it occurs *automatically without manual*

initiation from the user. Behbehani ¶206; *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).

5. Claim 25: ramping the applied pressure comprises delay in onset of applied pressure.

Sullivan995 discloses this limitation. Behbehani ¶207. As discussed for 1[e2], Sullivan995 ramps the applied pressure by "obtain[ing] a ramp voltage." *See* Section VIII.C.10 (Ground 1, 1[e2]). Sullivan995's *processing arrangement* includes control circuit 33 "comprising a delay control 25, a timer 24, a switch mode power supply (SMPS) 15, and an upper pressure control 17." EX1005, 12:4-7. "[T]he output of the timer 24 and the input of the SMPS 15 is a voltage increasing over time" and "[t]he output of the SMPS 14, and therefore the motor voltage and speed, follow the input." *Id.*, 12:12-15. A POSITA would understand that when "the delay control 25 is not set to zero minutes, the apparatus commences operation at the minimum motor speed over a period of time," such that *ramping the applied pressure comprises a delay in the onset of the applied pressure. Id.*, 12:27-32; Behbehani ¶210.

6. Claim 26: asleep state determined when regular breathing indicative of sleep state detected.

Sullivan995 discloses this limitation. *See* Section VIII.D.8 (Ground 1, Claim 12); Behbehani ¶211.

7. **Claim 30:** when patient has transitioned between at least awake state and asleep state and experiencing apnea event, the automatically increases pressure

Sullivan995 discloses this limitation. *See* Section VIII.D.9 (Ground 1, Claim 17); Behbehani ¶212.

8. **Claim 31:** when patient has transitioned between at least awake state and asleep state and experiencing elevated upper airway resistance, the automatically increases pressure

Sullivan995 discloses this limitation. *See* Section VIII.D.10 (Ground 1, Claim 18); Behbehani ¶213.

IX. GROUND 2: SULLIVAN995 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIMS 6 AND 23

A. Motivation to Combine

It would have been obvious to a POSITA to modify the system of Sullivan995 and Sullivan460 so that the *processing arrangement* applies a lower pressure when the patient is in a *troubled wakefulness state*, as taught by Matthews. Behbehani ¶214.

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 ¶215. The modification to Sullivan995 and Sullivan460's CPAP system would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort. Sullivan995 is already concerned

with the patient's comfort, and already discloses it is desirable to avoid causing discomfort for the patient by delivering a lower pressure when possible. EX1005, 2:31-39.

B. Reasonable Expectation of Success

The POSITA would have had a reasonable expectation of success in making the modification to Sullivan995 and Sullivan460's CPAP system. Behbehani ¶216. Sullivan995, Sullivan460, and Matthews are analogous art. All references describe CPAP systems with flow sensors and flow generators. Like Sullivan995 and Sullivan460, Matthews discloses a "flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34." EX1007, 7:12-16. The data from the flow sensor are monitored and used to determine how to control the pressure delivered to the patient. *Id.*, 8:54-9:15. Sullivan460 already discloses lowering the pressure upon detecting an awake state (EX1006, 6:30-7:19, cls. 22-28, 43-46), and the POSITA would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient. Behbehani ¶217.

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 ¶219.

C. Dependent Claims 6, 23

Sullivan995 and Sullivan460 in view of Matthews renders obvious this limitation. Behbehani ¶219. 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.*, 21:35-44; *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 '955 Patent's description of *troubled wakefulness* as "awake and anxious or distressed" (*id.*, 4:47-48) with "erratic" breathing (*id.* 4:47-59). In Matthews, when such a state is detected, Matthews "interrupt[s] the auto-CPAP controller," and to "decrease[] the pressure delivered to the patient." *Id.*, 21:39-41, 23:67-24:2; Behbehani ¶223.

X. GROUND 3: RAPOPORT502 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1-5, 8, 11-12, 16-22, 24-26 AND 30-31

A. Motivation to Combine

It would have been obvious to a POSITA to modify the *processing arrangement* in Rapoport502 so that it applies *a lesser pressure when the patient is*

in an awake state, and *determines that the patient has transitioned between at least an awake state and an asleep state*, as taught in Sullivan460. Behbehani ¶227.

First, the POSITA would have recognized that the advantages of using the same PAP system to treat both sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught in Sullivan460. EX1006, 7:3-12; Behbehani ¶228. An upper airway flow limitation characterized by at least one decrease in upper airway inspiratory flow rate, followed by at least one increase in flow rate, is indicative of pre-eclampsia (and not observed in typical snoring), and could be treated with the modified system. *See* EX1006, Fig. 1, 6:22-29, 9:31-10:7; Behbehani ¶228. Women with sleep apnea are at higher risk for pre-eclampsia, and each of pre-eclampsia, snoring, and apnea involve hypertension, high blood pressure, and obstructions during sleep. *See* EX1006, 1:5-8, 4:33-34, 5:29-35. 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* EX1006, 2:19-22, 4:33-34, 6:3-34, 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, 1:29-32; Behbehani ¶228.

Second, a POSITA would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment. Behbehani ¶229. Both Dr. Rapoport and Dr. Sullivan recognized that a major limitation with CPAP therapy was noncompliance due to discomfort. EX1014, 5. Both also recognized that lowering pressure when the patient is in an awake state could improve compliance. EX1012, 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 ¶229.

B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in making the modification to Rapoport502. Behbehani ¶230.

First, Rapoport502 and Sullivan460 are analogous art. Behbehani ¶231. Both references describe CPAP systems that include flow sensors and flow generators. Like Rapoport502, Sullivan460 discloses a flow rate measurement means 70 (Figure 2) located in the flow path for detecting the rate at which the

patient breathes. EX1006, 10:10-12. The flow rate measurement means or sensor 70 detects "interruptions" 10 (Fig 1) within the patient's breathing cycle. The "interruptions" are superimposed at the peak of each cycle and indicate upper airway flow limitation in the patient. *Id.*, 9:31-34. Also similar to Rapoport502, when Sullivan460 senses interruptions 10 in the patient's "breathing patterns" or determines the patient is asleep, a controller 100 activates a switch 110, which activates the nCPAP apparatus 90 to supply air to the patient 30 at a higher pressure, to ameliorate or eliminate the patient's upper airway flow limitation. EX1006, 10:3-16.

Second, Dr. Rapoport was familiar with Dr. Sullivan's work, and acknowledged that Dr. Sullivan and his colleagues were "a few months ahead of the rest of us." EX1012, 3; Behbehani ¶232. A POSITA improving CPAP machines would have naturally looked at the pioneer in CPAP machines for algorithms for different air pressure settings that could improve compliance. Behbehani ¶232. In fact, Dr. Rapoport would repeatedly cite to the work of Dr. Sullivan in his own published papers. EX1016, 7-8.

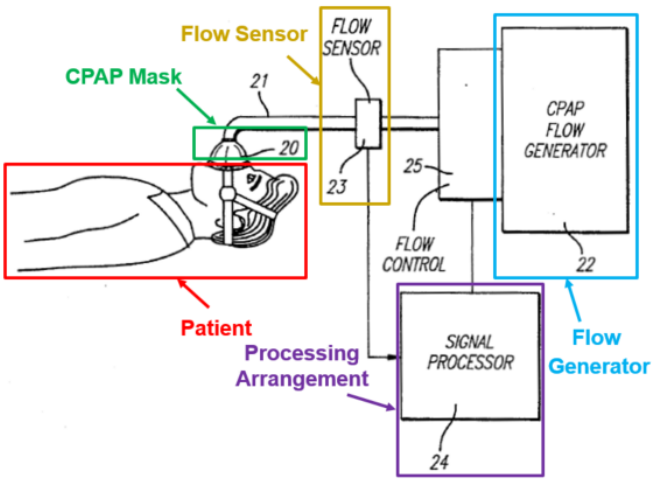
Given that the proposed modification involves a simple change in a programming algorithm, it is nothing more than a combination of known prior art elements according to known methods and known techniques to yield predictable

results, and involves use of a known technique to improve a similar device in the same way. Behbehani ¶233.

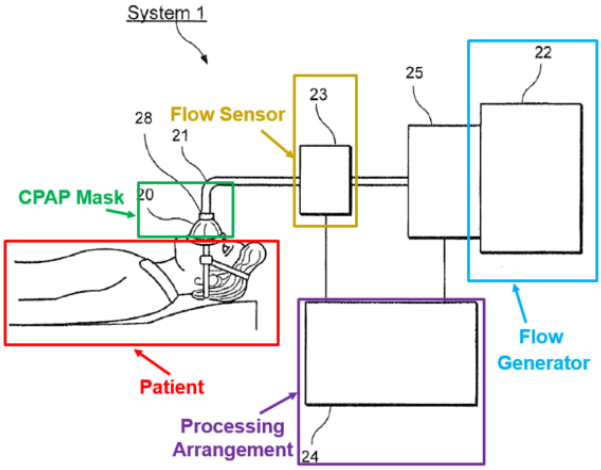
C. Independent Claims 1

1. Preamble

To the extent limiting, Rapoport502 discloses the preamble. Behbehani ¶234. Rapoport502 discloses a continuous *positive airway pressure system* in the same manner as the '955 Patent. *See* EX1008, 1:16-22 (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 ¶234.



Rapoport502, Fig. 9 (annotated)



'955 Patent, Fig. 1 (annotated)

2. 1[a]

Rapoport502 discloses this limitation. Behbehani ¶235. 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 ¶235.

3. 1[b]

Rapoport502 discloses this limitation. Behbehani ¶236; *see also* Section X.C.1. 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. A POSITA would have understood the flow sensor 21 to be *in* the flow path. Behbehani ¶237. 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 '955 Patent. EX1008, 3:34-36 (emphasis added).

Rapoport502 discloses this limitation. Behbehani ¶237. 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. A POSITA would have understood that

the conventional flow sensor 23 *measures data corresponding* to the "air through the flow sensor," and the measured data in the form of a waveform is *indicative of the patient's breathing patterns* analyzed by the processor 24. *Id.*, 3:24-26; Behbehani ¶238. 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 ¶238.

4. 1[c1]

Rapoport502 discloses this limitation. Behbehani ¶239. Rapoport502's CPAP system includes a signal processor 24 (purple) corresponding to a *processing arrangement*. *See* Section X.C.1. The '955 Patent illustrates the processing arrangement 24 as a "black box" but does not disclose what constitutes the processing arrangement 24. *See id.*; Behbehani ¶239. Rapoport502 illustrates the signal processor 24 connected in the same manner, and further uses the term "signal processor" which had a well-understood structure to a POSITA akin to an arrangement of elements that performs processing. *Id*.

Both the '955 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, 4:12-27, 5:47-55 *with* EX1008, 5:56-

63 (describing waveforms received and analyzed and the output to control other components of the CPAP system), 6:1-55 (disclosing the decision flow of the signal processor 24 in relation to Fig. 10); Behbehani ¶240.

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.

5. 1[c2]

Rapoport502 discloses this limitation. Behbehani ¶242. 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 ¶242. 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 ¶242.

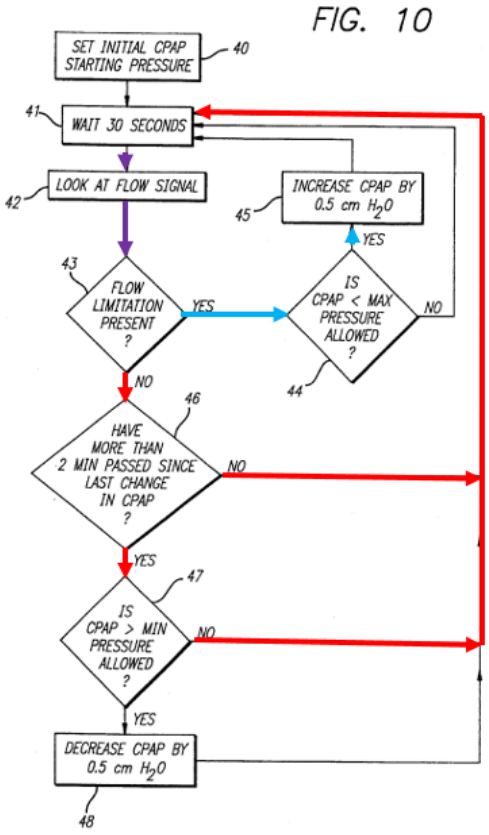
6. 1[c3]

Rapoport502 discloses this limitation. Behbehani ¶243. Further to the analysis *on the determined breathing patterns of the patient* (*see* Section VIII.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 ¶243. 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 ¶243.

7. 1[d1]

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani ¶244. Rapoport502 discloses increasing pressure upon determining a flow limitation for the patient, as seen by Figure10. EX1008, Fig. 10 (reproduced below).



EX1008, Fig. 10 (annotated)

Figure 10 represents Rapaport'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.

8. 1[d2]

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani ¶248. Rapoport502 discloses increasing pressure upon determining a flow limitation, but does not expressly disclose applying *a lesser positive treatment pressure in an awake state*. But this limitation is taught by Matthews.

a) Teachings of Sullivan460 on lesser pressure when awake.

See Section VIII.C.8.a) (Ground 1, 1[d2], discussing Sullivan460).

b) Motivation to Combine and Reasonable Expectation of Success

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

9. 1[e1]

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani ¶¶254-58. 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. Rapoport502 does not expressly disclose the patient is in an awake state when there is no flow limitation present, but this is disclosed in Sullivan460. Behbehani ¶256

a) Teachings of Sullivan460 on lesser pressure when awake.

See Section VIII.C.9.a) (Ground 1, 1[e1], discussing Sullivan460).

b) Motivation to Combine and Reasonable Expectation of Success

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

10. 1[e2]

Rapoport502 discloses this limitation. Behbehani ¶¶259-61. "[T]he controlled positive *pressure* could be changed" (*increased*, *see* Section X.C.7) "automatically via an automated system, either in response to feedback control or *using* pre-set *ramps* or steps in the controlled positive pressure throughout the night (in laboratory or at home)." EX1008, 13:37-41 (emphasis added). Also, Rapoport502 discloses "a slope parameter [of the ramp], e.g., 0.1 cm per two seconds." EX1008, 11:44-46.

D. Dependent Claims 2-6, 8, 11-12, 16-18, 20-26, 30-31

1. Claim 2

Rapoport502's detected flow limitation occurs *during an asleep state* when *the patient is experiencing elevated upper airway resistance*. *See* Sections X.D.2-3 (describing apneas and hypopneas as obstructions of the upper airway occurring during sleep); Behbehani ¶262.

2. Claim 3

Rapoport502 discloses that the flow limitations include *hyponeas*. *Id.* ("[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 ¶263.

3. Claim 4

Rapoport502 discloses that the flow limitations include *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 ¶264.

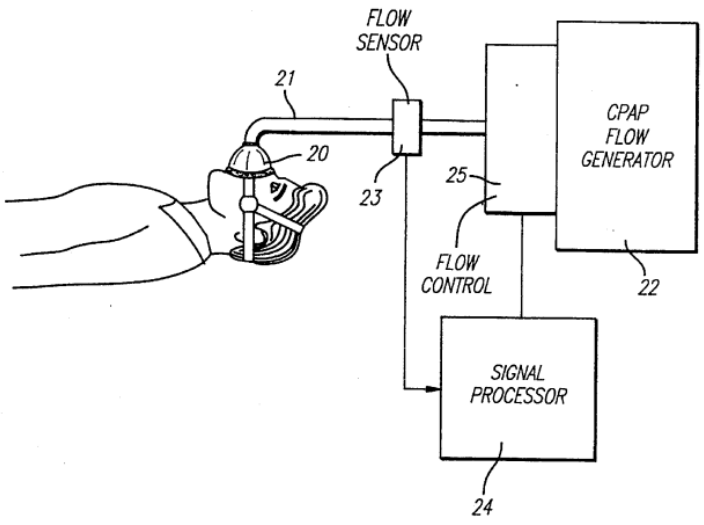
4. Claim 5

Rapoport502 in view of Sullivan460 renders obvious this limitation. *See* Section X.C.8 (Ground 3, 1[d2])

5. Claim 8

Rapoport502 discloses this limitation. Behbehani ¶¶266-68. A mask is connected to the patient end of the tube. EX1008, 5:51-53 ("a CPAP mask 20 is connected via tube 21 to receive air from a CPAP flow generator 22"), Fig. 9; Behbehani ¶267. As shown in Fig. 9 below, Rapoport502 teaches *a mask placed on a face of the patient and covering at least one of the mouth and the nose of the patient.* EX1008, 12:66-13:4 ("[T]he perimeter of the nasal mask may be configured with a pliable material which would confirm to the shape of the face of the patient.")

FIG. 9

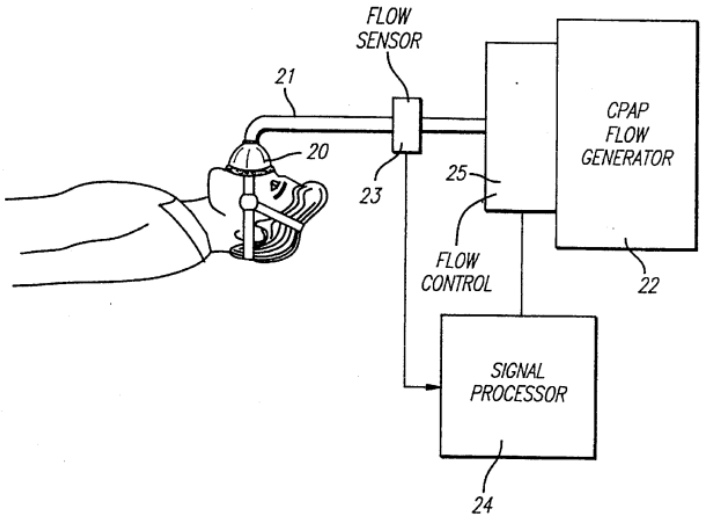


EX1008, Fig. 9

6. Claim 11

Rapoport502 discloses this limitation. Behbehani ¶¶269-70. As shown in Figure 9, flow sensor 23 is external to flow generator 22.

FIG. 9



EX1008, Fig. 9

7. Claim 12

Rapoport502 in view of Sullivan460 renders obvious this limitation. *See* Section VIII.C.7 (Ground 1, Claim 12, discussing knowledge of a POSITA). Rapoport502 discloses a *period of regular breathing*. Specifically, Rapoport502 describes a "normal" waveform "corresponding to apnea free inspiration." EX1008, 4:57-59. Rapoport502 explains that "this waveform, at least in the inspiration

periods, is substantially sinusoidal." Figure 1 illustrating this normal waveform below. Behbehani ¶¶271-79.

8. Claim 16

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani ¶¶280-81. As explained for claim 3, Rapoport502's *processing arrangement* determines *during an asleep state that the patient is experiencing a hypopnea event based on the determined patient's breathing pattern and increases the positive treatment pressure*. *See* Section X.D.2. Although Rapoport502 does not explicitly disclose that this occurs when *a patient has transitioned between at least awake state and asleep state*, this is taught by Sullivan460. *See* Section VIII.D.8 (Ground 1, Claim 16, discussing Sullivan460).

9. Claim 17

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani ¶282. As explained for claim 4, Rapoport502's *processing arrangement* determines *during an asleep state that the patient is experiencing an apnea event based on the determined patient's breathing pattern and increases the positive treatment pressure*. *See* Section X.D.3. Although Rapoport502 does not explicitly disclose that this occurs when *a patient has transitioned between at least awake state and asleep state*, this is taught by Sullivan460. *See* Section VIII.D.8 (Ground 1, Claim 16, discussing Sullivan460).

10. Claim 18

Rapoport502 in view of Sullivan460 renders obvious this limitation. Behbehani ¶283. As explained for claim 2, Rapoport502's *processing arrangement* determines *during an asleep state that the patient is experiencing an elevated upper airway resistance based on the determined patient's breathing pattern and increases the positive treatment pressure*. *See* Section VIII.D.1 (Ground 3, Claim 2). Although Rapoport502 does not explicitly disclose that this occurs when *a patient has transitioned between at least awake state and asleep state*, this is taught by Sullivan460. *See* Section VIII.D.8 (Ground 1, Claim 16, discussing Sullivan460).

E. Independent Claim 19

1. Preamble

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

2. 19[a]

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

3. 19[b]

Rapoport502 discloses this limitation. *See* Sections X.C.3 (Ground 3, 1[b]).

4. 19[c]

Rapoport502 discloses this limitation. *See* X.C.4 and X.C.5 (Ground 3, 1[c1] and 1[c2]).

5. 19[d]

Rapoport502 alone or in view of Sullivan460 discloses this limitation. Behbehani ¶¶288-89. As explained for 1[c1] and 1[c2] for this ground, Rapoport502's *processing arrangement* analyzes flow limitation data from the flow sensors. *See* Sections X.C.4 and X.C.5. Further, as explained for 1[c1] and 1[c2] for this ground, Rapoport502 detects flow limitations in *the patient's breathing patterns*, meaning the *sleep state of a patient* is an asleep state. *See id.*

To the extent Rapoport502 does not disclose this limitation, it would have been obvious to combine the teachings of Rapoport502 with Sullivan460, for the same reasons as explained for 1[d2] for this ground. *See* Section X.C.8.

6. 19[e]

Rapoport502 in view of Sullivan460 discloses this limitation. *See* Section X.D.1 (Ground 3, Claim 2).

7. 19[f]

Rapoport502 in view of Sullivan460 discloses this limitation. *See* Section X.C.8 (Ground 3, 1[d2]).

8. 19[g]

Rapoport502 in view of Sullivan460 renders obvious this limitation. *See* Sections X.C.9 (Ground 3, 1[e1]) and X.C.10 (Ground 3, 1[e2]).

F. Dependent Claims 20-26, 30-31

1. Claim 20

Rapoport502 discloses this limitation. *See* Section X.D.2 (Ground 3, Claim 3).

2. Claim 21

Rapoport502 discloses this limitation. *See* Section X.D.3 (Ground 3, Claim 4).

3. Claim 22

Rapoport502 discloses this limitation. *See* Section X.D.1 (Ground 3, Claim 2).

4. Claim 24

Rapoport502 discloses this limitation. Behbehani ¶297. "[T]he controlled positive *pressure* could be changed" (*increased*, *see* Section VIII.C.10) "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, 13:37-43 (emphasis added).

5. Claim 25

Rapoport502 discloses this limitation. Behbehani ¶¶298-99. "[T]he controlled positive *pressure* could be changed" (*increased*, *see* Section VIII.C.10) "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, 13:37-43 (emphasis added). A POSITA would understand that a pre-set ramp is *a delay in the onset of the applied pressure*. Behbehani ¶¶299.

6. Claim 26

Rapoport502 discloses this limitation. *See* Section VIII.D.8 (Ground 1, Claim 16).

7. Claim 30

Rapoport502 discloses this limitation. *See* Section VIII.D.9 (Ground 1, Claim 17).

8. Claim 31

Rapoport502 discloses this limitation. *See* Section VIII.D.10 (Ground 1, Claim 18).

XI. GROUND 4: RAPOPORT502 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIMS 6 AND 23

A. Motivation to Combine

It would have been obvious to a POSITA to modify the system of Rapoport502 and Sullivan460 so that the *processing arrangement* applies a lower pressure when the patient is in a *troubled wakefulness state*, as taught by Matthews. Behbehani ¶¶303-306.

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, 1:60-64. Rather than wait until more than two minutes have passed since the last change in CPAP (step 46), the system could also decrease CPAP when *troubled wakefulness* is determined, as taught by Matthews. The modification to Rapoport502 and Sullivan460's CPAP system would allow for interrupting the CPAP control upon detection of the distressed state so as to avoid causing the patient more discomfort by waiting as much as two minutes. Behbehani ¶305.

Second, the modification would have been a natural extension of Rapoport502's air pressure adjustment approach. "The air pressure setting is raised,

lowered or maintained depending on whether flow limitation has been detected and on the previous actions taken by the system." EX1008, 3:18-21. Rapoport502 already adjusts the air pressure based on flow limitation states. EX1008, Fig. 10. Adding a *troubled wakefulness* based on data from the flow sensors would have made the system even more effective. Behbehani ¶306.

B. Reasonable Expectation of Success

The POSITA would have had a reasonable expectation of success in making the modification to Rapoport502 and Sullivan460's CPAP system. Behbehani ¶307.

First, Rapoport502, Sullivan460, and Matthews are analogous art. All references describe CPAP systems with flow sensors and flow generators. Like Rapoport502 and Sullivan460, Matthews discloses a "flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34." EX1007, 7:12-16. The data from the flow sensor are monitored and used to determine how to control the pressure delivered to the patient. *Id.*, 8:54-9:15. Sullivan460 already discloses lowering the pressure upon detecting an awake state (EX1006, 6:30-7:19, cls. 22-28, 43-46), and the POSITA would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient. Behbehani ¶308.

Second, 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 already provided data to determine flow limitations, the algorithm shown in Figure 10 could simply be modified to add "Erratic Breathing Present" between step 43 and step 46. If yes, continue to step 47, and if no, continue step 46. Behbehani ¶309.

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 ¶310.

C. Dependent Claims 6, 23

Rapoport502 and Sullivan460 in view of Matthews renders obvious this limitation. Behbehani ¶¶311-14. Similar to Rapoport502 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.*, 21:35-44; *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 '955 Patent's description of *troubled wakefulness* as "awake and anxious or distressed" (*id.*, 4:47-48) with "erratic" breathing (*id.* 4:47-59). In Matthews, when such a state is detected, Matthews "interrupt[s] the auto-CPAP controller," and to "decrease[] the pressure delivered to the patient." *Id.*, 21:39-41, 23:66-24:2; Behbehani ¶314.

XII. SECONDARY CONSIDERATIONS

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

XIII. THE BOARD SHOULD REACH THE MERITS OF THIS PETITION

A. Institution is appropriate under § 325(d)

Institution is appropriate under § 325(d) because substantially the same art and arguments have never been presented to or considered by the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinishche Geräte GmBH*, IPR2019-01469, Paper 6 at 6-11 (Feb. 13, 2020) (precedential) (describing two-part framework based on the *Becton, Dickinson* factors). Specifically, 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. Regardless, the efficiency and fairness considerations discussed in *Fintiv* weigh strongly in favor of institution given the infancy and minimal investment in the parallel litigation.

XIV. CONCLUSION

For these reasons, Petitioner respectfully requests *inter partes* review.

Respectfully submitted,

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Claims Listing (Appendix)

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

   [a] a flow generator which supplies a positive treatment pressure flow of breathable gases to the entrance of a tube, the tube directing the flow of breathable gases to the airway of a patient to provide the patient with the positive treatment pressure flow of breathable gases;

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

   [c1] a processing arrangement which receives the measured data corresponding to the flow of breathable gases from the flow sensor and [c2] analyzes the data to determine the patient's breathing patterns, [c3] the processing arrangement also determines whether to alter the pressure supplied to the airway of the patient based, at least in part, on the determined breathing patterns of the patient, wherein the processing arrangement applies a greater positive treatment pressure in an asleep state and a lesser positive treatment pressure in an awake state, wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state, the processing arrangement automatically controls the flow generator to increase a positive treatment pressure supplied to the entrance of the tube using a ramp system.

2. The system of claim 1, wherein the processing arrangement determines during an asleep state that the patient is experiencing an elevated upper airway resistance based on the determined patient's breathing patterns and increases the positive treatment pressure supplied to the entrance of the tube.

3. The system of claim 1, wherein the processing arrangement determines during an asleep state that the patient is experiencing a hypopnea event based on the determined patient's breathing patterns and increases the positive treatment pressure.

4. The system of claim 1, wherein the processing arrangement determines during an asleep state that the patient is experiencing an apnea event based

on the determined patient's breathing patterns and increases the positive treatment pressure.

5. The system of claim 1, wherein the processing arrangement determines that the patient has transitioned to an awake state from an asleep state based on the determined patient's breathing patterns and lowers the positive treatment pressure.

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

8. The system of claim 1, further comprising a mask connected to a patient end of the tube and placed on a face of the patient and covering at least one of the mouth and the nose of the patient.

11. The system of claim 1, wherein the flow sensor is external to the flow generator.

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

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

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

18. The system of claim 1, wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state and is experiencing elevated upper airway resistance, the processing arrangement automatically increases the pressure to at least a first treatment pressure.

19. 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 patient's breathing patterns; and

[g] ramping 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.

20. The method of claim 19, further comprising increasing a previously provided pressure supplied to a patient when the patient is in an asleep state and a hypopnea is detected.

21. The method of claim 19, further comprising increasing a previously provided pressure supplied to a patient when the patient is in an asleep state and an apnea event is detected.

22. The method of claim 19, further comprising increasing a previously provided pressure supplied to a patient when the patient is in an asleep state and an elevated upper airway resistance is detected.

23. The method of claim 19, 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.

24. The method of claim 19, wherein ramping the applied pressure comprises automatically ramping the applied pressure without requiring a manual initiation from a user.

25. The method of claim 19, wherein ramping the applied pressure comprises a delay in the onset of the applied pressure.

26. The method of claim 19, wherein an asleep state is determined when regular breathing indicative of a sleep state is detected.

30. The method of claim 19, wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state and is experiencing an apnea event, the processing arrangement automatically increases the pressure to a treatment pressure.

31. The method of claim 19, wherein when the processor determines that the patient has transitioned between at least an awake state and an asleep state and is experiencing elevated upper airway resistance, the processing arrangement automatically increases the pressure to at least a first treatment pressure.

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

Under 37 C.F.R. § 42.24(b)(1), the undersigned certifies that the foregoing Petition contains 13,998 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. 9,867,955 and all Exhibits and other documents filed together with this Petition were served on the official correspondence address for the patent shown in PAIR via STANDARD OVERNIGHT FEDERAL EXPRESS next business day delivery on June 1, 2022:

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