UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ResMed Inc.,
Petitioner,

v.

New York University,
Patent Owner

Case No. IPR2022-00944

# PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,168,344

Claims 1, 3, 7, 9, 11, and 13

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| **1014** | D. Rapoport, "Methods to Stabilize the Upper Airway Using Positive Pressure," *Sleep* 19(9):S123-S130 ("Rapoport 1996") |
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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")). |
| **1017** | U.S. Patent No. 6,484,719 to Berthon-Jones ("Berthon-Jones719") |
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| **1020** | Reserved |
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| **1027** | ResMed, "AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1," (1999) |
| **1028** | ResMed, "Auotset T, Optimal Therapy for your OSA Patients," (2000) |

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| **1029** | Sunrise Medical, "DeVillibis, AutoAdjust, LT Nasal CPAP System Instructions Guide Model 8054," (1999) |
| **1030** | Respironics, "Introducing the REMstar Auto. A simply smarter Smart CPAP" (2002) |
| **1031** | ResMed Origins, downloaded from https://document.resmed.com/en-us/documents/articles/resmed-origins.pdf on May 3, 2022 |
| **1032** | U.S. Patent No. 7,966,061 to Al-Abed, et al. ("Al-Abed") |
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| **1034** | WO 03/075991 to Delache ("Delache") |
| **1035** | F. Roux, et al., "Continuous Positive Airway Pressure: New Generations," Clinics in Chest Medicine (2003) |
| **1036** | V. Hoffstein, et al., "Treatment of Obstructive Sleep Apnea with Nasal Continuous Positive Airway Pressure," Am. Rev. Respir. Dis. (1992) |
| **1037** | R. Berry, et al., "The Use of Auto-Titrating Continuous Positive Airway Pressure Treatment of Adult Obstructive Sleep Apnea," (2002) |
| **1038** | V. Hoffstein, ""Snoring and Sleep Architecture," Am. Rev. Respir. Dis. (1991) |

# I. INTRODUCTION

ResMed Inc. ("ResMed" or "Petitioner") respectfully requests *inter partes* review of claims 1, 3, 7, 9, 11, and 13 of U.S. Patent No. 9,168,344 (EX1001, "'344 Patent").

The '344 Patent relates to continuous positive airway pressure (CPAP) systems to address sleep apnea. Professor Colin Sullivan and his colleagues at the University of Sydney in 1981 were first to apply positive airway pressure to treat sleep apnea, and by 2003, CPAP became "the standard of care" for sleep apnea. EX1001, 1:47-54. By applying air pressure to keep a patient's airway open, these CPAP machines improve sleep quality for patients with snoring or other breathing problems during sleep. Patients, however, often struggle to use CPAP systems because of the discomfort caused by the high pressure while awake. The '344 Patent addresses this problem by decreasing the pressure when the patient has awakened as determined by an irregular breathing pattern. The '344 Patent refers to this as a "troubled wakefulness" state, a newly coined phrase for a well-known state. But this state, and the treatment of it by CPAP, was by no means new or inventive.

By the early 1990s, self-setting CPAP machines that "aid compliance by allowing a minimal awake pressure" were well-known. Ex. 1012, 1. By August 14, 2003 (the earliest priority date of the '344 Patent), many had already published

numerous references disclosing this feature demonstrating a clear evolution of PAP technology. For example, U.S. Patent No. 5,245,995 to Sullivan et al. (EX1005, "Sullivan995"), issued in 1993, by Dr. Sullivan, discloses increasing the pressure when the patient has fallen asleep upon detection of a snore or other abnormal sleep state breathing (e.g., apneas or hypopneas). Otherwise pressure would be maintained or decreased. In 2000, Dr. Sullivan filed another patent application (Sullivan460), which incorporates Sullivan995 by reference, disclosing a CPAP system that detects awake and asleep states and applies high pressure in the asleep mode and low pressure in the awake mode. By 2002, technology evolved further with U.S. Patent No. 7,168,429 to Matthews et al. ("Matthews"), which tackled the "troubled wakefulness" state and recognized that "[w]hen a patient is awake…or in distress, breathing tends to be more erratic." Ex. 1007, 21:34-39. In such event, Matthews taught to "interrupt the auto-CPAP controller if the patient's breathing pattern becomes too variable" to "decrease[] the pressure delivered to the patient." *Id.*, 21:39-41, 23:67-24:2. Consequently, the notion that '344 Patent provided for an inventive treatment of a new states associated with awake and sleep states is undermined by the prior art teachings.

Accordingly, ResMed respectfully requests the Board institute review and find all challenged claims of the '344 Patent unpatentable.

## II. MANDATORY NOTICES

### A. Real Party-in-Interest

The real party-in-interest is ResMed Inc.

### B. Related Matters

U.S. Patent Office records indicate that the '344 Patent is assigned to New York University ("PO"), which is currently asserting the '344 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. 9,427,539, U.S. Patent No. 9,533,115, U.S. Patent No. 9,867,955, and U.S. Patent No. 10,384,024.

### C. Notice of Counsel and Service Information

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

### D. Fee for *Inter Partes* Review

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

### E. Certification of Grounds for Standing

Petitioner certifies pursuant to 37 C.F.R. § 42.104(a) that the '344 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the ground identified in this Petition.

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

**Ground 1:** Claims 1, 3, 7, 9, 11, and 13 are obvious under 35 U.S.C. § 103 over Rapoport502[1] in view of Sullivan460[2] and Matthews[3].

**Ground 2:** Claims 1, 3, 7, 9, 11, and 13 are obvious under 35 U.S.C. § 103 over Sullivan995[4] in view of Sullivan460 and Matthews.

**Ground 3:** Claims 1, 3, 7, 9, 11, and 13 are anticipated under 35 U.S.C. § 102 by Sullivan995.

## IV. BACKGROUND

### A. Overview of the Technology

#### 1. PAP Machines

"Obstructive sleep apnea syndrome (OSAS) is a well-recognized disorder…[and] one of the most common causes of excessive daytime somnolence." EX1001, 1:22-27. OSAS "is characterized by an intermittent obstruction of [a patient's] upper airway occurring during sleep." EX1001, 1:28-31. "The obstruction results in a spectrum of respiratory disturbances ranging from the total absence of airflow (apnea) to significant obstruction with or without

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

2 PCT Publication No. WO 01/05460 A1 (EX1006, Sullivan460).

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

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

reduced airflow (hypopnea and snoring)." EX1001, 1:31-35. Because apnea, hypopnea, and heavy snoring produces decreased blood oxygenation, they "are recognised [] causes of sleep disruption and risk factors in certain types of heart disease." EX1013, 1:27-28, 1:43-48.

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 at the University of Sydney in 1981. EX1001, 1:61--2:2; EX1014, 1 (citing EX1015). "[T]he upper airway during sleep mimics the behavior of a collapsible tube." EX1014, 1. To prevent this collapse, positive airway pressure can oppose the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). *Id.*

Generally, a prescription and patient training for PAP therapy is "performed in, or directly under, the supervision of the sleep disorders laboratory." EX1014, 5. After a full night of observation in the laboratory, a physician will prescribe a therapeutic pressure for the patient and PAP machine for home use. But, as PAP therapy research developed, the industry began examining a variable approach that "would improve on, and possibly do away with, the one-size-fits-all pressure determination night." EX1012, 1.

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." EX1012, 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"); *see also* EX1020, [0013] ("Since it is desirable in apnea treatment to prevent the discomfort to the patient…while the patient is awake, it would be desirable to make a downward adjustment."). 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.

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 Decl. ¶47.

**2. Sleep and Breathing Patterns**

"Sleep is not a simple linear process whereby an individual enters into stage I non-REM sleep at the beginning of the night, progresses through to stage IV sleep, enters REM sleep, and then wakes up in the morning." EX1021, 4. "Rather, repeated episodes of non-REM and REM sleep alternate cyclically through the night." *Id.* "Frequently, a patient awakens during a period of extended sleep for any number of reasons," although "the time require for a patient to fall back to sleep once awakened is less than that initially required." EX1022, 16:39-42. The typical sleep pattern in a young adult is shown below.

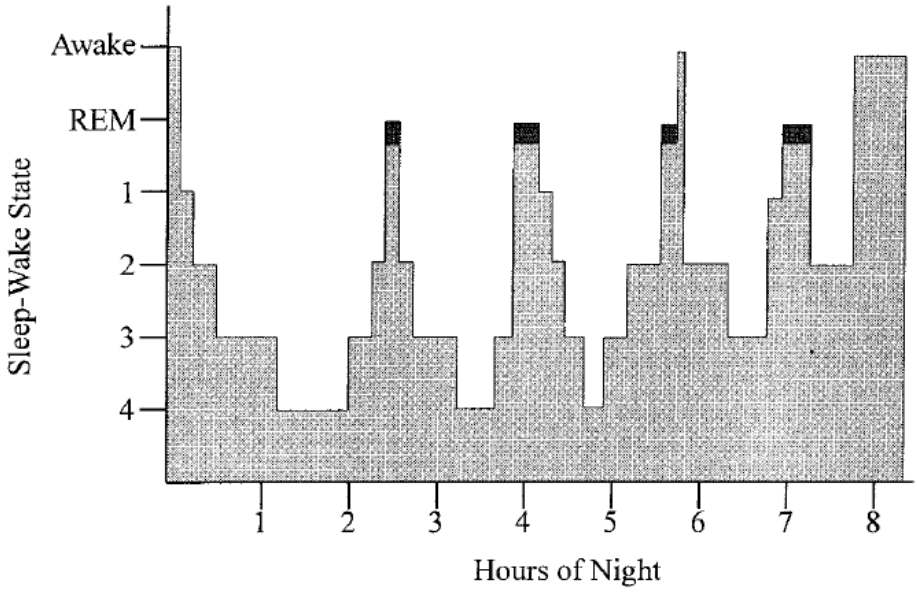



FIG. 2.

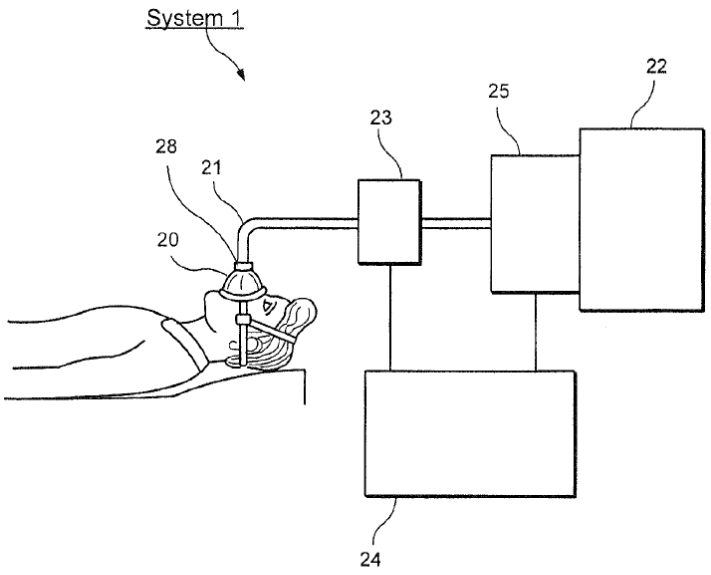
**EX1021, Fig. 2**

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

Thus, for decades, breathing patterns have been used to indicate the sleep-wake state of a patient, particularly in the awake state, the non-REM sleep state (stable breathing), REM state (unstable breathing), and disordered sleep state. *See, e.g.*, EX1023, 3 ("Two hundred fifteen respiratory cycles were randomly selected. They were observed in different sleep stages [stage 1, stage 2, stage 3/4, and rapid eye movement (REM) sleep] and during wakefulness."); EX1024, 2 ("Dynamic compliance, airflow resistance, and breathing pattern variables were calculated for at least 20 consecutive breaths during one period each of wakefulness, stage 2 sleep, and REM sleep."). These analyzed breathing patterns include those from nocturnal panic (or as coined in the '344 Patent, "troubled wakefulness"), where an individual "wak[es] from sleep in a state of panic," typically accompanied by "breathing irregularities." EX1025, 1, 5.

**B. The '344 Patent**

The '344 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, 2:53-3:11. 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.

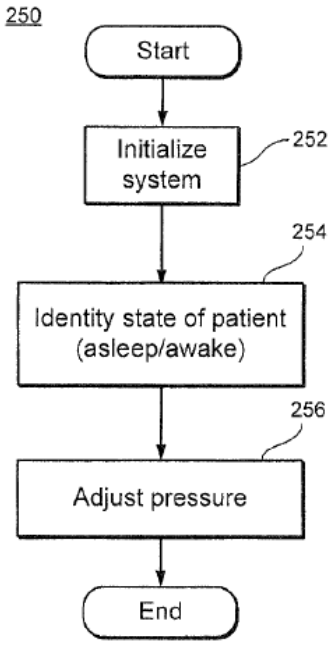



F I G. 1

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.* 3:46-52. "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.* 3:53-56.

The patent attempts to address limitations of "[s]ome conventional PAP systems [that] utilize algorithms which continuously and automatically titrate the

applied pressure." *Id.*, 2:41-42. 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.*, 2:26-28. To remedy the patient's discomfort, the patent describes the processing arrangement 24 as "mak[ing] a determination as to a current state of the patient" (*id.*, 4:18-22) and "adjust[ing] the pressure" to correspond to the patient's current state (*id.*, 8:35-37). 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.*, 5:60-61, 6:4-7. This allegedly inventive feature is reflected in Figure 10 below.




F I G. 10

### C. The Challenged Claims

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

The '344 Patent has 16 claims, 2 independent claims and 14 dependent claims. Independent claims 1 and 7 recite nearly identical systems, including:

(1) a flow sensor;

(2) a processing arrangement configured to analyze the breathing patterns; and

(3) a generator configured to supply an airflow to an airway of the patient from a first pressure to a second pressure.

The only difference between claim 1 and 7 is that the processing arrangement determines whether the patients' "breathing patterns are indicated of a troubled wakefulness state" (claim 1[b]) or "breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state" (claim 7[b]).

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[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.

### D. Prosecution History

The applicant only obtained allowance of the ’344 Patent by arguing that the prior art did not teach determining breathing patterns indicative of troubled wakefulness. In particular, the Examiner issued four rejections during the prosecution of the ’344 Patent. In the last two rejections, the Examiner found the independent claims anticipated by U.S. Patent No. 6,397,845 B1 (“Burton845”). The invention of Burton845 was “adapted to monitor, analyze, and compute the sequence of airflow shape and sound” including “breathing waveform profiles or sequence of waveform profiles or sounds of a patient [that] are matched to various templates which are correlated to specific arousal events or Sleep Breathing Disorders.” EX1002, 377, 379. The Examiner specifically found that Burton845 discloses *breathing patterns [that] are indicative of a troubled wakefulness state* by teaching adjustment to the therapeutic treatment based on index or derived data used to identify micro-arousals, including Respiratory Effort-Related Arousal (RERA). *Id.*

To overcome this rejection, PO expressly distinguished micro-arousals and RERA from a troubled wakefulness state and breathing patterns indicative of a troubled wakefulness state, respectively. PO argued that Burton845’s “diagnostic mode monitors the patient for ‘micro-arousals’ and that ‘[a]rousal, micro-arousal, wake and movement time are listed because the patient may wake, arouse or move

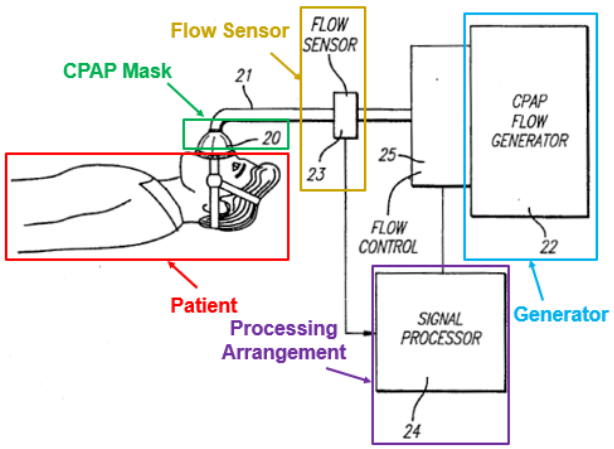
due to external factors such as noise disturbance.'" *Id.*, 402. As such, "Burton does not make a distinction between regular wakefulness and troubled wakefulness at all." *Id.,* 402-403. The Examiner subsequently allowed the claims.

But despite these clear disclaimers in the prosecution of the '344 Patent, PO now asserts that RERA (clearly disavowed from the scope of the claims) infringes the '344 Patent. EX1018, ¶¶ 117-18 (alleging infringement by citing to EX1033, 7 ("The AirSense 10 AutoSet for Her also provides a respiratory effort-related arousal (RERA) reporting feature within AirView. This logs and stores effort-related sleep disturbances.").

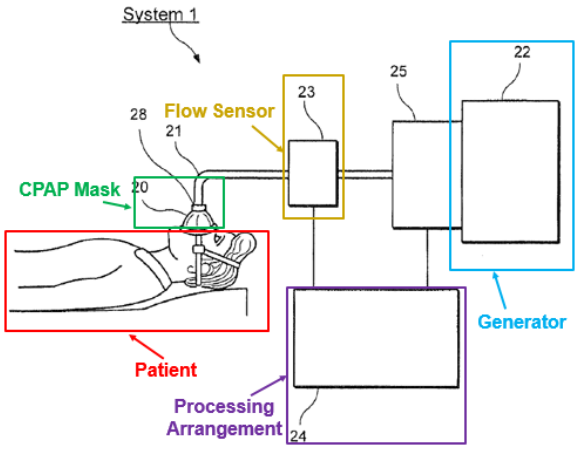
## V. OVERVIEW OF THE PRIOR ART

### A. 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 '344 Patent uses conventional hardware components for PAP machines. *See* Section IV.B. Indeed, Rapoport502 (published nearly a decade before the '344 Patent) discloses nearly identical hardware, including a conventional generator, flow sensor, and processor. EX1008, Fig. 9.




**Rapoport502, Fig. 9**




**'344 Patent, Fig. 1**

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

### B. Sullivan995 (EX1005)

U.S. Patent No. 5,245,995 to Sullivan et al. ("Sullivan995"), filed May 27, 1992 and issued on September 21, 1993, is prior art under 35 U.S.C. §§ 102 (a) and (b). Sullivan995 discloses each limitation of the independent claims, except it does not expressly disclose determining the patient is in troubled wakefulness state, under Petitioner's construction. *See* Section VIII.A.

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, 1:32-36, 2:15-19, 9:57-58. A CPAP nose mask covers

the patient's nose and creates an "enclosed airway" that forms a flow path for breathable gas to be inhaled and exhaled by the patient. *Id.*, Figs. 1A, 1B, 8:47-59.

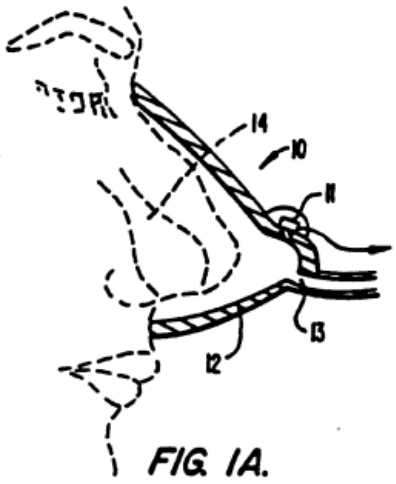



FIG. 1A.

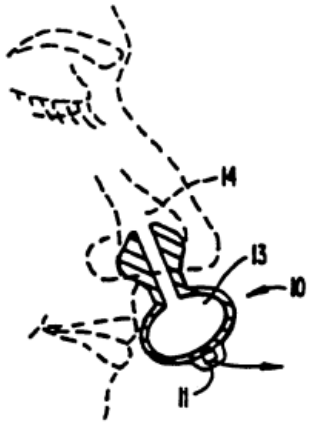



FIG. 1B.

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

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

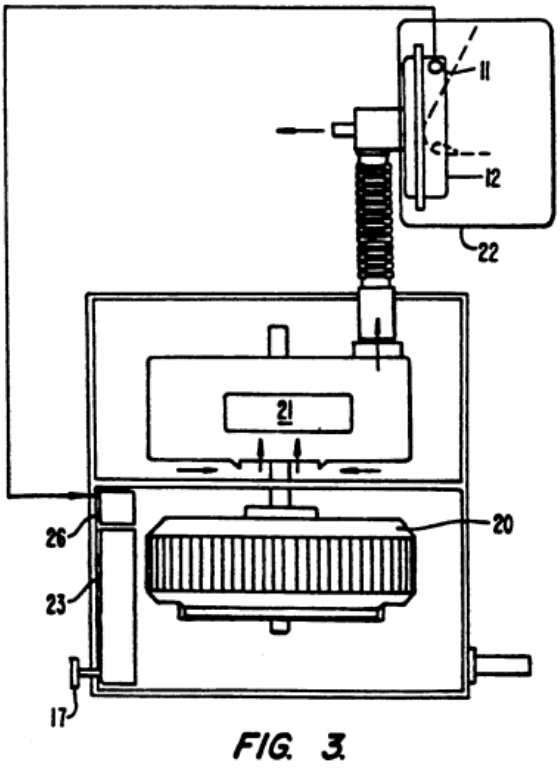



FIG. 3.

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

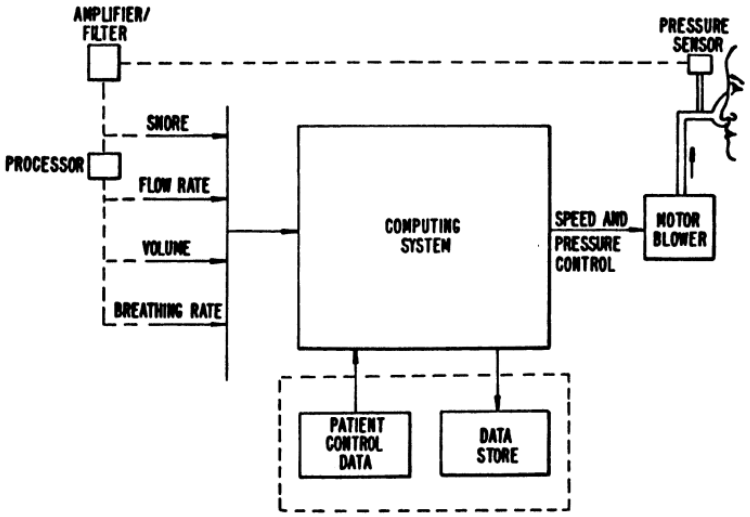



FIG. 12.

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

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

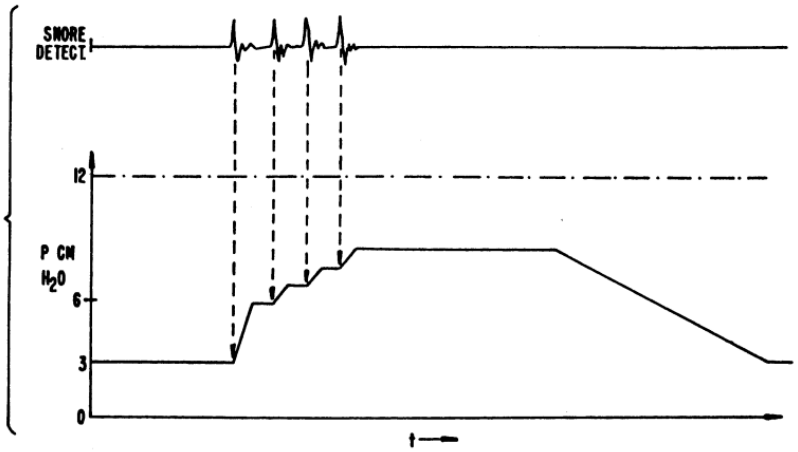



FIG. 13.

Figure 13 of Sulllivan995 depicts an incremental pressure increase for each detected snore and pressure decrease in the absence of snores. *Id.*, 18:6-18, 10:31-37, 15:18-23. 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.*, 6:40-68, 15:34-68, 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.

### C. Sullivan460 (EX1006)

Sullivan460 shares the same inventor as Sullivan995 and incorporates Sullivan995 by reference, stating Sullivan995 describes ResMed's AutoSet product: "the flow rate measurement means and the treatment means may be

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

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

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

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

**D. 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.

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.

## VI. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") in 2003 would have had at least a bachelor's degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience. Additional experience could substitute for less education, and additional education could likewise substitute for less experience. Behbehani Decl. ¶89.

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 Decl. ¶90.

## 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).[6]

### A. "troubled wakefulness" (all claims)

This term to a POSITA in the context of the '344 Patent means "state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable." Behbehani Decl. ¶93. This term is not an industry standard term and was coined in the '344 Patent. *Id.*, ¶94. As such, the

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

construction is derived directly from the specification, which describes "troubled wakefulness" as a state "in which the breathing pattern is characterized by irregularity variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient's airflow tracing indicating that the patient is awake and either anxious or uncomfortable." EX1001, 4:54:58, Fig. 7.

### B. "configured…to determine to which of the following states the detected breathing pattern is indicative" (claim 7)

The parties dispute whether this term is limited to determining the breathing patterns for only one of the listed states (as implied by PO's infringement contentions) or require determining the breathing patterns for each of the listed states (as proposed by Petitioner). This term to a POSITA in the context of the '344 Patent means "configured to analyze the breathing patterns to determine whether the breathing patterns" are indicative of the specified states. Behbehani Decl. ¶95.

This construction is supported by the specification, which explains that "the system 1 initiates a real-time monitoring procedure of the patient's breathing patterns." EX1001, 4:11-12. "During the monitoring procedure, the processing arrangement 24 makes a determination as to a current state of the patient (e.g., whether the patient is asleep, awake and breathing irregularly due to distress or anxiousness)." *Id.*, 4:18-2. As such, a POSITA would understand that the system of

the ’344 Patent is not just configured to identify one state, but differences between different states.

The specification uses specific examples that confirm that the system of the ’344 Patent determines different states based on “a number of characteristics of the patient’s breathing patterns that may be taken into account in making such determination.” *Id.*, 4:27-29. For example, “FIG. 3 is indicative of relaxed wakefulness (patient is not anxious or distressed).” *Id.*, 4:31-32. In contrast, “FIG. 7 shows a period of [] troubled wakefulness in which the breathing pattern is characterized by irregular[] variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient’s airflow tracing indicating that the patient is awake and either anxious or uncomfortable.” *Id.*, 4:53-58. By way of another example, “REM associated pattern of breathing may include, e.g., the absence of larger breaths, especially after pauses, generally high respiratory rates and low flow rates, and a tendency for clustering of small breaths.” *Id.*, 5:26-29. Importantly, “[t]hese differences in the pattern of the respiratory airflow…allow the separation of these states and can be used to make a change in the applied pressure.” *Id.*, 5:29-33. Put simply, the system requires the determination of different states to determine the applied pressure.

This is further confirmed by the prosecution history of the ’344 Patent. During prosecution, the Examiner found that Burton845 disclosed a “processing

arrangement analyzes the breathing patterns to determine whether the breathing patterns are indicative of an REM sleep state" recited in original claim 4. EX1002, 378. In response, PO cancelled original claim 4, and amended claim 9 (issued claim 7) to recite that a processing arrangement configured to determine "which of the following states the detected breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state." *Id.*, 398. In distinguishing Burton845, PO explained that Burton845 "does not teach or suggest a processing arrangement that distinguishes between regular wakefulness and troubled wakefulness." *Id.*, 404. Accordingly, a POSITA would understand that this term means that the system determines breathing patterns indicative of each of the four listed states; otherwise, Burton845 would anticipate since it discloses determining the detected breathing patterns for at least one state (the REM sleep state). Behbehani Decl. ¶106.

## VIII. GROUND 1: RAPOPORT502 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIMS 1, 3, 7, 9, 11, AND 13

### A. Motivation to Combine

It would have been obvious to a POSITA to modify the processing arrangement in Rapoport502 *to determine whether the breathing patterns are indicative of a troubled wakefulness* (Claim 1), and more specifically *to determine which of the following states the detected breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and*

*(iv) a troubled wakefulness state* (Claim 7), as taught in Sullivan460 and Matthews. It is logical that the modified system would be responsive to the determination of troubled wakefulness and *reduce pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure* (Claim 1), as taught in Matthews. Behbehani Decl. ¶107.

**First**, as to Claims 1 and 7, a POSITA would have recognized the advantages of detecting an awake state, 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'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 Decl. ¶¶ 108-09.

Further, Matthews has expressly recognized that "erratic" breathing is characteristic of *troubled wakefulness* and *REM sleep states*. *See* EX1007 21:37-40 ("[w]hen a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic."). Accordingly, in realizing the advantages of detecting *troubled wakefulness*, a POSITA would have understood the need to discern the difference between a wake state (for *troubled wakefulness*) and a sleep state (for *REM sleep*), so as to avoid incorrectly associating *REM sleep* for *troubled wakefulness* and vice versa. Behbehani Decl. ¶110.

Sullivan460 teaches how to determine whether a patient is awake or asleep, 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. "[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. Accordingly, Sullivan460 provides a solution to the problem of determining awake and asleep states for discerning between erratic breathing patterns characteristic with *troubled wakefulness* and *REM sleep*. Behbehani Decl. ¶111.

By modifying the CPAP system disclosed by Rapoport502 to detect multiple sleep states and wake states (as taught by Sullivan460) and further distinguish sleep states and wake states based on erratic breathing (as taught by Matthews), the modified CPAP system would allow for more precise pressure adjustment based on the patient's sleep state. Behbehani Decl. ¶112.

**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. For claim 1, adding a *troubled wakefulness state* based on data from the flow sensors would have been a known option. For claim 7, adding additional sleep and wake states based on data from the flow sensors would have made the CPAP system even more effective at treating the sleeping disorder without sacrificing comfort. Behbehani Decl. ¶¶113-14.

### B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in making the modification to Rapoport502. Behbehani Decl. ¶115.

**First**, Rapoport502, Sullivan460, and Matthews are analogous art to the '344 Patent. All references describe CPAP systems with flow sensors and flow

generators. Like Rapoport502 and Sullivan460, Matthews discloses a "flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34." Ex., 1007, 7:11-14. 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. Rapoport502 already discloses lowering the pressure upon the absence of detecting flow limitations (EX1008, 2:35-3:21), and the POSITA would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state* (claims 1 and 7) or a *non-troubled wake state* (claim 7), as taught in Matthews, to avoid causing discomfort to the patient. Likewise, Rapoport502 already discloses adjusting pressure for sleep states. EX1008, 3:18-21 ("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."). These include *a non-REM sleep state* and *a REM sleep state*, as taught in Matthews and Sullivan460. Ex. 1006, 6:30-7:12; Ex. 1007, 21:37-40.

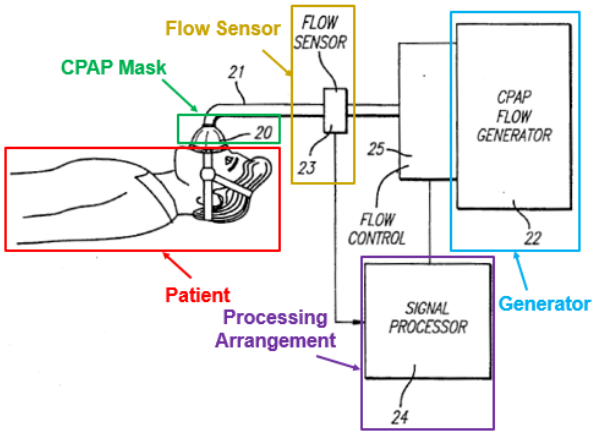
**Second**, modifying the CPAP system of Rapoport502 would have been as simple as adding another decision point in the algorithm. Specifically, because the flow sensors already provided data to determine flow limitations, the algorithm shown in Figure 10 could simply be modified to add "Erratic Breathing Present" (which is not a new state) between step 43 and step 46. If yes, continue to step 47, and if no, continue step 46. Behbehani Decl. ¶116.

Given that the proposed modification involves a simple change in a programming algorithm, it is nothing more than a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way. Behbehani Decl. ¶117.

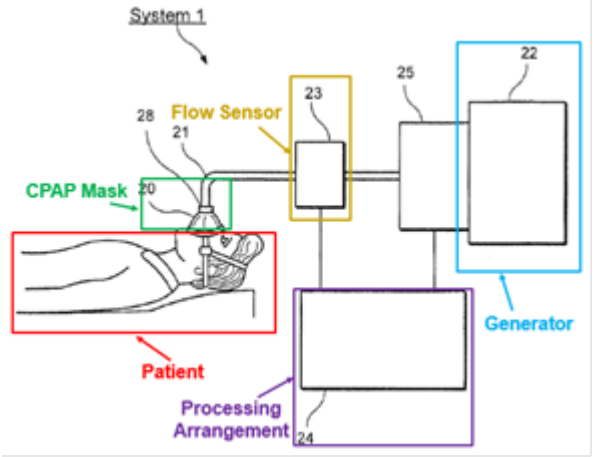
### C. Independent Claims 1, 7

#### 1. 1[preamble]/7[preamble]: *"A system comprising:"*

To the extent limiting, Rapoport502 discloses the preamble. Behbehani Decl. ¶¶118-19. Rapoport502 discloses a CPAP system in the same manner as the '344 Patent. *See* EX1008, 1:16-21 (describing the CPAP system is "for adjusting the positive airway pressure of a patient to an optimum value in the treatment of obstructive sleep apnea."), Fig. 9, Behbehani Decl. ¶118.




**Rapoport502, Fig. 9 (annotated)**




**'344 Patent, Fig. 1 (annotated)**

**2. 1[a]/7[a]:** "*a flow sensor provided in an airflow path and measuring data corresponding to a patient's breathing patterns; and*"

Rapoport502 discloses this limitation. Behbehani Decl. ¶¶120-23. Rapoport502's CPAP system includes a conventional *flow sensor* 21 (brown) "coupled to the tube 21," which defines *an airflow path* from the flow generator 22 to the patient worn CPAP mask 20. EX1008, Fig. 9; *see also* Section VIII.C.1. The flow sensor 21 is *provided in* the airflow path. Behbehani Decl. ¶121. 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 '344 Patent. EX1008, 3:22-28 (emphasis added), Behbehani Decl. ¶122. The conventional flow sensor 23 *measures data corresponding* to the "air through the flow sensor," and the measured data is in the form of a waveform *corresponding to the patient's breathing patterns* analyzed by the processor 24. *Id.*, 3:24-26, Behbehani Decl. ¶122. Rapoport502 further discloses that "[t]he microprocessor obtains the flow waveform from the digitized output of the flow sensor" in the same manner that the processing arrangement obtains from the flow sensor in the '344 Patent. EX1008, 3:36-37. Specifically, a POSITA would understand that the flow waveform is *data corresponding to the patient's breathing patterns* that is *measured* by the *flow sensor*. Behbehani Decl. ¶123.

**3. 1[b]/7[b]:** *"a processing arrangement configured to analyze the breathing patterns [to determine whether the breathing patterns are indicative of a troubled wakefulness state / to determine to which of the following states the detected breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state]; and"*

Rapoport502 in view of Matthews and Sullivan460 discloses this limitation. Behbehani Decl. ¶¶ 124-44.

Rapoport502's CPAP system includes a signal processor 24 (purple) corresponding to a *processing arrangement*. *See* Section VIII.C.1. The '344 Patent illustrates the processing arrangement 24 as a "black box" but does not disclose what constitutes the processing arrangement 24. *See id.*, Behbehani Decl. ¶126. 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. Behbehani Decl. ¶127.

Further, the signal processor 24 is *configured to analyze the breathing patterns*. Specifically, 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 in the form of a waveform that is indicative of *breathing patterns analyzed* by the signal processor 24 (*processing arrangement*). *Id.*, 3:56-63, Behbehani Decl. ¶127. 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 that the signal processor 24 would analyze. EX1008, 4:47-5:50, Figs. 1-5, Behbehani Decl. ¶129.

Accordingly, Rapoport502 discloses *a processing arrangement configured to analyze the breathing* patterns, but it does not expressly disclose specific types breathing patterns that it analyses. However, this limitation would have been obvious from Rapoport502 in view of Sullivan460 and Matthews.

*a) Teachings of Sullivan460 and Matthews regarding wake and asleep states and their types.*

Sullivan460 and Matthews teach *to determine whether the breathing patterns are indicative of a non-troubled wake state* and *a troubled wakefulness state* and *a non-REM sleep state* and *a REM sleep state.*[7] Specifically, Sullivan460 discloses 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." Ex. 1006 at 7:3-7, 7:10-12, 7:17-19. By using a sleep sensor, Sullivan460 discloses determining a wake state (which a POSITA would

[7] Claim 1 recites determining only the troubled wakefulness state.

have understood includes *a troubled wakefulness state* and *a non-troubled wake state*) and a sleep state (which a POSITA understands includes *a REM sleep state* and *a non-troubled wake state*). Behbehani Decl. ¶134. Sullivan460 employs "a switching means [to] respond[] to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," and as Sullivan460 further explains, "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep." Ex. 1006 at 6:30-7:12, claims 22-28, 43-46; Behbehani Decl. ¶134.

For the specific types of wake and sleep states, Matthews teaches using the detection of erratic breathing to distinguish *a troubled wakefulness state* from *a REM sleep state.* Behbehani Decl. ¶135. Similarly, for the sleep state, Matthews also teaches using the detection of erratic breathing to distinguish a REM sleep state. Specifically, Matthews recognizes that "[w]hen a patient is awake, in ***REM sleep***, or ***in distress***, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable." Ex. 1007 at 21:37-40. As discussed above, the *troubled wakefulness state* is denoted by a breathing pattern "characterized by irregular[] variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient's airflow tracing indicating that the patient is awake and either anxious or uncomfortable." EX1001, 4:53-58; *see also* Section VII.A (Claim Construction, "troubled wakefulness"). The erratic nature of a

troubled wakefulness state is demonstrated in Figure 7, particularly when contrasted with a regular sleep pattern demonstrated in Figure 4:

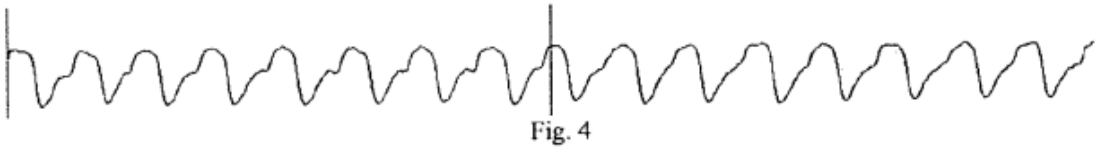


Fig. 4

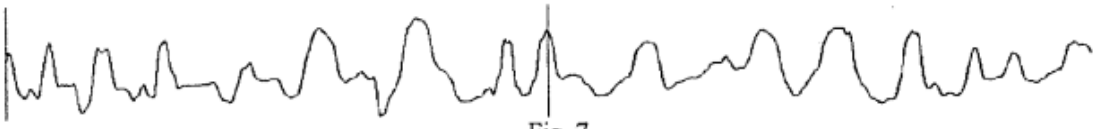


Fig. 7

EX1001, Figures 4, 7.

To address potential instability, Matthews discloses "a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing." Ex. 1007 at 40:25-30. The breathing control layer "performs statistical analysis on the scatter of the trended weighted peak flow data to detect unstable breathing patterns or abrupt changes in patient response," similar to those found in Figure 7. Matthews's disclosure of monitoring and detecting erratic or irregular breathing, meets the *determine whether a breathing pattern is indicative of a non-troubled wake state*, *a troubled wakefulness state* and *a REM sleep*. Further, it follows where Matthews detects no erratic breathing in a sleep state (as taught by Rapoport502 and also Sullivan460), Matthews determines *a non-REM sleep state*. Behbehani Decl. ¶137.

Accordingly, Sullivan460 and Matthews teach *breathing patterns indicative* of the four claimed states.

*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).

Further, a POSITA would have recognized that the teachings of Sullivan460 and Matthews could be combined to modify the *processing arrangement* of Rapoport502 to distinguish between types of wake states and sleep states, as taught by Sullivan460, and to detect erratic breathing, as taught by Matthews. Behbehani Decl. ¶141. If the breathing patterns indicate a sleep state and erratic breathing, the *processing arrangement* determines that the breathing patterns indicate the patient is in *a REM sleep state*. No erratic breathing indicates *a non-REM sleep state*. If the breathing patterns indicates a wake state and erratic breathing, the *processing arrangement* determines that the breathing patterns indicate the patient is in *a troubled wakefulness state*. No erratic breathing indicates *a non-troubled wake state*. Behbehani Decl. ¶137.

Importantly, adding the detection of a various states was a natural extension of Rapoport502's goal to adjust and minimize pressure to aid compliance. Behbehani Decl. ¶142. Such a modification involved a simple change in a programming algorithm, and was nothing more than a combination of known prior

art elements (identifying a breathing pattern) according to known methods and known techniques (matching breathing patterns) to yield predictable results (increase or decrease pressure), and involves use of a known technique to improve a similar device (CPAP machines) in the same way. Behbehani Decl. ¶144.

4. **1[c]/7[c]:** *"a generator configured to supply an airflow to an airway of the patient and to [reduce / adjust] a pressure of the airflow supplied to an airway of the patient [from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure / as a function of a state determined by the processing arrangement]."*

Rapoport502 in view of Matthews discloses this limitation. Behbehani Decl. ¶¶ 145-58. Rapoport502 discloses *a generator configured to supply an airflow to an airway of the patient*. Behbehani Decl. ¶146; *see also* Section VIII.C.1. Rapoport502's CPAP system includes a *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 VIII.C.1; Behbehani Decl. ¶147.

Rapoport502 further discloses that its generator is configured *to adjust a pressure of the airflow supplied to an airway of the patient as a function of a state determined by the processing arrangement* (claim 7). Behbehani Decl. ¶148. Rapoport502 discloses "[t]he pressure setting is raised, lowered or maintained depending on whether flow limitation has been detected and on the previous

actions taken by the system," which means adjusting the airflow based on the state as indicated by the flow limitation. EX1008, 3:18-21, Fig. 10. For example, Figure 8 shows the waveforms generated by the data from the sensors. Rapoport502 explains that these waveforms "are employed in order to control the flow of air from a CPAP generator, to thereby minimize the flow of air from the generator while still ensuring the flow limitation does not occur." *Id*., 5:47-50; Behbehani Decl. ¶[149.

Although Rapoport502 does not explicitly disclose *adjusting…from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure* (claim 1), this limitation would have been obvious from Rapoport502 in view of Matthews. Behbehani Decl. ¶150.

*a) Teachings of Matthews "to adjust the pressure to a second value" when in 'troubled wakefulness."*

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. EX1007, cl. 1. Matthews discloses that "[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 '344 Patent's description of *troubled wakefulness* as "awake and anxious or distressed"

(EX1001, 4:47-48) with "erratic" breathing (*id.* 4:47-59). In Matthews, when such a state is detected, Matthews "interrupts [] the auto-CPAP controller" and "decrease[] the pressure delivered to the patient." *Id.*, 21:57-61, 23:67-24:2. This lower pressure is a *second value*. Behbehani Decl. ¶153.

Further, Matthews's description of Figure 13 (reproduced below) helpfully teaches how to use the values of previously applied pressures as well as patient breathing pattern to recognize the patient's state and then optimize the applied pressure based on these considerations to new pressure values. Behbehani Decl. ¶154. This applies to *troubled wakefulness* and other states.

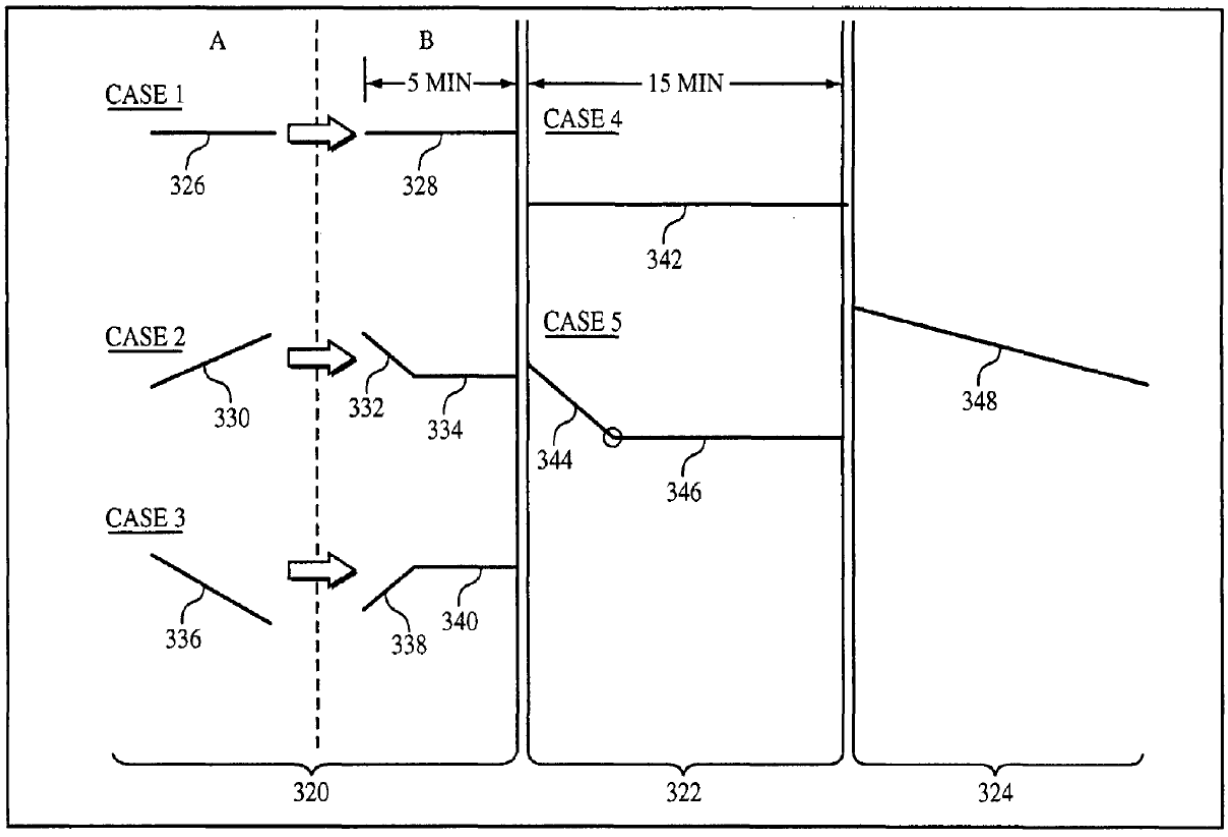



FIG. 13

For example, if the erratic breathing occurred when the prior pressure was flat such as what is shown as 334 in Figure 13, a POSITA by taking into account the determination of the sleep state of the patient in view of the teachings of Sullivan460 and Matthews would have recognized the erratic breathing as an indication of REM sleep. Ex. 1007 at 21:37-39 ("When a patient is awake, in REM sleep, or in distress, breathing tends to be more erratic."). As Matthews teaches in Case 1 of Figure 13, the pressure would therefore remain at the same level. Ex. 1007 at 23:55-65; *see also* Ex. 1001 at 5:61-65 ("[I]f the patient shows irregular breathing which suggests he is in REM sleep, as during this type of breathing the patient is asleep and the applied pressure must be maintained at the same level as during other periods of sleep (i.e., not reduced as during wakefulness)."). Similarly, if the erratic breathing occurred after a pressure increase and the patient is awake (as detected using the teachings of Sullivan460 and Matthews), a POSITA would have recognized the erratic breathing as an indication of a nocturnal awakening (*a troubled wakefulness state*) caused by the high pressure (*a first value*). Ex. 1016 at p. 1 ("Patients often complain of side effects caused by NCPAP treatment, including … nocturnal awakenings."), Ex. 1036 at p. 3 ("We note that the most common side effect of CPAP … was waking up during the night."). As Matthews teaches in Case 2 of Figure 13, the pressure would therefore

be decreased to *a second value* that is lower than *the first value*. Ex. 1007 at 23:65-24:10; Behbehani Decl. ¶155.

*b) Motivation to Combine and Reasonable Expectation of Success*

A POSITA would have been motivated to modify Rapoport502's generator to *reduce[] a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure, the second pressure being lower than the first pressure* when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, as taught in Matthews, with a reasonable expectation of success. *See* Section VIII.A (Ground 1, Motivation to Combine) and VIII.B (Ground 1, Reasonable Expectation of Success).

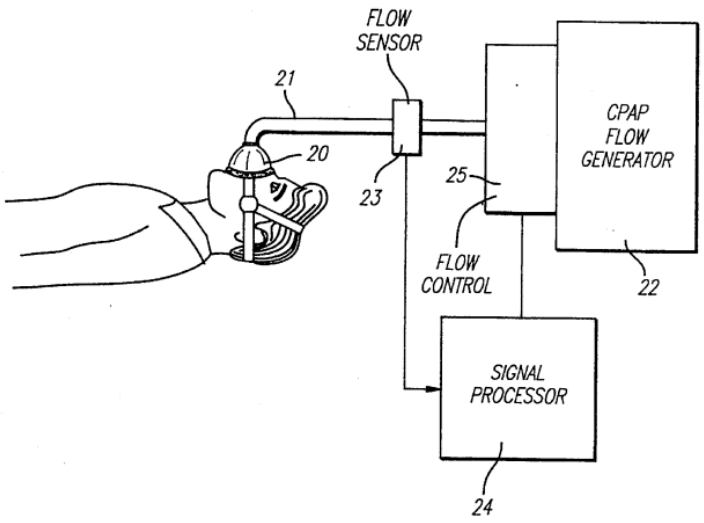
Importantly, reducing the pressure when the patient is awakened was a well-known design option. Such a modification involved a simple change in a programming algorithm, and was nothing more than a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way. Behbehani Decl. ¶158.

### D. Dependent Claims 3, 9, 11, and 13

#### 1. Claims 3, 9: *"further comprising: a mask coupled to the generator covering at least one of a nose and a mouth of the patient."*

Rapoport502 discloses this limitation. Behbehani Decl. ¶¶159-161. As shown in Fig. 9 below, Rapoport502 teaches *a mask coupled to the generator*. 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 Decl. ¶160. Rapoport502 further teaches that the *mask 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**

**2. Claim 11:** *"when the processing arrangement determines that the breathing patterns are indicative of state (iv), the processing arrangement decreases the pressure of the airflow supplied to the airway of the patient from a first pressure to a second pressure, the second pressure being lower than the first pressure."*

Rapoport502 in view of Matthews renders obvious this limitation. *See* Section VIII.C.4 (Ground 1, 1[c]).

**3. Claim 13:** *"when the processing arrangement determines that the breathing patterns are indicative of state (i), the processing arrangement increases the pressure of the airflow supplied to the patient from the first pressure to a third pressure, the third pressure being greater than the first pressure."*

Rapoport502 in view of Matthews renders obvious this limitation. Behbehani Decl. ¶¶163-69. As discussed for 7[c], Rapoport502 teaches that the *generator* is *configured to adjust a pressure of the airflow supplied to an airway of the patient as a function of a state determined by the processing arrangement*. *See* Section VIII.C.4 (Ground 1, 7[c]). Although Rapoport502 does not expressly teach that the *processing arrangement* sends a control signal to the *generator* that *increases the pressure of the airflow supplied to the patient from the first pressure a third pressure, the third pressure being greater than the first pressure* when the *processing arrangement determines that the breathing patterns are indicative* of *a REM sleep state*, this is taught by Matthews.

Matthews teaches that "[w]hen a patient is…in REM sleep, … breathing tends to be more erratic and the Auto-CPAP trending becomes unstable." EX1007,

21:37-38. As such, the variable breathing control layer, will "interrupt the auto-CPAP controller if the patient's breathing pattern becomes too variable." *Id.*, 21:39-41. In that situation, the variable breathing control layer will determine if there has been a decrease in pressure to a *first pressure. Id.*, 24:11-22. A POSITA would understand that such a *first pressure* is applied when the patient awakens. Behbehani Decl. ¶194. In this event, Matthews teaches that when the variable breathing control layer determines that the patient's breathing pattern then becomes erratic (*determines that the breathing patterns are indicative* of *a REM sleep state*), the variable breathing control layer then "increases the pressure delivered to the patient," such that a *third pressure* is applied. *Id.* 24:11-14. Because the *third pressure* is an increase from the *first pressure*, the *third pressure* is *greater than the first pressure.* Behbehani Decl. ¶169.

## IX. GROUND 2: SULLIVAN995 IN VIEW OF SULLIVAN460 AND MATTHEWS RENDERS OBVIOUS CLAIMS 1, 3, 7, 9, 11, AND 13

### A. Motivation to Combine

It would have been obvious to a POSITA to modify the processing arrangement in Rapoport502 *to determine whether the breathing patterns are indicative of a troubled wakefulness* (Claim 1), and more specifically *to determine which of the following states the detected breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state* (Claim 7), as taught in Sullivan460 and

Matthews. It is logical that the modified system would be responsive to the determination of troubled wakefulness and *reduce pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure* (Claim 1), as taught in Matthews. Behbehani Decl. ¶170.

A POSITA would have recognized the advantages of detecting different awake states, including a distressed state (*troubled wakefulness*) in which the patient has breathing that becomes "erratic," as taught in Matthews. Behbehani Decl. ¶171. The modification to Sullivan995 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; Behbehani Decl. ¶171.

**B. Reasonable Expectation of Success**

The POSITA would have had a reasonable expectation of success in making the modification to Sullivan995 CPAP system. Behbehani Decl. ¶172-74. Sullivan995 and Matthews are analogous art. All references describe CPAP systems with flow sensors and flow generators. Like Sullivan995, 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.*, 8:54-9:10. The POSITA would have had a reasonable expectation of success in lowering the pressure upon detecting a *troubled wakefulness state*, as taught in Matthews, to avoid causing discomfort to the patient. Behbehani Decl. ¶173.

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.

### C. Independent Claims 1, 7

#### 1. 1[preamble]/7[preamble]: *"A system comprising:"*

To the extent limiting, Sullivan995 discloses the preamble. Behbehani Decl. ¶¶175-77. Sullivan995 discloses a "continuous positive airway pressure (CPAP)" system.[8]. EX1005, Fig. 3, Abstract, 1:32-36, 2:15-19, 9:57-58. Sullivan995's CPAP system "deliver[s] appropriate airway pressure" to the patient's airway

[8] Sullivan995 refers to the same CPAP system of components as a CPAP apparatus, CPAP device, CPAP system, and CPAP unit. EX1005, 2:15-19, 9:57-64, 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.

passages. *Id.*, 2:15-19. As a POSITA would have understood, CPAP delivers "positive" airway pressure relative to atmospheric pressure. Behbehani Decl. ¶175.

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." EX1005, cl. 6, 5:12-34, 10:67-11:4, 11:23-43. This is 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. *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 Decl. ¶176.

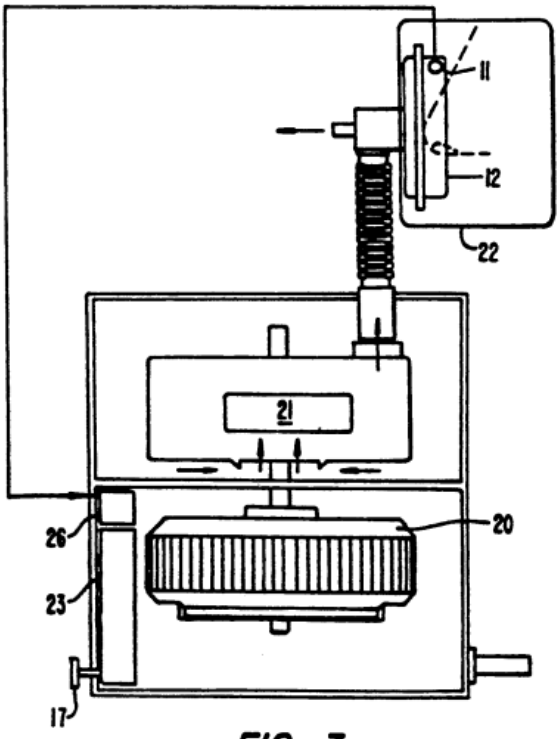



FIG. 3.

**EX1005, Fig. 3**

**2. 1[a]/7[a]:** *"a flow sensor provided in an airflow path and measuring data corresponding to a patient's breathing patterns; and"*

Sullivan995 discloses this limitation. Behbehani Decl. ¶178-187. Sullivan995's CPAP system includes a differential pressure sensor, e.g., microphone 11 (*flow sensor*). EX1005, Figs. 3, 7, 9:64-66 (the snoring detection means 22 is a pressure detection means and microphone 11 is a ***differential pressure sensor***."), Behbehani Decl. ¶178. To determine the differential pressure used to calculate air flow rate, the *flow sensor* is inside the mask (*provided in an airflow path*) as depicted in Figure 3. Behbehani Decl. ¶179.

Sullivan995 expressly teaches multiple places where snoring detection means 22 (and therefore microphone 11) can be located, including *provided in an airflow path*. 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; Behbehani Decl. ¶180.

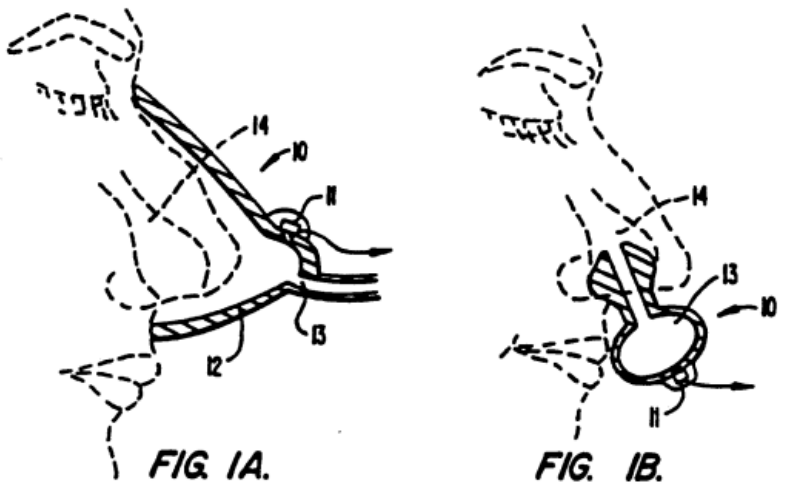
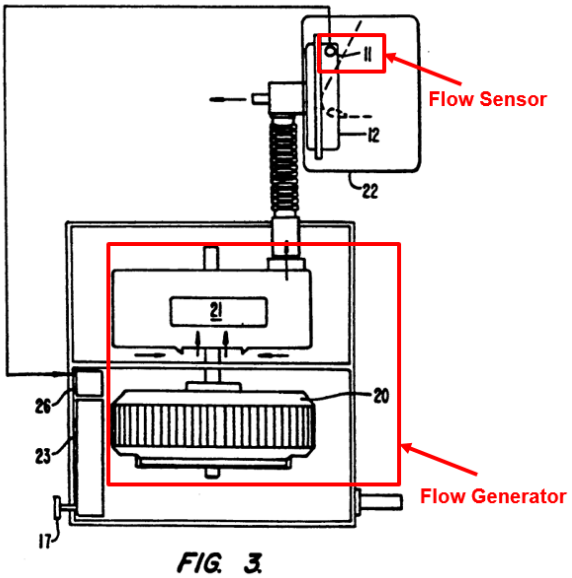
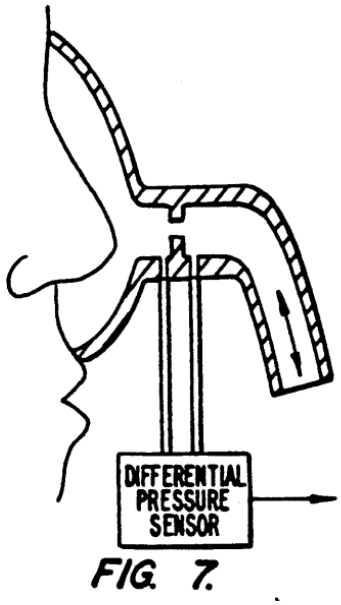



Figure 1A depicts the microphone 11 (*flow sensor*) located "in sound communication with the container 12 of [the] nose mask." *Id.*, 8:47-49. Sullivan995 discloses an "enclosed airway," which "extends from the source of snoring sounds …through the nasal passages 14 and out of the opening 13 in the nasal mask." *Id.*, 8:49-59. That enclosed airway includes air "being inhaled by the patient" that "enters the nasal passageways" and therefore forms a *provided in an airflow path*. *Id.*, Behbehani Decl. ¶181. The microphone 11 "is ideally located to take advantage of the natural stethoscope formed by the enclosed airway," which means it is *provided in an airflow path*. EX1005, 8:49-59. Similarly, Figure 1B depicts the microphone 11 as being "located within, or attached externally of, a nasal prong device" (*id.*, 8:59-61), which also discloses the microphone 11 (*flow sensor*) is *provided in an airflow path*. Behbehani Decl. ¶183.

The microphone "consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the ***rate of breathing***, inhaled air flow or inhaled ***air flow rate***." *Id.*, 3:21-30 (emphasis added); *see also id.*, Abstract; Behbehani Decl. ¶184.




**EX1005, Fig. 3**




**EX1005, Fig. 7**

The microphone 11 (*flow sensor*) performs a "form of measurement" (*measuring data*) by "detecting snoring sounds" and "other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate" (*indicative of the patient's breathing patterns*). EX1005, 3:21-33; *see also id.*, 11:5-20, 15:56-64 (describing, with reference to Figure 3, detecting "a snore, or snore patterns or abnormal breathing pattern"), Behbehani Decl. ¶185.

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

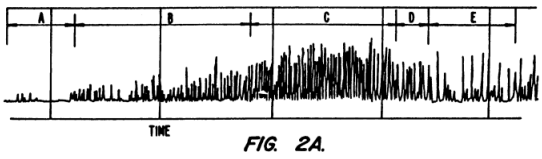



FIG. 2A.

**EX1005, Fig. 2A**

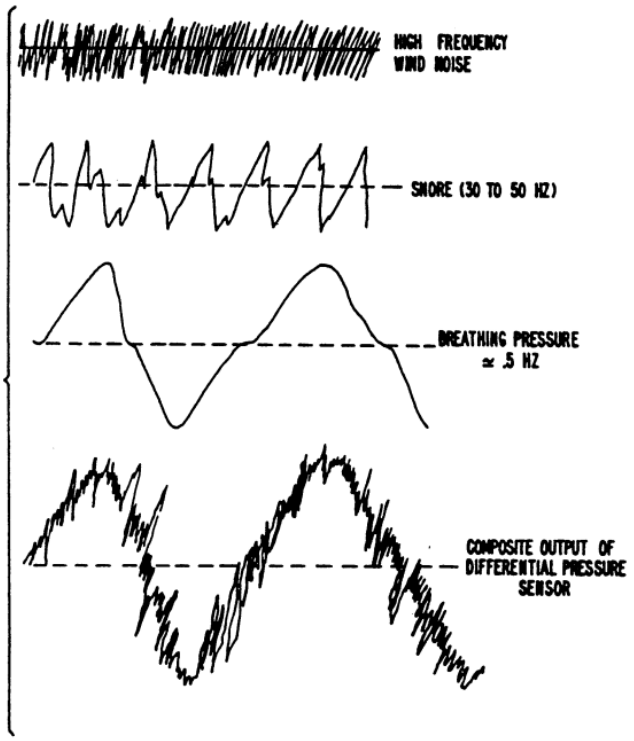



FIG. 9.

**EX1005, Fig. 9**

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

delivered to the patient and is *data indicative of the patient's breathing patterns.* Behbehani Decl. ¶187.

**3. 1[b]/7[b]:** *"a processing arrangement configured to analyze the breathing patterns [to determine whether the breathing patterns are indicative of a troubled wakefulness state / to determine to which of the following states the detected breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state]; and"*

Sullivan995 in view of Sullivan460 and Matthews discloses this limitation. Behbehani Decl. ¶¶188-200.

Sullivan995 discloses a *processing arrangement*. Behbehani Decl. ¶189. The combination of an amplifier/filter/processor unit 26[9] with a speed control unit 23[10] depicted in Figure 3 and described in part as the computing system in Figure 12 is

[9] Sullivan995 refers to the same processor unit 26 as an amplifier/filter/processor unit 26, amplifier/filter/processor 26, and processor 26. EX1005, 10:3-6, 10:40-46, 10:55-58, 11:58-62, 14:50-55, 15:27-33, 15:69-63. For ease of reference, Petitioner refers to each as processor unit 26.

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

*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; Behbehani Decl. ¶193.

Although Sullivan995 does not expressly disclose determining whether a breathing pattern is indicative of specific types breathing patterns, this is taught by Matthews and Sullivan460.

*a) Teachings of Sullivan460 and Matthews regarding wake and asleep states and their types*

Sullivan 460 and Matthews teach *breathing patterns indicative* of *(i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state. See* Section VIII.C.3.a) (Ground 1, 1[b]/7[b] discussing teachings of Sullivan460 and Matthews regarding wake and asleep states and their types).

*b) Motivation to Combine*

A POSITA would have been motivated to modify the *processing arrangement* in Sullivan995 to detect *breathing patterns indicative* of *(i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state,* as taught by Sullivan460 and Matthews. *See* Section IX.A (Ground 2, Motivation to Combine).

Further, a POSITA would have recognized that the teachings of Sullivan460 and Matthews could be combined to modify the *processing arrangement* of Sullivan995 to distinguish between types of wake states and sleep states, as taught by Sullivan460, and to detect erratic breathing, as taught by Matthews. This modification would have caused Sullivan995's CPAP system to detect additional breathing states to better tailor the CPAP output to a patient's needs. Behbehani Decl. ¶197.

Sullivan995 strives to provide the "lowest practicable airway pressure that is effective in preventing airway occlusion during CPAP therapy for the comfort and, possibly, the long term safety of the patient." EX1005, 2:36-39. To achieve this goal, Sullivan995 discloses continually monitoring breathing patterns while the patient is asleep to determine a patient's pressure flow needs. *See, e.g.*, EX1005, 10:52-61. A POSITA would recognize, however, that monitoring breathing patterns only during sleep is insufficient because users, particularly those with problems sleeping for whom a CPAP system is designed, can easily transition from

asleep to awake, and often in a distressed manner. Behbehani Decl. ¶198. Accordingly, a POSITA would be motivated to configure the CPAP system of Sullivan995 to determine when a user's breathing becomes so erratic that auto-CPAP controller is interrupted to alleviate the discomfort of the patient and facilitate compliance. EX1007, 21:40-44, Behbehani Decl. ¶198.

*c) Reasonable Expectation of Success*

A POSITA would have reasonably expected success in modifying the *processing arrangement* in Sullivan995. Sullivan995 is already configured to monitor breathing patterns while the patient is asleep to determine a patient's pressure flow needs. *See, e.g.*, EX1005, 10:52-61; *see also* Section IX.B (Ground 2, Reasonable Expectation of Success). A POSITA would have been able to program Sullivan995's CPAP system to incorporate the peak flow algorithm disclosed in Matthews (EX1007, 15:13-28, Figs, 4A-C, 6), Behbehani Decl. ¶199. Specifically, Matthew's algorithm could have been incorporated to interrupt Sullivan995's control in the same manner that Matthews discloses for interrupting an auto-CPAP controller. EX1007, 21:40-42, Behbehani Decl. ¶199.

Thus, the proposed modification to Sullivan995's CPAP system 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 Decl. ¶200.

**4. 1[c]/7[c]:** *"a generator configured to supply an airflow to an airway of the patient and to [reduce/adjust] a pressure of the airflow supplied to an airway of the patient [from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure / as a function of a state determined by the processing arrangement]."*

Sullivan995 in view of Matthews renders obvious this limitation. Behbehani Decl. ¶¶201-210.

First, Sullivan995 discloses *a generator configured to supply an airflow to an airway of the patient*. Behbehani Decl. ¶202. Specifically, Sullivan995's CPAP system includes a motor 20 with a variable speed that drives a blower 21 (*generator*). EX1005, 9:57-64. The blower 21 is *configured to supply an airflow to an airway of the patient* by providing pressurized air to the patient. *Id.*, 9:60-64 ("[A]n increase in motor speed also increases the blower speed which in turn increases the output air pressure of the blower 21."), Behbehani Decl. ¶202.

Second, Sullivan995 discloses to *reduce a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure* (claim 1) and *to adjust a pressure of the airflow supplied to an airway of the patient as a function of a state determined by the processing arrangement* (claim 7). Behbehani Decl. ¶203. Specifically, Sullivan995's *generator* is configured to adjust a pressure of the airflow supplied to an airway of the patient as a function of a state determined by the processing arrangement. *Id*. For example, Sullivan995 describes

that if "in the early stages of sleep some lesser CPAP pressure will suffice, the CPAP unit of the present invention will not increase the pressure until needed, that is, unless the airway becomes unstable and snoring or abnormal breathing patterns recommence." EX1005, 16:6-11. Sullivan995 further describes how its invention addresses the fact that "a patient's maximum propensity to suffer sleep apnea occurs during REM sleep" and that by detecting "snoring and/or particular deviations in breathing patterns" that set in before apnea occurs, Sullivan995 can "raise the CPAP pressure in response to the snoring or deviation in breathing patterns, thus preventing the onset of apnea or other undesirable respiratory condition." *Id.* 16:35-44. Sullivan995 goes on to note that after the REM sleep passes, the higher airway pressure is no longer required and "the CPAP pressure will be gradually reduced until the first sign of snoring and/or unacceptable breathing patterns reoccurs at which point the pressure will again be increased." *Id.* 16:44-50; Behbehani Decl. ¶206.

Accordingly, Sullivan995 discloses adjusting the pressure provided by the CPAP based on the patient's state, as determined by their breathing pattern. Sullivan995 describes that that the CPAP should operate at a higher pressure immediately before, and during an apnea event or REM sleep, and at a lower pressure at other times. *Id.* 11:23-35; Behbehani Decl. ¶207. However, Sullivan995 does not expressly disclose reduction of pressure *when the processing*

*arrangement determines that the breathing patterns are indicative of the troubled wakefulness state* (claim 1), but Matthews does. Behbehani Decl. ¶208.

*a) Teachings of Matthews "to adjust the pressure to a second value" when in 'troubled wakefulness."*

Matthews discloses this limitation. *See* Section VIII.C.4.a) (Ground 1, 1[c], discussing Matthews).

*b) Motivation to Combine and Reasonable Expectation of Success*

A POSITA would have been motivated to modify Sullivan995's *processing arrangement* to *adjust the pressure to a second value*, as taught in Matthews, with a reasonable expectation of success. *See* Section IX.A (Ground 2, Motivation to Combine) and IX.B (Ground 2, Reasonable Expectation of Success).

**D. Dependent Claims 3, 9, 11, and 13**

**1. Claim 3, 9:** *"further comprising: a mask coupled to the generator covering at least one of a nose and a mouth of the patient."*

Sullivan995 discloses this limitation. Behbehani Decl. ¶¶211-14.

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, 5:11-21, 18:47-60.

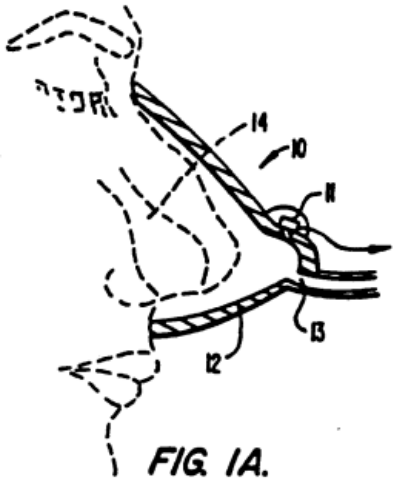



FIG. 1A.

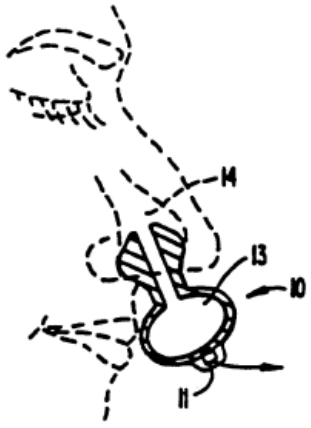



FIG. 1B.

Sullivan995 further shows there is an air line that connect blower 21 (*generator*) to the nose piece in Figure 3. *See e.g.,* EX1005, 7:13-25; *see also* Fig. 3.

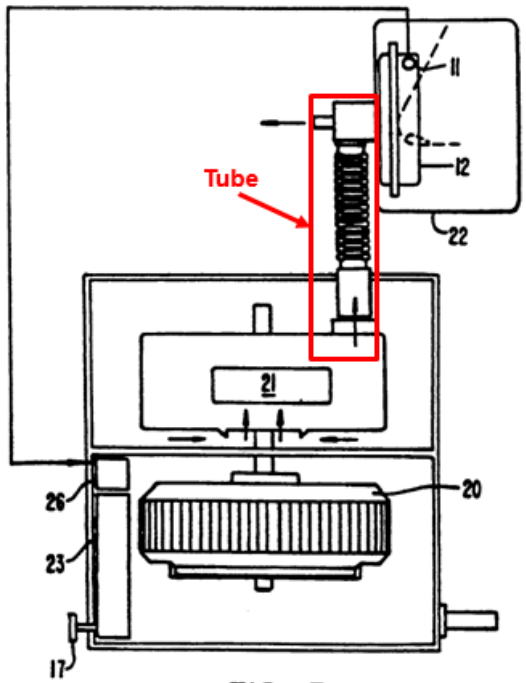



FIG. 3.

**EX1005, Fig. 3 (annotated)**

Sullivan995 therefore discloses a mask coupled to the generator covering at least one of a nose and a mouth of the patient.

**2. Claim 11:** *"when the processing arrangement determines that the breathing patterns are indicative of state (iv), the processing arrangement decreases the pressure of the airflow supplied to the airway of the patient from a first pressure to a second pressure, the second pressure being lower than the first pressure."*

Sullivan995 in view of Matthews renders obvious this limitation. *See* Section IX.C.4 (Ground 2, 1[c]/7[c]).

**3. Claim 13:** *"when the processing arrangement determines that the breathing patterns are indicative of state (i), the processing arrangement increases the pressure of the airflow supplied to the patient from the first pressure to a third pressure, the third pressure being greater than the first pressure.*"

Sullivan995 in view of Matthews renders obvious this limitation. Behbehani Decl. ¶¶216-17. As discussed for 7[c], Sullivan995 teaches that the *generator* is *configured to adjust a pressure of the airflow supplied to an airway of the patient as a function of a state determined by the processing arrangement*. Although Sullivan995 does not expressly teach that the *processing arrangement* sends a control signal to the *generator* that *increases the pressure of the airflow supplied to the patient from the first pressure a third pressure, the third pressure being greater than the first pressure* when the *processing arrangement determines that the*

*breathing patterns are indicative* of *a REM sleep state*, this is taught by Matthews. *See* Section VIII.D.3 (Ground 1, Claim 13 (discussing Matthews)).

## X. GROUND 3: SULLIVAN995 ANTICIPATES CLAIMS 1, 3, 7, 9 11, 13

As discussed in Ground 2 under Petitioner's constructions, Sullivan995 discloses each and every limitation of the challenged claims except for "a troubled wakefulness state" (claims 1 and 7) and "configured…to determine to which of the following states the detected breathing pattern is indicative" (claim 7). *See* Section IX.

But under PO's implied constructions based on PO's infringement allegations, Sullivan995 anticipates the challenged claims.

### A. "troubled wakefulness" (all claims)

In its Complaint, PO alleges that the AutoSet™ algorithm meets this limitation simply by determining breathing patterns indicating the patient is asleep. In other words, PO alleges that the patient is in a troubled wakefulness state when there is an absence of obstructions or other breathing patterns indicative of sleep. Behbehani Decl. ¶¶220, 222. Specifically, PO alleges that the system determines breathing patterns indicative of a troubled wakefulness state because "it decreases the pressure upon waking up." Ex. 1018, ¶ 102. To support this allegation, PO cites to an article entitled "Fall asleep faster with lower CPAP pressure." Ex. 1019. The article explains that the accused CPAP machine "starts you at a low air pressure

and stays there while you're still awake." Ex. 1019, 1; *see also id.,* 2 ("With lower pressures while you're awake, and a steady, comfortable ramp-up to keep you and your partner sleeping, AutoRamp is one of many new features in the AirSense 10 designed to make treatment more comfortable.").

Sullivan995 teaches providing lower pressure when the system has not determined the patient is asleep, just as alleged in the Complaint. Sullivan995 describes that if "in the early stages of sleep some lesser CPAP pressure will suffice, the CPAP unit of the present invention will not increase the pressure until needed, that is, unless the airway becomes unstable and snoring or abnormal breathing patterns recommence." Ex. 1005, 16:6-11. In particular, Figure 13 of Sullivan995 shows that the pressure will remain low until breathing events occur indicating that the patient is asleep.

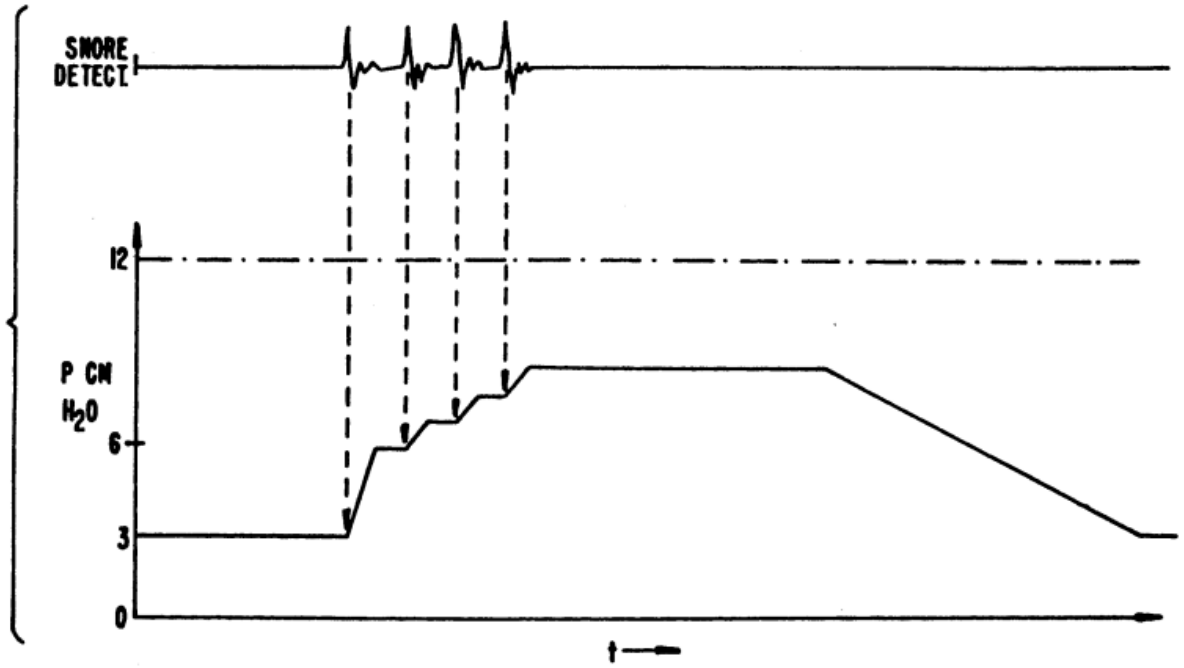



FIG. 13.

**Ex. 1005, Fig. 13**

As Sullivan995 explains, in addition to detecting snoring, microphone 11 (*flow sensor*) is able to detect "characteristic patterns of other respiratory parameters such as rate of breathing, inhaled/exhaled air volume and inhaled/exhaled air flow rate" that "can also be used for detecting apneas as well as the imminent onset of apneic episodes. Any one parameter or combination of parameters may be used for detecting apneas or other breathing disorders, as well as the imminent onset of apneas or other breathing disorders." Ex. 1005, 4:31-45 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.*, 11:5-22 (describing, with reference to Figure 3, detecting "a snore, or snoring patterns or abnormal breathing pattern"), Behbehani Decl. ¶226. Thus, under PO's implied construction, the absence of breathing patterns indicative of sleep is *indicative of a troubled wakefulness state*. *Id.* ¶¶220-27.

### B. "configured…to determine to which of the following states the detected breathing pattern is indicative" (claim 7)

Because the processing arrangement of Sullivan995 is configured to analyze the breathing patterns to determine that the detected breathing pattern is indicative of disordered breathing, Sullivan995 discloses this limitation under PO's constructions as implied in PO's infringement allegations. Behbehani Decl. ¶¶228-32. In its Complaint, PO alleges that the AutoSet™ algorithm meets this limitation when by detecting snores and other abnormal breathing. EX1018, ¶¶ 117-18.

Sullivan995 teaches determining that the patient is asleep based on a disordered breathing pattern, just as alleged in the Complaint. As Sullivan995 explains, in addition to detecting snoring, microphone 11 (*flow sensor*) is able to detect "characteristic patterns of other respiratory parameters such as rate of breathing, inhaled/exhaled air volume and inhaled/exhaled air flow rate" that "can also be used for detecting apneas as well as the imminent onset of apneic episodes. Any one parameter or combination of parameters may be used for detecting apneas or other breathing disorders, as well as the imminent onset of apneas or other

breathing disorders." EX1005, 4:31-45 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.*, 11:5-22 (describing, with reference to Figure 3, detecting "a snore, or snoring patterns or abnormal breathing pattern"), Behbehani Decl. ¶231. Thus, under PO's implied construction, the determination of breathing patterns indicative of disordered breathing by Sullivan995 is sufficient to meet this limitation. *Id.* ¶232.

## XI. 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.

## XII. THE BOARD SHOULD REACH THE MERITS OF THIS PETITION

### A. Institution is appropriate under § 325(d)

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

### B. Institution is appropriate under § 314(a)

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

## XIII. CONCLUSION

For these reasons, Petitioner respectfully requests *inter partes* review of claims 1, 3, 7, 9, 11, and 13 of the ’344 Patent.

Respectfully submitted,

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## Claims Listing (Appendix)

1. A system, comprising:

[a] a flow sensor provided in an airflow path and measuring data corresponding to a patient's breathing patterns; and

[b] a processing arrangement configured to analyze the breathing patterns to determine whether the breathing patterns are indicative of a troubled wakefulness state; and

[c] a generator configured to supply an airflow to an airway of the patient and to reduce a pressure of the airflow supplied to an airway of the patient from a first pressure to a second pressure when the processing arrangement determines that the breathing patterns are indicative of the troubled wakefulness state, the second pressure being lower than the first pressure.

3. The system according to claim 1, further comprising:

a mask coupled to the generator covering at least one of a nose and a mouth of the patient.

7. A system, comprising:

[a] a flow sensor provided in an airflow path and measuring data corresponding to a patient's breathing patterns; and

[b] a processing arrangement configured to analyze the breathing patterns to determine to which of the following states the detected breathing pattern is indicative: (i) a REM sleep state, (ii) a non-troubled wake state, (iii) a non-REM sleep state and (iv) a troubled wakefulness state; and

[c] a generator configured to supply an airflow to an airway of the patient and to adjust a pressure of the airflow supplied to an airway of the patient as a function of a state determined by the processing arrangement.

9. The system according to claim 7, further comprising:

a mask coupled to the generator covering at least one of a nose and a mouth of the patient.

11. The system according to claim 7, wherein, when the processing arrangement determines that the breathing patterns are indicative of state (iv), the processing arrangement decreases the pressure of the airflow supplied to the airway of the patient from a first pressure to a second pressure, the second pressure being lower than the first pressure.

13. The system according to claim 7, wherein, when the processing arrangement determines that the breathing patterns are indicative of state (i), the processing arrangement increases the pressure of the airflow supplied to the patient from the first pressure to a third pressure, the third pressure being greater than the first 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 11,886 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. 9,168,344 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 2, 2022

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