UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ResMed Inc.,
Petitioner,

v.

New York University,
Patent Owner,

Case No. IPR2022-00993

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,988,994

Claims 1, 6-7, 10-14, 19-20, 23-30, and 32

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1013	U.S. Patent No. 5,704,345 to Berthon-Jones ("Berthon-Jones345")
1014	D. Rapoport, "Methods to Stabilize the Upper Airway Using Positive Pressure," *Sleep* 19(9):S123-S130 ("Rapoport 1996")
1015	C. Sullivan, "Reversal of Obstructive Sleep Apnea by Continuous Positive Airway Pressure Applied through the Nares," *Lancet* 1981:1862-5 ("Sullivan 1981")
1016	M. Pressman et al., "Ramp Abuse: A Novel Form of Patient Noncompliance to Administration of Nasal Continuous Positive Airway Pressure for Treatment of Obstructive Sleep Apnea," Am. J of Respiratory and Critical Care Med., Vol. 151, 1632-1634 (1995)

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1020	Reserved
1021	S. Thompson et al., "Sleep as a Teaching Tool for Integrating Physiology and Motor Control," *Advances in Physiology Education* (June 2001)
1022	U.S. Patent No. 6,427,689 to Estes et al. ("Estes")
1023	R. Tamisier et al., "Characterization of pharyngeal resistance during sleep in a spectrum of sleep-disordered breathing," *J Appl Physiol* 89:120-130, 2000 ("Tamisier")
1024	D. Hudgel et al., "Mechanics of the respiratory system and breathing pattern during sleep in normal humans," *The American Physiology Society* (1984)
1025	M. Craske, "Nocturnal Panic," American Psychological Association 153 (1997)
1026	Teschler, H., et al., "Automated Continuous Positive Airway Pressure Titration for Obstructive Sleep Apnea Syndrome," Am. J. Respir. Crit. Care Med. 54:734-740 (1996)
1027	ResMed, "AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1," (1999)
1028	ResMed, "Auotset T, Optimal Therapy for your OSA Patients," (2000)
1029	Sunrise Medical, "DeVillibis, AutoAdjust, LT Nasal CPAP System

Exhibit	Description
	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")
1033	Reserved
1034	WO 03/075991 to Delache ("Delache")
1035	F. Roux, et al., "Continuous Positive Airway Pressure: New Generations," Clinics in Chest Medicine (2003)
1036	V. Hoffstein, et al., "Treatment of Obstructive Sleep Apnea with Nasal Continuous Positive Airway Pressure," Am. Rev. Respir. Dis. (1992)
1037	R. Berry, et al., "The Use of Auto-Titrating Continuous Positive Airway Pressure Treatment of Adult Obstructive Sleep Apnea," (2002)
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, 6-7, 10-14, 19-20, 23-30 and 32 of U.S. Patent No. 6,988,994 (EX1001, "'994 Patent") and a finding that all challenged claims of the '994 Patent are unpatentable.

Patients often struggle to use positive airway pressure systems because the high pressure treatment causes discomfort. The '994 Patent addresses this by decreasing pressure when the patient is in a "troubled wakefulness state" and increasing pressure in other sleep states. But many references, including Sullivan460 and Matthews disclosed this feature well before the '994 Patent priority date.

II. MANDATORY NOTICES

A. Real Party-in-Interest

The real party-in-interest is ResMed Inc.

B. Related Matters

U.S. Patent Office records indicate that the '994 Patent is assigned to New York University ("PO"), which is currently asserting the '994 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 this Petition was filed, petitions for *inter partes* review against related family members U.S. Patent No.

9,108,009, U.S. Patent No. 9,168,344, U.S. Patent No. 9,427,539, U.S. Patent No. 9,533,115, 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 '994 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the ground identified in this Petition.

III. IDENTIFICATION OF CHALLENGES

Ground 1: Claims 1, 6-7, 10-14, 19-20, 23-30 and 32 are obvious under 35 U.S.C. § 103 over Rapoport502[1] in view of Sullivan460[2] and Matthews.

Ground 2: Claims 1, 6-7, 10-14, 19-20, 23-30 and 32 are obvious under 35 U.S.C. § 103 over Sullivan995 in view of Sullivan460 and Matthews.[3]

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[1] U.S. Patent 5,490,502 to Rapoport et al. (EX1008, "Rapoport502") is 35 U.S.C. §§ 102 (a)/(b) prior art.

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

Ground 3: Claims 1, 6-7, 10-14, 19-20, 23-30 and 32 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), a well-recognized disorder, "is one of the most common causes of excessive daytime somnolence." EX1001, 1:7-10. OSAS "is characterized by an intermittent obstruction of [a patient's] upper airway occurring during sleep." *Id.*, 1:13-16. The obstruction ranges "from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring)." *Id.*, 1:16-20. They decrease blood oxygenation as well, and elevate "risk factors in certain types of heart disease." EX1013, 1:27-28, 1:42-45; EX1007, 1:35-48; *see also* Behbehani ¶¶32-33.

Positive airway pressure (PAP) therapy has been "the mainstay of treatment" since Dr. Colin Sullivan, Dr. Michael Berthon-Jones, and their colleagues first applied it to treat OSAS in 1981. EX1001, 1:37-2:2; EX1014, 1 (citing EX1015). To prevent this collapse, positive airway pressure can oppose the force created

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[3] U.S. Patent 7,168,429 to Matthews et al. (EX1007, "Matthews") is 35 U.S.C. §§ 102 (a)/(e) prior art.

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

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

Consequently, automatically adjusting PAP machines became common, particularly when the patient awakens. EX1017, Abstract. Further, by 2003, PAP machines on the market included one or more sensors and a processing unit that could detect breathing patterns and adjust pressure as appropriate based on those breathing patterns. Ex. 1035, 2; EX1037, 2; *see also* Behbehani ¶47.

2. Sleep and Breathing Patterns

Sleep is not a simple linear process whereby progress through stage I (non-REM sleep) to stage IV sleep (REM sleep) EX1021, 1. Rather, sleep is more random and patients alternate cyclically through sleep states *Id.* The typical sleep pattern in a young adult is shown below.

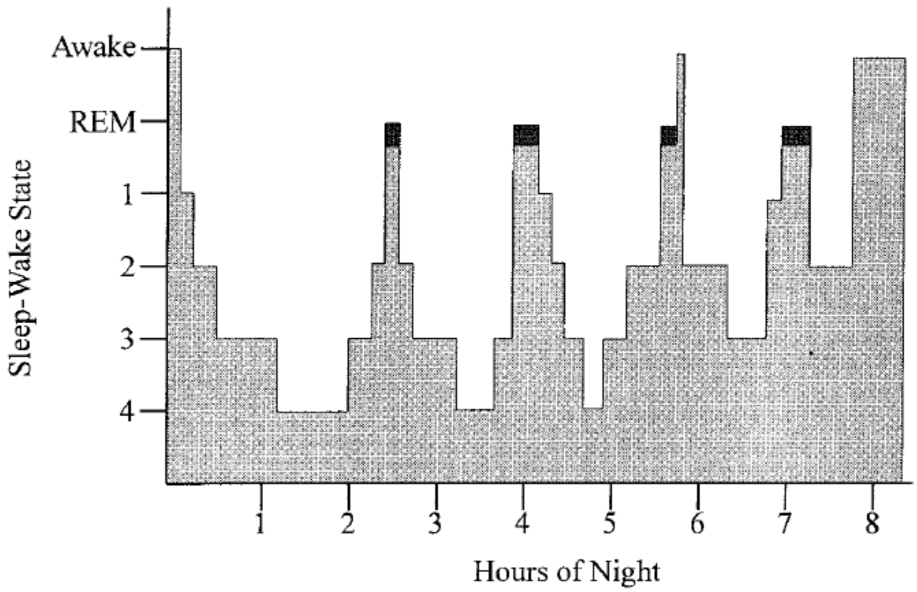


FIG. 2.

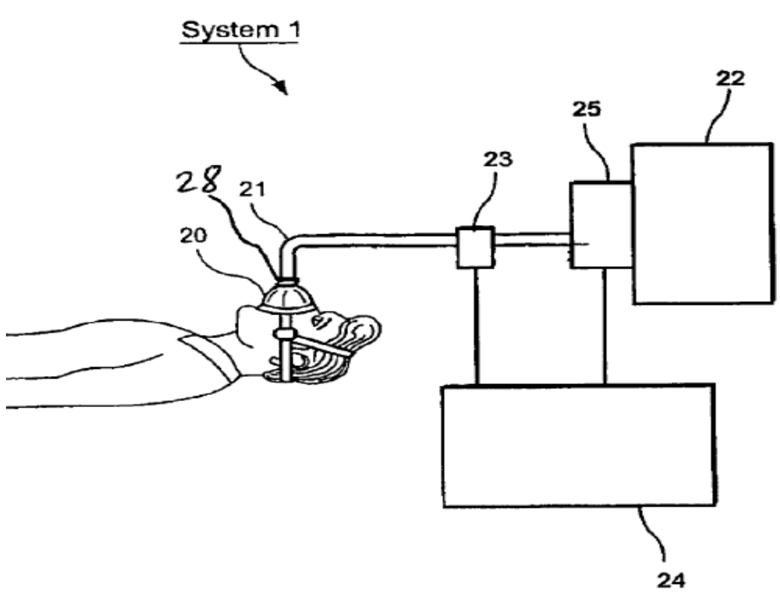
EX1021, Fig. 2

As seen, an individual will exhibit different breathing patterns where overall tidal volume and respiratory rate are stable in non-REM sleep but irregular in REM sleep. EX1021, 8. Importantly, "postural muscle tone is highest in wakefulness," and decreases as one progress through the sleet states EX1021, 5. Consequently, "during sleep, loss of muscle tone results in variable narrowing of the upper airway during inspiration, with consequent flow limitation." EX1023, 1; EX1021, 5.

Thus, for decades, breathing patterns have been used to indicate the sleep-wake state, non-REM sleep state (stable breathing), REM state (unstable breathing), and disordered sleep state. *See, e.g.*, EX1023, 3 (Clinically observing "different sleep stages [stage 1, stage 2, stage 3/4, and rapid eye movement (REM) sleep] and [] wakefulness."). These analyzed breathing patterns include those from nocturnal panic (or as coined in the '994 Patent, "troubled wakefulness"), where an individual "wak[es] from sleep in a state of panic," typically accompanied by "breathing irregularities." EX1025, 1, 10.

B. The '994 Patent

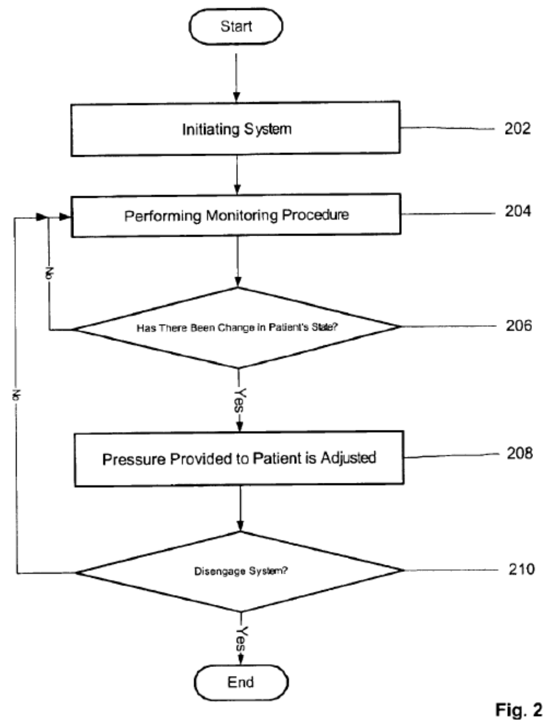
The '994 Patent describes a well-known system and method for treating a sleeping disorder by delivering a flow of breathable gas to a patient's airways. EX1001, Abstract, Fig. 1, 3:19-46. The patent describes Figure 1 (reproduced below) as illustrating an embodiment of "the present invention," yet admits the components in the figure are conventional and operate in a conventional way.



F I G. 1

The system uses "[c]onventional flow sensors 23 [to] detect the rate of airflow to/from patent [sic] and/or a pressure supplied to the patent [sic] by the generator 22," and sends signals to the processing arrangement 24, which "outputs a signal to a conventional flow control device 25" to control the pressure. *Id.* 3:28-41.

To purportedly 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.*, 3:59-67) and "adjust[ing] the pressure to correspond to the patient's current state," (*id.*, 5:28-30) such as by "reduce[ing] the applied pressure" when the patient is awakened (i.e., a troubled wakefulness state) and increasing when the patient falls asleep (e.g., a sleep disordered breathing state). *Id.*, 3:47-51, 5:44-65. Figure 2 illustrates this feature.



EX1001, Fig. 2

C. The Challenged Claims

The challenged claims are entitled to an effective filing date of no earlier than August 14, 2003.[4]

The '994 Patent has 32 claims, including 6 independent claims and 26 dependent claims.

[4] 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

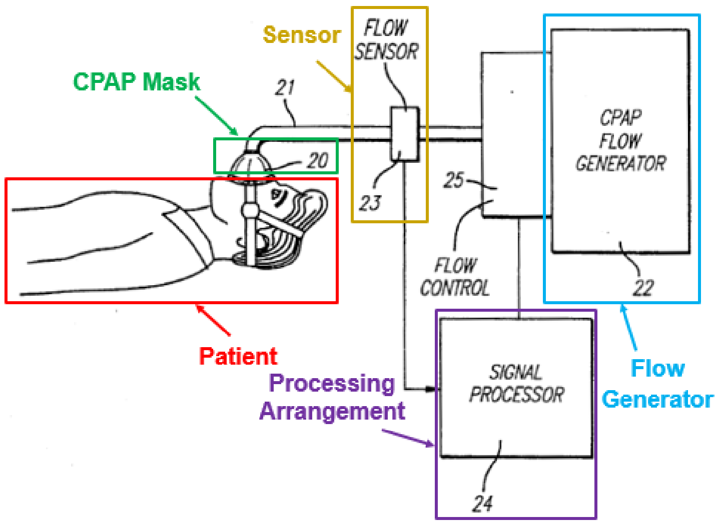
The applicant only obtained allowance of the ’994 Patent by arguing that the prior art did not teach determining breathing patterns indicative of troubled wakefulness. Specifically, on May 24, 2005, the Examiner issued a notice of allowance analyzing U.S. Patent No. 6,397,845 to Burton (“Burton845”) and U.S. Patent No. 6,398,739 to Sullivan (“Sullivan739”). EX1002, 119. The Examiner found that Burton845 teaches “adjusting a CPAP system in response to different states,” and Sullivan739 teaches “determining sleep states including REM and adjusting a CPAP system in response to REM sleep.” *Id.* But the Examiner concluded that neither “determine[s] breathing patterns indicative of a troubled wakefulness state.” *Id.*

Matthews was never considered by the Examiner during prosecution.

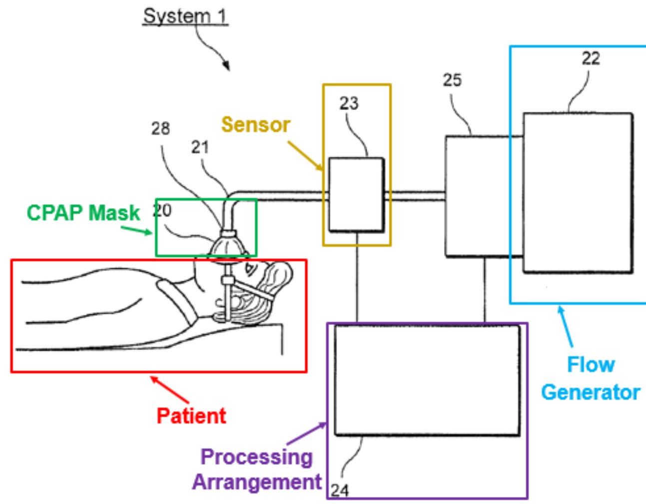
V. OVERVIEW OF THE PRIOR ART

A. Rapoport502 (EX1008)

Rapoport502 (published nearly a decade before the ’994 Patent) discloses nearly identical hardware as in the ’994 Patent, including a conventional flow generator, flow sensor, and processor. Ex. 1008, Fig. 9.



Rapoport502, Fig. 9



’994 Patent, Fig. 1

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

B. Sullivan460 (EX1006)

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

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 threshold, controller 100 determines the patient is in an awake state and switches the CPAP system into the “awake” mode. Id., 10:21-25, 14:7-36. When the system detects interruptions 10, or a reduced average airflow indicating that the patient is asleep, controller 100 determines the patient is in an asleep state and switches the CPAP system into an "asleep" mode, to eliminate the patient's upper airway flow limitation. *Id.*, 10:3-16.

C. Matthews (EX1007)

Matthews discloses the limitation determining breathing patterns indicative of troubled wakefulness not expressly disclosed by Sullivan 995 under Petitioner's construction.

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

D. Sullivan995 (EX1005)

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

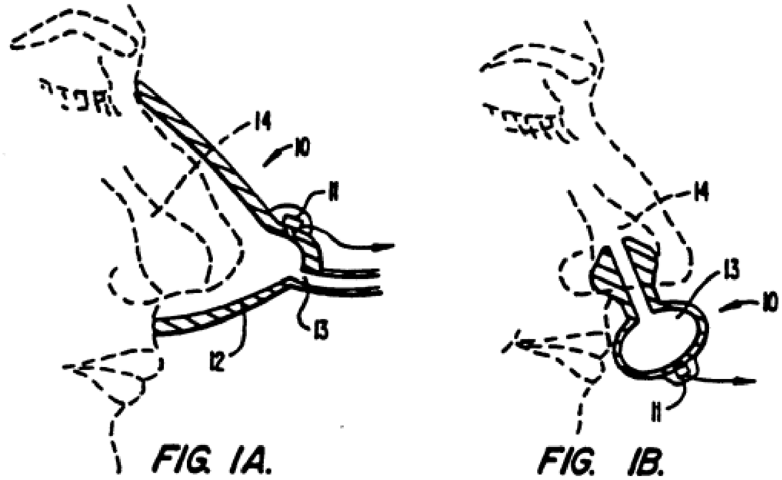


FIG. 1A. FIG. 1B.

Sullivan995 positions a microphone 11 (a differential pressure sensor) within the enclosed airway of the CPAP system for sensing various flow characteristics of the breathable gas, including exhaled and inhaled air flow volume, breathing rate and patterns, exhaled and inhaled air flow rates and/or indicators of snoring. *Id.*, 17:4-12, 12:54-66, 18:47-66, 18:27-32, 4:28-45, 6:54-66, 13:10-33, 13:65-14:16, 14:45-67, Abstract.

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

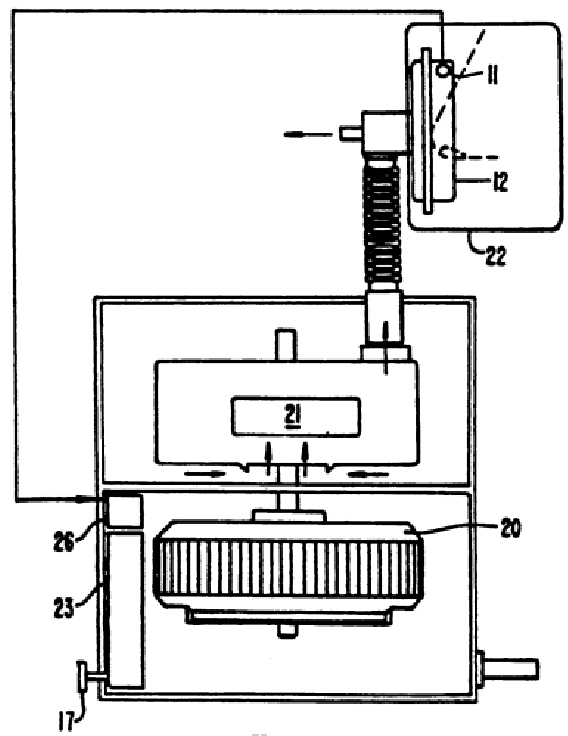


FIG. 3.

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

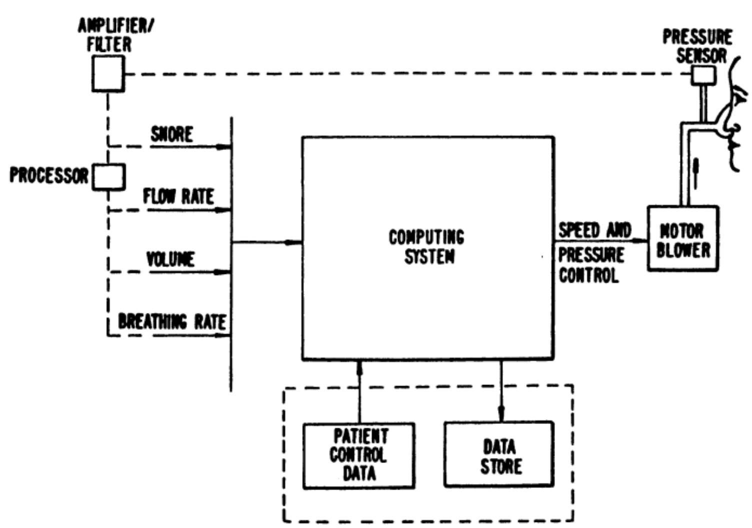


FIG. 12.

Accordingly, these outputs are a control signal that signals whether to "increase[] the speed of the electronic motor 20," which "increases the blower speed," thereby "increas[ing] the output air pressure of the blower 21." *Id.*, 9:58-64, 10:6-12, 10:55-58.

Because snores, apneas, hypopneas, and other abnormal breathing patterns occur when the patient is asleep, Sullivan995 increases the pressure when the patient has fallen asleep. *Id.*, 6:40-68, 15:34-68, 16:17-22, 16:51-59.

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 ¶90.

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 ¶91.

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).[5]

A. "troubled wakefulness" (all claims)

This term to a POSITA in the context of the '994 Patent means "state in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable." Behbehani Behbehani ¶94. This term is not an industry standard term and was coined in the '994 Patent. *Id.* ¶95. As such, the construction is derived directly from the specification, which describes "troubled wakefulness" as a state "in which the breathing pattern is characterized by irregularity variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient's airflow tracing indicating that the patient is awake and either anxious or uncomfortable." EX1001, 4:27-32, Fig. 7.

B. "when the breathing patterns indicate one of states (i) and (ii) and (iii),…adjust the [supplied] pressure to a first value" (cls. 1, 14)

This term in the context of the '994 Patent means "adjust the [supplied] pressure to a first value when the breathing patterns indicate states (i), (ii), or (iii)." Behbehani Behbehani ¶98. This construction is supported by the specification, which explains that "the applied pressure must be maintained at the same level as

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

during other period of sleep (i.e., not reduced during wakefulness).” EX1001, 5:58-65. For example, “the pressure should be at least maintained at the same value … if the patient’s breathing pattern indicates a repetitive obstructive apnea as shown in FIG. 6, or if the patient shows irregular breathing which suggests he is in REM sleep.” *Id*. This is because “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.” *Id.* (emphasis added); *see also id.,* 6:7-14 (“One of the advantages of…the present invention is that the pressure supplied to the patient is adjusted (e.g., reduced to zero or a preset low level) when the patient has an irregular breathing pattern that suggests that he is awake and anxious” and “[w]hen breathing is either regular (e.g., suggesting sleep) or shows sleep disorder breathing events, the pressure may be maintained or increased.”).

VIII. GROUND 1: RAPOPORT502 IN VIEW OF MATTHEWS RENDERS OBVIOUS CLAIMS 1, 6-7, 10-13, 14, 19-20, 23-29, 30 AND 32

A. Motivation to Combine

It would have been obvious to a POSITA to modify the system of Rapoport502 in view of Matthews so that the *processing arrangement* in Rapoport502 *determines a breathing pattern indicative of a troubled wakefulness state*.

First, a POSITA would have recognized the advantages of detecting different awake states, including a distressed state (*troubled wakefulness*) in which the patient has breathing that becomes "erratic," as taught in Matthews. Rapoport502 acknowledges that "[i]ncreasing the comfort of the system, which is partially determined by minimizing the necessary nasal pressure, has been a major goal of research aimed at improving patient compliance with therapy." EX1008, 1:60-63. Rather than wait until more than two minutes have passed since the last change in CPAP (step 46), the system could also decrease CPAP when *troubled wakefulness* is determined, as taught by Matthews. The modification to Rapoport502'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 ¶103.

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." EX008, 3:18-21. Rapoport502 already adjusts the air pressure based on flow limitation states. EX1008, Fig. 10. Adding a *troubled wakefulness* based on data from the flow sensors would have made the system even more effective. Behbehani ¶104.

B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in making the modification to Rapoport502. Behbehani Behbehani ¶105.

First, Rapoport502 and Matthews are analogous art to the ’994 Patent. All references describe CPAP systems with flow sensors and flow generators. Like Rapoport502, Matthews discloses a “flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34” (EX1007, 7:12-16) consistent with the ’994 Patent. 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 (Ex. 1008, 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*, as taught in Matthews, to avoid causing discomfort to the patient. Behbehani ¶106.

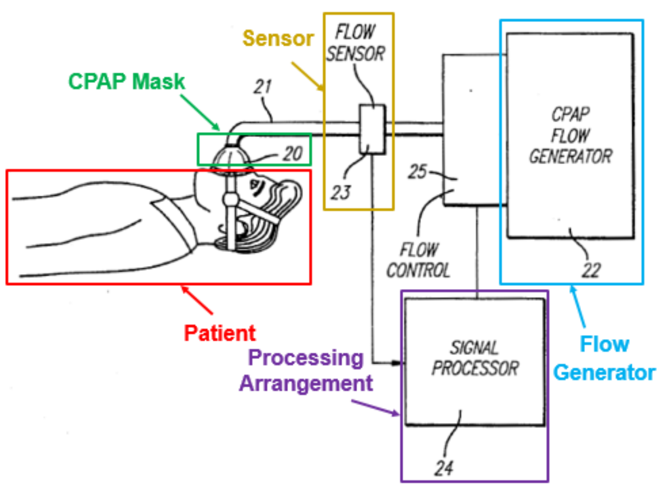
Second, modifying the CPAP system of Rapoport502 would have been as simple as adding another decision point in the algorithm. Specifically, because the flow sensors already provided data to determine flow limitations, the algorithm shown in Figure 10 could simply be modified to add “Erratic Breathing Present” between step 43 and step 46. If yes, continue to step 47, and if no, continue step 46. Behbehani ¶107.

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 ¶108.

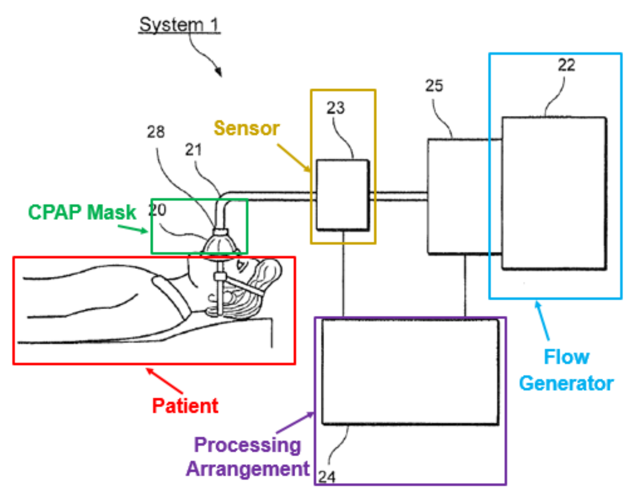
C. Independent Claims 1, 27

1. Preamble: *"A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:"*

To the extent limiting, Rapoport502 discloses the preamble. Behbehani ¶109. Rapoport502 discloses a continuous *positive airway pressure system for treatment of a sleeping disorder in a patient* in the same manner as the '994 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 ¶109.



Rapoport502, Fig. 9 (annotated)



'994 Patent, Fig. 1 (annotated)

2. 1[a]/27[a]: *"a generator supplying airflow and applying a pressure to an airway of a patient;"*

Rapoport502 discloses this limitation. Behbehani Behbehani ¶¶110. Rapoport502's CPAP system includes a flow *generator* 22 (blue), which *supplies* air to the *patient* (red) via a patient worn CPAP mask 20 (green). EX1008, 5:52-53 ("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. A POSITA would have understood that the air supplied to the patient is *a supplying airflow and applying a pressure to an airway of a patient*. Behbehani ¶110.

3. 1[b]/27[b]: *"a sensor measuring data corresponding to patient's breathing patterns; and;"*

Rapoport502 discloses this limitation. Behbehani ¶111. Rapoport502's CPAP system includes a conventional flow *sensor* 21 (brown). EX1008, Fig. 9; *see also* Section VIII.C.1. 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. 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 '994 Patent. Ex. 1008, 3:36-37. Specifically, a POSITA would understand that the flow waveform is *data corresponding to the patient's breathing patterns*. Behbehani ¶111.

4. 1[c1]/27[c]: *"a processing arrangement analyzing the breathing patterns to determine [whether the breathing patterns are indicative of one of the following patient's states: / which one of the following patient's states the breathing patterns are indicative of:] (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state,"*

Rapoport502 in view of Sullivan460 and Matthews renders obvious this limitation. Behbehani Behbehani ¶¶112-27.

Rapoport502 discloses *a processing arrangement analyzing breathing patterns*. Rapoport502's CPAP system includes a signal processor 24 (purple) corresponding to a *processing arrangement*. *See* Section VIII.C.1. The '994 Patent illustrates the processing arrangement 24 as a "black box" but does not disclose what constitutes the processing arrangement 24. *See id.*, Behbehani ¶113. Rapoport502 illustrates the signal processor 24 connected in the same manner, and further uses the term "signal processor" which had a well-understood structure to a POSITA akin to an arrangement of elements that performs processing. *Id*.

Rapoport502 further discloses determining *breathing patterns indicative of a sleep disorder breathing state.* Behbehani Behbehani ¶114. 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 processor 24 (*processing arrangement*). *Id.*, 3:24-26; Behbehani ¶114. Further, Figures 1-5 illustrate exemplary waveforms of airflow between the patient and the flow generator at various pressures that the sensor 23 would output, and shows the gradual onset of a sleep disorder with the change of the patient's breathing patterns. EX1008, 4:47-5:50, Figs. 1-5; Behbehani ¶114.

Rapoport502 further discloses *analyzing breathing patterns indicative of a sleep disorder breathing state*. Rapoport502 teaches that "[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. Ex. 1008, 3:18-21, Fig. 10. Rapoport502 explains that "any of a number of waveform analysis procedures" may be employed, including analyzing the flow data to determine whether apnea is present (*sleep disorder breathing state*). *Id.*, 5:31-45, 6:37-55; Behbehani ¶114.

Rapoport502 does not explicitly disclose *breathing patterns indicative of a regular breathing pattern, a REM sleep state, and a troubled wakefulness state*, but this would be obvious based on the teachings of Sullivan460 and Matthews. Behbehani ¶115.

a) Teachings of Sullivan460 and Matthews regarding sleep states.

Sullivan460 and Matthews teach *breathing patterns indicative* of *a regular breathing pattern, a REM sleep state,* and *a troubled wakefulness state*. Behbehani ¶¶116-25. Sullivan460 and Matthews each describe CPAP systems that detect and analyze breathing patterns and supplies pressurized air to a patient based on the breathing pattern to support and treat breathing disorders. EX1006, 10:3-25; EX1007, 1:15-22, 21:45-57; Behbehani ¶¶116-17.

Matthews teaches *determining whether the breathing patterns are indicative of a regular breathing state*. Behbehani ¶118. Generally, Matthews teaches that "a pressure support system to optimize the pressure delivered to the patient to treat the disordered breathing while otherwise minimizing the delivered pressure for patient comfort." EX1007, 1:19-22. Specifically, the Matthews system includes a controller with different layers to detect different breathing patterns. The Matthews controller "relies on the ability to trend the steady rhythmic breathing patterns associated with certain stages of sleep" to determine the different breathing patterns. *Id.*, 21:36-37. This ability to trend steady rhythmic breathing patterns *determines whether the breathing patterns are indicative of a regular breathing state.* Behbehani ¶118.

Further, Sullivan460 and Matthews together teach *determining the breathing patterns are indicative of a REM sleep state* and *a troubled wakefulness state.* Behbehani ¶119. 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 have understood includes *a troubled wakefulness state*) and a sleep state (which a POSITA understands includes *a REM sleep state*). Behbehani ¶119. 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 ¶119.

For wake and sleep states, Matthews teaches using the detection of erratic breathing to distinguish *a troubled wakefulness state.* Behbehani ¶120. 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. Behbehani ¶121.

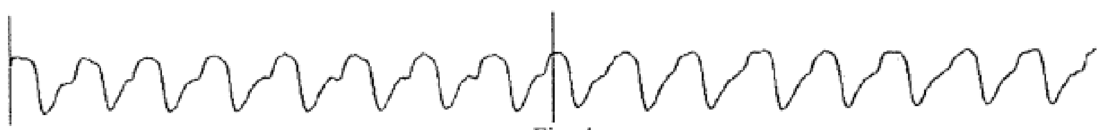


Fig. 4

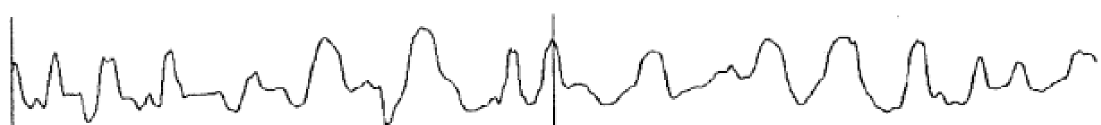


Fig. 7

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 ¶¶116, 118.

A POSITA would have recognized that the teachings of Sullivan460 and Matthews could be combined to modify a *processing arrangement* to distinguish between types of wake states and sleep states, as taught by Sullivan460, and further modified to detect erratic breathing, as taught by Matthews. 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*. 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*. Behbehani ¶122.

Accordingly, Sullivan460 and Matthews teach *breathing patterns indicative of a REM sleep state* and *a troubled wakefulness state.* Behbehani ¶125.

b) Motivation to Combine and Reasonable Expectation of Success

A POSITA would have had motivation to modify Rapoport502 with the teachings of Sullivan460 and Matthews and would have had a reasonable expectation of success in implementing that modification. *See* Section VIII.A

(Ground 1, Motivation to Combine) and VIII.B (Ground 1, Reasonable Expectation of Success). Further, a POSITA would have had motivation to include the determination of additional states to adjust the pressure appropriately. A POSITA would have reasonably expected success given that this was a simple change in a programming algorithm using known techniques in identifying breathing patterns. Behbehani ¶¶126-27.

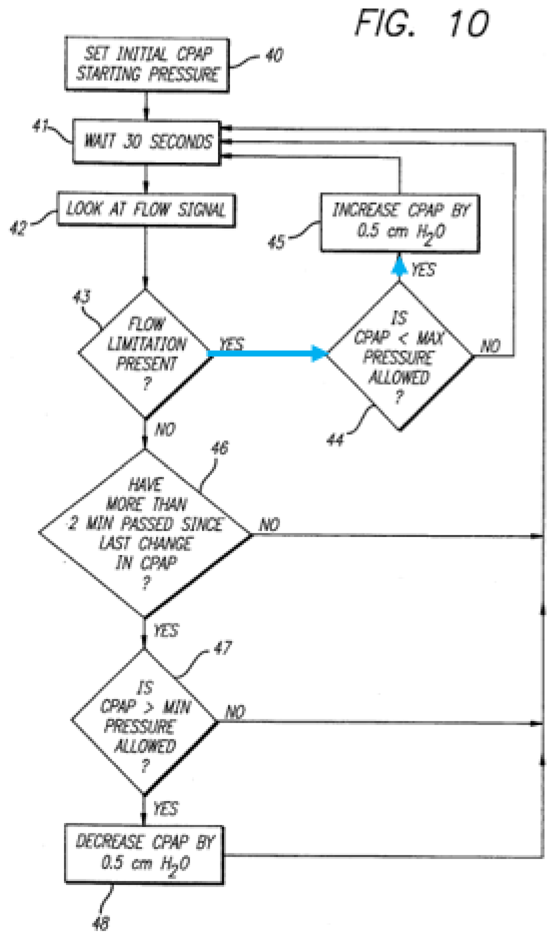
5. 1[c2]: *"the processing arrangement adjusting the applied pressure as a function of the patient's state"*

Rapoport502 discloses this limitation. Behbehani ¶128. 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. *See id.*, Fig. 8. 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 ¶128.

6. 1[d1]: *"wherein, when the breathing patterns indicate one states (i) and (ii) and (iii), the processing arrangement controls the generator to adjust the pressure to a first value and"*

Rapoport502 in view of Matthews or the knowledge of a POSITA discloses this limitation. Behbehani ¶¶129-147.

Rapoport502 teaches increasing the pressure upon detection of flow limitations or the presence of apnea, meaning *when the breathing patterns indicate a sleep disorder breathing state*, *the processing arrangement controls the generator to adjust the pressure to a first level*. Rapoport502 discloses *adjusting the supplied pressure to a first value* relative to determining a flow limitation state for the patient, as seen by Figure10. EX1008, Fig. 10 (reproduced below). Behbehani ¶¶130-31.



EX1008, Fig. 10 (annotated)

Figure 10 represents Rapaport's "automatic adjustment mode" effectuated by the *processing arrangement* in which "several input parameters…are used in the determination of the action to be taken." EX1008, 7:6-8. As seen in (blue), when the signal processor 24 determines "YES" for a flow limitation (Step 43), it applies *a pressure increase to the patient* of 0.5 cm H_20 (Step 45) provided that the current CPAP pressure is less than the maximum allowed (Step 44). *Id.*, 6:9-13; Behbehani ¶131.

Although Rapoport502 does not expressly disclose *adjusting the pressure to a first value* when breathing patterns indicates *a regular breathing pattern* or *a REM sleep state*, this limitation would have been obvious from Rapoport502 in view of Matthews or the knowledge of a POSITA. Behbehani ¶133.

a) Matthews or knowledge of a POSITA regarding adjusting the pressure upon detection of a regular breathing pattern or a REM sleep state.

It was known to a POSITA to adjust the pressure to a same first level (i.e., a therapeutic pressure) when breathing patterns indicate a sleep state (such as regular breathing, disordered breathing, or REM sleep). Behbehani ¶139.

This limitation would have been obvious in view of the knowledge of a POSITA. For example, during prosecution, the Examiner acknowledged that Burton845 "teaches determining sleep states, including sleep disordered states (i.e. hypopnea, obstructive apnea, central apnea, mixed apnea), REM sleep states, regular breathing states (stages 1, 2, 3, or 4 of sleep)" and "adjusting a CPA system in response to different states." EX1002, 120; Behbehani ¶140.

Similarly, Sullivan460 teaches "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. The first mode "provides a minimally intrusive air and pressure delivery to the patient, and hence is more comfortable," while the second mode "provides a relatively greater air and pressure delivery to the patient than in the first mode, which is sufficient to treat an air flow limitation." *Id.*, 6:32-7:2; Behbehani ¶141.

Providing a therapeutic pressure while the patient is asleep was an obvious design choice among a finite number of identified, predictable solutions. Behbehani ¶142.

b) Motivation to Combine

A POSITA would have been motivated to modify Rapoport502 in view of Matthews teachings on adjusting the pressure to a first value. Behbehani ¶¶143-45.

Further, it would have been obvious to a POSITA to modify the processing arrangement in Rapoport502 to adjust the pressure to a first value when the breathing patterns indicate states (i), (ii), or (iii). This modification would have incorporated a feature into Rapoport502's CPAP system that was already well-known. Further, a POSITA would have been motivated to implement an algorithm for patients to increase the applied pressure to a first value upon detection of different sleep states. A patient's muscle tone becomes more relaxed as the patient enters deeper levels of sleep. *See* Section IV.A.2 (Relationship Between Sleep and Breathing Patterns). A POSITA would understand that the pressure should be increased to a first value to prevent the airway from collapsing during these stages of sleep. Behbehani ¶230. For example, if a patient is vacillating between a regular breathing state and disordered breathing state, it could create too much instability to change the pressure between varying high pressures unique to each breathing state. *Id.* As such, a POSITA would be motivated to modify the *processing arrangement* to adjust the pressure to the first value for all three breathing patterns. Behbehani ¶145.

c) Reasonable Expectation of Success

A POSITA would reasonably expect success in modifying the processing arrangement in Rapoport502 to adjust the pressure to a first value when the breathing patterns indicate states (i), (ii), or (iii). Rapoport502 is already configured to monitor breathing patterns while the patient is asleep to determine a patient's pressure flow needs. Behbehani ¶146. A POSITA could have been able to program Rapoport502's CPAP system to maintain the same pressure at all three states, as it would just require the change in a variable. *Id*.

Given the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way. Behbehani ¶147.

7. 1[d2]: *"wherein, when the breathing patterns indicate state (iv), the processing arrangement controls the generator to adjust the pressure to a second value"*

Rapoport502 in view of Matthews discloses this limitation. Behbehani ¶¶148-50. As discussed in 1[c2], Rapoport502 teaches the processing arrangement adjusting the applied pressure as a function of the patient's state. *See* Section VIII.C.5 (Ground 1, 1[c2]).

Rapoport502's *processing arrangement* automatically decreases pressure if a flow limitation or other change in CPAP does not occur within a certain amount of time. *See* Section VIII.G.4 (Ground 1, 29[c]). This means the *flow generator* in Rapoport502 applies a lower pressure in the absence of snoring. Ex. 1005, 7:57-60; Behbehani ¶149.

Although Rapoport502 does not explicitly disclose this limitation, this limitation would have been obvious from Rapoport502 in view of Matthews. Behbehani ¶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. *Id.*, 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 '994 Patent's description of *troubled wakefulness* as "awake and anxious or distressed" (*id.*, 4:47-48) with "erratic" breathing (*id.* 4:47-59). When such a state is detected, Matthews taught to "interrupt the auto-CPAP controller if the patient's breathing pattern becomes too variable" and to "decrease[] the pressure delivered to the patient." *Id.*, 21:39-41, 23:67-24:1; Behbehani ¶152. This lower pressure is a *second value*. Behbehani ¶¶151-52.

b) Motivation to Combine and Reasonable Expectation of Success

A POSITA would have been motivated to modify Rapoport502's *processing arrangement* to *adjust the pressure to a second value* when in a troubled wakefulness, 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). Behbehani ¶153.

D. Dependent Claims 6-7, 10-13[6]

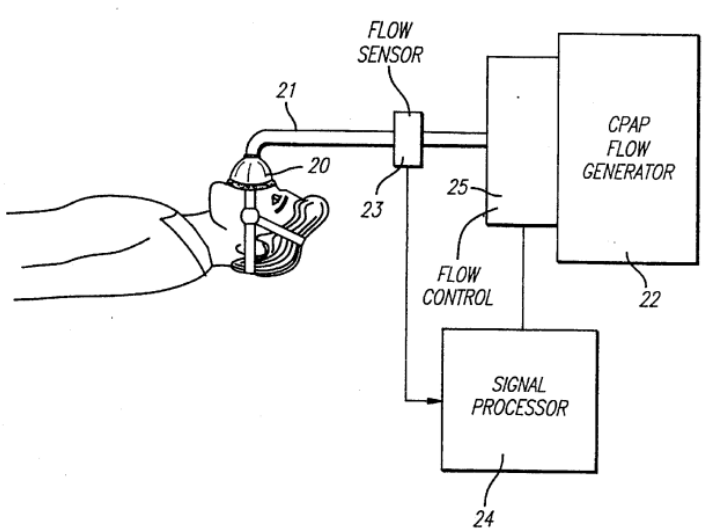
1. **Claim 6:** a mask paced on a face of the patient and covering at least one of the mouth and the nose of the patient.

Rapoport502 discloses this limitation. Behbehani ¶154. As shown in Fig. 9 below, Rapoport502 teaches *a mask placed on a face of the patient and covering at*

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

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.") Behbehani ¶154.

FIG. 9



Ex. 1008, Fig. 9

2. Claim 7: a tube connecting the mask to the flow generator for supplying the airflow to the patient.

Rapoport502 discloses this limitation. EX1008, 5:52-53 ("a CPAP mask 20 is connected via tube 21 to receive air from a CPAP flow generator 22"), Fig. 9, Behbehani ¶155.

3. Claim 10: the breathing patterns indicate a change from one of states (i), (ii), (iii) to the state (iv), the processing arrangement controls the generator to reduce pressure.

Rapoport502 in view of Matthews discloses this limitation. Behbehani ¶156. As discussed in 1[d2], the lower pressure applied when in a troubled wakefulness state is a *second value*. *See* Section VIII.C.7 (Ground 1, 1[d2]). Thus, a POSITA would understand that *when the breathing patterns indicate a change to state (iv)* from the higher pressure to the lower pressure, *the processing arrangement controls the generator to reduce the pressure.* Behbehani ¶156.

4. Claim 11: when the breathing patterns indicate a change from state (iv) to one of states (i), (ii), and (iii), the processing arrangement controls the generator to increase the pressure supplied by the generator.

Rapoport502 in view of Matthews discloses this limitation. Behbehani ¶157. As discussed in 1[d2], the lower pressure applied when in a troubled wakefulness state is a *second value*. *See* Section VIII.C.7 (Ground 1, 1[d2]). Thus, a POSITA would understand that *when the breathing patterns indicate a change from state (iv)* from the lower pressure to the higher pressure, *the processing arrangement controls the generator to increase the pressure supplied by the generator.* Behbehani ¶157.

5. Claim 12: when the breathing patterns, indicate one of an elevated upper airway resistance, hypopnea and a repetitive obstructive apnea, the processing arrangement controls the generator to increase the pressure supplied by the generator.

Rapoport502 discloses this limitation. Behbehani ¶158. Rapoport502 explains that when the breathing patterns indicate any flow limitation, including *an elevated upper airway resistance, hypopnea and a repetitive obstructive apnea*, the processor 24 *controls the generator to increase the pressure supplied by the* *generator*. EX1008, 5:41-45 ("FIG. 8 thus reflects the large increase in resistance across the Starling resistor, and mimics the increasingly negative intrathoracic pressure routinely seen in patients with an apnea, snoring and any increased upper airway resistance syndrome"), Behbehani ¶158.

6. **Claim 13:** when the detected breathing pattern is indicative of the state (iii), the processing arrangement controls to maintain a current level of the pressure supplied by the generator.

Rapoport502 in view of Matthews discloses this limitation. Behbehani ¶¶159-60. When the signal processor 24 (*processing arrangement*) determines "YES" for a flow limitation (Step 43), Rapoport502 *increases pressure applied to airway of patient* by 0.5 cm H_20 (Step 45). EX1008, 6:9-13, Fig. 10. A POSITA would have understood that Rapoport502's detected flow limitation occurs during an asleep state. *See* Section VIII.C.6 (Ground 1, 1[d1]). ¶159.

Although Rapoport502 does not expressly discloses *determining whether the breathing pattern is indicative of a REM asleep state*, this is taught by Matthews. A POSITA would have understood that if the patient was transitioning from one stage of sleep to *a REM sleep* (such as *a regular breathing state* to *a REM sleep state*), *the processing arrangement controls the generator to maintain a current level of the pressure supplied by the generator*. Matthews teaches that "the variable breathing control module 274 interrupts the operation of the auto-CPAP controller when breathing becomes unstable," such as when the patient is in REM sleep.

EX1007, 21:35-61. Matthews further teaches that the variable breathing control module will determine if "a prior pressure 326 is flat (not increasing, not decreasing)" and if so, "cause the pressure delivered to the patient to remain at the same level." *Id.*, 23:61-65. Thus, Matthews teaches that the *processing arrangement* will *maintain a current level of the pressure supplied by the generator* when *the breathing pattern is indicative of a REM sleep state.* ¶160.

E. Independent Claims 14, 28

1. **Preamble:** *"A method for treatment of sleeping disorder in a patient using a positive airway pressure, comprising the steps of:"*

To the extent limiting, Rapoport502 discloses the preamble. *See* VIII.C.1 (Ground 1, 1[preamble]/27[preamble]), Behbehani ¶161.

2. **14[a]/28[a]:** *"supplying an airflow to an airway of a patient using a flow generator;"*

Rapoport502 discloses this limitation. *See* Section VIII.C.2 (Ground 1, 1[a]/27[a]), Behbehani ¶162.

3. **14[b]/28[b]:** *"measuring, using a sensor, data indicative of the patient's breathing patterns;"*

Rapoport502 discloses this limitation. *See* Section VIII.C.3 (Ground 1, 1[b]/27[b]), Behbehani ¶163.

4. **14[c]/28[c]:** *"analyzing with the processing arrangement the data corresponding to the breathing patterns to determine whether the breathing patterns are indicative of at least one of the following patient states: (i) a regular breathing state, (ii) a*

sleep disordered breathing state, (iii) a REM sleep state, (iv) a troubled wakefulness state;"

Rapoport502 in view of Matthews discloses this limitation. *See* VIII.C.4 (Ground 1, 1[c1]/27[c]), Behbehani ¶164.

5. 14[d]: *"using the processing arrangement, controlling the generator to adjust the supplied pressure as a function of the patient's state;"*

Rapoport502 discloses this limitation. *See* Section VIII.C.5 (Ground 1, 1[c2]), Behbehani ¶165.

6. 14[e]: *"when the breathing patterns indicate one of states (i) and (ii) and (iii), controlling the generator to adjust the supplied pressure to a first value; and"*

Rapoport502 discloses this limitation under PO's construction as implied by PO's infringement allegations. Alternatively, Rapoport502 in view of the knowledge of a POSITA discloses this limitation under Petitioner's construction. *See* Section VIII.C.6 (Ground 1, 1[d1]), Behbehani ¶166.

7. 14[f]: *"when the breathing patterns indicate state (iv), controlling with the processing arrangement the flow generator to adjust the supplied pressure to a second value"*

Rapoport502 discloses this limitation under PO's construction of "troubled wakefulness" as implied by PO's infringement allegations. Alternatively, Rapoport502 in view of Matthews discloses this limitation under Petitioner's construction. *See* Section VIII.C.7 (Ground 1, 1[d2]), Behbehani ¶167.

F. Dependent Claims 19-20

1. **Claim 19:** placing a mask on a face of the patient and covering at least one of the mouth and the nose of the patient.

Rapoport502 discloses this limitation. *See* Section VIII.D.1 (Ground 1, Claim 6), Behbehani ¶168.

2. **Claim 20:** connecting to the mask to the generator using a tube.

Rapoport502 discloses this limitation. *See* Section VIII.D.2 (Ground 1, Claim 7), Behbehani ¶169.

3. **Claim 23:** controlling the generator to reduce the supplied pressure when the breathing pattern indicates a change from one of the states (i), (ii) & (iii) to the state (iv).

Rapoport502 discloses this limitation. *See* Section VIII.D.3 (Ground 1, Claim 10), Behbehani ¶170.

4. **Claim 24:** controlling the flow generator to increase the supplied pressure when the breathing pattern indicate change from state (iv) to one of states (i), (ii) & (iii).

Rapoport502 discloses this limitation. *See* Section VIII.D.4 (Ground 1, Claim 11), Behbehani ¶171.

5. **Claim 25:** controlling the generator to increase the supplied pressure when breathing pattern indicates one of an elevated upper airway resistance hypopnea and a repetitive obstructive apnea.

Rapoport502 discloses this limitation. *See* Section VIII.D.5 (Ground 1, Claim 12), Behbehani ¶172.

6. **Claim 26:** controlling the generator to maintain the supplied pressure at a current level when the breathing pattern indicates the state (iii)

Rapoport502 discloses this limitation. *See* Section VIII.D.6 (Ground 1, Claim 13), Behbehani ¶173.

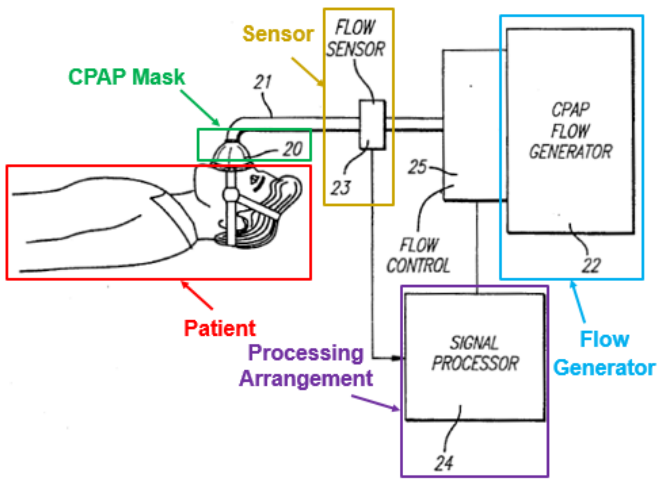
G. Independent Claims 29, 30

1. Preamble

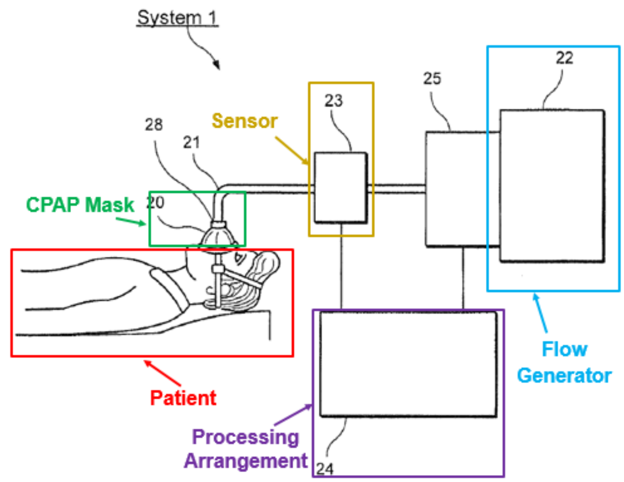
> 29[preamble]: *"A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:"*
>
> 30[preamble]: *"A method for treatment of sleeping disorder in a patient using a positive airway pressure, comprising the steps of:"*

To the extent limiting, Rapoport502 discloses the preamble. *See* Section VIII.C.1 (Ground 1, 1[preamble]/27[preamble]); Behbehani ¶174.

Rapoport502 discloses a continuous *positive airway pressure system for treatment of a sleeping disorder in a patient* in the same manner as the '994 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 ¶174.



Rapoport502, Fig. 9 (annotated)



'994 Patent, Fig. 1 (annotated)

2. Claim 29[a]/30[a]

29[a]: *"a generator supplying airflow and applying a pressure to an airway of a patient;"*

30[a]: "*supplying an airflow to an airway of a patient using a flow generator;"*

Rapoport502 discloses this limitation. *See* Section VIII.C.2 (Ground 1, 1[a]/27[a]), Behbehani ¶175.

3. Claim 29[b]/30[b]

29[b]: *"a sensor measuring data corresponding to a patient's breathing patterns; and"*

30[b]: "*measuring data corresponding to the patient's breathing patterns; and"*

Rapoport502 discloses this limitation. *See* Section VIII.C.3 (Ground 1, 1[b]/27[b]), Behbehani ¶176.

4. Claim 29[c]/30[c]

> 29[c]: *"a processing arrangement determining whether the breathing patterns are indicative of a troubled wakefulness state."*
>
> 30[c]: "*determining, based on the data, whether the breathing patterns are indicative of a troubled wakefulness state."*

Rapoport502 in view of Matthews discloses this limitation under Petitioner's construction of "troubled wakefulness." Behbehani ¶177.

Rapoport502's CPAP system includes a signal processor 24 (purple) corresponding to a *processing arrangement*. *See* Section VIII.C.4. The '994 Patent illustrates the processing arrangement 24 as a "black box" but does not disclose what constitutes the processing arrangement 24. *See id.*, Behbehani ¶177. Rapoport502 illustrates the signal processor 24 connected in the same manner, and further uses the term "signal processor" which had a well-understood structure to a POSITA akin to an arrangement of elements that performs processing. *Id*.

Although Rapoport502 does not explicitly disclose *breathing patterns indicative of a regular breathing pattern, a REM sleep state, and a troubled wakefulness state*, this limitation would have been obvious from Rapoport502 in view of Matthews. Behbehani ¶177.

a) Teachings of Matthews regarding "troubled wakefulness"

Matthews describes a CPAP system that detects and analyzes breathing patterns and supplies pressurized air to a patient based on the breathing pattern to support and treat breathing disorders. Ex. 1007, 1:15-22, 21:45-57; Behbehani ¶177.

Matthews discloses *determining whether a breathing pattern is indicative of a troubled wakefulness state* under Petitioner's construction. Behbehani ¶177. 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." Ex. 1001, 4:27-32; *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. Behbehani ¶177.

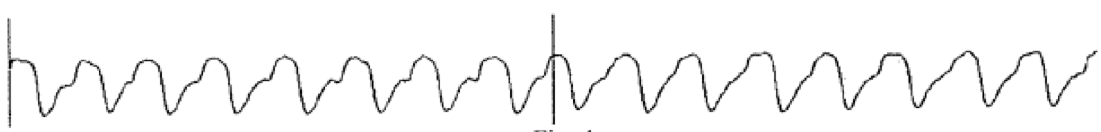


Fig. 4

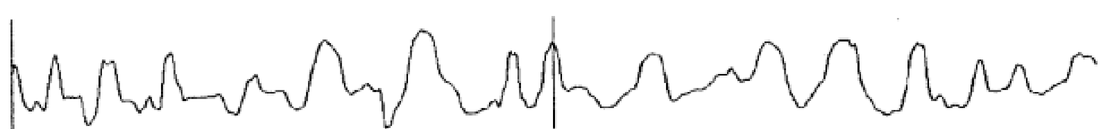


Fig. 7

Ex. 1001, Figures 4, 7.

Matthews recognizes that "[w]hen a patient is awake…or in distress, breathing tends to be more erratic and the Auto-CPAP trending becomes unstable." Ex. 1007, 21:37-40. To address potential instability, Matthews discloses "a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing." *Id.*, 40:25-30. The breathing control layer "performs statistical analysis on the scatter of the trended weighted peak flow data to detect unstable breathing patterns or abrupt changes in patient response," similar to those found in Figure 7. Matthews's disclosure of monitoring and detecting erratic or irregular breathing, meets the *determining whether a breathing pattern is indicative of a troubled wakefulness state* claim limitation. Behbehani ¶177.

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).

H. Dependent Claim 32

1. **Claim 32:** adjusting the airflow based on the state

Rapoport502 discloses this limitation. *See* Section VIII.C.5 (Ground 1, 1[c2]). Behbehani ¶178.

IX. GROUND 2: SULLIVAN995 IN VIEW OF MATTHEWS RENDERS OBVIOUS THE CHALLENGED CLAIMS

A. Motivation to Combine

It would have been obvious to a POSITA to modify Sullivan995 so that the *processing arrangement* in Sullivan995 determines whether the breathing patterns are indicative of a troubled wakefulness state and to adjust the pressure to a second value, as taught in Matthews. Behbehani ¶179. A POSITA would have been motivated to implement this modification to cause Sullivan995's CPAP system to apply a lower pressure upon detecting the patient's erratic breathing. Behbehani ¶180.

A POSITA would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment. As explained above, the modified CPAP system would apply a low pressure whenever the sensor detects that the patient has awakened. Reverting to a low pressure upon wake-up would add to patient comfort and decrease the likelihood that the patient will remove the mask due to uncomfortably high pressure. Sullivan995 strongly suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (which would include an awake period). EX1005, 10:13-46, 14:45-64. Moreover, as Sullivan995 explains, prior to Sullivan995, therapy pressure was often delivered at levels higher than necessary for substantial periods, causing discomfort (4:23-25), and Sullivan995 partially solves the problem by reducing the pressure at the beginning of therapy, when the patient connects themselves to the CPAP system. Behbehani ¶180.

B. Reasonable Expectation of Success

The POSITA would have had a reasonable expectation of success in making the modification to Sullivan995 CPAP system. Behbehani ¶181. Sullivan995 and Matthews are analogous art to the ’994 patent. All references describe CPAP systems with flow sensors and flow generators. Like Sullivan995 and the ’994 patent, Matthews discloses a “flow sensor 46 that measures a rate at which the breathing gas flows within patient circuit 34.” EX1007, 7:12-16. The data from the flow sensor are monitored and used to determine how to control the pressure delivered to the patient. *Id.*, 8:54-9:15. Behbehani ¶182.

Because the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements (adjusting pressure based on a patient’s state) according to known methods and known techniques (analyzing breathing patterns to determine whether the patient has an irregular breathing indicative of an awake state) to yield predictable results (lower pressure when the patient has an irregular breathing pattern indicative of an awake state), and involves use of a known technique to improve a similar device (CPAP machines) in the same way. Behbehani ¶183.

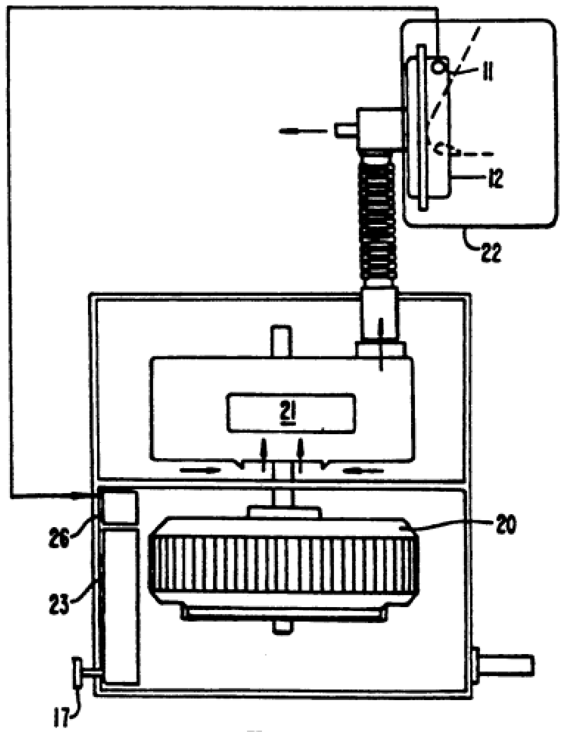
C. Independent Claims 1, 27

1. Preamble

To the extent limiting, Sullivan995 discloses the preamble. Behbehani ¶¶ 184-87. Sullivan995 discloses a “continuous positive airway pressure (CPAP)” system[7] which is *a positive airway pressure system*. EX1005, Fig. 3, Abstract, 1:33-36, 2:15-19, 9:57-58. Sullivan995's CPAP system "deliver[s] appropriate airway pressure" to the patient's airway passages. *Id.*, 2:15-16. As a POSITA would have understood, CPAP delivers "positive" airway pressure relative to atmospheric pressure. Behbehani ¶¶ 184-87.

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," meaning the CPAP system delivers the elevated air pressure *to an entrance of a patient's airways*. EX1005, cl. 6, 5:12-34, 10:67-11:4, 11:23-43. Behbehani ¶185.

[7] Sullivan995 refers to the same CPAP system of components as a CPAP apparatus, CPAP device, CPAP system, and CPAP unit. EX1005, 2:15-19, 9:57-64, 11:44-47, 11:55-56, 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.



Ex. 1005, Fig. 3

Sullivan995's CPAP system delivers the breathable gas in order to assist in *treatment of a sleeping disorder in a patient* by providing air pressure at a certain level to "prevent the onset of apnea" in the patient, where Sullivan995 characterizes sleep apnea as a complete occlusion of the upper airway passage during sleep, which is a *sleeping disorder*. *Id.*, 10:31-35, 1:20-31, 11:15-20; *see also* 1:32-48 (explaining that CPAP is used to "treat[] the occurrence of obstructive sleep apnea" and "is effective in treating central and mixed apnea"), Behbehani ¶186.

2. 1[a]/27[a]

Sullivan995 discloses this limitation. Behbehani ¶188. Sullivan995's CPAP system includes a motor 20 with a variable speed that drives a blower 21 (*flow* *generator*). EX1005, 9:57-64. The blower 21 is *supplying airflow and applying a pressure to an airway of a patient* by providing pressurized air to the patient. *Id.*, 9:60-64 ("[A]n increase in motor speed also increases the blower speed which in turn increases the output air pressure of the blower 21."); Behbehani ¶188.

3. 1[b]/27[b]

Sullivan995 discloses this limitation. *See* IX.G.3 (Ground 2, 29[b]/30[b]).

Sullivan995 discloses this limitation. Behbehani ¶¶189-98. Sullivan995's CPAP system includes a differential pressure sensor (microphone 11), which is a *sensor*. Ex. 1005, Fig. 3, 9:64-66; Behbehani ¶189. As shown in Figure 3 (reproduced below), "the snoring detection means 22 is a pressure detection means and microphone 11 is a ***differential pressure sensor***." EX1005, 9:66-10:1. (emphasis added). Sullivan995 explains that the microphone is a sound transducer that "consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate." *Id.*, 3:21-30 (emphasis added); *see also id.*, Abstract. This is consistent with the '994 Patent's description of "[c]onventional flow sensors 23" as "detect[ing] the rate of airflow to/from patent [sic] and/or a pressure supplied to the patent [sic]." Ex. 1001, 3:27-30 (emphasis added). By detecting respiratory parameters, microphone 11 is *measuring data* *corresponding to the patient's breathing patterns* as shown in Figures 1Aa, 1Bb, 2Aa, 2Bb, and 3. EX1005, 10:1-6. Behbehani ¶189.

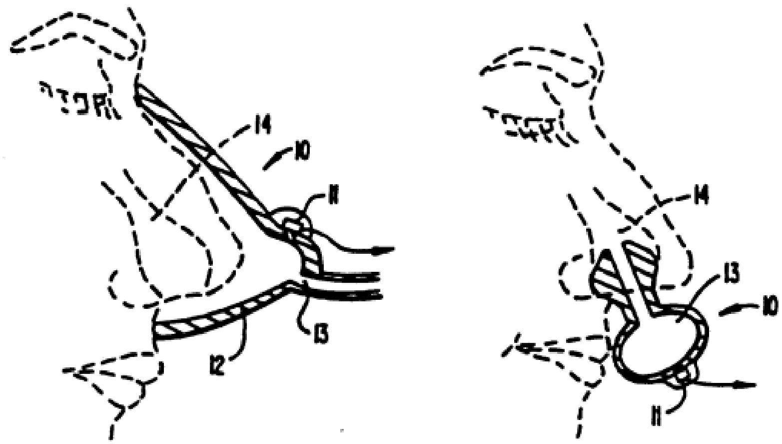


FIG. 1A. FIG. 1B.

4. 1[c1]/27[c]

Sullivan995 in view of Sullivan460 and Matthews renders obvious this limitation. Behbehani ¶¶199-218.

Sullivan995 discloses *a processing arrangement analyzing the breathing patterns*. Behbehani ¶200. The combination of an amplifier/filter/processor unit 26[8]

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[8] Sullivan995 refers to the same processor unit 26 as an amplifier/filter/processor unit 26, amplifier/filter/processor 26, and processor 26. EX1005, 10:3-6, 10:41-42, 10:56, 11:59, 14:51-52, 15:28-29, 15:61. For ease of reference, Petitioner refers to each as processor unit 26.

with a speed control unit 23[9] depicted in Figure 3 and described in part as the computing system in Figure 12 is *a processing arrangement.* As Sullivan995 describes, the microphone 11 (*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 ¶201.

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[9] Sullivan995 refers to the same speed control unit 23 as an electronic speed control unit 23, a speed control unit 23, a feedback speed controller 23, and a speed controller 23. EX1005, 9:59-60, 10:15, 11:63-64, 14:40-41, 15:2-3. For ease of reference, Petitioner refers to each as the speed control unit 23.

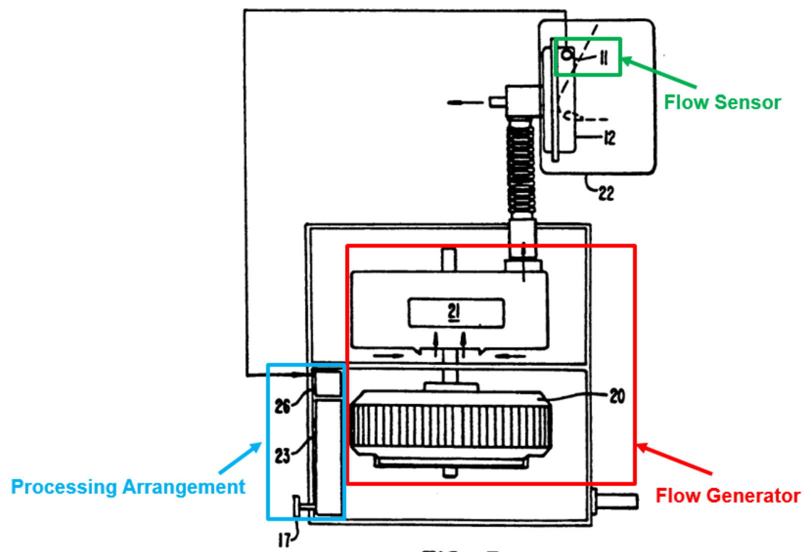


FIG. 3.

Further, Sullivan995 describes that the circuitry of the CPAP system in Figure 4 (and therefore in Figure 3 as well) includes the feedback speed controller 23 illustrated in Figure 12 (reproduced below annotated) in block form and includes a "computing system." EX1005, 17:3-4; Behbehani ¶202.

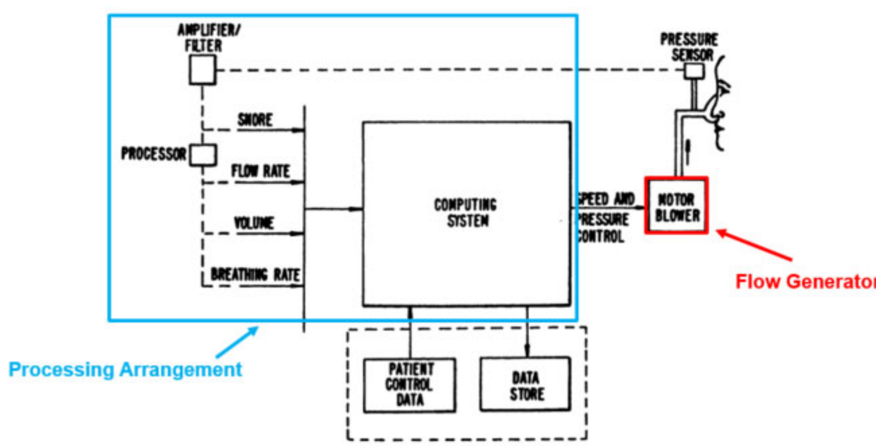


FIG. 12.

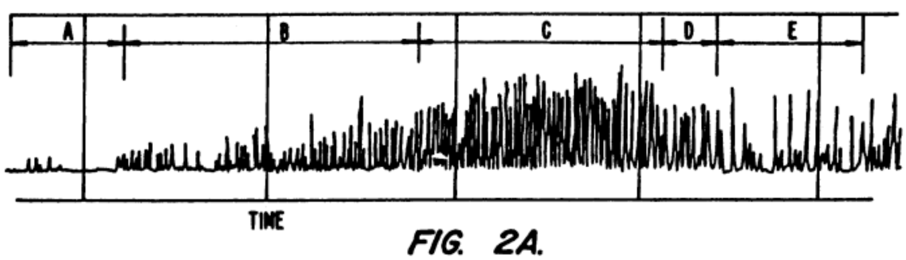
When Sullivan995 describes its Figure 12, Sullivan995 states "[t]he electrical signals from the pressure transducer are amplified and filtered to provide pressure waves of the desired frequencies indicative of snoring and breathing. The pressure wave indicative of breathing is further processed to generate signals indicative of flow rate, volume and breathing rate." EX1005, 17:6-12. As the POSITA would have readily understood, these steps of amplification, filtering, and processing would have been performed by the amplifier/filter/processor depicted in Figure 12 and would have therefore also been included as part of the amplifier/filter/processor unit 26 (which is included in the claimed *processing arrangement*) of Figures 3 and 4. Behbehani ¶203.

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." EX1005, 11:55-62; Behbehani ¶204.

Sullivan995 further discloses analyzing *breathing patterns indicative of a regular breathing state* and *a sleep disorder breathing state*. Behbehani ¶205. As Sullivan995 explains, in addition to detecting snoring, the 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, 4:31-453. Sullivan995 describes detecting "a snore, or snoring patterns or abnormal breathing pattern" after the patient has gone to sleep, and then increasing the CPAP pressure in response. *Id.*, 16:17-22, Behbehani ¶205.

Sullivan995 describes that if "for example 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 ¶206.

Another example of Sullivan995's identification of *breathing patterns indicative of a patient's state* is depicted in Figure 2A and described in the associated text. *Id.*, Figure 2A, Behbehani ¶207.



Ex. 1005, Fig. 2A

Specifically, Sullivan995 describes that the waveforms in Figure 2A depict various patient states (identified by the letters across the top of the chart) with normal breathing (part A), soft to moderate snoring (part B), constant loud snoring (part C), a pre-apneic pattern indicative of obstructive hypopnea (part D), and periods of silence punctuated by snoring, which is indicative of sleep apnea (part E). EX1005, 9:16-32, Behbehani ¶208. Part A of Figure 2A shows "normal breathing" and is therefore *(i) a regular breathing state*. Behbehani *Id*. Part E of Figure 2A is indicative of sleep apnea and therefore *(ii) a sleep disorder breathing state*. EX1001, 4:10-14 ("Indices of sleep disordered breathing include apnea"), Behbehani ¶208.

Sullivan995 discloses a breathing pattern associated with a REM sleep state shown in Parts B and C of Figure 2A. Specifically, Sullivan995 explains that "a patient's maximum propensity to suffer sleep apnea occurs during REM sleep." EX1005, 16:35-36. "An airway that was otherwise stable at a given CPAP pressure may become unstable during REM sleep." *Id.*, 16:26-38. Accordingly, Sullivan995 teaches that during REM sleep "snoring and/or particular deviations in breathing patterns will set in before apnea occurs." *Id.,* 16:38-40, *see also*, 16:36-44 ("An airway that was otherwise stable at a given CPAP pressure may become unstable during REM sleep. Should this happen snoring and/or particular deviation in breathing patterns will set in before apnea occurs. In such circumstances, the present invention will 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."), Behbehani ¶219.

a) Teachings of Sullivan460 and Matthews regarding sleep states.

As discussed with Ground 1, 1[c1]/27[c], Sullivan460 and Matthews teach *determining whether a breathing pattern is indicative of a REM sleep state* and *a troubled wakefulness state*. *See* Section VIII.C.4.a) (Ground 1, 1[c1]/27[c], discussing teachings of Sullivan460 and Matthews on sleep states). Behbehani ¶210.

b) Motivation to Combine

It would have been obvious to a POSITA to modify the *processing arrangement* in Sullivan995 to determine breathing patterns *indicative of a REM sleep state* and *a troubled wakefulness state*, as taught by Sullivan460 and Matthews, with a reasonable expectation of success. *See* Section IX.A (Ground 2, Motivation to Combine). 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 ¶211.

Importantly, Sullivan995 is a part Sullivan460. Specifically, Sullivan460 incorporates Sullivan995 by reference, stating: "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. Thus, Sullivan460 itself directs a POSITA to combine the teachings of Sullivan995 and Sullivan460. Behbehani ¶212.

Further, 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.*, Ex. 1005, 10:52-61. A POSITA would recognize, that one could increase the patient comfort, further than what is taught by Sullivan995, by detecting the transition of the patient from a sleep state to an awake state and lowering the pressure, as it was well known that lower pressure during an awake state would increase patient's comfort. *See* Section VII.A (Overview of the Technology). Hence, POSITA would have been motivated to combine the teaching of Matthews in detecting *troubled wakefulness state* breathing pattern (i.e., erratic breathing as taught by Matthews). 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. EX1005, 2:36-39, 2:42-46; Ex. 1007 at 21:40-44; Behbehani ¶213.

c) Reasonable Expectation of Success

A POSITA would have reasonably expected success in modifying the *processing arrangement* in Sullivan995 to *determin[e] whether the breathing patterns are indicative of a troubled wakefulness state*. *See* Section IX.B (Ground 2, Reasonable Expectation of Success). Behbehani ¶¶214-18.

Importantly, Sullivan460 incorporates Sullivan995 by reference. As such, a POSITA would understand that their teachings could be implemented together. Further, 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. A POSITA could have been able to program Sullivan995's CPAP system to incorporate the erratic flow detection algorithm disclosed in Matthews (EX1007, 15:13-28, Figs. 4A-C, 6). 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, 21:37-42. 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 ¶218.

5. 1[c2]

Sullivan995 discloses this limitation. Behbehani ¶¶219-21. 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 ¶219.

As described above, 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 ¶220.

Sullivan995 describes that a "predetermined deviation of any or all of the breathing parameters, flow rate, volume or breathing rate from a predetermined common value can generate a signal" that can be used to either increase or decrease the pressure based on the desired treatment of the pattern detected. *Id.* 15:34-44. Further, Sullivan995 describes that its invention "provides a CPAP device which modifies the CPAP pressure according to variations in a patient's requirements throughout an entire sleep period" and that it will be clear to those skilled in the art that Sullivan995 "can cope with the variation in airway pressure requirements such as may occur during a single sleep period." *Id.* 11:44-54; Behbehani ¶221.

6. 1[d1]

Sullivan995 in view of the knowledge of a POSITA discloses this limitation under Petitioner's construction. Behbehani ¶222-33.

a) Knowledge of a POSITA regarding adjusting the pressure to the same first level during sleep.

It was well-known to a POSITA to adjust the pressure to a same first level (i.e., a therapeutic pressure) when breathing patterns indicate a sleep state (such as regular breathing, disordered breathing, or REM sleep). Behbehani ¶227.

For example, during prosecution, the Examiner acknowledged that Burton845 "teaches determining sleep states, including sleep disordered states (i.e. hypopnea, obstructive apnea, central apnea, mixed apnea), REM sleep states, regular breathing states (stages 1, 2, 3, or 4 of sleep)" and "adjusting a CPA system in response to different states." EX1002, 120; Behbehani ¶140.

Similarly, Sullivan460 teaches "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. The first mode "provides a minimally intrusive air and pressure delivery to the patient, and hence is more comfortable," while the second mode "provides a greater air and pressure delivery to the patient than in the first mode, which is sufficient to treat an air flow limitation." *Id.*; Behbehani ¶141.

Providing a therapeutic pressure while the patient is asleep was an obvious design choice among a finite number of identified, predictable solutions. Behbehani ¶139.

b) Motivation to Combine

It would have been obvious to a POSITA to modify Sullivan995 so that the *processing arrangement* adjusts the pressure to a first value when breathing patterns indicate a sleep state (such as regular breathing, disordered breathing, or REM sleep). Behbehani ¶228.

First, such a modification would have been consistent with Professor Sullivan's other work. In particular, Sullivan460 taught a second mode of treatment to be applied when the patient is awake because it "provides a greater air and pressure delivery to the patient than in the first mode, which is sufficient to treat an air flow limitation." EX1006, 6:30-7:12; Behbehani ¶229.

Second, a POSITA would have been motivated to implement an algorithm for patients to increase the applied pressure to a first value upon detection of different sleep states. A patient's muscle tone becomes more relaxed as the patient enters deeper levels of sleep. *See* Section IV.A.2 (Relationship Between Sleep and Breathing Patterns). A POSITA would understand that the pressure should be increased to a first value to prevent the airway from collapsing during these stages of sleep. Behbehani ¶230. As such, a POSITA would be motivated to modify the *processing arrangement* to adjust the pressure to the same level for all three breathing patterns. *Id*.

c) Reasonable Expectation of Success

A POSITA would reasonably expect success in modifying Sullivan995 so that the processing arrangement in Sullivan995 adjust the pressure to a first value when the breathing patterns indicate states (i), (ii), or (iii). 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. A POSITA could have been able to program Sullivan995's CPAP system to maintain the same pressure at all three states, as it would just require the change in a variable. Behbehani ¶¶231-32.

Given the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements according to known methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way. Behbehani ¶233.

7. 1[d2]

Sullivan995 in view of Matthews discloses this limitation. Behbehani ¶234. As discussed in 1[c2] Sullivan995 teaches *the processing arrangement adjusting the applied pressure as a function of the patient's state*. *See* Section VIII.C.5 (Ground 2, 1[c2]). Behbehani ¶235-36.

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

See Section VIII.C.7.a) (Ground 1, 1[d2], teaching of Matthews). Behbehani ¶237.

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 VIII.A (Ground 2, Motivation to Combine) and VIII.B (Ground 2, Reasonable Expectation of Success). Behbehani ¶230. Behbehani ¶238.

D. Dependent Claims 6-7, 10-13

1. Claim 6

Sullivan995 discloses this limitation. Behbehani ¶¶239-40. 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, 8:47-60. Behbehani ¶239.

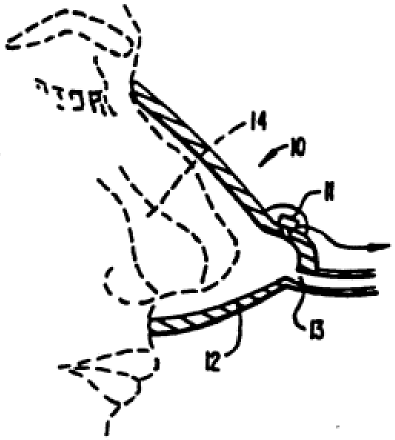


FIG. 1A.

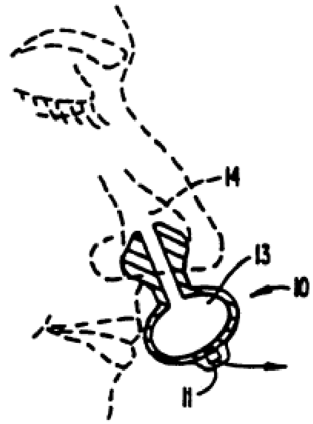


FIG. 1B.

Sullivan995 therefore discloses a mask paced on a face of the patient and covering at least one of the mouth and the nose of the patient. Behbehani ¶240.

2. Claim 7

Sullivan995 discloses this limitation. Behbehani ¶241. For example, Sullivan995 discloses that there is an air line that connect the compressor to the nose piece. *See e.g.,* EX1005, 7:13-25; *see also* Fig. 3. Behbehani ¶241.

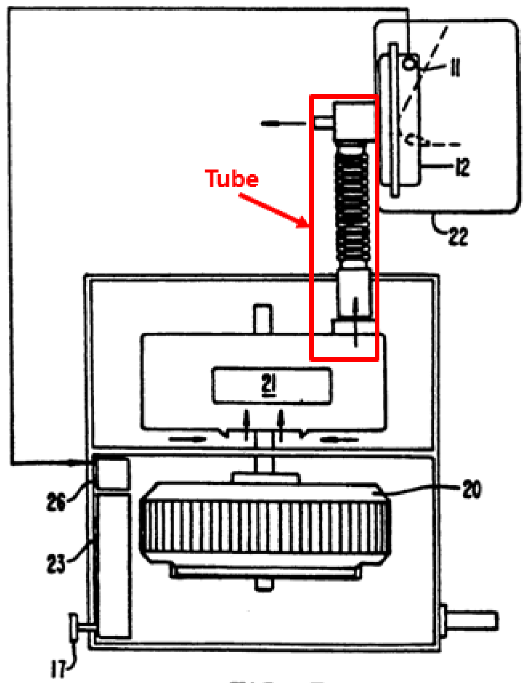


FIG. 3

Ex. 1005, Fig. 3 (annotated)

3. Claim 10

Sullivan995 in view of Matthews discloses this limitation. Behbehani ¶242. As discussed in 1[d2], the lower pressure applied when in a troubled wakefulness state is a *second value*. *See* Section IX.C.7 (Ground 2, 1[d2]). Thus, a POSITA would understand that *when the breathing patterns indicate a change to state (iv)* from the higher pressure to the lower pressure, *the processing arrangement controls the generator to reduce the pressure.* Behbehani ¶242.

4. Claim 11

Sullivan995 in view of Matthews discloses this limitation. Behbehani ¶243. As discussed in 1[d2], the lower pressure applied when in a troubled wakefulness state is a *second value*. *See* Section VIII.C.7 (Ground 1, 1[d2]). Thus, a POSITA would understand that *when the breathing patterns indicate a change from state (iv)* from the lower pressure to the higher pressure, *the processing arrangement controls the generator to increase the pressure supplied by the generator.* Behbehani ¶243.

5. Claim 12

Sullivan995 discloses this limitation. Behbehani ¶244. For example, Sullivan995 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." EX1005, at 16:35-44. Behbehani ¶244.

6. Claim 13

Sullivan995 discloses this limitation. Behbehani ¶245. Sullivan995 teaches: "The speed and pressure are increased until signals are detected from the patient are within acceptable range of control values or patterns and the speed and pressure are maintained at that level." EX1005, 17:24-27. A POSITA would have understood this to mean that when breathing patterns during REM sleep are acceptable (i.e., do not include obstructions), the pressure would be maintained at the current level. Behbehani ¶245.

E. Independent Claims 14, 28

1. Preamble

To the extent limiting, Sullivan995 discloses the preamble. Behbehani ¶246, EX1005, 1:14-17, 1:20-22. As discussed for 29[preamble]/30[preamble], Sullivan995's *positive airway pressure delivery system* employs a method for "treatment of partial or complete upper airway occlusion" such as "snoring and sleep apnea", which is a *method for treatment of a sleeping disorder in a patient using a positive airway pressure. See* Section IX.G.1 (Ground 2, 29[preamble]/30[preamble]).

2. 14[a]/28[a]

Sullivan995 discloses this limitation. *See* Section IX.G.1 (Ground 2, 29[a]/30[a]), Behbehani ¶247.

3. 14[b]/28[b]

Sullivan995 discloses this limitation. Behbehani ¶248. Sullivan995's CPAP system includes a differential pressure sensor (microphone 11), which is a *sensor*. Ex. 1005, Fig. 3, 9:64-66, Behbehani ¶248. As shown in Figure 3 (reproduced below), "the snoring detection means 22 is a pressure detection means and microphone 11 is a ***differential pressure sensor***." EX1005, 9:66-10:1. (emphasis added). Sullivan995 explains that the microphone is a sound transducer that "consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the rate of breathing, inhaled air flow or inhaled air flow rate." *Id.*, 3:21-30 (emphasis added); *see also id.*, Abstract. This is consistent with the '994 Patent's description of "[c]onventional flow sensors 23" as "detect[ing] the rate of airflow to/from patent [sic] and/or a pressure supplied to the patent [sic]." Ex. 1001, 3:27-30 (emphasis added). By detecting respiratory parameters, microphone 11 is *measuring data corresponding to the patient's breathing patterns* as shown in Figures 1A, 1B, 2A, 2B, and 3. EX1005, 10:1-6. Behbehani ¶248.

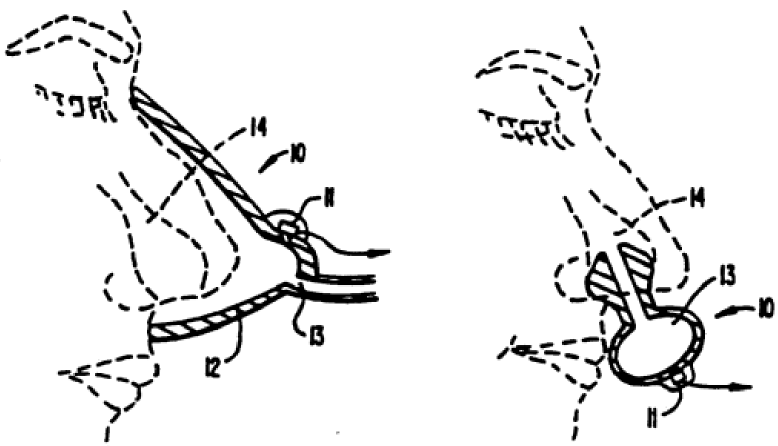


FIG. 1A. FIG. 1B.

4. 14[c]/28[c]

Sullivan995 discloses this limitation under PO's construction of "troubled wakefulness" as implied in PO's infringement allegations. Alternatively, Sullivan995 in view of Matthews discloses this limitation under Petitioner's construction of "troubled wakefulness." *See* Section IX.C.4 (Ground 2, 1[c1]/27[c]), Behbehani ¶249.

5. 14[d]

Sullivan995 discloses this limitation. *See* IX.H.1 (Ground 2, Claim 32), Behbehani ¶250.

6. 14[e]

Sullivan995 in view of the knowledge of a POSITA discloses this limitation under Petitioner's construction. *See* Section IX.C.6 (Ground 2, 1[d1]), Behbehani ¶251.

7. 14[f]

Sullivan995 in view of Matthews discloses this limitation under Petitioner's construction. *See* Section IX.C.7 (Ground 2, 1[d2]), Behbehani ¶252.

F. Dependent Claims 19-20, 23-26

1. Claim 19

Sullivan995 discloses this limitation. *See* Section IX.D.1 (Ground 2, Claim 6), Behbehani ¶253.

2. Claim 20

Sullivan995 discloses this limitation. *See* Section IX.D.2 (Ground 2, Claim 7), Behbehani ¶254.

3. Claim 23

Sullivan995 discloses this limitation. *See* Section IX.D.3 (Ground 2, Claim 10), Behbehani ¶255.

4. Claim 24

Sullivan995 discloses this limitation. *See* Section IX.D.4 (Ground 2, Claim 11), Behbehani ¶256.

5. Claim 25

Sullivan995 discloses this limitation. *See* Section IX.D.5 (Ground 2, Claim 12), Behbehani ¶257.

6. Claim 26

Sullivan995 discloses this limitation. *See* Section IX.D.6(Ground 2, Claim 13), Behbehani ¶258.

G. Independent Claims 29, 30

1. Preamble

To the extent limiting, Sullivan995 discloses the preamble. Behbehani ¶259, EX1005, 1:14-17, 1:20-22. As discussed for Section IX.C.1 (Ground 2, 1[preamble]/27[preamble]), Sullivan995 discloses the recited *positive airway pressure system for treatment of a sleeping disorder in a patient*. *See id*.

2. Claim 29[a]/30[a]

Sullivan995 discloses this limitation. *See* Section IX.C.2 (Ground 2, 1[a]/27[a]). Behbehani ¶260.

3. Claim 29[b]/30[b]

Sullivan995 discloses this limitation. *See* Section VIII.C.3 (Ground 2, 1[b]/27[b]), Behbehani ¶261.

4. Claim 29[c]/30[c]

Sullivan995 in view of Matthews discloses this limitation under Petitioner's construction of "troubled wakefulness." Behbehani ¶262.

Sullivan995 discloses a *processing arrangement*. Behbehani ¶262. The combination of an amplifier/filter/processor unit 26[10] with a speed control unit 23[11] depicted in Figure 3 and described in part as the computing system in Figure 12 is *a processing arrangement.* As Sullivan995 describes, the microphone 11 (*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,

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[10] Sullivan995 refers to the same processor unit 26 as an amplifier/filter/processor unit 26, amplifier/filter/processor 26, and processor 26. EX1005, 10:3-6, 10:41-42, 10:56, 11:59, 14:51-52, 15:28-29, 15:61. Petitioner refers to each as processor unit 26.

[11] Sullivan995 refers to the same speed control unit 23 as an electronic speed control unit 23, a speed control unit 23, a feedback speed controller 23, and a speed controller 23. EX1005, 9:59-60, 10:15, 11:63-64, 14:40-41, 15:2-3. Petitioner refers to each as the speed control unit 23.

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 ¶262.

a) Teachings of Matthews regarding "troubled wakefulness."

See VIII.G.4.a) (Ground 1, 29[c]/30[c]).

b) Motivation to Combine

It would have been obvious to a POSITA to modify the *processing arrangement* in Sullivan995 to *determin[e] whether the breathing patterns are indicative of a troubled wakefulness state*, as taught by Matthews. *See* Section IX.A (Ground 2, Motivation to Combine). 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 ¶262.

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 ¶262. 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 ¶262.

c) Reasonable Expectation of Success

A POSITA would have reasonably expected success in modifying the *processing arrangement* in Sullivan995 to *determin[e] whether the breathing patterns are indicative of a troubled wakefulness state*. 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. A POSITA could 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 ¶262. 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 ¶262.

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 ¶262.

H. Dependent Claim 32

1. Claim 32

Sullivan995 discloses this limitation. *See* Section IX.C.5 (Ground 2, Claim 1[c2]), Behbehani ¶263.

X. GROUND 3: SULLIVAN995 ANTICIPATES THE CHALLENGED CLAIMS

Under Petitioner's constructions, Sullivan995 discloses each and every limitation of the challenged claims except for "a troubled wakefulness state" (claims 1, 14, 27, 28, 29, 30) and "configured…to determine to which of the following states the detected breathing pattern is indicative" (claim 7). *See* Section IX. Behbehani ¶264.

But under PO's implied constructions, Sullivan995 anticipates the challenged claims. Behbehani ¶265.

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. Behbehani ¶266. 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. 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."). Behbehani ¶¶267-68.

Sullivan995 teaches providing lower pressure when the system has not determined the patient is asleep, like the Complaint. Sullivan995 describes that if "in the early stages of sleep some lesser CPAP pressure will suffice, the CPAP unit [] 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. Figure 13 of Sullivan995 shows that the pressure will remain low until breathing events occur indicating that the patient is asleep. Behbehani ¶269.

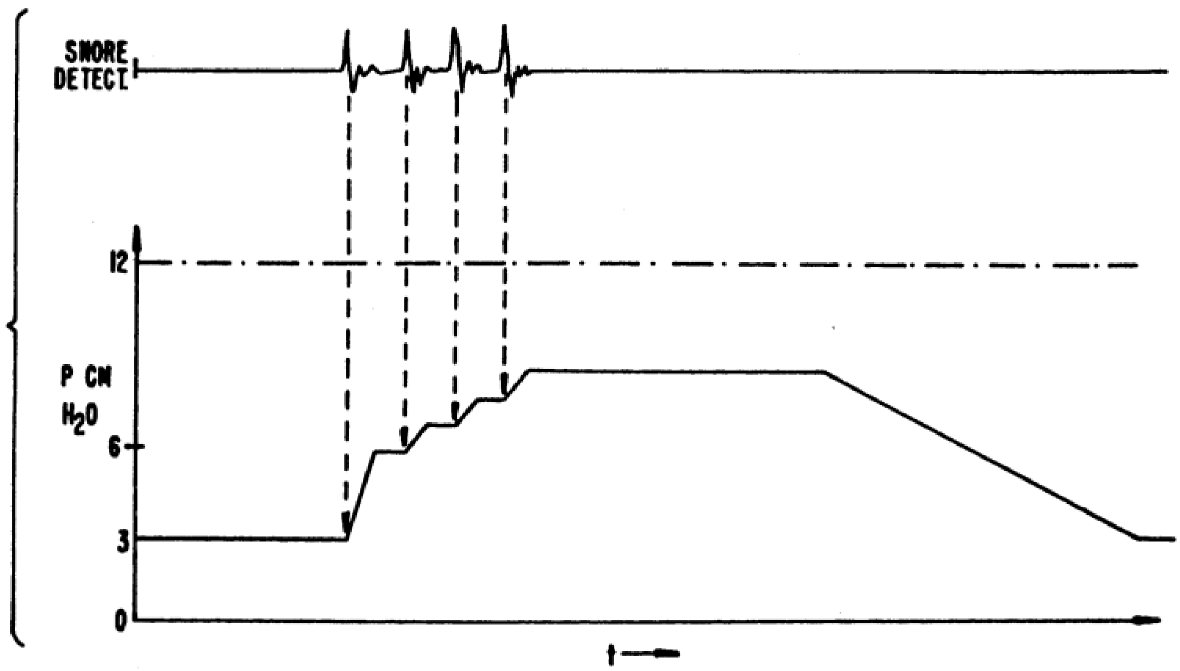

FIG. 13.

EX1005, Fig. 13

As Sullivan995 explains, additionally microphone 11 (flow *sensor*) detects "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 ¶¶264-73. Thus, under PO's implied construction, the absence of breathing patterns indicative of sleep is *indicative of a troubled wakefulness state*. Behbehani ¶¶270-73.

B. "when the breathing patterns indicate one of states (i) and (ii) and (iii),…adjust the [supplied] pressure to a first value " (cls. 1, 14)

Because the *processing arrangement* of Sullivan995 is configured to *adjust the [supplied] pressure to a first value* when the breathing patterns indicate that the patient is in *a sleep disorder breathing state* (i.e., *when the breathing patterns indicate of states (i) and (ii) and (iii*), Sullivan995 discloses this limitation under PO's constructions as implied in PO's infringement allegations. Behbehani ¶¶274-78. In its Complaint, PO alleges that a processing arrangement meets this limitation when it determines the detected breathing pattern of at least one of the states (not all of the listed states). EX1018, ¶ 101 (citing to EX1033, EX1019). Specifically, PO alleges that the AutoSet™ algorithm meets this limitation simply by controlling the "generator to adjust the pressure to a first value," i.e. the prescribed treatment pressure level when a sleep disorder breathing state is detected. *Id.*; Behbehani ¶276.

Sullivan995 teaches that when the breathing patterns indicate a sleep disorder breathing state, to adjust the pressure to a prescribed treatment pressure, just as alleged in the Complaint. Behbehani ¶277. 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*) measures 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 ¶272, 274-77. As Sullivan995 explains with reference to Figure 3, "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-16. Thus, under PO's implied construction, adjusting the pressure to a higher level when a snore or abnormal breathing pattern is detected is sufficient to meet this limitation. Behbehani ¶278.

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 the challenged claims.

Respectfully submitted,
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Claims Listing (Appendix)

1. A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:

   [a] a generator supplying airflow and applying a pressure to an airway of a patient;

   [b] a sensor measuring data corresponding to patient's breathing patterns; and

   [c1] a processing arrangement analyzing the breathing patterns to determine whether the breathing patterns are indicative of one of the following patient's states: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state, [c2] the processing arrangement adjusting the applied pressure as a function of the patient's state,

   [d1] wherein, when the breathing patterns indicate one of states (i) and (ii) and (iii), the processing arrangement controls the generator to adjust the pressure to a first value and [d2] wherein, when the breathing patterns indicate state (iv), the processing arrangement controls the generator to adjust the pressure to a second value.

6. The system according to claim 1, further comprising: a mask placed on a face of the patient and covering at least one of the mouth and the nose of the patient.

7. The system according to claim 6, further comprising: a tube connecting the mask to the flow generator for supplying the airflow to the patient.

10. The system according to claim 1, wherein when the breathing patterns indicate a change from one of states (i), (ii), (iii) to the state (iv), the processing arrangement controls the generator to reduce the pressure.

11. The system according to claim 1, wherein when the breathing patterns indicate a change from state (iv) to one of states (i), (ii) and (iii), the processing arrangement controls the generator to increase pressure supplied to by the generator.

12. The system according to claim 1, wherein when the breathing patterns indicate one of an elevated upper airway resistance, hypopnea and a repetitive obstructive apnea, the processing arrangement controls the generator to increase the pressure supplied by the generator.

13. The system according to claim 1, wherein when the detected breathing pattern is indicative of the state (iii), the processing arrangement controls the generator to maintain a current level of the pressure supplied by the generator.

14. A method for treatment of sleeping disorder in a patient using a positive airway pressure, comprising the steps of:

[a] supplying an airflow to an airway of a patient using a flow generator,

[b] measuring data corresponding to the patient's breathing patterns,

[c] analyzing with the processing arrangement the data corresponding to the breathing patterns to determine whether the breathing patterns are indicative of at least one of the following patient states: (i) a regular breathing state, (ii) a sleep disorder breathing State, (iii) a REM sleep state, and (iv) a troubled wakefulness state;

[d] using the processing arrangement, controlling the generator to adjust the supplied pressure as a function of the patient's state; and

[e] when the breathing patterns indicate one of states (i) and (ii) and (iii), controlling the generator to adjust the supplied pressure to a first value; and

[f] when the breathing patterns indicate state (iv), controlling with the processing arrangement the flow generator to adjust the supplied pressure to a second value.

19. The method according to claim 14, further comprising the step of:

placing a mask on a face of the patient and covering at least one of the mouth and the nose of the patient.

20. The method according to claim 19, further comprising the step of:

connecting to the mask to the generator using a tube.

23. The method according to claim 14, further comprising the step of:

controlling the generator to reduce the supplied pressure when the breathing pattern indicates a change from one of the states (i), (ii) & (iii) to the state (iv).

24. The method according to claim 14, further comprising the step of:

controlling the flow generator to increase the supplied pressure when the breathing pattern indicate change from the state (iv) to one of the states (i), (ii) & (iii).

25. The method according to claim 14, further comprising the step of:

controlling the generator to increase the supplied pressure when the breathing pattern indicates one of an elevated upper airway resistance, hypopnea and a repetitive obstructive apnea.

26. The method according to claim 14, further comprising the step of:

controlling the generator to maintain the supplied pressure at a current level when the breathing pattern indicates the state (iii).

27. A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:

[a] a generator supplying airflow and applying a pressure to an airway of a patient;

[b] a sensor measuring data corresponding to patient's breathing patterns; and

[c] a processing arrangement analyzing the breathing patterns to determine which one of the following patient's states the breathing patterns are indicative of: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state.

28. A method for treatment of sleeping disorder in a patient wing a positive airway pressure, comprising the steps of:

[a] supplying an airflow to an airway of a patient using a flow generator,

[b] measuring data corresponding to the patient's breathing patterns, and

[c] analyzing data corresponding to the breathing patterns to determine which one of the following patient's states the breathing patterns are indicative of: (i) a regular breathing state, (ii) a sleep disorder breathing state, and one of (iii) a REM sleep state and (iv) a troubled wakefulness state.

29. A positive airway pressure system for treatment of a sleeping disorder in a patient, comprising:

[a] a generator supplying airflow and applying a pressure to an airway of a patient;

[b] a sensor measuring data corresponding to patient's breathing patterns; and

[c] a processing arrangement determining whether the breathing patterns are indicative of a troubled wakefulness state.

30. A method for treatment of sleeping disorder in a patient using a positive airway pressure, comprising the steps of:

[a] supplying an airflow to an airway of a patient using a flow generator,

[b] measuring data corresponding to the patient's breathing patterns, and

[c] determining, based on the data, whether the breathing patterns are indicative of a troubled wakefulness state.

32. The method of claim 30, further comprising:

adjusting the airflow based on the state.

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

Under 37 C.F.R. § 42.24(b)(1), the undersigned certifies that the foregoing Petition contains 13,995 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. 6,988,994 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 FEDERAL EXPRESS next business day delivery on June 1, 2022:

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