UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ResMed Inc.,
Petitioner,

v.

New York University,

Patent Owner,

Case No. IPR2022-00989

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,427,539

Claims 1-2, 5-11, 13, 15-30

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1027	ResMed, "AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1," (1999)
1028	ResMed, "Auotset T, Optimal Therapy for your OSA Patients," (2000)
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1035	F. Roux, et al., "Continuous Positive Airway Pressure: New Generations," Clinics in Chest Medicine (2003)
1036	V. Hoffstein, et al., "Treatment of Obstructive Sleep Apnea with Nasal Continuous Positive Airway Pressure," Am. Rev. Respir. Dis. (1992)
1037	R. Berry, et al., "The Use of Auto-Titrating Continuous Positive Airway Pressure Treatment of Adult Obstructive Sleep Apnea," (2002)

I. INTRODUCTION

ResMed Inc. ("ResMed" or "Petitioner") respectfully requests *inter partes* review of claims 1-2, 5-11, 13, 15-30 of U.S. Patent No. 9,427,539 (EX1001, "'539 Patent").

Positive airway pressure (PAP) systems to address sleep apnea were invented by Professor Colin Sullivan and his colleagues at the University of Sydney in 1981. EX1001, 1:58-67. Applying air pressure to keep a patient's airway open, these PAP machines improve sleep quality for patients with snoring or other breathing problems during sleep. Patients, however, often struggle to use PAP systems because of the discomfort caused by the high pressure while awake. The '539 Patent addresses this problem by automatically increasing the pressure when the patient is asleep and decreasing the pressure when the patient is awake. But this feature was by no means inventive in August 2003—the claimed priority date for the '539 Patent. By 2003, Professor Sullivan and his colleagues had already published numerous references disclosing this feature. This prior art includes WO 01/05460 (EX1006, "Sullivan460"), which discloses "a first mode for use when the patient is awake, and a second mode for use when the patient is asleep" to provide "minimally intrusive air and pressure delivery to the patient, and hence is more comfortable." EX1006, 6:30-32. The Examiner did not consider Sullivan460 when allowing the '539 Patent.

Accordingly, ResMed respectfully requests the Board institute review and find all challenged claims of the '539 Patent unpatentable.

II. MANDATORY NOTICES

A. Real Party-in-Interest

The real party-in-interest is ResMed Inc.

B. Related Matters

U.S. Patent Office records indicate that the '539 Patent is assigned to New York University ("PO"), which is currently asserting the '539 Patent in the following concurrent litigation filed on June 2, 2021: *New York University v. ResMed Inc*., 1:21-cv-00813-JPM (D. Del.).

Petitioner has filed, at substantially the same time that this Petition was filed, petitions for *inter partes* review against related family members U.S. Patent No. 6,988,994, U.S. Patent No. 9,108,009, U.S. Patent No. 9,168,344, U.S. Patent No. 9,533,115, 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 '539 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from

requesting an *inter partes* review challenging the patent claims on the ground identified in this Petition.

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

Ground 1: Claims 1-2, 5-11, 13, 15-30 are obvious under 35 U.S.C. § 103 over Sullivan995[1] in view of Sullivan460[2].

Ground 2: Claims 1-2, 5-11, 13, 15-30 are obvious under 35 U.S.C. § 103 over Rapoport502[3] in view of Sullivan460.

Ground 3: Claims 1-2, 5-11, 13, 15-30 are anticipated under 35 U.S.C. § 102 by Sullivan995.

Ground 4: Claims 1-2, 5-11, 13, 15-30 are anticipated under 35 U.S.C. § 102 by Rapoport502.

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[1] U.S. Patent No. 5,245,995 (EX1005, "Sullivan995") is §§ 102 (a), (b), and (e) prior art.

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

[3] U.S. Patent No. 5,490,502 (EX1008, "Rapoport502") is §§ 102 (a) and (b) prior art.

IV. BACKGROUND

A. Overview of the Technology

1. PAP Machines

"Obstructive sleep apnea syndrome (OSAS) is a well recognized disorder…[and] one of the most common causes of excessive daytime somnolence." EX1001, 1:7-10. OSAS "is characterized by an intermittent obstruction of [a patient's] upper airway occurring during sleep." *Id.*, 1:13-16. "The obstruction results in a spectrum of respiratory disturbances ranging from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring)." *Id.*, 1:16-20. Because apnea, hypopnea, and heavy snoring produces decreased blood oxygenation, they "are recognised [] causes of sleep disruption and risk factors in certain types of heart disease." EX1013, 1:27-28, 1:43-48; *see also* Behbehani ¶¶32-33.

Positive airway pressure (PAP) therapy has been "the mainstay of treatment" since Dr. Colin Sullivan, Dr. Michael Berthon-Jones, and their colleagues first applied it to treat OSAS in 1981. EX1001, 2:1-8; EX1014, 1 (citing EX1015). "[T]he upper airway during sleep mimics the behavior of a collapsible tube." EX1014, 1. To prevent this collapse, positive airway pressure can oppose the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). *Id.*; *see also* Behbehani ¶¶33-37.

Generally, a prescription and patient training for PAP therapy is "performed in, or directly under, the supervision of the sleep disorders laboratory." EX1014, 5. After a full night of observation in the laboratory, a physician will prescribe a therapeutic pressure for the patient and PAP machine for home use. But, as PAP therapy research developed, the industry began examining a variable approach that "would improve on, and possibly do away with, the one-size-fits-all pressure determination night." EX1012, 1; Behbehani ¶38.

By 1993, 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.*, 1. "The major limitation of CPAP therapy relates to discomfort or other factors leading to incomplete compliance with the necessary use of the device." EX1014, 5; EX1016, 1 ("Patients often complain of side effects caused by NCPAP treatment, including nasal congestion, dry mouth, difficulty exhaling, and nocturnal awakenings."). By the mid-1990s, it was well-recognized that lowering the pressure when the patient is awake could increase compliance. *See* EX1012, 4 ("lower pressure … will be more comfortable for the patient, particularly when they are awake, which may result in a higher compliance and better CPAP therapy than may result from a very high pressure"). As Dr. Berthon-Jones explained, "patients feel

uncomfortable at high CPAP pressures," and will "object violently to [high pressure] while they are wide awake trying to go to sleep on an ordinary night." *Id.*, 4; *see also* Behbehani ¶¶39-42.

Consequently, automatically adjusting PAP machines became common, particularly those that "while the subject is awake…automatically adjust the degree of assistance to maintain at least a specified minimum ventilation." EX1017, Abstract. By 2003, machines for delivering PAP therapy were on the market that included one or more sensors and a processing unit that could detect breathing patterns and adjust pressure as appropriate based on those breathing patterns. Ex. 1035, 2; EX1037, 2; *see also* Behbehani ¶¶43-48.

2. Sleep and Breathing Patterns

"Sleep is not a simple linear process whereby an individual enters into stage I non-REM sleep at the beginning of the night, progresses through to stage IV sleep, enters REM sleep, and then wakes up in the morning." EX1021, 1. "Rather, repeated episodes of non-REM and REM sleep alternate cyclically through the night." *Id.* "Frequently, a patient awakens during a period of extended sleep for any number of reasons," although "the time require for a patient to fall back to sleep once awakened is less than that initially required." EX1022, 16:39-42. The typical sleep pattern in a young adult is shown below. Behbehani ¶¶49-50.

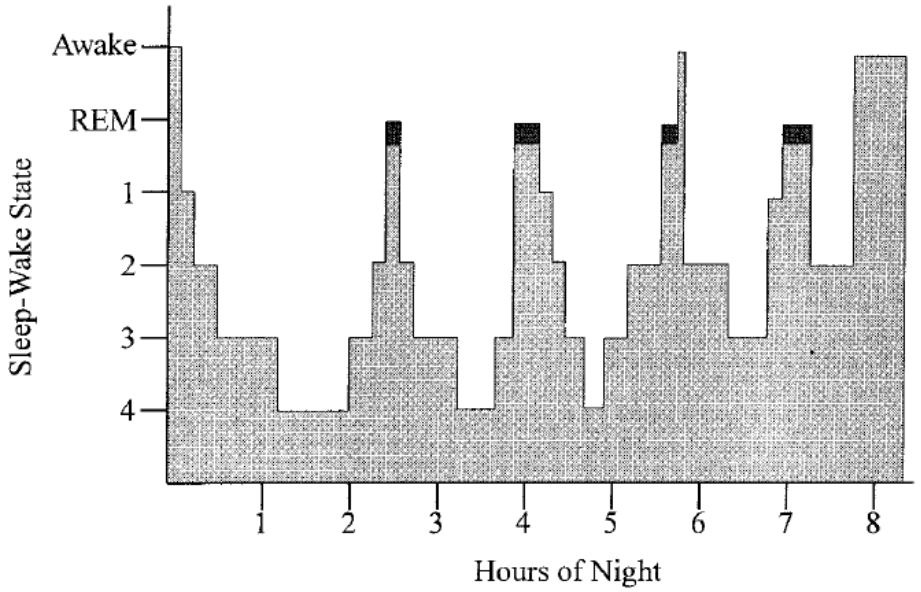


FIG. 2.

EX1021, Fig. 2

At different sleep-wake states, an individual will exhibit different breathing patterns. "[O]verall tidal volume and respiratory rate are stable in non-REM sleep but are characteristically irregular in REM sleep." EX1021, 8. Importantly, "postural muscle tone is highest in wakefulness, decreased in non-REM sleep, and minimal or absent in REM absent in REM sleep with the exception occasional muscle twitches." EX1021, 5. Consequently, "during sleep, loss of muscle tone results in variable narrowing of the upper airway during inspiration, with consequent flow limitation." EX1023, 1; EX1021, 5 ("The reduction in pharyngeal muscle tone in sleep leads to upper airway narrowing or even complete collapse in sleep producing snoring and episodes of obstructive sleep apnea (Fig. 6B), which is an absence of effective breathing due to an airway obstruction."); Behbehani ¶¶51-52.

Thus, for decades, breathing patterns have been used to indicate the sleep-wake state of a patient, particularly in the awake state, the non-REM sleep state (stable breathing), REM state (unstable breathing), and disordered sleep state. *See, e.g.*, EX1023, 3 ("Two hundred fifty respiratory cycles were randomly selected. They were observed in different sleep stages [stage 1, stage 2, stage 3/4, and rapid eye movement (REM) sleep] and during wakefulness."); EX1024, 2 ("Dynamic compliance, airflow resistance, and breathing pattern variables were calculated for at least 20 consecutive breaths during one period each of wakefulness, stage 2 sleep, and REM sleep."). These analyzed breathing patterns include those from nocturnal panic (or as coined in the '994 Patent, "troubled wakefulness"), where an individual "wak[es] from sleep in a state of panic," typically accompanied by "breathing irregularities." EX1025, 1, 10; Behbehani ¶¶53-54.

B. '539 Patent

The '539 Patent describes a well-known system and method for treating a OSAS with CPAP therapy by delivering a flow of breathable gas to a patient's airways. EX1001, Abstract, Fig. 1, 2:60-3:18. The patent describes Figure 1 (reproduced below) as illustrating an embodiment of "the present invention," yet admits the components in the figure are conventional and operate in a conventional way.

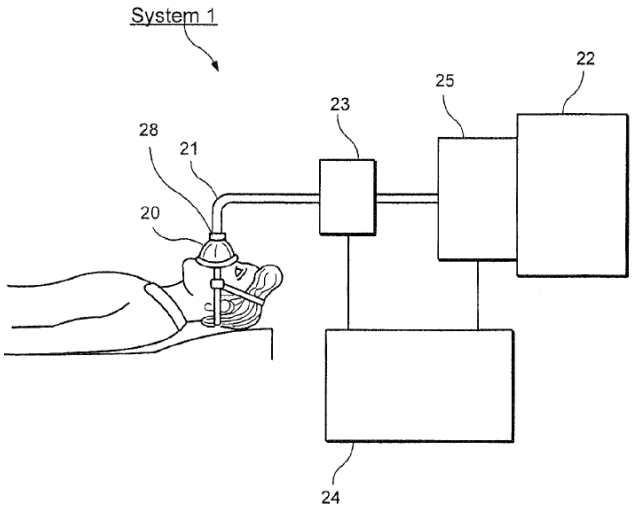
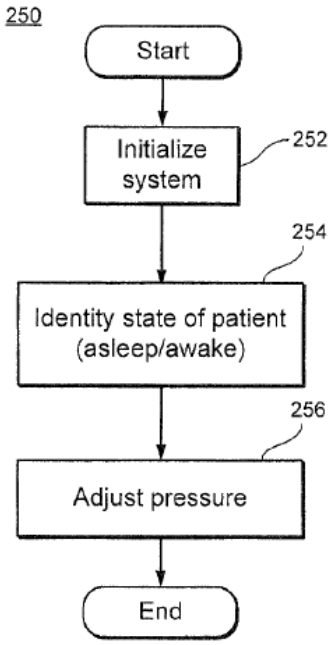


FIG. 1

A patient wears "a mask 20 which is connected via a tube 21 to receive airflow having a particular pressure from a flow generator 22" where the amount of pressure is determined with "any conventional PAP [positive airway pressure] therapy methods." *Id.* 3:52-59. "Conventional flow sensors 23…detect the rate of airflow to/from patent [sic] and/or a pressure supplied to the patent [sic] by the generator 22," and send signals to the processing arrangement 24, which "outputs a signal to a conventional flow control device 25" to control the pressure. *Id.* 3:61-4:2.

The patent attempts to address limitations of "[s]ome conventional PAP systems [that] utilize algorithms which continuously and automatically titrate the applied pressure." *Id.*, 2:48-49. Delivering high pressure airflow to the patient causes discomfort when the patient is awake and is therefore desirable "only when

the patient is asleep." *Id.*, 2:33-35. To remedy the patient's discomfort, the patent describes the processing arrangement 24 as "mak[ing] a determination as to a current state of the patient" (*id.*, 4:24-28) and "adjust[ing] the pressure supplied to the patient based on the state." *Id.*, 8:48-50). Specifically, the processing arrangement 24 "reduce[s] the applied pressure" when the patient is awakened and "instruct[s] the flow control device 25 to elevate the pressure" when the patient falls asleep. *Id.*, 5:62-66, 6:9-12. Figure 10 (reproduced below) illustrates this feature.



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C. The Challenged Claims

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

The '539 Patent has 30 claims, 3 independent claims and 27 dependent claims. Independent claim 24 is the broadest, generally requiring three components:

(1) generator supplying airflow and applying pressure;

(2) sensor measuring data corresponding to breathing patterns; and

(3) hardware processor to determine whether breathing patterns indicate an asleep or awake state has occurred.

Independent system claim 1 and method claim 11 further require the hardware processor provide instruction to the generator to adjust the applied pressure in response to the breathing patterns.

D. Prosecution History

On April 28, 2016, the Examiner rejected the pending claims as anticipated by U.S. Patent Application Publication No. 2006/0084877 to Ujhazy ("Ujhazy"). The applicant only obtained allowance of the '539 Patent by arguing that Ujhazy was not prior art. Specifically, the applicant argued that the application was

[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.

supported by earlier application, which entitled it to a priority date of August 14, 2003. The Examiner "found this argument persuasive [and] agreed to withdraw the rejection." EX1002, 137.

V. OVERVIEW OF THE PRIOR ART

A. Sullivan995 (EX1005)

Sullivan995 discloses each limitation of the independent claims (including increasing pressure when combinations of obstructions are detected), except it does not expressly disclose determining the patient is in an asleep state. Sullivan995 discloses a CPAP system that delivers a controllable airway pressure to a patient's airway passages. EX1005, Fig. 3, Abstract, 1:33-36, 2:15-20, 9:57-59. A CPAP nose mask covers the patient's nose and creates an "enclosed airway" that forms a flow path for breathable gas to be inhaled and exhaled by the patient. *Id.*, Figs. 1A, 1B, 8:47-59.

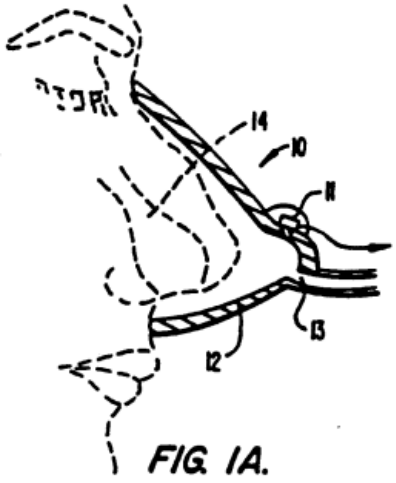


FIG. 1A.

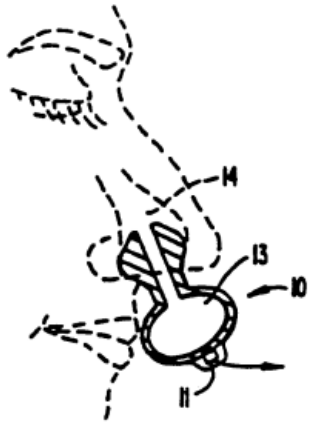


FIG. 1B.

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

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

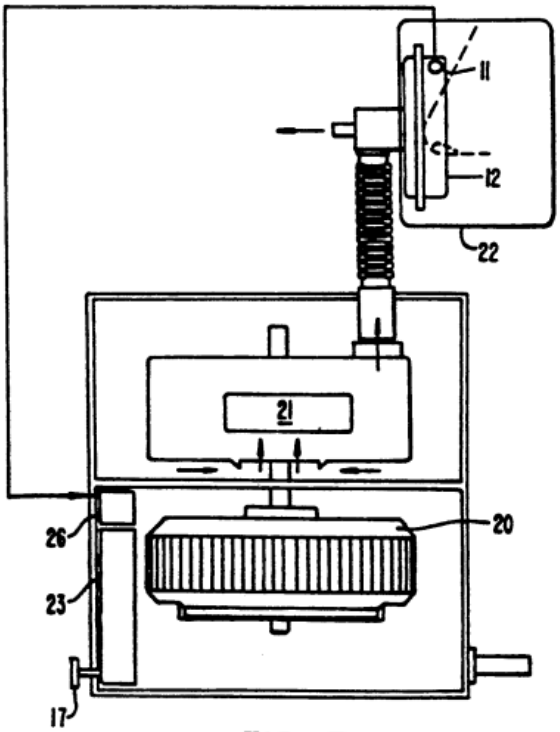


FIG. 3.

Figure 12 of Sullivan995 also depicts a computing system that receives and processes various breathing pattern data (e.g., snore, flow rate, volume, breathing

rate) from an amplifier/filter/processor combination that provide the data based on a signal from the pressure sensor. *Id.*, 17:6-12.

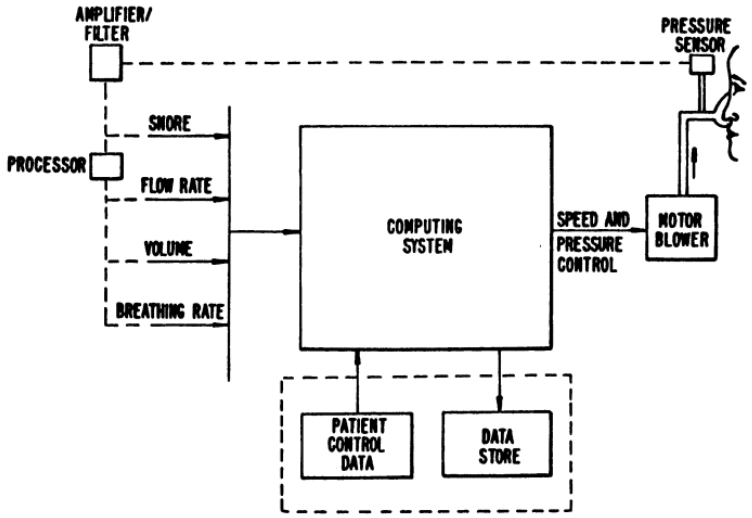


FIG. 12.

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

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

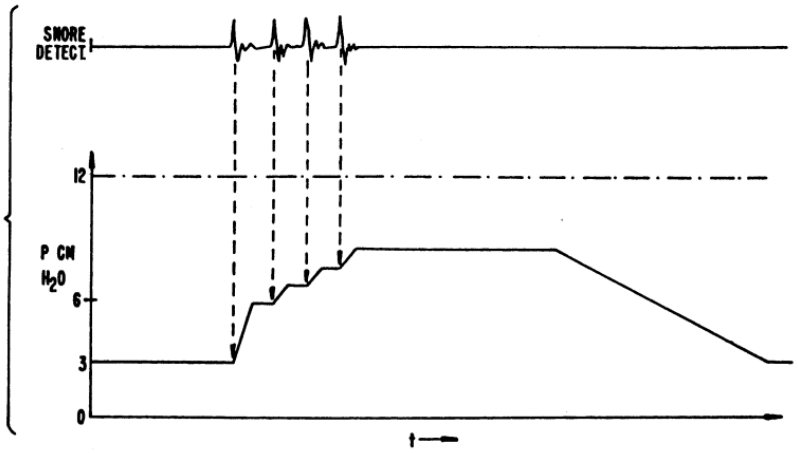


FIG. 13.

Figure 13 of Sulllivan995 depicts an incremental pressure increase for each detected snore and pressure decrease in the absence of snores. *Id.*, 18:6-18, 10:31-37, 15:18-24. Because the patient only snores when asleep, Sullivan995 only increases the pressure when the patient has fallen asleep. Similarly, Sullivan995 also describes increasing treatment pressure upon detection of other abnormal breathing patterns that occur while in a sleep state, such as apneas or hypopneas. *Id.*, 6:41-68, 15:34-64, 16:17-22, 16:51-59. Specifically, if the patient's air flow rate drops below a baseline, Sullivan995 increases the pressure. *Id.*, 6:41-57, Figs. 10-12.

B. Sullivan460 (EX1006)

Sullivan460 shares the same inventor as Sullivan995 and incorporates Sullivan995 by reference, stating Sullivan995 describes ResMed's AutoSet product: "the flow rate measurement means and the treatment means may be constructed together as part of one apparatus, such as the AutoSet product from

ResMed described in US Patent No 5245995 [Sullivan995], the contents of which are incorporated by reference." EX1006, 6:22-29.

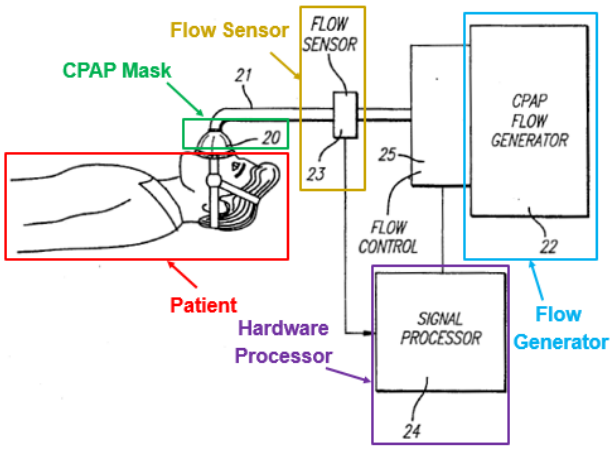
Like Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep. *Id.*, 6:17-29, 7:3-12, 10:9-33, 11:10-13, cls. 22-28, 43-46, Figs. 2-4. Sullivan460 also discloses that the system selects between an "awake" mode and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

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

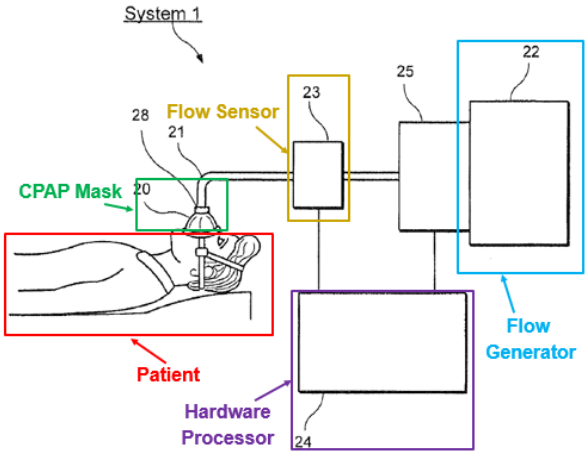
When the flow rate increases above a certain level, the controller determines the patient is in an awake state and switches the CPAP system into a first mode in which a reduced air pressure is applied to the patient's airways. *Id.*, 10:21-25, 14:7-36. Likewise, when interruptions 10 are detected in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

C. Rapoport502 (EX1008)

As discussed, the '539 Patent uses conventional hardware components for PAP machines. *See* Section IV.A.2 (Background, '539 Patent). Indeed, Rapoport502 (published nearly a decade before the '539 Patent by the same inventor) discloses nearly identical hardware, including a conventional flow generator, flow sensor, and hardware processor. EX1008, Fig. 9.



Rapoport502, Fig. 9



'539 Patent, Fig. 1

'539 Patent, Fig. 1

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

VI. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") in 2003 would have had at least a bachelor's degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience. Additional experience could substitute for less education, and additional education could likewise substitute for less experience. Behbehani Decl. ¶77.

This Petition does not turn on this precise definition, and the challenged claim would be unpatentable from the perspective of any reasonable person of ordinary skill in the art at the relevant time. Behbehani Decl. ¶78.

VII. CLAIM CONSTRUCTION

The Board construes the claims "using the same claim construction standard that would be used" in district courts. 37 C.F.R. §42.100(b). This Petition establishes the prior art meets each of the claim limitations under any reasonable construction.[5]

VIII. GROUND 1: SULLIVAN995 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1-2, 5-11, 13, 15-30

A. Motivation to Combine

It would have been obvious to a POSITA to modify the *hardware processor* in Sullivan995 to *determine whether breathing patterns indicate an asleep state or an awake state have occurred*, and in response to a determination of a transition between awake and asleep, *adjust the applied pressure [to a first value]*, as taught in Sullivan460. Behbehani Decl. ¶81. A POSITA would have been motivated to implement this modification to cause Sullivan995's CPAP system to apply a lower pressure or higher pressure upon detecting the patient's awake state or asleep state, respectively.

First, a POSITA would have recognized the advantages of using the same CPAP system to treat both sleep apnea and blood pressure elevations associated

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

with pre-eclampsia, as taught in Sullivan460. EX1006, 7:3-12; Behbehani Decl. ¶82. An upper airway flow limitation characterized by at least one decrease in upper airway inspiratory flow rate, followed by at least one increase in flow rate, is indicative of pre-eclampsia (and not observed in typical snoring), and could be treated with the modified system. *See* EX1006, Fig. 1, 6:22-29, 9:31-10:6; Behbehani Decl. ¶83. Women with sleep apnea are at higher risk for pre-eclampsia, and each of pre-eclampsia, snoring, and apnea involve hypertension, high blood pressure, and obstructions during sleep. *See* EX1006, 1:5-28, 4:33-34, 5:29-6:2. The modification to Sullivan995's CPAP system would allow for detection of inaudible low frequency vibrations, including those associated with pre-eclampsia, so that the patient may be treated with high pressure. *See* EX1006, 2:19-22, 4:33-34, 6:3-34, 9:31-10:6. Sullivan995 even suggests that such modifications would be desirable, as its CPAP system is not limited to treating apnea and snoring, but also apply to other upper airway disorders, which the POSITA would have understood to include vibrations related to pre-eclampsia. EX1005, 1:14-31, 4:36-45.

Second, a POSITA would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment. The modified CPAP system would apply a low pressure upon wake-up, adding to patient comfort and decreasing the likelihood the patient

will remove the mask due to uncomfortably high pressure. Sullivan995 strongly suggests this modification by explaining that pressure is reduced when an extended period of snore-free breathing is detected (e.g., which would include an awake period). EX1005, 10:13-46, 14:45-64. Moreover, as Sullivan995 explains, prior to Sullivan995, therapy pressure was often delivered at levels higher than necessary for substantial periods, causing discomfort (4:21-25), and Sullivan995 partially solves the problem by reducing the pressure at the beginning of therapy, when the patient connects herself to the CPAP system. Behbehani Decl. ¶¶86-87.

B. Reasonable Expectation of Success

The POSITA would have had a reasonable expectation of success in making the modification to Sullivan995. Behbehani Decl. ¶88.

First, Sullivan460 explicitly recognizes the combination of Sullivan995 with the teachings in Sullivan460. Behbehani Decl. ¶89. Sullivan460 expressly states that Sullivan995 may be modified to include features of Sullivan460, such as "sens[ing] an upper airway flow limitation characterised by at least one decrease in upper airway inspiratory flow rate followed by at least one increase in flow rate." EX1006, 6:22-29. As Sullivan460 discloses in further embodiments, a sleep sensor detects "reduced average airflow in the patient's upper airway" to detect the sleep state and a higher average airflow to detect the awake state, and switching between different pressure delivery depending on which state is determined. *Id.*, 6:22-7:22,

cls. 22-28, 43-47. Therefore, a POSITA, upon reading the teachings of Sullivan995 and Sullivan460, would have had a reasonable expectation of success in performing this modification because Sullivan460 already describes Sullivan995 as being used to sense flow limitations, and Sullivan460 further explains that flow data may be used to determine an awake/sleep state. Behbehani Decl. ¶91.

Second, Sullivan995 and Sullivan460 are analogous art. Behbehani Decl. ¶92. Both references describe CPAP systems that include flow sensors and flow generators. Like Sullivan995, Sullivan460 discloses a flow rate measurement means 70 (Fig. 2) located in the flow path for detecting the rate at which the patient breathes. Sullivan460 at 10:10-12. The flow rate measurement means or sensor 70 detects "interruptions" 10 (Fig 1) within the patient's breathing cycle. The "interruptions" are superimposed at the peak of each cycle and indicate upper airway flow limitation in the patient. EX1006, 9:31-34. Also similar to Sullivan995, when Sullivan460 senses interruptions 10 in the patient's "breathing patterns" or determines the patient is asleep, a controller 100 activates a switch 110, which activates the nCPAP apparatus 90 to supply air to the patient 30 at a higher pressure, to ameliorate or eliminate the patient's upper airway flow limitation. EX1006, 10:4-16.

Given the proposed modification would simply be a change in programming, it merely involves a combination of known prior art elements according to known

methods and known techniques to yield predictable results, and involves use of a known technique to improve a similar device in the same way.

C. Independent Claim 24

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

To the extent limiting, Sullivan995 discloses the preamble. Behbehani Decl. ¶95. Sullivan995 discloses a "continuous positive airway pressure (CPAP)" system[6] which is *a positive airway pressure system*. EX1005, Fig. 3, Abstract, 1:32-36, 2:15-19, 9:57-58. Sullivan995's CPAP system "deliver[s] appropriate airway pressure" to the patient's airway passages. *Id.*, 2:15-19. As a POSITA would have understood, CPAP delivers "positive" airway pressure relative to atmospheric pressure. Behbehani Decl. ¶95.

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.

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

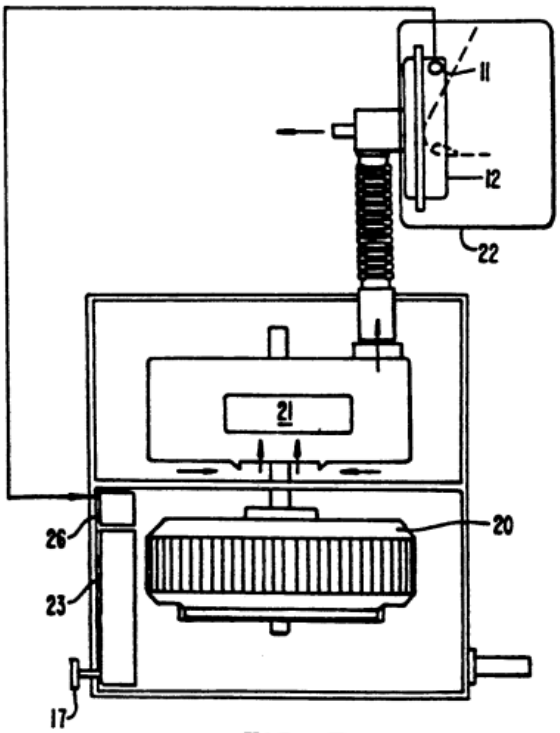


FIG. 3

EX1005, 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 Decl. ¶97.

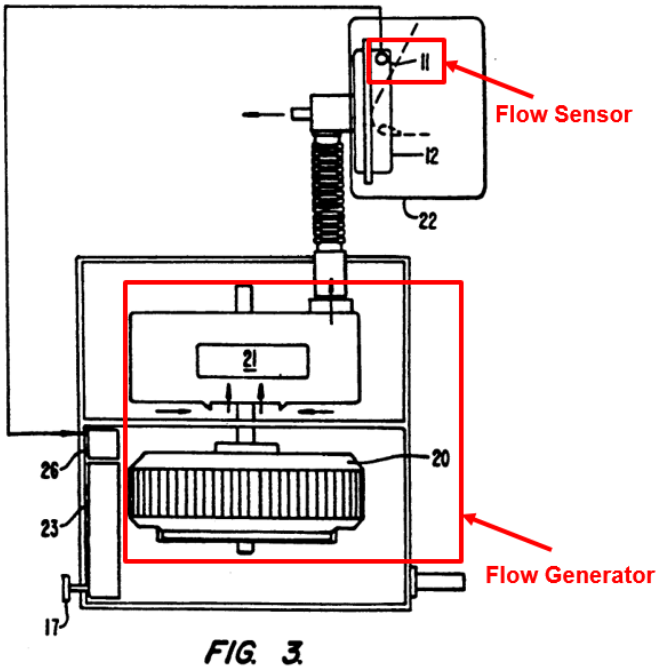
2. 24[a]: *"a generator supplying airflow and applying a pressure to an airway of a patient;"*

Sullivan995 discloses this limitation. Behbehani Decl. ¶98. Sullivan995's CPAP system includes a motor 20 with a variable speed that drives a blower 21 (*generator*). EX1005, 9:57-64. The blower 21 is *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 Decl. ¶98.

3. 24[b]: "*a sensor measuring data corresponding to patient's breathing patterns from data indicate of the airflow supplied to the patient using at least one of a flow sensor or pressure sensor; and*"

Sullivan995 discloses this limitation. Behbehani Decl. ¶99. Sullivan995's CPAP system includes a differential pressure sensor (microphone 11), which is a *sensor*. EX1005, Fig. 3, 9:64-66; Behbehani Decl. ¶99. As shown in Figure 3 (reproduced below), "the snoring detection means 22 is a pressure detection means and microphone 11 is a differential pressure sensor." EX1005, 9:66-10:1. Sullivan995 explains that the microphone is a sound transducer that "consists of a pressure transducer, which, in addition to detecting snoring sounds, can detect other respiratory parameters such as the ***rate of breathing***, inhaled air flow or inhaled ***air flow rate***." *Id.*, 3:21-30 (emphasis added); *see also id*., Abstract. This is consistent with the '539 Patent's description of "[c]onventional flow sensors 23" as

"detect[ing] the ***rate of airflow*** to/from patent [sic] and/or a ***pressure*** supplied to the patent [sic]." EX1001, 3:61-63 (emphasis added).



EX1005, Fig. 3

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

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

system. The patterns in Figure 9 show a "high frequency wind noise," meaning the CPAP system is actively delivering *data indicat[iv]e of the airflow supplied to the patient*. EX1005, 13:10-21.

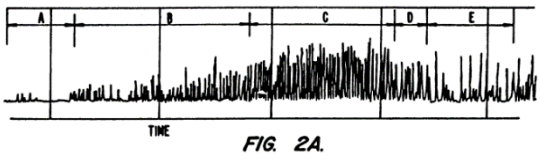


FIG. 2A.

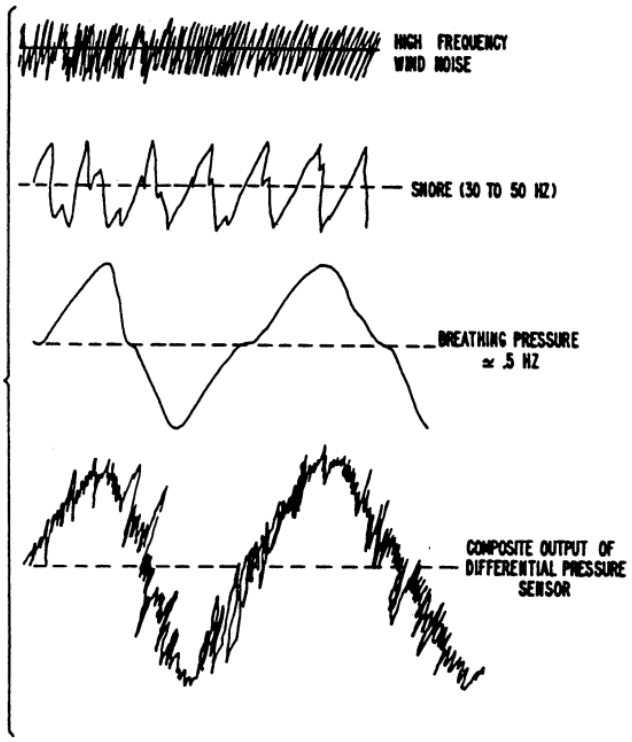


FIG. 9.

EX1005, Fig. 2A **EX1005, Fig. 9**

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

patterns from data indicate of the airflow supplied to the patient. Behbehani Decl. ¶104.

With microphone 11, Sullivan995 is *using at least one of a flow sensor or pressure sensor* because microphone 11 is both flow and pressure sensor. A POSITA would understand that certain pressure sensors, like microphone 11, can measure both pressure and flow using two ports as shown in Figure 7. Behbehani Decl. ¶111.

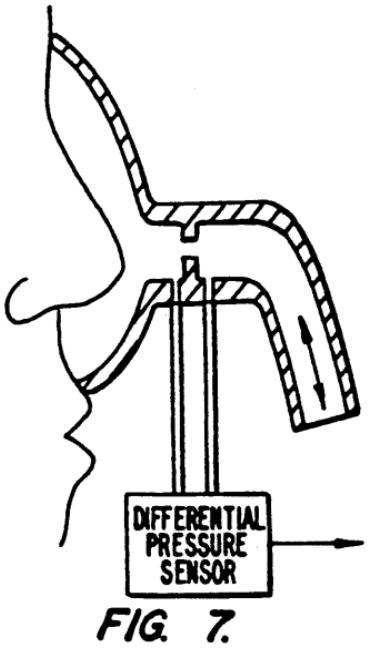


FIG. 7.

EX1005, Fig. 7

4. 24[c]: *"a hardware processor analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state have occurred."*

Sullivan995 in view of Sullivan460 discloses this limitation. Behbehani Decl. ¶112. The combination of an amplifier/filter/processor unit 26[7] with a speed control unit 23[8] depicted in Figure 3 and described in part as the computing system in Figure 12 is *a hardware processor.* As Sullivan995 describes, the microphone 11 (*flow sensor*) provides its *measured data* to processor unit 26. EX1005, 10:3-6 ("[e]lectrical impulses are fed from said microphone 11 to an amplifier/filter/processor unit 26"); *see also id.,* 10:37-66 (describing the processor unit 26 receiving an electronic signal from the microphone 11 and detecting snores). Additionally, in relation to Figure 4, which depicts the circuitry of the CPAP system in Figure 3 in block form, Sullivan995 states "[t]he electrical signals

[7] Sullivan995 refers to the same processor unit 26 as an amplifier/filter/processor unit 26, amplifier/filter/processor 26, and processor 26. EX1005, 10:3-6, 10:40-46, 10:55-58, 11:58-62, 14:50-55, 15:27-33, 15:59-64. For ease of reference, Petitioner refers to each as processor unit 26.

[8] Sullivan995 refers to the same speed control unit 23 as an electronic speed control unit 23, a speed control unit 23, a feedback speed controller 23, and a speed controller 23. EX1005, 9:59-60, 10:14-16, 11:63-64, 14:40-41, 15:1-. For ease of reference, Petitioner refers to each as the speed control unit 23.

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.

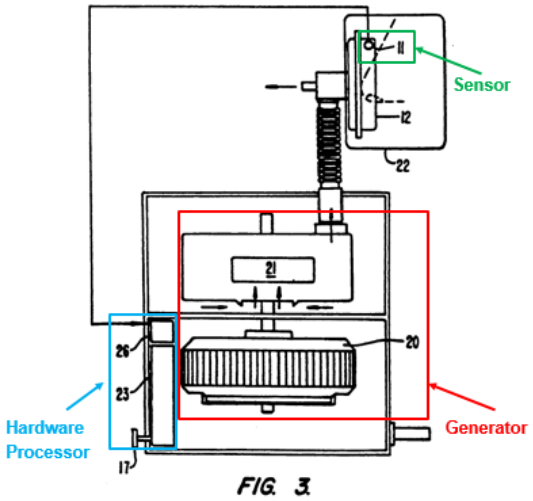


FIG. 3

Therefore, the processor unit 26 is part of a *hardware processor* that receives the measured data corresponding to the airflow to the patient.

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

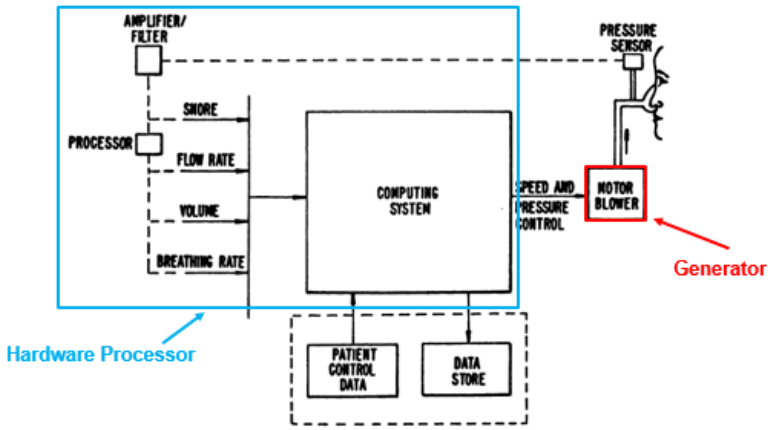


FIG. 12.

In describing Figure 12, Sullivan995 states "[t]he electrical signals from the pressure transducer are amplified and filtered to provide pressure waves of the desired frequencies indicative of snoring and breathing. The pressure wave indicative of breathing is further processed to generate signals indicative of flow rate, volume and breathing rate." EX1005, 17:6-12. These amplification, filtering, and processing steps would have been performed by the amplifier/filter/processor depicted in Figure 12 and would have been included as part of the amplifier/filter/processor unit 26 (included in the *hardware processor*) of Figures 3 and 4. Accordingly, Sullivan995's *hardware processor* receives the measured data corresponding airflow to the patient.

Sullivan995 describes various *breathing patterns* for the patient. Referencing Figure 4, Sullivan995's *hardware processor* includes the processor unit 26, "which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern." EX1005, 11:55-62. In generating this

control signal, the processor unit 26 (included in the *hardware processor*) therefore *analyzes the data [from the sensor] to determine the patient's breathing patterns*, which are the snoring patterns or predetermined patterns in Sullivan995.

As Sullivan995 describes with reference to Figure 12, the computing system (including processing unit 26 and speed controller 23) "analyses and records signals from the pressure sensor," and analyzes "the sound and breathing patterns" to record "indexes such as the number of apneic episodes, the number of hypopneas, their duration, etc." Id., 12:67-13:8. Therefore, the computing system is part of the hardware processor and analyzes the data [from the sensor] to determine the patient's breathing patterns.

Sullivan995 further discloses hardware processor determine whether breathing patterns indicate an asleep state. As Sullivan995 explains, in addition to detecting snoring, the microphone 11 (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. Sullivan995 describes detecting "a snore, or snoring pattern or

abnormal breathing pattern" after the patient has gone to sleep, and then increasing the CPAP pressure in response. *Id*., 16:17-22; Behbehani Decl. ¶¶112, 117.

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.

Another example of Sullivan995's identification of *breathing patterns indicative of an asleep state* is depicted in Figure 2A and described in the associated text. *Id.*, Figure 2A; Behbehani Decl. ¶120.

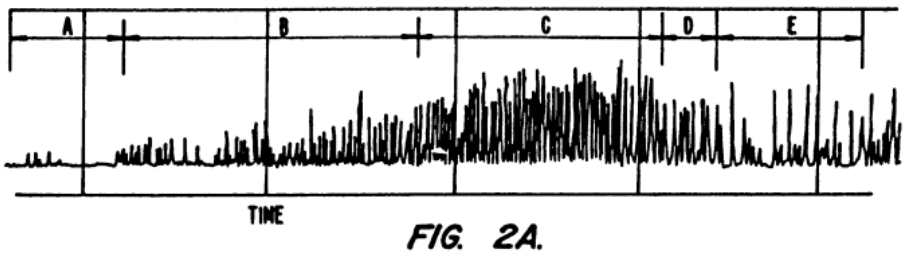


FIG. 2A.

EX1005, 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 Decl. ¶121.

Although Sullivan995 does not explicitly disclose that the *hardware processor* determines *whether the breathing patterns indicate an awake state*, this limitation would have been obvious from Sullivan995 in view of Sullivan460.

a) Teachings of Sullivan460 on determining awake state

Sullivan460 incorporates Sullivan995 by reference and refers to Sullivan995 as describing a "flow rate measurement means and [a] treatment means [as being] constructed together as part of one apparatus." EX1006, 6:22-29. Like Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep. *Id.*, 6:17-29, 7:3-12, 10:9-33, 11:10-12, cls. 22-28, 43-46, and Figs. 2-4; Behbehani Decl. ¶123.

Sullivan460 discloses determining *whether breathing patterns indicate an awake state* by describing embodiments in which "a sleep sensor [] senses whether or not the patient is asleep" by determining "when there is a reduced average airflow in the patient's upper airway." EX1006, 7:3-7, 7:10-12, 7:17-19; Behbehani Decl. ¶124. According to Sullivan460, "a switching means responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46.

b) Motivation to Combine and Reasonable Expectation of Success

See Sections VIII.A and VIII.B.

D. Dependent Claims 25-30[9]

1. Claim 25: hardware processor further analyzes to determine breathing patterns indicative of transition from awake to asleep

Sullivan995 discloses "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-16, Fig. 3. The presence of

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

snoring is *a breathing pattern indicative of a transition from an awake state to an asleep state*. EX1018, ¶178.

To the extent that Sullivan995 does not expressly disclose this limitation, it would have been obvious in view of Sullivan460. Sullivan460 discloses a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19; *see* Section VIII.C.4.a). "[S]witching means responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. *Id.*, 6:30-7:12, cls. 22-28, 43-46. This means that a *transition from an awake state to an asleep state* has occurred. Behbehani Decl. ¶¶127-128, 131.

It would have been obvious to a POSITA to modify Sullivan995 so that the hardware processor in Sullivan995 further analyzes the breathing patterns to determine whether a breathing pattern indicative of a transition from an awake to an asleep state has occurred, as taught in Sullivan460, for the same reasons as explained for 24[c]. *See* Section VIII.C.4.b). As a POSITA would have recognized from the teachings of Sullivan995 and Sullivan460, a lower pressure is desirable when the patient is awake because it ensures the patient is comfortable and reduces the likelihood the patient will remove the mask. Behbehani Decl. ¶133.

2. Claim 26: hardware processor determines transition when regularity of breathing detected

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 Decl. ¶121. Part A of Figure 2A shows "normal breathing" and is therefore *a regularity of breathing*, such that the *hardware processor determines that breathing pattern indicative of a transition to an asleep state occurs when a regularity of breathing is detected*. Behbehani Decl. ¶¶135-136.

This is consistent with the knowledge of a POSITA that *a regularity of breathing* can be used to indicate that the patient has transitioned to a sleep state. *See* Ex. 1034, 5:34-35 ("When a patient is asleep his respiration becomes stable, this is used to detect the instant when the patient falls asleep.").

3. Claim 27: hardware processor determines transition when series of obstructions detected

Each of Sullivan995 and Sullivan460 expressly discloses that four (4) snores are detected. *Id.*, Figs. 2A (section E), 13, 8:36-43, 9:16-32, 14:48-15:15; EX1006 Fig. 1, 3:1-3, 3:20-23, 5:7-9, 9:31-36, Cls. 2, 33; Behbehani Decl. ¶143. The recognition of these snores is *a series of obstructions*, such that the *hardware*

processor determines that breathing pattern indicative of a transition to an asleep state occurs when a series of obstructions is detected. Behbehani Decl. ¶145.

4. Claim 28: hardware processor determines transition when regularity of breathing or series of obstructions present

Sullivan995 discloses this limitation. *See* Sections VIII.D.2 (Ground 1, Claim 26) and VIII.D.3 (Ground 1, Claim 26).

5. Claim 29: hardware processor sends control signal to generator to increase pressure when hardware processor determines transition has occurred

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. EX1005, 17:3-12.

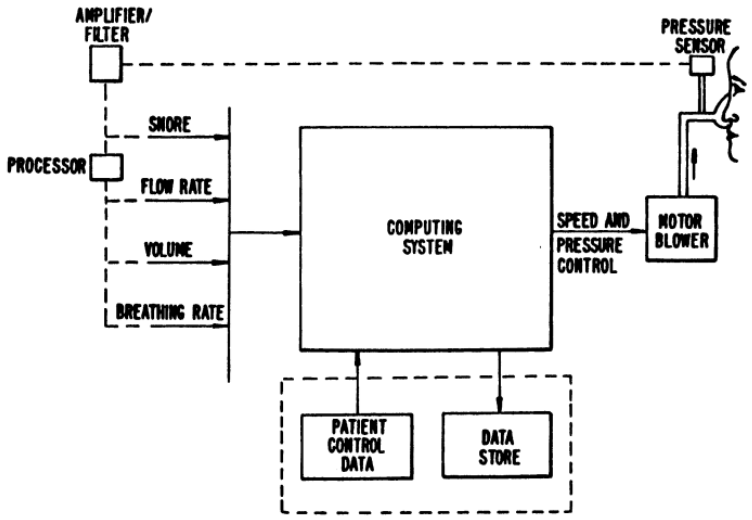


FIG. 12.

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.

6. Claim 30: generator configured to use ramp system to increase pressure

As Sullivan995 depicts in Figure 13, the *generator is configured to increase pressure* incrementally with each snore that is detected. EX1005, 14:17-20. The incremental increase depicted in Figure 13 is *using a ramp system* because the incremental increases occur at different times, upon detection of each snore. Behbehani Decl. ¶155; *see also* EX1005, Figs. 4-6, 11:55-12:26 (discussing "a ramp generator" and "obtain[ing] a ramp voltage" to gradually increase the motor speed over time).

E. Independent Claims 1 and 11

1. Preamble

To the extent limiting, Sullivan995 discloses the preamble. *See* Section VIII.C.1 (Ground 1, 24[preamble]); Behbehani Decl. ¶156.

2. 1[a]/11[a]: generator supplying airflow

Sullivan995 discloses this limitation. *See* Section VIII.C.2 (Ground 1, 24[a]); Behbehani Decl. ¶157.

3. 1[b]/11[b]: flow sensor measuring data corresponding to supplied airflow

Sullivan995 discloses this limitation. *See* Section VIII.C.3 (Ground 1, 24[b]); Behbehani Decl. ¶158.

4. 1[c]: hardware processor

Sullivan995 discloses this limitation. *See* Section VIII.C.4 (Ground 1, 24[c]); Behbehani Decl. ¶159.

5. 1[d]: receives measured data and provides operational control signals to generator

Sullivan995 discloses this limitation. *See* Sections VIII.C.4 (Ground 1, 24[c]) and VIII.D.5 (Ground 1, Claim 29); Behbehani Decl. ¶160.

6. 11[c]: analyze measured data to determine whether breathing pattern indicative of awake or asleep state

Sullivan995 discloses this limitation. *See* Sections VIII.C.4 (Ground 1, 24[c]); Behbehani Decl. ¶161.

7. 1[e]/11[d]: when breathing pattern indicative of transition between awake and asleep, increase pressure

Sullivan995 discloses *providing instructions to the generator to adjust the applied pressure in response to the patient's breathing patterns.* Behbehani Decl. ¶163. Specifically, Sullivan995 discloses "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-16, Fig. 3. Also, the pressure is decreased "if an extended period of snore free breathing occurs" by "automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected." *Id*., 10:31-46; *see also id.* 10:47-61 (the CPAP pressure increases "via the processor 26," in response to the "snore, or snore pattern."). By *adjust[ing]*

the applied pressure to a therapeutic pressure (*a first value*) upon the detection of snores, Sullivan995 discloses this limitation.

Although Sullivan995 does not explicitly disclose increasing pressure when the breathing pattern is indicative of a transition to an asleep state, this is taught by Sullivan460.

a) Teachings of Sullivan460 on determining awake state.

Sullivan460 incorporates Sullivan995 by reference and refers to Sullivan995 as describing a "flow rate measurement means and [a] treatment means [as being] constructed together as part of one apparatus." EX1006, 6:22-29. Like Sullivan995, Sullivan460 describes a CPAP system that initially applies a low pressure before increasing the pressure when the patient is asleep. *Id.*, 6:17-29, 7:3-12, 10:9-33, 11:10-12, cls. 22-28, 43-46, and Figs. 2-4; Behbehani Decl. ¶167.

Sullivan460 discloses determining the patient is in *an awake state* by describing embodiments in which "a sleep sensor [] senses whether or not the patient is asleep" by determining "when there is a reduced average airflow in the patient's upper airway." EX1006, 7:3-7, 7:10-12, 7:17-19; Behbehani Decl. ¶167. According to Sullivan460, "a switching means responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is

higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46. Because Sullivan460 discloses responding to the sleep sensor by switching between the awake mode and asleep mode, Sullivan460 discloses the *transition between an awake state and an asleep has occurred*. Behbehani Decl. ¶168.

b) Motivation to Combine and Reasonable Expectation of Success

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

F. Dependent Claims 2, 5-10, 13, 15-23

1. Claim 2 : flow sensors comprise airflow sensor or pressure sensor

Sullivan995 discloses this limitation. *See* Section VIII.C.3 (discussing *using at least one of a flow sensor or pressure sensor*); Behbehani Decl. ¶169.

2. Claim 5, 17: when breathing pattern indicative of change has occurred, hardware processor transmits operational control signal to generator to increase

Sullivan995 discloses this limitation. *See* Section VIII.D.5 (Ground 1, Claim 29); Behbehani Decl. ¶170.

3. Claim 6, 19: determines breathing pattern indicative of change has occurred when breathing pattern indicates regularity of breathing

Sullivan995 discloses this limitation. *See* 0- VIII.D.2 (Ground 1, Claim 26); Behbehani Decl. ¶171.

4. **Claim 7, 20:** hardware processor determines breathing pattern indicative of change when breathing pattern indicates regular period of obstructions / series of obstructions

Sullivan995 discloses this limitation. *See* Section VIII.D.3 (Ground 1, Claim 27); Behbehani Decl. ¶172.

5. **Claim 8, 21:** hardware processor monitors measured data for at least regularity of breathing or regular period of obstructions / series of obstructions

Sullivan995 discloses this limitation. *See* Section VIII.D.4 (Ground 1, Claim 28; Behbehani Decl. ¶173.

6. **Claim 9:** when breathing pattern indicative of change has occurred, hardware processor transmits control signal to generator to decrease pressure

Sullivan995's processor unit 26 and/or the speed control unit 23 (parts of the *hardware processor*) reduces pressure "if an extended period of snore free breathing occurs" by "automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected." EX1005, 10:31-46. A POSITA would understand that the *hardware processor* would send a signal to blower 21 to decrease pressure. Behbehani Decl. ¶174. Moreover, as already explained in Section VIII.A, Sullivan995 in view of Sullivan460 renders this limitation obvious.

7. Claim 10: when breathing pattern indicative of elevated upper airway resistance, hypopnea or repetitive obstructive apnea has occurred, hardware processor transmits control signal to generator to increase pressure

Sullivan995 alone or in view of the knowledge of a POSITA discloses this limitation. Behbehani Decl. ¶176.

The *breathing patterns* in Sullivan995 referenced in 1[e]/11[d] include those *indicative of elevated upper airway resistance*. Behbehani Decl. ¶177. Sullivan995 states "the output pressure of the CPAP unit increases in response to detection of snoring." EX1005, 10:10-16; *see also id.,* 10:47-61 (the CPAP pressure increases "via the processor 26," which is part of the *hardware processor*, in response to the "snore, or snore pattern"). Moreover, Figure 13 depicts how the Figure 12 computing system (included in the *hardware processor*) increases pressure based on the snoring detection. *Id.*, 14:17-20.

The *breathing patterns* in Sullivan995 referenced in in 1[e]/11[d] include those *indicative of hypopneas*. EX1005, 13:4-9 (indexing detected "hypopneas"). Specifically, the *obstructions* in section D of Fig. 2A are "indicative of obstructive hypopnea, a condition in which the breath-by-breath intensity decreases progressively, and then increases" and "is a 'pre-apneic' pattern." *Id.*, 13:46-54; *see also id.*, 13:4-8 and 14:17-32 (describing the computing system of Fig. 13 as diagnosing "hypopnea" and processing "the number of hypopneas"). Moreover, Sullivan995 describes determining "flow rate," "breathing rate," "time interval,"

and "volume" data to detect sleep apnea or hypopneas (*see, e.g.,* parts D and E of Fig. 2A). *Id.*, Fig. 12, 6:41-68, 15:34-64, 17:3-27; Behbehani Decl. ¶178.

As Sullivan995 describes, "snoring is caused by vibration of the soft palate [and] is therefore indicative of an unstable airway and… is a warning signal of the imminence of upper airway occlusion." *Id.*, 10:16-21, 15:3-8. Moreover, a "decreasing intensity of the snoring occurs when the upper airway is almost, but not entirely, sucked closed by strong inspiratory efforts." *Id.*, 9:21-26, 13:50-53. As would have understood from Sullivan995's teachings of snoring as indicating an "unstable airway," an "imminence of upper airway occlusion," and a nearly closed "upper airway," the snoring in Sullivan995 is *an elevated upper airway pressure.* Behbehani Decl. ¶¶177, 182.

To the extent that Sullivan995 does not expressly disclose the *breathing pattern* is indicative of a *hypopnea*, this would have been obvious to a POSITA. Hypopneas indicate a sleep state and should be treated with increased pressure, as taught by Sullivan995. Behbehani Decl. ¶179. Snores do not always precede hypopneas, such that detecting hypopneas would have been particularly desirable. Behbehani Decl. ¶179.

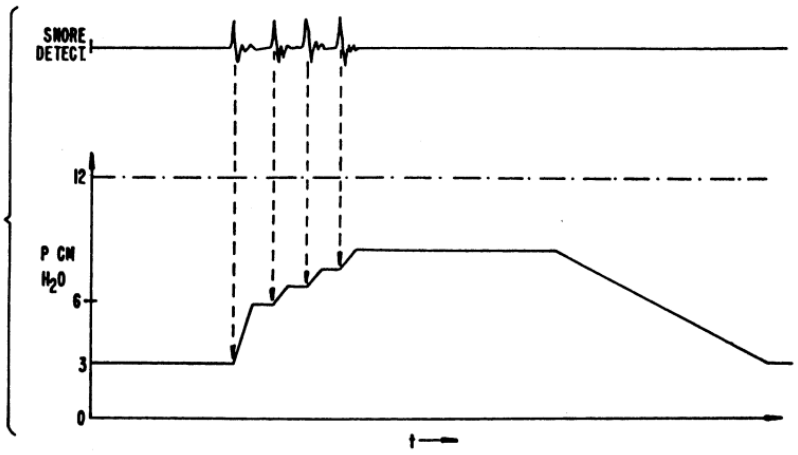


FIG. 13.

The *breathing patterns* in Sullivan995 referenced in in 1[e]/11[d] include those *indicative of repetitive obstructive apnea*. *See* EX1005, 4:28-45 (detecting "apneas"), 13:4-9 (indexing "the number of apneic episodes); *see* Section VIII.C.7. Specifically, the *obstructions* in Fig. 2A are "indicative of sleep apnea, with periods of airway occlusion which terminate with one or more loud breathing sounds followed by further occlusions" and are therefore *apneas*. *Id.*, 13:55-59; Behbehani Decl. ¶180.

To the extent that Sullivan995 does not expressly disclose a *repetitive obstructive apnea*, this would have been obvious to a POSITA. Apneas indicate a sleep state and should be treated with increased pressure, as taught by Sullivan995. Behbehani Decl. ¶181. Snores do not always precede apneas, such that detecting apneas would have been particularly desirable. Behbehani Decl. ¶181.

In Sullivan995, when a breathing pattern indicative of an elevated upper airway resistance, hypopnea or repetitive obstructive apnea has occurred, the

hardware processor transmits control signal to generator to increase pressure. *See* Section VIII.D.5 (Ground 1, Claim 29).

8. Claim 13: placing mask on face of patient and covering mouth or nose of patient

Sullivan995 discloses this limitation. Behbehani Decl. ¶183. As shown in Figures 1A and 1B (reproduced below), the CPAP system of Sullivan995 includes a nose mask 12 or nasal prongs that are "fluidly sealable to the nasal air passages of a patient" and are "for delivery of air to the patient's nasal passages." EX1005, Figs. 1A, 1B, 5:11-21, 18:47-60.

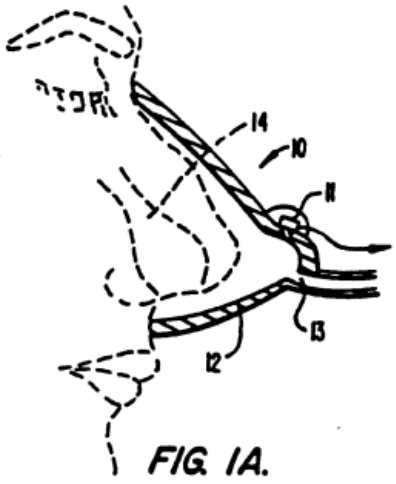


FIG. 1A.

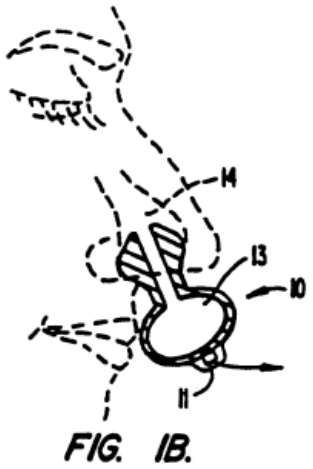


FIG. 1B.

Sullivan995 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.

9. Claim 15: controlling generator to reduce supplied pressure when breathing pattern indicative of change from asleep to awake

Sullivan995's processor unit 26 and/or the speed control unit 23 (parts of the *hardware processor*) reduces pressure "if an extended period of snore free

breathing occurs" by "automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected." EX1005, 10:31-46. This means the *hardware processor* in Sullivan995 *is controlling the generator to reduce the supplied pressure* in the absence of snoring.

Although Sullivan995 does not explicitly disclose *a breathing pattern indicative of a change from an asleep state to an awake state*, this is taught by Sullivan460. Sullivan460 discloses a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19. "[S]witching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. *Id.*, 6:30-7:12, cls. 22-28, 43-46. This means that *when* the patient *has changed from an asleep state to an awake state*, Sullivan460 *is controlling the generator to reduce the applied pressure*. Behbehani Decl. ¶187.

It would have been obvious to a POSITA to modify Sullivan995 so that *hardware processor* in Sullivan995 determines that the patient has *a change from an asleep state to an awake*, as taught in Sullivan460. Behbehani Decl. ¶188. As the POSITA would have recognized from the teachings of Sullivan995 and Sullivan460, a lower pressure is desirable when the patient is awake because it

ensures the patient is comfortable and reduces the likelihood the patient will remove the mask. Behbehani Decl. ¶188.

10. **Claim 16:** controlling flow generator to increase supplied pressure when breathing pattern indicative change from awake to asleep

Sullivan995 in view of Sullivan460 renders obvious this limitation. *See* Sections VIII.D.5 (Ground 1, Claim 29); Behbehani Decl. ¶189.

11. **Claim 18:** analyzing breathing patterns determine when patient transitions from awake to asleep

Sullivan995 in view of Sullivan460 renders obvious this limitation. *See* Sections VIII.E.7 (Ground 1, 1[e], 11[d]); Behbehani Decl. ¶190.

12. **Claim 22:** increasing pressure when determination of transition from awake to asleep has occurred

Sullivan995 in view of Sullivan460 renders obvious this limitation. *See* Sections VIII.E.7 (Ground 1, 1[e], 11[d]); Behbehani Decl. ¶191.

13. **Claim 23:** ramping pressure provided when breathing pattern indicative of transition from awake to asleep has occurred

Sullivan995 discloses this limitation. *See* Sections VIII.D.6 (Ground 1, Claim 30); Behbehani Decl. ¶192.

IX. GROUND 2: RAPPORT502 IN VIEW OF SULLIVAN460 RENDERS OBVIOUS CLAIMS 1-2, 5-11, 13, 15-30

A. Motivation to Combine

It would have been obvious to a POSITA to modify the *hardware processor* in Rapoport502 to *determine whether breathing patterns indicate an asleep state or*

an awake state have occurred, and in response to a determination of a transition between awake and asleep, *adjust the applied pressure [to a first value]*, as taught in Sullivan460. Behbehani Decl. ¶193.

First, the POSITA would have recognized that the advantages of using the same PAP system to treat both sleep apnea and blood pressure elevations associated with pre-eclampsia, as taught in Sullivan460. EX1006, 7:3-12; Behbehani Decl. ¶195. An upper airway flow limitation characterized by at least one decrease in upper airway inspiratory flow rate, followed by at least one increase in flow rate, is indicative of pre-eclampsia (and not observed in typical snoring), and could be treated with the modified system. *See Id.*, Fig. 1, 6:22-29, 9:31-10:6; Behbehani Decl. ¶196. Women with sleep apnea are at higher risk for pre-eclampsia, and each of pre-eclampsia, snoring, and apnea involve hypertension, high blood pressure, and obstructions during sleep. *See Id.*, 1:5-8, 4:33-34, 5:29-36. The modification to Rapport502's PAP system would allow for detection of inaudible low frequency vibrations, including those associated with pre-eclampsia, so that the patient may be treated with high pressure. *See Id.*, 2:19-22, 4:33-34, 6:3-7:2, 9:31-10:6. Rapport502 even suggests that such modifications would be desirable, as it acknowledges that obstructive sleep apnea syndrome (OSAS) is not limited to any particular disorder, but rather "is associated with all conditions in which there is anatomic or functional narrowing of the patient's upper airway, and

is characterized by an intermittent obstruction of the upper airway occurring during sleep," which the POSITA would have understood to include vibrations related to pre-eclampsia. EX1008, 1:29-33; Behbehani Decl. ¶198.

Second, a POSITA would have recognized that the modification is advantageous because it improves patient comfort upon wake-up, making it less likely that patients would remove their CPAP masks and more likely patients will continue with treatment. Behbehani Decl. ¶199. Both Dr. Rapoport and Dr. Sullivan recognized that a major limitation with CPAP therapy was noncompliance due to discomfort. EX1014, 5. Both also recognized that lowering pressure when the patient is in an awake state could improve compliance. EX1015, 5. As explained above, the modified CPAP system would apply a low pressure whenever the sensor detects that the patient is awake. Reverting to a low pressure upon wake-up would add to patient comfort and decrease the likelihood the patient will remove the mask due to uncomfortably high pressure. Behbehani Decl. ¶199.

B. Reasonable Expectation of Success

A POSITA would have had a reasonable expectation of success in making the modification to Rapport502. Behbehani Decl. ¶200.

First, Rapport502 and Sullivan460 are analogous art. Behbehani Decl. ¶201. Both references describe CPAP systems that include flow sensors and flow generators. Like Rapport502, Sullivan460 discloses a flow rate measurement means

70 (Figure 2) located in the flow path for detecting the rate at which the patient breathes. EX1006, 10:6-16. The flow rate measurement means or sensor 70 detects "interruptions" 10 (Fig 1) within the patient's breathing cycle. The "interruptions" are superimposed at the peak of each cycle and indicate upper airway flow limitation in the patient. *Id.*, 9:31-34. Also similar to Rapport502, when Sullivan460 senses interruptions 10 in the patient's "breathing patterns" or determines the patient is asleep, a controller 100 activates a switch 110, which activates the nCPAP apparatus 90 to supply air to the patient 30 at a higher pressure, to ameliorate or eliminate the patient's upper airway flow limitation. *Id.*, 10:4-16.

Second, Dr. Rapoport was familiar with Dr. Sullivan's work, and acknowledged that Dr. Sullivan and his colleagues were "a few months ahead of the rest of us." EX1012, 3; Behbehani Decl. ¶202. A POSITA improving CPAP machines would have naturally looked at the pioneer in CPAP machines for algorithms for different air pressure settings that could improve compliance. Behbehani Decl. ¶202. In fact, Dr. Rapoport would repeatedly cite to the work of Dr. Sullivan in his own published papers. EX1014, 7-8.

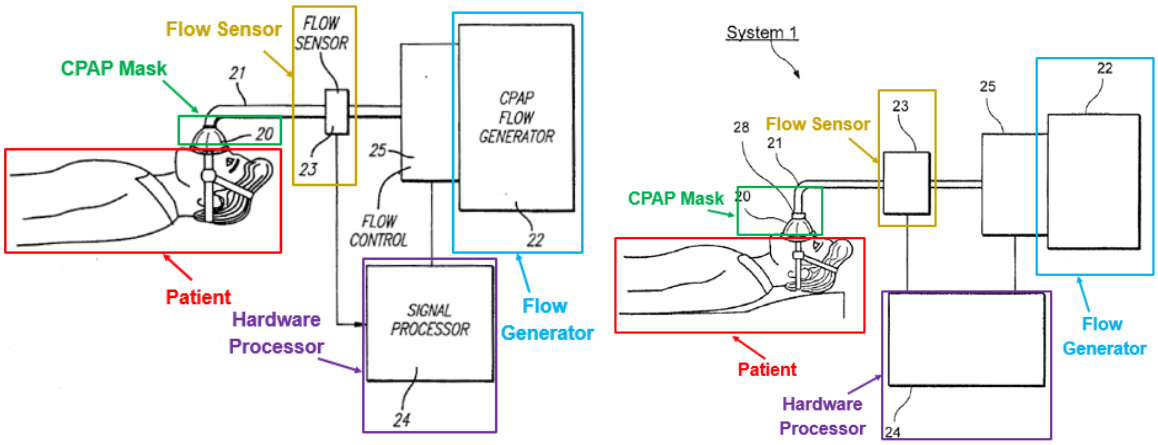
Given that the proposed modification involves a simple change in a programming algorithm, it is nothing more than a combination of known prior art elements according to known methods and known techniques to yield predictable

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

C. Independent Claim 24

1. Preamble

To the extent limiting, Rapport502 discloses the preamble. Behbehani Decl. ¶204. Rapport502 discloses a continuous *positive airway pressure system for treatment of a sleeping disorder in a patient* in the same manner as the '539 Patent. *See* EX1008, 1:16-21 (describing the CPAP system is "for adjusting the positive airway pressure of a patient to an optimum value in the treatment of obstructive sleep apnea."), Fig. 9; Behbehani Decl. ¶204.



Rapoport502, Fig. 9 (annotated) **'539 Patent, Fig. 1 (annotated)**

2. 24[a]

Rapoport502's CPAP system includes a *generator* 22 (blue), which *appl[ies] a pressure to an airway of* the *patient* (red) via a patient worn CPAP mask 20

(green). EX1008, 5:51-53 ("a CPAP mask 20 is connected via tube 21 to receive air from a CPAP flow generator 22"), Fig. 9; *see also* Section IX.C.1.

3. 24[b]

Rapoport502's "conventional flow sensor 23…provide[s] an electric output signal corresponding to the waveform of the airflow in the tube 21. This signal is applied to a signal processor 24, which detects the existence in the waveforms of conditions that indicate flow limitation." EX1008, 5:56-61. The conventional flow sensor 23 is a *sensor measuring data* corresponding to the "air through the flow sensor," which *corresponds to the supplied airflow*. *Id.*, 3:34-36; Behbehani Decl. ¶207. Further, Figures 1-5 illustrate exemplary waveforms of airflow between the patient and the flow generator at various pressures sensed by the sensor 23, 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 Decl. ¶208.

4. 24[c]

Rapoport502's CPAP system includes a signal processor 24 (purple) corresponding to a *hardware processor*. *See* Section X.C.1. The '539 Patent illustrates the processing arrangement 24 as a "black box" but does not disclose what constitutes the processing arrangement 24. *See id.* (illustrating '539 patent Fig. 1); Behbehani Decl. ¶209. Rapoport502 illustrates the signal processor 24 connected in the same manner, and further uses the term "signal processor" which

had a well-understood structure akin to an arrangement of elements that performs processing. Behbehani Decl. ¶209.

Both the ’539 Patent and Rapoport502 describe the processing arrangement 24 and signal processor 24, respectively, functionally in terms of the information that it receives and analyzes, and the control of pressure in the CPAP system based on that analysis. *Compare* EX1001, 3:60-64, 4:13-27, 5:48-54 *with* EX1008, 5:56-63 (describing waveforms received and analyzed and the output to control other components of the CPAP system), *id.,* 6:1-55 (disclosing the decision flow of the signal processor 24 in relation to Fig. 10); Behbehani Decl. ¶210.

The processor 24 analyzes the data to determine the patient's breathing patterns to determine whether breathing patterns indicate whether an asleep state has occurred by “detect[ing] the existence in the waveforms [supplied by the flow generator 23] of conditions that indicate flow limitation” of the patient. EX1008, 5:59-61; Behbehani Decl. ¶212. Figures 1-5 illustrate exemplary breathing pattern waveforms that are analyzed by the signal processor 24 and depict the gradual onset of a sleep disorder with the change of the patient’s breathing patterns. EX1008, 4:47-5:50, Figs. 1-5; Behbehani Decl. ¶212.

Although Rapoport502 does not explicitly disclose that the *hardware processor* determines *whether the breathing patterns indicate an awake state*, this limitation would have been obvious from Rapoport502 in view of Sullivan460.

a) Teachings of Sullivan460 on determining awake state

Sullivan460 discloses *whether the breathing patterns indicate an awake state*. *See* Section VIII.C.4.a).

b) Motivation to Combine and Reasonable Expectation of Success

See Sections X.A and X.B.

D. Dependent Claims 25-30

3. Claim 25

Figure 10 represents Rapoport502's "automatic adjustment mode" effectuated by the *hardware processor* in which "several input parameters…are used in the determination of the action to be taken" including applying a pressure increase to the patient. EX1008, 7:6-8. As seen in (blue), 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.

Although Rapoport502 does not explicitly disclose *a breathing pattern indicative of a transition from an awake state to an asleep state*, this is taught by Sullivan460. Sullivan460 discloses a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19. "[S]witching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the

patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. *Id.*, 6:30-7:12, cls. 22-28, 43-46. This means that the patient *has transitioned to an awake state from an asleep state*. Behbehani Decl. ¶217.

It would have been obvious to a POSITA to modify Rapoport502 so that the hardware processor in Rapoport502 further analyzes the breathing patterns to determine whether a breathing pattern indicative of an awake to an asleep state has occurred, as taught in Sullivan460, for the same reasons as explained for 24[c]. *See* Section VIII.C.4. As the POSITA would have recognized from the teachings of Rapoport502 and Sullivan460, a lower pressure is desirable when the patient is awake because it ensures the patient is comfortable and reduces the likelihood the patient will remove the mask. Behbehani Decl. ¶218.

4. Claim 26

Rapoport502 in view of the knowledge of a POSITA discloses this limitation. *See* Section VIII.D.2 (discussing Sullivan460); Behbehani Decl. ¶219.

5. Claim 27

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA renders obvious this limitation. Behbehani Decl. ¶220. Sullivan460's sleep sensor also detects *series of obstructions*. The flow rate measurement means 70 detects multiple "interruptions," which Fig. 1 depicts, and are a *series of obstructions*.

EX1006, 10:12-16. Sullivan460's claim 1 specifies a sensor that detects at least one interruption cycle and claim 2 specifies that detection of a plurality of interruption cycles, either of which are detectable only with a *series of obstructions*. *See also id.*, claims 22, 25-27. Further, Sullivan460 detects the occurrence of "two or more interruption cycles" (which are regularly-spaced obstructions) in the upper inspiratory flow rate and the treatment means treats the airway limitation on the detection of said at least two interruption cycles. *Id.*, 3:20-23. Thus, the sleep detection technique in Sullivan460 (which may also be used in the modified device as explained above) is also based on detection of a *series of obstructions.*

6. Claim 28

Rapoport502 in view of Sullivan460 or the knowledge of a POSITA renders obvious this limitation. *See* Sections IX.D.4 (Ground 2, Claim 26) and IX.D.5 (Ground 2, Claim 27).

7. Claim 29

Rapoport502 discloses this limitation. *See* EX1008, 11:66-12:1 ("The microprocessor produces a speed control signal which adjusts a motor speed control circuit 82 which controls the speed of a blower motor 84."); Behbehani Decl. ¶223; *see also* Section IX.C.4 (Ground 2, 24[c]).

8. Claim 30

"[T]he controlled positive *pressure* could be changed" (*increased*) "automatically via an automated system, either in response to feedback control or *using* pre-set *ramps* or steps in the controlled positive pressure throughout the night (in laboratory or at home)." EX1008, 13:37-41. Also, Rapoport502 discloses "a slope parameter [of the ramp], e.g., 0.1 cm per two seconds." EX1008, 11:44-46. A POSITA would understand to increase the pressure using the ramp system disclosed by Rapoport502. Behbehani Decl. ¶224.

E. Independent Claims 1 and 11

1. Preamble

To the extent limiting, Rapoport502 discloses the preamble. *See* Section IX.C.1 (Ground 2, 24[preamble]); Behbehani Decl. ¶225.

2. 1[a]/11[a]

Rapoport502 discloses this limitation. *See* Section IX.C.2 (Ground 2, 24[a]); Behbehani Decl. ¶226.

3. 1[b]/11[b]

Rapoport502 discloses this limitation. *See* Section IX.C.3 (Ground 2, 24[b]); Behbehani Decl. ¶227.

4. 1[c]

Rapoport502 discloses this limitation. *See* Section IX.C.4 (Ground 2, 24[c]); Behbehani Decl. ¶228.

5. 1[d]

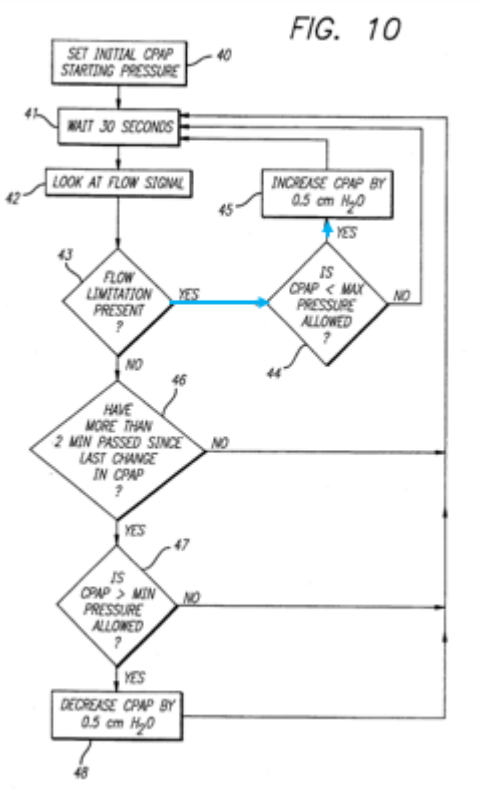
Rapoport502 discloses this limitation. *See* Sections IX.C.4 (Ground 2, 24[c]) and IX.D.5 (Ground 2, Claim 29); Behbehani Decl. ¶229.

6. 11[c]

Rapport discloses this limitation. *See* Sections IX.C.4 (Ground 2, 24[c]); Behbehani Decl. ¶230.

7. 1[e]/11[d]

Rapoport502 discloses providing instructions to the generator to adjust the applied pressure [to a first value] in response to the patient's breathing patterns indicative of a transition to an asleep state by determining a flow limitation state for the patient, as seen by Figure 10. EX1008, Fig. 10 (reproduced below).



EX1008, Fig. 10 (annotated)

Figure 10 represents Rapoport502's "automatic adjustment mode" effectuated by the *hardware processor* in which "several input parameters…are used in the determination of the action to be taken" including applying a delay before onset of a pressure increase to the patient. EX1008, 7:6-8. As seen in (blue), 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. By *adjust[ing] the applied pressure* by 0.5 cm H_20 (*a first value*) upon the detection of snores, Rapoport502 discloses this limitation.

Although Rapoport502 does not explicitly teach a transition *from an awake state*, this is taught by Sullivan460.

a) Teachings of Sullivan460

Sullivan460 discloses that the patient transitions *from an awake state*. *See* Section VIII.E.7.a).

b) Motivation to Combine and Reasonable Expectation of Success

See Section IX.A and IX.B.

F. Dependent Claims 2, 5-10, 13, 15-24

1. Claim 2

Rapoport502 discloses this limitation. *See* Section IX.C.3 (discussing *using at least one of a flow sensor or pressure sensor*); Behbehani Decl. ¶234.

2. Claim 5, 17

Rapoport502 discloses this limitation. *See* Section IX.D.7 (Ground 2, Claim 29); Behbehani Decl. ¶235.

3. Claim 6, 19

Rapoport502 discloses this limitation. *See* Section IX.D.4 (Ground 2, Claim 26); Behbehani Decl. ¶236.

4. Claim 7, 20

Rapoport502 discloses this limitation. *See* Section IX.D.5 (Ground 2, Claim 27); Behbehani Decl. ¶237.

5. Claim 8, 21

Rapoport502 discloses this limitation. *See* Section IX.D.6 (Ground 2, Claim 28); Behbehani Decl. ¶238.

6. Claim 9

Rapoport502's signal processor 24 (*hardware processor*) detects a patient changing from a flow limitation state and a no flow limitation state, and *decrease[s] a pressure of airflow provided to the patient* by 0.5 cm H_20 (Step 48) when it determines a "NO" flow limitation state (step 43) and the CPAP pressure is greater than the minimum pressure allowed (Step 47). EX1008, 6:17-29. As explained in Sections IV.A and IV.B, it would have been obvious to a POSITA to detect *an asleep state* and *an awake state* based on the flow or no flow limitation states in Rapoport502, based on the teachings of Sullivan460. A POSITA would understand that the *hardware processor* would *transmit[] an operational control signal to the generator* 22 to decrease pressure. Behbehani Decl. ¶239.

7. Claim 10

Rapoport502 discloses this limitation. Behbehani Decl. ¶240. The *breathing patterns* in Rapoport502 referenced in 1[e]/11[d] include those *indicative of elevated upper airway resistance*. EX1008, 1:29-36 ("[Obstructive sleep apnea syndrome]…is characterized by an intermittent *obstruction* of the *upper airway* occurring during sleep. The *obstruction* results in a spectrum of respiratory

disturbances [including]… significant obstruction with or without reduced airflow (hypopnea and snoring)…") (emphasis added); Behbehani Decl. ¶240.

The *breathing patterns* in Rapoport502 referenced in in 1[e]/11[d] include those *indicative of hypopneas*. *Id.* ("The obstruction results in a spectrum of respiratory disturbances [including]… significant obstruction with or without reduced airflow (*hypopnea* and snoring)…") (emphasis added); Behbehani Decl. ¶241.

The *breathing patterns* in Rapoport502 referenced in in 1[e]/11[d] include those *indicative of repetitive obstructive apnea*. *Id.* ("The obstruction results in a spectrum of respiratory disturbances [including]…the total absence of airflow (*apnea*)…") (emphasis added); Behbehani Decl. ¶242.

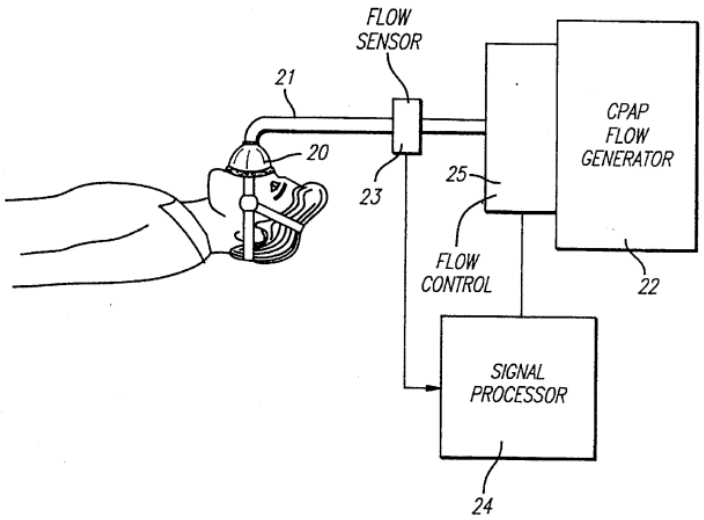
In Rapoport502, when a breathing pattern indicative of an elevated upper airway resistance, hypopnea or repetitive obstructive apnea has occurred, the hardware processor transmits control signal to generator to increase pressure. See Section IX.D.7 (Ground 2, Claim 29).

8. Claim 13

Rapoport502 discloses this limitation. Behbehani Decl. ¶243. As shown in Fig. 9 below, Rapoport502 teaches *a mask placed on a face of the patient and covering at least one of the mouth and the nose of the patient.* EX1008, 12:66-13:4

("[T]he perimeter of the nasal mask may be configured with a pliable material which would confirm to the shape of the face of the patient.")

FIG. 9



EX1008, Fig. 9

9. Claim 15

Rapoport502's signal processor 24 (*hardware processor*) detects a patient transitioning between a flow limitation state and a no flow limitation state, and *reduce[s] the supplied pressure* by 0.5 cm H_20 (Step 48) when it determines a "NO" flow limitation state (step 43) and the CPAP pressure is greater than the minimum pressure allowed (Step 47). EX1008, 6:17-29.

Although Rapoport502 does not expressly disclose an awake state, this is taught by Sullivan460. Sullivan460 discloses a sleep sensor that detects whether the patient is in an awake state or in an asleep state. EX1006, 7:3-19; *see* Section

VIII.C.4.a) (Ground 1, 24[c], discussing Sullivan460). "[A] switching means which responds to the sleep sensor and automatically switches the treatment means between [] two modes of air delivery," where "a first mode [is] for use when the patient is awake, and a second mode [is] for use when the patient is asleep," where the pressure for the second mode is higher than the pressure for the first mode. EX1006, 6:30-7:12, cls. 22-28, 43-46. This means that *when* the patient *change[s] from an asleep state to an awake state*, Sullivan460 *reduce[s] the supplied pressure* to the patient.

It would have been obvious to a POSITA to modify Rapoport502 so that *when the hardware processor* in Rapoport502 *detect[s]* that the patient has *change[s] from an asleep state* (as indicated by a flow limitation) *to an awake state* (including no flow limitation)*, the hardware processor reduce[s] the supplied pressure* to the patient, as taught in Sullivan460, for the same reasons as explained above. As the POSITA would have recognized from the teachings of Rapoport502 and Sullivan460, a lower pressure is desirable when the patient is awake because it ensures the patient is comfortable and reduces the likelihood the patient will remove the mask. Behbehani Decl. ¶248.

10. Claim 16

Rapoport502 in view of Sullivan460 renders obvious this limitation. *See* Sections VIII.D.5 (Ground 2, Claim 29).

11. Claim 18

Rapoport502 in view of Sullivan460 renders obvious this limitation. *See* Sections IX.E.7 (Ground 2, 1[e]/11[d]).

12. Claim 22

Rapoport502 discloses this limitation. *See* Sections IX.E.7 (Ground 2, 1[e]/11[d]).

13. Claim 23

Rapoport502 discloses this limitation. *See* Sections IX.D.8 (Ground 2, Claim 30).

X. GROUND 3: SULLIVAN995 ANTICIPATES CLAIMS 1-2, 5-11, 13, 15-30

As discussed for Ground 1, under reasonable constructions, Sullivan995 discloses each and every limitation of the challenged claims except for determining breathing patterns that indicate "an awake state." But under PO's implied construction of "an awake state" based on its infringement allegations, Sullivan995 anticipates the challenged claims.

In its Complaint, PO alleges that the AutoSet™ algorithm meets this limitation simply by determining breathing patterns indicating the patient is asleep. In other words, PO alleges that the patient is in an awake 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 an awake

state because "it decreases the pressure upon waking up." EX1018, ¶102; *see also id.*, ¶¶158-59 (citing EX1019, EX1033). To support this allegation, PO cites to an article entitled "Fall asleep faster with lower CPAP pressure." EX1019. The article explains that the accused CPAP machine "starts you at a low air pressure and stays there while you're still awake." EX1019, 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."); EX1033 (discussing AutoRamp feature).

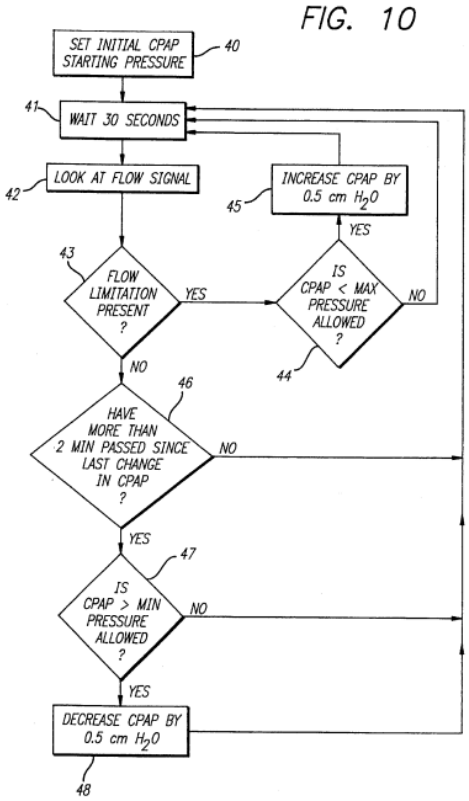
Just as alleged in the Complaint, Sullivan995 discloses that the *hardware processor* uses the data from microphone 11 to determine *whether breathing patterns indicate an awake state*. Behbehani Decl. ¶253.

Thus, Sullivan995 discloses the absence of breathing patterns indicative of sleep, which is indicative of *an awake state* under PO's implied construction.

XI. GROUND 4: RAPOPORT502 ANTICIPATES CLAIMS 1-2, 5-11, 13, 15-30

As discussed for Ground 2, under reasonable constructions, Rapoport502 discloses each and every limitation of the challenged claims except for determining breathing patterns that indicate "an awake state." But under PO's implied construction of "an awake state" based on its infringement allegations, Rapoport502 anticipates the challenged claims. Behbehani Decl. ¶¶254-56.

In its Complaint, PO alleges that the patient is in an awake state when there is an absence of obstructions or other breathing patterns indicative of sleep. *See* Section X (discussing PO's interpretation of "an awake state" in Complaint). Just as alleged in the Complaint, Rapoport502 discloses that the *hardware processor* uses the data from the *sensor* to determine whether the breathing patterns indicate *an awake state* has occurred. Behbehani Decl. ¶254. Rapoport502 teaches providing lower pressure in the absence of a determination that the patient is asleep, just as alleged in the Complaint. Rapoport502 generally 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." EX1008, 3:18-21. In particular, Figure 10 of Rapoport502 shows that the pressure will decrease if no obstruction is detected. Rapoport502 explains that "[i]f it has determined that flow limitation has occurred (step 43) and that the CPAP pressure is less than the maximum allowed (step 44), then the CPAP pressure is increased." *Id.*, 6:9-13. But "[i]f it was determined that a flow limitation was ***not present*** (step 43)," and if a predetermined time has elapsed and the current pressure is greater than the minimum pressure, "then the CPAP pressure is decreased…and the method returns to the settling step 31." *Id.*, 6:18-30. Thus, Rapoport502 meets PO's implied construction that patient is in an awake state when there is an absence of obstructions or other breathing patterns indicative of sleep.



EX1008, Fig. 10

Thus, Rapoport502 discloses the absence of breathing patterns indicative of sleep, which is indicative of *an awake state* under PO's implied construction.

XII. SECONDARY CONSIDERATIONS

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

XIII. THE BOARD SHOULD REACH THE MERITS OF THIS PETITION

A. Institution is appropriate under § 325(d)

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

B. Institution is appropriate under § 314(a)

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

XIV. CONCLUSION

For these reasons, Petitioner respectfully requests *inter partes* review of claims 1-2, 5-11, 13, 15-30 of the ’539 Patent.

Respectfully submitted

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Claims Listing (Appendix)

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

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

   [b] one or more flow sensors measuring data corresponding to the supplied airflow; and

   [c] at least one hardware processor,

   [d] wherein the hardware processor receives the measured data from the one or more flow sensors and provides operational control signals to the generator,

   [e] wherein the hardware processor analyzes the measured data to determine whether a patient breathing pattern indicative at least one transition between an awake state and an asleep state has occurred, the hardware processor providing instructions to the generator to adjust the applied pressure in response to the patient's breathing patterns indicative of the at least one transition.

2. The system according to claim 1, wherein the one or more flow sensors comprise at least one of an airflow sensor or a pressure sensor.

5. The system according to claim 1, wherein when the patient breathing pattern indicative of a change from the awake state to the asleep state has occurred, the hardware processor transmits an operational control signal to the generator to increase a pressure of airflow provided to the patient.

6. The system according to claim 5, wherein the hardware processor determines that the patient breathing pattern indicative of a change from the awake state to the asleep state has occurred when the patient breathing pattern indicates regularity of breathing.

7. The system according to claim 5, wherein the hardware processor determines the patient breathing pattern indicative of a change from the awake state to the asleep state has occurred when the patient breathing pattern indicates a regular period of obstructions.

8. The system according to claim 5, wherein the hardware processor monitors the measured data for at least one of a regularity of breathing or a regular period of obstructions.

9. The system according to claim 1, wherein when the hardware processor determines that a patient breathing pattern indicative of a change from an asleep state to an awake state has occurred, the hardware processor transmits an operational control signal to the generator to decrease a pressure of airflow provided to the patient.

10. The system according to claim 1, wherein when the hardware processor determines that a breathing pattern indicative of one of an elevated upper airway resistance, hypopnea or a repetitive obstructive apnea has occurred, the hardware processor transmits an operational control signal to the generator to increase the pressure Supplied by the generator.

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

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

[b] measuring data corresponding to changes in flow or pressure of the airflow supplied to the patient using at least one of a flow sensor or a pressure sensor,

[c] analyzing, using a hardware processor, the measured data to determine whether the data includes breathing patterns indicative of at least one of an awake state or an asleep state;

[d] when a breathing pattern indicates a transition has occurred between an awake state and an asleep state, adjusting the supplied pressure to a first value.

13. The method according to claim 11, further comprising placing a mask on a face of the patient and covering at least one of the mouth and the nose of the patient.

15. The method according to claim 11, further comprising controlling the generator to reduce the supplied pressure when a breathing pattern indicative of a change from an asleep state to an awake state is detected.

16. The method according to claim 11, further comprising controlling the flow generator to increase the supplied pressure when a breathing pattern indicative of a change from an awake state to an asleep state is detected.

17. The method according to claim 11, further comprising controlling the generator to increase the supplied pressure when a breathing pattern indicative of one of an elevated upper airway resistance, hypopnea or a repetitive obstructive apnea is detected.

18. The method according to claim 11, further comprising analyzing the breathing patterns to determine when the patient transitions from an awake state to an asleep state.

19. The method according to claim 18, wherein a transition from an awake state to an asleep state is determined to have occurred when a regularity of breathing is detected.

20. The method according to claim 18, wherein a transition from an awake state to an asleep state is determined to have occurred when a series of obstructions are detected.

21. The method according to claim 18, wherein a transition from an awake state to an asleep state is determined to have occurred when one of a plurality of indictors is present, the indicators being regularity of breathing and a series of obstructions.

22. The method according to claim 18, further comprising increasing pressure provided to the patient when a determination of a transition from an awake State to an asleep state has occurred.

23. The method according to claim 18, further comprising ramping pressure provided to the patient when a breathing pattern indicative of a transition from an awake state to an asleep state has occurred.

24. 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 from data indicate of the airflow supplied to the patient using at least one of a flow sensor or pressure sensor; and

[c] a hardware processor analyzing the breathing patterns to determine whether breathing patterns indicate an asleep state or an awake state have occurred.

25. The positive airway pressure system according to claim 24, wherein the hardware processor further analyzes the breathing patterns to determine whether breathing patterns indicative of a transition from an awake State to an asleep state have occurred.

26. The positive airway pressure system according to claim 25, wherein the hardware processor determines that breathing pattern indicative of a transition from an awake state to an asleep state occurs when a regularity of breathing is detected.

27. The positive airway pressure system according to claim 25, the hardware processor determines that a transition from an awake State to an asleep state occurs when a series of obstructions are detected.

28. The positive airway pressure system according to claim 25, the hardware processor determines that a breathing pattern indicative of a transition from an awake state to an asleep state occurs when one of a plurality of indictors is present, the indicators being regularity of breathing and a series of obstructions.

29. The positive airway pressure system according to claim 28, wherein the hardware processor sends a control signal to the generator to increase pressure provided to the patient when the hardware processor determines that a breathing pattern indicative of a transition from an awake state to an asleep state has occurred.

30. The positive airway pressure system according to claim 29, wherein the generator is configured to use a ramp system to increase pressure.

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

Under 37 C.F.R. § 42.24(b)(1), the undersigned certifies that the foregoing Petition contains 12,467 words, excluding table of contents, mandatory notices under § 42.8, and a certificate of service or word count, as measured by the word-processing system used to prepare this paper. 37 CFR. § 42.24(a)(1).

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CERTIFICATE OF SERVICE

The undersigned certifies that a complete copy of this Petition for *Inter Partes* Review of U.S. Patent No. 9,427,539 and all Exhibits and other documents filed together with this Petition were served on the official correspondence address for the patent shown in PAIR via STANDARD OVERNIGHT FEDERAL EXPRESS next business day delivery on May 31, 2022:

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