

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES,
Patent Owner

Case IPR2025-00157

**DECLARATION OF JASON KIRKNESS, PH.D. IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,602,284**

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Declaration of Jason Kirkness, Ph.D. in Support of
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I. INTRODUCTION

1. I, Jason Kirkness, Ph.D., have been retained by ResMed Corp. (“Petitioner”) to provide an analysis of the scope and content of U.S. Patent No. 11,602,284 relative to the state of the art at the time of the earliest application to which the ’284 patent claims priority. My analysis relates to claims 1-3, 6, and 12-20. I have also been retained to provide analysis regarding what a person of ordinary skill in the art (“POSITA”) would have understood at the time of the earliest application underlying the ’284 patent.

2. This declaration summarizes the opinions I have formed to date. I reserve the right to modify or amend my opinions, if necessary, based on further review and analysis of information that I receive subsequent to the filing of this declaration, including in response to positions taken by Cleveland Medical Devices, Inc. (“CleveMed”) or its experts that I have not yet seen, including any secondary considerations evidence that CleveMed or its expert may consider and present.

3. It is my opinion that claims 1-3, 6, and 12-20 of the ’284 patent are invalid based on the following grounds:

Ground 1	Truitt in view of Kumar renders obvious claims 1-3, 6, 12-15, 18, and 19.
Ground 2	Truitt in view of Kumar and Dong renders obvious claims 15, 16, and 18.

Ground 3	Truitt in view of Kumar and Wright renders obvious claims 17 and 20.
Ground 4	Truitt in view of Kumar and Mumford renders obvious claims 1-3, 6, 12-15, 18-19.
Ground 5	Truitt in view of Kumar, Dong, and Mumford renders obvious claims 15, 16, and 18.
Ground 6	Truitt in view of Kumar, Wright, and Mumford renders obvious claims 17 and 20.

II. EXPERIENCE AND QUALIFICATIONS

4. My curriculum vitae (“CV”) is Exhibit 1004. I am a Voluntary Associate Professor, in the Division of Pulmonary, Critical Care and Sleep Medicine at the Miller School of Medicine, University of Miami in Miami, Florida and serve on the Board of Directors of the American Thoracic Society. My career has focused on technology and devices to diagnose, monitor, and treat chronic respiratory-related diseases and disorders, including obstructive sleep apnea, chronic obstructive airway diseases, and acute respiratory diseases. I have published dozens of papers on obstructive sleep apnea in peer-reviewed journals.

5. In 1996, I was awarded a Bachelor of Science degree in Biology from the University of Western Sydney, Kingwood, Australia.

6. In 1997, I was awarded a Bachelor of Science degree with First-Class Honors in Physiology from the University of Western Sydney, Australia.

7. In 2003, I was awarded a Ph.D. in Medicine from the University of Sydney, Camperdown, Australia. My thesis was entitled “The role of surface tension of liquid lining the upper airway in upper airway patency and the obstructive sleep apnoea hypopnoea syndrome.” This included the design and use of pressure control devices to alter upper airway patency, a crucial element in treating patients with sleep disorders.

8. While pursuing my Bachelor of Science degrees, I researched devices used to modify airway resistance in order to determine effectiveness for decreasing the occurrence of apnea, hypopnea, snoring, or inspiratory airflow limitation. The specific products were external nasal dilators that were placed over the nose to modify the mechanical properties of the nasal and subsequent nasopharyngeal airflow during wakefulness, sleep, and during exercise.

9. I have extensive experience in analyzing physiological sensor design, performance, output characteristics, and signal analysis including in assessment of sleep disordered breathing. For example, I was involved in a project examining performance of elite rowers using telemetry based ventilatory and physiological recording in 1997 as part of a collaborative research project at Sydney Athletics Centre with NSW Institute of Sport, Department of Respiratory Medicine, Westmead Hospital and Department of Biological Sciences, University of Western

Sydney, Nepean. From 1999 onward, I contributed to numerous publications examining respiratory flow measurement and diagnostics.

10. My collaborations with Westmead Hospital included work relating to the physiological impact of nasal airflow interventions and the development of devices to assess nasal wall elasticity, with research published in journals such as the Journal of Applied Physiology. This work emphasized diagnostic tools to monitor airflow dynamics, which are key to the development of effective respiratory support systems.

11. I was also involved in the development of an anatomical positioning device for assessing the therapeutic mechanism of nasal vestibule wall elasticity in response to a nasal dilator strip, which resulted in several publications, including one on nasal airflow dynamics associated with an external nasal dilator strip. (European Respiratory Journal, 2000, 15 (5): 929-936).

12. During my later thesis work, I collaborated with the Department of Physics and Biomedical Engineering at the Australian National University to create a novel instrument for determining the surface tension of microliter liquid samples from the upper airway. This research led to multiple publications, including studies on the effect of surface tension on upper airway mechanics in anesthetized humans. (Journal of Applied Physiology, 2003, 95 (1): 357-363).

13. I examined the biomechanical and physiological properties of airways in response to products known as exogenous surfactants. The products were known to treat the lower airways, particularly in neonates, yet it was unknown how a product that lowered airway lining liquid surface tension would impact the upper airway physiology in individuals with obstructive sleep apnea hypopnea syndrome. In order to assess surfactant product performance, I utilized airway pressure support devices to raise and lower the airway pressure via a nasal mask to generate and eliminate airway closure and reopening that occurs in patients with collapsible airways, as occurs in sleep apnea.

14. To conduct my thesis work, I was required to design and develop instrumentation to detect, quantify, monitor, display, collect, record, store, process, analyze and/or interpret physical systems and physiological responses for the purpose of characterizing the role of modifying airway surface-liquid-surface properties and their effect on upper airway collapse in sleep apnea and hypopnea.

15. I was also awarded two post-doctoral research fellowships at the Johns Hopkins School of Medicine through the Thoracic Society of Australia and New Zealand and The National Health and Medical Research Council of Australia. My 2004 fellowship was focused on neurohumoral and neuromuscular control of upper airway patency in severe obesity and sleep apnea. This project included the design and use of specialized equipment to assess upper airway patency.

16. I was also involved in testing the design of a skin conductance monitor at Westmead Hospital in collaboration with the University of Western Sydney and the Ludwig Engel Centre for Respiratory Research. This work focused on monitoring sleep and breathing related to the sympathetic nervous system and resulted in a publication on the skin conductance response to repeated inspiration (Clinical Neurophysiology, 2005, 116 (5): 1172-1180). While at the Ludwig Engel Centre for Respiratory Research I was also involved with the design and construction of a tonometry device to assess the tone of the soft palate muscle, as part of my role as an honorary associate scientist at the Ludwig Engel Centre for Respiratory Research, Westmead Millennium Institute.

17. I was further awarded a professional society fellowship from the American Thoracic Society.

18. I became a part of the faculty at the School of Medicine at John Hopkins University in 2009, where I served as a Research Associate. I then went on to become an Assistant Professor of Medicine in 2012. I became an Adjunct Assistant Professor of Medicine in 2017.

19. From 2014 to 2016, I was the Chief Technology Officer for RespEQ, which focused on developing technology to monitor adherence to respiratory therapies via connected devices. This included monitoring adherence to the use of

pressure systems used to treat sleep and breathing disorders such as obstructive sleep apnea.

20. Between the years of 2008 and 2017, I also served as a scientific consultant for technology and medical device companies engaged in developing treatments for breathing disorders, obstructive sleep apnea, sleep disorders, and sleep disordered breathing. This included pressure support devices and systems, high flow systems, humidification systems, lifestyle and behavioral approaches, and neurostimulation.

21. In 2008, I also served as an Instructor at the University of Western Australia and assisted in the creation of sleep science educational course content.

22. I am a named inventor on two (2) patent applications for quantifying inspiratory and expiratory airflow. These patents include:

- “Apparatus for quantifying expiratory and inspiratory airflow.” U.S. Publication No. 20130345590 A1, Inventors: H. Schneider and J. P. Kirkness; Filed: September 3, 2012.
- “Whole-body plethysmography system for the continuous characterization of sleep and breathing in a mouse,” PCT Publication No. WO2013003841 A1, Inventors: A. B. Hernandez, J. Kirkness, H. Schneider, M. Polotsky, A. Schwartz, P. Smith; W. Hernandez; Filed: July 2, 2012.

23. I have also worked on the design of pneumotachographs for respiratory airflow measurement, which are the gold standard for short-term and specific long-term measurements. I also contributed to the development of alternative devices to address these issues, which led to the following patent applications WO2006026387A2 and WO2012122506A9.

24. Beginning in 2017, I served as the Director of Clinical Affairs at Fisher and Paykel Healthcare, a leading manufacturer, designer, and marketer of products and systems for use in respiratory care, acute care, and the treatment of obstructive sleep apnea.

25. In 2020 I became the Vice President of Medical Clinical Affairs for 4D Medical, and subsequently served as Senior Vice President of Medical and Clinical Affairs.

26. In January of 2023, I also began to serve as a Voluntary Associate Professor of Medicine at University of Miami where I am currently.

27. I have published over 50 articles in peer-reviewed journals. Throughout my career, I have published findings relating to medical devices and systems and methods for assessing the physiological characteristics of breathing during wakefulness and sleep. I have served as a peer reviewer and editorial board member for sleep and breathing journals. I have also written several book chapters on upper airway obstruction and sleep apnea.

28. I have had several roles in chairing, creating, and presenting at international symposiums for topics that include systems, methods, and approaches for assessing, monitoring, and treating sleep disordered breathing and sleep apnea.

29. In addition, I have served on advisory and review committees as a scientific reviewer for The National Institutes of Health, The National Health and Medical Research Council of Australia, as well as other foundations and national and international grant awarding bodies. I have served as a scientific reviewer for Institutional Review Boards and the Hospital Ethics Committee.

30. I am a member of several professional societies, including the American Thoracic Society where I serve on Board of Directors, chair the Drug Device Discovery and Development Committee and serve on the Respiratory Innovation Summit Organizing Committee. I also serve on the Industry Advisory Committee for the Respiratory Compromise Institute.

III. ENGAGEMENT AS AN INDEPENDENT EXPERT

31. I am being compensated at the rate of \$700 per hour for my work related to this matter. My fee is not contingent on the outcome of this or any matter or on any position I have related to this matter.

32. I have no financial interest in ResMed. I have been informed that CleveMed claims ownership of the '284 patent. I have no financial interest in CleveMed.

IV. UNDERSTANDING OF GOVERNING LAW

33. I have been informed that statutory and judicially created standards must be considered to determine the validity of a patent claim. I am not an attorney and, consequently, will offer no opinion on the law itself. My understanding of the pertinent law is described in this section and is the result of explanations provided by counsel. I have applied this understanding in my analysis.

34. I have been informed that a patent claim is unpatentable if it is anticipated or obvious in view of the prior art. I further understand that the frame of reference for determining whether a claim is anticipated or obvious is from the perspective of a person of ordinary skill in the relevant art (“POSITA”) at the time the invention. I have been asked to assume that the effective priority date is November 4, 2005. I have not been asked to determine whether this date is appropriate.

A. Anticipation

35. I have been informed that for a patent claim to be anticipated by the prior art, each and every limitation of the claim must be found, expressly or inherently, in a single prior art reference as recited in the claim. I understand a claim limitation not expressly found in a prior art reference is inherent if the prior art necessarily functions in accordance with, or includes, the claim limitation. Mere probability that a limitation is included is not sufficient to establish inherency.

B. Obviousness

36. In analyzing obviousness in light of the prior art I have been informed that it is important to understand the scope of the claims, the level of skill in the relevant art, the scope and content of the prior art, the differences between the prior art and the claims, and any objective indicia of non-obviousness (also called secondary considerations).

37. I have been informed that a patent claim is unpatentable for obviousness if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a POSITA to which said subject matter pertains. I have been informed that obviousness may be based on one reference or a combination of references. I have been informed that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

38. I have been informed that when a patented invention is a combination of known elements, the Board must determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue by considering the teachings of prior art references, the effects of demands known to people working in the field or present in the marketplace, and the background knowledge possessed by a POSITA.

39. I have been informed that the Supreme Court has recognized several rationales for combining references or modifying a reference to show obviousness of the claimed subject matter. I understand that several of these rationales are: (1) combining prior art elements according to known methods to yield predictable results; (2) simple substitution of one known element for another to obtain predictable results; (3) use of a known technique to improve a similar device (method or product) in the same way; (4) applying a known technique to a known device (method or product) ready for improvement to yield predictable results; (5) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (6) and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

40. I have been informed that in order to prove that a claimed invention is not patentable for obviousness, a petitioner must (1) identify the differences between the claim and particular disclosures in the prior art references, singly or in combination, (2) specifically explain how the prior art references could have been combined in order to arrive at the subject matter of the claimed invention, and (3) specifically explain why a POSITA would have had reasons to so combine the prior art references.

II. RELEVANT TIME PERIOD FOR THE OBVIOUSNESS ANALYSIS

41. I understand that the '284 patent originates from Patent Application 17/825,266 filed on May 26, 2022, which claims priority back to Patent Application No. 11/266,899 filed on November 4, 2005, through a series of continuation applications. I have arrived at my opinions in this declaration by relying on the knowledge of a POSITA as of November 4, 2005.

V. LEVEL OF ORDINARY SKILL IN THE ART

A. Legal Principles

42. I have been informed that a person of ordinary skill in the art ("POSITA") is a hypothetical construct used for certain analyses in patent law. I understand that the claims are construed from the viewpoint of a POSITA and the factual determinations underlying obviousness (such as the scope and content of the prior art and the differences between the prior art and the claims) are performed from the perspective a POSITA. I understand that a POSITA is presumed to be aware of all pertinent prior art, thinks along conventional wisdom in the art, and is a person of ordinary creativity.

43. I have been informed by counsel that the following five non-exclusive factors may be used to determine the level of skill in the relevant art: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3)

the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active works in the field.

B. Bases for Level

44. In my opinion, a POSITA in 2005 would have had at least a bachelor's degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems, such as networked PAP machines. Additional experience could substitute for less education, and additional education could likewise substitute for less experience.

45. The five factors support this conclusion. The field of art is “integrated sleep diagnosis and treatment device.” Ex. 1001, 1:28-29. As Truitt, Kumar, and Mumford explain, some problems in the prior art include how to improve systems to get more accurate data and how to more effectively use the data collected. Some of the solutions include making the patient more comfortable, such as using wireless sensors or observing the patient remotely from home, and providing real-time analysis of the data, such as programming algorithms to determine efficacy or real-time streaming data to the physician.

46. Given the progress and sophistication of network and wireless technology, innovations were made quickly as the availability, cost, and size of

hardware and equipment made solutions to these problems simple to implement. This also allowed many of those active in the field to quickly learn mechanical, systems, and computer engineering basics.

C. Application of POSITA Standard

47. By 2005, I met or exceeded the level of a POSITA. My background in respiratory physiology and the design and testing of diagnostic systems and therapeutic devices reflects the skills and understanding required for product design and sensor system diagnostics in respiratory and sleep medicine. My specific experience includes the following:

48. Testing the design of a skin conductance monitor at Westmead Hospital in collaboration with the University of Western Sydney and the Ludwig Engel Centre for Respiratory Research. This work focused on monitoring sleep and breathing related to the sympathetic nervous system and resulted in a publication on the skin conductance response to repeated inspiration and was also used during sleep in the development of novel indices of sleep and breathing (Clinical Neurophysiology, 2005, 116 (5): 1172-1180).

49. Collaboration with the Department of Physics and Biomedical Engineering at the Australian National University to create a novel instrument for determining the surface tension of microliter liquid samples from the upper airway. This research led to multiple publications, including studies on the effect of surface

tension on upper airway mechanics in anesthetized humans (Journal of Applied Physiology, 2003, 95 (1): 357-363) and patients with obstructive sleep apnea/hypopnea syndrome (Sleep, 2005, 28(4): 771-77).

50. Design and construction of a tonometry device to assess the tone of the soft palate muscle, as part of my role as an honorary associate scientist at the Ludwig Engel Centre for Respiratory Research, Westmead Millennium Institute.

51. Development of an anatomical positioning device for assessing the therapeutic mechanism of nasal vestibule wall elasticity in response to a nasal dilator strip. This resulted in several publications, including one on nasal airflow dynamics associated with an external nasal dilator strip (European Respiratory Journal, 2000, 15 (5): 929-936).

52. Extensive experience in analyzing physiological sensor design, performance, output characteristics, and signal analysis including in assessment of sleep disordered breathing. Since 1999 I have contributed to numerous publications examining respiratory flow measurement, diagnostic indices of sleep and breathing, and mechanisms of therapy.

53. Project examining performance of elite rowers using telemetry based ventilatory and physiological recording in 1997. I was part of a collaborative research project at Sydney Athletics Centre with NSW Institute of Sport, Department

of Respiratory Medicine, Westmead Hospital and Department of Biological Sciences, University of Western Sydney, Nepean.

54. Engagement in the design of pneumotachographs for respiratory airflow measurement, which are the gold standard for short-term and specific long-term measurements. I contributed to the development of alternative devices to address these issues, which led to patents WO2006026387A2 and WO2012122506A9.

55. Awarded a PhD in Medicine in 2003, focused on factors controlling the upper airway. This included the design and use of pressure control devices to alter upper airway patency, a crucial element in treating patients with sleep disorders.

56. Recognition through the Thoracic Society of Australia and New Zealand (TSANZ) fellowship in 2004, focusing on neurohumoral and neuromuscular control of upper airway patency in severe obesity and sleep apnea. This project included the design and use of specialized equipment to assess upper airway patency.

57. Multiple research projects on the relationship between surface tension and upper airway collapsibility, specifically addressing its impact on obstructive sleep apnea, which were published and reviewed in respected journals, establishing a foundation in diagnostic methodologies for respiratory diseases.

58. Early work with Westmead Hospital in the late 1990s on the physiological impact of nasal airflow interventions and the development of devices to assess nasal wall elasticity, with research published in journals such as the Journal of Applied Physiology. This work emphasized diagnostic tools to monitor airflow dynamics, key to the development of effective respiratory support systems.

59. I was the Chief Technology Officer for RespEQ, which focused on developing technology to monitor adherence to respiratory therapies via connected devices. This included monitoring adherence to the use of pressure systems used to treat sleep and breathing disorders such as obstructive sleep apnea.

60. These experiences collectively align with and surpass the defined POSITA requirements in 2005, demonstrating advanced knowledge in respiratory diagnostic systems, product design, and sensor application in the clinical setting.

61. My experience in design, development, validation, clinical development of medical devices in the pathogenesis, diagnosis and treatment of sleep disorders more than sufficiently substitute for specific education.

62. My opinions do not turn on this precise definition, and the claims would be unpatentable from the perspective of any reasonable POSITA.

63. For the purpose of this Declaration, and unless otherwise noted, my statements and opinions, such as those regarding my experience and understanding of a POSITA generally (and specifically related to the references I consulted,) reflect

the knowledge that existed in the field as of November 4, 2005. This is true even if stated in the present tense.

VI. BACKGROUND

A. History of CPAP Therapy

64. Continuous positive airway pressure (CPAP) therapy is used for patients with a spectrum of sleep apnea severity with or without symptoms. CPAP therapy involves delivering a constant supply of pressurized gas through a mask worn over the nose, mouth, or both. This pressurized air creates a “splinting” effect in the upper airway, keeping the soft tissues (such as the tongue, soft palate, and pharyngeal walls) from collapsing and blocking the airway during sleep. By maintaining an open airway, respiratory related events are reduced, allowing for uninterrupted flow of gases into the lungs and stabilizing oxygen levels during CPAP use. The mechanisms of CPAP enable improved restorative sleep and reduction of the associated symptoms. The appropriate pressure required to meet an individual’s needs to reduce sleep disorder symptoms is determined by titrating the pressure.

65. The total absence of airflow, or apnea, results when the patient’s airway has completely collapsed such that air cannot pass through. *See also* Ex. 1019 at 8 (discussing reduction of muscle tone in sleep leading to upper airway narrowing or complete collapse). Because apnea, hypopnea, and heavy snoring produces decreased blood oxygenation, they are recognized causes of sleep disruption and risk

factors in certain types of heart disease. Ex. 1020 at 1:43-45; *see also Id* at 1:27-28 (“apnea leads to decreased blood oxygenation and thus to disruption of sleep”); Ex. 1021 at 1:35-38 (“Those afflicted with OSA experience sleep fragmentation and complete or nearly complete cessation of ventilation intermittently during sleep with potentially severe degrees of oxyhemoglobin desaturation”). The symptoms of obstructive sleep apnea or OSA include loud snoring, choking or gasping during sleep, impaired concentration, hypersomnolence (i.e., daytime sleepiness), and cardiovascular effects due to hypoxemia (i.e., low oxygen levels) or hypercapnia (i.e., high carbon dioxide levels).

66. Metrics of sleep disruption, such as the Apnea-Hypopnea Index (AHI) and Respiratory Disturbance Index (RDI), quantify the frequency of obstructive, central and mixed respiratory events and help gauge the severity of sleep-disordered breathing. Generally, a patient’s condition can be represented by index, a number representing a property or number of properties. For example, the “apnea hypopnea index” or “AHI” is a measured number of apnea and hypopnea events per unit time. Ex. 1012, 8:8-17. Because AHI includes the detection of hypopnea events (in addition to apnea events), a POSITA would have known that AHI, like hypopnea, can be determined by measuring both breathing volume and blood oxygen saturation.

67. By way of another example, RDI is calculated as the number of apnea events per hour plus the number of hypopnea events per hour plus the number of respiratory-effort related arousals per hour of sleep. There are also metrics such as Oxygen Desaturation Index (ODI), that focus on the sufficiency/insufficiency of blood oxygen levels during sleep. In describing one device developed in the mid-1990s, a number of indices were used to determine the efficacy of the auto-adjusting device and the level of severity that remained after treatment.

	Untreated (mean + SEM)	Treated (mean ± SEM)
Apnea Index (events/hr)	35.5 ± 5.9	1.5 ± 0.32
Time in Apnea (Percent of night)	24.5 ± 4.7	1.0 ± 0.37
Slow Wave Sleep (Percent of night)	7.0 ± 1.6	20.0 ± 2.2
REM Sleep (Percent of night)	9.4 ± 1.4	20.3 ± 2.1
Arousal Index (Events/hr)	55.9 ± 5.3	10.8 ± 1.9
Respiratory Arousals (Events/hr)	51.5 ± 5.4	4.2 ± 1.5

Ex. 1020, 17:52-60.

68. Obstructive and central sleep apneas are differentiated by the presence or absence of respiratory effort, with obstructive events involving persistent effort and central events showing none. Periodic breathing, or Cheyne-Stokes breathing, is a cyclic pattern of breathing characterized by gradual increases and decreases in tidal volume separated by periods of apnea, commonly associated with conditions like congestive heart failure and certain neurological disorders. The severity of these disorders is further characterized by indices like oxygen desaturation levels, arousal

frequency, and specific sleep stage distribution, aiding in tailoring PAP therapies or medications to individual patient responses. Ex. 1034.

69. Prior to 1981, OSA was treated with a highly invasive procedure called a tracheotomy, in which a surgical hole is made through the front of the neck and into the trachea, and a tube is placed into the hole for breathing.

70. In order to treat OSA non-invasively, Dr. Colin Sullivan, Dr. Michael Berthon-Jones, and their colleagues at the University of Sydney introduced positive airway pressure (PAP) therapy in 1981, which has since become the most effective treatment for OSA and is now the standard of care. *See* Ex. 1023 (first to discuss CPAP to treat sleep apnea). Rather than requiring a tracheotomy, PAP therapy is applied with a tight fitting nasal mask worn during sleep. Ex. 1023 at Summary, Fig. 2.

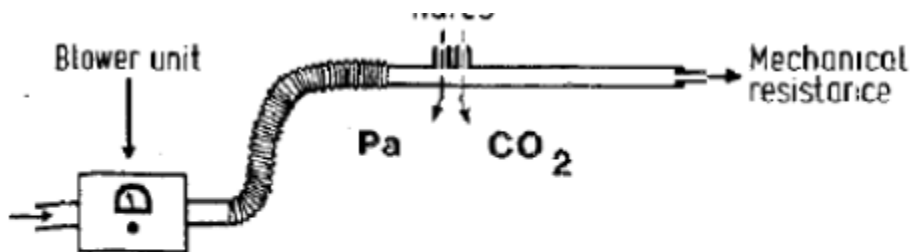
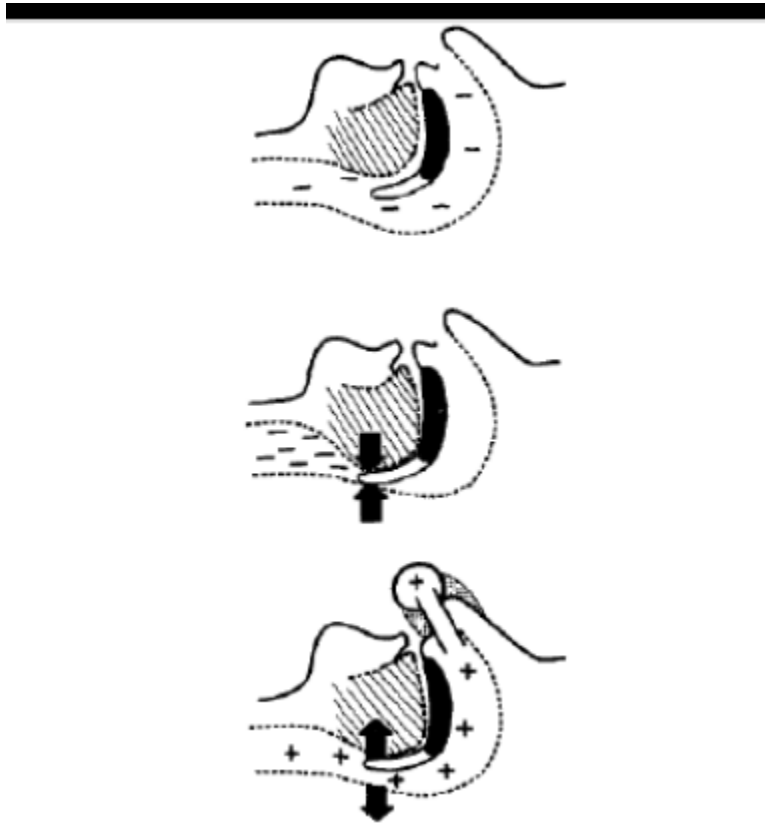


Fig. 2—Diagram of apparatus used to provide continuous positive airway pressure through the nares.

71. To prevent collapse of the patient's airway, PAP therapy applies positive airway pressure, which opposes the force created during inspiration (i.e.,

inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). Ex. 1016 at p. 1, Fig. 1 (reproduced below).



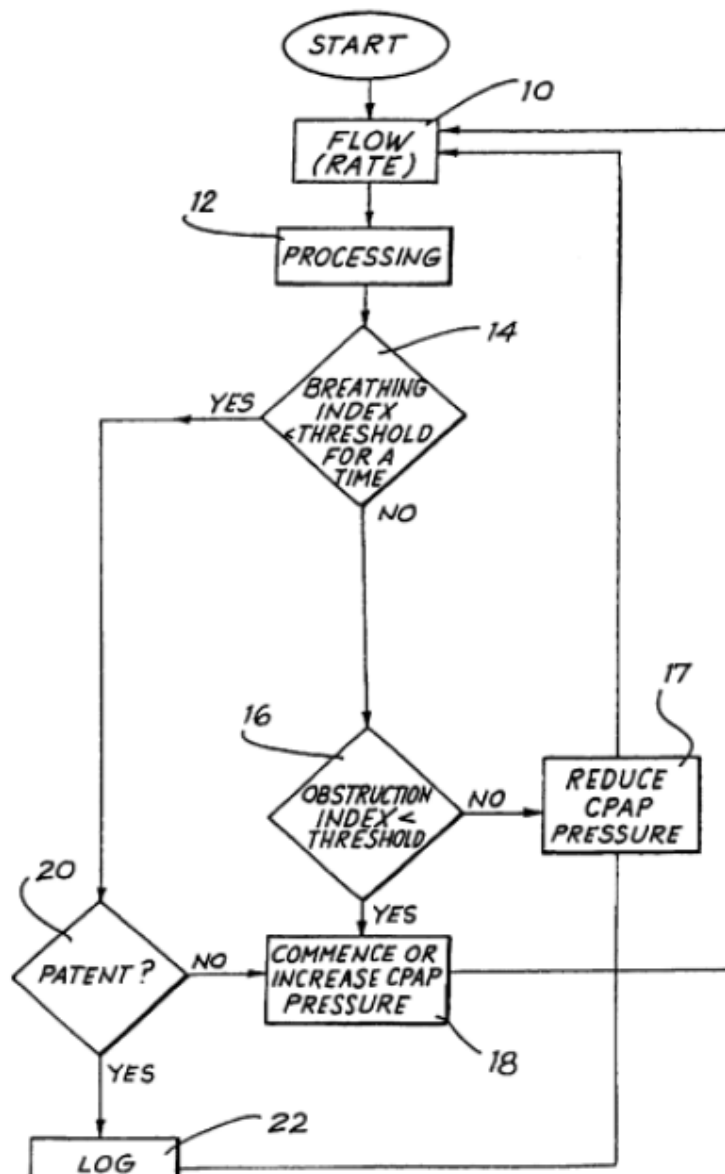
72. In their 1981 paper describing continuous PAP (“CPAP”), Dr. Sullivan, Dr. Berthon-Jones, and their colleagues described treating five OSA patients with CPAP therapy, applying low pressure levels (4.5-10 cm H₂O), which “completely prevented upper airway occlusion during sleep in each patient” and was “remarkably effective.” Ex. 1023 at Summary, Discussion, p. 3 col. 2.

73. Generally, a prescription and patient training for PAP therapy is “performed in, or directly under, the supervision of the sleep disorders laboratory.”

Ex. 1016 at p. 5 col 1. 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.” Ex. 1015 at p. 1 col. 1.

74. By 1993, Dr. Sullivan, Dr. Berthon-Jones, and their colleagues had developed a self-setting CPAP machine that adjusts CPAP pressure on a minute-by-minute basis according to the degree of upper airway obstruction. *Id.* By adjusting to changing upper airway resistance produced by changing sleep state, this approach had several advantages including (1) allowing a minimal awake pressure, thereby improving comfort and aiding compliance, and (2) potentially doing away with the need for a full night of observation in the laboratory. *Id.*

75. In November 1993, Dr. Berthon-Jones filed for patent protection, which eventually resulted in U.S. Patent No. 5,704,345, entitled “Detection of apnea and obstruction of the airway in the respiratory system.” *See* Ex. 1020 at Title.



76. As that patent makes clear, Dr. Berthon-Jones came up with a CPAP treatment protocol that would “commence or increase CPAP pressure” when “closed airway apneas, snoring, and inspiratory air flow limitation” were detected, and would reduce the CPAP treatment pressure when there is no obstruction and breathing is normal. Ex. 1020 at Fig. 1, 17:43-49.

77. By the mid-1990s, it was well-understood that the major limitation of CPAP therapy relates to discomfort or other factors leading to incomplete compliance with the necessary use of the device. Ex. 1025 at p. 5. 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.” Ex. 1015 at p. 4. Thus, it quickly became well-recognized that lowering to the minimal pressure could increase compliance. *Id.* Consequently, automatically adjusting PAP machines became common, particularly those that “automatically adjust the degree of assistance to maintaining at least a specified minimum ventilation.” Ex. 1024 at Abstract.

78. In 1996, Dr. Berthon-Jones and his colleagues published a study testing a CPAP device called the AutoSet™ self-setting CAP device. Ex. 1025 at p. 1, Fig. 4. The 1996 study found that AutoSet device produced an adequate improvement in sleep and breathing when used in an autosetting mode, which increased or decreased CPAP pressure depending on whether an obstruction was detected. *Id.*

79. In 1997, ResMed released the AutoSet Portable II Plus device, which had an automatic mode enabling the device to “continuously monitor[] the patient’s upper airway and increase[] and decrease[] pressure based on the presence or absence of events,” such as “snore, inspiratory flow limitation, or a closed airway apnea.” Ex. 1026 at pp. 9, 30.

80. In 1999, ResMed released the AutoSet device, which “adjusts pressure on a breath-by-breath basis to suit patient needs as they vary throughout the night.” Ex. 1027 at p. 2. Recognizing that “[i]nsufficient pressure results in ineffective therapy while too much pressure can lead to discomfort, non-compliance, and pressure-related side effects,” *Id.* at p. 2, ResMed developed the AutoSet T device to “act[] preemptively by increasing pressure in response to inspiratory flow limitation and snore, both of which typically precede obstruction.” *Id.* The AutoSet T device “calculates the pressure required based on the severity of the event. *Id.* For example, “[i]f an apnea suddenly occurs without any preceding flow limitation or snore, AutoSet T will increase pressure in order to prevent subsequent apneas,” and “[i]f no further events occur, AutoSet T reduces the pressure back to a minimum level.” *Id.* In this manner, AutoSet T “effectively normalizes sleep while delivering mean pressures up to 37% lower than fixed pressure therapy.” *Id.*

81. Additional CPAP devices have been released well before the earliest possible priority date of the '284 patent, including Sunrise Medical's DeVilbiss AutoAdjust LT Nasal CPAP System (Ex. 1028 at p. 24), Respiration's REMstar Auto device (Ex. 1029 at p. 6), as well as additional AutoSet devices released by ResMed, including AutoSet Clinical in 1994 and AutoSet Portable in 1995. Ex. 1030 at p. 39.

82. By 2003, machines for delivering PAP therapy were on the market that included one or more sensors and a central processing unit that could detect

breathing patterns and adjust pressure as appropriate based on those breathing patterns. Ex. 1032 at p. 2; Ex. 1037 at p. 2 (“A number of different auto-titrating CPAP devices are commercially available. They vary with respect to what physiological variable is monitored to decide changes in pressure and the algorithms (decision paths) used to determine if and how much to increase or decrease pressure. In general, the devices measure some or all of the following: snoring (airway vibration), airflow (apnea or hypopnea), and the flow vs. time profile (evidence of flattening as a surrogate for airflow limitation).”).

83. The industry did not consistently use the same name to describe PAP systems. Accordingly, various names have been used to describe the same PAP systems, including continuous PAP (CPAP), nasal PAP (NPAP), automatic PAP (APAP), nasal continuous PAP (NCPAP).

84. Despite the effectiveness of positive pressure therapy, patient adherence and comfort are significant challenges, as many users find the masks uncomfortable or intrusive, which can lead to inconsistent use. Issues with mask fit, air pressure, and machine noise can make wearing the device throughout the night difficult for some patients. Additionally, CPAP therapy can cause side effects such as dry mouth, nasal congestion, and skin irritation, as well as a feeling of claustrophobia in some users. These side effects may require further adjustments,

like adding humidification, changing mask types or the delivered air pressure, which can complicate consistent use.

85. The severity of sleep disorder symptoms of sleep apnea for which PAP therapy may be used, among others include the metrics: the Apnea-Hypopnea Index (AHI), Oxygen Desaturation Index (ODI), Respiratory Disturbance Index (RDI), snoring intensity and duration, arousal index, sleep fragmentation, and heart rate variability (HRV) during sleep. These indicators can quantify the frequency and impact of breathing disturbances, sleep quality disruptions, and cardiovascular stress, helping to assess sleep disorder severity, guide treatment, and track therapy effectiveness.

86. Autotitrating CPAP (Auto-CPAP) addresses the main limitations of standard CPAP—patient adherence and side effects—by adjusting the air pressure based on the user’s breathing needs during use. Ex. 1033. Unlike standard CPAP, which delivers a fixed pressure, Auto-CPAP continuously monitors airflow and automatically increases pressure as needed to prevent airway collapse, but decreases pressure when appropriate to improve comfort and compliance and minimize side effects.

87. Airway collapsibility fluctuates throughout the night due to changes in sleep stages, body position, blood gas levels, arousal responses, and circadian hormonal variations, all of which affect muscle tone and airway stability. Auto-

CPAP adaptability improves comfort, as users are not subjected to higher pressures than necessary, which can reduce side effects like arousal from sleep, dry mouth, nasal congestion, and air pressure-related discomfort. By tailoring pressure therapy to each user's needs, Auto-CPAP can enhance overall comfort and improve adherence, making it a more tolerable and effective solution for a wider range of patients. Exs. 1025, 1035.

B. Remote Diagnosis and Monitoring Patients at Home versus Clinic

88. During the 1960s, groundwork was laid for remote physiological monitoring in hospitals by anesthesiologists (Ex. 1036) and acute care physicians (Ex. 1037) by adapting process control computers—initially designed for industrial automation—to track vital signs in clinical settings. Early efforts led to the development of a computerized monitoring system at Los Angeles County General Hospital, which became operational in 1965 and allowed real-time digital transmission of physiological data within the hospital. Building on these early advances, other researchers digitized analog medical data, enabling it to be transmitted across newly forming long-distance networks, which eventually supported nationwide remote monitoring.

89. National Aeronautics and Space Administration (NASA) early work in monitoring astronauts' physiological data remotely was instrumental in advancing telemetry technology, proving that vital signs could be reliably tracked from great

distances. Ex. 1038. This capability influenced healthcare significantly, as it demonstrated how real-time physiological monitoring could assess acute changes in health, even in extreme environments. The success of these technology advancements confirmed that physiological data could be transmitted and analyzed remotely to monitor and manage patients' health status.

90. With communication technology advancements in the 1980s (such as cellular, cordless, satellite, digital switching) the ability of remote monitoring expanded further, allowing hospital and acute care settings to implement remote consultative services and collaborative care. Ex. 1038. These innovations led to trials, such as the Johns Hopkins University study using a commercially available remote monitoring platform (VisICU, Baltimore MD), which demonstrated that remote monitoring of acute care patients could effectively reduce mortality rates and healthcare costs by enabling immediate interventions and continuous oversight. Ex. 1039.

91. In the 1990s telemetry systems such as portable device designed for real-time monitoring of metabolic and respiratory parameters were deployed during exercise or field testing. Wireless data transmission enabled clinicians and scientists to track oxygen consumption, heart rate, and other physiological metrics in dynamic environments outside the laboratory in “real-world” settings. The New South Wales Institute of Sport used the COSMED K4 telemetry system monitoring elite rowers

measuring exercise performance at the Penrith Regatta in 1997. Similarly, TeleDiagnostic Systems of San Francisco a home monitoring equipment vendor patented and develop a system for recording sleep patterns for all-night monitoring at the patients home rather than in a hospital. In a patent filing they described physiological parameters monitored by the TeleDiagnostics Systems to include EEG, EKG, EMG, EOG, respiration, oximetry being able to detect and monitor over ten different channels of physiological data. Ex. 1040.

92. These and other remote monitoring advancements and solutions were used and well described for quantifying the frequency and impact of breathing disturbances, health indicators and sleep quality disruptions, thus providing access to assess sleep disorder severity, guide treatment, and track therapy effectiveness.

93. By the late 1990s and early 2000s, the focus on convenience and accessibility led to the development of home-based diagnostic tools, such as portable monitors capable of recording essential parameters. These tools enabled patients to undergo initial diagnostic studies in their own homes. Around the same time “data modules’ with CPAP systems to collect, store, and transfer treatment data for clinical review became commonplace. When connected to the flow generator through a docking mechanism, these modules recorded treatment data and, if connected to a pulse oximeter, can also capture pulse oximetry information. A removable memory card allows for automated data collection, which the patient can download and

transmit to the clinic for the clinician to review. This data was then analyzed on a PC using specialized software, enabling the clinician to monitor therapy efficacy and make any necessary adjustments to the treatment plan. Ex. 1033 (see Fig 1 below).

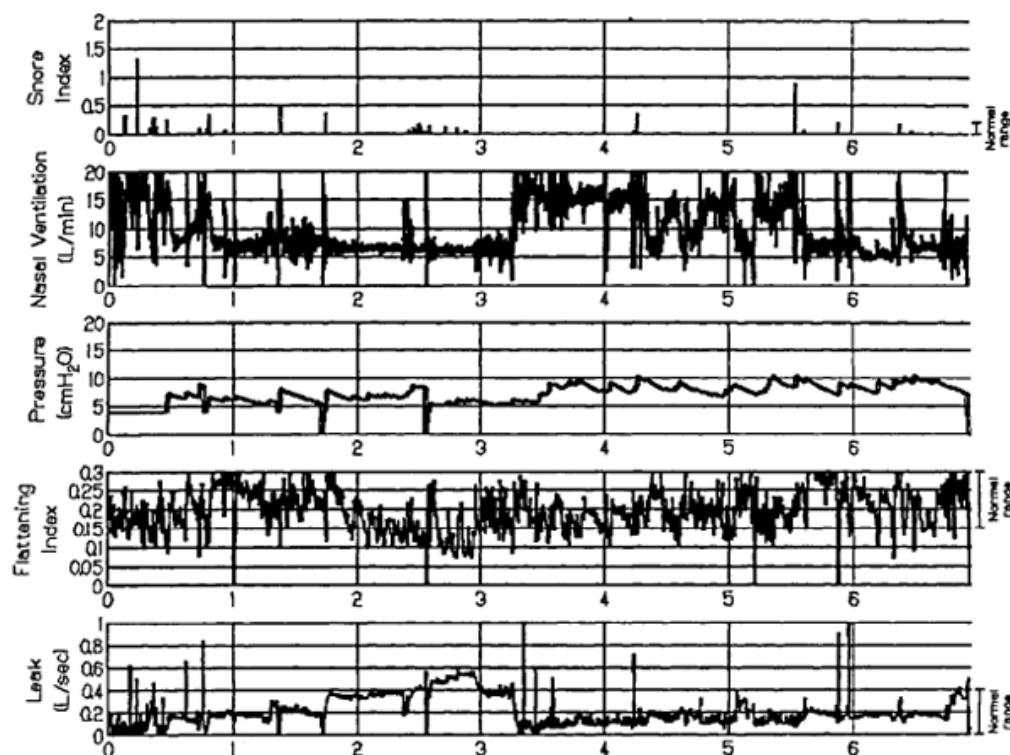


FIGURE 1. Example of cumulative overnight automatic CPAP data report for a patient with severe OSAS. Used with permission of ResMed Corporation.

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C. Telemedicine

94. The development of home sleep testing (HST) solutions began in the mid to late 1980s, with early devices focusing on ambulatory monitoring of arterial oxygen saturation and cardiopulmonary sleep studies. These initial systems were relatively primitive compared to modern standards. By the 1990s, there was a

growing awareness of OSA and its health consequences, which increased the urgency to develop cost-effective diagnostic methods. This led to the creation of more reliable, portable, and user-friendly HST devices in early 2000's, allowing patients to undergo sleep studies in their own homes. Recorded physiological data stored on the device is transferred to a personal computer through an integrated interface (FDA 510(K) K040576). These advancements made sleep testing more accessible and convenient, reducing the need for in-lab studies.

95. Prior to 2000, managing sleep disorders typically required in-person consultations at sleep clinics, with diagnoses and treatment largely reliant on traditional, lab-based polysomnography. This setup limited access to care, especially in rural areas where sleep specialists were scarce. Telehealth options were minimal, with initial consultations often occurring over the phone for basic assessments rather than the virtual, face-to-face interactions available today. Patients faced lengthy wait times for in-person appointments, and sleep studies required overnight stays, which posed logistical challenges for many.

96. In the same period, sleep apnea management with CPAP therapy required patients to regularly visit clinics for machine adjustments and adherence monitoring. Home-based sleep testing was less prevalent, and remote monitoring of CPAP data was not yet standard practice, making therapy less flexible and accessible. Symptom management strategies, such as guidance on sleep hygiene or

relaxation techniques, were typically discussed only during in-office visits, and ongoing support for these interventions was limited, often resulting in inconsistent adherence and follow-up.

97. In the management of sleep disorders, Auto-CPAP similarly played a role in transforming CPAP titration. Initially CPAP titration was performed physically at the bedside, whereby a clinician would modify the pressure settings manually on the device. Advancements in remote management within hospital settings enabled technicians in central control room location to adjust CPAP pressure remotely and in real-time, allowing them to monitor and manage multiple patients simultaneously. Remote monitoring of the physiological and treatment data (e.g. pressure, airflow, SaO₂) from CPAP moved into the home setting. Auto-CPAP devices emerged, offering the capability to adjust CPAP pressure dynamically without the need for sleep lab titration. This innovation marked a significant shift away from hospital-based titration, allowing patients to initiate and adjust CPAP therapy at home, which eased the burden on crowded sleep labs and improved access to treatment for a larger population. This shift made therapy adjustments more efficient during the night in both hospital and home, reducing the need for continuous bedside monitoring and enabling sleep centers to treat more patients with fewer resources (more cost effective).

98. In 1999, Loube wrote that “Compensation issues may be critical to the clinical utilization of new technologies including automatic CPAP. In the United States, Medicare and most third-party payers currently will not reimburse for either attended or unattended automatic CPAP titration studies. The future trend may be for the automatic CPAP manufacturers to add additional diagnostic recording capabilities to these systems to allow for compensation as an attended cardiorespiratory (four-channel) study monitoring airflow, respiratory effort, oxygen saturation, and heart rate.” Ex. 1033.

99. Advances in connectivity during this period improved the functionality of Auto-CPAP devices. Early networking capabilities, such as direct data transfer through memory cards or local networks, allowed therapy data to be shared within the hospital system, where healthcare providers could review and adjust treatment. Ex. 1042. This development helped facilitate timely adjustments to therapy settings and allowed clinicians to collaborate more easily in monitoring patient progress, even if they were not physically present at the bedside.

100. Methods described by Lankford 2004 for wireless data transmission attaching a transmission device (Cyracat wire-less transmitter), to the flow generator (CPAP and Auto-CPAP). Ex. 1043. Then, by accessing a secure Web site, a request for data sent from a secure sever, located centrally, through land lines to the carrier’s local transmission antenna, located within several miles of the device and location

set up, where it is transmitted wirelessly to the device. Once the device received the request, the data were retrieved from the memory of the flow generator, transmitted wirelessly to a receiving antenna, located within several miles of the device. Then, through land lines back to the secure server, the data became available on the aforementioned Web site. *Id.*

101. These improvements in technology also paved the way for APAP titration outside the hospital. By allowing automatically adjusting pressure in response to patients' breathing patterns, Auto-CPAP made CPAP titration feasible in attended locations, such as home settings, minimizing the need for direct supervision. Storage of the air pressure and flow data would permit assessing both the delivered CPAP pressure and airflow fluctuations indicative of sleep disordered breathing. With early forms of remote monitoring, healthcare providers could oversee therapy progress from a distance or remote location, ensuring that patients were adhering to and benefiting from treatment.

102. The ability of Auto CPAP to adjust CPAP pressure flexibly based on real-time needs—alongside connectivity tools that enabled basic data sharing and remote oversight—expanded access to treatment, reduced costs, and supported individualized management in both hospital and home environments. These technological advances particularly helped patients with a range of severity of sleep apnea, by making sleep therapy more accessible and adaptable.

103. Remote physiological and treatment monitoring has evolved into comprehensive systems encompassing data collection, analysis, and decision-making support, for delivery of telemedicine by enhancing access to high-quality metrics that allow responsive care through real-time off-site patient monitoring. Today, advancements in telehealth and digital health technology have significantly improved the accessibility and quality of sleep disorder management. Patients can now initiate consultations over the phone or through video calls, allowing for faster assessments and guidance on managing symptoms at home. With the development of remote monitoring and mobile apps, healthcare providers can track CPAP use and adjust therapy settings remotely, and patients have continuous access to resources for managing sleep symptoms. These technological advancements have made sleep disorder care more patient-centered and accessible, supporting better adherence and outcomes.

VII. THE '284 PATENT

104. The '284 Patent describes “an integrated apnea diagnosis and treatment device.” Ex. 1001, 1:28-29. The '284 Patent generally focuses on a PAP device “which analyzes a subject’s sleeping disorder or symptoms and adjusts a treatment device, based, in part on this analysis.” *Id.*, 2:47-49.

105. As shown in Figure 7, the system includes a PAP device “that can be used to physically treat a subject’s sleep disorder” by adjusting pressure based on

“the level of severity of the subject’s sleep disorder.” *Id.*, 22:49-52. The PAP device includes a blower, an airflow sensor, a processor, and a mask or nasal cannula.

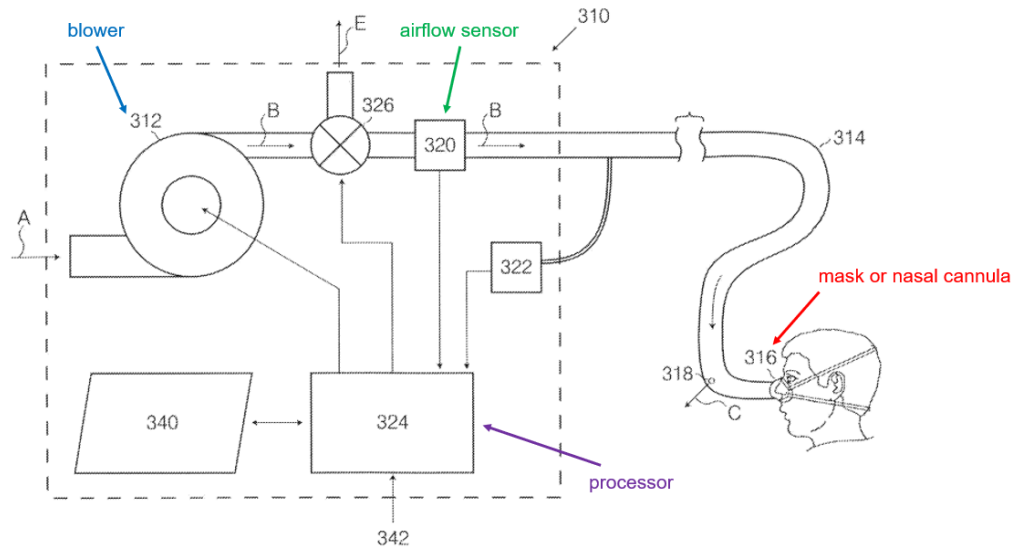


Fig. 7

106. “Sensors which can be used are known to those skilled in the art.” *Id.*, 6:21-22. These sensors “measur[e] the subject’s respirations or oxygen levels” and can “include sensors to measure airflow, respiratory effort, oxygenation and ventilation.” *Id.*, 3:21-23. Using the processor, “[s]ignals from these sensors are then analyzed to determine the level of severity of the symptoms of the subject’s sleep disorder.” *Id.*, 3:37-39. The information from the sensor can also be used to “monitor the usage of the pressure support device.” *Id.*, 23:23-25.

107. I note that the specification includes no discussion of an “index of treatment efficacy” or how to base it in part “on data of severity of sleep disorder

symptoms of the subject and data of usage of the PAP device of the subject.” *See id.*, cl. 1.

108. The specification discloses numerous embodiments, only briefly referencing one implemented in a “remote communication system.” *Id.*, 19:3-55. In this embodiment, the specification states “the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.” *Id.*, 19:14-17. “[A] PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information...to a remote site for analysis.” *Id.*, 19:46-51.

VIII. OVERVIEW OF THE PRIOR ART

A. Truitt (Ex. 1007)

109. Truitt discloses a conventional “continuous positive airway pressure (CPAP) device to supply a constant positive pressure to the airway of a patient to treat obstructive sleep apnea (OSA) as well as other disorders.” Ex. 1007, 1:24-30. The pressure of gas delivered to the patient may vary “with the patient’s breathing cycle” or “with the patient’s effort to increase the comfort to the patient.” *Id.*, 1:30-35. The pressure of gas may also vary “based on the detected conditions of the patient, such as whether the patient is snoring or experiencing an apnea, hypopnea

or upper airway resistance,” where “the pressure support system automatically attempts to titrate the pressure support to suit the needs of the patient.” *Id.*, 1:35-43.

110. As shown in Figure 1, Truitt discloses a conventional pressure support system 10 including a pressure generator 12 (e.g., a blower), “create[ing] a flow of breathing gas, as indicated by arrows B.” *Id.*, 1:44-50. A patient circuit 14 (e.g., a flexible conduit), which is coupled with a patient interface device 16 (e.g., a mask or nasal cannula) delivers elevated pressure breathing gas to the airway of the patient. *Id.*, 1:50-61.

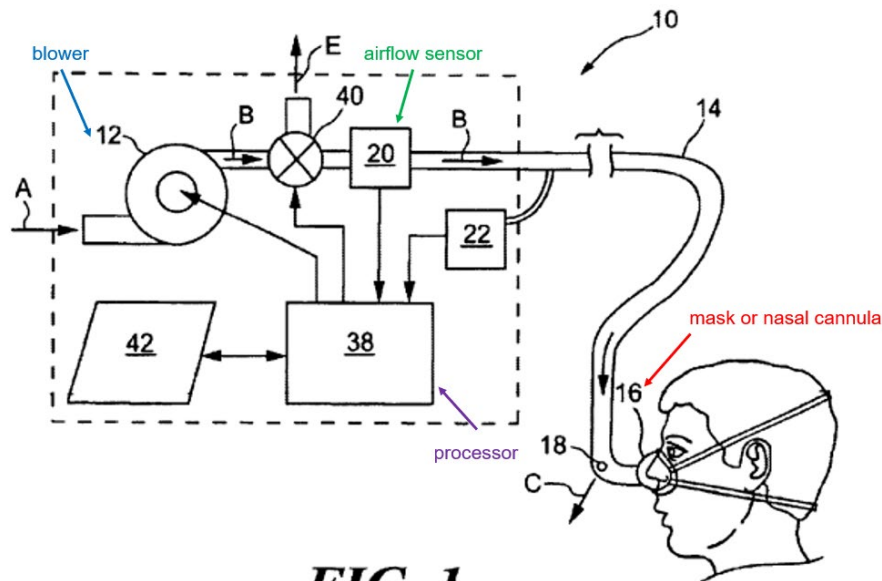


FIG. 1
(PRIOR ART)

Ex. 1007, FIG. 1

111. Figure 1 shows PAP system 10 also includes a flow sensor 20 and pressure sensor 22 to monitor the flow and pressure of gas passing through patient circuit 14, where the flow information provided by the sensor(s) are used to “control

the pressure or flow of gas provided to the patient, monitor the condition of the patient, monitor the usage of the pressure support device (patient compliance), or any combination thereof.” *Id.*, 2:1-11; *see also id.*, 2:12-56 (discussions regarding flow and pressure sensors and associated pressure/flow control method).

112. PAP system 10 further includes a controller 38 that receives signals from flow sensor 20 used for “control[ing] the pressure or flow of gas provided to the patient or monitor[ing] the patient’s usage of the medical device.” *Id.*, 2:38-48; *see also id.*, 2:48-64. Controller 38 may also receive the signals from flow sensor 20 and pressure sensor 22, and “uses this information to determine when the patient has transitioned from the inspiratory phase to the expiratory phase of the breathing cycle, or vice versa, to control the pressure accordingly.” *Id.*, 2:64-3:4. Moreover, the pressure level may be “controlled based on the conditions of the patient,” where “pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc.” and “[t]he pressure and/or flow is then controlled to counteract or prevent these conditions.” *Id.*, 3:4-11. Additionally, PAP system 10 includes an input/output device 42, e.g., a keypad and a display for entering information and commands to the system and to display information. *Id.*, 3:12-20.

113. Truitt additionally discloses another PAP system 50 similar to system 10 described above, but includes an improved flow sensor, i.e., flow sensing system 72, as shown in Figure 3 below. *Id.*, 4:61-67, Fig. 1.

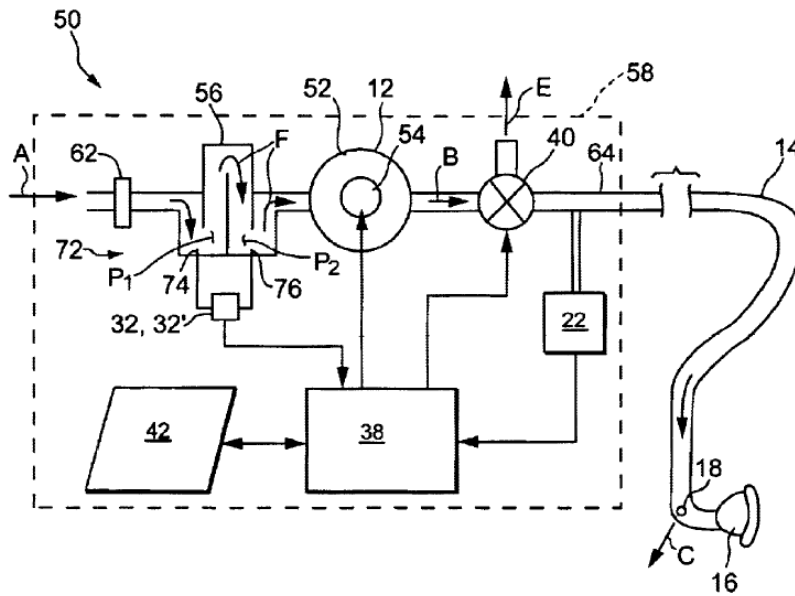


FIG. 3

114. In particular, PAP system 50 includes a housing 58, a pressure generator 12 in the form of a blower assembly 52 driven by a motor 54, providing a gas flow (as indicated by arrow B) to patient circuit 14 for delivery to a patient. *Id.*, 5:1-3; *see also id.*, 5:4-35. Like PAP system 10, the pressure signal output by pressure sensor 22 is provided to controller 38 for “controlling the operation of the pressure support system, monitoring the operation of the system, or monitoring the patient, for example.” *Id.*, 6:1-10. Under the control of controller 38, blower assembly 52 and/or valve 40 may adjust the flow or pressure of the gas delivered to the patient. *Id.*, 5:36-59.

115. The improved flow sensing system 72, unlike the conventional system 10, does not require a dedicated flow element (*id.*, 6:18-25), but similarly provides

a signal to controller 38 to “control the operation of the pressure support system, monitor the operation of the system, or monitor the patient” (*id.*, 6:11-17; *see also id.*, 6:49-62).

B. Kumar (Ex. 1008)

116. Kumar discloses various claimed features, including features associated with claimed “cell phone” in limitation [1.a] and features associated with the claimed “remote internet site” in limitation [1.c].

117. Like Truitt, Kumar discloses a system/method for monitoring physiological data collected by a patient-side device. Ex. 1008, Abstract. For example, Kumar discloses monitoring “sleep apnea-hypopnea syndrome” that is “characterized by repetitive episodes of upper airway obstruction that occur during sleep usually associated with reduction in blood oxygen concentration.” *Id.*, [0240].

118. Kumar additionally discloses “remote monitoring of medical and/or biofeedback devices over a wide area network (WAN) such as the Internet,” allowing “real-time streaming of raw, interpreted, and processed physiological data as well as textual/audio/video data from a patient/client to a health care provider.” *Id.*, [0010].

119. One specific example from Kumar is with respect to the management of pulmonary disorders, and Kumar’s ability to include “web-enabled spirometers and oximeters, allowing healthcare practitioners to perform remote spirometry and

oximetry tests.” *Id.* [0201-0206], Figs. 24A-26. Kumar describes that “Web-enabled spirometry allows for real-time remote testing, retrieval, and analysis of a patient's pulmonary function tests from any Internet-enabled computer. Such remote spirometry greatly improves the management and prevention of pulmonary problems in various healthcare segments, including pharmaceutical research, HMO's, educational institutions, and from isolated areas such as on aircrafts and ships.” *Id.*, [0204].

120. Kumar's system includes “at least one patient-side device for collecting data from a patient/client, a provider-side device, and an engine, each coupled to the WAN.” *Id.*, [0011]. Kumar's engine manages the transmission of the data from the patient-side device to the provider-side device to allow the provider to evaluate the data. *Id.*, [0011]. Kumar provides some examples of how its engine can be configured, including that the engine can be configured to provide for 1) the direct transfer of data from one device to another; 2) to receive the raw data from the patient-side device and transmit either the raw or processed data to the provider-side device; and/or 3) to receive the data and store it for later transmission to the provider-side device. *Id.*, [0011]; *see also id.*, [0012], [0069]. Kumar describes numerous potential use cases and patient side devices and makes clear that the patient-side device may be “a medical and/or biofeedback device that communicates through a serial, parallel, wireless, or customized interface” and “may then be connected via a

computing device, such as a computer, personal digital assistant (PDA), etc., to the WAN.” *Id.*, [0013]; *see also id.*, [0014].

121. For example, as shown in Figure 1 below, Kumar discloses an exemplary system 100 for “network-based monitoring of data from a patient-side physiological collecting device,” where the system includes patient-side device(s) 102 for collecting data from a patient/client, provider-side device(s) 104, and an engine implemented on a central server 106.” *Id.*, [0067]. The devices and engine are connected to a wide area network (WAN) 108, e.g., the Internet, and the system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider. *Id.*

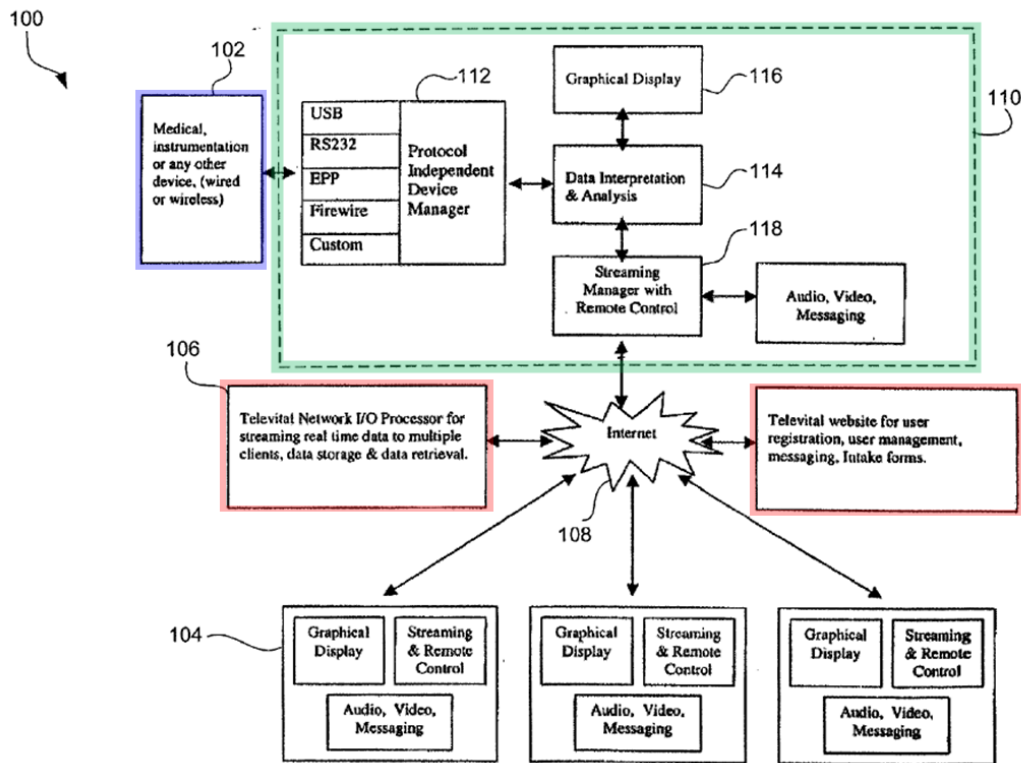


Fig. 1A

Ex. 1008, Fig. 1A

122. The system allows for various applications, including, e.g., “telemedicine, remote sleep studies, physical evaluations, remote monitoring, event recordings, holter monitoring [sic], home health care, disease management applications, biofeedback, pharmaceutical research, wireless monitoring, anesthesiology-related monitoring, and stress, health and wellness education.” *Id.*, [0068]; *see also id.*, [0069]. Kumar also includes an exemplarily listing of various medical conditions that it’s system may be adapted to treat that includes “Sleep Apnea Hypopnea Syndrome.” *Id.*, [0239]-[0241].

123. The patient-side device 102 in Kumar “is located with a patient and can be any device that gathers physiological data from the patient.” *Id.*, [0071]. Kumar discloses that its patient-side device may be connected to the WAN via a computing device 110, and then includes an identification of potential computing devices including personal digital assistants (PDAs), pocket PCs, wireless telephone, or any other computing device. *Id.*, [0072], Fig. 1B (showing a wireless Internet connection using a pocket PC). Computing device 110 may also communicate directly with patient-side devices (*id.*) and each patient-side device may communicate through a wireless protocol (*id.*; *see also id.*, [0073]).

124. Kumar also describes that its computing device 110 may send a request to the engine such that the engine will download a plug-in to facilitates communications between the computing device and the patient-side device. *Id.*, [0074]; *see also id.*, claim 5 (“the computing device receiving a software module for managing communication with the at least one patient-side device from the engine”). Kumar also makes clear that the data may also be transmitted to doctors or other remote providers to enable them to perform real-time or post-session analysis, as well as for the storage and retrieval of raw or interpreted data via the Internet connection. *Id.*, [0076]-[0077]. Kumar system provides the provider the benefit of being able to monitor the patient’s physiology and to provide treatment in real-time based on the data received from the patient side device “allow[ing] for daily or

periodic monitoring of patients without the need for the patient to travel to the provider's location.” *Id.*, [0078]; *see also id.*, [0079].

125. Kumar also discloses that computing device 110 may be a wireless phone or pocket PCs, e.g., an iPAQ device. *Id.*, [0072]. Kumar explains that computing device 110 downloads a plug-in, i.e., a software module, to facilitate communications with the patient-side device (Ex. 1008, [0074], claim 5), provides customized graphical user interfaces (GUIs), such as that depicted in Figure 2 below (*id.*, [0074]), and analyzes/processes received data (*id.*, [0075]).

126. For example, a doctor could log in using the webpage depicted in Figure 2, by inputting their TeleVital ID and then Password.

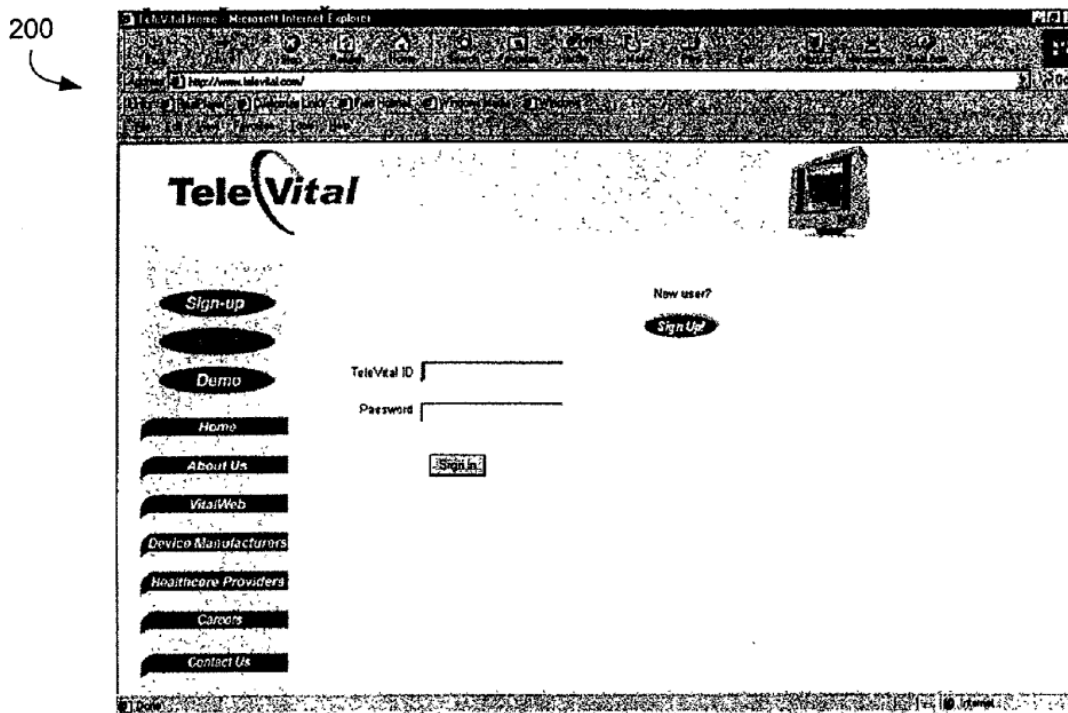


Fig. 2

Ex. 1008, Fig. 2

127. They could then access the real-time data coming from the patient device relating to the patient of interest would be able to remotely view and analyze the patient's blood oxygen saturation as depicted in Figure 24B.

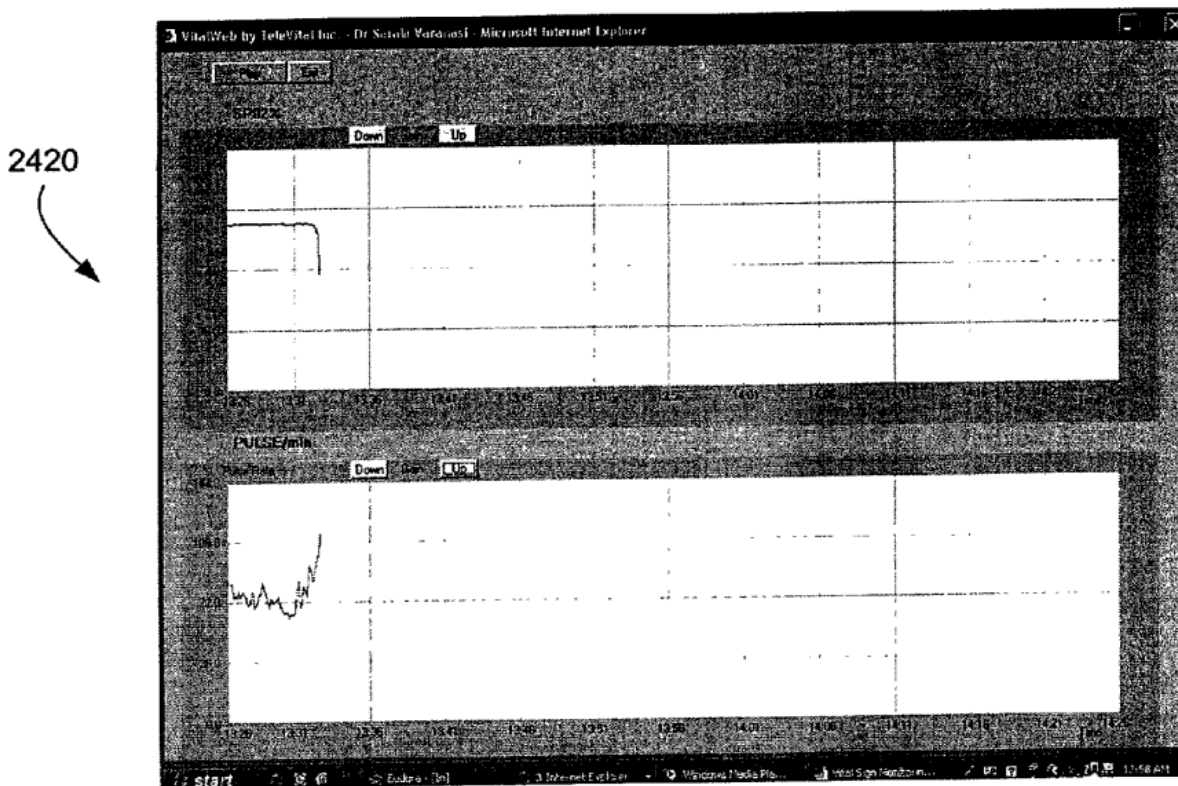


Fig. 24B

128. Kumar discloses that its system and web-enables protocols include “customizable display screens, summary reports, statistical calculations” and other features. *Id.*, [0205].

C. Wright (Ex. 1013)

129. Wright discloses features associated with “distinguish[ing] between and calculate[ing] the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device” as recited in claims 17 and 20. Like Truitt, Wright discloses uses of a PAP device to assess and treat a patient’s sleep apnea. Ex. 1013, Abstract.

130. As shown in Figure 1, Wright discloses a CPAP device that includes a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, air delivery conduit 8. *Id.*, [0029]. At the time, this kind of CPAP device was to be expected as these were generally considered standard components of CPAPs. The CPAP device includes communication module 10 for a wireless communication transceiver for communication with or computers, e.g., hand-held display (e.g., a Palm Pilot) and control devices 12. *Id.*, [0029]-[0030].

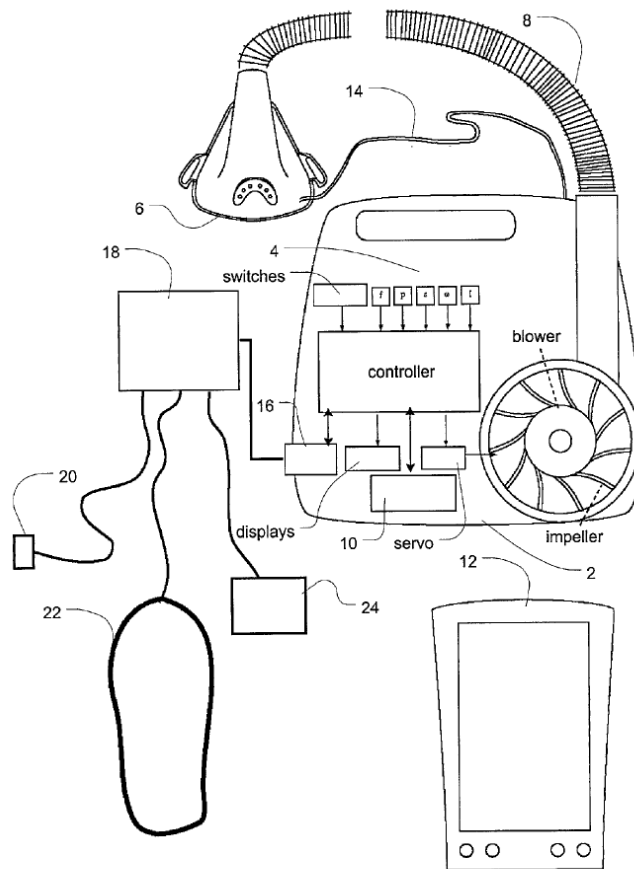


Fig. 1

Ex. 1011, Fig. 1

Moreover, Wright explains that “[w]ith such a device, a physician may, for example, remotely monitor, analyze or record the status or data history of a patient or diagnose the patient's condition using the device.” *Id.*, [0030].

131. Wright additionally discloses using the CPAP device for “for assessing the condition of and treating patients for stroke.” *Id.*, Abstract. “By determining central and obstructive apnea occurrences or the percentile of pressure delivered to the patient from patient airflow, stroke indicators may be calculated and analyzed to

provide information on the type of stroke a patient has suffered and the degree of a patient's neuro-recovery.” *Id.* “The apparatus may be programmed with a particular protocol intended to identify between alternative forms of CPAP treatment appropriate for the patient based upon an assessment of the patient's condition.” *Id.*

132. Wright explains that “CPAP devices can detect the presence of apneas, distinguish between central and obstructive apneas and provide an increased pressure if needed to stabilize an obstructed or partially obstructed airway.” *Id.*, [0027]. In particular, Wright discloses that the CPAP device “has two treatment modes, a first mode for treating obstructive apneas and a second mode for treating central apneas,” where “[i]n the first mode, the device provides a generally constant pressure throughout a breathing cycle, but may vary the pressure in accordance with indications of partial or complete obstruction of the airway.” *Id.*, [0031]. In the second mode, “the apparatus provides a higher pressure to the mask during the inspiratory portion of the breathing cycle, the so-called IPAP, and a lower pressure to the mask during the expiratory portion of the breathing cycle, the so-called EPAP. This may be accomplished by monitoring the respiratory flow to the patient and defining a threshold level.” *Id.*, [0032]. Wright explains that the CPAP device “may be used to monitor patient health characteristics including, for example, oral and/or nasal airflow, snore, abdominal movement, chest wall movement, oximetry, pulse

rate, body position and flattening index via the diagnosis unit and sensors in the blower.” *Id.*, [0034].

133. For instance, the CPAP device may generate indices “determined from an analysis of the patient’s health characteristics useful for assessing appropriate treatment or diagnosing the condition of the patient,” and “[s]uch indices serve as stroke indicators to indicate patient improvement or stroke type....” *Id.*, [0035]. “When the patient is being treated with CPAP, the device continuously monitors whether the patient is having an apnea and if so, whether the apnea is central or obstructive.” *Id.*, [0036]. “The apparatus determines an index from a comparison of the number of central and obstructive apneas or a function of the ratio of the number of central to obstructive apneas during a particular time period.” *Id.*; *see also id.*, [0037]-[0038] (methods for distinguishing between central and obstructive apneas). The index may serve as “an indication of the degree of neuro-recovery for a stroke patient” because the stroke may damage portions of the brain “participate in respiratory drive, causing a relatively high incidence of central apneas compared to obstructive apneas.” *Id.*, [0039].

D. Dong (Ex. 1014)

134. Dong discloses features associated with “an extended horizon, adaptive, predictive controller” as recited in claims 15, 16 and 18. Dong describes that its “invention is particularly applicable to real time automatic control systems

and apparatus and more specifically to a class of adaptive controllers utilizing dynamic system prediction techniques.” Ex. 1014 at 1:9-12. Like Truitt, which discloses a controller determining a PAP device’s operation based on input from sensors, Dong discloses a controller determining a system’s operation (e.g., operations of actuators) based on multiple inputs (e.g., input from sensors). *Id.*, Abstract, Fig. 15 (disclosing an exemplary embodiment including sensors providing input signals and actuators receiving output signals), 19:5-20:56 (discussions associated with the exemplary embodiment relating to Figure 15).

135. Dong additionally discloses that the controller is an “extended horizon adaptive block predictive controller” that includes a block control system and an adaptive block prediction system. *Id.*, Abstract. The system performs “a block of k output predictions, consisting of output predictions at each future time step up to the prediction horizon k, for dynamic systems with N outputs, M inputs and model parameter order n,” where “[t]he prediction system is organized for performing the calculation of a k-step ahead predictor in a highly computationally and memory efficient manner.” *Id.*

136. Dong explains that, because a “dynamic system has an input-output delay, predictive controllers are used to account for such a delay. *Id.*, 1:49-54. “[P]redictive controllers that consider time horizons beyond the system input-output delay (extended horizon predictive controllers) have been used in engineering

applications,” for example, to maintain “the system input-output stability.” *Id.*, 1:54-68. Dong discloses that its controller/system “avoids computation of a large number of the predictor parameters associated with the prior art...method, so that memory requirements and computational complexity are significantly reduced.” *Id.*, Abstract; *see also id.*, 6:42-46 (“The subject invention contemplates a new and improved prediction system for multivariable dynamic system output prediction. The subject invention reduces run time and memory requirements.”)

E. Mumford (Ex. 1009)

137. To the extent that Truitt does not disclose calculating “data of usage of the PAP device by the subject,” “data of severity of sleep disorder symptoms of the subject,” and/or “the index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject,” Mumford discloses these features.

138. Like Truitt, Mumford discloses treatment systems for treating obstructive sleep apnea using a PAP device that includes sensors for measuring physiological signals of the wearer. Ex. 1009, Abstract. The physiological signals are used “to determine the efficacy of the PAP treatment and to vary operational parameters of the PAP device.” *Id.*

IX. CLAIM CONSTRUCTION

139. I have applied the plain meaning of the terms and phrases in the claims in my analysis, as a POSITA would have understood those terms and phrases at the relevant time (around 2005).

**X. OPINIONS ON GROUND 1: TRUITT IN VIEW OF KUMAR
RENDERS OBVIOUS CLAIMS 1-3, 6, 12-15, AND 18-19**

A. A POSITA Would Have Been Motivated to Combine

140. In my opinion, a POSITA would have been motivated to combine the teachings of Truitt and Kumar to implement a networked PAP treatment system. Specifically, a POSITA looking to improve the PAP device of Truitt would have looked at known ways to incorporate medical devices into a telemedicine system, as taught by Kumar. There are several reasons that a POSITA would have motivated to do so.

141. First, a POSITA would have been motivated to obtain more representative data. A POSITA would have understood that by monitoring and treating a patient in their typical sleep environment the observations and data that they use to evaluate and diagnose a patient would be more representative of the patient's typical sleep experience than the data that could be collected through observation of that patient in a laboratory or clinic which was the traditional method. A POSITA would have understood that such an evaluation would be limited, as the patient would not have been observed in their typical sleep environment. When a

patient is out of their routine sleep environment, they may face different challenges that impact the relevance of the sleep data, as the patients are likely less comfortable and often experience more anxiety in the laboratory or clinic than they would in their home sleeping environment. It is also more difficult for the patient to perform their usual sleep routine and numerous possibilities for poor adherence to treatment may be present. As a result, the traditional method of collecting data is less representative of the patient's usual sleeping conditions. By networking the PAP machine, the patient can be allowed to sleep at home in their routine sleep environment, giving the physician access to more relevant data that reflects the usual sleep conditions and avoiding the additional stress on the patient of sleeping in an unfamiliar environment.

142. Further, as I discussed above, airway collapsibility fluctuates throughout the night due to changes in sleep stages, body position, blood gas levels, arousal responses, and circadian hormonal variations. *See* Section VI.A (History of CPAP Therapy). Providing a means to observe the patient at home also allows a physician to observe the patient's breathing patterns when the patient is in different situations (after drinking alcohol, during a cold, etc.).

143. Second, a POSITA would have been motivated by convenience and efficiency. *See also* Section VI.B (Remote Diagnosis and Monitoring Patients at Home versus Clinic). OSA is a chronic condition and PAP therapy requires ongoing

management, support, and frequent follow-up between patient and care providers and physicians. By collecting data through a networked-home device, the need to invest time in coordinating time and resources for the doctor and patient to be in the same location at the same time is avoided. The challenges and time associated with setting an appointment at a laboratory or clinic expended by both the physician and patient would be minimized as the networked-home device allows for the patient to use the PAP machine without needing to travel to the doctor's office or some other location for a sleep study, while simultaneously allowing the physician significant flexibility as to when they review the data. The doctor would be able to review the data at a time convenient to them, without having to coordinate with the patient's schedule. Further, the patient's condition may change over time, and the ability to evaluate the patient at home over a period of time avoids the unnecessary time and cost associated with follow-up trips to a doctor's office that may or may not be necessary.

144. Third, a POSITA would have been motivated to provide health access to more people. Health accessibility has been a longstanding problem. Examples of such problems include distance as well as the ability to collect data. For example, a patient who lives in a remote part of the country, far from the doctor's office, would be required to expend significant time and resources just to travel to and from the physician's office. As Kumar observes, telemedicine has provided "access to health

assessments, diagnoses, interventions, supervision, consultations, education, and information across a distance.” Ex. 1008, ¶[0003]. Telemedicine’s ability to provide assessment and treatment to remote areas explains why many early advancements in telemedicine came from NASA (to monitor the health of astronauts). Additionally, the ability to avoid the scheduling challenges between doctor and patients mean that more patients can be seen by a doctor, as the remote access would allow a doctor to review data during any downtime in their schedule. For example, if a doctor has a patient cancel an appointment that time can now be used to review the remotely gathered data relating to other patients leading to increased efficiency.

145. Fourth, a POSITA would have been motivated to leverage the advances in mobile computing and wireless communications. As I saw from my own work, the late 1990 and early 2000s saw significant technological advances in semiconductors, energy-efficient wireless communication, and reduced budgets for computational devices that allowed wireless networks of smart sensors to become feasible for many applications, including medical applications. The sensors of Truitt would have been ideal to combine with these advances in order to improve health care. Ex. 1007, 2:3-5. This is particularly true given the diagnostic advantages of using wireless, as opposed to wired, sensors. One example of this is the work I did with respect to real-time monitoring of metabolic and respiratory parameters in the “real-world” in conjunction with the New South Wales Institute of Sport using the

COSMED K4 telemetry system for monitoring elite rowers and measuring exercise performance at the Penrith Regatta in 1997. Similarly, TeleDiagnostic Systems of San Francisco a home monitoring equipment vendor patented and develop a system for recording sleep patterns for all-night monitoring at the patients home rather than in a hospital. In a patent filing they described physiological parameters monitored by the TeleDiagnostics Systems to include EEG, EKG, EMG, EOG, respiration, oximetry being able to detect and monitor over ten different channels of physiological data. Ex. 1040.

146. A POSITA would have understood that the sensors of Truitt would have been ideal to combine with the advances discussed above in order to improve a patient's treatment. Ex. 1007, 2:3-5. This is particularly true given the diagnostic advantages of using wireless, as opposed to wired, sensors.

147. Last, a POSITA would have naturally looked for known design options for telemedicine like Kumar's "plug-and-play" telemedicine system. By the priority date of the '284 patent, advances in connectivity and networking capabilities, such as direct data transfer through memory cards or local networks, allowed therapy data to be shared within the hospital system, where healthcare providers could review and adjust treatment. Ex. 1042. This is supported by the methods described by Langford 2004 for "wireless data transmission attaching a transmission device (Cyracat wireless transmitter), to the flow generator (CPAP and Auto-CPAP). Ex. 1043.

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

148. A POSITA would have had a reasonable expectation of success in implementing the Truitt PAP device as a networked system as taught by Kumar.

149. First, there are express statements in Kumar that directly teach that devices like the Truitt PAP device, can be incorporated into its system: “Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI. Thus, virtually *any* device may be easily incorporated into the system.” Ex. 1008, ¶ [0018].

150. Second, the components in the flow sensing assembly in Truitt were known hardware that could be implemented wirelessly. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, Ex. 1044, Abstract (“Enabling remote monitoring of the patient’s conditions during the use of a positive pressure artificial respiration assisting device”), Fig. 3 (transceiver unit 251); Ex. 1045, ¶ [0155] (“communication module 350 supports ‘blue-tooth’ RF bidirectional wireless communication”), Fig. 3 (communication module 350). The work I did tacking oxygenation and other data on competitive rowers described above is another example of how a POSITA would have understood that you could take a traditionally wired device and operate it wirelessly. Further, as Truitt teaches, a POSITA would have understood that microphones are often used for flow sensors in PAP machines. Ex. 1009, 3:4-9.

Given that wireless microphones have been around since the 1950s, a POSITA would have understood that they could easily be used in PAP devices.

151. Third, the proposed modification would simply be a change of programming and the addition of wireless transceivers. The combination of known prior art elements (sensors and wireless transceivers) according to known methods and techniques (to collect and transmit data) to yield predictable results (networked data system) was similar to the work that I did at RespEQ, developing technology to monitor adherence to respiratory therapies via connected devices.

152. Finally, a telemedicine system (including a PAP device, mobile phone, and physician-side computer, all of which are connected to a network) was already known by 2005. Ex. 1044, [0008] (The remote “telemedicine system comprises a positive pressure artificial respiration assisting device 2, a relay device 3, and...a physician-side computer 4 and a mobile terminal 5, all connected to communication network 1.”), Fig. 1.

153. Thus, a person of ordinary skill in the art would have had a reasonable expectation of success in implementing the Truitt PAP device as a networked system as taught by Kumar.

C. Independent Claim 1

1. Preamble: *“A positive airway pressure (PAP) sleep disorder treatment system comprising:”*

154. It is my opinion that Truitt discloses the preamble. As I described above in the overview of the prior art section, Truitt discloses a CPAP machine, that was well known by 2005. Ex. 1007, 1:24-30 (“continuous positive airway pressure (CPAP) device to supply a constant positive pressure to the airway of a patient to treat obstructive sleep apnea (OSA) as well as other disorders.”). Truitt’s CPAP machine, similar to many of the CPAPs from its time, allowed for the varying of the pressure of gas delivered to the patient “with the patient’s breathing cycle” or “with the patient’s effort to increase the comfort to the patient.” *Id.*, 1:30-35. Truitt also disclosed that the pressure of gas being delivered to the patient may be automatically varied “based on the detected conditions of the patient, such as whether the patient is snoring or experiencing an apnea, hypopnea or upper airway resistance.” *Id.*, 1:35-43 (“the pressure support system automatically attempts to titrate the pressure support to suit the needs of the patient.”).

155. Figure 1 of Truitt discloses a conventional prior art pressure support system bearing the label 10. The title of Figure 1 of Truitt, is “prior art” which make sense given that the type of CPAP system depicted in Figure 1, including the component parts, was well known at the time. The components of Figure 1 of Truitt

are the traditional components of a CPAP machine that a POSITA from the time would have expected to be included given their inclusion in a broad array of CPAP devices at that time. The CPAP system disclosed in Figure 1 of Truitt includes a pressure generator bearing the label 12. Pressure generators are sometimes referred to as a “blower” and are used to create the pressure in the device by pushing breathing gas through the tubing of the device to the patient as indicated by the arrows B in Figure 1. Ex. 1007, 1:44-50. Figure 1 also depicts a patient circuit 14 (e.g., a flexible conduit or hose), which is coupled with a patient interface device 16 (e.g., a mask or nasal cannula) and delivers elevated pressure breathing gas to the airway of the patient. Ex. 1007, 1:50-61.

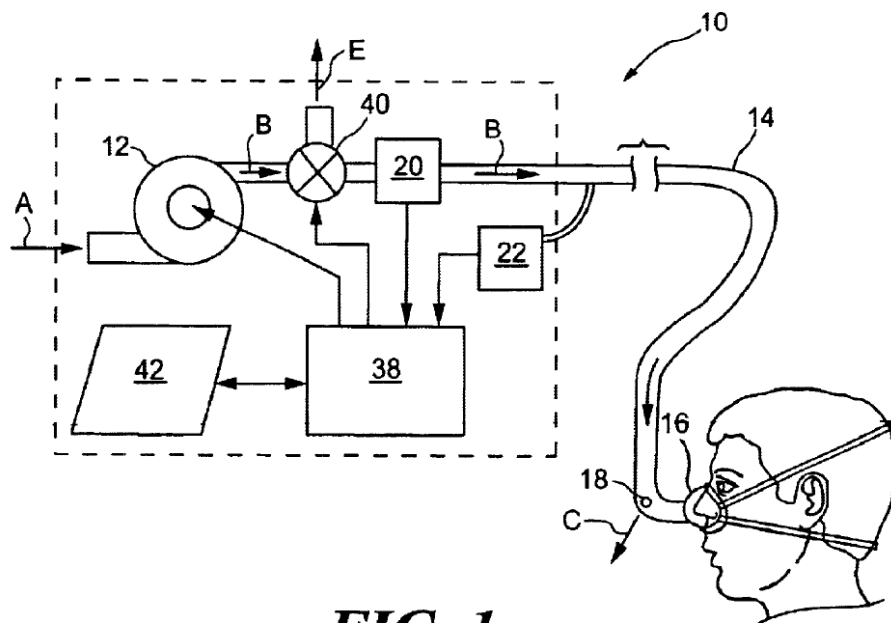


FIG. 1
(PRIOR ART)

Ex. 1007, Fig. 1

156. Like the systems of the time, Figure 1 of Truitt's PAP system includes various sensors, such as the flow sensor labeled 20 and the pressure sensor labeled 22. These sensors are used to monitor the flow and pressure of gas passing through patient circuit 14. The information from these sensor(s) relating to the flow and pressure is used to "control the pressure or flow of gas provided to the patient, monitor the condition of the patient, monitor the usage of the pressure support device (patient compliance), or any combination thereof." Ex. 1007, 2:1-11; *see also id.*, 2:12-56 (discussions regarding flow and pressure sensors and associated pressure/flow control method).

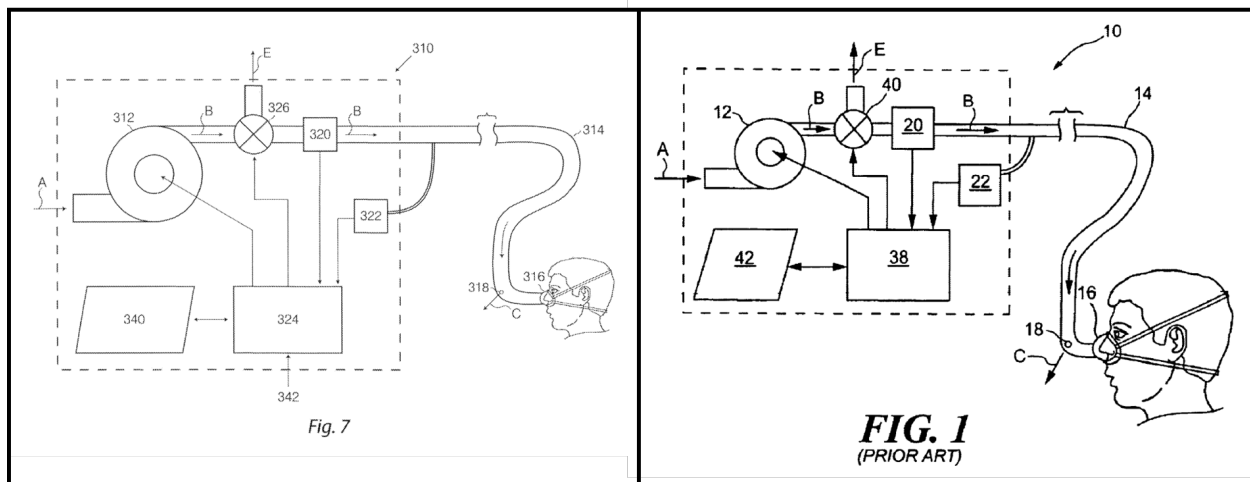
157. In order to actually control the pressure and flow of gas, prior art PAP devices like that disclosed in Truitt used controllers that received signals from sensors, such as flow and pressure sensors, and then adjusted the flow and pressure according to the devices programming. Truitt's controller is depicted in Figure 1 with the label 38. The controller 38 of Truitt receives signals from flow sensor 20 that are used for "control[ing] the pressure or flow of gas provided to the patient or monitor[ing] the patient's usage of the medical device." Ex. 1007, 2:38-48; *see also id.*, 2:48-56.

158. Truitt describes that "[c]ontroller 38 receives the signals output from sensors 20 and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof in a feedback fashion based on these received signals." *Id.*,

2:57-60. So if a patient has a prescribed pressure for treatment, controller 38 would evaluate the data regarding the pressure and flow it receive from the sensors to determine if the pressure in the actual device was correct. If the pressure was too low, then the controller would increase the pressure generator or blower until the desired pressure was being achieved. *Id.*, 2:60-64 (describing that the controller 38 may “monitor[] the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.”). Additionally, it was well known that the controllers of the prior art, such as controller 38, were capable of using the data they received from the sensors to make determinations regarding the state of the patient and adjust the pressure accordingly. *Id.*, 2:64-3:4 (describing using the signals from the flow and pressure sensors to “determine when the patient has transitioned from the inspiratory phase to the expiratory phase of the breathing cycle, or vice versa, to control the pressure accordingly.”). It was also well known to a POSITA that the prior art controllers, including controller 38 of Truitt, were able to use information from “pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc.” and to then control “[t]he pressure and/or flow” being applied to the patient to “controlled to counteract or prevent these conditions.” *Id.*, 3:4-11.

159. In order to control the PAP device, it was common for PAP systems to have input and output devices, such as keyboards and screens for displaying information associated with the patient and the PAP system's performance. Truitt discloses such an input/output device 42, e.g., a keypad and a display for entering information and commands to the system and to display information. *Id.*, 3:12-20.

160. Truitt's conventional PAP system 10, as shown in Figure 1, is substantially similar to the "pressure support system" depicted in Figure 7 of the '284 patent, as shown side by side below. *See* Ex. 1007, Fig. 1; Ex. 1001, Fig. 7, 5:31 ("FIG. 7 is a schematic view of a pressure support system"), 22:49-23:25 (description of the system's components).



Ex. 1001, Fig. 7 (left); Ex. 1007, Fig. 1 (right)

161. PAP system 50 of Truitt is similar to system 10 described above, but system 50 includes an improved flow sensor, i.e., flow sensing system 72, as shown in Figure 3 below. Ex. 1007, 4:61-67, Fig. 1;

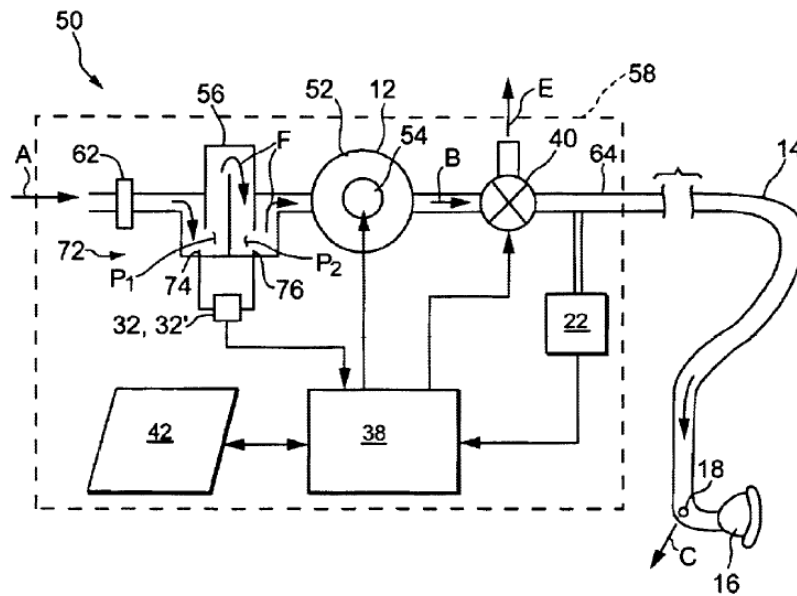


FIG. 3

162. Similar to the PAP system 10 Truitt references as prior art that I discussed above, Truitt's PAP system 50 includes a pressure generator 12 in the form of a blower assembly 52 driven by a motor 54, providing a gas flow (as indicated by arrow B) to patient circuit 14 for delivery to a patient through a mask or other delivery device. Ex. 1007, 5:1-3; *see also id.*, 5:4-35. Similar to what I discussed above with respect to PAP system 10, the pressure signal output by pressure sensor 22 of PAP system 50 is provided to controller 38 for "controlling the operation of the pressure support system, monitoring the operation of the system, or monitoring the patient,

for example.” *Id.*, 6:1-10. Controller 38 in turn controls the blower assembly 52 and/or valve 40 of PAP system 50 and may maintain the current flow/pressure if the desired result is being achieved, or alternatively may increase or decrease the flow/pressure of the gas delivered to the patient if such a change is desirable for the patient’s treatment. *Id.*, 5:36-59.

163. Unlike its earlier described system 10, Truitt’s improved flow sensing system 72, does not require a dedicated flow element. (Ex. 1007, 6:18-25). That said, like system 10 Truitt’s PAP system 50 similarly provides a signal to controller 38 to “control the operation of the pressure support system, monitor the operation of the system, or monitor the patient.” *Id.*, 6:11-17; *see also id.*, 6:49-62.

164. Accordingly, Truitt discloses “[a] positive airway pressure (PAP) sleep disorder treatment system.”

2. [1.a]: “a non-transitory computer readable medium, the non-transitory computer readable medium comprising a first software, the first software executable by a first processor and configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the index on the cell phone, the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone, the cell phone comprising at least

one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display;”

165. It is my opinion that Truitt in view of Kumar discloses limitation [1.a]. Given the length of this limitation, I will break it out into four sections below and discuss each in turn.

166. **First**, Truitt discloses a PAP device calculating “data of usage of the PAP device by the subject.” Specifically, Truitt discloses that “the information from flow sensor 20 and/or pressure sensor 22 is used, for example, to ... monitor *the usage of the pressure support device (patient compliance)*.” *Id.* 2:1-11.

167. Data calculation is a common feature in PAP devices. Accordingly, many PAP devices calculate various types of data and use that information to, among others, monitor the patient’s usage of the device. For example, Truitt discloses that the output of the flow sensor is provided to controller 38 “for calculating the flow and/or volume of gas passing through conduit 56.” Ex. 1007, 6:46-48. This is disclosed in other places in Truitt. For example, Truitt describes a more sophisticated pressure support device that “include[s] a flow sensor 20, pressure sensor 22 or both that monitor the flow and/or pressure of gas passing in patient circuit 14. The flow information can also be used to determine the volume of gas passing through patient circuit 14.” *Id.*, 2:1-5.

168. Truitt's disclosure of exemplarily data calculations includes using the "pressure differential [measured by the pressure sensor]" to "calculate the flow of gas passing through conduit 24, which, in turn, is used to calculate the volume of gas flowing through conduit 24 over any given period of time." *Id.* 2:21-26. Furthermore, Truitt discloses how "[t]he signal from flow sensor 20...is provided to a controller 38...to control the pressure or flow of gas provided to the patient or monitor the patient's usage of the medical device." *Id.*, 2:38-42. The flow sensor provides information that is used to determine the volume of gas passing through the patient circuit. For example, "the information from flow sensor 20 and/or pressure sensor 22 is used, for example, to control the pressure or flow of gas provided to the patient, monitor the condition of the patient, monitor the usage of the pressure support device (patient compliance), or any combination thereof." *Id.* 2:1-11.

169. A POSITA would have understood that controller 38 likewise calculates the information or data of the patient's usage of the PAP device in order to monitor the patient's usage of the PAP device, which is consistent with how controller 38 calculates the flow and/or volume of gas using information provided by the sensor(s). In fact, Patent Owner acknowledges this common feature by noting that "a skilled artisan would immediately discern that to monitor the usage of the PAP device, the usage data is calculated by the PAP device." Ex. 1010, 25-26. Thus,

Truitt discloses a PAP device calculating “data of usage of the PAP device by the subject.”

170. **Second**, Truitt discloses the PAP device calculating “data of severity of sleep disorder symptoms of the subject.” As mentioned above, data calculation is a common feature for PAP devices, and there are various forms of data calculations. For example, Truitt discloses controller 38 adjusts the pressure and flow provided by the PAP system based on the sensor signals “in a feedback fashion.” Ex. 1007, 2:57-59 (“Controller 38 receives the signals output from sensors 20 and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof *in a feedback fashion* based on these received signals.”). In other words, controller 38 will monitor the pressure or flow of the breathing gas delivered to the patient and then based on this data and the prescribed pressure and flows, it will adjust the pressure or flow in incremental levels and analyze the feedback from the incremental change to see if an additional change is necessary to meet the desired prescription pressure level, or if the adjustment was more or less than required and needs to be modified. *Id.* 2:60-64 (“For example, in a simple CPAP device, controller 38 monitors the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.”).

171. In addition to the traditional CPAP discussed above, Truitt also discloses that in a more sophisticated bi-level pressure support system where the pressure is greater during inspiration than during expiration. These bi-level systems are sometimes referred to as BiPAP devices due to their two different pressure settings, one used during inhalation and the other used during exhalation. BiPAP treatments are primarily used to treat Central Sleep Apnea (CSA), as well as other lung, and neurological disorders that require structured airway support during sleep, but can also be used to treat obstructive sleep apnea in patients who have complex disorders not sufficiently addressed by CPAP treatment.

172. Truitt also describes that the auto-titration mode provides for the control of flow and pressure in response to the specific patient conditions at that time and that the pressure and flow sensors (or other sensors, such as a microphone) are used to detect snoring, apneas, hypopneas, etc., in response to which, the system will increase the pressure and flow to “counteract or prevent these conditions” *Id.*, 3:4-11.

173. Sleep disorder symptoms have different levels of severity. A POSITA would have understood that the patient’s conditions, such as snoring, apneas, and hypopneas, reflect the different levels of severity of sleep disorder symptoms. As I described above in the background section, CPAP therapy is used for patients with a spectrum of sleep apnea severity with or without symptoms. CPAP therapy

involves delivering a constant supply of pressurized gas through a mask worn over the nose, mouth, or both. This pressurized air creates a “splinting” effect in the upper airway, keeping the soft tissues (such as the tongue, soft palate, and pharyngeal walls) from collapsing and blocking the airway during sleep. By maintaining an open airway, respiratory related events are reduced, allowing for uninterrupted airflow into the lungs and stabilizing oxygen levels during CPAP use.

174. The total absence of airflow, or apnea, results when the patient’s airway has completely collapsed such that air cannot pass through. *See also* Ex. 1019 at 8 (discussing reduction of muscle tone in sleep leading to upper airway narrowing or complete collapse). The appropriate pressure required to meet an individual’s needs to reduce sleep disorder symptoms is determined by titrating the pressure and can vary based on the individual and their specific condition.

175. As I previously discussed, Dr. Colin Sullivan, Dr. Michael Berthon-Jones, and their colleagues at the University of Sydney introduced Positive Airway Pressure (PAP) therapy in 1981 to treat sleep apnea by applying positive airway pressure to prevent collapse of the patient’s airway by opposing the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). Ex. 1016 at p. 1, Fig. 1.

176. As such, PAP devices account for these different levels of severity, as shown in the ’284 patent’s disclosure equating “conditions” and “symptoms” and

acknowledging that there are different levels conditions or symptoms, e.g., non-critical conditions versus critical conditions/symptoms. Ex. 1001, 21:6-8 (“the subject’s physiological conditions move toward various critical conditions or symptoms”). The varying levels of severity are widely known, in fact, the Patent Owner states that “[a] skilled artisan would know that apnea and hypopnea events, which are indicated based on breathing metrics, represent data of severity of the patient’s sleep disorder symptoms.” Ex. 1010, 27. Therefore, given that the flow of breathing gas and the pressure level thereof are controlled based on the conditions of the patient, a POSITA would have understood that the conditions of the patient are determined or calculated by the PAP device in order to control the gas flow and pressure. Accordingly, this is shown in how Truitt discloses the PAP device calculating “data of severity of sleep disorder symptoms of the subject.”

177. **Third**, Truitt discloses that an “index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” As I explained above Truitt discloses using the data received from the system’s gas pressure/flow pressure sensors to adjust/control the system in “feedback fashion to meet the desired prescription pressure level.” Ex. 1007, 2:57-3:4. Truitt also discloses using the data received from the system’s gas pressure/flow pressure sensors to “counteract or prevent [] conditions” the patient is experiencing. *Id.*, 3:4-

11. Truitt therefore discloses using the data signal(s) from the sensor(s) to adjust the operations of the PAP system in order to treat or prevent the sleep disorder symptoms. Such adjustments are dependent upon the data/signal(s) from the sensor(s) so that they may be calculated. A POSITA would have understood that this involves determining/calculating the effectiveness of the PAP system's operation with respect to treating the patient ("the index [of treatment efficacy of the subject using a PAP device]") based on the data of level of severity of the patient's conditions/symptoms and the data of the patient's usage of the PAP system (including those calculated based on the information from the sensors) in order to meet the desired prescription pressure level and/or "counteract or prevent these conditions."

178. Truitt's PAP system operates in a way that is substantially similar to that of the '284 patent. The '284 patent's PAP system likewise uses sensor signals to adjust the treatment based on the patient's conditions/symptoms. Further similarity can be seen in both Truitt and the '284 patents disclosures of systems using the sensor signals in a feedback fashion to adjust the patient treatment. Ex. 1001, 22:37-45 ("With the present invention, ... modifications can be made to a subject's treatment regiment as the severity or level of the subject's symptoms increase or decrease better regulating the therapeutic treatment of the subject's sleeping disorder. For example, ... CPAP can be adjusted during the treatment based on the sleep diagnosis results.").

179. In other words, what the '284 patent discloses as an “index” is what Truitt discloses as the sensor signals used to control the operation of the PAP system in “feedback fashion to meet the desired prescription pressure level” and to “counteract or prevent the[] conditions.” Ex. 1010, 10 (Patent Owner indicating that the disclosure of the '284 patent at 22:37-45 describes determining the claimed “index”); 1007, 2:57-3:4 (disclosing Truitt’s feedback fashion use of data signals). A POSITA would have understood that determining whether to increase or decrease or pressure or flow requires calculating the effectiveness of the PAP system to meet the desired prescription pressure level and/or “counteract or prevent these conditions.” For example, if the patient is still experiencing apneas and hypopneas, the effectiveness of the treatment is not high enough to treat the sleep disorder. Accordingly, the processor would determine that the efficacy is too low, and will increase the pressure.

180. A POSITA would have further understood that this determination would have been based on the patient’s condition (the detection of snoring, apnea, and/or hypopneas) and patient compliance (whether the patient is using the PAP device as prescribed). For example, the patient could be experiencing apneas and hypopneas because the patient is not complying with the prescribed therapeutic pressure. In such a situation, the processor may determine that the pressure does not need to increase, but rather, the patient just needs to comply with the treatment.

181. Despite the differing names, the function of the control signal remains the same as the data on the level of severity—adjusting the pressure based on the analysis. Further, I understand that the Patent Owner took this position, stating that “[i]n this context—where the level of severity is determined during treatment (not to mention used to adjust that treatment)—the level of severity is just another name for an index of treatment efficacy.” Ex. 1010, 10. The Patent Owner also states that “a skilled artisan would recognize that ‘an index of treatment efficacy’ is just another term for the level of severity of a patient’s symptoms determined while the patient is being treated.” *Id.* 12-14.

182. Furthermore, a POSITA would understand that, as the Patent Owner acknowledged, the “‘level of severity’ is ... an ‘index of treatment efficacy...*based* in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject’ because it is *based on* breathing metrics collected while the patient is using the device.” Ex. 1010, 3. Given the synonymy, because Truitt discloses using sensor signals collected while using the PAP device to adjust the treatment based on the patient’s conditions/symptoms, including at least an auto-titration mode, Truitt therefore discloses an “index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.”

183. **Fourth**, Truitt in view of Kumar discloses “*a non-transitory computer readable medium, the non-transitory computer readable medium comprising a first software, the first software executable by a first processor and configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded an index of treatment efficacy of the subject using a PAP device, the first software used for displaying the index on the cell phone, the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device and received by the cell phone, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display.*”

184. First, as I explained above, it was common for PAP systems to have input and output devices, such as keyboards and screens for displaying information associated with the patient and the PAP system’s performance. Truitt discloses such an input/output device 42, e.g., a keypad and a display for entering information and commands to the system and to display information. *Id.*, 3:12-20.

185. While not expressly disclosed by Truitt, a POSITA would have understood that such a display may include information associated with the PAP system and the patient, e.g., “data of usage of the PAP device by the subject,” “data

of severity of sleep disorder symptoms of the subject,” and/or “an index of treatment efficacy of the subject using a PAP device,” as discussed above. For example, it was common for PAP devices to include information regarding time of use and historical pressures that could be viewed by the patient on their PAP system.

186. Truitt discloses “the index based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject, the data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device” (*see above*). Though Truitt does not expressly disclose the remaining cell phone related features (as italicized above) of limitation [1.a], a POSITA nevertheless would have been motivated and found it obvious to implement these features in view of Kumar.

187. Kumar discloses a system/method for monitoring physiological data collected by a patient-side device, which is similar to Truitt’s system for monitoring patient’s conditions/symptoms and the usage of a medical treatment device discussed in detail above. Ex. 1008, Abstract. Kumar and Truitt relate to similar areas as, for example, Kumar discloses monitoring “sleep apnea-hypopnea syndrome” as characterized by “repetitive episodes of upper airway obstruction that occur during sleep usually associated with reduction in blood oxygen concentration.” *Id.*, [0240]. At least because they are in the same field, a POSITA

would have been motivated to consider Kumar's teachings for sleep apnea-hypopnea syndrome when implementing the PAP method/system disclosed by Truitt.

188. I will now discuss Kumar and its disclosures in more detail. Kumar describes a "remote monitoring of medical and/or biofeedback devices over a wide area network (WAN) such as the Internet," that allows a physician or other medical profession access to "real-time streaming of raw, interpreted, and processed physiological data as well as textual/audio/video data from a patient/client...." Ex. 1008, [0010]. Like the '284 patent, Kumar's includes a patient-side device for collecting data from a patient and a "provider-side device, and an engine, each coupled to the WAN." *Id.*, [0011]. Kumar's engine manages the transmission of the data from the patient-side device to the provider-side device to allow the provided to evaluate the data. *Id.*, [0011]. Kumar provides some examples of how its engine can be configured, including that the engine can be configured to provide for: 1) the direct transfer of data from one device to another; 2) to receive the raw data from the patient-side device and transmit either the raw or processed data to the provider-side device; and/or 3) to receive the data and store it for later transmission to the provider-side device, etc." *Id.*, [0011].

189. Kumar also discloses that "the system may be capable of networking the numerous devices and/or engines into individual, group, clinic, hospital, or other electronic record systems." *Id.* [0012]. Kumar further discloses that "the system may

be capable of networking the numerous devices and/or engines into individual, group, clinic, hospital, or other electronic record systems.” *Id.* [0069]. Kumar describes numerous potential use cases and patient side devices and makes clear that the patient-side device may be “a medical and/or biofeedback device that communicates through a serial, parallel, wireless, or customized interface” and “may then be connected via a computing device, such as a computer, personal digital assistant (PDA), etc., to the WAN.” *Id.*, [0013]; *see also id.*, [0014]. Kumar also includes an exemplarily listing of various medical conditions that its system may be adapted to treat that includes “Sleep Apnea Hypopnea Syndrome.” *Id.*, [0239-0241].

190. For example, as shown in Figure 1 below, Kumar discloses an exemplary system 100 for “network-based monitoring of data from a patient-side physiological collecting device,” where the system includes patient-side device(s) 102 for collecting data from a patient/client, provider-side device(s) 104, and an engine implemented on a central server 106.” Ex. 1008, [0067]. Here, the devices and engine are connected to a wide area network (WAN) 108, e.g., the Internet, and the system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider. *Id.*

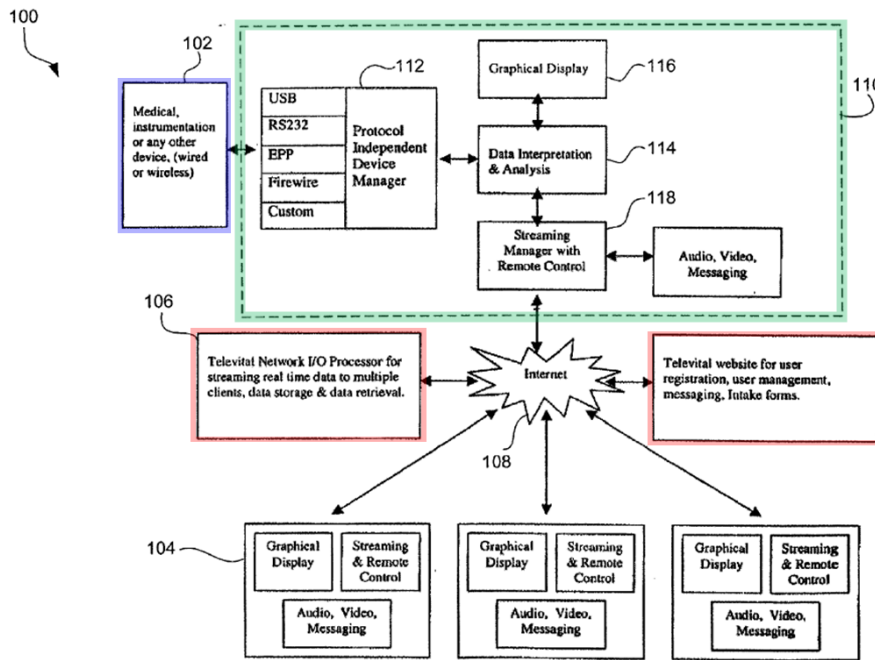


Fig. 1A

Ex. 1008, Fig. 1A

191. The system shown above in Figure 1 allows for various applications, including, e.g., “telemedicine, remote sleep studies, physical evaluations, remote monitoring, event recordings, holter monitoring, home health care, disease management applications, biofeedback, pharmaceutical research, wireless monitoring, anesthesiology-related monitoring, and stress, health and wellness education.” *Id.*, [0068]; *see also id.*, [0069].

192. The patient-side device 102 in Kumar “is located with a patient and can be any device that gathers physiological data from the patient.” Ex. 1008, [0071]. Kumar discloses that to gather data and transmit data, the patient-side device may be connected to the WAN via a computing device 110, and includes an identification

of potential computing devices including personal digital assistants (PDAs), pocket PCs, wireless telephone, or any other computing device. *Id.*, [0072], Fig. 1B (showing a wireless Internet connection using a pocket PC). The computing device 110 may also communicate directly with patient-side devices (*id.*) and each patient-side device may communicate through a wireless protocol (*id.*; *see also id.*, [0073]).

193. Kumar's computing device 110 may send a request to the engine such that the engine will download one or more plug-ins to facilitate communications between the computing device and the patient-side device. Ex. 1008, [0074]. To do so, "the computing device receiv[es] a software module for managing communication with the at least one patient-side device from the engine." *Id.*, claim 5. The computing device 110 also includes display module 116 and graphical user interfaces (GUIs), which may display data received from patient-side device 102.

194. Kumar goes on to describe this in more detail explaining that to do so, "the computing device...can send a request to the engine..., and the engine will send the appropriate plug-in which allows the computing device to communicate with the patient-side device. Thus, the present invention may support both plug-and-play web device drivers and customized graphical user interfaces (GUIs) for the various devices. Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI." *Id.*, [0074]. Kumar also explains that "the data interpretation and analysis module 114 is used to interpret

the data stream from the client-side device, perform mathematical analysis on the data using FFT, DFT, etc., and generate statistics. The data may be displayed graphically on the display module 116.” *Id.* [0075]. A POSITA would have understood that this was common practice at the time to use various methods, including Fourier Transforms, to analyze data collected by the patient side device and then to present this data using plug-and-play web device drivers and customized graphical user interfaces (GUIs).

195. Kumar also makes clear that data from the client side device may also be transmitted to doctors or other remote providers to enable them to perform real-time or post-session analysis, as well as for the storage and retrieval of raw or interpreted data via the Internet connection. *Id.*, [0076]-[0077]. Kumar’s system provides the doctor with the benefit of being able to “monitor the patient’s physiology and to provide treatment in real-time based on the data received from the patient side device “allow[ing] for daily or periodic monitoring of patients without the need for the patient to travel to the provider's location.” *Id.*, [0078]; *see also id.*, [0079].

196. Kumar explains that the data that is collected “may be stored in a secured storage device at the central server for later access, replay, and/or analysis,” and “[t]he storage device may also be used to store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any

electronic medical records system.” Ex. 1008, [0083]. For example, Kumar explains that the disclosed features “may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium.” *Id.*, [0087].

197. As I described above, Kumar discloses “a non-transitory computer readable medium, the non-transitory computer readable medium comprising a first software, the first software executable by a first processor and configured to be used with a cell phone to display to a subject for viewing on the cell phone on to which the first software is downloaded..., the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded and a display.” This is consistent with everything I have discussed above and below.

198. For example, Kumar discloses that the computing device 110 may be any number of a variety of wireless devices, including a wireless phone or pocket PCs, e.g., an iPAQ device and a POSITA would understand and either of these devices would constitute a “cell phone” as that term is used in the ’284 patent. Ex. 1008, [0072].

199. Additionally, a POSITA would have understood that “the HP iPAQ h6315 is a voice calling, Wi-Fi hotspot finding, wireless emailing, Internet connecting, instant message chatting, MP3 playing, picture taking, keypad typing, 64MB data storing powerhouse. The iPAQ h6315 is the first all-in-one wireless

device to include built-in GSM global phone capabilities with integrated GPRS wireless data, Wi-Fi (802.11b) wireless broadband, and Bluetooth™ functionality to allow customers to easily navigate and wirelessly communicate through e-mail, text messaging, Internet and phone calls.” Ex. 1011, 2. This description makes clear that the HP iPAQ h6315 is in fact a cell phone as a POSITA would have understood at the time.

200. Kumar further explains a software module (also known as a plug-in), downloaded by computing device 110 facilitate communications with the patient-side device. Ex. 1008, [0074], claim 5. The software module also provides customized graphical user interfaces (GUIs) (*id.*, [0074]), and analyzes/processes received data (*id.*, [0075]).

201. So for example a doctor could log in using the webpage depicted in Figure 2 of Kumar, by inputting their TeleVital ID and then Password.

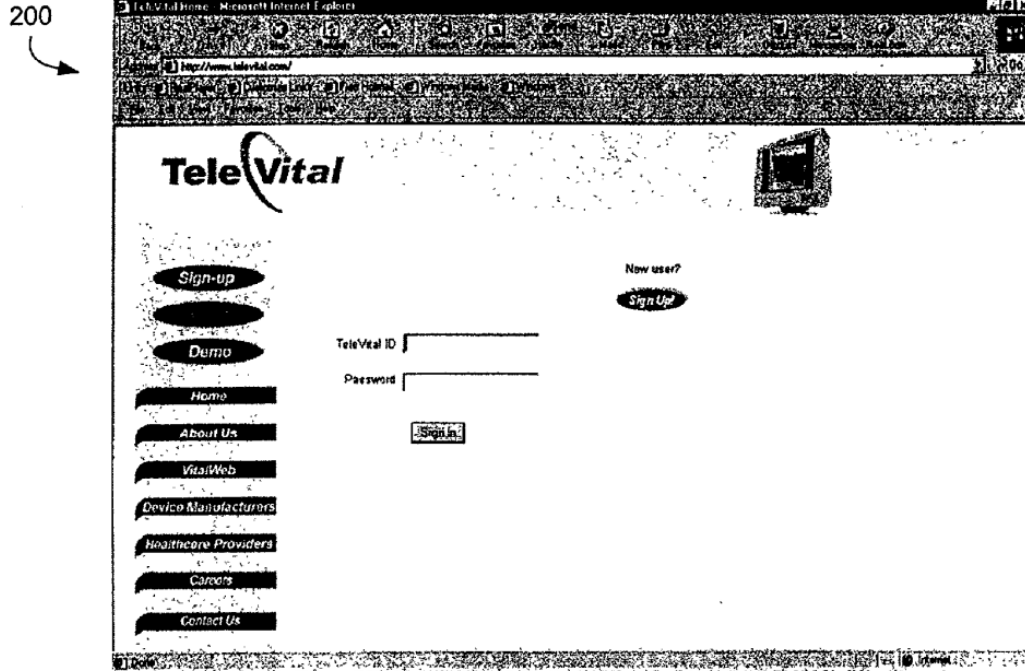


Fig. 2

Ex. 1008, Fig. 2

202. They could then access the real-time data coming from the patient device relating to the patient of interest would be able to remotely view and analyze the patient's blood oxygen saturation as depicted in Figure 24B.

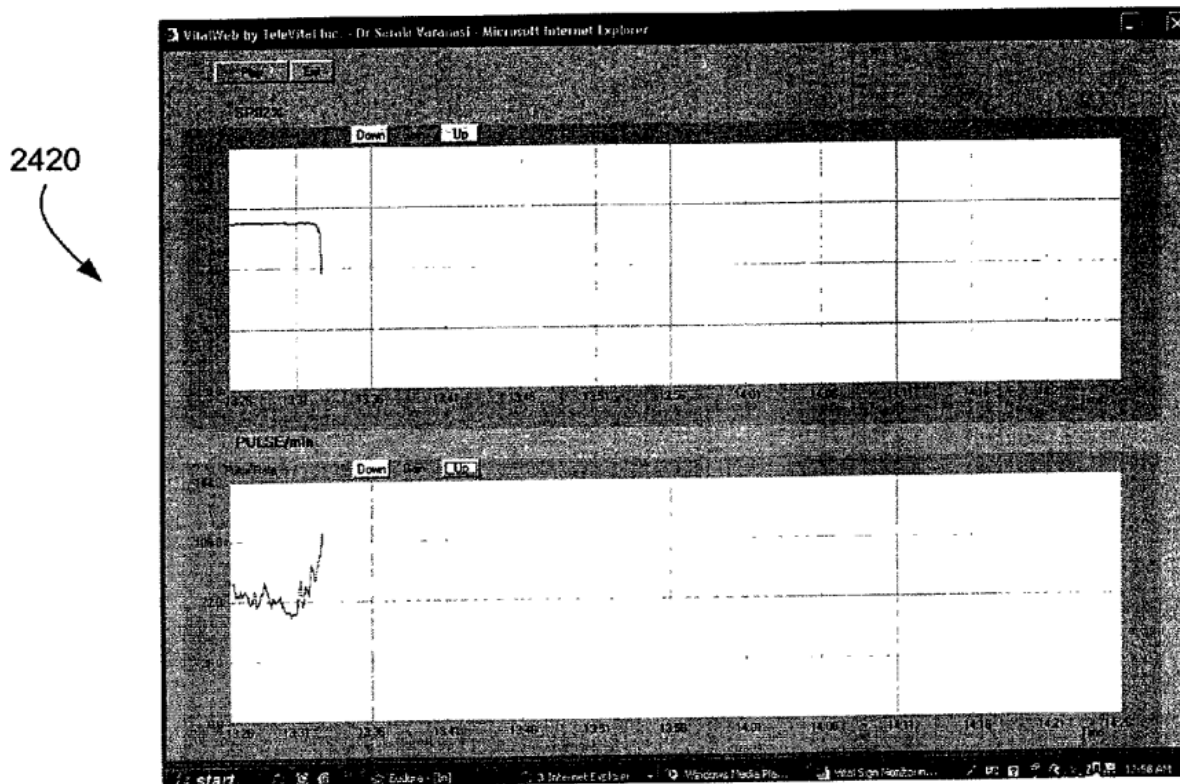


Fig. 24B

203. Kumar explains that these disclosed features “may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium.” *Id.*, [0087]. Additionally, the computing device 110 includes a display module 116 (“a display”) for displaying data received from patient-side device 102. Ex. 1008, [0075].

204. Thus, it would have been clear to a POSITA that Kumar’s computing device 110 (“cell phone”) includes a non-transitory computer readable medium comprising a downloaded software including a plug-in (“first software”) that is

executed by a processor (“first processor”) and configured to be used with a cell phone to display to a patient for viewing information/data.

205. Additionally, a POSITA would have understood that Kumar’s computing device 110 could be a wireless phone or iPAQ, either of which would include a radio frequency wireless transceiver (“first radio frequency wireless transceiver”) to facilitate wireless communications. Ex. 1008, [0072].

206. A POSITA would have been motivated and found it obvious to combine the teachings of Truitt and Kumar to implement the claimed features recited in limitation [1.a]. For example, a POSITA would have been motivated to configure the PAP device of Truitt to wirelessly transmit to a patient’s cell phone data associated with the patient’s treatment consistent with Kumar’s teaching of computing device 110 receiving data wirelessly from patient-side device 102 and displaying data to the user described above.

207. Such a configuration would provide for various data to be presented to the patient including “an index of treatment efficacy of the subject using a PAP device,” “data of severity of sleep disorder symptoms of the subject,” and “data of usage of the PAP device by the subject” and display the data/index and associated information to the patient. This feature/configuration would provide the patient with the ability to view the data/index on their personal cell phone and to store their

medical information and treatment data for later viewing from their cell phone when they are away from their PAP device.

208. A POSITA would understand that it would also be beneficial for the patient to be able to review information relating to their medical treatment so that the patient themselves is able to see first-hand how they are responding to the treatment and would therefore encourage the patient to comply with the prescribed treatment s seeing positive results would encourage more usage. Additionally, the combined device would have a reduced form factor as the PAP device would no longer need to include a screen suitable for displaying data to the patient, as the patient would be able to review such data from their own mobile device. This would have the added benefit of improving the device's portability and would make the combination PAP device more suitable for use during travel or in confined spaces. Moreover, a POSITA would have been motivated to transmit the data/index from the PAP device to the cell phone via certain wireless protocol(s) given that such a feature was known/prevalent at the time of the alleged invention. A POSITA would understand that using a wireless protocol can prevent a wired connection interfering with the user's range of motion, physical movement, or mobility, as I experienced first had in my research relating to the rowers described above.

209. A POSITA would have had the skill and a reasonable expectation of success in combining the teachings of Truitt and Kumar. Notably, Truitt and Kumar

are in the same field of art and both expressly relate to healthcare for sleep disorder. Kumar states that “virtually any device may be easily incorporated into the system.” Ex. 1008, [0074]. Kumar also includes an exemplarily listing of various medical conditions that it’s system may be adapted to treat that includes “Sleep Apnea Hypopnea Syndrome.” *Id.*, [0239-0241].

210. At the time of the alleged invention, a POSITA would have understood that interfacing with a PAP device could be done with a computing device via wireless communication. Kumar expressly discloses this by stating that “while this apparatus [a PAP device] is generally described as a single unit, it is understood that a combination of devices and/or computers linked by any available communications method may be used to accomplish the goals of the invention. For example, the apparatus can interface with a variety of hand-held devices such as a Palm Pilot via wireless communication or it may interface with a network for 25 transmission between the devices.” Ex. 1012, 6:20-25; *see also* 7:2-6 (describing that the apparatus is a PAP device). Ex. 1044, [0006] (“a positive pressure artificial respiration assisting device...is connected to a relay device and a physician-side terminal device via a wireless...communication network to conduct remote monitoring of the positive pressure artificial respiration assisting device via the communication network”), [0008] (The remote “telemedicine system comprises a positive pressure artificial respiration assisting device 2, a relay device 3, and...a

physician-side computer 4 and a mobile terminal 5, all connected to communication network 1.”), [0009] (“The communication network 1 may be any of a public telephone network, the Internet, a mobile communication network, or a dedicated line network; alternatively, it may also be a combination of these networks.”), Fig. 1. Ex. 1009, 14:54-15:12 (use of wireless/Bluetooth protocol to transmit data associated with a CPAP device). Moreover, it would have involved a combination of known technologies (e.g., known PAP device that monitors the usage and calculates data/index associated with sleep disorder treatment as per Truitt) according to known methods (e.g., known methods of transmitting data via wireless protocol(s) from patient-side device to computing device, e.g., cell phone, to display the data as per Kumar) to yield the predictable result of a system including a PAP device of improved portability and an associated system that improves patient compliance, as discussed above. Accordingly, Truitt in view of Kumar discloses and/or suggests this limitation.

3. [1.b] *“the PAP device with an enclosure further comprising:*

[1.b.i] *“a blower having an air output,”*

[1.b.ii] *“an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data,”*

[1.b.iii] *“a second processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms*

*of the subject and/or the index, and for calculating the data of
usage of the PAP device,”*

[1.b.iv] *“a mask or a nasal cannula, and”*

211. It is my opinion that Truitt discloses limitations [1.b]-[1.b.iv]. As a starting point, these limitations are standard components of a CPAP device, as indicated by Figure 1 of Truitt depicting a standard prior art device. Nonetheless, I will walk through these here. Figure 3 of Truitt discloses that the PAP device includes a housing 58 (“enclosure”). Ex. 1007, 5:12-13. As discussed above with respect to the preamble, Truitt’s PAP system 50 is similar to its system 10, but system 50 includes an improved flow sensor. *See* Section X.C.1 (Ground 1, Claim 1, Preamble). Truitt’s PAP system 50 includes a pressure generator 12 in the form of a blower assembly 52 (“blower having an air output”) driven by a motor 54 providing a gas flow as indicated by arrow B to patient circuit 14. Ex. 1007, 5:1-3; *see also id.*, 5:4-35.

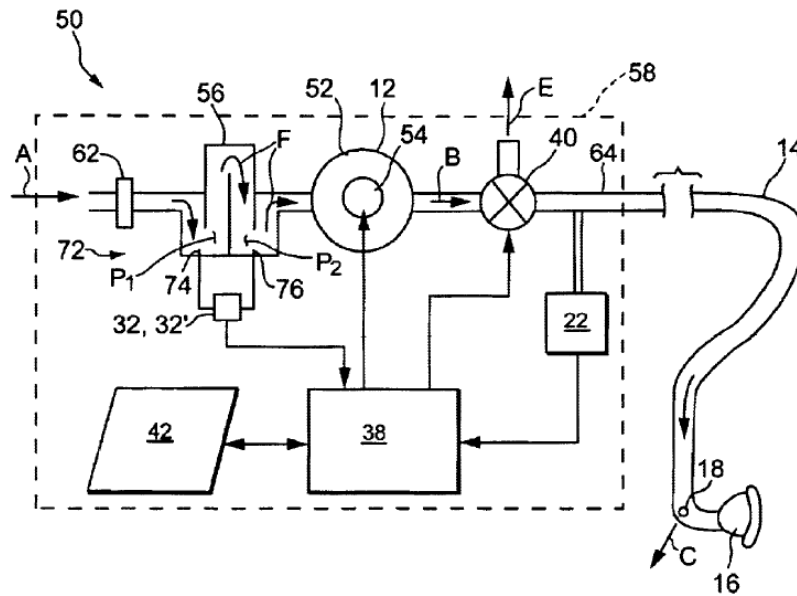


FIG. 3

212. Truitt's PAP system 50 also discloses that it includes an improved flow sensing system 72 ("airflow sensor internal to the PAP device") within the housing 58, as shown in Figure 3 (above). It provides a signal that controller 38 uses to calculate gas flow and/or volume passing through conduit 56. Based on this information the operations of the PAP device are controlled, including the operations of blower assembly 52 (driven by motor 54) and/or the operation of valve 40 that controls air flow and pressure provided to the patient. Specifically, Truitt discloses an air flow sensor "adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data." Ex. 1007, 6:11-62.

213. Additionally, as discussed for limitation [1.a], Truitt discloses a controller 38 ("second processor") that receives signals provided by a flow sensing

system 72 (“adapted for receiving the airflow sensor data”) (Ex. 1007, 6:11-17) for calculating “the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device.” Controller 38 is thereby able to maintain the current flow/pressure if the desired result is being achieved, or alternatively may increase or decrease the flow/pressure of the gas delivered to the patient if such a change is desirable for the patient’s treatment. *Id.*, 5:36-59.

214. As depicted in Figure 3 above, Truitt also discloses that the PAP device includes a patient interface device such as, a mask or a nasal cannula. Ex. 1007, 1:56-61, 6:2, Figure 3 (depicting patient circuit 14 (e.g., a flexible conduit) coupled with a patient interface device 16 (e.g., a mask or nasal cannula).

215. Accordingly, Truitt discloses limitations [1.b]-[1.b.iv].

4. [1.b.v] *“at least one second radio frequency wireless transceiver, the at least one second radio frequency wireless transceiver adapted for transmitting the data of severity of the symptoms of the subject and/or the index, and the data of usage calculated by the second processor; and ”*

216. It is my opinion that Truitt in view of Kumar discloses this limitation. As discussed above for limitation [1.a], a POSITA would have been motivated to combine teachings of Truitt and Kumar such that the PAP device would wirelessly transmit to a patient’s cell phone data associated the patient’s treatment, including “an index of treatment efficacy of the subject using a PAP device,” “data of severity

of sleep disorder symptoms of the subject,” and “data of usage of the PAP device by the subject” and display on the cell phone the data/index to the patient.

217. A POSITA would have been motivated and found it obvious to implement a radio frequency wireless transceiver in the PAP device to facilitate wireless communication with the cell phone to transmit data.

218. Kumar discloses that the patient-side device is connected via computing device 110 to the WAN and a “two-way communication” is “establish[ed]” between computing device 110 and the patient-side device. Ex. 1008, [0072]. Additionally, the “patient-side device can be...wireless, and communicates through...wireless...interface/protocol.” *Id.* Given that computing device 110 and the patient-side device establish a “two-way” “wireless” communication, a person of ordinary skill in the art would have understood that each of computing device 110 and the patient-side device includes a wireless “transceiver” for the two-way (transmitting and receiving) wireless communication.

219. As discussed for limitation [1.a], it was well known that computing devices, such wireless phones, an example of computing device 110, included radio frequency wireless transceivers to facilitate wireless communications using wireless protocols including, e.g., GSM, GPRS, Wi-Fi, and Bluetooth.

220. A POSITA would have been motivated to implement a radio frequency wireless transceiver in the PAP device to enable to use of protocols similar to those

used by computing device 110, for example, GSM, GPRS, Wi-Fi, and Bluetooth, to enable the PAP device itself to wirelessly communicate with other devices, including by way of transmitting the “data” and/or “index,” as discussed above to these other devices which would similarly include radio frequency wireless transceivers.

221. It was well known to a POSITA that one could use a Bluetooth-enabled radio frequency wireless transceiver that allowed a short-range radio link between devices, including between the PAP device and computing device 110 for data communication. Ex. 1018, 9:56-57 (“a short-range radio link, such as Bluetooth”). Additionally, a POSITA would have understood that Wi-Fi-enabled radio frequency wireless transceivers could have been used to connect devices, and that including one with the PAP device would have allowed the PAP device to connect to both the cell phone and the remote engine providing a connection for uploading data to either, or GSM- or GPRS-enabled radio frequency wireless transceiver when the PAP device is not connected to Wi-Fi.

222. A POSITA would have had the skill and a reasonable expectation of success in implementing a radio frequency wireless transceiver in the PAP device. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, Ex. 1044, Fig. 5; Ex. 1045, Fig. 3; Ex. 1013, [0029] (a CPAP device including “a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with

other devices or computers such as hand-held display and control devices 12.”); Ex. 1044, Fig. 3, [0006]-[0007], [0023], [0030], [0070].

223. Moreover, as I describe above, it would have involved a combination of known technologies (e.g., known PAP device that monitors the usage and calculates data associated with sleep disorder treatment as per Truitt) according to known methods (e.g., known methods of transmitting data from patient-side device to computing device, e.g., cell phone, by using a radio frequency wireless transceiver as per Kumar) to yield the predictable result of a PAP device including a radio frequency wireless transceiver to facilitate wireless communication with the cell phone. Accordingly, it is my opinion that Truitt in view of Kumar discloses and/or suggests this limitation.

5. [1.c] *“a remote internet site, the remote internet site adapted to receive the data of the severity of the symptoms of the subject and/or the index, and the data of usage of the PAP device by the subject both related to the subject's treatment and the treatment's efficacy, in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.”*

224. It is my opinion that Truitt in view of Kumar discloses this limitation. As discussed above for limitation [1.a] of Ground 1, Kumar discloses “at least one patient-side device for collecting data from a patient/client, a provider-side device, and an engine, each coupled to the WAN,” such as the Internet. Ex. 1008, [0011]; *see also* Section X.C.2 (Ground 1, Claim 1, Limitation [1.a]). Furthermore, a

POSITA would have been motivated to consider the teachings of Kumar when implementing the method/system disclosed by Truitt.

225. Kumar describes a “remote monitoring of medical and/or biofeedback devices over a wide area network (WAN) such as the Internet,” that allows a physician or other medical profession access to “real-time streaming of raw, interpreted, and processed physiological data as well as textual/audio/video data from a patient/client....” Ex. 1008, [0010]. Kumar further discloses a “browser-based engine” (“a remote internet site”) that supports real-time streaming of information over the internet, and provides the physician or other medical professional with real time access Ex. 1008, [0010], [0087]. Kumar describes that its system “may be implemented using Apache web server, MySql on Linux, Oracle on Linux, Java servlets, Applets, HTML, JavaScript, Java, C#, Microsoft's .NET etc.” and further describes “that the server may be implemented on the Internet, intranet, or an extranet.” Ex. 1008, [0011]. Kumar’s use of a WAN, such as the internet, means that Kumar’s engine “manages transmission of the data from the patient-side device to the provider-side device” and that Kumar’s engine “may configure the devices to transfer the data directly from one device to the other; may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device; may store the data for later transmission to the provider-side device, etc.” *Id.*

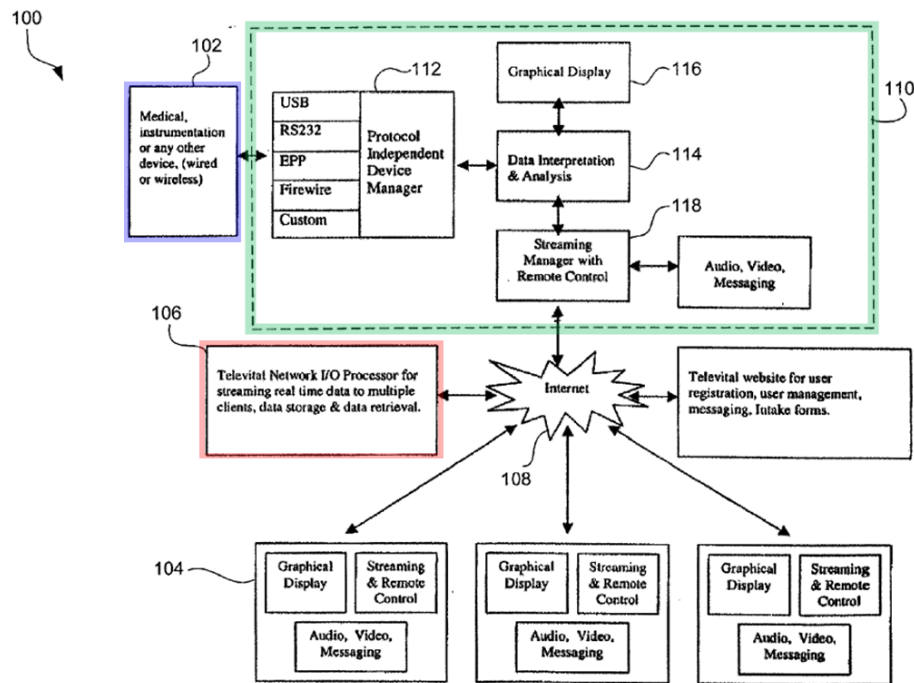


Fig. 1A

Ex. 1008, Fig. 1A

226. A POSITA would understand that Kumar teaches a telemedicine system that communicates data from patient-side devices, like a PAP machine, and makes that data accessible through a central server or mobile devices like a cell phone. The system as shown in the above figure includes patient-side devices 102 for collecting data from a patient/client, provider-side devices 104, and an engine implemented on a central server 106, where the devices and engine are connected to a wide area network (WAN) 108 such as the Internet. Ex. 1008, [0067]. By connecting to a WAN, “the system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data

from a patient to a health care provider.” *Id.*; *see also id.*, [0068]. Additionally, Kumar discloses that the engine “may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device” and “may store the data for later transmission to the provider-side device, etc.” *Id.*, [0081], [0082]. Kumar also discloses that the patient-side device may communicate through a wireless interface and may communicate over the Internet. *Id.*, [0013].

227. Kumar explains that “the entire system runs in the context of an Internet browser.” Ex. 1008, [0086]-[0087]; *see also id.*, [0010] (“a browser-based engine”), [0015]. This means that a patient or doctor can access Kumar’s engine by way of a login function within the internet browser, such as that depicted in Figure 2. *Id.*, [0089], [0192] (“the system’s Internet browser-based software that allows the remote provider, and other healthcare providers, to remotely view their patient's real-time physiology”).

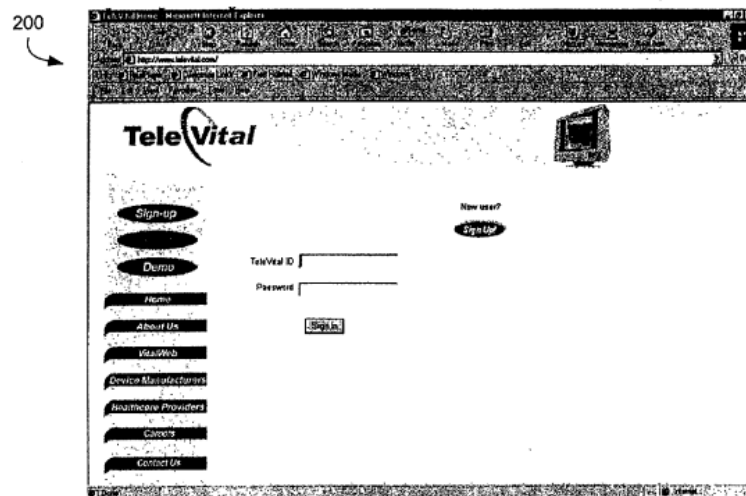


Fig. 2

Ex. 1008, Fig. 2

228. A POSITA would have understood that the data sent to the engine could be accessed by way of the web pages which serve as a graphical user interface, such as the “patient’s real-physiological data” depicted in Figure 7. Ex. 1008, [0092], Figs. 6-8; *see also id.*, [0010], [0015] (“the communications are provided via a browser-based interface” and “the provider can start these devices remotely to read the data periodically or whenever needed”).

229. This would allow the doctor to remotely access the real-time data coming from the patient device relating to the patient of interest, enabling the doctor to remotely view and analyze patient data, such as the patient’s blood oxygen saturation depicted in Figure 24B of Kumar.

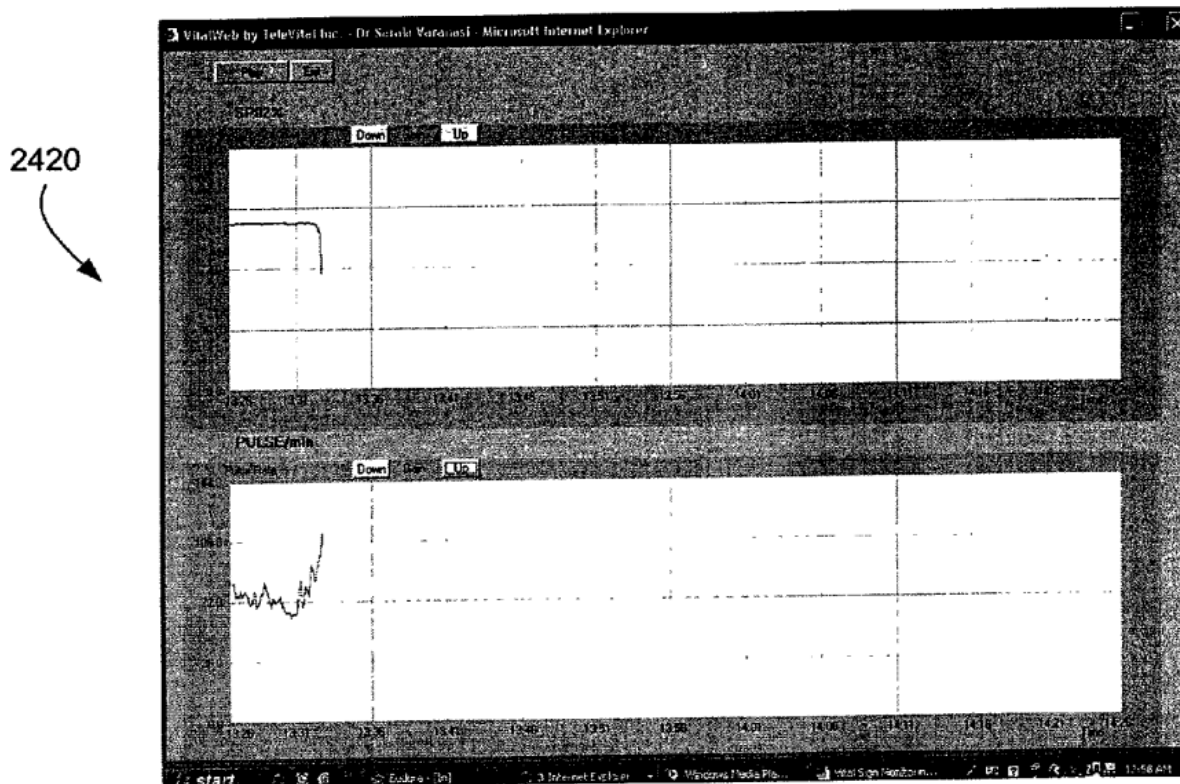


Fig. 24B

230. A POSITA would have been motivated to implement a remote-monitoring feature, including a browser-based engine (“a remote internet site”) as described in Kumar (*see, e.g., above*), to enable a PAP device, such as that in Truitt, to wirelessly transmit to the remote engine data associated the patient’s treatment. Examples of such remote data include “an index of treatment efficacy of the subject using a PAP device,” “data of severity of sleep disorder symptoms of the subject,” and “data of usage of the PAP device by the subject.”

231. A remote-monitoring feature that enables a PAP device to wirelessly transmit remote engine data associated with a patient’s treatment would have been

beneficial as Kumar explains that the data from its system “may be stored in a secured storage device at the central server for later access, replay, and/or analysis” and to “store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system,” which would allow a treating physician the ability to access, retrieve, print, analyze or otherwise interact with the data “from anywhere in the world with access to the storage device.” Ex. 1008, [0083]. In fact, Kumar states that such a feature is beneficial, e.g., because it allows a provider to seek expert consultation for clinically difficult cases by sharing the patient history and medical test results online.

232. Kumar teaches: “This beneficially allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. Further, storage of the data allows for the creation of statistical databases, including development of a database of biomedical test results, for example. For example the results of routine medical tests may be stored from the biomedical device directly into the patient’s electronic medical record. Further, personal health information can be stored in smart-cards that can be carried by a patient, and which may also carry other personal information such as credit card and bank account data.” *Id.*

233. Kumar goes on to explain that “[t]he system may also track trends during the recording, and using artificial intelligence, predict future behaviors and

physiological responses based on the habits of the particular client hooked up.” *Id.*, [0084].

234. In light of the disclosures of the references, and my discussion above, a POSITA would have had a reasonable expectation of success in implementing the above-discussed PAP device that wirelessly transmits remote engine data associated with a patient’s treatment in the Truitt-Kumar combination.

235. My opinion is supported by Kumar’s own disclosure which states that “virtually any device may be easily incorporated into the system.” Ex. 1008, [0074], and in light of Kumar disclosure of “Sleep Apnea Hypopnea Syndrome” in its exemplarily listing of various medical conditions that it’s system may be adapted to treat. *Id.*, [0239-0241].

236. Additionally, it was well known to transmit data using wireless protocol(s) to a remote Internet site, e.g., for the purpose of later access to the data. For example, Langford 2004 describes methods for “wireless data transmission attaching a transmission device (Cyracat wire-less transmitter), to the flow generator (CPAP and Auto-CPAP). Ex. 1043. Then, by accessing a secure Web site, a request for data sent from a secure server, located centrally, through land lines to the carrier’s local transmission antenna, located within several miles of the device and location set up, where it is transmitted wirelessly to the device. Once the device received the request, the data were retrieved from the memory of the flow generator, transmitted

wirelessly to a receiving antenna, located within several miles of the device. Then, through land lines back to the secure server, the data became available on the aforementioned Web site. *Id.*

237. Further, as I described above, in the 90's, I worked with the New South Wales Institute of Sport in using the COSMED K4 telemetry system for the monitoring of elite rowers exercise performance at the Penrith Regatta in 1997. Similarly, TeleDiagnostic Systems of San Francisco a home monitoring equipment vendor patented and develop a system for recording sleep patterns for all-night monitoring at the patients home rather than in a hospital. In a patent filing they described physiological parameters monitored by the TeleDiagnostics Systems to include EEG, EKG, EMG, EOG, respiration, oximetry being able to detect and monitor over ten different channels of physiological data. Ex. 1040.

238. Moreover, in my opinion it would have involved a combination of known technologies (e.g., known PAP device that monitors the usage and calculates data associated with sleep disorder treatment (Truitt)) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine on the Internet (Kumar)) to yield the predictable result of a system including a remote engine that receives and stores data received from a patient-side device, e.g., the PAP device, for simultaneous storage, retrieval, analysis, and play back from anywhere in the world, as discussed above.

239. Accordingly, the Truitt-Kumar combination discloses a browser-based engine (“a remote internet site”) that receives the claimed “data” and “index” both related to the patient’s treatment and the treatment’s efficacy, generated by the PAP device and transmitted via the radio frequency wireless transceiver included in the PAP device.

D. Dependent Claims

1. **Claim 2. The system of claim 1, wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol.**

240. It is my opinion that the Truitt-Kumar combination discloses this limitation. As I discussed in relation to limitation [1.a], of Ground 1 above, Kumar discloses that the computing device 110 (“cell phone”) may be an iPAQ device. At the time of the alleged invention, a POSITA would have understood that an exemplary cell phone, such as the iPAQ device would be able to transmit and receive data by way of the Bluetooth wireless protocol. This is supported by the iPAQ’s documentation which states that “the iPAQ h6315 is the first all-in-one wireless device to include built-in GSM global phone capabilities with integrated GPRS wireless data, Wi-Fi (802.11b) wireless broadband, and **Bluetooth™** functionality to allow customers to easily navigate and wirelessly communicate through e-mail, text messaging, Internet and phone calls.” Ex. 1011, 2 (emphasis added).

241. A POSITA would have been motivated to implement similar Bluetooth capability in the PAP device of Truitt in order to provide an additional or alternative wireless data communication channel between the PAP device and the iPAQ pocket PC (“cell phone”). Bluetooth functionality has been known to provide a simple setup process for connecting two devices for data transmission and was known for using relatively low power since 1999 when the first Bluetooth specification named Bluetooth 1.0 was published, and certainly since Bluetooth 2.0 was released in 2004.

242. A POSITA would have also had a reasonable expectation of success in implementing Bluetooth capability in the PAP device. It was known at the time of the alleged invention that PAP devices could include Bluetooth capability, as Kumar describes that the “*monitoring unit 16 may be directly integrated within the CPAP device 14.... The monitoring unit 16 includes a control unit 600, a mask interface 602, a remote communications unit 604,.... the remote communications unit 604 employs an appropriate communications protocol such as the BLUETOOTH™ protocol....*” Ex. 1009, 14:53-15:10.

243. Moreover, it would have involved a combination of known technologies according to known methods, for example, the known use of Bluetooth protocol for wireless data communication between two devices, to yield the predictable result of a PAP device communicating with a cell phone using the

Bluetooth protocol, as discussed above. It was well known to a POSITA that one could use a Bluetooth-enabled radio frequency wireless transceiver that allowed a short-range radio link between devices, including between the PAP device and computing device 110 for data communication. Ex. 1018, 9:56-57 (“a short-range radio link, such as Bluetooth”). Further, at the time, there were only a handful of known techniques for transmitting data wirelessly, including radio frequency communication and optical wireless communications. Because there were only a handful of known techniques, using one of these handful, Bluetooth, to implement communications via radio frequency would have been obvious because it would have been one of a finite number of identified, predictable solutions. Accordingly, Truitt in view of Kumar discloses this limitation.

2. **Claim 3. The system of claim 1, wherein the at least one second radio frequency wireless transceiver is configured to transmit the data to the remote internet site and/or the cell phone of the data of the severity of the symptoms of the subject and/or the index, and the data of usage via in part by cell towers.**

244. It is my opinion that the Truitt-Kumar combination discloses this limitation. As discussed in Ground 1 for limitation [1.a], Kumar discloses that computing device 110 may be a wireless phone or pocket PCs, e.g., an iPAQ device. *Id.*, [0072]. Kumar explains that computing device 110 downloads a plug-in, i.e., a software module, to facilitate communications with the patient-side device (Ex.

1008, [0074], claim 5), provides customized graphical user interfaces (GUIs), such as that depicted in Figure 2 below (*id.*, [0074]), and analyzes/processes received data (*id.*, [0075]). Further, Kumar discloses that “[t]he lightweight HP iPAQ h613 has “the muscle of T-Mobile’s national GSM/GPRS wireless voice and high-speed data network.” Ex. 1011, 2. At the time of the alleged invention, it would have been clear to a POSITA that an exemplary cell phone, such as the aforementioned iPAQ device, would be able to both transmit and receive data using the GSM and GPRS wireless protocol that transmits data in part by cell towers.

245. As explained in Ground 1 for limitation [1.a], a POSITA would have been motivated to configure a PAP device, similar to Truitt, to wirelessly transmit to a patient’s cell phone data associated the patient’s treatment as disclosed in Kumar. As described above, Kumar directly teaches that devices like the Truitt PAP device, can be incorporated into its system: “Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI. Thus, virtually *any* device may be easily incorporated into the system.” Ex. 1008, ¶ [0018].

246. The patient data being transmitted includes “an index of treatment efficacy of the subject using a PAP device,” “data of severity of sleep disorder symptoms of the subject,” and “data of usage of the PAP device by the subject” and display the “data” and “index” to the patient. Kumar also discloses that the patient-

side device may be connected via a computing device to the Internet, with which the engine/central server 106 is connected in Figure 1A below. Ex. 1008, [0013], [0067], [0073], Fig. 1.

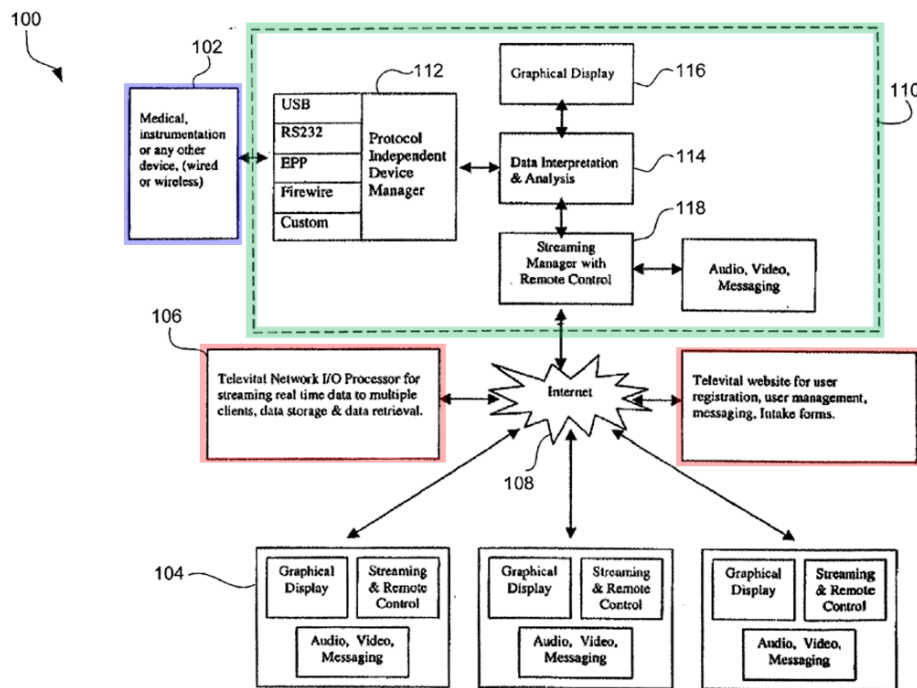


Fig. 1A

Ex. 1008, Fig. 1A

247. Furthermore, Kumar discloses that the engine may “receive the data from the patient-side device and transmit the raw or processed data to the provider-side device.” *Id.*, [0081]. In view of the above and as discussed for Ground 1 limitation [1.b.v], the Truitt-Kumar combination discloses transmitting “data...of the data of the severity of the symptoms of the subject and/or the index” wirelessly from patient-side device 102 by a radio frequency wireless transceiver in the PAP

device to computing device 110 (“cell phone”), which in turn transmits the “data” via the Internet to the central server. A POSITA would understand that there is a radio frequency wireless transceiver on both sides of the above described communication.

248. This is further supported by the fact that an exemplary computing device, i.e., the iPAQ device, may transmit/receive data using the GSM/GPRS wireless protocol, which transmits data in part via cell towers. 1011, 2 (“[t]he lightweight HP iPAQ h613 has ‘the muscle of T-Mobile’s national GSM/GPRS wireless voice and high-speed data network.’” Ex. 1011, 2. In light of these disclosures and those previously discussed, a POSITA would understand that the Truitt-Kumar combination discloses the second radio frequency wireless transceiver of the PAP device transmits the “data” to the remote engine by using the iPAQ device’s wireless protocol “via in part by cell towers.”

3. **Claim 5. The system of claim 4, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the data measured, calculated and then transmitted to the remote internet site.**

249. It is my opinion that Truitt in view of Kumar discloses this limitation. As discussed in Ground 1 for limitation [1.c], the Truitt-Kumar combination

discloses transmitting to the “remote internet site” “the data of the severity of the symptoms of the subject and/or the index” measured/calculated by the PAP device.

250. Kumar discloses that the provider may “remotely control the client-side device[s].” An example is “when the patient is sleeping in his/her home..., the provider can start these devices remotely to read the data periodically or whenever needed.” Ex. 1008, [0015]. By “[u]sing optional remote control features built in to the system, remote providers can control the software on the patient’s end.” *Id.*, [0080], [0085]. Kumar explains that the remote engine is “responsible for streaming...remote control information between multiple clients and hosts.” *Id.*, [0082].

251. A POSITA would have been motivated to implement these features as it would have allowed the provider to remotely control/adjust the PAP device, after receiving via the remote engine “the data of the severity of the symptoms of the subject and/or the index” measured/calculated by the PAP device. A provider may monitor the received data and adjust the PAP device to operate in different modes, e.g., operating as “bi-level pressure support” or as “an auto-titration mode of pressure support,” as discussed in Truitt. Ex. 1007, 1:30-43. In the case of changes in either acute or progressive factors that contribute to the severity of sleep apnea (i.e. pathogenic or behavioral) may be intermittent or slowly change over time. Changes in such factors may very likely require alternations in either the gas pressure

delivery level or other therapy settings. As an example surgical weight loss procedures may reduce upper airway collapsibility during sleep requiring progressive less pressure support. Whereas, progressive motor neuron diseases may decrease inspiratory muscle strength over time requiring more inspiratory but not expiratory pressure support during sleep. Moreover, as explained in Kumar itself, the remote control features (e.g., those discussed above) would have been beneficial as the “patients do not need to know how to operate the software.” Ex. 1008, [0080]. Additionally, a POSITA would have been motivated to modify the processor of the PAP device, e.g., controller 38 disclosed in Truitt, such that it may be adjusted remotely (“at least one electronic component adapted to allow the PAP device to be adjusted remotely”) given that such a processor/controller controls operations of the PAP device, and thus adjustments to the PAP device operations may be readily executed by the processor. Ex. 1007, 2:38-42, 2:57-64, 6:6-10.

252. A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described features as it would have would have been a routine and conventional implementation of known methods using known hardware components performing their known functions, well within a POSITA’s skills and ability to accomplish. The remote treatment and adjustment of patients was well-known by this time, as I discussed in the background section. *See* Section VI.B (Remote Diagnosis and Monitoring Patients at Home versus Clinic). For

example, the Johns Hopkins University study using a commercially available remote monitoring platform (VisICU, Baltimore MD), which demonstrated that remote monitoring of acute care patients could effectively reduce mortality rates and healthcare costs by enabling immediate interventions and continuous oversight. Ex. 1039. Accordingly, Truitt in view of Kumar discloses and/or suggests this limitation.

4. Claim 6. The system of claim 1, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data of the severity of the symptoms of the subject and/or the index, based in part on the data measured, calculated and then transmitted to the remote internet site.

253. It is my opinion that Truitt in view of Kumar discloses this limitation. As discussed in Ground 1 for limitation [1.c], the Truitt-Kumar combination discloses transmitting to the “remote internet site” “the data of the severity of the symptoms of the subject and/or the index” measured/calculated by the PAP device.

254. Kumar discloses that the provider may “remotely control the client-side device[s].” An example is “when the patient is sleeping in his/her home..., the provider can start these devices remotely to read the data periodically or whenever needed.” Ex. 1008, [0015]. By “[u]sing optional remote control features built in to the system, remote providers can control the software on the patient’s end.” *Id.*, [0080], [0085]. Kumar explains that the remote engine is “responsible for

streaming...remote control information between multiple clients and hosts.” *Id.*, [0082].

255. A POSITA would have been motivated to implement these features as it would have allowed the provider to remotely control/adjust the PAP device, after receiving via the remote engine “the data of the severity of the symptoms of the subject and/or the index” measured/calculated by the PAP device. A provider may monitor the received data and adjust the PAP device to operate in different modes, e.g., operating as “bi-level pressure support” or as “an auto-titration mode of pressure support,” as discussed in Truitt. Ex. 1007, 1:30-43. In the case of changes in either acute or progressive factors that contribute to the severity of sleep apnea (i.e. pathogenic or behavioral) may be intermittent or slowly change over time. Changes in such factors may very likely require alternations in either the gas pressure delivery level or other therapy settings. As an example surgical weight loss procedures may reduce upper airway collapsibility during sleep requiring progressive less pressure support. Whereas, progressive motor neuron diseases may decrease inspiratory muscle strength over time requiring more inspiratory but not expiratory pressure support during sleep. Moreover, as explained in Kumar itself, the remote control feature would have been beneficial as the “patients do not need to know how to operate the software.” Ex. 1008, [0080]. Additionally, a POSITA would have been motivated to modify the processor of the PAP device, e.g.,

controller 38 disclosed in Truitt, such that it may be adjusted remotely (“at least one electronic component adapted to allow the PAP device to be adjusted remotely”) given that such a processor/controller controls operations of the PAP device, and thus adjustments to the PAP device operations may be readily executed by the processor. Ex. 1007, 2:38-42, 2:57-64, 6:6-10. A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described feature as it would have would have been a routine and conventional implementation of known methods using known hardware components performing their known functions, well within a POSITA’s skills and ability to accomplish. The remote treatment and adjustment of patients was well-known by this time, as I discussed in the background section. *See* Section VI.B (Remote Diagnosis and Monitoring Patients at Home versus Clinic). For example, the Johns Hopkins University study using a commercially available remote monitoring platform (VisICU, Baltimore MD), which demonstrated that remote monitoring of acute care patients could effectively reduce mortality rates and healthcare costs by enabling immediate interventions and continuous oversight. Ex. 1039. Accordingly, Truitt in view of Kumar discloses and/or suggests this limitation.

5. **Claim 12. The system of claim 1, wherein the airflow sensor data is processed by the second processor, in part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time**

Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

256. It is my opinion that Truitt in view of Kumar discloses this limitation for the same reasons discussed for Ground 1 claim 9.

257. It is my opinion that Truitt in view of Kumar discloses this limitation. As discussed in Ground 1 above for limitation [1.b.iii], Truitt discloses “a second processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms of the subject and/or the index, and for calculating the data of usage of the PAP device.” Thus, Truitt discloses that “the airflow sensor data is processed by the second processor.”

258. While Truitt does not expressly disclose the airflow sensor data is processed/calculated by the second processor, in part, using “a discrete Fourier transform technique” or “a fast Fourier transform technique,” a POSITA would have found it obvious to implement this feature in view of Kumar. Kumar discloses that data received by the patient-side device may be analyzed “using FFT, DFT, etc.” Ex. 1008, [0075]. A POSITA would have understood that FFT and DFT each refers to the claimed “fast Fourier transform technique” and “discrete Fourier transform technique,” which is consistent with the '284 patent. In fact, the '284 Patent states that “[a] Discrete Fourier transform (DFT), and its numerically efficient complement

the Fast Fourier Transform (FFT), both provide frequency information of a digitized signal or data from the sensors.” Ex. 1001, 21:26-30.

259. A POSITA implementing the Truitt-Kumar combination would have been motivated to use the FFT and DFT techniques to process/calculate the received airflow sensor data as these techniques were well-known at the time of the alleged invention and Truitt itself does not expressly teach the techniques used to process/calculate the data. For example, U.S. Patent No. 6,675,797 describes the use of Fourier transform to process airflow signals from CPAP devices, while WO 2003/024335 A1 discloses using a “Fast Fourier Transform (FFT) algorithm” to identify occlusions of the patient’s airway.

260. A POSITA would have also had a reasonable expectation of success in in implementing this feature in the Truitt-Kumar combination. Moreover, it would have involved a combination of known technologies. For example, a known PAP device that processes/calculates airflow sensor data (Truitt)) according to known methods of analyzing patient-side device data using FFT or DFT (Kumar)) to yield the predictable result of a PAP device where the airflow sensor data is processed/calculated by the second processor, in part, using the FFT or DFT technique, as discussed above. Accordingly, Truitt in view of Kumar discloses and/or suggests this limitation.

6. **Claim 13. The system in claim 12, wherein the airflow sensor data is processed by the second processor, in part, using a Fourier transform technique.**

261. It is my opinion that Truitt in view of Kumar discloses this limitation for the same reasons discussed for Ground 1 claim 12.

7. **Claim 14. The system of claim 1, wherein the remote internet site is configured to retransmit to the first radio frequency wireless transceiver on the cell phone the data of the severity of the symptoms of the subject, the index, a second index and/or the data of usage related to the subject's treatment and the treatment's efficacy, in whole or part, calculated by the PAP device.**

262. It is my opinion that Truitt in view of Kumar discloses this limitation. As discussed in Ground 1 above for limitation [1.c], a POSITA would have been motivated to combine Truitt and Kumar's teachings such that the remote engine ("the remote internet site") is configured to receive and store the various data/index generated/calculated by the PAP device. Kumar explains that the data from its system "may be stored in a secured storage device at the central server for later access, replay, and/or analysis" as well as to store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system," which would allow a treating physician the ability to access, retrieve, print, analyze or otherwise interact with the data. Ex. 1008, [0083].

263. A POSITA would have been motivated to configure the Truitt-Kumar combination such that it enables the remote engine (“remote internet site”) to retransmit to the first radio frequency wireless transceiver on the cell phone the claimed data/index, in whole or part, calculated by the PAP device. For instance, as a POSITA would have understood, the patient would be interested in reviewing data/index associated with prior use of the PAP device and/or a set of data/index integrated/summarized by the remote engine as the patient would then be able to review such data from their own mobile device. A POSITA would understand that it would also be beneficial for the patient to be able to review information relating to their medical treatment so that the patient themselves is able to see first-hand how they are responding to the treatment and would therefore encourage the patient to comply with the prescribed treatment as seeing positive results would encourage more usage.

264. Moreover, given that the remote engine may store the analysis of the data/index (e.g., those analyzed by the doctor), a POSITA would have found it beneficial to configure the remote engine to transmit those data/index, in whole (e.g., data/index stored from prior treatment(s)) or in part (e.g., analysis of the data/index provided by the doctor), to the first radio frequency wireless transceiver on the cell phone to allow the patient to review those information. In some instances, a doctor may want to provide the patient with all of the data for full transparency, or support

for their conclusions, while in other instances, it may be more efficient to only transmit the most relevant data or summary of data to prevent overwhelming the patient or obscuring the most important information. The ability to alter the amount of data transmitted not only allows for better communication between the patient and the medical care provider, but can also provide for better performance for the system by allowing only the pertinent data to be sent and not clogging up the transmission bandwidth with less relevant data.

265. A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described feature as it would have would have been a routine and conventional implementation of known methods using known hardware components performing their known functions. This is well within a POSITA's skills and ability to accomplish.

266. Given that Claim 10 recites "and/or" when describing the information to be retransmitted, claim 10 requires one of "the data of the severity of the symptoms of the subject," "the index," "a second index" **or** "the data of usage related to the subject's treatment and the treatment's efficacy," in whole or part, calculated by the PAP device to be retransmitted. To the extent that the claim is read to require all of the above-listed information, it was well within the skill of a POSITA to implement the features discussed in claim 1 to transmit a "second" index, e.g., an

index associated with another treatment that is different from the treatment used for calculating “the [first] index.”

267. Accordingly, Truitt in view of Kumar discloses and/or suggests this limitation

8. **Claim 15. The system of claim 14, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.**

268. It is my opinion that Truitt alone or in view of the knowledge of a POSITA discloses this limitation.

269. Truitt’s PAP system 50 includes a pressure generator 12 in the form of a blower assembly 52 driven by a motor 54, providing a gas flow (as indicated by arrow B) to patient circuit 14 for delivery to a patient through a mask or other delivery device. Ex. 1007, 5:1-3; *see also id.*, 5:4-35. Similar to what I discussed above with respect to PAP system 10, the pressure signal output by pressure sensor 22 of PAP system 50 is provided to controller 38 for “controlling the operation of the pressure support system, monitoring the operation of the system, or monitoring the patient, for example.” *Id.*, 6:1-10. Controller 38 in turn controls the blower assembly 52 and/or valve 40 of PAP system 50 and may maintain the current flow/pressure if the desired result is being achieved, or alternatively may increase or decrease the

flow/pressure of the gas delivered to the patient if such a change is desirable for the patient's treatment. *Id.*, 5:36-59.

270. A POSITA would therefore understand that Truitt discloses that the controller 38 is configured to control the gas flow provided by pressure generator 12 (“blower”) based on the conditions of the patient in order to “counteract or prevent” these conditions. Ex. 1007, 2:57-3:11. A POSITA would have understood that the process of counteracting or preventing the patient's conditions require the PAP device operation to adapt and/or predict the patient's condition. For example, to counteract an obstructed airway, the air flow/pressure of the blower would have to be increased adaptively. In order to prevent an obstructed airway, the air flow/pressure of the blower would have to be predictively increased prior to the condition occurs.

271. As discussed above for Ground 1 claim 4, a POSITA would have been motivated and found it obvious to implement processes performed by the PAP device in a software stored on certain memory and executed by controller 38 in view of Kumar's teaching. A POSITA would have recognized that one or a combination of (1) the software implementing the above-described adapting and/or predicting method(s) and (2) the hardware (e.g., controller 38 and associated sensor) performing the method(s) constitutes the claimed “extended horizon, adaptive, predictive controller.” Ex. 1013, 1:18-22.

272. Accordingly, Truitt alone or in view of the knowledge of a POSITA discloses and/or suggests this limitation.

9. **Claim 18. The system of claim 1, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.**

273. It is my opinion that Truitt in view of Kumar discloses this limitation for the same reasons discussed for Ground 1 claim 15.

10. **Claim 19. The system of claim 1, wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.**

274. It is my opinion that Truitt in view of Kumar discloses this limitation. Kumar discloses that the engine (“remote internet site”) is hosted on central server 106 (“a remote communication system”), which includes a network I/O processor (“a third processor”) that runs the engine. Ex. 1008, [0067], [0082] (“The network I/O processor running the engine preferably forms the core of the real time data streaming portion of the engine”). Kumar explains that the network I/O processor “is responsible for streaming device data, audio, video, messages, and remote control information between multiple clients and hosts. The processor may also handle data

storage and retrieval of the streamed data.” *Id.*, [0082]. Thus, Kumar discloses its network I/O processor (“a third processor”) is “for reprocessing and/or outputting data.”

275. Kumar further discloses that “wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.” For example, Kumar “may allow for simultaneous storage, retrieval, *print*, analysis, and play back from anywhere in the world with access to the storage device” of the central server, where “a statistical summary report” may be provided. Ex. 1008, [0083], [0092] (“the healthcare provider can view a statistical summary report 600, shown in Fig. 6, and that includes a field for adding clinical notes”).

276. Additionally, consistent with as shown in Figure 1 of Kumar, the provider-side device includes a graphical display for outputting received data. Ex. 1008, [0067] (“The system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider.”), [0074] (“customized graphical user interfaces (GUIs) for the various devices”; “These teachings can also apply to the provider-side device.”) Moreover, Kumar explains that “[b]y receiving data from the patient-side device, a provider is able to monitor the patient/client’s physiology for research,

keeping track of documentation, performing analysis, managing and maintaining records, diagnosing the patient/client, providing treatment in real-time to the patient/client, etc.” Ex. 1008, [0014]. Thus, Kumar discloses “wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy”

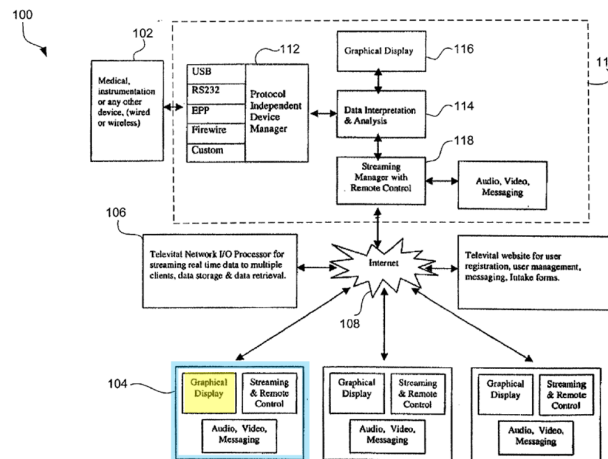


Fig. 1A

277.

278. Accordingly, it is my opinion that Truitt in view of Kumar discloses and/or suggests this limitation.

XI. OPINIONS ON GROUND 2: TRUITT IN VIEW OF KUMAR AND DONG RENDERS OBVIOUS CLAIMS 15, 16, AND 18

A. A POSITA Would Have Been Motivated to Combine

279. In my opinion a POSITA would have been motivated to modify the Truitt-Kumar combination to incorporate the controller teachings of Dong. A POSITA would have understood that by incorporating Dong’s teachings the

performance of the Truitt-Kumar PAP controller could be improved. Dong's controller addresses two potential limitations with existing adaptive controllers: "(1) computational complexity, which limits their feasibility in multivariable applications; and (2) sensitivity to the choice of input-output delays and model order selection." Ex. 1014, 1:38-42. Dong describes that its "invention is particularly applicable to real time automatic control systems and apparatus and more specifically to a class of adaptive controllers utilizing dynamic system prediction techniques." Ex. 1014 at 1:9-12. A POSITA would understand that a real time controller like Dong's would be particularly well suited to process and identify respiratory patterns that are dependent on the patient, and are more accurate if determined in real-time.

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

280. A POSITA would have had a reasonable expectation of success in modifying the Truitt-Kumar to incorporate the teachings of the Dong controller. Specifically, a POSITA would have modified the Truitt-Kumar system to incorporate the Dong controller.

281. Like Truitt, which discloses a controller determining a PAP device's operation based on input from sensors, Dong discloses a controller determining a system's operation (e.g., operations of actuators) based on multiple inputs (e.g., input from sensors). Ex. 1014, Abstract, Fig. 15 (disclosing an exemplary

embodiment including sensors providing input signals and actuators receiving output signals), 19:5-20:56 (discussions associated with the exemplary embodiment relating to Figure 15).

282. Neither Truitt nor Kumar specifies any particular type of controller, therefore, the Dong controller would have just been one of a limited number of design choices that a POSITA would have needed to select to implement the system.

C. Dependent Claims

- 1. Claim 15. The system of claim 14, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.**

283. In my opinion Truitt in view of Kumar and Dong discloses this limitation. As discussed for claim 15 in Ground 1, the Truitt-Kumar combination discloses claim 15. To the extent that the Truitt-Kumar combination does not disclose claim 15, it is my opinion that a POSITA would have found it obvious to implement the features recited therein in view of Dong.

284. Like Truitt, which discloses a controller determining a PAP device's operation based on input from sensors. Ex. 1014, Abstract, Fig. 15 (disclosing an exemplary embodiment including sensors providing input signals and actuators receiving output signals), 19:5-20:56 (discussions associated with the exemplary embodiment relating to Figure 15).

285. , Dong also discloses a controller determining a system's operation (e.g., operations of actuators) based on multiple inputs (e.g., input from sensors). Ex. 1014, Abstract (“A hardware implementation of the subject extended horizon predictive control system includes a computing means, memory means, and dynamic system input and output signal processing means.”), Fig. 15 (disclosing an exemplary embodiment including sensors providing input signals and actuators receiving output signals), 19:5-20:56 (discussions associated with the exemplary embodiment relating to Figure 15).

286. Dong additionally discloses that the controller is a “extended horizon adaptive block predictive controller” that includes a block control system and an adaptive block prediction system. Ex. 1014, Abstract. The system performs “a block of k output predictions, consisting of output predictions at each future time step up to the prediction horizon k, for dynamic systems with N outputs, M inputs and model parameter order n,” where “[t]he prediction system is organized for performing the calculation of a k-step ahead predictor in a highly computationally and memory efficient manner.” *Id.*

287. Figure 1 of Dong discloses an “overall structure of extended horizon adaptive block predictive controller with an efficient prediction system,” where the “[a]daptive Block Predictive Controller 8 resides within a computational engine.” Ex. 1014, 8:14-16; *see also id.*, 7:60-8:53.

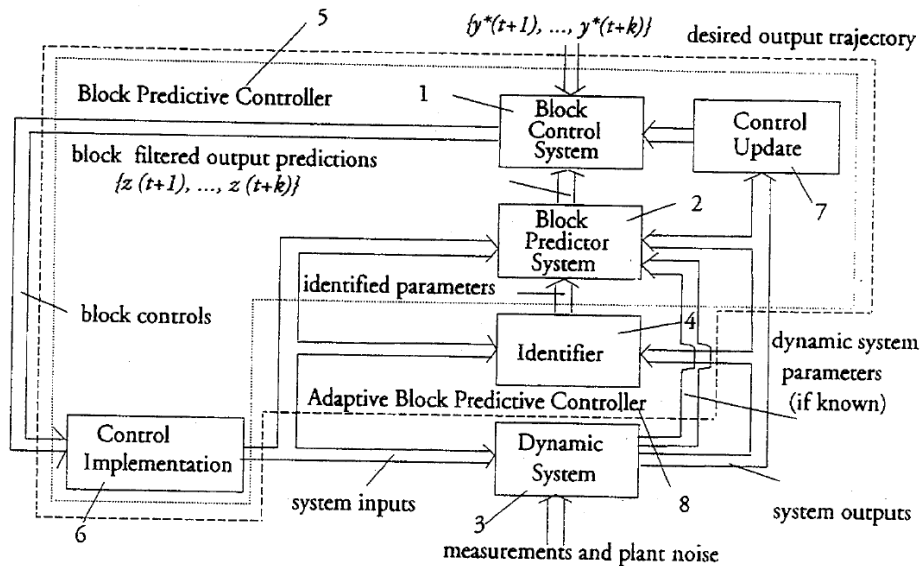


FIG. 1

Ex. 1014, Fig. 1

288. A POSITA would have been motivated and found it obvious to include in the Truitt-Kumar combination an extended horizon adaptive block predictive controller, similar to that of Dong. As Dong explained, because a “dynamic system has an input-output delay, predictive controllers are used to account for such a delay. Ex. 1014, 1:49-54. “[P]redictive controllers that consider time horizons beyond the system input-output delay (extended horizon predictive controllers) have been used in engineering applications,” for example, to maintain “the system input-output stability.” *Id.*, 1:54-68.

289. Moreover, Dong’s controller/system “avoids computation of a large number of the predictor parameters associated with the prior art...method, so that

memory requirements and computational complexity are significantly reduced.” *Id.*, Abstract; *see also id.*, 6:42-46 (“The subject invention contemplates a new and improved prediction system for multivariable dynamic system output prediction. The subject invention reduces run time and memory requirements.”) Accordingly, a POSITA would have been motivated to implement such a controller in the Truitt-Kumar combination to control the PAP device without requiring significant memory resource or computational complexity while achieving system stability. This is particularly true given that Truitt or Kumar does not expressly disclose in detail its control system and thus a POSITA implementing the Truitt-Kumar combination would have been motivated to implement an efficient controller, similar to that of Dong.

290. A POSITA would have had the skill and a reasonable expectation of success in implementing features similar to those disclosed in Dong in the Truitt-Kumar combination. Dong explains that “[t]here are many computational engines which can work in conjunction with the extended horizon adaptive block predictive controller with efficient prediction system,” such as microcontrollers/microprocessors, which the Truitt-Kumar combination already uses to control the PAP device. Ex. 1014, 19:5-9. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that includes sensors to monitor physiological information of a patient and a controller/processor to

control the PAP operation based on the physiological information (Truitt-Kumar combination)) according to known methods (e.g., known methods of using an extended horizon adaptive block predictive controller capable of controlling a dynamic system associated with multiple input and output (Dong)) to yield the predictable result of a system including a PAP device with an improved control without requiring significant memory resource or computational complexity while achieving system stability, as discussed above. Accordingly, Truitt in view of Kumar and Wright discloses this limitation.

2. **Claim 16. The system of claim 15, wherein the remote internet site is hosted on a remote communication system with a third processor for reprocessing and/or outputting data received from the first or second radio frequency wireless transceiver in whole or part, wherein the remote internet site is configured to output to a printer in a report form or to a second display the reprocessed and/or outputted data, for review by a clinician to determine the treatment efficacy.**

291. Truitt in view of Kumar discloses this limitation for the same reasons discussed in Ground 1 claim 19. The modification of the Truitt-Kumar combination in view of Dong does not materially affect the combination's disclosure of claim 19 as discussed in Ground 1 because it only impacts the controller choice of Truitt.

3. **Claim 18. The system of claim 1, wherein the PAP device further comprises an extended horizon, adaptive, predictive controller to adjust the flow of the blower based in part on**

**the data of the severity of the symptoms of the subject
calculated by the second processor.**

292. Truitt in view of Kumar and Dong discloses this limitation for the same reasons discussed in Ground 2 claim 15 above.

**XII. OPINIONS ON GROUND 3: TRUITT IN VIEW OF KUMAR AND
WRIGHT RENDERS OBVIOUS CLAIMS 17 AND 20**

A. A POSITA Would Have Been Motivated to Combine

293. In my A POSITA would have been motivated to modify the Truitt-Kumar combination to incorporate the teachings of Wright to distinguish and calculate the severity of both obstructive apnea and central apnea. A POSITA would have understood that the teachings of Wright would have advanced the purpose of Truitt “to provide a positive pressure therapy in which the pressure of gas delivered to the patient varies with the patient’s breathing cycle, or varies with the patient’s effort to increase the comfort of the patient.” Ex. 1007, 1:30-34.

294. Positive pressure does not effectively treat central apnea, as this sleep disorder is not caused by the collapse of the upper airway, but rather is due to dysfunction within the control (drive) of breathing. Consequently, treatment of these sleep disorders are not the same. For central apnea, a physician may prescribe medications to stimulate breathing, or treat other underlying conditions that may be causing the central apnea, such as heart failure.

295. Although positive airway pressure can be used to treat both obstructive apnea and central apnea, the prescribed treatments are also different. For example, while continuous positive pressure is more commonly used for obstructive apnea, bi-level positive airway pressure (providing increased pressure at inhalation and decreased pressure at exhalation) is more commonly used for central apnea. Thus, increasing positive pressure is more generally used to improve efficacy of treatment in obstructive apnea, but not central apnea.

296. A POSITA would have been motivated to distinguish obstructive apnea and central apnea to improve the efficacy of the treatment and increase comfort. In particular, increasing pressure may improve efficacy of treatment for obstructive apnea, but that same increase in pressure may not improve efficacy of treatment for central apnea and instead unnecessarily increase discomfort.

297. A POSITA would have also been motivated to calculate the level of severity for both obstructive apnea and central apnea. Physicians are always motivated to obtain more data. The level of severity of the obstructive apnea will impact whether the pressure therapy should be increased or decreased. The level of severity of the central apnea will impact whether the physician may decide that medication or an implanted device may be more effective in treating the central apnea.

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

298. A POSITA would have had a reasonable expectation of success in modifying the Truitt-Kumar to incorporate the teachings of Wright. Truitt and Wright are analogous art as both references describe CPAP systems that include flow sensors and processors. Further, like Truitt, Wright discloses that the processor analyzes the signals from the flow sensors of the CPAP device. The proposed modification of the Truitt-Kumar CPAP would only involve a simple change in a programming. The modification is merely a combination of known prior art elements according to known methods and known techniques (programming a processor based on signals from flow sensors) to yield predictable results (provide signals that increase or decrease the gas pressure). Nothing in Kumar would have prevented the implementation of this modification.

C. Dependent Claims

- 1. Claim 17. The system in claim 16, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.**

299. It is my opinion that Truitt in view of Kumar and Wright discloses this limitation. As discussed for Grounds 1 limitation [1.a] above, a POSITA would have been motivated to combine Truitt and Kumar. To the extent that the Truitt-Kumar

combination does not disclose claim 17, it is my opinion that a POSITA would have found it obvious to implement the features recited therein in view of Wright.

300. Like Truitt, Wright discloses uses of a CPAP device to assess and treat a patient's sleep apnea. Ex. 1013, Abstract. Figure 1 of Wright discloses a traditional CPAP device like that of Truitt, that includes a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, air delivery conduit 8. Ex. 1013, [0029]. Wright's CPAP device includes a "communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communications with other devices or computers such as hand-held display and control devices 12." *Id.*, [0029]-[0030].

301. Moreover, Wright explains that the apparatus can for example, "interface with a variety of hand-held devices such as a Palm Pilot via wireless communication" and that "[w]ith such a device, a physician may, for example, remotely monitor, analyze or record the status or data history of a patient or diagnose the patient's condition using the device." *Id.*, [0030]. Therefore, a POSITA would have been motivated to consider the teachings of Wright when implementing the method/system disclosed by Truitt and/or the Truitt-Kumar combination.

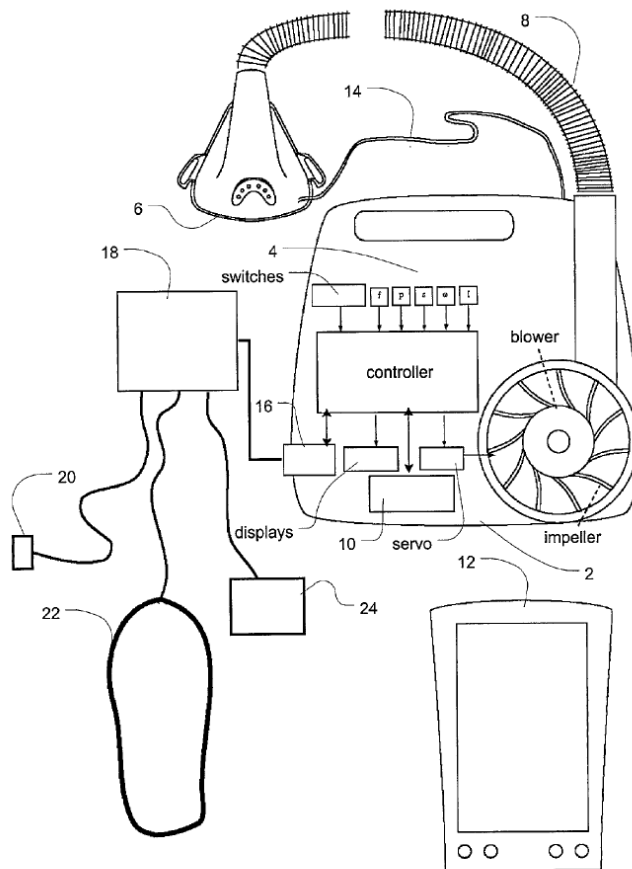


Fig. 1

302. Moreover, and similar to the Truitt, and Truitt-Kumar systems discussed above, Wright explains that “[w]ith such a device, a physician may, for example, remotely monitor, analyze or record the status or data history of a patient or diagnose the patient's condition using the device.” *Id.*, [0030]. Therefore, a POSITA would have been motivated to consider the teachings of Wright when implementing the method/system disclosed by Truitt and/or the Truitt-Kumar combination.

303. In addition to the treatment of apneas, Wright discloses CPAP devices can be used for “for assessing the condition of and treating patients for stroke.” Ex. 1013, Abstract. Wright discloses that by “determining central and obstructive apnea occurrences or the percentile of pressure delivered to the patient from patient airflow, stroke indicators may be calculated and analyzed to provide information on the type of stroke a patient has suffered and the degree of a patient's neuro-recovery.” *Id.* Wright goes on to state that its “apparatus may be programmed with a particular protocol intended to identify between alternative forms of CPAP treatment appropriate for the patient based upon an assessment of the patient's condition.” *Id.*

304. Wright explains that “CPAP devices can detect the presence of apneas, **distinguish between central and obstructive apneas** and provide an increased pressure if needed to stabilize an obstructed or partially obstructed airway.” Ex. 1013, [0027](emphasis added). In particular, Wright discloses that the CPAP device “has two treatment modes, a first mode for treating obstructive apneas and a second mode for treating central apneas,” where “[i]n the first mode, the device provides a generally constant pressure throughout a breathing cycle, but may vary the pressure in accordance with indications of partial or complete obstruction of the airway.” *Id.*, [0031]. In the second mode, “the apparatus provides a higher pressure to the mask during the inspiratory portion of the breathing cycle, the so-called IPAP, and a lower pressure to the mask during the expiratory portion of the breathing cycle, the so-

called EPAP. This may be accomplished by monitoring the respiratory flow to the patient and defining a threshold level.” *Id.*, [0032]. Wright explains that the CPAP device “may be used to monitor patient health characteristics including, for example, oral and/or nasal airflow, snore, abdominal movement, chest wall movement, oximetry, pulse rate, body position and flattening index via the diagnosis unit and sensors in the blower.” *Id.*, [0034].

305. A POSITA would understand that the CPAP device in Wright may **generate indices** “determined from an analysis of the patient’s health characteristics useful for assessing appropriate treatment or diagnosing the condition of the patient,” and “[s]uch indices serve as stroke indicators to indicate patient improvement or stroke type...” Ex. 1013, [0035]. “When the patient is being treated with CPAP, the device continuously **monitors whether the patient is having an apnea and if so, whether the apnea is central or obstructive.**” *Id.*, [0036]. “The apparatus **determines an index** from a comparison of **the number of central and obstructive apneas** or a function of the ratio of the number of central to obstructive apneas during a particular time period.” *Id.*; *see also id.*, [0037]-[0038] (methods for distinguishing between central and obstructive apneas).

306. A POSITA would understand that, as Wright discloses, the index may serve as “an indication of the degree of neuro-recovery for a stroke patient” because the stroke may damage portions of the brain that “participate in respiratory drive,

causing a relatively high incidence of central apneas compared to obstructive apneas.” *Id.*, [0039]. Additionally Wright discloses that one can “distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.” *Id.*, [0027]. Wright can further “monitor[] whether the patient is having an apnea and if so, whether the apnea is central or obstructive” when the patient is being treated with PAP. *Id.*, [0036]. Wright further discloses that the treatment of obstructive apnea is adjusted “in accordance with indications of partial or complete obstruction of the airway.” *Id.*, [0027].

307. Additionally, Wright describes that its system “determines an index from a comparison of the number of central and obstructive apneas.” *Id.*, [0036]. A POSITA would have understood that this index involves separately determining the number of occurrences of central apnea and obstructive apnea, which indicate “the severity of both obstructive apneas and central apneas of the subject during a treatment.” This opinion is further supported by claims 2 and 3 of Wright which respectively recite “analyzing said airflow to determine an occurrence of central apnea” and “analyzing said airflow to determine an occurrence of obstructive apnea”). Accordingly, it is my opinion that Wright discloses any elements of claim 17 that may be missing from Truitt or the Truitt-Kumar combination.

308. It is my opinion that a POSITA would have been motivated to combine, and found it obvious to implement, the above-discussed features disclosed in Wright in the Truitt-Kumar combination. For example, Wright explains that “it has become recognized that **stroke patients may benefit from treatment with CPAP**” (Ex. 1013, [0016]), including improved “rate and degree of recovery of vital signs and patient stabilization in the acute phase” (*id.*, [0026]). In fact, Wright explains that “[t]he advantages of the use of CPAP in assisting stroke rehabilitation are greater than that provided by oxygenation per se.” *Id.*, [0027]. Additionally, Wright discloses that the index, calculated based on the number of central and obstructive apneas, as discussed above, “may serve as an indication of the degree of neuro-recovery for a stroke patient.” *Id.*, [0039]. For example, such an “index” may be used in “determin[ing] the type of stroke which the patient has suffered,” “assessing the location of the stroke, and in determining the appropriate form of therapy.” *Id.*, [0040]; *see also id.*, [0041]-[0042] (disclosing that the index may be used to determine “the dosage of pharmacological agents given to the patient” and “CPAP-device management strategy.”). Accordingly, a POSITA would have been motivated to and found it obvious to configure the processor of a PAP device, e.g., the controller of the PAP device in Truitt or the Truitt-Kumar combination, such that it perform the above-discussed features/processes (disclosed with respect to Wright).

309. A POSITA would have had the skill and a reasonable expectation of success in implementing features (discussed above) similar to those disclosed in Wright in the Truitt-Kumar combination. For example, the Truitt-Kumar combination discloses a PAP device similar to that of Wright, both containing a PAP device having a controller and sensors to measure physiological information of a patient, where the PAP device is connected to a computing device via a wireless protocol. *See* Ex. 1013, Fig. 1 above and Ground 3 claim 1. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that includes a processor and sensors to monitor physiological information of a patient (Truitt-Kumar combination)) according to known methods (e.g., known methods of calculating an index based on a comparison of the number of central and obstructive apneas (Wright)) to yield the predictable result of a system including a PAP device with additional functionality, including assessing and treating stroke, as discussed above. Accordingly, Truitt in view of Kumar and Wright discloses this limitation.

2. Claim 20. The system in claim 1, wherein the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject during a treatment with the PAP device.

310. Truitt in view of Kumar and Wright discloses claim 20 for the same reasons discussed for claim 17. *See* Section XII.C.1 (Ground 3, Claim 17).

XIII. OPINIONS ON GROUNDS 4-6

Ground 4: Truitt in view of Kumar and Mumford Renders Obvious Claims 1-3, 6, 12-15, 18-19

Ground 5: Truitt in view of Kumar, Dong, and Mumford Renders Obvious Claims 15, 16, 18

Ground 6: Truitt in view of Kumar, Wright, and Mumford Renders Obvious Claims 17, 20

A. A POSITA Would Have Been Motivated to Combine

311. In my opinion a POSITA would have been motivated to modify the Truitt PAP device to incorporate the sleep efficacy algorithm of Mumford. **First**, combining Truitt's PAP device with the sleep efficacy algorithm of Mumford would have advanced Truitt's stated objective of providing "a positive pressure therapy in which the pressure provided to the patient changes based on the detected conditions of the patient, such as whether the patient is snoring or experiencing an apnea, hypopnea or upper airway resistance." Ex. 1007, 1:35-39. A POSITA would have understood that Mumford's algorithm's ability to evaluate both compliance and efficacy would allow for a better determination as to a patient's treatment protocol. Mumford's algorithm would take into account a lack of compliance (e.g., not wearing the CPAP device for the appropriate period of time) as well as the severity of the patient's symptoms to determine whether or not the pressure setting should be updated. If the severity of symptoms was linked to a lack of compliance and not a

lack of effectiveness of the prescribed pressure, a POSITA would understand that increasing the pressure would likely not benefit the patient as it would likely just increase discomfort and lead to more non-compliance. In contrast, if the data shows full compliance with the treatment protocol, and the severity of symptoms did not decrease, then a POSITA would understand that the pressure of the CPAP should be increased.

312. In other words, Mumford's ability to "determine the efficacy of the CPAP treatment" and "vary operation parameters of the treatment," based on the efficacy determined by Mumford's algorithm would have improved the performance of the Truitt PAP device by increasing the pressure when obstructions were still occurring and the patient was satisfying their treatment protocols. Ex. 1009, Abstract. Further, utilizing Dong's predictive controller would avoid the computational complexity and memory requirements of the prior art, and "reduce the run time and memory requirements." Ex. 1014, 6:42-46. The reduced runtime and memory requirements would have motivated a POSITA to combine the predictive controller of Dong into the Truitt-Kumar PAP device.

313. **Second**, it would have advanced the purpose of Truitt "to provide a positive pressure therapy in which the pressure of gas delivered to the patient varies with the patient's breathing cycle, or varies with the patient's effort to increase the comfort of the patient." Ex. 1007, 1:30-34. A major limitation of CPAP therapy was

non-compliance due to discomfort. Ex. 1016, 5. A POSITA would have understood that by combining Truitt's PAP device with the sleep efficacy algorithm of Mumford, to the pressure applied to the patient may be minimized which would increase comfort, and therefore improve compliance.

314. Nothing in Kumar, Dong, or Wright would have taught away from this modification. In fact, far from teaching away, one of Kumar's big selling points, was its plug and play nature. Kumar touts that "[e]xisting devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI. Thus, *virtually any device* may be easily incorporated into the system." Ex. 1008, ¶ [0018]. And none of Truitt, Kumar, or Wright expressly disclose the details of their respective control systems. Therefore a POSITA would have been motivated to implement the Truitt-Kumar-Mumford PAP device with Dong's predictive controller. Additionally, a POSITA would have been motivated to implement the Truitt-Kumar-Mumford PAP device with Wrights index.

315. Therefore, a POSITA would have been motivated to modify the Truitt PAP device as described above.

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

316. In my opinion a POSITA would have had a reasonable expectation of success in modifying the Truitt combinations with the teachings of Mumford. First, Truitt and Mumford are analogous art as both references describe PAP systems that

include flow sensors and processors as well as sensors for measuring physiological signals of the patient and “to determine the efficacy of the PAP treatment and to vary operational parameters of the PAP device.” Ex. 1009, Abstract.

317. As Mumford explains, the “sleep efficacy algorithm 36 may use standard techniques, as is commonly known to those skilled in the art, to process the physiological signals, determine the quality of sleep and generate the control signal.” *Id.*, 7:51-54. Truitt discloses a flow sensing assembly “for measuring the gas flow and/or gas volume passing through the pressure support system.” Ex. 1007, Abstract. It was well within the skill of a POSITA to use this data for the sleep efficacy algorithm. Sleep stages, arousals, and sleep fragmentation can all be detected by analyzing the breathing patterns indicative of these conditions. *See, e.g.*, Ex. 1021, 8 (“changes in magnitude and frequency of respiratory inputs also contribute to the observed breathing patterns, especially the variable breathing of REM sleep”); Ex. 1020, 1:66-2:1 (“Various techniques are known for sensing and detecting abnormal breathing patterns indicative of obstructed breathing.”).

318. **Second**, the proposed modification involves a simple change in a programming algorithm. The modification involves nothing more than a combination of known prior art elements according to known methods and known techniques (programming a processor based on signals from flow sensors) to yield predictable results (provide signals that increase or decrease the gas pressure).

319. Nothing in Kumar, Dong, or Wright would have prevented the implementation of this modification. As mentioned above, neither Truitt, Kumar, or Wright expressly disclose the details of their respective control systems, meaning that a POSITA would have been motivated to implement the Truitt-Kumar PAP device with the efficient predictive controller of Dong. Additionally, a POSITA would have been motivated to implement the Truitt-Kumar-Mumford PAP device with Wrights index.

C. Challenged Claims

320. As I discussed above, Truitt in view of Kumar renders obvious each and every limitation of claims 1-3, 6, 12, 14-15, and 18-19 (*see* Section X), Truitt in view of Kumar and Dong renders obvious each and every limitation of claims 15-16, 18 (*see* Section XI), and Truitt in view of Kumar and Wright renders obvious each and every limitation of claims 17 and 20 (*see* Section XII).

321. As I discussed above, Truitt discloses “data of usage of the PAP device by the subject,” “data of severity of sleep disorder symptoms of the subject,” and/or “the index of treatment efficacy of the subject using a PAP device” that is “based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” Even if Truitt does not disclose these limitations, Mumford discloses these features through its teachings on the implementation of its sleep efficacy algorithm. It is my opinion that it would have been obvious to

implement these features in the combinations discussed in Grounds 1-3 further in light of Mumford.

322. Like Truitt, Mumford discloses treatment systems for obstructive sleep apnea using a PAP device that includes sensors for measuring physiological signals of the wearer. Ex. 1009, Abstract. Specifically, Mumford discloses “integrated sensors for sensing the efficacy of treatment of medical conditions, such as obstructive sleep apnea during treatment with continuous positive airway pressure.” *Id.*, 2:66-3:2; *see also* 1:20-22.

323. Mumford explains that “physiological signals are used to determine the efficacy of the PAP treatment” and “to vary operational parameters of the PAP device.” *Id.*, Abstract. The system includes a “remote processing unit [that] include[s] a sleep efficacy algorithm for processing the physiological information and generating a sleep information profile for the wearer.” *Id.*, 4:37-41; *see also* 7:34-37 (“The physiological information provided by the sensors is preprocessed by the monitoring unit 16 to improve signal quality and then processed according to a sleep efficacy algorithm 36.”).

324. Figure 1 of Mumford (shown below) discloses a CPAP system 10 that includes mask assembly 12 and CPAP device 14 having monitoring unit 16 therein for use by a CPAP device wearer 18. Ex. 1009, 6:63-7:14.

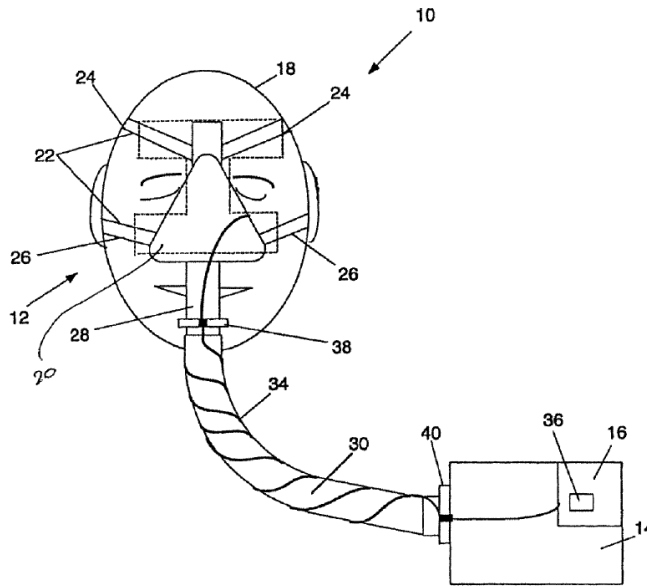


Figure 1

325. Mumford discloses that the mask assembly 12 further includes sensors for detecting physiological information of CPAP wearer 18. *Id.*, 12:42-47 (pressure sensor used to detect the pressure within the cavity of the mask from which the breathing rate of the wearer can be derived), 7:15-33, 12:22-41, 12:48-61.

326. Mumford discloses that its “sleep efficacy algorithm 36 monitors the quality of sleep for the wearer 18” which can be used to analyze various aspects of the patient’s sleep. Ex. 1009, 7:34-57. For example, Mumford describes that it can 1) determining how long the wearer is in a given sleep state, 2) how many different sleep states the wearer has experienced during sleep, 3) the fragmentation of the wearer’s sleep states, and 4) how many arousals the wearer 18 has experienced. Ex. 1009, 7:34-57.

327. Sleep is not a simple linear process, but instead “repeated episodes of non-REM and REM sleep alternate cyclically through the night.” Ex. 1022, 4. “[S]leep begins with ~80 min of non-REM sleep followed by a REM period of ~210 min. This 90-min non-REM-to-REM sleep cycle is then repeated about three to six times during the night.” *Id.* To have good quality of sleep, a patient must be in a given sleep state for a certain amount of time in order to move on to the next stage of sleep, and to repeat this cycle a number of times. This process can also be interrupted by sleep fragmentation and arousals.

328. Mumford goes on to describe that the “sleep efficacy control algorithm 36 can generate sleep profile information for the wearer 18 (the sleep profile information may include data, such as a test score, related to efficacy and compliance)” and that based on this the “sleep efficacy algorithm 36 further generates a control signal to control the operational parameters of the CPAP device.” Ex. 1009, 7:42-46. Mumford states that the “sleep efficacy algorithm 36 may use standard techniques, as is commonly known to those skilled in the art, to process the physiological signals, determine the quality of sleep and generate the control signal. The sleep efficacy algorithm 36 may identify sleep stages and generate the sleep profile information based on the physiological information sensed from the wearer 18.” *Id.*, 7:51-57.

329. Accordingly, it is my opinion that Mumford discloses the various features of claim 1 discussed above and identified below. **First**, Mumford discloses calculating “data of usage of the PAP device by the subject,” as recited in claim 1, because Mumford provides data on compliance. Mumford discloses that the sleep efficacy control algorithm can generate sleep profile information including a test score related to compliance. Ex. 1009, 7:42-46, 15:30-33. When a patient is not in compliance, the patient is not using the PAP device as prescribed. As a threshold to determining the efficacy of treatment, the physician must understand the degree to which the patient is complying with the prescribed therapy.

330. Truitt confirms that a POSITA would have understood that compliance is data of usage of the PAP device by the patient. Truitt explains that “The information from flow sensor 20 and/or pressure sensor 22 is used, for example, to ... monitor the usage of the pressure support device (patient compliance).” Ex. 1007, 2:5-10.

331. Thus, a POSITA would have understood that a test score related to compliance would refer to a measure of usage of the PAP therapy device, and thus, data related to compliance is “data of usage of the PAP device by the subject.”

332. **Second**, Mumford discloses calculating “data of severity of sleep disorder symptoms of the subject.” For example, Mumford discloses that the sleep efficacy algorithm 36 monitors “the fragmentation of their sleep states” and “how

many arousals the wearer 18 has experienced.” Ex. 1009, 7:34-42. Mumford explains that Obstructive Sleep Apnea (OSA) is “caused by a blockage of the airway typically resulting from the collapse and closure of the soft tissue in the rear of the throat during sleep” and “[w]ith each apnea event, *the brain arouses the individual in order for the individual to resume breathing, but consequently sleep is extremely fragmented and of poor quality.*” *Id.*, 1:27-35; *see also id.*, 1:36-45 (“the disrupted and/or poor quality sleep that is associated with OSA may lead to serious health issues including hypertension, heart disease, diabetes, and stroke”), 1:46-55 (“When an individual is diagnosed with OSA, the individual may be prescribed a therapeutic regime involving the use of a Continuous Positive Airway Pressure (CPAP) device. The CPAP device works by delivering a steady flow of air through a soft, pliable mask worn over the individual's nose. The CPAP device essentially pressurizes the throat of the individual thereby preventing the collapse of the soft tissue and keeping the airways open and allowing the individual to breathe uninterrupted during sleep”), 2:4-12 (“Arousals due to upper airway resistance may be detected from a shift in frequency of the patient’s EEG and/or EOG as well as a decrease in blood oxygen levels. The monitoring unit includes an algorithm that detects the arousals and sleep stages....”).

333. The more sleep fragmentation and arousals, the more severe the sleep disorder symptoms. This quality of sleep was often indicated by different scores or

indices (a number representing a property or properties). For example, in a system developed in the mid-1990s, data related to severity could be represented as an apnea index (events/hr), time in apnea (percent of night), slow wave sleep (percent of night), REM sleep (percent of night), arousal index (events/hr), or respiratory arousals. Ex. 1020, 17:55-60. This allowed the system to employ “progressive use of pre-obstructive and obstructive indications to trigger CPAP treatment pressure increases of magnitude and duration appropriate for the severity of the event.” *Id.*, 16:28-32. A POSITA would have understood that the quality of sleep, as indicated by sleep fragmentation and arousals, is “data of severity of sleep disorder symptoms of the subject.”

334. **Third**, Mumford discloses that “the index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject” as a test score of efficacy. For example, Mumford discloses a test score of efficacy (“index [of treatment efficacy of the subject using a PAP device is]”) is generated by sleep efficacy control algorithm 36 based on (1) “the fragmentation of their sleep states” and “how many arousals the wearer 18 has experienced” (either of which being “data of severity of sleep disorder symptoms of the subject”) and (2) compliance. Ex. 1009, 7:34-46. Sleep fragmentation and “[a]rousals are important for determining the quality of sleep and the efficacy of therapy.” *Id.*, 11:44-47. A

person of ordinary skill in the art would have understood that by comparing the severity of the symptoms (the degree to which the patient is experiencing a high number of arousals and fragmentations) compared to the degree of compliance (the degree by which the patient is following the prescribed therapy), an index of efficacy of treatment can be determined.

335. Moreover, “[t]he sleep efficacy algorithm 36 further generates a control signal to control the operational parameters of the CPAP device 14 such as activating or deactivating the CPAP device 14 or altering the amount of pressure that is provided to the gas inlet 28 to improve the quality of sleep of the wearer 18.” Ex. 1009, 7:46-57. A person of ordinary skill in the art would have understood that to generate the control signal to alter the pressure, the score related to efficacy would need to meet a certain threshold.

336. A POSITA would have been motivated and found it obvious to implement Mumford’s teaching in the Truitt-based combinations discussed in Grounds 1-3. For example, as discussed above, Mumford teaches using sensors for detecting physiological information of CPAP wearer and controlling the operational parameters of the CPAP device. A POSITA would have understood that use of sensors, in addition to Truitt’s use of air flow/pressure sensor(s), would have improved the accuracy of the sleep disorder detection and provided improved treatments. Moreover, Mumford’s integrated sensor design would have increased

mobility and lessened discomfort, allow the wearer to enjoy a better quality of sleep when additional sensors are deployed. Mumford's sensor design enables real-time feedback on adverse factors or complications that could diminish therapeutic effectiveness, including issues like mask removal, improper mask fit, head position, and more.

337. A POSITA would have also had the skill and reasonable expectation of success in combining the teachings of Mumford and Truitt (including Truitt-based combinations). Mumford states that "[t]he sleep efficacy algorithm 36 may use standard techniques, as is *commonly known to those skilled in the art*." Ex. 1009, 7:51-54. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that already uses sensors to detect and treat sleep disorder (Truitt-based combinations)) according to known methods (e.g., known methods of using additional sensors integrated in a mask to gather physiological information (Mumford)) to yield the predictable result of a system including a PAP device of improved accuracy for detecting and treating sleep disorder, as discussed above.

338. Accordingly, for the reasons above, to the extent that Truitt is read not to disclose calculating "data of usage of the PAP device by the subject," "data of severity of sleep disorder symptoms of the subject," and/or "the index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the

subject,” it would have been obvious to modify Truitt and Truitt-based combinations to implement additional sensors to gather the associated physiological information to calculate the above-noted “data” and “index,” as claimed. Thus, the positions above (along with those in each respective ground above) demonstrate how the asserted prior art combinations in further view of Mumford disclose and/or suggest claims 1-3, 6, and 12-20.

339. Namely, a POSITA would have had the same motivations, capabilities, and expectations discussed above in Grounds 1-3 and knowledge of those discussed above regarding Mumford to modify each asserted combination to implement the above-discussed features. Therefore, for the same reasons discussed above and in the respective sections for Grounds 1-3, the prior art combination discloses and/or suggests claims 1-3, 6, and 12-20.

XIV. CONCLUSION

340. For all the reasons stated above, it is my opinion that the challenged claims of the '284 patent are unpatentable.

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,602,284

This declaration and my opinions are made to the best of my knowledge and understanding, and based on the material available to me at the time of signing this declaration. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Further, I am aware that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001. I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 15, 2024.

A handwritten signature in dark ink, appearing to read "Jason Kirkness", written over a horizontal line.

Jason Paul Kirkness Ph.D.