

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

Case IPR2025-00160

**DECLARATION OF JASON KIRKNESS, PH.D. IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,786,680**

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generated by the one or more PAP device(s) and then
received by the remote internet site.” 110

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Claim 8. “The system in claim 7, wherein the second radio frequency wireless transceiver of the one or more PAP device and the first software adapted to use the at least one first radio frequency wireless transceiver of the cell phone are further adapted to transmit PAP therapy efficacy data and/or a reprocessed data based in part on the PAP therapy efficacy data from the one or more PAP device(s) to the cell phone using a Bluetooth wireless protocol.” 112

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- Claim 12. “The system in claim 4, wherein the first software adapted to be executed by the first processor of the cell phone to receive, in whole or part, the PAP therapy efficacy data generated by the one or more PAP device and/or the modified therapy efficacy data based in part on the PAP therapy efficacy data that is first received at least in part from the PAP device by the remote internet site and then retransmitted to the first software from the remote internet site.” 115
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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. 11,375,680 relative to the state of the art at the time of the earliest application to which the ’680 patent claims priority. My analysis relates to claims 1-5, 7, 8, 10-13, 15-18, 20-31. 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 ’680 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 1-5, 7, 8, 10-13, 15-18, 20-31 of the ’680 patent are invalid based on the following grounds.

Ground 1	Toge in view of Burton and Kumar renders obvious claims 1-5, 7, 8, 10-13, 15-18, 20-31
Ground 2	Toge in view of Burton, Kumar, and Kisner renders obvious claims 10, 15, and 20

II. EXPERIENCE, QUALIFICATIONS, AND STATUS AS AN INDEPENDENT EXPERT

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 apnea hypopnea 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 '680 patent. I have no financial interest in CleveMed.

IV. UNDERSTANDING OF GOVERNING LAW

33. I understand 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 understand that a patent claim is unpatentable if it is obvious in view of the prior art. I further understand that the frame of reference for determining

whether a claim is obvious is from the perspective of a POSITA at the time of 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 have been informed that 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 a 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.

V. RELEVANT TIME PERIOD FOR THE OBVIOUSNESS ANALYSIS

41. I understand that the '680 patent originates from Patent Application 16/599,410 filed on October, 11, 2019, 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.

VI. 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, 1:14-15. As Toge, Kumar, and

Burton 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.

VII. 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 mid1990s, 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.

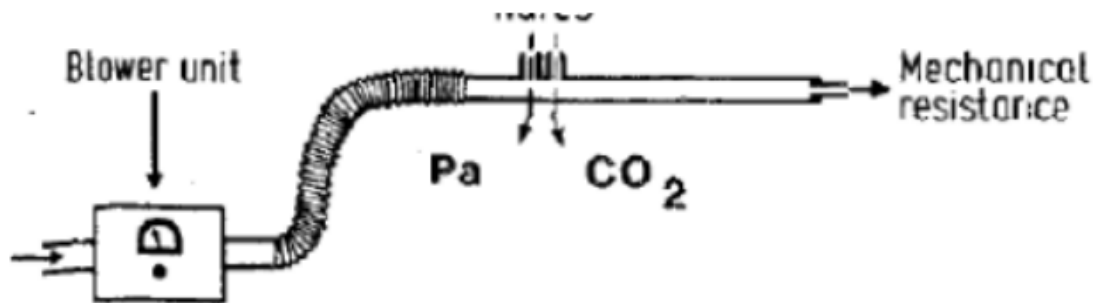
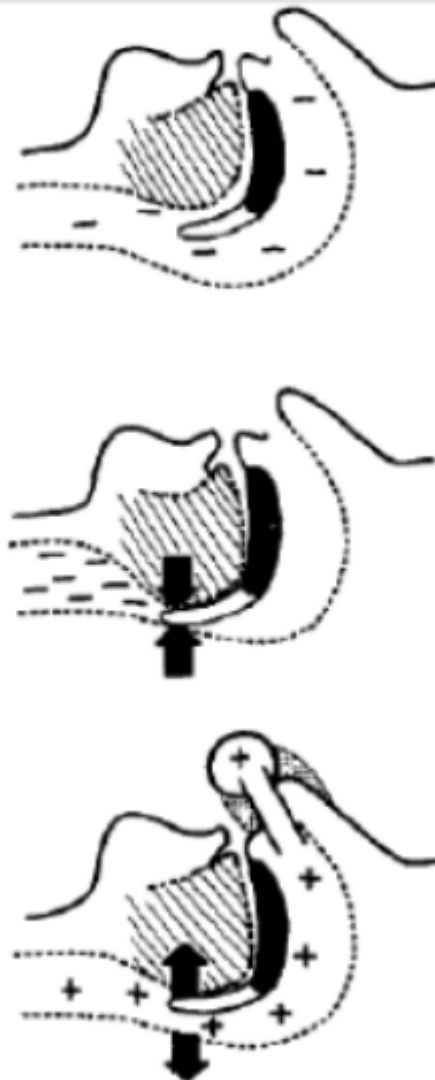


Fig. 2—Diagram of apparatus used to provide continuous positive airway pressure through the nares.

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).

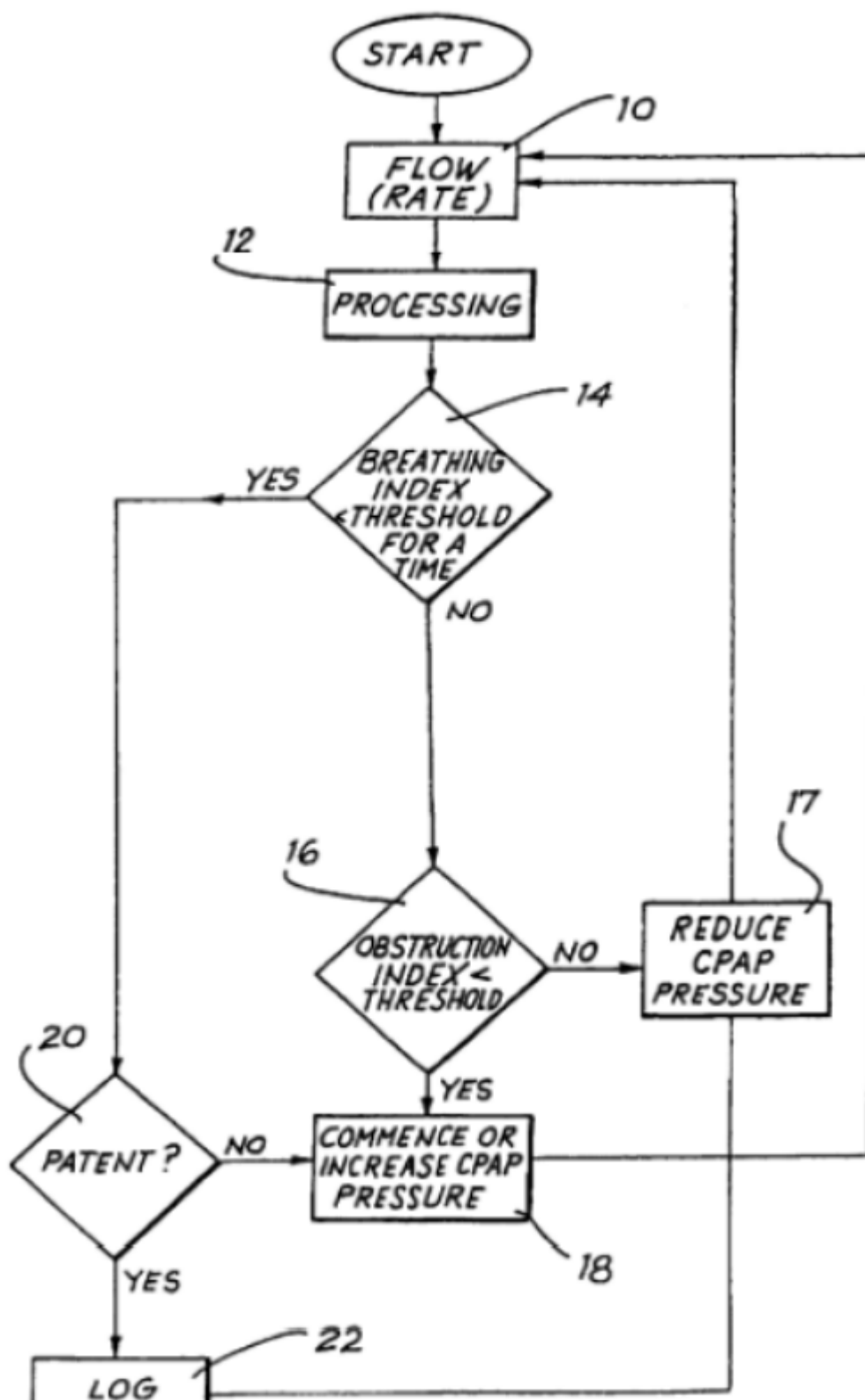


72. In their 1981 paper describing continuous PAP (“CPAP”), Dr. Sullivan, Dr. Berthon-Jones, and their colleagues described treating five OSA patients with CPAP therapy, applying low pressure levels (4.5-10 cm H₂O), which “completely prevented upper airway occlusion during sleep in each patient” and 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. BerthonJones 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 ’680 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).

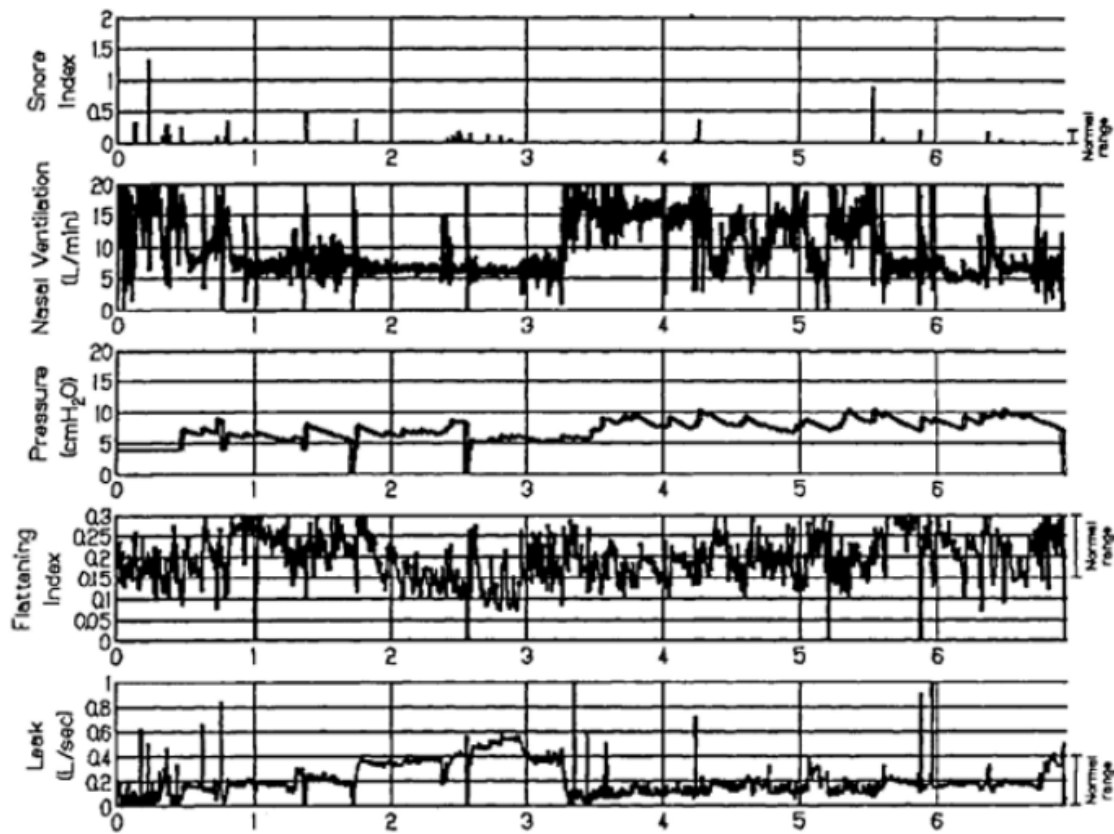


FIGURE 1. Example of cumulative overnight automatic CPAP data report for a patient with severe OSAS. Used with permission of ResMed Corporation.

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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 decisionmaking

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.

VIII. THE '680 PATENT

104. The claims of the '680 Patent describe well-known PAP sleep disorder treatment devices implemented in a networked system. The '680 Patent generally focuses on a PAP device that “adjust[s] the treatment gas flow or pressure delivered to the subject based on the subject's current physiological state or symptoms.” Ex. 1001, 2:53-56.

105. The system includes a PAP device 428, as shown in Figure 8 below, that provides positive air pressure to a subject 410 with a mask 412 connected by air hose 416. *Id.*, 53:64-54:3. The system also includes “a diagnostic device 441, which

comprises a radio 436; an antenna 434; and a microprocessor 438 for processing the data or signals to determine a level of severity of the subject's sleeping disorder or symptoms." *Id.*, 54:3-10. "The diagnostic device 441 then transmits a signal based on this level of severity by either a tether 444 or radio signal (not shown) to an actuator (not shown) in the CPAP device 428, which controls the flow of air or gas provided to the subject by the air hose or subject circuit 416." *Id.*, 54:10-16.

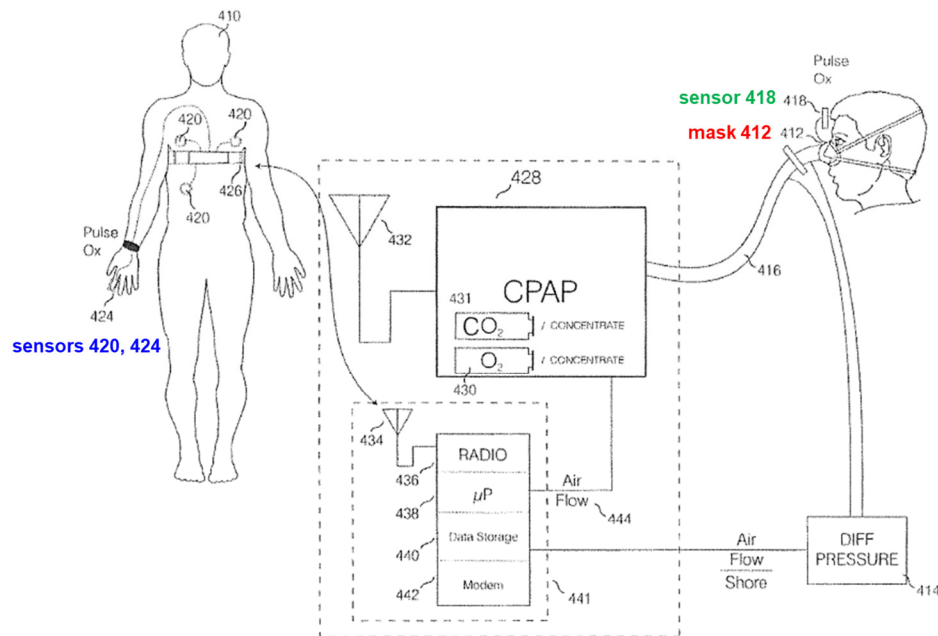


Fig. 8

Ex. 1001, Figure 8 (annotated)

106. The '680 patent also discloses that a wireless data acquisition system 50 may receive signals from sensors on a subject and transmit the signals to a server 70 for analysis via the Internet. Ex. 1001, 56:8-45. As discussed in Sections XI-XII

below, the above-described features, including those recited in the challenged claims, were well-known in the art, and disclosed by Toge, Burton, and/or Kumar. In fact, the '680 patent acknowledges that various claimed features were known in the art. For example, the '680 patent acknowledges that “a sensor for providing a sensor data to determine airflow,” “radio frequency wireless transceiver,” calculation of “data related to a quantitative measure of symptom severity,” and “signal processing techniques [e.g.,] wavelet analysis,” as recited in the '680 patent claims were known. In particular, the '680 patent acknowledges:

- “[m]ethods of determining airflow or air pressure from sensors placed in or on a PAP or CPAP device are generally known in the art, and any such method is appropriate for the present invention.” *Id.*, 17:7-10.
- “The receiver...of the wireless data acquisition system can be any device known to receive RF transmissions used by those skilled in the art to receive transmissions of data.” *Id.*, 24:61-65.
- “Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms.” *Id.*, 26:42-45.
- “The present invention would also include other on-line signal processing algorithms known to those skilled in the art, such as wavelet analysis, which is similar to time-

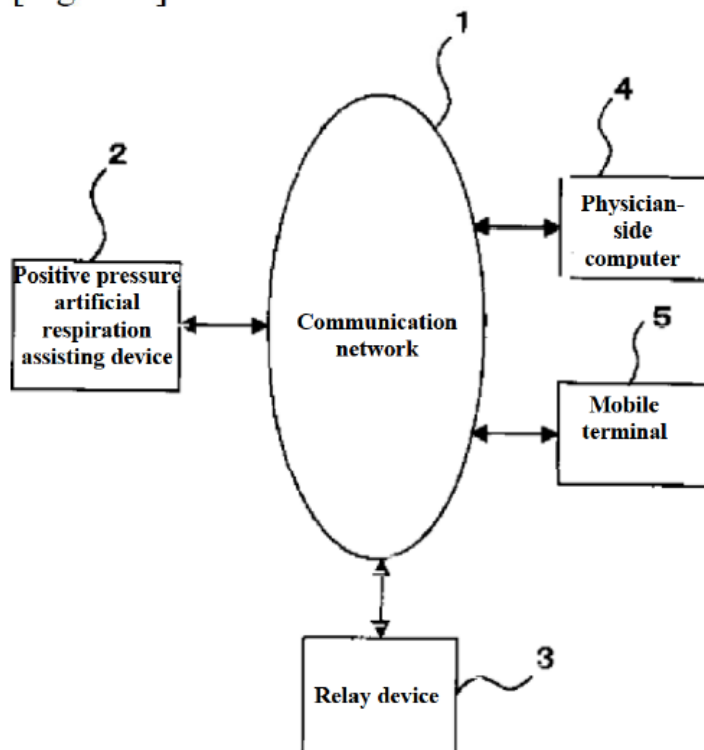
frequency analysis with a particular kernel function, to identify the shift in power spectrum associated with imminent flow separation that is discussed herein.” *Id.*, 26:67-27:5.

IX. OVERVIEW OF THE PRIOR ART

A. Toge (Ex. 1044)

107. Toge discloses various claimed features, including features associated with claimed “PAP device(s)” and use of the “Internet” for “remote...monitoring.” Toge discloses a remote monitoring method for a patient using a positive pressure artificial respiration assisting device as shown by Figure 1.

[Figure 1]



108. Toge discloses a telemedicine system where a PAP device is connected to a communications network by a relay device (3), and physician-side terminal devices (4 and 5) all connected to a communication network (1). Ex. 1044, [0008]. Toge's communications network (1) may be any of the following: a public telephone network, the Internet, a mobile communication network, or a dedicated line network. It may also be a combination of these networks. *Id.*, [0009].

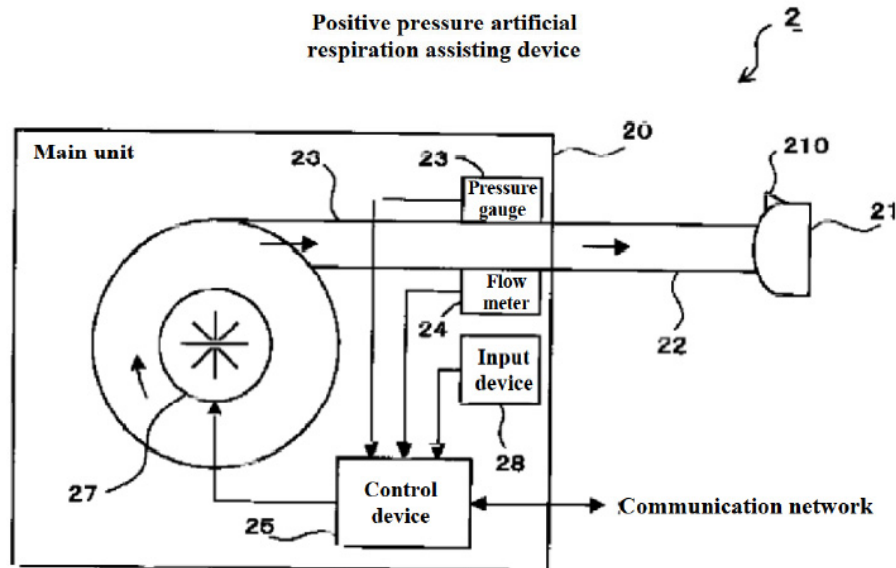
109. Toge's PAP device includes a relay device (3) that is installed within the PAP device and that receives data from the PAP device and then transmits all or part of the data to the physician side terminal device (4). *Id.*, [0016] The relay device (3) can also download all or specified data received from the positive pressure artificial respiration assisting device (2) to the physician-side device in response. *Id.*, [0059]. The functionality of the relay device (3) can be incorporated into the positive pressure artificial respiration assisting device (2), specifically the control unit (250) of the control device (25), allowing it to be configured as an integrated unity with the positive pressure artificial respiration assisting device (2). *Id.*, [0060]. These processes done by the relay device (3) can be implemented by either a program describing these processes and a CPU, or microcomputer with peripheral circuits to execute this program, or by hardware circuits dedicated to the executing the above processes. *Id.*, [0062].

110. The physician side terminal devices (4 and 5) are devices that receive all or part of the data transmitted from the positive pressure artificial respiration assisting device (2) to relay device (3), from a relay device (3). *Id.*, [0017]. These devices can be computers, mobile devices, PHS, PDAs, or PocketBells. *Id.*, [0019].

111. The positive pressure artificial respiration assisting device (2) is one of the home medical devices and is designed to deliver positive pressure air to the nasal mask of a patient receiving home medical care to assist the patient's breathing. *Id.*, [0010]. The home medical device includes both bilevel and continuous positive airway devices. *Id.*, [0012]. These devices can deliver inspiratory pressure (IPAP), expiratory pressure (EPAP), and continuous positive pressure (CPAP) air to the patient. The pressures are set to the prescribed pressure by the physician. *Id.*, [0013].

112. Figure 2 below shows a positive pressure artificial respiration assisting device.

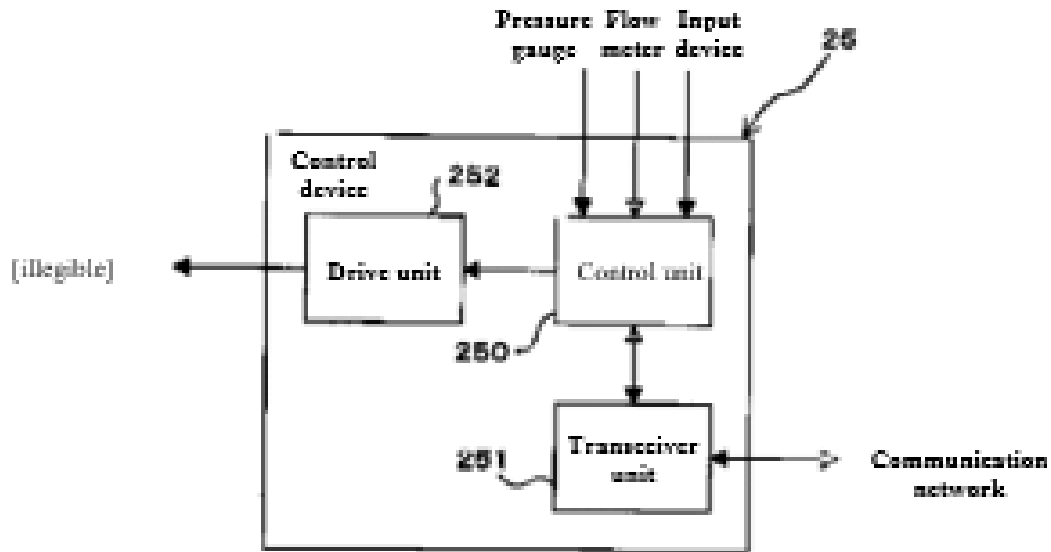
[Figure 2]



113. The positive pressure artificial respiration assisting device as shown in figure 2 comprises a main unit (20), a nasal mask (21) attached to the patient's nose, and an air tube (22). The air tube (22) is connected between the main unit (20) and the nasal mask (21) to deliver air from the main unit (20) to the nasal mask (21). *Id.*, [0021]. Within the main unit (20) is a pressure gauge (23), a flow meter (24), a control device (25), a flow path (26), a blower (27), and an input device (28). *Id.*, [0023].

114. Figure 3 below shoes the control device (25).

[Figure 3]



115. The control device (25) as shown in Figure 3, further comprises a control unit (250), a transceiver unit (251), and a drive unit (252). *Id.*, [0023]. The transceiver unit (251) provides the reception data to the control unit (250). *Id.*, [0031].

116. Toge explains that its system enables “remote monitoring of the patient’s condition during the use of a [PAP] device, or the condition of the [PAP] device” via the wireless communication network. *Id.*, Abstract, [0001], [0005], [0006] (disclosing that the PAP device is “connected to a relay device and a physician-side terminal device via a wireless...communication network to conduct remote monitoring of the [PAP] device via the communication network”). Toge

describes that by “transmitting the tidal volume F_p almost in real-time or at regular intervals (such as every hour), physicians can remotely monitor the patient’s condition during the use of the [PAP] device 2 remotely from hospitals or other locations. Furthermore, if there is a decreasing trend in the tidal volume F_a , emergency measures, such as adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4 or mobile terminal 5.” *Id.*, [0039]. Further, Toge describes that based on the received oxygen saturation data “physicians can take emergency measures such as adjusting the prescription pressure to a higher level remotely from the physician-side computer 4 or mobile terminal 5, operating the [PAP] device 2 in conjunction with an oxygen concentrator, or adjusting the flow rate from the oxygen concentrator if one is being used in conjunction.” *Id.*, [0047]. Additionally, Toge allows a physician “remotely monitor both the patient’s condition during the use of the positive pressure artificial respiration assisting device and the status of the device itself.” *Id.*, [0085].

B. Kumar (Ex. 1008)

117. Kumar discloses “remote internet site” limitations of claim 1, including “the remote internet site adapted to receive” certain data from a patient-side device, e.g., a PAP device.

118. Kumar discloses a telemedicine system “for network-based monitoring of physiological data.” Ex. 1008, Abstract. Figure 1A shows the system includes a

patient-side device 102, computing device 110 (like a wireless phone or pocket PC such as the IPAQ), and central server 106 that hosts a browser-based engine that can be accessed through web pages. *See* Ex. 1008, [0067] (“[T]he system includes one or more patient-side devices 102 for collecting data from a patient/client, one or more provider-side devices 104, and an engine implemented on a central server 106.”), [0072] (“The *patient-side device* may then be connected via a *computing device 110*, such as a computer, handheld devices such as personal digital assistants (PDAs) and pocket PCs such as *IPAQ* with Windows CE operating System and Palm devices based on Palm OS), wireless telephone, or any other computing device, to the WAN.”). The computing device can download a plug-in to communicate with the patient-side device and the central server. *Id.*, [0018] (“[T]he engine will send the appropriate *plug-in* which allows the computing device to communicate with the patient-side device.”).

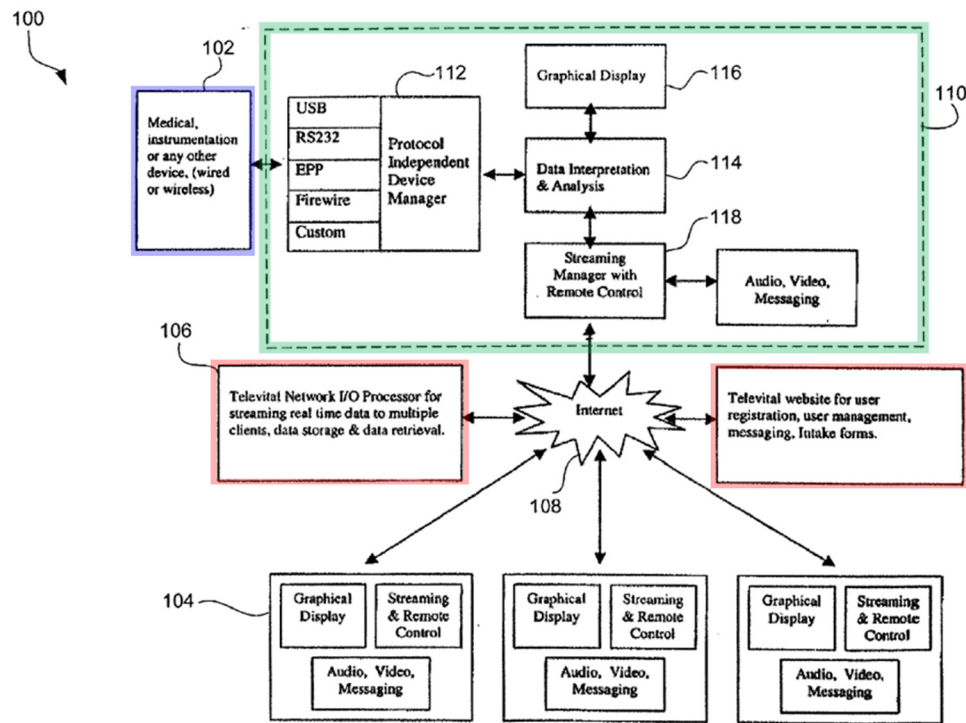


Fig. 1A

119. Kumar teaches that “virtually any [patient-side] device may be easily incorporated into the system.” *Id.*, [0018]. One of the devices that Kumar teaches can be incorporated into the system is a device to address sleep apnea-hypopnea syndrome. Kumar recognizes that “[s]leep apnea-hypopnea syndrome is characterized by repetitive episodes of upper airway obstruction that occur during sleep usually associated with reduction in blood oxygen concentration.” *Id.*, [0240]. Kumar teaches that incorporating devices for sleep apnea-hypopnea “allows remote monitoring of such devices by providing in-home monitoring.” *Id.*, [0241].

C. Burton (Ex. 1050)

120. Burton discloses several features of claim 1, including a processor “generating and outputting the data related to the subject’s treatment and the treatment’s efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device, and data of usage of the PAP device.”

121. Burton relates to providing PAP treatments to patients. Ex. 1050, 1:20-27. Burton explains that, while PAP treatments may achieve intended results, “they also often severely affect the quality of sleep” of the patient undergoing these treatments, “causing transient arousals.” *Id.*, 1:9-12. “While these arousals do not result in the awakening of the patient, they often pull patients from deeper stages or higher quality states of sleep.” *Id.*, 1:12-14; *see also id.*, 1:15-19, 2:1-3:13. For example, the PAP device’s inaccuracy in detecting the upper airway resistance (UAR) events may cause “[e]xcessively rapid or excessively insensitive pressure changes” of the air delivered to the patient, leading to patient’s arousal and sleep fragmentation. *Id.*, 2:2-31.

122. To resolve these issues, Burton discloses a system that “deliver[es] therapeutic treatments to patients without adversely affecting their sleep.” Ex. 1050, 1:4-6, 3:15-16. The system “maintain[s] the sleep quality of a patient undergoing a therapeutic treatment” by “predict[ing] the onset of arousal and using **an adaptive**

algorithm to modify a patient's therapeutic treatment.” *Id.*, 3:21-24. The therapeutic control algorithm is “**adapted during real-time operation** based on any combination of a) empirical clinical data, b) individual patient collected or alternative (to laboratory) collected data (from diagnostic study within sleep laboratory or other alternative site) or c) real-time monitored and analyzed data.” *Id.*, 3:24-28.

123. “[T]o minimize arousals while maintaining the integrity of the treatment, these rates and absolute pressure changes are adjusted in accordance to various patient states including (for example only) the patient's current sleep state....” *Id.*, 3:29-4:7. Burton's algorithm “**detect[s] variation in airflow shape** that could be indicative of the incidence or probable onset of upper airway resistance (UAR) or variations of UAR, respiratory event related arousals (RERA) or treatment event related arousals (TERA).” *Id.*, 4:24-32; *see also id.*, 5:1-5. It allows a PAP device to “predict the UAR, RERA and TERA events or the onset of such events and adjust the treatment to avoid such events.” *Id.*, 5:10-12. “[T]he process of detecting and monitoring for arousals could occur simultaneously or **in virtual real-time** with automated gas delivery treatment algorithms which are able to **adapt to reduce or eliminate both sleep breathing disorders and sleep fragmentation.**” *Id.*, 5:13-16. The algorithm also “recognize[s] when the pressure adjustment of the gas delivery device is either too severe and leading to the promotion of RERAs or

TERAs or avoid[s] the failure to compensate for less obvious (without comprehensive shape analysis and possibly patient specific calibration) or more subtle SBD such as UARs, hypopnea events, and shallow breathing.” *Id.*, 5:16-20.

124. Specifically, Burton discloses using “the **shape characteristics of the airflow signal**” to record and determine “the likelihood of arousal or upper airway flow limitation.” Ex. 1050, 4:18-20. “[A]rousals are detected by **monitoring the presence of waveform signal disturbance evident**” from the “**analysis...of the airflow waveform and pressure waveform.**” *Id.*, 13:21-23. “Apnea events, shallow breathing, upper airway resistance and hypopnea events can also be detected and pre-empted by analysis of the change in shape of the high bandwidth **monitoring of the airflow waveforms and pressure waveforms.**” *Id.*, 13:23-26.

125. Burton explains that, when a patient receives CPAP treatment, arousal monitoring “includes **monitoring pressure and airflow associated with a patient’s breathing** in order to determine UAR (which may induce RERA)” and “[t]o prevent RERA, it is necessary to **detect a number of patterns which are indicative of sleep apnea symptoms, namely inspiratory flow limitation (flattening), snoring and flow amplitude reduction.**” Ex. 1050, 14:1-7; *see also id.*, 14:8-18. Based on the analysis of the pressure and airflow, the controller “**generates pressure adjustment signal.**” *Id.*, 14:19-22; *see also id.*, 14:23-30, 23:20-27 (describing that “[t]he controller 12 is implemented as a combination of

rules for pressure change”), 23:28-24:12 (describing conditions for various pressure change rules “represent a number of physiological scenarios”), 24:14-15 (“The present invention is capable of overcoming varying arousal dependent factors by applying adaptive algorithm techniques.”).

126. Additionally, Burton discloses using “profiles...determined from **patient-specific diagnostic studies**” and “changes in airflow pressure” to “determine whether the changes in the airflow shape resulting from these subtle treatment changes are able to counteract the shape or profile characteristics indicative of the incidence or on-set of arousals (TERA or RERA) or OSAH and UAR.” *Id.*, 20:8-13. Burton’s system may also “down-load from sleep laboratory studies or other types of **previous sleep, respiratory and/or cardiac related investigations,**” where “[t]he specific data is associated with a subject’s breathing and sleep arousal parameters and is used to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of UARS, OSAHS, RERAs and TERAs, while still minimizing sleep fragmentation and optimizing sleep quality.” *Id.*, 20:14-23; *see also id.*, 26:9-15 (“control algorithm has the capability to be adapted during realtime operation based on any combination of a) empirical clinical data, b) **individual patient collected or collected data (from diagnostic study within sleep laboratory or other alternative 15...**”).

127. Moreover, the process of minimizing arousals “includes the capability to **automatically adjust the therapeutic treatment based on at least one index or derived data set,**” which includes, e.g., Upper Airway Resistance (UAR), Respiratory Effort-Related Arousal (RERA), Therapeutic-control Event-Related Arousal (TERA), **Respiratory Disturbance Index (RDI)**, Respiratory Arousal Index (RAI), **Apnea-hypopnea index (AHI)**, Sleep efficiency Index, Pressure change rate, Mixed Sleep Apnea events, Sleep Quality index, classification of respiratory events with noisy or poor quality effort signals, Obstructive Sleep Apnea/Hypopnea event or syndrome (OSA, OSH, OSAHS). *Id.*, 21:4-22:21.

C. Burton (Ex. 1050)

128. Burton discloses several features of claim 1, including a processor “generating the PAP therapy efficacy data based on a first data and a second data by receiving the sensor data, and calculating both i) the first data related to a quantitative measure of symptom severity during use of the PAP device and ii) the second data related to a usage of the PAP device by the subject.”

129. Burton relates to providing PAP treatments to patients. Ex. 1050, 1:20-27. Burton explains that, while PAP treatments may achieve intended results, “they also often severely affect the quality of sleep” of the patient undergoing these treatments, “causing transient arousals.” *Id.*, 1:9-12. “While these arousals do not result in the awakening of the patient, they often pull patients from deeper stages or

higher quality states of sleep.” *Id.*, 1:12-14; *see also id.*, 1:15-19, 2:1-3:13. For example, the PAP device’s inaccuracy in detecting the upper airway resistance (UAR) events may cause “[e]xcessively rapid or excessively insensitive pressure changes” of the air delivered to the patient, leading to patient’s arousal and sleep fragmentation. *Id.*, 2:2-31.

130. To resolve these issues, Burton discloses a system that “deliver[es] therapeutic treatments to patients without adversely affecting their sleep.” Ex. 1050, 1:4-6, 3:15-16. The system “maintain[s] the sleep quality of a patient undergoing a therapeutic treatment” by “predict[ing] the onset of arousal and using **an adaptive algorithm to modify a patient’s therapeutic treatment.**” *Id.*, 3:21-24. The therapeutic control algorithm is “**adapted during real-time operation** based on any combination of a) empirical clinical data, b) individual patient collected or alternative (to laboratory) collected data (from diagnostic study within sleep laboratory or other alternative site) or c) real-time monitored and analyzed data.” *Id.*, 3:24-28.

131. “[T]o minimize arousals while maintaining the integrity of the treatment, these rates and absolute pressure changes are adjusted in accordance to various patient states including (for example only) the patient’s current sleep state....” *Id.*, 3:29-4:7. Burton’s algorithm “**detect[s] variation in airflow shape** that could be indicative of the incidence or probable onset of upper airway resistance

(UAR) or variations of UAR, respiratory event related arousals (RERA) or treatment event related arousals (TERA).” *Id.*, 4:24-32; *see also id.*, 5:1-5. It allows a PAP device to “predict the UAR, RERA and TERA events or the onset of such events and adjust the treatment to avoid such events.” *Id.*, 5:10-12. “[T]he process of detecting and monitoring for arousals could occur simultaneously or **in virtual real-time** with automated gas delivery treatment algorithms which are able to **adapt to reduce or eliminate both sleep breathing disorders and sleep fragmentation.**” *Id.*, 5:13-16. The algorithm also “recognize[s] when the pressure adjustment of the gas delivery device is either too severe and leading to the promotion of RERAs or TERAs or avoid[s] the failure to compensate for less obvious (without comprehensive shape analysis and possibly patient specific calibration) or more subtle SBD such as UARs, hypopnea events, and shallow breathing.” *Id.*, 5:16-20.

132. Specifically, Burton discloses using “the **shape characteristics of the airflow signal**” to record and determine “the likelihood of arousal or upper airway flow limitation.” Ex. 1050, 4:18-20. “[A]rousals are detected by **monitoring the presence of waveform signal disturbance evident**” from the “**analysis...of the airflow waveform and pressure waveform.**” *Id.*, 13:21-23. “Apnea events, shallow breathing, upper airway resistance and hypopnea events can also be detected and pre-empted by analysis of the change in shape of the high bandwidth **monitoring of the airflow waveforms and pressure waveforms.**” *Id.*, 13:23-26.

133. Burton explains that, when a patient receives CPAP treatment, arousal monitoring “includes **monitoring pressure and airflow associated with a patient’s breathing** in order to determine UAR (which may induce RERA)” and “[t]o prevent RERA, it is necessary to **detect a number of patterns which are indicative of sleep apnea symptoms, namely inspiratory flow limitation (flattening), snoring and flow amplitude reduction.**” Ex. 1050, 14:1-7; *see also id.*, 14:8-18. Based on the analysis of the pressure and airflow, the controller “**generates pressure adjustment signal.**” *Id.*, 14:19-22; *see also id.*, 14:23-30, 23:20-27 (describing that “[t]he controller 12 is implemented as a combination of rules for pressure change”), 23:28-24:12 (describing conditions for various pressure change rules “represent a number of physiological scenarios”), 24:14-15 (“The present invention is capable of overcoming varying arousal dependent factors by applying adaptive algorithm techniques.”).

134. Additionally, Burton discloses using “profiles...determined from **patient-specific diagnostic studies**” and “changes in airflow pressure” to “determine whether the changes in the airflow shape resulting from these subtle treatment changes are able to counteract the shape or profile characteristics indicative of the incidence or on-set of arousals (TERA or RERA) or OSAH and UAR.” *Id.*, 20:8-13. Burton’s system may also “down-load from sleep laboratory studies or other types of **previous sleep, respiratory and/or cardiac related**

investigations,” where “[t]he specific data is associated with a subject’s breathing and sleep arousal parameters and is used to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of UARS, OSAHS, RERAs and TERAs, while still minimizing sleep fragmentation and optimizing sleep quality.” *Id.*, 20:14-23; *see also id.*, 26:9-15 (“control algorithm has the capability to be adapted during realtime operation based on any combination of a) empirical clinical data, b) **individual patient collected or collected data (from diagnostic study within sleep laboratory or other alternative 15...**”).

135. Moreover, the process of minimizing arousals “includes the capability to **automatically adjust the therapeutic treatment based on at least one index or derived data set,**” which includes, e.g., Upper Airway Resistance (UAR), Respiratory Effort-Related Arousal (RERA), Therapeutic-control Event-Related Arousal (TERA), **Respiratory Disturbance Index (RDI)**, Respiratory Arousal Index (RAI), **Apnea-hypopnea index (AHI)**, Sleep efficiency Index, Pressure change rate, Mixed Sleep Apnea events, Sleep Quality index, classification of respiratory events with noisy or poor quality effort signals, Obstructive Sleep Apnea/Hypopnea event or syndrome (OSA, OSH, OSAHS). *Id.*, 21:4-22:21.

X. CLAIM CONSTRUCTION:

136. 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).

XI. OPINIONS ON GROUND 1: TOGE IN VIEW OF KUMAR AND BURTON RENDERS OBVIOUS CLAIMS 1-5, 7, 8, 10-13, 15-18, AND 20-31

A. A POSITA Would Have Been Motivated to Combine

137. In my opinion, a POSITA would have been motivated to combine the teachings of Toge and Kumar to implement a networked PAP treatment system. Specifically, a POSITA looking to improve the physician-side computer of Toge would have looked at known ways to improve a telemedicine system by providing better data access by implementing browser-based engine accessible through web pages as taught by Kumar for at least the following reasons.

138. First, a POSITA would have been motivated by convenience and efficiency. *See also* Section VII.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. Appointments/traveling to see providers requires an investment in time/resources for both the provider and patient. *See, e.g.*, EX1044. By collecting data accessible anywhere by the provider and physicians through web pages, the

need to invest time in coordinating time and resources for multiple doctors and patient is avoided. In particular, if a patient needs multiple specialist, the physicians and providers need not download particular software to access the data. Instead, the physicians and providers can access the data through an Internet browser.

139. Second, 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 would be required to expend time and resources to coordinate appointment schedules with other aspects of daily life/routines, including 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 and doctor, as the remote access would allow any doctor to review data during any downtime in their schedule, and not just doctors with specific software to view the data.

140. In my opinion a POSITA would have understood that the sensors of Toge would have been ideal to combine with the advances discussed above in order to improve a patient's treatment. Ex. 1044, [0028]

141. Also, 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 '680 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 (Cyrcat wireless transmitter), to the flow generator (CPAP and Auto-CPAP). Ex. 1043.

142. Additionally, a POSITA would have been motivated to modify the Toge-Kumar PAP device and system to incorporate Burton's PAP therapy efficacy data analysis.

143. First, including Burton's PAP therapy efficacy data analysis would have advanced the objective of Toge to "enable remote monitoring of the patient's condition during the used of the positive pressure artificial respiration assisting device and the condition of the positive pressure artificial respiration assisting device itself." Ex. 1044, [0005]. Toge also discusses setting limits and adjusting the prescription pressure based on the patient's condition. Ex. 1044, [0039], [0055]. In

my opinion a POSITA would have understood that “determin[ing] the efficacy of the CPAP treatment” and “vary[ing] operation parameters of the treatment,” as taught by Burton would have improved the performance of the Toge-Kumar PAP system by incorporating Burton’s PAP therapy efficacy data analysis, which allows the system to “recognize[s] when the pressure adjustment of the gas delivery device is either too severe and leading to the promotion of RERAs or TERAs or avoid[s] the failure to compensate for less obvious (without comprehensive shape analysis and possibly patient specific calibration) or more subtle SBD such as UARs, hypopnea events, and shallow breathing.” Burton., 5:16-20.

144. Second, it would have advanced the purpose of Toge “enabling remote monitoring of the patient’s condition during the use of a positive pressure artificial respiration assisting device” and preventing “leakage causing discomfort and potentially affecting the patient’s ability to sleep.” Ex. 1044, Abstract, [0040]. A major limitation of CPAP therapy was non-compliance due to discomfort. Ex. 1016, 5. The modification would have been advantageous to minimize the pressure applied, increase comfort, and therefore improve compliance.

145. As I discussed in Section VII.A, automatically adjusting CPAP machines had already been used for more than a decade by 2005. Such PAP therapy efficacy data analysis, including indexes, were well-known tools in automatically

adjusting the pressure to ensure that the treatment was high enough to treat the sleep disordered breathing, but low enough to minimize any discomfort.

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

146. In my opinion a POSITA would have had a reasonable expectation of success in implementing the physician-side computer of Toge to incorporate a browser-based engine accessible by webs pages as taught by Kumar and to modify the control unit 250 of Toge to output the PAP therapy efficacy data analysis taught by Burton.

147. First, there are express statements in Kumar that directly teach that the user interface of Kumar can be incorporated into systems like Toge: “Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI.” Ex. 1008, [0018]. Further, Toge itself utilized wireless communication. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.*, Ex. 1044, Abstract, Fig. 5, Ex. 1045, Fig. 3; Ex. 1013, [0029]. Thus, the systems are structurally and functionally similar.

148. Second, Toge and Burton are analogous art as both references describe CPAP systems that include flow sensors and processors. Ex. 1044, [0023] (“control unit 250”); Ex. 1050, 10:10-12 (“controller...includes a processor”). Both further

discloses that the processor analyzes the signals from the flow sensors. Ex. 1044, [0008]; Ex. 1050, 1:20-27.

149. Toge already discloses a telemedicine system (including a PAP device, mobile phone, and physician-side computer, all of which are connected to a network). 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. The modifications would simply be a change of programming to the control unit 250 of Toge to output the PAP therapy efficacy data analysis of Burton, and a change of programming on the physician-side computer to allow it to host web pages. Given this, a POSITA would have had a reasonable expectation of success in implementing the system resulting from the combination of the teachings of Toge, Burton, and Kumar.

C. Independent Claim 1

Preamble: “A system for remote internet server-based diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment comprising”

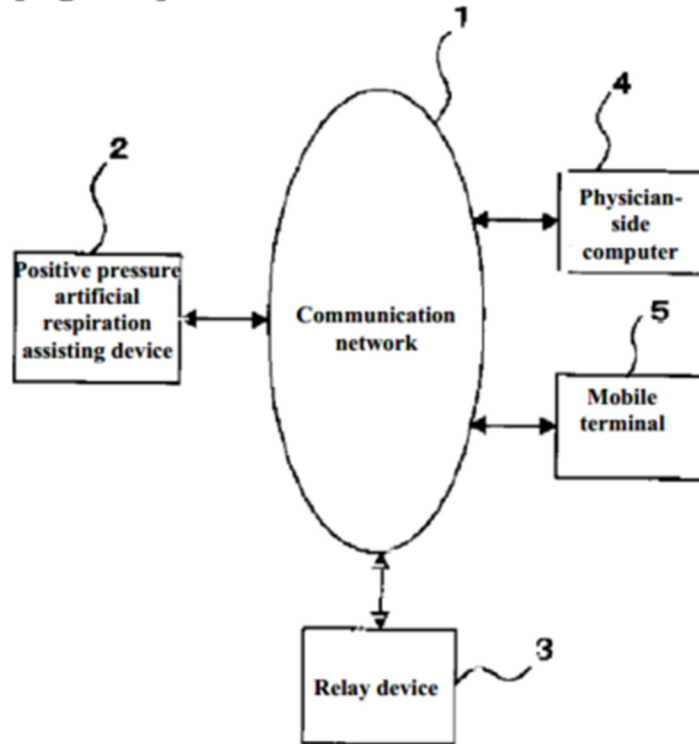
150. In my opinion, Toge in view of Kumar discloses the preamble.

151. Toge discloses “one or more positive airway pressure (PAP) device(s) for sleep disorder treatment.” As shown in Figure 1, Toge discloses a remote medical

(telemedicine) system including a positive pressure artificial respiration assisting device (“one or more positive airway pressure (PAP) device(s)”) for treating patients having sleep apnea (“sleep disorder treatment”). Ex. 1044, [0008], [0015]. Toge’s system includes a positive pressure artificial respiration assisting device 2 (referred to as “PAP device 2” hereafter), a relay device 3, physician-side terminal devices, e.g., a physician-side computer 4, and a mobile terminal 5, all of which are connected to communication network 1. *Id.*, [0008]. Toge discloses that “the functionality of such a relay device 3 can be incorporated into the positive pressure artificial respiration assisting device 2 (the control unit 250 of the control device 25), allowing it to be configured as an integrated unit with the positive pressure artificial respiration assisting device 2.” *Id.*, [0060]. Toge goes on to explain that in this case the “positive pressure artificial respiration assisting device 2 then directly transmits all or part of the treatment data to the physician-side computer 4 or mobile terminal 5 via the communication network 1. The physician-side computer 4 or mobile terminal 5 then directly sets the thresholds on the positive pressure artificial respiration assisting device 2 and sends download requests.” *Id.*, [0061], [0063]-[0076] (examples of remote monitoring), [0085] (“remotely monitor both the patient’s condition during the use of the positive pressure artificial respiration assisting device and the status of the device itself.”).

152. Additionally, Toge discloses that network 1 may be the “Internet” or “a mobile communication network.” *Id.*, [0009].

[Figure 1]



153. PAP device 2 provides treatments to patients having “weakened spontaneous breathing ability” and/or “conditions such as sleep apnea” at the patient’s residence. *Id.*, [0010], [0015]; *see also id.*, [0011]-[0014] (describing features associated with PAP device 2).

154. Computer 4, installed at, e.g., a hospital or clinic, receives data from a relay device 3 (e.g., data transmitted from PAP device 2 to relay device 3) and allows care providers, e.g., physicians, to access the transmitted data using the computer. *Id.*, [0017]-[0018]. By using computer 4, care providers may send a “data download

request” to relay device 3 to download data onto computer 4 and may also “set the necessary data...for [PAP] device 2.” *Id.*, [0018].

155. Mobile terminal 5 may be “mobile phones, PHS, PDAs and PocketBell...etc.” Ex. 1044, [0019]. Mobile terminal 5, possessed by the care provider, may be “mobilized in emergencies by the physician-side computer 4, relay device 3, or other mobile terminals possessed” by the care provider. *Id.*, [0019]. The care provider may operate the mobile terminal 5 to “set the necessary data...for [PAP] device 2.” *Id.* Toge also discloses that the PAP device 2, relay device 3, and physician-side computer 4 are wirelessly connected to communication network 1 for transmitting data, e.g., “treatment data.” *Id.*, [0006]-[0007]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1.

156. Toge explains that its system enables “remote monitoring of the patient’s condition during the use of a [PAP] device, or the condition of the [PAP] device” via the wireless communication network. Ex. 1044, Abstract, [0001], [0005], [0006] (disclosing that the PAP device is “connected to a relay device and a physician-side terminal device via a wireless...communication network to conduct remote monitoring of the [PAP] device via the communication network”), [0039] (“By transmitting the tidal volume F_p almost in real-time or at regular intervals (such as every hour), physicians can remotely monitor the patient’s condition during the use of the [PAP] device 2 remotely from hospitals or other locations. Furthermore,

if there is a decreasing trend in the tidal volume F_a , emergency measures, such as adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4 or mobile terminal 5.”), [0085] (“remotely monitor both the patient’s condition during the use of the positive pressure artificial respiration assisting device and the status of the device itself.”). PAP device 2 may transmit treatment data via network 1 to physician-side computer 4 (*id.*, [0006], [0016]-[0017]) or mobile terminal 5 (*id.*, [0019]), by which a physician may “access the transmitted data” and update the settings on PAP device 2 based on the physician’s diagnosis of the patient’s conditions (*id.*, [0018], [0027], [0039]-[0042], [0046]-[0047]). Given that Toge discloses a physician accessing the treatment data and updates/adjusts settings of the PAP device 2 for patient’s sleep disorder treatment, a POSITA would have understood that the physician reviews, monitors, analyzes, and/or diagnoses the patient’s condition based on the received data in order to adjust/update the settings of the PAP device. *See, e.g., id.*, [0039] (“By transmitting the tidal volume F_p almost in real-time or at regular intervals (such as every hour), **physicians can remotely monitor the patient’s condition** during the use of the positive pressure artificial respiration assisting device 2 remotely from hospitals or other locations. Furthermore, if there is a decreasing trend in the tidal volume F_a , emergency measures, such as **adjusting the prescription pressure to a higher level**, can be taken remotely from the physician-side computer 4 or mobile terminal

5.”), [0046] (“**By transmitting the operating status in real-time, physicians can address emergencies involving the patient.**”), [0047] (“**By transmitting the oxygen saturation measured by the oxygen saturation monitor almost in real-time or at regular intervals, physicians can almost instantly or periodically know the patient's oxygen saturation level.** Then, if the oxygen saturation, for example, falls below 90%, **physicians can take emergency measures such as adjusting the prescription pressure to a higher level remotely** from the physician-side computer 4 or mobile terminal 5, operating the positive pressure artificial respiration assisting device 2 in conjunction with an oxygen concentrator, or adjusting the flow rate from the oxygen concentrator if one is being used in conjunction.”). Thus, Toge disclose “diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment.”

157. Toge discloses a system for “diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment” via network 1 (e.g., “Internet”), as discussed above, but Toge does not expressly close such a system is “remote internet server-based.” Nevertheless, a POSITA would have been motivated and found it obvious to implement a “remote internet server-based” system in view of Kumar.

158. Like Toge, Kumar discloses a telemedicine system “for network-based monitoring of physiological data,” including remote studies and monitoring

physiological data associated with sleep apnea-hypopnea syndrome. Ex. 1008, Abstract, [0068], [0239]-[0241].

159. Figure 1A of Kumar shows the system includes a patient-side device 102 (like the Toge PAP device), computing device 110, and **central server 106 that hosts a browser-based engine that can be accessed through web pages.** Ex. 1008, [0067], [0072]; *see also id.*, [0018].

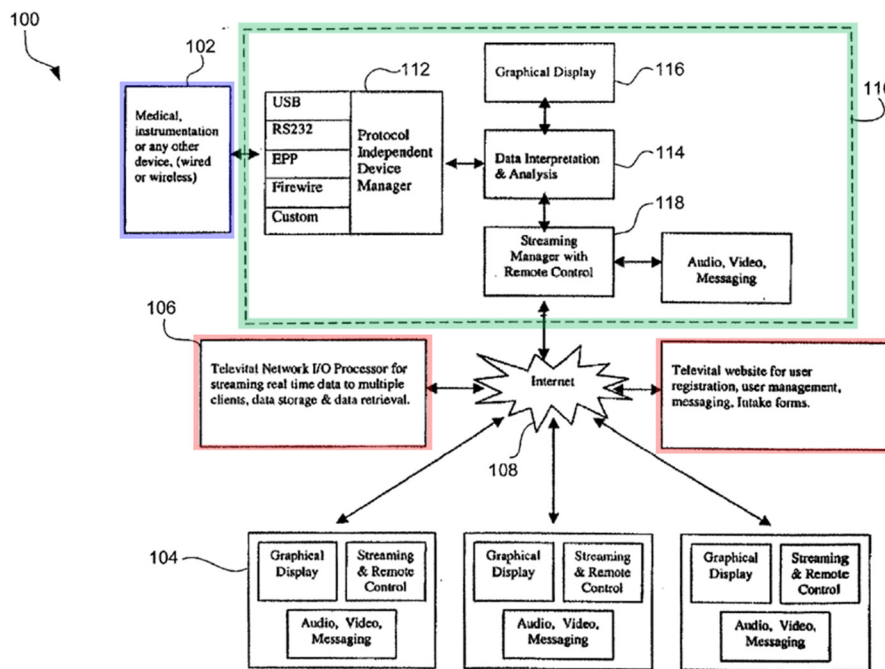


Fig. 1A

160. Kumar additionally discloses that the browser-based engine supports real-time streaming of information over the Internet. Ex. 1008, [0010], [0087] (“The 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.

Note also that the server may be implemented on the Internet, intranet, or an extranet.”). “The engine manages transmission of the data from the patient-side device to the provider-side device” and “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.” Ex. 1008, [0011];

161. For example, 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**, where the devices and engine are connected to a wide area network (WAN) 108 such as the **Internet**. 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.” *Id.*; *see also id.*, [0068]. Kumar also 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]; Thus, Kumar discloses a “remote internet server-based” system” for remote studies and monitoring physiological data associated with sleep apnea-hypopnea syndrome.

162. Additionally, 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]. A patient can access the engine through a login, such as that 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”).

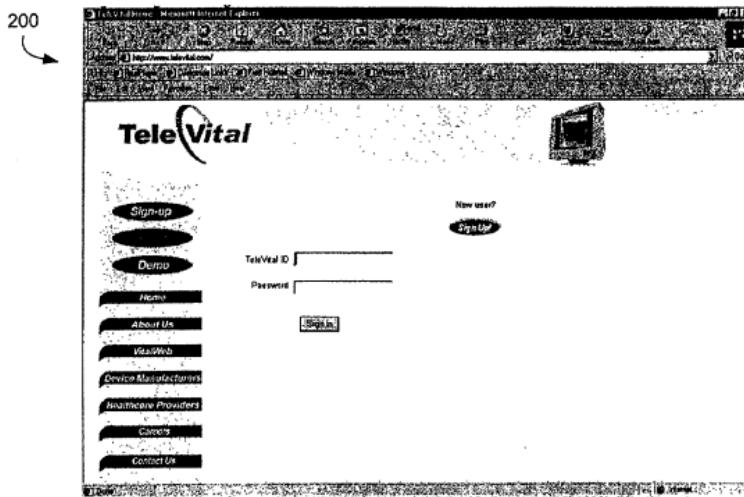


Fig. 2

163. In my opinion, a POSITA would have understood that the data sent to the engine could be accessed through 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”).

164. In my opinion a POSITA would have been motivated to implement the “remote internet server-based” features, including a browser-based engine implemented on an Internet web server similar to as described in Kumar (*see, e.g., above*), to enable the PAP device to wirelessly transmit to the remote engine, *e.g.,* data associated the patient’s treatment.

165. Such a feature would have been beneficial as **Kumar explains that “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis.”** Ex. 1008, [0083]. “The 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,” “allow[ing] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device.” *Id.* In fact, Kumar states that such a feature is beneficial, *e.g.,* by allowing a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. *Id.* Additionally, “[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].

166. In my opinion a POSITA would have also had a reasonable expectation of success in combining the above-discussed features with the Toge system.

167. Kumar states that “virtually any device may be easily incorporated into the system.” Ex. 1008, [0074]. Additionally, it was well known to transmit data using wireless protocol(s) to a remote Internet site that is implemented on a server, e.g., for later access of the data.

168. In fact, Toge itself is already capable of transmitting treatment data from a PAP device to a physician/provider-side device via a communication network, e.g., the Internet. *See above; see also* Ex. 1044, [0060]-[0061]. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that provides data relate to the subject’s treatment through a communication network/Internet (Toge)) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine implemented on an Internet server (Kumar)) to yield the predictable result of a system including an Internet server-based 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. Accordingly, the Toge-Kumar combination discloses a system including an Internet server-based remote engine (“remote internet server-based” system) capable of receiving data associated with patient treatments for “diagnostic monitoring” via a wireless communication network from a PAP device providing “sleep disorder treatment.”

[1.a]: “A. one or more PAP device(s);”

169. In my opinion, Toge discloses claim [1.a].

170. As discussed for the preamble, Toge discloses a PAP device 2. *See, e.g.*, Ex. 1044, [0008].]. Burton also discloses a PAP device. *See, e.g.*, EX1050, 1:20-27.

[1.b] “B. a first non-transitory computer readable medium comprising a first software stored on the first non-transitory computer readable medium, the first software adapted to be executed by a first processor when the first software is downloaded to a cell phone of a subject(s) receiving treatment, the cell phone requiring:”

[1.b.i] 1) at least one first radio frequency wireless transceiver,

[1.b.ii] 2) the first processor,

[1.b.iii] 3) the first software, and

[1.b.iv] 4) a display,

171. In my opinion, Toge in view of Kumar discloses limitations [1.b]-[1.b.iv].

172. While Toge does not expressly disclose “a cell phone of a subject(s) receiving treatment” and the features recited in limitations [1.b]-[1.b.iv], a POSITA would have been motivated and found it obvious to implement these features in view of Kumar.

173. As discussed for the preamble, Kumar discloses a telemedicine system “for network-based monitoring of physiological data.” Ex. 1008, Abstract. Figure 1A shows the system includes a patient-side device 102 (like the Toge PAP device), computing device 110 (“cell phone”), and central server 106 that hosts a browser-based engine that can be accessed through web pages. To communicate with the patient-side device and the central server, the computing device can download a plug-in (“first software”). *Id.*, [0018].

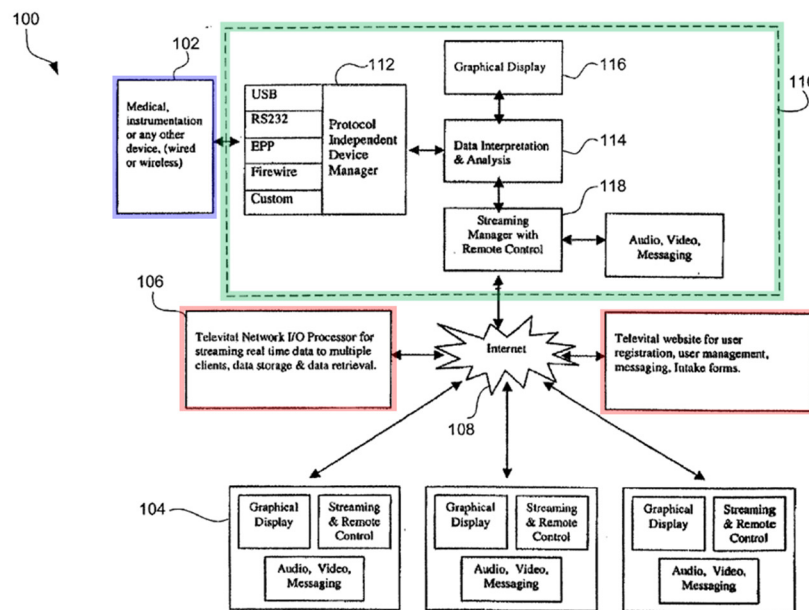


Fig. 1A

174. Kumar discloses “a first non-transitory computer readable medium.” Specifically, Kumar discloses that “[t]he present invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium,” such as the memory on the computing device. Ex. 1008, ¶

[0020]. In my opinion a POSITA would have understood that the downloaded plug-in is stored on Kumar's "non-transitory computer readable medium."

175. Kumar discloses a "cell phone" that includes "a display."

176. Kumar discloses that computing device 110 may be a wireless phone or pocket PCs, e.g., an iPAQ device. Ex. 1008, [0072]; Ex. 1011, 2 ("[T]he 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."). Moreover, Kumar explains that computing device 110 receives "data stream from the client-side device" and analyzes the same, which may be displayed on a display module 116 ("display"). Ex. 1008, [0075].

177. Kumar discloses "a first radio frequency wireless transceiver." Kumar teaches using the iPAQ device ("cell phone"), which a POSITA would have understood included a radio frequency wireless transceiver to enable GPRS, Wi-Fi, and Bluetooth. Ex. 1008, [0072]; Ex. 1011, 2.

178. Kumar discloses “the first software adapted to be executed by a first processor when the first software is downloaded to a cell phone of a subject(s) receiving treatment.”

179. Specifically, Kumar discloses a plug-in (“first software”) downloaded by the computing devices, e.g., a cellular device such as an iPAQ (“cell phone”) that allows communications with the patient-side devices (such as Toge PAP device) through a wireless protocol. Ex. 1008, [0074], [0073]. In my opinion a POSITA would have understood that the plug-in allows the patient to access the patient’s data on the computing device and display that data on the display of the computing device.

180. In fact, Kumar, following the discussions of plug-in, discloses that “[t]he data may be displayed graphically on the display module 116” of the computing device. Ex. 1008, [0075]. In my opinion a POSITA would have further understood that the plug-in would be executable on the processor of the computing device (“first processor”) and configured to be used by the computing device, otherwise the plug-in would not function on the computing device.

181. In my opinion, a POSITA would have been motivated and found it obvious to implement the “cell phone” and associated features recited in limitations [1.b]-[1.b.iv]. The cell phone associated features would have allowed the patient to view the treatment data on the patient’s personal cell phone and storing such

information for later viewing even when away from the PAP device. In fact, Toge already expressly describes that the doctor or other medical professionals are able to access treatment related data via a mobile phone. EX1044, [0019]. It would have also been beneficial for the patient to review such information as it would have indicated how the patient responded to the treatment and encouraging the patient to comply with the prescribed treatment. Additionally, such a modification would have reduced the PAP device's form factor as the PAP device would not need to include a screen suitable for displaying data to the patient, which in turn improves the device's portability as PAP devices may be used during travel. In fact, it was known by at least 2002 that making a smaller and less expensive PAP device that is easier to use than the prior bulky PAP devices was desirable:

An earlier version of a PAP device] was too big and expensive to go home with a patient, but it did a very good job at automatically determining how much pressure the patient needed. They could then go home on a conventional CPAP machine set at that pressure. Over time, we came up with AutoSet T, the take home device, which is much smaller and simpler for a patient to use.

Ex. 1056, 4.

Continuous positive airway pressure (CPAP) has undergone significant changes since being introduced to the public in 1981. The machines developed decades ago

were heavy, loud, and with limited capabilities when
compared to the sleek, lightweight ones today.

Ex. 1057, 1.

182. In my opinion a POSITA would have had the skill and a reasonable expectation of success in combining the teachings of Toge and Kumar. Toge and Kumar are in the same field of art and both relate to providing healthcare for sleep disorder. Moreover, Kumar states that “virtually any device may be easily incorporated into the system” (Ex. 1008, [0074]) and specifically discussed devices to monitor “[s]leep apnea-hypopnea syndrome” (*id.*, [0241]). Indeed, it was known at the time to interface a PAP device with a computing device, e.g., a PDA or a handheld device, via wireless communication. EX1044, [0019]; Ex. 1012, 6:20-25 (“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.”), 7:2-6 (describing that the apparatus is a PAP device); Ex. 1009, 14:54-15:12 (use of wireless/Bluetooth protocol to transmit data associated with a CPAP device).

183. Moreover, it would have involved a combination of known technologies (PAP device that provides treatment data) according to known methods (interface a PAP device with a computing device, such as a PDA or cell phone) to yield the predictable result of a system including a PAP device of improved portability, e.g., reduced form factor, and a cell phone that allows the patient to review the associated treatment data, which improves patient compliance, as discussed above.

[1.b.v] the first software further adapted for:”

[1.b.v.A] “i) receiving a PAP therapy efficacy data or a modified PAP therapy efficacy data based in part on the PAP therapy efficacy data both based on treatment of the subject and its efficacy in whole or in part, and”

184. In my opinion, the Toge-Kumar combination in view of Kumar discloses this limitation. As discussed for limitations [1.b]-[1.b.iv], the downloaded plug-in (“first software”) allows computing device 110 (“cell phone”) to communicate with the patient-side devices (such as Toge PAP device) through a wireless protocol and also to **receive data from the patient-side device**. *See, e.g.*, Ex. 1008, [0075] (“The data interpretation and analysis module 114 [on computing device 110] is used to interpret the **data stream from the client-side device....**”). Further, Toge already expressly describes that the doctor or other medical professionals are able to access treatment related data via a mobile phone. EX1044,

[0019]. Accordingly, the Toge-Kumar combination at least suggests the subject receiving treatment's cell phone "receiving" data based on the treatment of the subject from the PAP device.

185. Toge and Kumar do not expressly disclose the subject receiving treatment's cell phone receiving "a PAP therapy efficacy data or a modified PAP therapy efficacy data based in part on the PAP therapy efficacy data both based on treatment of the subject and its efficacy in whole or in part." Nevertheless, a POSITA would have been motivated to implement in the Toge-Kumar combination these features in view of Burton.

186. As an initial matter, for clarity, I first explain below how the Toge-Kumar-Burton combination discloses "generating *the PAP therapy efficacy data*" as recited in limitation [1.d.iii] ("a second processor [of the PAP device] adapted for generating *the PAP therapy efficacy data* based on a first data and a second data by receiving the sensor data, and calculating both i) the first data related to a quantitative measure of symptom severity during use of the PAP device and ii) the second data related to a usage of the PAP device by the subject") and then discuss how the combination disclose the subject receiving treatment's cell phone receiving "a PAP therapy efficacy data....," as recited in limitation [1.b.v.A].

187. To begin, Toge at least suggests "*generating the PAP therapy efficacy data based on a first data and a second data...*," as recited in limitation [1.d.iii]. For

example, Toge's control unit 250 (corresponding to "second processor" as recited in limitation [1.d.iii]) **generates "transmission data"** ("*generating the PAP therapy efficacy data*"). Ex. 1044, [0030], [0033]. Toge explains that the **transmission data** includes "the patient's **treatment data** such as the **tidal volume Fp**." *Id.*, [0031]. **Tidal volume Fp** (including its trend) is calculated based on the measurements of **flow meter 24** ("sensor data") and is used to assess and treat the patient's condition when using the PAP device. *Id.*, [0033]-[0035], [0038]-[0039]. Thus, the patient's tidal volume Fp is "the first data related to a quantitative measure of symptom severity during use of the PAP device."

188. Moreover, Toge discloses that the **treatment data** also includes "the **operational time T** of [PAP] device 2." *Id.*, [0031]. Toge discloses control unit 250 calculating "*the second data related to a usage of the PAP device by the subject*" because Toge discloses calculating operational time T, which represents the amount time the patient uses the PAP device. *Id.*, [0042]. In fact, Toge explains that "[b]y analyzing this operational time, physicians can determine whether the patient is **using** the [PAP] device 2 and assess the treatment (patient) **compliance**." *Id.*

189. To the extent that Toge does not disclose "*generating the PAP therapy efficacy data*" as recited in limitation [1.d.iii], it is my opinion that a POSITA would have found it obvious to implement the recited features in the Toge-Kumar combination in view of Burton.

190. Like Toge, Burton teaches providing PAP treatments to patients. Ex. 1050, 1:20-27. Burton explains that, while PAP treatments may achieve intended results, “they also often severely affect the quality of sleep” of the patient undergoing these treatments by “causing transient arousals.” *Id.*, 1:9-12. “While these arousals do not result in the awakening of the patient, they often pull patients from deeper stages or higher quality states of sleep.” *Id.*, 1:12-14; *see also id.*, 1:15-19, 2:1-3:13. For example, the PAP device’s inaccuracy in detecting the upper airway resistance (UAR) events may cause “[e]xcessively rapid or excessively insensitive pressure changes” of the air delivered to the patient, leading to patient’s arousal and sleep fragmentation. *Id.*, 2:2-31.

191. To resolve these issues, Burton discloses a system that “deliver[s] therapeutic treatments to patients without adversely affecting their sleep.” Ex. 1050, 1:4-6, 3:15-16. The system “maintain[s] the sleep quality of a patient undergoing a therapeutic treatment” by “predict[ing] the onset of arousal and using **an adaptive algorithm to modify a patient’s therapeutic treatment.**” *Id.*, 3:21-24. The therapeutic control algorithm is “**adapted during real-time operation** based on any combination of a) empirical clinical data, b) individual patient collected or alternative (to laboratory) collected data (from diagnostic study within sleep laboratory or other alternative site) or c) real-time monitored and analyzed data.” *Id.*, 3:24-28.

192. “[T]o minimize arousals while maintaining the integrity of the treatment, rates [of pressure change] and absolute pressure changes are adjusted in accordance to various patient states including (for example only) the patient’s current sleep state....” Ex. 1050, 3:29-4:7. Burton’s algorithm “**detect[s] variation in airflow shape**...indicative of the incidence or probable onset of upper airway resistance (UAR) or variations of UAR, respiratory event related arousals (RERA) or treatment event related arousals (TERA).” *Id.*, 4:24-32; *see also id.*, 5:1-5. It allows a PAP device to “predict the UAR, RERA and TERA events or the onset of such events and adjust the treatment to avoid such events.” *Id.*, 5:10-12. “[T]he process of detecting and monitoring for arousals could occur simultaneously or **in virtual real-time** with automated gas delivery treatment algorithms which are able to **adapt to reduce or eliminate both sleep breathing disorders and sleep fragmentation**.” *Id.*, 5:13-16. The algorithm also “recognize[s] when the pressure adjustment of the gas delivery device is either too severe and leading to the promotion of RERAs or TERAs or avoid[s] the failure to compensate for less obvious (without comprehensive shape analysis and possibly patient specific calibration) or more subtle SBD such as UARs, hypopnea events, and shallow breathing.” *Id.*, 5:16-20.

193. Specifically, Burton discloses using “the **shape characteristics of the airflow signal**” to record and determine “the likelihood of arousal or upper airway

flow limitation.” Ex. 1050, 4:18-20. “[A]rousals are detected by **monitoring the presence of waveform signal disturbance evident**” from the “**analysis...of the airflow waveform and pressure waveform.**” *Id.*, 13:21-23. “**Apnea events, shallow breathing, upper airway resistance and hypopnea events can also be detected** and pre-empted by analysis of the change in shape of the high bandwidth **monitoring of the airflow waveforms and pressure waveforms.**” *Id.*, 13:23-26.

194. Burton explains that, when a patient receives CPAP treatment, arousal monitoring “includes **monitoring pressure and airflow associated with a patient’s breathing** in order to determine UAR (which may induce RERA)” and “[t]o prevent RERA, it is necessary to **detect a number of patterns which are indicative of sleep apnea symptoms, namely inspiratory flow limitation (flattening), snoring and flow amplitude reduction.**” Ex. 1050, 14:1-7; *see also id.*, 14:8-18. Based on the analysis of the pressure and airflow, the controller “**generates pressure adjustment signal.**” *Id.*, 14:19-22; *see also id.*, 14:23-30, 23:20-27 (describing that “[t]he controller 12 is implemented as a combination of rules for pressure change”), 23:28-24:12 (describing conditions for various pressure change rules “represent a number of physiological scenarios”), 24:14-15 (“The present invention is capable of overcoming varying arousal dependent factors by applying adaptive algorithm techniques.”).

195. Additionally, Burton discloses using “profiles...determined from **patient-specific diagnostic studies**” and “changes in airflow pressure” to “determine whether the changes in the airflow shape resulting from these subtle treatment changes are able to counteract the shape or profile characteristics indicative of the incidence or on-set of arousals (TERA or RERA) or OSAH and UAR.” Ex. 1050, 20:8-13. Burton’s system may also “down-load from sleep laboratory studies or other types of **previous sleep, respiratory and/or cardiac related investigations**,” where “[t]he specific data is associated with a subject’s breathing and sleep arousal parameters and is used to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of UARS, OSAHS, RERAs and TERAs, while still minimizing sleep fragmentation and optimizing sleep quality.” *Id.*, 20:14-23; *see also id.*, 26:9-15 (“control algorithm has the capability to be adapted during realtime operation based on any combination of a) empirical clinical data, b) **individual patient collected or collected data (from diagnostic study within sleep laboratory or other alternative 15...**”).

196. Moreover, the process of minimizing arousals “includes the capability to **automatically adjust the therapeutic treatment based on at least one index or derived data set**,” which includes, e.g., Upper Airway Resistance (UAR), Respiratory Effort-Related Arousal (RERA), Therapeutic-control Event-Related Arousal (TERA), **Respiratory Disturbance Index (RDI)**, Respiratory Arousal

Index (RAI), **Apnea-hypopnea index (AHI)**, Sleep efficiency Index, Pressure change rate, Mixed Sleep Apnea events, Sleep Quality index, classification of respiratory events with noisy or poor quality effort signals, Obstructive Sleep Apnea/Hypopnea event or syndrome (OSA, OSH, OSAHS). Ex. 1050, 21:4-22:21. As I discussed above in Section VII.A (History of CPAP Therapy), 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. AHI is a measured number of apnea and hypopnea events per unit time. 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.

197. Burton discloses limitation [1.d.iii] (“a second processor adapted for generating the PAP therapy efficacy data based on a first data and a second data by receiving the sensor data, and calculating both i) the first data related to a quantitative measure of symptom severity during use of the PAP device and ii) the second data related to a usage of the PAP device by the subject,”).

198. **First**, Burton discloses “*receiving sensor data*,” e.g., from an airflow sensor. As discussed above, Burton’s algorithm uses received airflow and pressure sensor data to analyze, e.g., “**the shape characteristics of the airflow signal**,” including “the airflow waveform and pressure waveform.” Ex. 1050, 4:18-20, 13:21-

26. **Second**, Burton discloses “*calculating...i) the first data related to a quantitative measure of symptom severity during use of the PAP device.*” For example, Burton’s algorithm **detects or calculates “a number of patterns which are indicative of sleep apnea symptoms**, namely inspiratory flow limitation (flattening), snoring and flow amplitude reduction (hypopneas and apneas),” where, as a POSITA would have understood, such patterns are “*related to*” the patient’s “*symptom severity during use of the PAP device.*” *Id.*, 14:1-7; *see also id.*, 14:8-18. The breathing patterns observed during the use of a PAP device reflect the severity of sleep apnea, with snoring representing the mildest form, where airflow is partially restricted but sustained over long periods without arousal. In contrast, apnea represents the most severe condition, characterized by a complete absence of airflow that terminates in arousal from sleep. Inspiratory airflow limitation and hypopnea fall between these extremes, with progressively greater restrictions in airflow leading to varying degrees of oxygen desaturation and sleep disruption.

199. Additionally, Burton discloses calculating an index of a subject’s symptoms measured during use of the PAP device. For example, as discussed above, Burton discloses “automatically adjust[ing] the therapeutic treatment based on at least one index or derived data set,” which includes, e.g., Respiratory Disturbance Index (RDI), Respiratory Arousal Index (RAI), Apnea-hypopnea index (AHI), Sleep efficiency Index, Mixed Sleep Apnea events, Sleep Quality index, Obstructive Sleep

Apnea/Hypopnea event or syndrome (OSA, OSH, OSAHS). *Id.*, 21:4-22:21. In my opinion a POSITA would have understood that each of the above-described indices is “*related to*” the patient’s “*symptom severity during use of the PAP device.*”

200. **Third**, Burton discloses “*calculating...ii) the second data related to a usage of the PAP device by the subject.*” As discussed above, Burton discloses using “profiles...determined from patient-specific diagnostic studies” (Ex. 1050, 20:8-13) and information from patient’s “**previous sleep, respiratory and/or cardiac related investigations**” (*id.*, 20:14-23, 26:9-15) to customize the algorithm and the gas delivery device. Additionally, as discussed above, Burton discloses determining, e.g., AHI and RDI, which involves calculating sleep disorder events **per unit time during the patient’s usage of the PAP device.**

201. Burton discloses “*generating the PAP therapy efficacy data based on a first data and a second data by receiving the sensor data, and calculating both i) the first data related to a quantitative measure of symptom severity during use of the PAP device and ii) the second data related to a usage of the PAP device by the subject*” in two ways.

202. **First**, As discussed above, Burton’s controller/algorithm uses the received sensor data, calculations of patterns indicative of sleep apnea symptoms, index/indices or derived data set, and the patient’s prior sleep analysis as well as patient’s usage of the PAP device to control/adjust the therapeutic treatment. In my

opinion a POSITA would have understood that corresponding signals/data (that is generated and output by the algorithm) used to control/adjust the treatment are “the PAP therapy efficacy data” because these signals/data are derived from data collected during the treatment/therapy and for adjusting the treatment based on the received sensor signal indicating the efficacy and/or severity of the patient’s symptoms. Indeed by analyzing breathing patterns - ranging from snoring to complete apnea - this data serves as both a measure of therapy effectiveness and an indicator of the underlying severity of sleep apnea symptoms.

203. Burton discloses this limitation in **a second way**. Burton discloses that its system is “adapted to record, meter, index or **display**, in real time or on a replay or review basis, a number of sleep or arousal related physiological data or statistics,” where “[s]tatistics and indexes such as RAI, AHI, RERA, RDI, arousals, sleep fragmentation, or sleep architecture index are derived from the monitored parameters and this information is stored for analysis.” Ex. 1050, 27:11-13. Moreover, Burton includes “graphical and statistical tools...to enable a user to manipulate and display raw data or derived values in a meaningful format,” including “displaying raw data and then using visual clues to mark the occurrence of an event such as arousal in the raw data” and “link[ing] an event or events to specific index values or derived values which reflect the occurrence of the event.” *Id.*, 28:20-25. Given that Burton discloses displaying the above-described data/index

(“the PAP therapy efficacy data”), Burton discloses “generating” these data/index in this second way.

204. In my opinion a POSITA would have been motivated to implement the above-described features (similar to those disclosed in Burton) such that a PAP device’s processor (e.g., Toge’s processor in the PAP device, i.e., control unit 250, corresponding to “second processor” as recited in limitation [1.d.iii]) is implemented with the above-described algorithm. These features would have been beneficial as they would have minimized or avoided transient arousals when the patient is undergoing PAP treatments and would have improved the patient’s sleep quality. Additionally, the disclosed algorithm would have provided an improved accuracy in detecting arousals and treating patient’s sleep disorders given that it uses individual patient’s collected data to “customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of UARS, OSAHS, RERAs and TERAs, while still minimizing sleep fragmentation and optimizing sleep quality.” Ex. 1050, 20:14-23; *see also id.*, 26:9-15.

205. As such, a POSITA would have been motivated to implement the above-described algorithm (e.g., as disclosed in Burton) in control unit 250 (e.g., as disclosed in the Toge-Kumar combination) such that the modified control unit is configured to receive and analyze the sensor data (e.g., data provided by pressure gauge 23 and flow meter 24, either component or collectively being the claimed

“airflow sensor”), determine/calculate the airflow’s shape characteristics, patterns indicative of sleep apnea symptoms, indices of a subject’s symptoms measured during use of the PAP device, and data of usage of the PAP device, all of which are used to generate data for adjusting the PAP device operation and/or displayed to the user for additional analysis, for example.

206. In my opinion a POSITA would have had a reasonable expectation of success in implementing the above-discussed feature in the Toge-Kumar combination. Burton’s disclosed features are “adapted for use with a CPAP machine.” Ex. 1050, 19:25-26. Additionally, Burton explains that “[o]ne skilled in the art can readily appreciate that the subject invention is **easily adapted for use with, or incorporated within, other known therapeutic devices.**” *Id.*, 19:26-28. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that controls the device operations using a processor based on received sensor data (Toge-Kumar)) according to known methods (e.g., known methods/algorithm implemented on a controller/processor to generate/output data relating to PAP therapy efficacy data based on sensor data and calculations of associated information (Burton)) to yield the predictable result of a PAP device implemented with an algorithm that minimizes/avoids transient arousals when the patient is receiving PAP treatments and improves the patient’s sleep quality, as

discussed above. Accordingly, the Toge-Kumar-Burton combination discloses limitation [1.d.iii].

207. The Toge-Kumar-Burton combination discloses limitations [1.b.v]-[1.b.v.A]. As discussed above, Kumar discloses that the downloaded plug-in (“first software”) allows computing device 110 (“cell phone”) to communicate with the patient-side devices (such as Toge PAP device) through a wireless protocol and also to **receive data from the patient-side device**. *See, e.g.*, Ex. 1008, [0075] (“The data interpretation and analysis module 114 [on computing device 110] is used to interpret the data stream from the client-side device....”).

208. As discussed for limitations [1.b]-[1.b.iv], a POSITA would have been motivated and found it obvious to implement the “cell phone” and associated features because, for example, they would have allowed the patient to view the treatment data on the patient’s personal cell phone, storing such information for later viewing even when away from the PAP device, and would have encouraged the patient to comply with the prescribed treatment. Thus, for reasons similar to those discussed for limitations [1.b]-[1.b.iv], a POSITA would have been motivated and found it obvious to configure the downloaded plug-in (“first software”) on the cell phone such that the cell phone receives “PAP therapy efficacy data or a modified PAP therapy efficacy data based in part on the PAP therapy efficacy data both based on treatment of the subject and its efficacy in whole or in part.” In my opinion a

POSITA would have had the motivations, capabilities, and reasonable expectation of success discussed for limitations [1.b]-[1.b.iv] to modify the Toge-Burton-Kumar combination to provide the above-discussed feature.

[1.b.v.B]: “ii) outputting one or more PAP therapy efficacy measures(s) on the display of the cell phone for viewing by the subject based in whole or in part on the data received by the first software; and”

209. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

210. As discussed for limitation [1.b.v.A], the Toge-Burton-Kumar combination discloses computing device 110 (“cell phone”) receiving “PAP therapy efficacy data.” Kumar discloses a “cell phone” in multiple ways including mobile terminal 5 of Toge and that computing device 110 of Kumar may process the received data, e.g., “perform mathematical analysis” and/or “generate statistics,” and then display the processed data. Ex. 1008, [0075] (“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.”). In my opinion a POSITA would have understood that the processed “PAP therapy efficacy data” are “PAP therapy efficacy measures(s)” given that the process involves performing mathematical analysis and/or generating statistics.

211. Thus, the Toge-Burton-Kumar combination discloses outputting/displaying mathematically and/or statistically analyzed data on the cell phone's display for viewing by the patient ("outputting one or more PAP therapy efficacy measures(s) on the display of the cell phone for viewing by the subject") based on the received "PAP therapy efficacy data" ("based in whole or in part on the data received by the first software").

[1.c]: "C. a second non-transitory computer readable medium comprising at least one second software for a remote internet site and a database, the remote internet site and the database stored on a non-transitory computer readable medium and adapted to:"

212. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

213. As discussed for the preamble, Kumar discloses a browser-based engine ("remote internet site"), which can be accessed through web pages and is implemented on an Internet web server. *See, e.g.*, Ex. 1008, [0010], [0018], [0067], [0072], [0087]. Kumar also discloses that "the data may be stored in **a secured storage device at the central server** for later access, replay, and/or analysis" and "storage of the data allows for the creation of statistical **databases.**" *Id.*, [0083].

214. Kumar discloses that "[t]he present invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium." Ex. 1008, ¶ [0020]. Thus, a POSITA would have understood

that Kumar's a browser-based engine ("remote internet site") and secured storage device ("database") are implemented on program(s)/code ("second software") stored on computer-readable (or electronically-readable) medium ("non-transitory computer readable medium").

[1.c.1]: 1) be hosted on at least one server, and

215. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

216. Kumar discloses that the engine is "implemented on a central server 106" (Ex. 1008, [0067]) and that the "secured storage device [is] at the central server" (*id.*, [0083]). Thus, the Toge-Burton-Kumar combination discloses that the remote internet site and the database are "hosted on at least one server."

[1.c.2]: 2) be used for remote monitoring of multiple subjects receiving PAP therapy;

217. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

218. Toge discloses that "**multiple [PAP] devices 2** are provided for each of several patients." Ex. 1044, [0058]. Likewise, Kumar discloses "[t]he embodiments presented herein contemplate connection of **multiple patient-side devices**, provider-side devices, and engines." Ex. 1008, [0012]. The Toge-Kumar-

Burton combination discloses the remote internet site and the database are “used for remote monitoring of multiple subjects receiving PAP therapy.”

[1.d]: “wherein the one or more PAP device(s) that is each used for treating the sleeping disorder of the subject(s) or their symptoms, and further comprises:”

[1.d.i]: “a blower having an air output,”

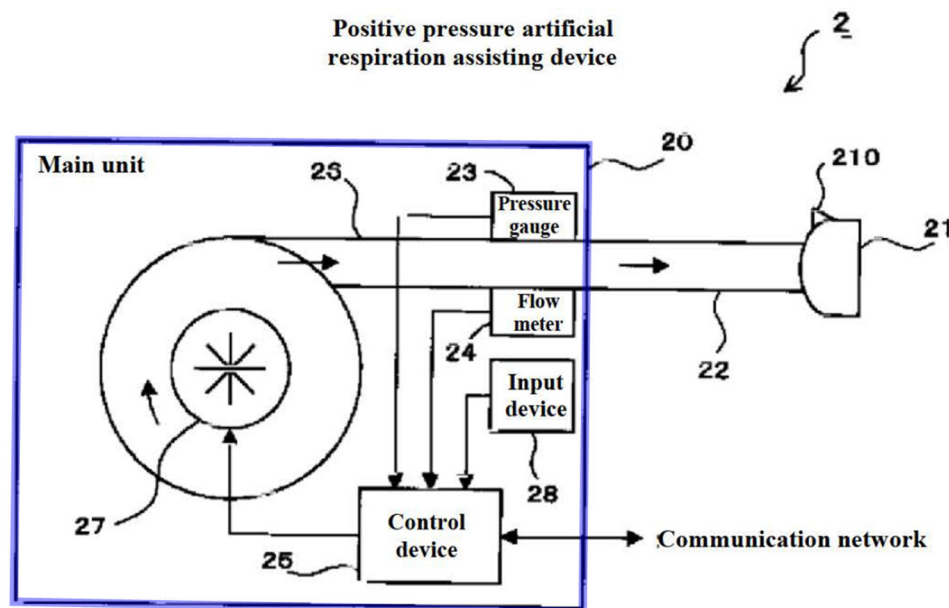
[1.d.ii]: “a sensor for providing a sensor data to determine airflow, the sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of the subject while using the PAP,”

219. In my opinion, Toge discloses this limitation.

220. As discussed for the preamble, Toge discloses remote medical (telemedicine) system that includes PAP device 2 for treating patients having sleep apnea (“treating the sleeping disorder of the subject(s) or their symptoms”). Ex. 1044, [0008], [0015].

221. As shown in Figure 2, Toge’s PAP device 2 is configured to be a single enclosure (highlighted in blue), where the PAP device includes a main unit 20, a nasal mask 21, an air tube 22, a pressure gauge 23, a flow meter 24, a control device 25, a flow path 26, a blower 27, and an input device 28. Ex. 1044, [0021], [0023]-[0024]. Toge explains that positive pressure air is delivered to nasal mask 21 via the air tube 22 from main unit 20, where nasal mask 21 is equipped with an exhalation vent 210 to expel the patient’s exhaled breath to the exterior of the nasal mask 21. *Id.*, [0022].

222. Blower 27 supplies air to nasal mask 21 via air tube 22. Ex. 1044, [0024] (“The flow path 26 is a guide airway that directs the air supplied from the blower 27 to the air tube 22 for delivery to the nasal mask 21.”), [0025] (“blower 27 functions by rotating to supply air into the flow path 26. The air pressure supplied is adjusted based on the rotational speed of the blower 27. The blower 27 is driven by the drive unit 252 of the control device 28. The drive of the drive unit 252 is controlled by the control unit 250 of the control device 25, thereby controlling the rotation of the blower 27.”). Thus, Toge discloses that the PAP device includes “a blower having an air output.”



As discussed above, Toge’s PAP device includes pressure gauge 23 and flow meter 24 (either component or collectively being the claimed “sensor for providing a sensor data to determine airflow”). Ex. 1044, [0021], [0023]-[0024]. As shown in

Figure 2, both pressure gauge 23 and flow meter 24 reside within main unit 20 of the PAP device (sensor “internal to the PAP device”). Toge explains that “pressure gauge 23 detects and **measures** the air pressure inside the flow path 26” and the “measured air pressure is provided to the control unit 250 of the control device 25.” *Id.*, [0028]. Flow meter 24 “detects and **measures** the airflow” within the flow path 26 and the “measured flow rate is then provided to the control unit 250 of the control device 25.” *Id.* Thus, Toge discloses “the sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of the subject while using the PAP.” Burton similarly discloses these limitations. *See, e.g.*, EX.1050, 6:12-19, FIG.1. Accordingly, Toge and Burton both disclose limitations [1.d], [1.d.i], [1.d.ii].

[1.d.iii]: “a second processor adapted for generating the PAP therapy efficacy data based on a first data and a second data by receiving the sensor data, and calculating both i) the first data related to a quantitative measure of symptom severity during use of the PAP device and ii) the second data related to a usage of the PAP device by the subject,”

223. In my opinion, Toge in view of Kumar and Burton discloses this limitation for the reasons discussed for limitation [1.b.v.A].

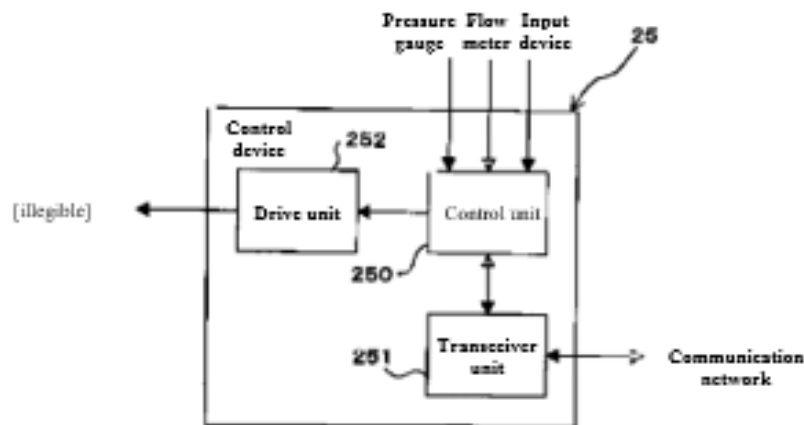
[1.d.iv]: “at least one second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data, and”

224. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

225. As discussed for limitations [1.b.v.A] and [1.b.v.B], a POSITA would have been motivated to **transmit “the PAP therapy efficacy data”** from the PAP device to the patient’s cell phone, e.g., to allow the patient to view the associated data.

226. As show in Figure 3 below, Toge discloses control device 25 includes a transceiver unit 251. Ex. 1044, [0023].

[Figure 3]



227. Toge discloses that, under the control of control unit 250, transceiver unit 251, via network 1, transmits data provided from the control unit 250 to the relay device 3, and receives data from the physician-side computer 4 or mobile terminal 5. *Id.*, [0030]; *see also id.*, [0008]-[0009], Fig. 1. Toge explains that the functionality of “relay device 3 can be incorporated into the [PAP] device 2 (the control unit 250 of the control device 25), allowing it to be configured as an

integrated unit with the positive pressure artificial respiration assisting device 2.” *Id.*, [0060]. Toge also explains that in this case the “[PAP] device 2 then directly transmits all or part of the treatment data to the physician-side computer 4 or mobile terminal 5 via the communication network 1. The physician-side computer 4 or mobile terminal 5 then directly sets the thresholds on the positive pressure artificial respiration assisting device 2 and sends download requests.” *Id.*, [0061].

228. As discussed for the preamble, Toge discloses that network 1 may be “a **mobile** communication network” (*id.*, [0009]) and that PAP device 2, relay device 3, physician-side computer 4 are **wirelessly** connected to communication network 1 for transmitting data (*id.*, [0006]-[0007]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1). Given that Toge’s disclosures that PAP device 2 is wirelessly connected to network 1, which may be a mobile network, a POSITA would have understood that PAP device 2 includes a radio frequency wireless transceiver (“at least one second radio frequency wireless transceiver”) in order to connect and communicate via network 1 operating mobile/wireless network protocols.

229. To the extent that Toge does not disclose that the PAP device includes “at least one second radio frequency wireless transceiver,” such a feature would have been obvious to a POSITA. Indeed, there were only a handful of known techniques for transmitting data wirelessly, including radio frequency communication and optical wireless communications. Thus, using a radio frequency wireless transceiver

to implement communications via radio frequency would have been obvious because it would have been one of a “finite number of identified, predictable solutions.”

230. In my opinion, 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. 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.”); Moreover, it would have involved a combination of known technologies (PAP device that transmits treatment data via a mobile network) according to known methods (known methods of transmitting data using a radio frequency wireless transceiver) to yield the predictable result of a PAP device using a RF wireless transceiver to communicate via a mobile network, as discussed above.

231. Accordingly, the Toge-Kumar-Burton combination discloses “at least one second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data.”

[1.d.v]: “a mask or a nasal cannula; and”

232. In my opinion, Toge and Burton both disclose this limitation.

233. Toge discloses that PAP device 2 includes a nasal mask 21. Ex. 1044, [0021], [0023]-[0024], Fig. 2. Burton similarly discloses this limitation. *See, e.g.*, EX1050,8:1-6 (“pressure transducers and a pneumotachograph are used in cooperation or integration with an airtube or a patient mask to detect patient airflow and airway pressure....”).

[1.e]: “the at least one second software for the remote internet site and the database is further adapted to receive the PAP therapy efficacy data, in whole or in part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.”

234. In my opinion, Toge in view of Kumar and Burton discloses this limitation. As discussed for the preamble and limitation [1.c], Kumar discloses a browser-based engine (“remote internet site”), where “the data may be stored in a secured storage device...for later access, replay, and/or analysis” and “storage of the data allows for the creation of statistical databases.” Ex. 1008, [0010], [0018], [0067], [0072], [0083], [0087]. As discussed for limitation [1.c], a POSITA would have understood that Kumar’s a browser-based engine (“remote internet site”) and secured storage device (“database”) are implemented on program(s)/code (“second software”).

235. As discussed in the preamble, a POSITA would have been motivated to implement the remote internet site to enable the PAP device to wirelessly transmit to the remote engine data associated the patient’s treatment. As discussed for

limitations [1.b.v.A] and [1.d.iii], the modified PAP device generates “the PAP therapy efficacy data” based on “treatment of the subject and its efficacy.” Consistent with the reasons discuss for the preamble, a POSITA would have been motivated to implement the remote internet site, including configure the “second software for the remote internet site and the database” such that it is adapted to receive data associated the patient’s treatment, including “the PAP therapy efficacy data,” wirelessly transmitted from the PAP device. For example, such a feature would have been beneficial as **Kumar explains that “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis.”** Ex. 1008, [0083]. “The 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,” “allow[ing] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device.” *Id.* In fact, Kumar states that such a feature is beneficial, e.g., by allowing a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. *Id.* Additionally, “[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]. In my opinion a POSITA would have had the motivations, capabilities, and reasonable expectation of success

discussed for the preamble to modify the Toge-Burton-Kumar combination to provide the above-discussed feature.

236. Moreover, as discussed for limitation [1.d.iv], the Toge-Kumar-Burton combination discloses that the PAP device includes a “second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data.” Accordingly, the Toge-Kumar-Burton combination discloses “the at least one second software for the remote internet site and the database is further adapted to receive the PAP therapy efficacy data, in whole or in part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver” of the PAP device.

D. Dependent Claims 2-5, 7, 8, 10, 11-13, 15-18, 20-31

Claim 2: “The system of claim 1, wherein the one or more PAP therapy efficacy measure(s) includes an index.”

237. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

238. As discussed for limitation [1.b.v.A], Burton discloses that calculating an index of a subject’s symptoms measured during use of the PAP device, including, e.g., Respiratory Disturbance Index (RDI) and Apnea-hypopnea index (AHI), is a part of the process of “generating the PAP therapy efficacy data.” Ex. 1050, 21:4-22:21. As discussed for limitation [1.b.v.B], “PAP therapy efficacy measures(s),” as

disclosed by the Toge-Burton-Kumar combination, is an output of the processed/analyzed “PAP therapy efficacy data.”

239. Accordingly, the Toge-Burton-Kumar combination discloses “the one or more PAP therapy efficacy measure(s) includes an index,” such as the RDI and AHI.

Claim 3, 21: “The system of claim [2/17], wherein the one or more PAP device(s) further comprises an electronic component adapted to utilize a cellular network and allow the one or more PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site.”

240. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

241. Toge discloses Network 1 may be “a **mobile** communication network” (*id.*, [0009]) and that PAP device 2, relay device 3, physician-side computer 4 are **wirelessly** connected to communication network 1 for transmitting data (*id.*, [0006]-[0007]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1). Thus, a POSITA would have understood that the PAP device includes an electronic component, such as control unit 250 (incorporating relay device 3, as discussed in Ex. 1050, [0060]), adapted to utilize a mobile network (“cellular network”).

242. Kumar discloses that the provider may “remotely control the client-side device[s],” e.g., “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 browser-based engine is “responsible for streaming...remote control information between multiple clients and hosts.” *Id.*, [0082].

243. As discussed for limitation [1.b.v.A], Burton discloses controlling/adjusting the treatment based on “the PAP therapy efficacy data.”

244. In my opinion 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 (“remote internet site”) “the PAP therapy efficacy data.” 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., control unit 250, such that it may be adjusted remotely (“an electronic component adapted to utilize a cellular network and allow the one or more PAP device to be adjusted remotely based on the PAP therapy efficacy data received by the remote internet site”) 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. 1044, [0025].

245. In my opinion a POSITA would have had the skill and a reasonable expectation of success in implementing the above-described remote control 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.

246. Accordingly, the Toge-Burton-Kumar combination discloses and/or suggests this limitation.

Claim 4: "The system of claim 2, wherein the index is based on both the first data and the second data from the one or more PAP device(s)."

247. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

248. As discussed for claim 2, the index includes, e.g., Respiratory Disturbance Index (RDI) and Apnea-hypopnea index (AHI). In my opinion a POSITA would have understood that AHI is a measured number of apnea and hypopnea events per unit time determined during the patient's usage of the PAP device.

249. Accordingly, The Toge-Burton-Kumar combination discloses the index is based on both the first data (which is "related to a quantitative measure of

symptom severity during use of the PAP device”) and the second data (which is “related to a usage of the PAP device by the subject”).

Claim 5. “The system in claim 4, wherein the PAP device for treating the sleeping disorder of the subject is adjusted based in whole or part on the PAP therapy efficacy data generated by the one or more PAP device(s) and then received by the remote internet site.”

250. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

251. As discussed for limitation [1.b.v.A], Burton’s controller/algorithm uses “the PAP therapy efficacy data” generated by a PAP device to adjust the treatment, and a POSITA would have been motivated to implement the algorithm in control unit 250 (e.g., as disclosed in the Toge-Kumar combination) for adjusting the PAP device operation.

252. Moreover, as discussed for limitation [1.e], a POSITA would have been motivated and found it obvious to transmit “the PAP therapy efficacy data” to the browser-based engine (“remote internet site”) because, e.g., “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis.” Ex. 1008, [0083].

Claim 7. “The system in claim 4, wherein the first software adapted to be executed by the cell phone receives, in whole or part, the PAP therapy efficacy data related to treatment of the subject generated by the one or more PAP device(s) and is then used to retransmit, in whole or part the PAP

therapy efficacy data and/or a reprocessed data based in part on the PAP therapy efficacy data related to treatment of the subject to the remote internet site with the at least one first radio frequency wireless transceiver.”

253. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

254. As discussed for limitations [1.b.v] and [1.b.v.A], the first software implemented on the computing device 110 (“cell phone”) receives “PAP therapy efficacy data” that is “based on treatment of the subject and its efficacy” (“first software adapted to be executed by the cell phone receives, in whole or part, the PAP therapy efficacy data related to treatment of the subject generated by the one or more PAP device(s)”).

255. As discussed for limitation [1.b.v.B], Kumar discloses that computing device 110 (“cell phone”) may process the received data, e.g., “perform mathematical analysis” and/or “generate statistics,” and then display the processed data. Ex. 1008, [0075]. In my opinion a POSITA would have been motivated and found it obvious to transmit from computing device 110 (“cell phone”) by using its RF transmitter (“first radio frequency wireless transceiver”) the processed data to the browser-based engine (“remote internet site”) for secured storage, later access, replay, and/or analysis.

256. In my opinion, a POSITA would have also had a reasonable expectation of success in implementing the above-described features. Kumar states that “virtually any device may be easily incorporated into the system.” Ex. 1008, [0074]. Additionally, it was well known to transmit data using wireless protocol(s) to a remote Internet site that is implemented on a server, e.g., for later access of the data.

257. Moreover, it would have involved a combination of known technologies (a cell phone that processes received data) according to known methods (receiving from the cell phone the processed data for storage at a browser-based engine) to yield the predictable result of a system including a browser-based engine receiving processed data from a cell phone for secured storage, later access, replay, and/or analysis, as discussed above.

Claim 8. “The system in claim 7, wherein the second radio frequency wireless transceiver of the one or more PAP device and the first software adapted to use the at least one first radio frequency wireless transceiver of the cell phone are further adapted to transmit PAP therapy efficacy data and/or a reprocessed data based in part on the PAP therapy efficacy data from the one or more PAP device(s) to the cell phone using a Bluetooth wireless protocol.”

258. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

259. To begin, Bluetooth wireless protocol is one of the well-known wireless protocols for data transmission at the time of the alleged invention. Ex. 1009, 14:54-

15:12 (use of wireless/Bluetooth protocol to transmit data associated with a CPAP device); Ex. 1011, 2 (disclosing that an iPAQ cell phone is capable of communicating using Bluetooth protocol).

260. Burton explains that “user data viewing and reports” can be interfaced using “W-LAN and even Bluetooth™ wireless devices.” Ex. 1050, 8:28-9:2. Moreover, Kumar explains that the data from the PAP device may be processed and displayed on computing device 110 (“cell phone”). Ex. 1008, [0075]. Thus, as a POSITA would have recognized, following a treatment session, the patient would have been interested in downloading and viewing the data related to the treatment on the cell phone.

261. In addition to Burton’s express teaching using Bluetooth for data/report viewing, there were only a handful of other protocol for transmitting data wirelessly, including WiFi, mobile network protocol, optical connection, for example. Thus, using the Bluetooth protocol for wireless transmission would have been obvious because it would have been one of a “finite number of identified, predictable solutions.”

262. Thus, a POSITA would have been motivated and found it obvious to use the Bluetooth protocol for “transmit[ting] PAP therapy efficacy data” from the PAP device (via its “second radio frequency wireless transceiver”) to computing

device 110 (via its “first software adapted to use the at least one first radio frequency wireless transceiver”).

Claim 10, 15, 20. “The system in claim [7/12/17], wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or 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 time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.”

263. In my opinion, Toge in view of Kumar and Burton discloses this limitation. Burton discloses processing the airflow sensor data by “calculat[ing] some statistical measurements...such as mean, **deviation**, average and maximum error....” Ex. 1050, 17:22-25. In my opinion a POSITA would have understood that calculating deviation encompasses calculating one of the known types of deviation, e.g., mean deviation, standard deviation, and quartile deviation. Ex. 1055, 28-30 (disclosing various processing techniques known at the time including “wavelet analysis”, “standard deviation or variance”, and “Fast Fourier Transform (FFT) algorithm”).

264. Thus, processing sensor data using a known signal processing technique such as the standard deviation technique would have been obvious because it would have been one of a “finite number of identified, predictable solutions.”

Claim 11, 16, 22. “The system of claim 7/12/17, wherein the first data of the PAP therapy efficacy data includes specific symptom data related to both obstructive, and central apneas.”

265. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

266. As discussed for limitation [1.b.v.A], the “first data” includes “at least one index or derived data set,” which may include “**Mixed Sleep Apnea** events, **Central Sleep Apnea** events, Upper Airway Resistance Syndrome (UARS) events, **Obstructive sleep apnea** and hypopnea syndrome (OSAHS) events....” Ex. 1050, 21:4-22:21. In my opinion a POSITA would have understood that “Mixed Sleep Apnea events” include events of both central apnea and obstructive apnea.

Claim 12. “The system in claim 4, wherein the first software adapted to be executed by the first processor of the cell phone to receive, in whole or part, the PAP therapy efficacy data generated by the one or more PAP device and/or the modified therapy efficacy data based in part on the PAP therapy efficacy data that is first received at least in part from the PAP device by the remote internet site and then retransmitted to the first software from the remote internet site.”

267. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

268. As discussed for claim 7, a POSITA would have been motivated and found it obvious to transmit from computing device 110 (“cell phone”) by using its

RF transmitter (“first radio frequency wireless transceiver”) the processed “PAP therapy efficacy data generated by the one or more PAP device” to the browser-based engine (“remote internet site”) for secured storage, **later access, replay, and/or analysis**. Ex. 1008, [0083], [0084].

269. Thus, for similar reasons, a POSITA would have found it obvious to receive/download those “data” previously transmitted to the browser-based engine (“the remote internet site”) for “later access, replay, and/or analysis.” Ex. 1008, [0083], [0084].

Claim 13. “The system in claim 12, wherein the one or more PAP device(s) and the first software adapted for use with the cell phone are further adapted to transmit and receive data based on the PAP therapy efficacy via a cellular network or through the Internet.”

270. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

271. As discussed for limitation [1.b.iv], Toge discloses that network 1 may be “a **mobile** communication network” (*id.*, [0009]) and that **PAP device 2**, relay device 3, physician-side computer 4 are wirelessly **connected to communication network 1** for transmitting data (*id.*, [0006]-[0007]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1). Thus, the PAP device and the cell phone are “adapted to transmit and receive data based on the PAP therapy efficacy via a cellular network.”

Claim 17. “The system in claim 4, wherein the first software is adapted to be executed by the first processor of the cell phone and the remote internet site both independently receives, in whole or part, the PAP therapy efficacy data generated by the one or more PAP device and/or the modified therapy efficacy data based in part on the PAP therapy efficacy data.”

272. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

273. As discussed for limitation [1.e], the Toge-Kumar-Burton combination discloses a browser-based engine (“remote internet site”) that receives “PAP therapy efficacy data” generated by the PAP device. Kumar additionally discloses that data may be transferred “**directly** from one device to the other” (Ex. 1008, [0081]), e.g., from the PAP device to the computing device 110 (“cell phone”). Accordingly, the Toge-Burton-Kumar combination discloses the software adapted to be executed by the processor of computing device 110 (“cell phone”) and the browser-based engine (“remote internet site”) each separately/independently receive “PAP therapy efficacy data” generated by the PAP device.”

Claim 18. “The system in claim 17, the one or more PAP device(s) further comprises an electronic component adapted to transmit the PAP therapy efficacy data to the remote internet site at least in part via a cellular network, and the second radio frequency wireless transceiver of the one or more PAP device(s) is used to transmit PAP therapy efficacy data of the subject to the first software adapted to use the first radio frequency wireless transceiver of the cell

phone using a Bluetooth wireless protocol.”

274. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

275. As discussed for limitation [1.e], the Toge-Burton-Kumar combination discloses that the PAP device transmits “the PAP therapy efficacy data” to the browser-based engine (“remote internet site”). As discussed for the preamble, Toge discloses the PAP device is connected to a mobile network (“cellular network”). In my opinion a POSITA would have understood that the PAP device “further comprises an electronic component adapted to transmit the PAP therapy efficacy data to the remote internet site at least in part via a cellular network.”

276. As discussed for claim 8, the Toge-Burton-Kumar combination discloses using the Bluetooth protocol to transmit “PAP therapy efficacy data” from the PAP device to the cell phone. Thus, for reasons discussed for claim 8, the Toge-Burton-Kumar combination discloses “the second radio frequency wireless transceiver of the one or more PAP device(s) is used to transmit PAP therapy efficacy data of the subject to the first software adapted to use the first radio frequency wireless transceiver of the cell phone using a Bluetooth wireless protocol.”

Claim 23, 25. “The system of claim [4/2], wherein the at least one second software with the remote internet site and the database are adapted to be accessible to a clinician or

doctor of the subject for a remote monitoring of the patient and/or their PAP therapy when hosted on the at least one server.”

277. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

278. As discussed for limitations [1.c] and [1.c.1], the Toge-Burton-Kumar combination discloses that a browser-based engine (“remote internet site”) and database/storage are implemented/hosted on a central server. *See*, e.g., Ex. 1008, [0010], [0018], [0067], [0072], [0083], [0087]. Kumar explains that “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.” *Id.*, [0192]; *see also id.* [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”).

Claim 24, 26. “The system of claim [23/25], wherein the at least one second software is adapted to perform automatic data analysis for the clinician or doctor for use with the remote monitoring when hosted on the at least one server or with a third processor.”

279. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

280. Kumar discloses that storing data at the browser-based engine allows “the creation of statistical databases.” Ex. 1008, [0083]. Moreover, Kumar explains

that “the healthcare provider can view a statistical summary report” and “a graphical report that can also be displayed” for use with remote monitoring. *Id.*, [0092]. In my opinion a POSITA would have understood that the statistical summary report and/or the graphical report are automatically generated by the central server, on which the “software” is executed. Additionally, a POSITA would have understood that either of the statistical summary report or the graphical report is an example of “data analysis.” Accordingly, Kumar discloses that the “software” is adapted to perform “automatic data analysis” for healthcare provider (“the clinician or doctor”) “for use with the remote monitoring when hosted on the at least one server or with a third processor.”

Claim 27: “The system in claim 1, wherein the remote internet site and/or the database are adapted to be accessible one or more of clinicians, technicians, researchers or doctors for analysis or a remote monitoring of one or more of the subjects in another country.”

281. In my opinion, Toge in view of Kumar and Burton discloses this limitation.

282. Kumar discloses that “[t]he system can also be adapted to make such specialized treatment available worldwide via the Internet, by allowing the provider to use his existing protocol to treat patients in another state or **country**.” Ex. 1008, [0181].

Claim 28: “The system in claim 1, wherein the database

with the PAP therapy efficacy data is adapted to be analyzed to recognize patterns of sleep disorders or therapy for sleep disorders.”

Claim 29: “The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to train a neural network.”

Claim 30: “The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to correlate more robust data from multiple subjects to teach or train the sensor on the one or more PAP device(s).”

Claim 31: “The system in claim 28, wherein the database with the PAP therapy efficacy data is adapted to be analyzed with a relationship algorithm.”

283. The Toge-Burton-Kumar combination discloses claims 28-31. As discussed for limitation [1.e], based on the teachings of Toge, Burton, and Kumar, a POSITA would have been motivated to implement the remote internet site, including configure the “second software for the remote internet site and the database” such that it is adapted to receive data associated the patient’s treatment, including “the PAP therapy efficacy data.” Such a feature would have been beneficial as Kumar explains that “the data may be stored in a secured storage device at the central server for **later access, replay, and/or analysis.**” EX1008, [0083].

284. Kumar also explains that the database may “**integrate** the [stored] data, whether as raw data, **trended data**, or **summary data**, into any electronic medical records system” and “allows for the creation of **statistical databases.**”

EX1008, [0083]. Accordingly, Kumar discloses and/or suggests performing additional analysis, e.g., data integration, data trend recognition, and statistical analysis on the data stored at the database (e.g., the PAP therapy efficacy data stored at the database as disclosed by the Toge-Burton-Kumar combination).

285. Kumar and Burton each discusses various techniques to analyze data. For example, Kumar discloses “using **artificial intelligence**” to “**track trends**” and “predict future behaviors and physiological responses.” EX1008, [0084]. Burton discloses that its algorithm detects “**patterns** which are indicative of sleep apnea symptoms.” EX1050, 14:1-7. Burton also discloses techniques including “**neural networks** or other methods that are capable of **adopting self-learning and algorithm adaptation techniques**.” *Id.*, 4:29-32.

286. In my opinion a POSITA would have been motivated to use the above-described techniques to analyze the PAP therapy efficacy data stored at the database because, for example, Kumar expressly discloses that data stored at the database allows for “**later access...and/or analysis**” from “anywhere in the world,” which “beneficially allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online.” EX1008, [0083]. In my opinion a POSITA would have understood that subsequent studies of the data stored on the database would have allowed the care providers to analyze

patterns and statistical significances of the patients' long-term or cumulative data associated with the sleep disorder treatment/efficacy.

287. In my opinion a POSITA would have had a reasonable expectation of success in implementing the above-discussed features in the Toge-Kumar-Burton combination. Indeed, it would have involved a combination of known technologies (*e.g.*, known database storing the PAP therapy efficacy data for later access/analysis (Toge-Kumar-Burton)) according to known methods (*e.g.*, known techniques to analyze data associated with sleep disorder (Kumar and Burton)) to yield the predictable result of database storing the PAP therapy efficacy data adapted for later access and analysis based on various known techniques, as discussed above.

288. The Toge-Kumar-Burton combination discloses claims 28-31. Specifically, the Toge-Kumar-Burton combination discloses claim 28 (“the PAP therapy efficacy data is adapted to be analyzed to **recognize patterns** of sleep disorders or therapy for sleep disorders”) given that Kumar discloses applying techniques to recognize data trends (EX1008, [0083]) and Burton discloses detecting patterns on data associated with sleep disorder (EX1050, 14:1-7). The Toge-Kumar-Burton combination discloses claim 29 (“the database with the PAP therapy efficacy data is adapted to be analyzed to train **a neural network**”) because Burton discloses applying techniques including “neural networks or other methods that are capable of adopting self-learning and algorithm adaptation techniques.” EX1050, 4:29-32.

289. Additionally, the Toge-Kumar-Burton combination discloses claim 30 (“the database with the PAP therapy efficacy data is adapted to be analyzed to **correlate more robust data from multiple subjects to teach or train the sensor on the one or more PAP device(s)**”). Burton explains that data analysis may be based on “individual patient collected or collected data (from diagnostic study within sleep laboratory or other alternative site.” EX1050, 26:12-15. In my opinion a POSITA would have understood that “collected data (from diagnostic study within sleep laboratory or other alternative site” are “data from multiple subjects,” as claimed. Moreover, as discussed above, Burton discloses applying “self-learning and algorithm adaptation techniques.” In my opinion a POSITA would have understood that such techniques involve using data (including those from various patients) to improve/train the algorithm on the PAP device that operates based on sensor data.

290. Lastly, the Toge-Kumar-Burton combination discloses claim 31 (“the database with the PAP therapy efficacy data is adapted to be **analyzed with a relationship algorithm**”) given that Kumar discloses applying “using artificial intelligence” to “predict future behaviors and physiological responses.” EX1008, [0084]. Furthermore, Burton discloses “down-load[ing] [data] from sleep laboratory studies or other types of previous sleep, respiratory...related investigations.” EX1050, 20:14-15. These data are “associated with a subject’s breathing and sleep

arousal parameters,” are “used to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of [different types of arousal events], while still minimizing sleep fragmentation and optimizing sleep quality.” *Id.*, 20:15-19.

XII. OPINIONS ON GROUND 2: TOGE IN VIEW OF KUMAR, BURTON, AND KISNER RENDERS OBVIOUS CLAIMS 10, 15, AND 20

A. A POSITA Would Have Been Motivated to Combine

291. In my opinion a POSITA would have been motivated to implement Kisner’s teaching in the Toge-Kumar-Burton combination. Kisner teaches analyzing sensor data on a processor, including using the wavelet analysis to extract breathing parameters. Ex. 1051, 13:36-53. Based on the extracted parameters, the processor may alert the care provider of the patient’s condition. *Id.*

292. Moreover, a POSITA would have understood that wavelet analysis is known to be used for assessing breathing patterns because it can analyze signals at multiple time scales, capturing both short-term fluctuations and long-term trends. Indeed, wavelet analysis allows for signal decomposition into various frequency bands, and by classifying various frequency component, relevant breathing signal features, properties and classifications of the breathing signal can be determined. Real time monitoring of signals using a wavelet analysis is one of the known ways to examine dynamic breathing patterns that change over time, such as for apnea or hypopnea classification/detection. Thus, a POSITA would have understood that

using the disclosed feature with the air flow/pressure sensor(s) disclosed in the Toge-Burton-Kumar combination would have improved treatments and/or remote monitoring.

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

293. In my opinion a POSITA would have had a reasonable expectation of success in implementing Kisner's teaching in the Toge-Burton-Kumar combination.

294. First, similar to the Toge-Kumar-Burton combination, where the PAP device control algorithm is implemented in a processor (*see* limitation [1.b.v.A]), Kisner explains that the algorithm for the wavelet analysis is implemented in a microprocessor system. Ex. 1051, 13:36-53.

295. Second, similar to Burton that discloses using neural networks to detect airflow shape variations (Ex. 1050, 4:29-32), Kisner also discloses using neural networks to analyze/process the sensor signals (Ex. 1051, 13:42-45).

296. Third, such an implementation would have involved a combination of known technologies (PAP device that use sensors to detect and treat sleep disorder, as taught by the Toge-Kumar-Burton combination) according to known methods (using a wavelet analysis algorithm to extract breathing patterns as taught by Kisner) to yield the predictable result of a system including an improved PAP device in treating sleep disorder.

- C. **Dependent Claims 10, 15, and 20: “The system in claim [7/12/17], wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or 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 time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.”**

297. In my opinion Ground 1 establishes that the combinations of prior art teachings a POSITA would have implemented to improve the Toge PAP device in view of Kumar and Burton that discloses the challenged claims. Section XI (Ground 1). To the extent that the prior art combination does not disclose claims 10, 15, and 20, reciting “wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of...a wavelet analysis,” in my opinion, it would have been obvious to implement this feature into the system resulting from these combinations in light of Kisner.

298. Like Toge and Burton, Kisner discloses a method for monitoring a patient’s respiration, including monitoring sleep disorders, e.g., apnea. Ex. 1051, Abstract, 12:59-13-11 (“In the case of the apnea monitor, this system performs the following digital signal processing actions....”). Kisner additionally discloses the monitoring process may be implemented in a microprocessor system that extracts “[b]reathing parameters...using **wavelet analysis** or similar means,” where the

extracted signals “are processed using threshold, fuzz-logic, neural networks or similar processing technique...to determine if an alarm or other desired output condition exists.” *Id.*, 13:36-53. In particular, as shown in Figure 11 below, Kisner explains that sensor signals 104 are first reconstructed using neural networks or other algorithms to form true components signals 108. *Id.*, 13:42-45.

299. Kisner goes on to explain that “[b]reathing parameters are extracted from...signals 108 using wavelet analysis or similar means to generate signal 116,” where “signal 108 are [also] matched with known anomalies at 114 to generate signals 118.” *Id.*, 13:45-49. “Signals 116 and 118 are processed using threshold, fuzz-logic, neural networks or similar processing technique at 120 **to determine if an alarm or other desired output condition exists which is expressed and communicated by signal 122.**” *Id.*, 13:49-53, Fig. 11 (immediately below).

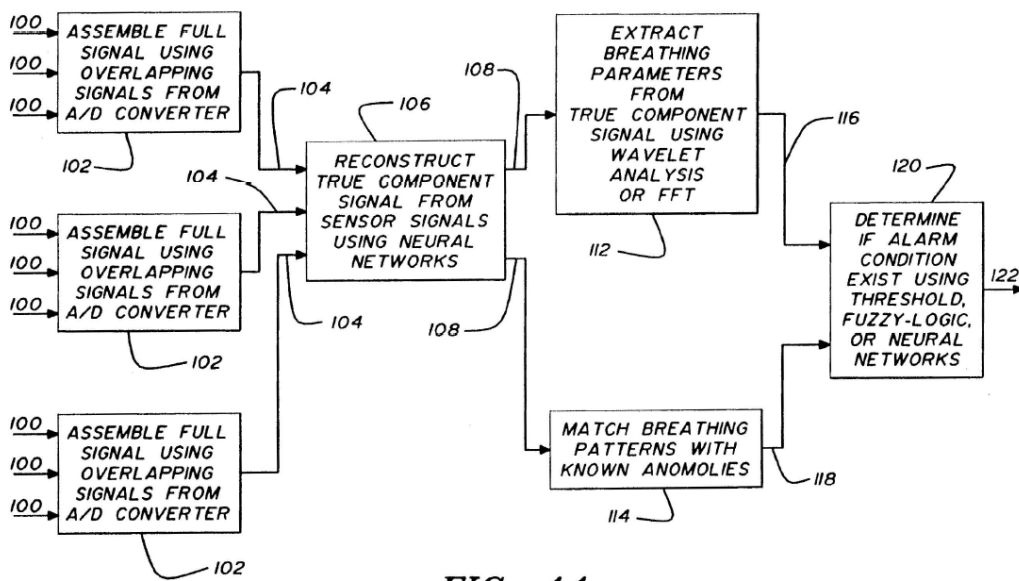


FIG. 11

300. Accordingly, Kisner discloses “wherein the signal from the sensor...is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of...a wavelet analysis” as recited in claims 10, 15, and 20.

301. In my opinion, a POSITA would have been motivated and found it obvious to implement Kisner’s teaching in the Toge-Burton-Kumar combination discussed in Ground 1. As discussed above, Kisner teaches using the result from the wavelet analysis to notify the care provider. Ex. 1051, 15:27-31 (“The output signal can be used as the input signal to any desired output device such as a digital display or an audio alarm which would alert the caregiver or person monitoring the subject to a change in the subject’s condition.”). Moreover, a POSITA would have understood that wavelet analysis is known at the time (Ex. 1055, 28-30 (disclosing various processing techniques known at the time including “wavelet analysis”, “standard deviation or variance”, and “Fast Fourier Transform (FFT) algorithm”)) and is be used for assessing breathing patterns because it can analyze signals at multiple time scales, capturing both short-term fluctuations and long-term trends. Indeed, wavelet analysis allows for signal decomposition into various frequency bands, and by classifying various frequency component, relevant breathing signal features, properties and classifications of the breathing signal can be determined. Real time monitoring of signals using a wavelet analysis is one of the known ways

to examine dynamic breathing patterns that change over time, such as for apnea or hypopnea classification/detection. Thus, a POSITA would have understood that using the disclosed feature with the air flow/pressure sensor(s) disclosed in the Toge-Kumar-Burton combination would have improved treatments and/or remote monitoring. *Id.*

302. In my opinion a POSITA would have also had the skill and reasonable expectation of success in implementing the teachings of Kisner in the Toge-Kumar-Burton combination. Similar to the Toge-Kumar-Burton combination, where the PAP device control algorithm is implemented in a processor (*see* limitation [1.b.v.A]), Kisner explains that the algorithm for the wavelet analysis is implemented in a microprocessor system. Ex. 1051, 13:36-53. Additionally, similar to Burton that discloses using neural networks to detect airflow shape variations (Ex. 1050, 4:29-32), Kisner also discloses using neural networks to analyze/process the sensor signals (Ex. 1051, 13:42-45). Furthermore, the '680 patent acknowledges that the wavelet analysis is one of the “signal processing algorithms known to those skilled in the art.” Ex. 1001, 26:67-27:5. Moreover, it would have involved a combination of known technologies (PAP device that use sensors to detect and treat sleep disorder, as taught by the Toge-Kumar-Burton combination) according to known methods (using a wavelet analysis algorithm to extract breathing patterns as

taught by Kisner) to yield the predictable result of a system including an improved PAP device in treating sleep disorder, as discussed above.

XIII. CONCLUSION

303. For all the reasons stated above, it is my opinion that the challenged claims of the '680 patent are unpatentable.

304. This declaration and my opinions are made to the best of my knowledge and understanding, and are 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 December 6, 2024.