

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

Case IPR2025-00246

**DECLARATION OF JASON KIRKNESS, PH.D. IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,857,333**

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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. 11,857,333 relative to the state of the art at the time of the earliest application to which the ’333 patent claims priority. My analysis relates to claims 15-29. 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 ’333 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 15-29 of the ’333 patent are unpatentable based on the following grounds.

Ground 1	Toge in view of Kumar renders obvious claims 15-17, 20-24, 26-29
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Ground 3	Toge in view of Kumar and Burton renders obvious claim 19

Ground 4	Toge in view of Kumar, Norman, and Burton renders obvious claim 19
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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 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 '333 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 '333 patent originates from Patent Application 15/641,715 filed on July 5, 2017, 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 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.

A. 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, Abstract. As Toge, Kumar, Norman, 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.

B. 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), in my opinion, a POSITA would have known that AHI, like hypopnea, can be determined a number of different ways, including by measuring both breathing volume and blood oxygen saturation, or by measuring breathing patterns through measured flow or air pressure data.

67. By way of another example, RDI is calculated as the number of apnea events per hour plus the number of hypopnea events per hour plus the number of respiratory-effort related arousals per hour of sleep. There are also metrics such as Oxygen Desaturation Index (ODI), that focus on the sufficiency/insufficiency of blood oxygen levels during sleep. In describing one device developed in the mid-1990s, a few 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. 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. *Id.* at Summary, Fig. 2.

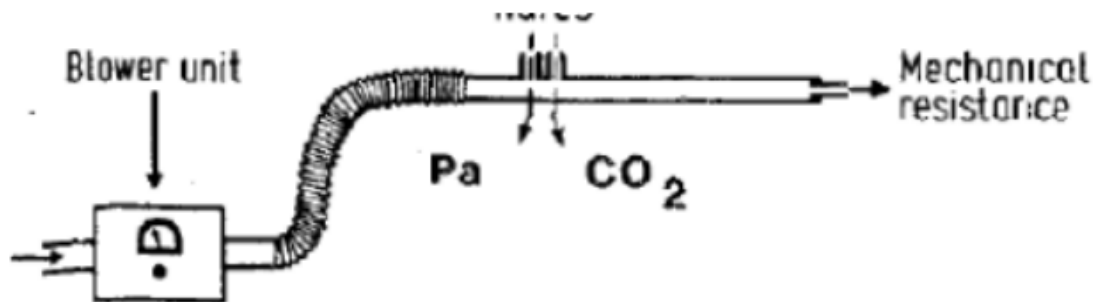
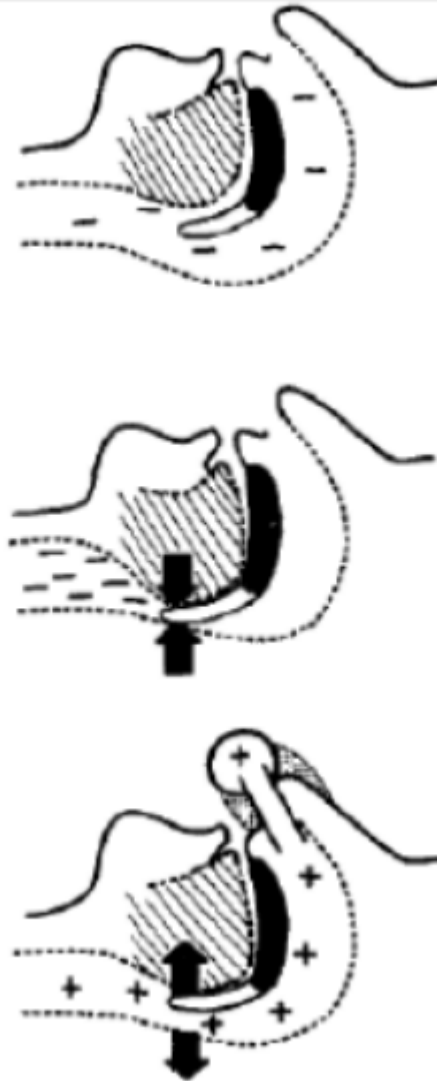


Fig. 2—Diagram of apparatus used to provide continuous positive airway pressure through the nares.

71. To prevent collapse of the patient's airway, PAP therapy applies positive airway pressure, which opposes the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). Ex. 1016 at p. 1, Fig. 1 (reproduced below).

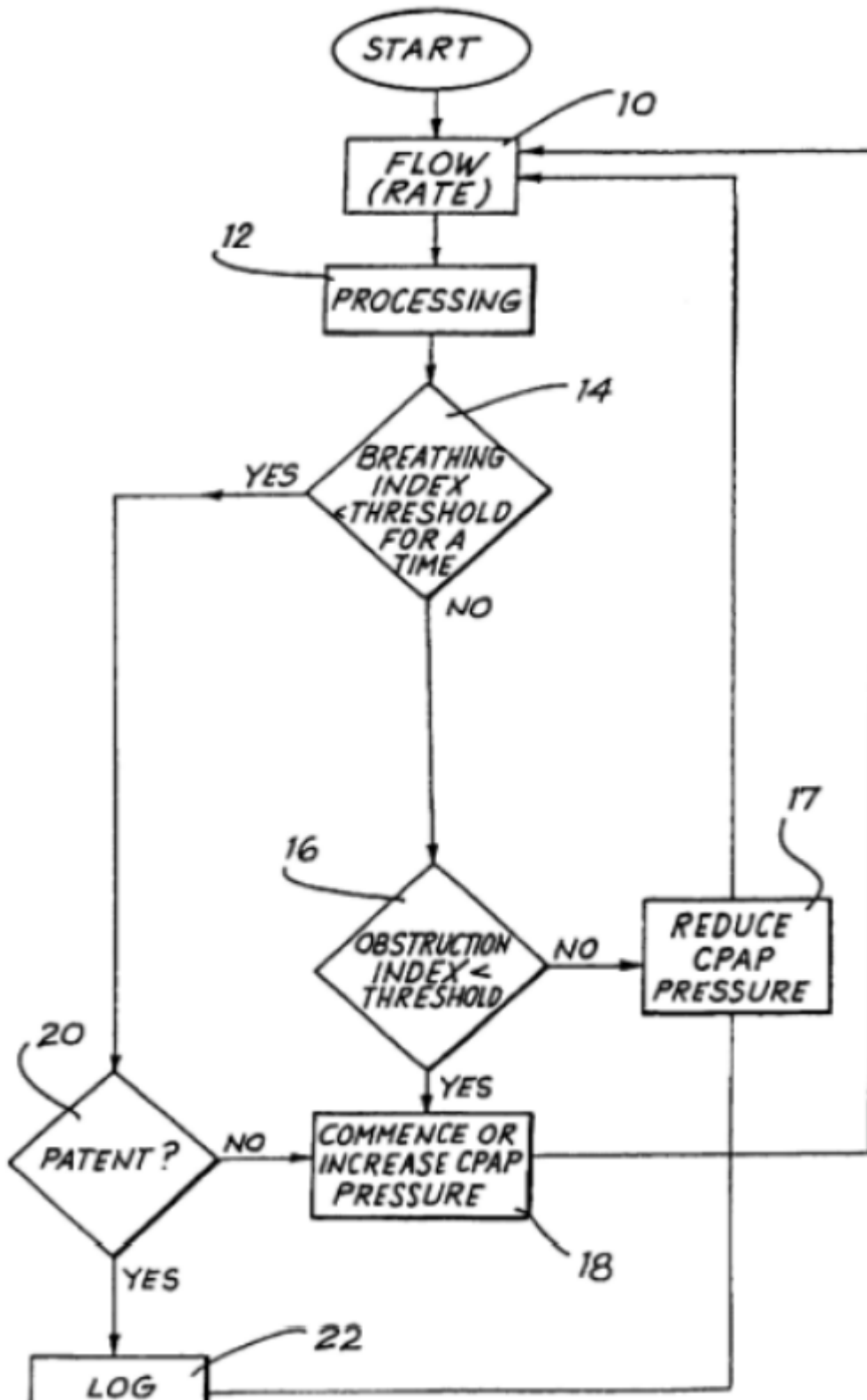


72. In their 1981 paper describing continuous PAP (“CPAP”), Dr. Sullivan, Dr. Berthon-Jones, and their colleagues described treating five OSA patients with CPAP therapy, applying low pressure levels (4.5-10 cm H₂O), which “completely prevented upper airway occlusion during sleep in each patient” and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

73. Generally, a prescription and patient training for PAP therapy is “performed in, or directly under, the supervision of the sleep disorders laboratory.” Ex. 1016 at p. 5 col 1. After a full night of observation in the laboratory, a physician will prescribe a therapeutic pressure for the patient and PAP machine for home use. But, as PAP therapy research developed, the industry began examining a variable approach that “would improve on, and possibly do away with, the one-size-fits-all pressure determination night.” Ex. 1015 at p. 1 col. 1.

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

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



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

77. By the mid-1990s, it was well-understood that the major limitation of CPAP therapy relates to discomfort or other factors leading to incomplete compliance with the necessary use of the device. Ex. 1025 at p. 5. As Dr. Berthon-Jones explained, “patients feel uncomfortable at high CPAP pressures,” and will “object violently to [high pressure] while they are wide awake trying to go to sleep on an ordinary night.” Ex. 1015 at p. 4. Thus, it quickly became well-recognized that lowering to the minimal pressure could increase compliance. *Id.* Consequently, automatically adjusting PAP machines became common, particularly those that “automatically adjust the degree of assistance to maintaining at least a specified minimum ventilation.” Ex. 1024 at Abstract.

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

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

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

81. Additional CPAP devices have been released well before the earliest possible priority date of the ’333 patent, including Sunrise Medical’s DeVilbiss

AutoAdjust LT Nasal CPAP System (Ex. 1028 at p. 24), Resironics' 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 enhances 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).

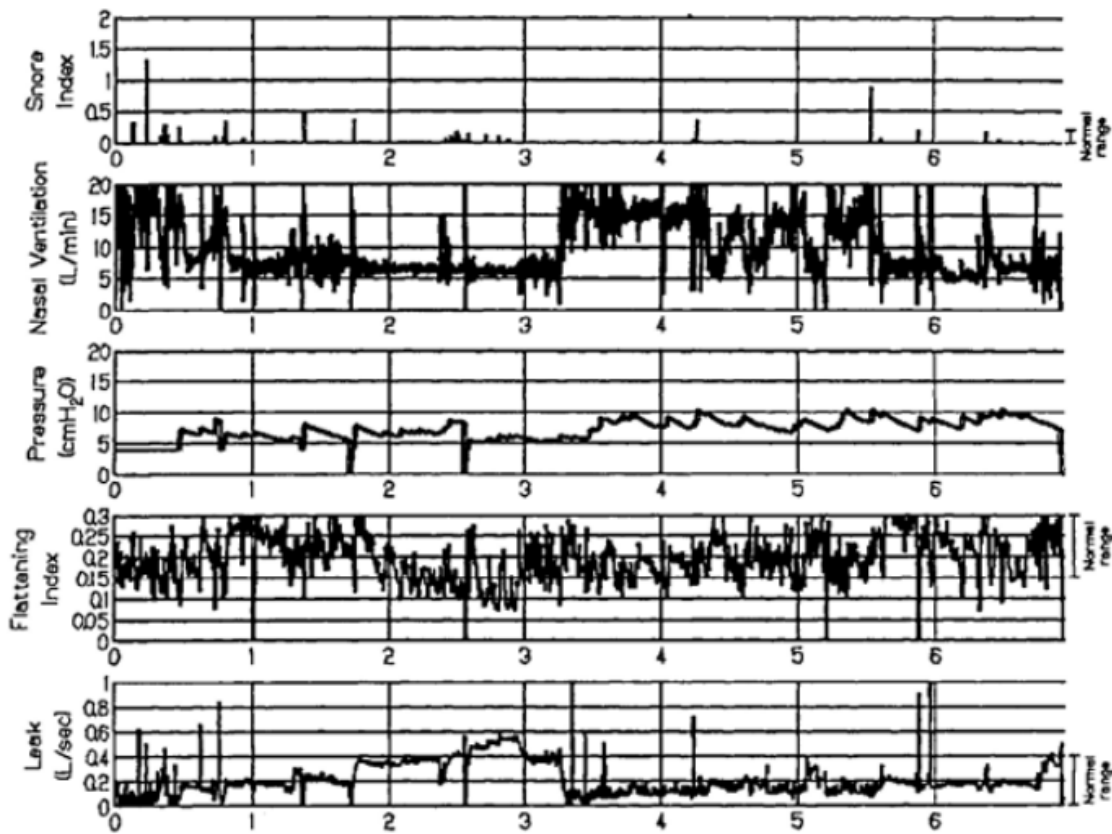


FIGURE 1. Example of cumulative overnight automatic CPAP data report for a patient with severe OSAS. Used with permission of ResMed Corporation.

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A. TELEMEDICINE

94. The development of home sleep testing (HST) solutions began in the mid to late 1980s, with early devices focusing on ambulatory monitoring of arterial oxygen saturation and cardiopulmonary sleep studies. These initial systems were relatively primitive compared to modern standards. By the 1990s, there was a growing awareness of OSA and its health consequences, which increased the urgency to develop cost-effective diagnostic methods. This led to the creation of

more reliable, portable, and user-friendly HST devices in early 2000's, allowing patients to undergo sleep studies in their own homes. Recorded physiological data stored on the device is transferred to a personal computer through an integrated interface (FDA 510(K) K040576). These advancements made sleep testing more accessible and convenient, reducing the need for in-lab studies.

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

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

ongoing support for these interventions was limited, often resulting in inconsistent adherence and follow-up.

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

98. In 1999, Loube wrote that “Compensation issues may be critical to the clinical utilization of new technologies including automatic CPAP. In the United

States, Medicare and most third-party payers currently will not reimburse for either attended or unattended automatic CPAP titration studies. The future trend may be for the automatic CPAP manufacturers to add additional diagnostic recording capabilities to these systems to allow for compensation as an attended cardiorespiratory (four-channel) study monitoring airflow, respiratory effort, oxygen saturation, and heart rate.” Ex. 1033.

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

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

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

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

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

103. Remote physiological and treatment monitoring has evolved into comprehensive systems encompassing data collection, analysis, and decision-

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

VIII. THE '333 PATENT

104. The claims of the '333 patent describe well-known PAP sleep disorder treatment devices implemented in a networked system. The '333 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, 2:45-48.

105. The system includes a PAP device 428, (Figure 8 below) that provides positive air pressure to a subject 410 with a mask 412 connected by air hose 416. *Id.*, 49:26-49:33. 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.*, 49:35-38. Diagnostic device 441 "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.*, 49:40-45.

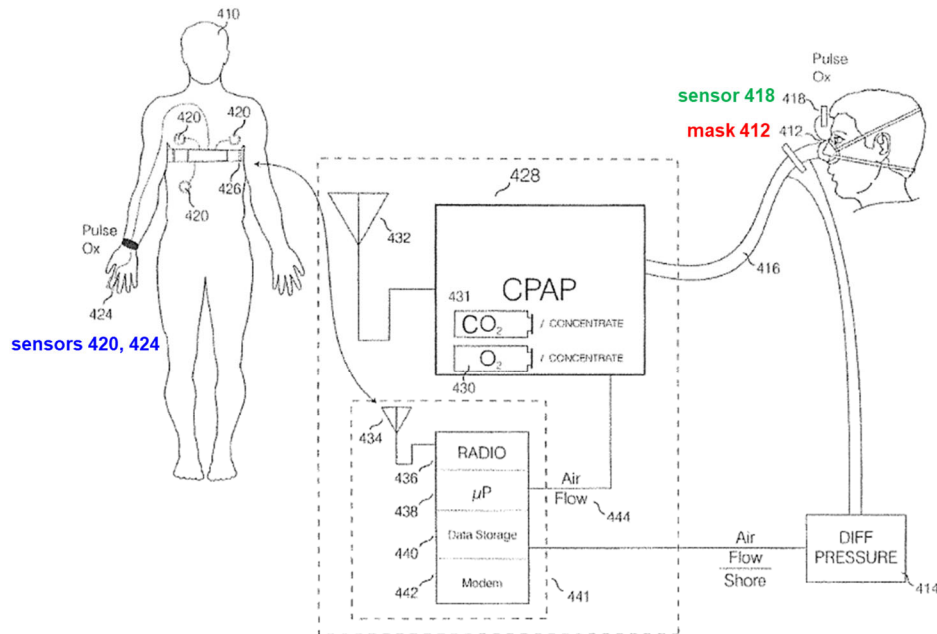


Fig. 8

Ex. 1001, Figure 8 (annotated)

106. The '333 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, 51:37-52:7. As discussed in Sections XI-

XV below, the above-described features, including those recited in the challenged claims, were well-known in the art, and disclosed by Toge, Norman, Burton, and/or Kumar. In fact, the '333 patent acknowledges that various claimed features were known in the art. For example, the '333 patent acknowledges that “collecting data with the PAP or CPAP device from the flow or pressure sensor ,” “radio frequency wireless link,” determination of “a quantified level of severity data,” and “Wavelet signal analysis,” as recited in the '333 patent claims were known. In particular, the '333 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.*, 13:9-11.
- “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.*, 20:66-21:3.
- “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.*, 22:47-22:50.
- “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-

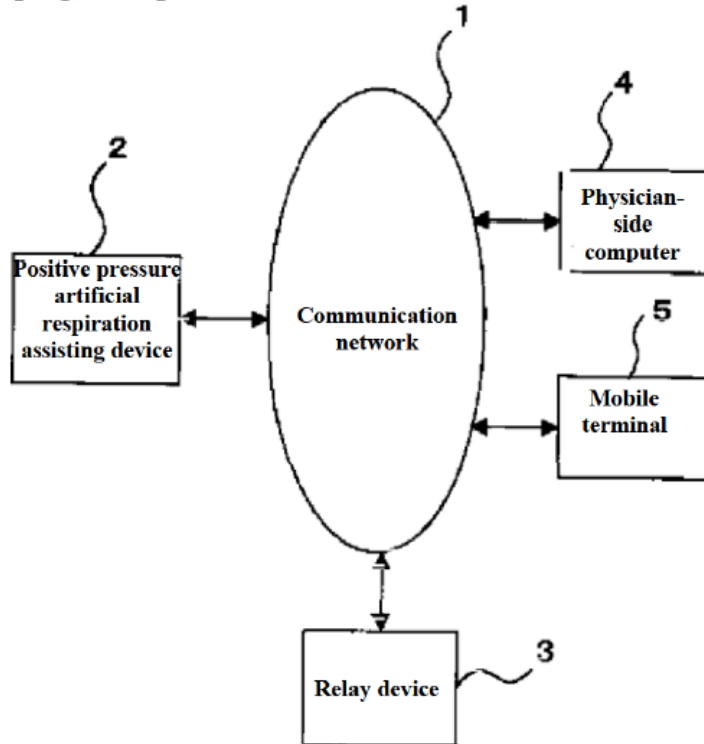
frequency analysis with a particular kernel function, to identify the shift in power spectrum associated with imminent flow separation that is discussed herein.” *Id.*, 23:5-10.

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]



Ex. 1044, 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, a dedicated line network, or a combination of these networks. *Id.*, [0009].

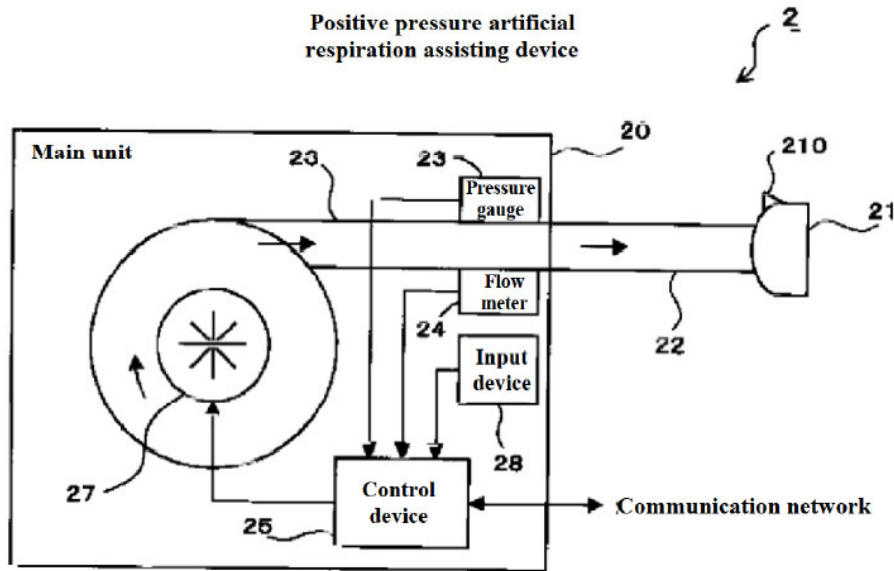
109. Toge's PAP device includes a relay device (3) that is installed within the PAP device and that receives data from the PAP device and then transmits all or part of the data to the physician side terminal device (4). *Id.*, [0016]. The relay device (3) can also download all or specified data received 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]

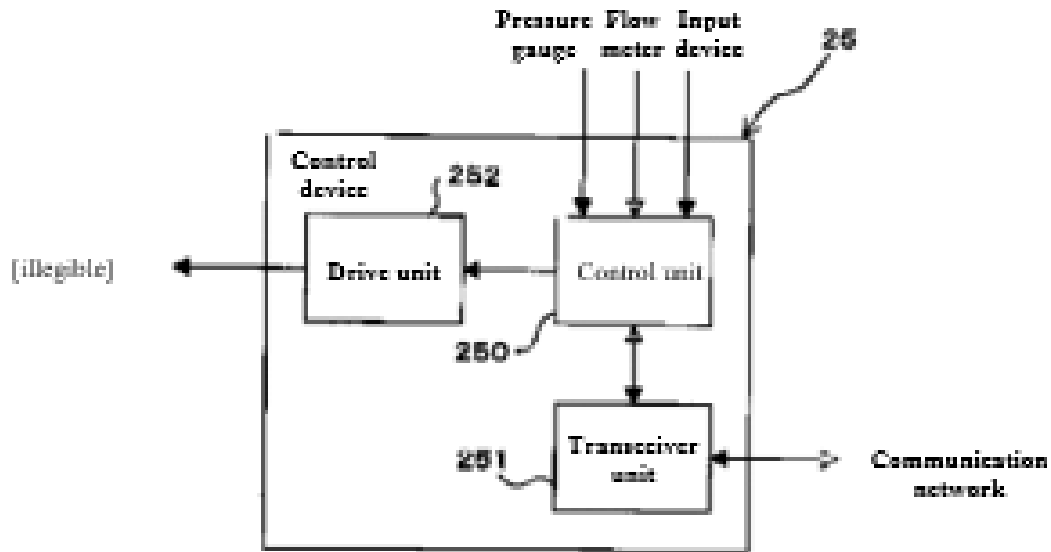


Ex. 1044, FIG. 2

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]



Ex. 1044, FIG. 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 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. *Id.*, [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.”).

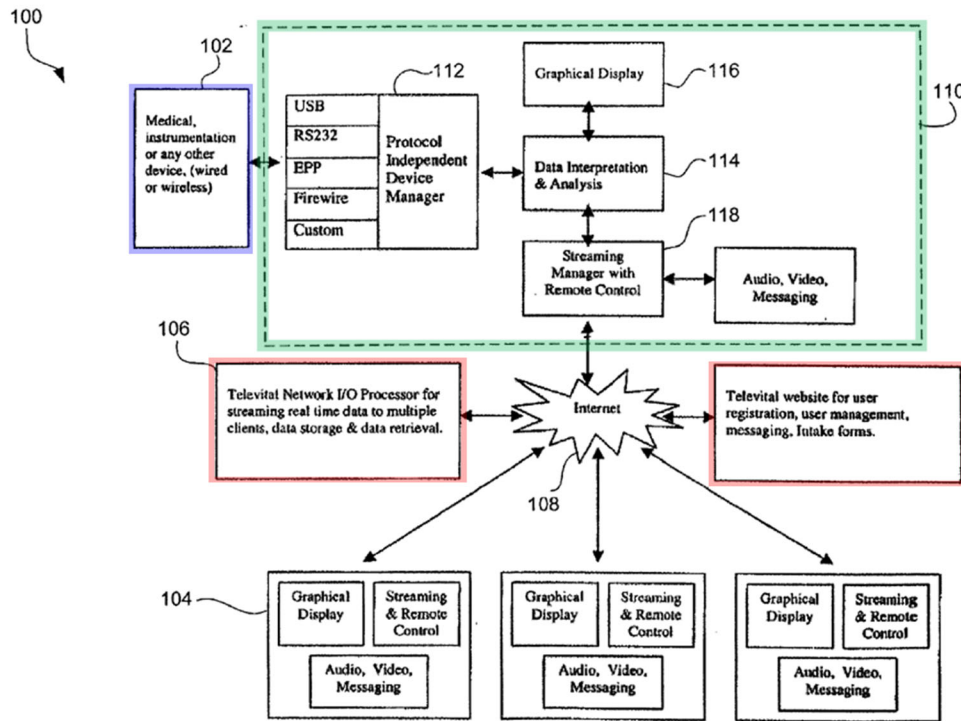


Fig. 1A

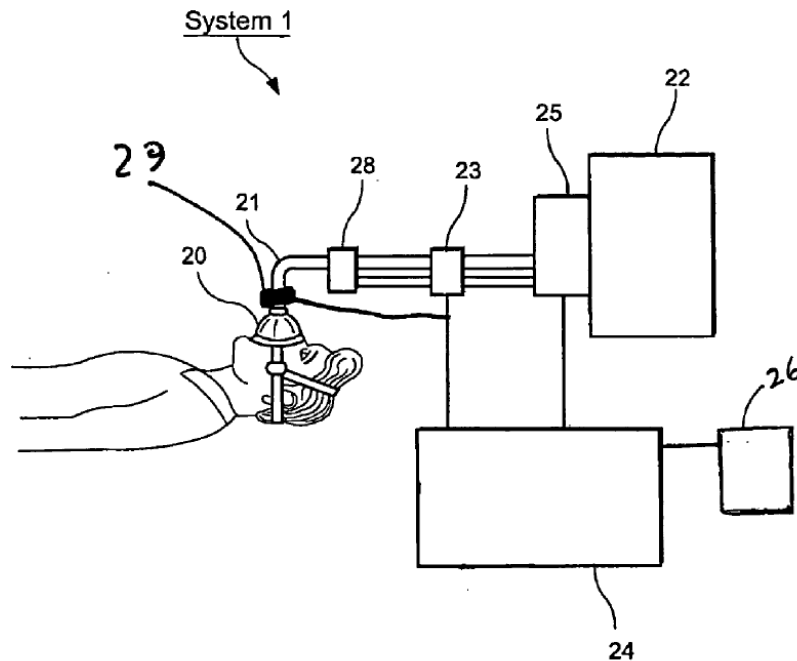
Ex. 1008, FIG. 1A

118. 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. NORMAN (EX. 1059)

119. Norman discloses a CPAP system including “an air pressure supply providing air pressure to a patient’s airways and a sensor detecting input data corresponding to a patient’s breathing patterns of a plurality of breaths.” Ex. 1059, Abstract.

120. Norman discloses a CPAP system 1 (*see* Figure 6 below) including a mask 20 that is connected via a tube 21 to receive airflow at a particular pressure from a flow generator 22, where “[t]he amount of pressure provided to a particular patient varies depending on that patient’s particular condition.” *Id.*, [0019]. “Flow and/or pressure sensors 23” are coupled to the tube 21 to “detect “the volume of the airflow to and from the patient and the pressure supplied to the patient,” by the generator 22, where “sensors 23 may be internal...to the generator 22.” *Id.*, [0020]. “Signals corresponding to the airflow and the pressure from the sensors 23 are provided to a processing arrangement 24,” which then “generates pressure control outputs signals to a flow control device 25 that “controls the pressure applied to the flow tube 21 by the flow generator 22.” *Id.*



Ex. 1059, FIG. 6

121. Norman's system may "detect[] abnormal respirations and flow limitations in the patient's airway" and/or detect "sleeping disorders (e.g., flow limitations), and may be used for "autotitration and treatment of such sleeping disorders." *Id.*, [0022]. "[S]ystem 1 also includes an automatic titration device 26 which provides an initial titration (i.e., determination of an appropriate pressure or an appropriate varying pressure function for a particular patient) as well as subsequent retitrations." *Id.*, [0023]. Titration device 26 may be "built into the system 1 (e.g., the titration device 26 may be combined with the processing arrangement 24)."

D. BURTON (EX. 1050)

122. 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.

123. Burton discloses a system that “deliver[es] therapeutic treatments to patients without adversely affecting their sleep.” *Id.*, 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.

124. “[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.

125. 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.

126. 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.”** *Id.*, 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.”**).

127. 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 [i.e., upper airway resistance], OSAHS [i.e., Obstructive sleep apnea and hypopnea syndrome], RERAs [i.e., Respiratory Effort-Related Arousals] and TERAs [i.e., Therapeutic control Related Arousals] 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...**”).

128. 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:

129. I have applied the plain meaning of the terms and phrases in the claims in my analysis, in my opinion, as a POSITA would have understood those terms and phrases at the relevant time (around 2005). However, with respect to the following two limitations, I have been asked to adopt the Patent Owner’s interpretations of these terms as described in Patent Owner’s opening claim construction brief in the parallel district court action, for the purpose of forming my opinions:

- “transmitting, in either order, both 1) the collected data and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone to a remote station via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician” (recited in claim limitation [15.d]).

- “therapy efficacy data” (recited in limitation [15.e.1])

130. Specifically, I reviewed the portion of the Patent Owner’s Opening Claim Construction Brief relating to these two terms. I understand that Patent Owner interprets limitation [15.d] as being definite. Ex. 1054, 22 (“A POSITA would understand from the detailed description of the method for transmitting collected data or the level of severity to a cell phone or a remote station that this term is definite.”); *see also id.*, 21-23. Patent Owner states that the ’333 patent specification includes exemplary methods for transmitting data or the level of severity (*id.*, 22) and “the data transferred is the collected data or the quantified level of severity” (*id.*, 23). Additionally, Patent Owner’s expert in the district court litigation states that “[s]ince the time of the invention, a commonly used term within the clinical sleep setting has been ‘level of severity’ which clinicians understand to represent the how dire a patient’s calculated symptom data may be.” Ex. 1058, ¶ 32; *see also* Ex. 1054, 23 (citing to Ex. 1058, ¶ 32).

131. I also understand that the Patent Owner in the Opening Claim Construction brief interprets the claimed “therapy efficacy data” (recited in limitation [15.e.1]) as being definite. Ex. 1054, 25 (“the Court should find this term definite”); *see also id.*, 23-25. The Patent Owner states that “[a] POSITA would understand the term ‘therapy efficacy data’ to mean data calculated based on data collected while a subject is undergoing treatment to determine the severity of a

subject's sleep disorder symptoms and whether the PAP device that is part of the method needs to be adjusted." *Id.*, 23-24.

**XI. OPINIONS ON GROUND 1: TOGE IN VIEW OF KUMAR RENDERS
OBVIOUS CLAIMS 15-17, 20-24, AND 26-29**

**A. A POSITA WOULD HAVE BEEN MOTIVATED TO
COMBINE**

132. In my opinion, a POSITA would have been motivated to combine the teachings of Kumar with Toge. For example, in my opinion, a POSITA would have been motivated to implement a remote-monitoring feature, including a browser-based engine ("remote station") similar to as described in Kumar, to enable the PAP device to wirelessly transmit to the remote engine data associated the patient's treatment, including "the collected data and/or the quantified level of severity data."

133. First, such a feature would have been beneficial because 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].

134. Second, in my opinion, a POSITA would have understood that storing data at the secured storage of the engine would have provided a backup of the data. While Toge discloses that the data may be transmitted from the PAP device to physician-side device 4, in my opinion, a POSITA would have appreciated that a copy of the data stored at the engine would have beneficially served as backup data in the event when the PAP device and/or physician-side device 4 is misplaced or malfunctioned, losing access to the data thereon.

B. A POSITA WOULD HAVE HAD A REASONABLE EXPECTATION OF SUCCESS

135. In my opinion, a POSITA would have also had a reasonable expectation of success in implementing Kumar’s features related to remote-monitoring through its browser-based engine in Toge.

136. First, there are express statements in Kumar that directly teach combining similar systems like Kumar and Toge. Kumar states that “virtually any device may be easily incorporated into the system.” Ex. 1008, [0074]. Kumar further teaches that existing devices can implement similar user interfaces of a browser-

based engine: “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]. Additionally, it was well known to transmit data using wireless protocol(s) to a remote engine, e.g., for later access of the data.

137. Second, the networked systems of Toge and Kumar are structurally and functionally similar. Many PAP devices and other sensor diagnostic systems, like those Toge and Kumar, already included wireless transceivers. *See, e.g.*, Ex. 1044, Abstract, Fig. 5, Ex. 1045, Fig. 3; Ex. 1013, [0029]. Toge itself utilized wireless communication to communicate data in the same way as Kumar. For example, both utilize mobile terminals, such as PDAs and cell phones.

138. Third, it would have involved a combination of known technologies (e.g., known PAP device that provides sensor data and/or the quantified level of severity data, such as Toge) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine, such as Kumar) to yield the predictable result of a system including a remote engine that receives and stores data received from a patient-side device, e.g., the PAP device, for simultaneous storage, retrieval, analysis, and play back from anywhere in the world.

C. INDEPENDENT CLAIM 15

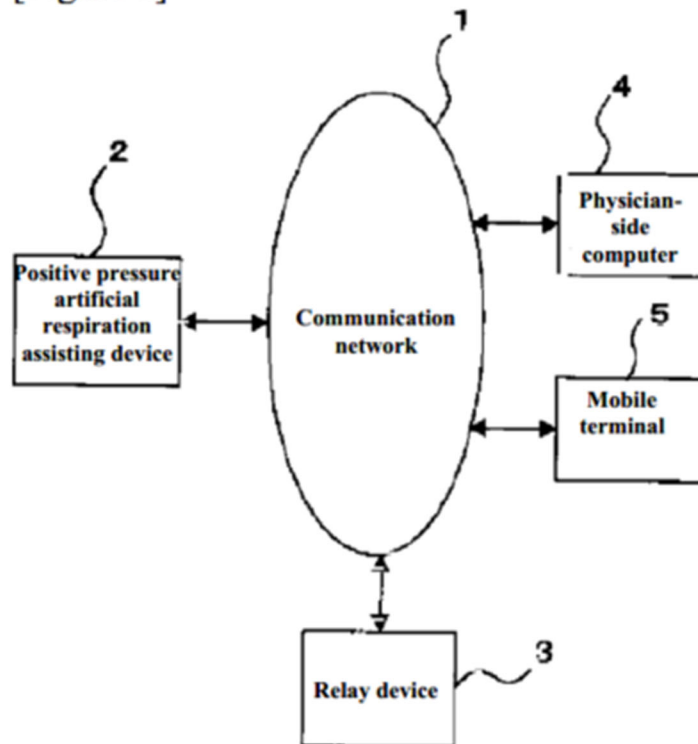
i. PREAMBLE: “A METHOD OF TREATING A SUBJECT’S SLEEP APNEA COMPRISING STEPS OF:

139. In my opinion, Toge discloses the preamble to the extent it is limiting. As shown in Figure 1 and discussed below, Toge discloses a remote medical (telemedicine) system for treating patients having sleep apnea (“method of treating a subject’s sleep apnea”). Ex. 1044, [0008] (“Figure 1 is a block diagram illustrating the overall configuration of a remote medical (telemedicine) system according to the present invention”), [0015] (“The bilevel positive airway pressure device are primarily provided to patients with spontaneous breathing ability is weakened, while continuous positive airway pressure devices are primarily provided to patients with conditions such as *sleep apnea*, where there is still capacity for spontaneous breathing but a risk nonetheless of a temporary cessation of breathing during sleep”).

140. The networked system of Toge includes a positive pressure artificial respiration assisting device 2 (which I will refer to as “PAP device 2”) to provide positive airway pressure therapy, collect data related to the treatment including data from flow and pressure sensors, and analyze the sensor data. *See also infra* [15.a]-[15.c] (Sections XI.C.2-4). Toge enables “remote monitoring of the patient’s condition during the use of a [PAP] device, or the condition of the [PAP] device” via a network connection. Ex. 1044, Abstract. For example, Toge’s system includes

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 to transmit and analyze the data among them. *Id.*, [0008]; *See also infra* [15.d]-[15.e] (Sections XI.C.5-7).

[Figure 1]



Ex. 1044, Fig. 1

141. Moreover, physician-side computer 4 or mobile terminal 5 can configure and adjust the settings of the PAP device, including the prescribed air pressure, by transmitting commands via network 1. Ex. 1044, [0039].

142. As I discussed in the Background, positive air pressure (PAP) therapy is a mainstay treatment for sleep apnea. *See* Section VII.A. A patient's upper airway

acts like a collapsible tube. In a patient with sleep apnea, the collapse of soft tissue in the upper airway (such as the tongue) results in the complete cessation of ventilation producing decreased blood oxygenation, that causes sleep disruption and increased risk factors such as heart disease.

143. Positive airway pressure treats sleep apnea by opposing the force created during inspiration (i.e., inhalation) and the gravitational effects during expiration (i.e., exhalation). Toge discloses a method of treating a patient's sleep apnea by applying this positive airway pressure. Toge explains that the PAP device "delivers positive pressure air . . . to assist the patient's breathing." Ex. 1044, [0070].

144. Further, Toge explains that the treatment, and specifically, the prescribed air pressure, can be adjusted. For example, "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." Ex. 1044, [0039].

145. Given that Toge discloses treating a patient's sleep apnea using a PAP device, including remote monitoring of the patient and remote adjustment of the PAP device, Toge discloses "[a] method of treating a subject's sleep apnea."

ii. [15.A]: "PROVIDING A THERAPY TO A SUBJECT USING A PAP OR CPAP DEVICE WHILE SLEEPING, THE PAP OR CPAP"

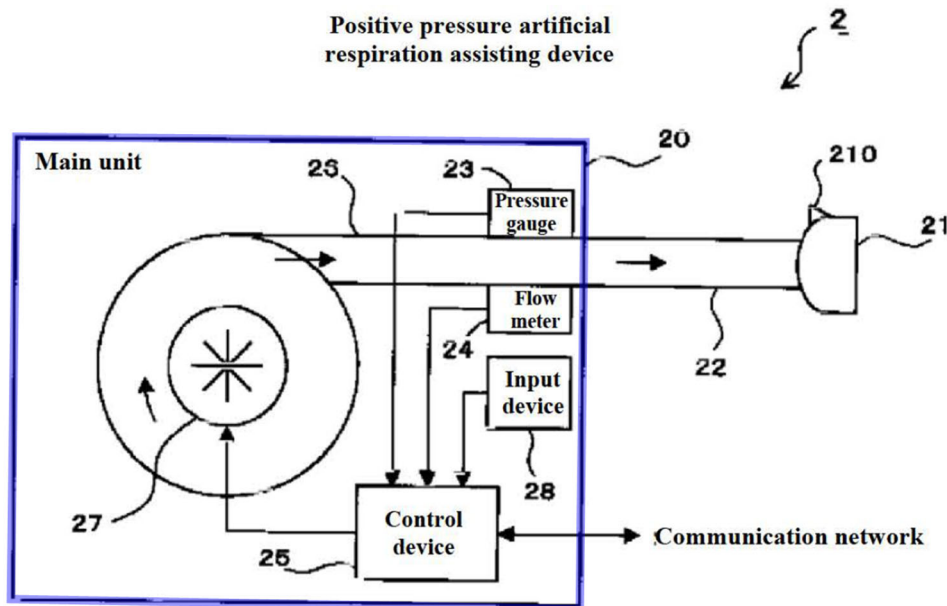
**COMPRISING A FLOW OR PRESSURE SENSOR, AND A PROCESSOR
BOTH WHICH ARE INTEGRATED INTO THE PAP OR CPAP DEVICE;”**

146. Toge discloses this limitation. As I discussed for the preamble, Toge discloses treating a patient by using a PAP device, and therefore discloses “providing a therapy to a subject using a PAP or CPAP device.” *See, e.g.*, Ex. 1044, [0008], [0015]. PAP device 2 treats 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]. It is “[a] home medical device[]” and “designed to deliver positive pressure air to the nasal mask of a patient...to assist the patient’s breathing.” *Id.*, [0010]; *see also id.*, [0011]-[0015]. The pressure of the PAP device is “set to the prescribed pressure...by the physician.” *Id.*, [0013].

147. Toge explains that the treatment occurs “during sleep.” *Id.*, [0015] (“continuous positive airway pressure devices are primarily provided to patients with conditions such as sleep apnea, where there is still capacity for spontaneous breathing but a risk nonetheless of a temporary cessation of breathing during sleep”), [0040] (disclosing that during the PAP treatment the physicians may assess a patient’s level of discomfort, which may affect “the patient’s ability to sleep”). Further, as I discussed above in the Background, positive airway pressure therapy is a treatment that is applied while the patient is sleeping. *See* Section VII.A. Obstructive sleep disordered breathing, such as sleep apnea, occurs when the

reduction of muscle tone as the body relaxes during sleep causes the upper airway to collapse. The positive airway pressure prevents that collapse during sleep. Thus, Toge discloses “providing a therapy to a subject using a PAP or CPAP device while sleeping.”

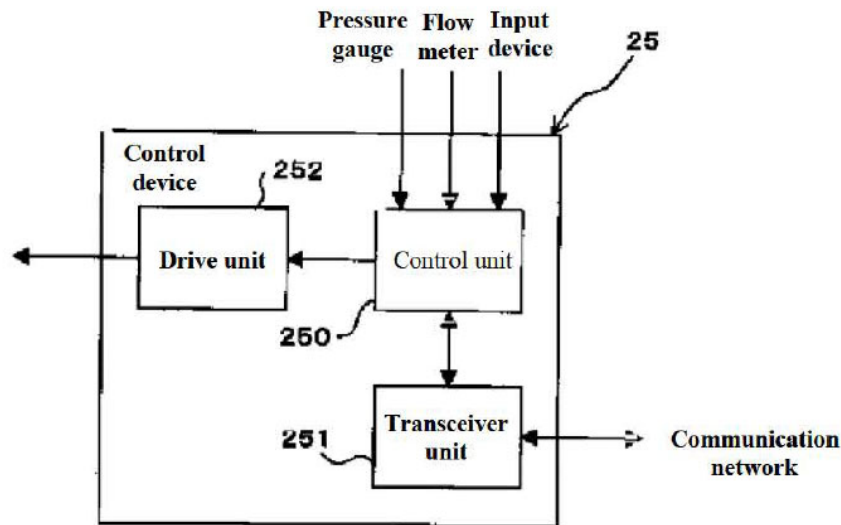
148. Additionally, Toge discloses “the PAP or CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device.” At the time, PAP and CPAP devices all generally included flow and pressure sensors to detect the airflow and breathing patterns of a patient. As shown in Figure 2, Toge’s PAP device 2 has an enclosure (highlighted in blue), which 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]-[0024]. Positive pressure air is delivered to nasal mask 21 from main unit 20. *Id.*, [0022]. Blower 27 supplies air to nasal mask 21. *Id.*, [0024]-[0025].



Ex. 1044, FIG. 2 (annotated)

149. “[P]ressure gauge 23 detects and measures the air pressure inside the flow path 26.” Ex. 1044, [0028]. Flow meter 24 “detects and measures the airflow” within the flow path 26. *Id.* Thus, flow meter 24 and pressure gauge 23 are respectively the claimed “flow [sensor]” and “pressure sensor.” Additionally, as shown in Figure 2, both pressure gauge 23 and flow meter 24 reside within main unit 20, which serves as an enclosure for the PAP device. Thus, they are “integrated into the PAP or CPAP device.”

150. Toge’s PAP device includes a “processor... integrated into the PAP or CPAP device.” As shown in Figures 2 (above) and 3 (below), control device 25 resides within main unit 20 of the PAP device and comprises a control unit 250 (“processor”).



Ex. 1044, Figure 3

151. “[C]ontrol unit 250 can be constructed using a program describing the processing of the control unit 250..., along with a CPU....” Ex. 1044, [0048]. Additionally, Toge explains that relay device 3 may 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 [PAP] device 2.” Ex. 1044, [0060]; *see also id.*, [0016].

152. Relay device 3 (incorporated into control unit 250 of the control device 25) transmits from PAP device 2 “all or part” of the data to physician-side computer 4. *Id.*, [0016] (“The relay device is installed within the company providing the positive pressure artificial respiration assisting device or in a visiting nursing station.”), [0060] (“[T]he 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)”), [0061] (“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.”).

iii. [15.B] “COLLECTING DATA WITH THE PAP OR CPAP DEVICE FROM THE FLOW OR PRESSURE SENSOR DURING A TIME PERIOD OF THE THERAPY;”

153. Toge discloses this limitation. Toge explains that “air pressure” measured by pressure gauge 23 (“pressure sensor”) and “flow rate” measured by flow meter 24 (“flow [sensor]”) are both “provided to the control unit 250” of the PAP device. Ex. 1044, [0028].

154. Toge explains that the positive air pressure is delivered to the patient during the treatment (*id.*, [0022]) (“during a time period of the therapy”) according to the prescribed air pressure (*id.*, [0027]), and the air pressure and/or flow rate provided to control unit 250 are used to determine various parameters and control the PAP device (*id.*, [0032]-[0038], [0046]). Toge even describes that the data collected and transmitted during treatment as treatment data. *Id.*, [0031] (describing transmitted data including sensor data as “treatment data”).

155. In my opinion, as a POSITA would have understood, given that Toge discloses device 2 transmits data “at regular intervals” (*id.*, [0030], [0039], [0040], [0041], [0044], [0047]), device 2 discloses “collecting data” between transmissions. In my opinion, a POSITA would have also understood that Toge discloses “during

a time period of the therapy” because Toge discloses that the time between the transmissions is a time period or interval when the positive airway pressure is applied to the patient during sleep. Moreover, control unit 250 determines “[t]he operational time T...measuring the time, from ‘power on’ to ‘power off’ using its internal timer (internal clock)” (*id.*, [0042]) and “the operating status of the positive pressure artificial respiration assisting device 2 (such as alarms if the nasal mask is detached)” (*id.*, [0031]). “By analyzing this operational time, physicians can determine whether the patient is using the [PAP] device 2 and assess the treatment (patient) compliance.” *Id.* Accordingly, Toge discloses “collecting data with the PAP or CPAP device,” e.g., air pressure and/or flow rate, from “the flow or pressure sensor during a time period of the therapy.”

iv. [15.C] “ANALYZING WITH THE PROCESSOR THE COLLECTED DATA TO DETERMINE A QUANTIFIED LEVEL OF SEVERITY DATA BASED ON THE SUBJECT’S SLEEP APNEA SYMPTOMS DURING THE THERAPY;”

156. Toge discloses this limitation. Toge discloses that air pressure measured by pressure gauge 23 and/or flow rate measured by flow meter 24 (either the air pressure or flow rate measurements or both being the “collected data”) is used by control unit 250 (“processor”) to calculate/determine certain parameters. For example, control unit 250 calculates the tidal volume (EX1044, [0038]) based on the afore-mentioned air pressure and/or flow rate measurements (*id.*, [0033]-[0037]).

See, e.g., id., [0035] (explained that tidal volume F_p is a function of F_t , F_a , and F_b , where “ F_t is the flow rate measured by the flow meter 24”), [0036] (“the pressure value measured by the pressure gauge 23...is used” to determine “the internal pressure P ,” which is used for calculating F_a), [0037] (“air leakage volume F_b from the nasal mask 21 is determined by subtracting the exhalation vent flow rate F_a from the flow rate value F_t of the flow meter 24. This difference is then integrated over a single breath as well as over multiple breaths to obtain the air leakage volume F_b .”).

157. The tidal volume calculated/determined by control unit 250 is “a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy.” In my opinion, a POSITA would have understood that the calculated tidal volume represents the level of severity based on the patient’s sleep apnea symptoms during the treatment, because it represents, for example, level of airway obstruction the patient experiences during the sleep apnea treatment using the PAP device. In fact, Toge explains that the physician, through the tidal volume information, can monitor the “patient’s condition” which, in my opinion, a POSITA would have understood, corresponds to “subject’s sleep apnea symptoms during the therapy,” as claimed. *Id.*, [0039]. I note that the ’333 patent uses “symptoms” and “condition” (or patient’s “state”) interchangeably. For example, the ’333 patent states: “Apnea treatment is provided based on the type of apnea, and can be adjusted by re-testing the subject at some later time to determine whether the condition or the

symptoms have been alleviated.” Ex. 1001, 2:9-12; *see also* 2:45-48 (“It is therefore an object of the present invention to adjust the treatment gas flow or pressure delivered to the subject based on the subjects current physiological state or symptoms.”). The ’333 patent further explains that “[t]he quantitative method for estimating or determining the severity of the subject’s sleeping disorder or symptoms is preferably accomplished by using signal or data from the one or more sensors described herein.” *Id.*, 22:25-28. Thus, a POSITA would have understood that the quantified level of severity is based on the data from the sensors indicating the patient’s condition (i.e., symptoms).

158. Just like the ’333 patent, Toge discloses that treatment can be adjusted to address the quantified level of severity based on the patient’s condition, explaining that “if there is a decreasing trend in the tidal volume..., 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]. Such an adjustment, and in my opinion, a POSITA would have understood, is used to counter/treat the more severe level of airway obstruction observed from the decreasing tidal volume.

159. Additionally, Toge explains that threshold values associated with the patient’s tidal volume can be set for triggering the transmission the tidal volume to physician-side computer 4. *Id.*, [0051]. Thus, in my opinion, a POSITA would have

understood that the tidal volume is “a quantified level of severity data.” Given that the tidal volume, which is determined by control unit 250 based on analyzing of the collected data, corresponds to a quantified level of patient’s severity that is based on the patient’s sleep apnea symptoms (e.g., level of airway obstruction) during the treatment, Toge discloses “analyzing with the processor the collected data to determine a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy.” As a simple example, during apnea, which is the most severe form of reduction in airflow, the absence of airflow results in quantified tidal volume of *zero* milliliters per breath. A POSITA would have understood that the processor may calculate volume, which is a quantified level of severity data based on the subject’s sleep apnea symptoms that they are experiencing during the therapy. Therefore, in my opinion, Toge discloses this limitation.

160. Additionally, for the reasons I discussed above, the tidal volume as described by Toge is consistent with Patent Owner expert’s interpretation of the claimed “level of severity” as discussed in Section X. *See* Section X (Claim Construction); Ex. 1058, ¶ 32 (“a commonly used term within the clinical sleep setting has been ‘level of severity’ which clinicians understand to represent the how dire a patient’s calculated symptom data may be”); *see also* Ex. 1054, 23 (citing to Ex. 1058, ¶ 32).

- v. [15.D] **“TRANSMITTING, IN EITHER ORDER, BOTH**
1) THE COLLECTED DATA AND/OR THE QUANTIFIED LEVEL
OF SEVERITY DATA TO A CELLULAR PHONE VIA A RADIO
FREQUENCY WIRELESS LINK; AND
2) THE COLLECTED DATA AND/OR THE QUANTIFIED LEVEL
OF SEVERITY DATA TO THE REMOTE STATION FROM EITHER
A) THE PAP OR CPAP DEVICE VIA A CELLULAR
SYSTEM, OR
B) THE CELLULAR PHONE TO A REMOTE STATION VIA THE
CELLULAR SYSTEM OR THE INTERNET FOR FURTHER ANALYSIS
WITH A SECOND PROCESSOR OR A SERVER AT THE REMOTE
STATION AND REVIEW OF THE COLLECTED DATA, THE
QUANTIFIED LEVEL OF SEVERITY AND/OR THIS ANALYSIS BY A
CLINICIAN, TECHNICIAN OR PHYSICIAN; AND”

161. Toge alone or in combination with Kumar discloses this limitation. For clarity, I address limitation [15.d] in subsections (a)-(e) below. Element 15.d has many alternatives with the use of conjunctive and disjunctive language such as “or,” “and,” or “and/or.” To aid in the understanding, I use the color codes in the claim language above and headings for subsections (a)-(e) to identify the specific alternatives for this element on which I am providing an opinion.

A) “TRANSMITTING...1)...THE
QUANTIFIED LEVEL OF SEVERITY
DATA TO A CELLULAR PHONE VIA A
RADIO FREQUENCY WIRELESS LINK”

162. Toge discloses “transmitting...1)...the quantified level of severity data to a cellular phone via a radio frequency wireless link.” Toge discloses that the mobile terminal 5 may be “mobile phones” or “PDAs” (either being the claimed “cell phone”). Ex. 1044, [0019] (“The mobile terminal 5 includes mobile phones,

PHS, PDAs and PocketBell (registered trademark), etc.”). 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.* The care provider may operate the mobile terminal 5 to “set the necessary data...for [PAP] device 2.” *Id.*

163. Toge discloses that the treatment data, including tidal volume (“the quantified level of severity data”), may be transmitted to mobile terminal 5 from PAP device 2, which is also connected to network 1, which may be a mobile network. Ex. 1044, Abstract (“relay device 3...transmits...treatment data to...mobile terminal 5 via the communication network 1”), [0008]-[0009] (mobile terminal 5 connected to network 1, which may be a mobile network), [0019] (mobile terminal 5 includes “mobile phones” or “PDAs”). In my opinion, a POSITA would have understood that network 1 and its communication with Toge’s mobile terminal 5 is “via a radio frequency wireless link.” Mobile phones and PDAs using a mobile network, like a cellular network, must create a radio frequency wireless link to send data. Thus, Toge discloses “transmitting...1)...the quantified level of severity data to a cellular phone via a radio frequency wireless link.”

164. To the extent that limitation [15.d] is interpreted to require “transmitting...1)...the quantified level of severity data to a cellular phone via a radio frequency wireless link...**from...a) the PAP or CPAP device via a cellular**

system,” Toge likewise discloses the claim features that are emphasized in bold. As I discussed above, the treatment data, including tidal volume (“the quantified level of severity data”), may be transmitted to mobile terminal 5 (“cellular phone”) from PAP device 2 (“the PAP or CPAP device”), which is also connected to network 1, which may be a mobile network. In my opinion, a POSITA would have understood that **mobile** networks (e.g., Toge’s mobile communication network 1) are connected via “**a cellular system.**” Accordingly, Toge discloses these claim features.

**B) “TRANSMITTING...2)...THE
QUANTIFIED LEVEL OF SEVERITY
DATA TO THE REMOTE STATION
FROM...A) THE PAP OR CPAP DEVICE
VIA A CELLULAR SYSTEM”**

165. Toge discloses “transmitting...2)...the quantified level of severity data to the remote station from...a) the PAP or CPAP device via a cellular system.” Toge discloses that network 1 may be “a **mobile** communication network” (Ex. 1044, [0009]) and that PAP device 2 (“PAP”), relay device 3, physician-side computer 4 (“remote station”) are **wirelessly** connected to network 1 for transmitting data (*id.*, [0006]-[0007]; *see also id.*, [0016], [0060], [0063], [0070], [0078], [0080]-[0081], claim 1). 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 and receiving “treatment data,” including tidal volume (“the quantified

level of severity data”). *Id.*, [0008]-[0009], [0016]-[0018], [0031]; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1.

166. Toge explains that PAP device 2 may transmit data by having “the functionality of...relay device 3...incorporated into the [PAP device 2] (the control unit 250 of the control device 25)” and may transmit “all or part” of the data to physician-side computer 4. Ex. 1044, [0039]; *see also id.*, [0016], [0060]. Toge further explains that the physician-side computer 4 (“remote station”) receives the data from PAP device 2 and allows care providers, e.g., physicians, to access the transmitted data using the computer. *Id.*, [0017]-[0018]. Toge also explains that PAP device 2 “transmits all or part of the treatment data to the physician-side computer 4...**via...network 1.**” Ex. 1044, [0061]. “By transmitting the tidal volume...physicians can remotely monitor the patient’s condition during the use of the [PAP] device 2.” *Id.*, [0039]; *see also id.*, [0051], [0061], [0063]-[0076] (examples of remote monitoring), [0051], [0085].

167. In my opinion, a POSITA would have understood that **mobile** networks (e.g., Toge’s mobile communication network 1) are connected via “**a cellular system.**” During this time, many medical devices were being mobilized by connecting them through a long-range cellular wireless network which would allow the devices to be “mobile.” Additionally, in my opinion, a POSITA would have understood that physician-side computer 4 is a “**remote station,**” as claimed, given

that it receives treatment data from the PAP device and/or provides physicians remote access to monitor the patient's condition. Ex. 1044, Abstract (“[e]nabling remote monitoring”; “physician-side computer 4 or mobile terminal 5 receives all or part of the treatment data transmitted from the relay device 3.”), [0006], [0017]-[0018], [0039]. Moreover, Toge explains that “physician-side computer 4 is a **computer**,” which, in my opinion, as a POSITA would have understood, includes a processor, consistent with claim 15's recitation of “a second **processor**...at the remote station.” Ex. 1044, [0017]. I noticed that that the term “remote station” is not recited in the '333 patent specification. *See generally* Ex. 1001. If the “remote communication station” discussed in the specification corresponds to the claimed “remote station,” physician-side computer 4 likewise discloses the claimed “remote station.” Ex. 1001, 22:20-24 (“Another example is where the remote communication system is a **computer** or processor, which receives the data transmission and displays the data or records it on some recording medium, which can be displayed or transferred for analysis at a later time.”); *see also id.*, 21:54-22:20 (describing various non-limiting examples of a “remote communication station”).

168. Given that Toge discloses transmitting the tidal volume (“quantified level of severity data”) from PAP device 2 to physician-side computer 4 (“remote station”) via mobile communication network 1 (including “a cellular system”), Toge

discloses “transmitting...2)...the quantified level of severity data to the remote station from...a) the PAP or CPAP device via a cellular system.”

**C) “TRANSMITTING...2)...THE
QUANTIFIED LEVEL OF SEVERITY
DATA TO THE REMOTE STATION
FROM...A) THE PAP OR CPAP DEVICE
VIA A CELLULAR SYSTEM”**

169. To the extent that Toge does not disclose the claimed “remote station” or “transmitting...2)...the quantified level of severity data to the remote station from...a) the PAP or CPAP device via a cellular system,” Toge in view of Kumar discloses this feature.

170. 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].

171. Figure 1A (below) shows that the Kumar system includes a patient-side device 102 for collecting data from a patient/client (in blue, similar to Toge’s PAP device), computing device 110 (in green), provider-side device(s) 104, and central server 106 (in red) that hosts a browser-based engine accessible through web pages. Ex. 1008, [0018], [0067]-[0068], [0072], [0089].

Declaration of Jason Kirkness, Ph.D. in Support of
 Petition for *Inter Partes* Review USP No. 11,857,333

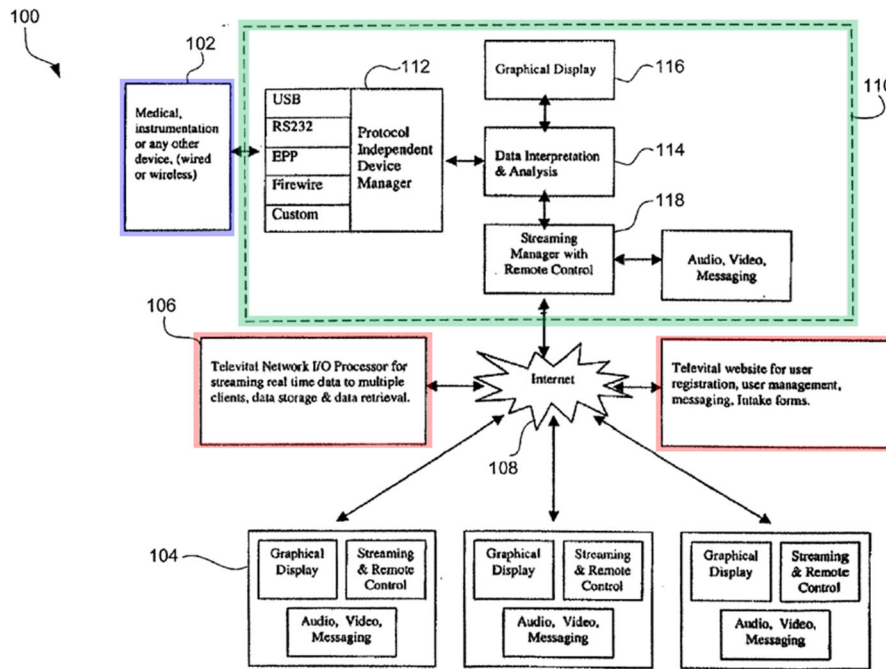


Fig. 1A

Ex. 1008, FIG. 1A

172. The aforementioned devices and engine are connected to a wide area network (WAN) 108 such as the Internet. Ex. 1008, [0067]-[0068]. The patient-side device may communicate through a wireless interface and communicate over the Internet. *Id.*, [0013].

173. Kumar additionally discloses that the browser-based engine supports real-time streaming of information over the Internet and provides secured data storage, e.g., for later access, analysis, and integration of the patient's data into an electronic medical records system. Ex. 1008, [0010], [0081]-[0082], [0083], [0087]. For example, Kumar discloses that “[t]he engine manages transmission of the data

from the patient-side device to the provider-side device” and “may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device; **may store the data for later transmission to the provider-side device**, etc.” *Id.*, [0081], [0082].

174. Accordingly, in my opinion, a POSITA would have understood that a browser-based engine hosted on a central server is a “remote station” as claimed because it provides remote monitoring and, for example, relaying, storing, and processing patient’s data as well as providing access to the data. As discussed above, I note that the term “remote station” is not recited in the ’333 patent specification. If the “remote communication station” discussed in the specification corresponds to the claimed “remote station,” Kumar’s browser-based engine likewise discloses the claimed “remote station.” Ex. 1001, 21:61-65 (“The remote communication station or base station by way of example but not limitation can include a communications device for relaying the transmission, a communications device for re-processing the transmission....”); *see also id.*, 21:54-22:20 (describing various non-limiting examples of a “remote communication station”).

175. 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]. The engine provides a secured storage and access, e.g., where one can access the engine through a login, such as that in Figure 2. *Id.*, [0089], [0192]. 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].

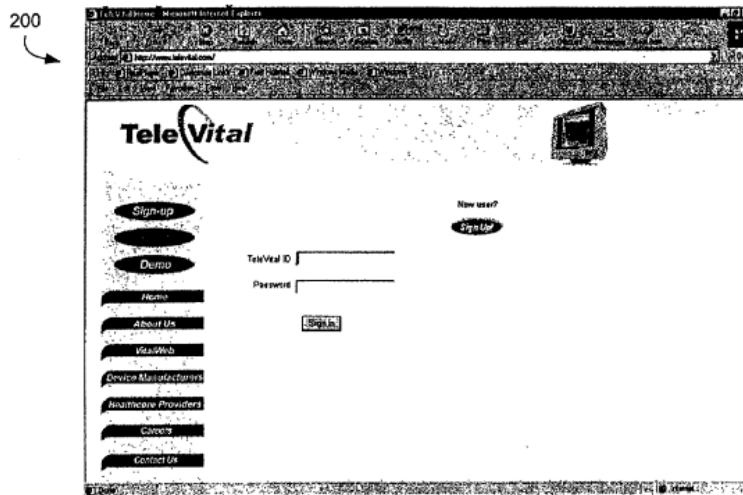


Fig. 2

Ex. 1008, FIG. 2

176. Accordingly, in addition to disclosing the claimed “remote station,” Kumar discloses “transmitting...2)...data to the remote station from...a) the [patient-side] device...,” because Kumar discloses transmitting data, such as raw, interpreted, and processed physiological/patient data, to the engine (“remote station”) from the patient-side device. *See supra*; *see also* Ex. 1008 [0072] (“the patient-side device may have a built-in computing device for communication over the WAN”), [0081] (the engine “may receive the data from the patient-side device”).

177. In my opinion, a POSITA would have been motivated to implement a remote-monitoring feature, including a browser-based engine implemented on a server (“remote station”) similar to as described in Kumar (*see supra*), to enable the PAP device to wirelessly transmit to the browser-based engine data associated the patient’s treatment, including “the collected data and/or the quantified level of severity data,” such as the measured air pressure and/or flow rate (“collected data”) and/or tidal volume (“quantified level of severity data”) disclosed in Toge for, e.g., secured storage, data backup, later analysis, creation of a database, and sharing of data.

178. 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].

179. Moreover, in my opinion, a POSITA would have understood that storing data at the secured storage of the engine would have provided a backup of the data. While Toge discloses that the data may be transmitted from the PAP device to physician-side device 4, in my opinion, a POSITA would have appreciated that a copy of the data stored at the engine would have been beneficial as it would serve as backup data in the event when the PAP device and/or physician-side device 4 is misplaced or malfunctioned, losing access to the data thereon.

180. In my opinion, a POSITA would have understood that Toge and Kumar share similar goals, such as providing access to data collected/analyzed by a treatment device. For instance, Toge discloses “download all or specified data received from [PAP] device 2 to the physician-side computer or mobile terminal 5 in response to download requests from the physician-side computer 4 or mobile terminal 5.” Ex. 1044, [0059]; *see also id.*, [0018], [0061]. And Kumar discloses that its “the engine manages transmission of the data from the patient-side device.” Ex. 1008, [0081].

181. In my opinion, a POSITA would have had a reasonable expectation of success in combining the above-discussed feature with Toge’s teaching. 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 engine, e.g., for later access of the data. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that is wirelessly connected to a mobile communication network and provides sensor data and/or the quantified level of severity data (Toge)) according to known methods (e.g., known methods of transmitting data wirelessly from patient-side device to a remote engine (Kumar)) to yield the predictable result of a system including a remote engine that receives and securely 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 browser-based engine (“remote station”) that receives the claimed “collected data and/or the quantified level of severity data” from the PAP device via a mobile network, e.g., mobile network 1 of Toge (including “a cellular system”).

**D) TRANSMITTING “IN EITHER ORDER,
BOTH”**

182. Toge alone and/or the Toge-Kumar combination discloses transmitting both (1) and (2) in **“either order.”**

183. Toge discloses that PAP device 2 “transmits all or part of the treatment data to the physician-side computer 4 **or** mobile terminal 5 via the communication

network 1.” Ex. 1044, [0061]. Moreover, Toge discloses that each of physician-side computer 4 and mobile terminal 5 may request all data from PAP device 2, and the data is sent to the requested computer/terminal. *Id.*, [0059]. Thus, Toge discloses that the treatment data may be transmitted both of computer 4 and terminal 5. Moreover, based on the above disclosure, Toge at least discloses a scenario where the treatment data, which includes the tidal volume (“the quantified level of severity data”), is transmitted to either “the physician-side computer 4 **or** mobile terminal 5” instead of being simultaneously transmitted to both of them. For example, the data may be transmitted to computer 4 (“remote station”) that requested the data, and then transmitted to terminal 5 (“cellular phone”) that subsequently requested the data.

184. Toge in view Kumar also discloses transmitting both (1) and (2) **in “either order.”** As discussed above, Kumar’s system includes patient-side device 102 (e.g., Toge’s PAP device), computing device 110, provider-side device(s) 104, and central server 106 hosting an engine. Ex. 1008, [0018], [0067]-[0068], [0072], [0089]. The aforementioned devices and engine are connected to a wide area network (WAN) 108. Ex. 1008, [0067]-[0068]. Kumar also discloses that “the provider-side device can be any type of computing device, such as a computer, PDA, wireless telephone” (“cellular phone”) and “has a wireless connection to the WAN so that, even though the doctor is not at a hospital or in his office, he may still be consulted remotely without the need to rush to the hospital.” *Id.*, [0072].

185. Kumar additionally discloses that “the engine manages transmission of the data from the patient-side device to the provider-side device,” which “means that the engine may configure the devices to **transfer the data directly from one device to the other.**” Ex. 1008, [0081]. Thus, Kumar discloses that the provider-side device (“cellular phone”) may directly receive data from a patient-side device. As discussed above, in my opinion, a POSITA would have been motivated to store the patient’s data, such as the measured air pressure and/or flow rate (“collected data”) and/or tidal volume (“quantified level of severity data”) disclosed in Toge, at the engine’s storage to allow later access/analysis, integration of data into an electronic medical records system, and a secured backup. For similar reasons, in my opinion a POSITA would have been motivated to transmit patient’s data (“collected data and/or the quantified level of severity data”), having received by the provider-side device (“cellular phone”) directly from the patient-side device (e.g., PAP device)), to the engine (“remote station”) from the provider-side device. Such a process would have allowed storage of the physician’s analysis/diagnosis/notes along with the patient’s data in the secured storage of the engine, as discussed above.

186. In my opinion, a POSITA would have also had a reasonable expectation of success in implementing this feature in the Toge-Kumar combination as it would have involved a combination of known technologies (e.g., known PAP device that analyze collected data (Toge)) according to known methods (e.g., known methods

of transmitting data amongst devices and providing secured storage (Kumar)) to yield the predictable result of a PAP device transmitting patient's data to a physician's computing device for physician's analysis, where the patient's data and the physician's analysis are then transmitted to a remote engine for secured storage, as discussed above. Accordingly, Toge in view of Kumar discloses this limitation.

187. Lastly, in my opinion, the "order[ed]" data transmission feature recited in claim 15 would have been obvious to a POSITA. Indeed, there were only three options to execute the above-described two transmission steps with respect to the timing of the transmissions. The first option is to execute both transmission steps simultaneously, the second option is to transmit to the "cellular phone" first and then to the "remote station" (disclosed by Toge or the Toge-Kumar combination), and the third option is to transmit to the "remote station" and then to the "cellular phone." Thus, the "order[ed]" data transmission feature recited in claim 15 would have been obvious because it was one of a "finite number of identified, predictable solutions."

**E) "FOR FURTHER ANALYSIS WITH A
SECOND PROCESSOR OR A SERVER AT
THE REMOTE STATION AND REVIEW
OF...THE QUANTIFIED LEVEL OF**

**SEVERITY...BY A CLINICIAN,
TECHNICIAN OR PHYSICIAN”**

188. In my opinion, Toge alone or in combination with Kumar discloses this limitation.

189. Toge discloses that physicians may “access the transmitted data [including tidal volume] using the physician-side computer 4” and “operate the physician-side computer 4 to...download the necessary data.” Ex. 1044, [0018]; *see also id.*, [0050], [0051]. “Moreover, medical institution personnel can operate the physician-side computer 4 to set the necessary data...for [PAP] device 2,” including adjusting the prescription pressure of the PAP device based on the received data, e.g., tidal volume. *Id.*, [0018], [0027], [0039], [0055], [0059], [0061].

190. In my opinion, a POSITA would have understood that the physician would have reviewed and analyzed the received tidal volume data before/while adjusting the PAP device’s pressure using physician-side computer 4 (“remote station”), which includes a “second processor.” Accordingly, Toge discloses transmitting the tidal volume “**for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis** by a clinician, technician or **physician.**”

191. The Toge-Kumar combination also discloses this limitation. As discussed above, in view of Toge and Kumar’s teachings, in my opinion, a POSITA

would have been motivated to transmit to the remote engine (hosted on central server 106) data associated the patient's treatment, including "the collected data and/or the quantified level of severity data" for "secured storage device at the central server for **later access, replay, and/or analysis**" e.g., which **allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online**. Ex. 1008, [0083]. 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]. Accordingly, Toge discloses transmission the data "**for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis** by a clinician, technician or **physician.**"

vi. [15.E.1] **"FURTHER DETERMINING THE THERAPY EFFICACY DATA WITH EITHER THE PROCESSOR OF THE PAP OR CPAP DEVICE, THE SECOND PROCESSOR OR SERVER CONFIGURED WITH A SECOND SOFTWARE AT THE REMOTE STATION, OR THE CELLULAR PHONE USING THE FIRST SOFTWARE"**

192. Toge alone or in combination with Kumar discloses this limitation. Toge discloses that "physician-side computer 4 is a computer installed at a medical institution." Ex. 1044, [0017]. In my opinion, a POSITA would have understood that computer 4 ("remote station") includes a processor ("second processor") that

executes code/program (“second software”) in order to receive the treatment data (which may be based on a physician’s download request) and allow the care provider/physician to review/analyze the received treatment data as well as setting certain parameters for PAP device 2. *See, e.g.*, Ex. 1044, [0018], [0047].

193. Toge discloses that PAP device 2 receives mode settings/parameters for adjusting the PAP device from physician-side computer 4. Ex. 1044, [0030]-[0031]. “The control unit 250 [of PAP device 2] controls the drive unit 252 **based on the configured mode and prescription pressure**, as well as the pressure value from the pressure gauge 23 that is entered....” *Id.*, [0032].

194. In my opinion, a POSITA would have understood that the data for adjusting mode settings/parameters corresponds to the claimed “therapy efficacy data” because these are data that physician provides to PAP device 2 in order to adjust the mode settings/parameters of the PAP device when treating the patient based on monitoring and analysis of the treatment data (including, e.g., tidal volume), representing the patient’s condition and efficacy of the treatment. For example, Toge discloses that “[b]y **transmitting the tidal volume...**, physicians can remotely **monitor the patient’s condition** during the use of the [PAP] device 2 remotely.... Furthermore, if there is a decreasing trend in the tidal volume..., emergency measures, such as **adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4...**” Ex. 1044,

[0039]; *see also id.*, [0040]-[0041], [0044]-[0047]. Accordingly, Toge discloses “**further determining the therapy efficacy data with** either the processor of the PAP or CPAP device, **the second processor** or server **configured with a second software at the remote station**, or the cellular phone using the first software.” Additionally, for reasons discussed above, Toge’s data for adjusting mode settings/parameters is consistent with Patent Owner’s interpretation in the district court for the claimed “therapy efficacy data” as discussed in Section X (Claim Construction). *See* Section X (Claim Construction); Ex. 1054, 23-24 (“[a] POSITA would understand the term ‘therapy efficacy data’ to mean data calculated based on data collected while a subject is undergoing treatment to determine the severity of a subject’s sleep disorder symptoms and whether the PAP device that is part of the method needs to be adjusted.”).

195. The Toge-Kumar combination also discloses this limitation. As discussed for limitation [15.d], in view of Toge and Kumar’s teachings, in my opinion, a POSITA would have been motivated to transmit to the remote engine (hosted on central server 106) data associated the patient’s treatment, including “the collected data and/or the quantified level of severity data” for “secured storage device at the central server for **later** access, replay, and/or **analysis**” e.g., which allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. Ex. 1008, [0083]. Kumar explains

that “[a] remote client module...allows remote hosts to view the data being streamed in real time. The remote client module can **also control the software being run on the patient’s...end.**” *Id.*, [0085]. “[B]ased on real-time streaming of vital patient information, [Kumar’s system] may be tailored to **forward proper responses to the patient.**” *Id.*, [0088].

196. For instance, a physician may use the browser-based engine to “view streaming and/or saved data relating to the patient.” Ex. 1008, [0091], [0092] (“By joining the session, the healthcare provider can immediately view their patient’s real-physiological data”).

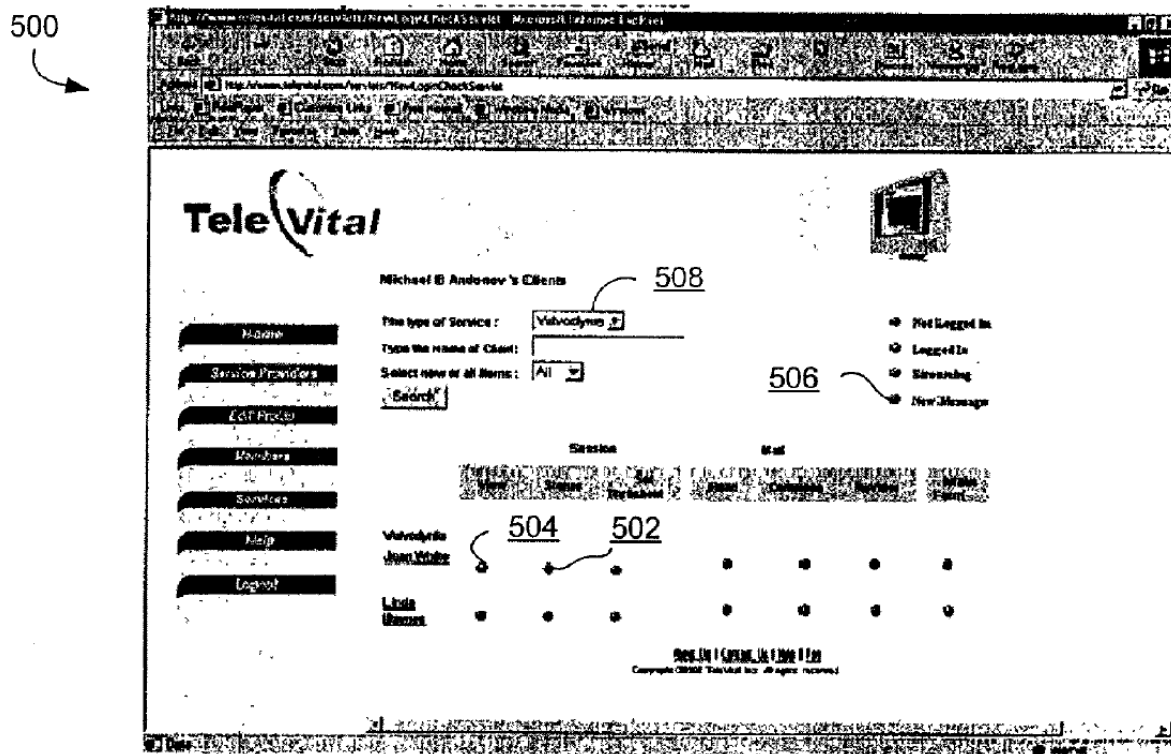


Fig. 5

Ex. 1008, FIG. 5

197. Given that Kumar discloses a physician using the browser-based engine (“remote station”) that is implemented on a server to adjust/control the patient-side device based on the received patient data and for similar reasons discussed for Toge, the Toge-Kumar combination discloses “**further determining the therapy efficacy data with** either the processor of the PAP or CPAP device, the second processor or **server configured with a second software at the remote station**, or the cellular phone using the first software.”

vii. [15.E.2] “FURTHER PROVIDED TO RECEIVE AND DISPLAY THE QUANTIFIED LEVEL OF SEVERITY DATA AND/OR THERAPY EFFICACY DATA TO THE SUBJECT OR A CARE PROVIDER.”

198. In my opinion, Toge alone or in view of Kumar discloses this limitation. As discussed for limitation [15.d], tidal volume (“quantified level of severity data”) is provided to and received by physician-side computer 4 for the physician’s analysis. Ex. 1044, [0030]-[0031], [0039]-[0042]. Additionally, by using computer 4, care providers may send a “data download request” to download data onto computer 4 and may also “set the necessary data...for [PAP] device 2.” *Id.*, [0018].

199. 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.” Ex. 1044, Abstract, [0001], [0005]-[0006], [0039], [0085]. Moreover, settings of the PAP device, e.g., the prescribed pressure, can be configured or

adjusted using physician-side computer 4 or mobile terminal 5. *Id.*, [0027], [0039]. In my opinion, POSITA would have understood that, for the physicians to monitor and analyze the tidal volume (“quantified level of severity data”), such information is displayed to the physicians (“a care provider”) on physician-side computer 4. Likewise, a POSITA would have understood that the data for adjusting mode settings/parameters (“therapy efficacy data”) is displayed on physician-side computer 4 to allow the physician to review, monitor, adjust, and provide associated settings.

200. In my opinion, the Toge-Kumar combination also discloses this limitation. For example, as discussed for limitation [15.e.1], Kumar discloses that a physician may use a browser-based engine to receive and review patient data (e.g., “quantified level of severity data”). In my opinion, a POSITA would have understood that, for the physicians to monitor and analyze the patient data (e.g., “quantified level of severity data”), such information is displayed to the physicians (“a care provider”) via the web-browser user interface. Likewise, a POSITA would have understood that the data for adjusting mode settings/parameters (“therapy efficacy data”) is displayed via the web-browser user interface to allow the physician to review, monitor and provide associated settings.

B. DEPENDENT CLAIMS 16, 17, 20-24, AND 26-29

i. CLAIM 16. THE METHOD OF CLAIM 15, WHEREIN THE CELLULAR PHONE AND THE PAP OR CPAP DEVICE EACH HAVE A BLUETOOTH STANDARD WIRELESS RF CONNECTION AND CAN COMMUNICATE DIRECTLY WITH EACH OTHER THROUGH THE WIRELESS CONNECTION IN REAL TIME.

201. In my opinion, Toge in view of Kumar discloses this limitation. While Toge does not expressly disclose this limitation, in my opinion, a POSITA would have found it obvious to implement the recited features in Toge in view of Kumar.

202. Kumar discloses that a patient-side device may establish with “a two-way communication” with a computing device 110, e.g., a “wireless phone” or an “IPAQ.” Ex. 1008, [0072]; *see also id.*, [0071], [0239]-[0241] (disclosing that the system allows for “remote monitoring” associated with “[s]leep apnea-hypopnea syndrome”). In my opinion, POSITA would have understood that a “wireless phone” or an “IPAQ” is capable of establishing wireless communications using the Bluetooth protocol. Ex. 1011, 2 (disclosing that an iPAQ cell phone is capable of communicating using Bluetooth protocol). Moreover, Kumar explains that the patient-side device may likewise communicate through a “wireless...protocol.” *Id.*, [0072]. Thus, Kumar at least suggests that the patient-side device (e.g., Toge’s PAP device) may communicate with a wireless/mobile phone using the Bluetooth protocol.

203. In my opinion, a POSITA would have been motivated to configure Toge's PAP device 2 and mobile terminal 5 ("cell phone") such that they can communicate directly with each other through the Bluetooth protocol. For example, Toge discloses that PAP device 2 has an input device 28 that allows a physician to adjust/control operations such as power on/off, mode selection, prescription pressure settings. Ex. 1044, [0026]. Providing Bluetooth capability would have allowed the physician to conveniently control/adjust the PAP device as well as to download/review data directly from the PAP device using mobile terminal 5 wirelessly, e.g., during the patient's initial/follow-up appointment(s) with the physician. In my opinion, POSITA would have also been motivated to implement such a wireless capability because Toge expressly teaches that "settings can be adjusted by the physician using a separate input terminal that can be **detached** from the main unit 20 [of PAP device 2]." *Id.*, [0027].

204. In my opinion, a POSITA would have also had the skill and reasonable expectation of success in implementing the above-discussed modification. It was known to use the Bluetooth protocol to transmit and/or view data associated with a PAP device. Ex. 1050, 8:28-9:2 (explaining that "user data viewing and reports" can be interfaced using "W-LAN and even BluetoothTM wireless devices"). Moreover, it would have involved a combination of known technologies according to known methods to yield the predictable result of a method allowing a PAP device to

establish a wireless communication with a mobile terminal through the Bluetooth protocol for improved convenience, as discussed above.

ii. CLAIM 17. THE METHOD OF CLAIM 15, WHEREIN THE THERAPY CAN BE MODIFIED BASED IN PART ON THE WIRELESSLY TRANSMITTED DATA OR INFORMATION.

205. In my opinion, Toge discloses this limitation. For example, Toge discloses the transmitted tidal volume allows physicians to “remotely monitor the patient’s condition during the use of the [PAP] device 2” and “if there is a decreasing trend in the tidal volume Fa, 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.” Ex. 1044, [0039]. As discussed for limitation [15.d], the PAP device and the physician-side computer 4 are wirelessly connected to communication network 1 for data transmission. Ex. 1044, [0006]-[0007]; *see also id.*, [0016], [0060], [0063], [0070], [0078], [0080]-[0081], claim 1. Thus, Toge discloses “the therapy can be modified based in part on the wirelessly transmitted data or information.”

iii. CLAIM 20. THE METHOD OF CLAIM 15, WHEREIN THE THERAPY CAN BE ADJUSTED OR TITRATED THROUGH A WIRELESS CONNECTION FROM THE REMOTE LOCATION BY THE TECHNICIAN, CLINICIAN OR PHYSICIAN.

206. In my opinion, Toge discloses this limitation for the same reasons discussed for claim 17. *See, supra*, Section XI.D.2.

iv. CLAIM 21. THE METHOD OF CLAIM 20, WHEREIN THE PAP OR CPAP IS ADJUSTED OR TITRATED IN REAL-TIME BY THE TECHNICIAN, CLINICIAN OR PHYSICIAN FROM A REMOTE LOCATION.

207. In my opinion, Toge discloses this limitation. As discussed for claim 17, Toge's PAP device may be adjusted by a physician from a remote location. Toge further discloses that "[b]y transmitting the tidal volume...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" and "if there is a decreasing trend in the tidal volume..., 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." Ex. 1044, [0039]. Moreover, Toge explains that "[b]y transmitting the operating status in real-time, physicians can address emergencies involving the patient." *Id.*, [0046].

208. The '333 patent explains that "[b]y real-time it is meant that the quantitative diagnosis step is **accomplished predictively or within a short period of time** after symptoms occur which allows for immediate treatment, thereby more effectively reducing the health affects of such disorder while at the same time also minimizing side effects of the treatment chosen," including "preferably the diagnosis is **accomplished within 24 hours of receiving the signals** from the one or more

sensors on the subject.” Ex. 1001, 22:31-46. Accordingly, Toge discloses this limitation.

v. CLAIM 22. THE METHOD OF CLAIM 15, INCLUDING THE STEP OF STORING THE COLLECTED DATA, THE QUANTIFIED LEVEL OF SEVERITY DATA FROM EITHER THE PAP OR CPAP DEVICE TRANSMITTED TO THE REMOTE STATION, AND/OR DATA BASED ON THE TRANSFERRED DATA ON A DATABASE WITH SIMILAR DATA FROM TREATMENTS OF MANY OTHER SUBJECTS.

209. In my opinion, Toge-Kumar combination discloses this limitation. As discussed for limitation [15.d], in view of Toge and Kumar’s teachings, in my opinion, a POSITA would have been motivated to transmit data to a browser-based engine (“remote station”), including “the collected data, the quantified level of severity data from...the PAP or CPAP device,” 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]. Kumar additionally discloses that “storage of the data allows for the creation of statistical databases, including development of **a database of biomedical test results**, for example.” *Id.*, [0083]. Accordingly, for reasons discussed for limitation [15.d], in my opinion, a POSITA would have been motivated to implement this feature in the Toge-Kumar combination and would also have a reasonable expectation of success in doing so. Moreover, Toge explains that the PAP treatment may be provided to “several patients” (*see, e.g.*, Ex. 1044, [0015], [0058]) and thus, in my opinion, a POSITA would have also found it obvious to store each

patient's data on the same database of the browser-based engine for the creation of a statistical database, for example.

vi. CLAIM 23. THE METHOD OF CLAIM 22, WHEREIN THE DATABASE IS STORED ON A CENTRAL SERVER OR ON A GROUP OF SERVERS REMOTE TO THE TEST LOCATION, THE CENTRAL SERVERS OR THE GROUP OF SERVERS UPON WHICH THE SECOND SOFTWARE IS STORED ON A COMPUTER READABLE MEDIUM AND EXECUTED BY THE CENTRAL SERVER OR THE GROUP OF SERVERS.

210. In my opinion, Toge-Kumar combination discloses this limitation. As discussed for claim 22, in my opinion, a POSITA would have been motivated to implement a database for storing, e.g., the collected data and the quantified level of severity data. Toge further discloses that the database or the storage of the data is “at the central server.” Ex. 1044, [0083]. Consistent with Kumar's disclosure of “remote monitoring” (*id.*, [0010]), “telemedicine, remote sleep studies” (*id.*, [0068]) and that “patient-side device is remotely controlled” (*id.*, claim 22), in my opinion, a POSITA would have understood that the central server (on which the browser-based engine is implemented) is remote to the patient-side device (e.g., the PAP device of Toge). *See also id.*, [0087] (“the server may be implemented on the Internet”). Thus, the Toge-Kumar combination discloses “the database is stored on a central server...remote to the test location.”

211. Kumar also discloses that “[t]he present invention may be implemented on a program or code that can be stored in a computer-readable...medium” (“second

software is stored on a computer readable medium”). Ex. 1008, [0020]; *see also id.*, [0087]. Moreover, in my opinion, a POSITA would have understood that the implemented program/code is executed by the central server. Accordingly, the Toge-Kumar combination discloses “the central servers...upon which the second software is stored on a computer readable medium and executed by the central server...”

vii. CLAIM 24. THE METHOD OF CLAIM 23, INCLUDING THE STEP OF ANALYZING THE DATA ON THE DATABASE WITH A RELATIONSHIP ALGORITHM OR A NEURAL NETWORK TO DETERMINE AN OPTIMAL TREATMENT FOR THE SUBJECT.

212. In my opinion, Toge in view of Kumar discloses this limitation. Kumar discloses that storing data “in a secured storage device at the central server” allows “**for later** access, replay, and/or **analysis**” and “the creation of statistical databases, including development of a database of biomedical test results.” Ex. 1008, [0083]. Additionally, Kumar discloses that the system may “track trends” 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 understood that these analyses are used to improve/optimize treatments for the patient (“determine an optimal treatment for the subject”). Moreover, in my opinion, a POSITA would have understood that use of “artificial intelligence” involves applying “a relationship algorithm or a neural network,” as claimed.

viii. CLAIM 26. THE METHOD OF CLAIM 23, WHEREIN THE PROCESSOR OF THE PAP OR CPAP DEVICE ANALYZES THE

COLLECTED DATA, IN PART, USING ONE OR MORE OF A SHORT-TIME FOURIER TRANSFORM, A DISCRETE FOURIER TRANSFORM, A FAST FOURIER TRANSFORM, A RECURSIVELY IDENTIFIED SYSTEM MODEL, A STANDARD DEVIATION TECHNIQUE, A TIME-FREQUENCY SIGNAL ANALYSIS AND/OR A WAVELET SIGNAL ANALYSIS TO DETERMINE THE QUANTIFIED LEVEL OF SEVERITY DATA.

213. In my opinion, Toge in view of Kumar discloses this limitation. Kumar discloses that data may be analyzed “using FFT, DFT, etc.” Ex. 1044, [0075]. In my opinion, a POSITA would have understood that FFT and DFT each refers to the claimed “fast Fourier transform technique” and “discrete Fourier transform technique,” consistent with the ’333 patent’s use of DFT and FFT. *See* Ex. 1001, 23:63-65 (“A Discrete Fourier transform (DFT), and its numerically efficient complement the Fast Fourier Transform (FFT).”)

214. In my opinion, a POSITA implementing the Toge-Kumar combination would have been motivated to use the FFT and/or DFT techniques to analyze the collected data in order to determine, e.g., the tidal volume, as these techniques were well-known and commonly used at the time of the alleged invention to determine physiological parameters. For example, U.S. Patent No. 6,675,797 (Ex. 1060, 12:1-11) describes the use of Fourier transform to process airflow signals from CPAP devices, while WO 2003/024335A1 (Ex. 1061, claim 1) discloses using a “Fast Fourier Transform (FFT) algorithm” to identify occlusions of the patient’s airway.

215. In my opinion, a POSITA would have also had a reasonable expectation of success in implementing this feature in the Toge-Kumar combination as it would have involved a combination of known technologies (e.g., known PAP device that analyze collected data (Toge)) according to known methods (e.g., known methods of analyzing data using FFT or DFT (Kumar)) to yield the predictable result of a PAP device where the collected data is analyzed by the PAP device's processor, in part, using the FFT or DFT technique, as discussed above. Accordingly, Toge in view of Kumar discloses this limitation.

ix. CLAIM 27. THE METHOD OF CLAIM 23, WHEREIN THE PROCESSOR OF THE PAP OR CPAP DEVICE ANALYZES THE COLLECTED DATA, IN PART, USING A TIME-FREQUENCY SIGNAL ANALYSIS TO DETERMINE THE QUANTIFIED LEVEL OF SEVERITY DATA.

216. In my opinion, Toge in view of Kumar discloses this limitation. As discussed for claim 26, the Toge-Kumar combination teaches using Discrete Fourier Transform (DFT) and/or Fast Fourier Transform (FFT) to analyze the collected data to determine tidal volume (“quantified level of severity data”). In my opinion, a POSITA would have understood that the Fourier Transform analysis, including DFT and FFT, itself is a “time-frequency signal analysis” technique because the Fourier Transform analysis because that it transforms **time**-domain signals/data into **frequency**-domain signals/data. Thus, the Toge-Kumar combination discloses this limitation.

x. CLAIM 28: THE METHOD OF CLAIM 15, WHEREIN THE PAP OR CPAP FURTHER COMPRISES A FIRMWARE AND/OR A THIRD SOFTWARE WHICH ALONG WITH THE FIRST SOFTWARE CAN BE UPDATED FROM THE REMOTE STATION OR A DIFFERENT REMOTE SERVER.

217. In my opinion, Toge in view of Kumar discloses this limitation. Toge discloses that the PAP 2 is controlled based on “configured mode and prescription pressure” (Ex. 1044, [0032]) and the “the control unit 250 can be constructed using a **program** describing the processing of the control unit 250..., along with a CPU or microcontroller” (*id.*, [0048].) Thus, Toge discloses “the PAP or CPAP further comprises...a third software.”

218. Toge discloses that “medical institution personnel can operate the mobile terminal 5 (“cellular phone”) to set the necessary data...for the [PAP] device 2.” Ex. 1044, [0019]. “The mobile terminal 5 includes mobile phones..., PDAs...” *Id.* Thus, in my opinion, a POSITA would have understood that mobile terminal 5 operates by executing a program/software (“first software”).

219. Given that each of PAP device 2 (operating based on “third software”) and mobile terminal 5 (operating based on “first software”) are connected to communication network 1, in my opinion, a POSITA would have found it obvious to update the software on these devices using a remote server (“remote station” or “a different remote server”). For instance, Kumar discloses that “updates to the software are done by simply running the latest software from a website.” Ex. 1008,

[0086]; *see also id.*, [0067]. A POSITA would have understood that because the device 2 and the mobile terminal 5 are connected to communication network 1 (*id.*, [0008], [0061]), a POSITA would have found it obvious to have the software of those devices updated from a “remote station” or any “different remote server.”

220. In my opinion, a POSITA would have been motivated to have the software of the PAP device 2 and the mobile terminal 5 updated from a browser-based engine or any server. A POSITA would have looked to Kumar’s teaching of updating software and been motivated to have the software of the device 2 and the mobile terminal 5 (“cellular phone”) updated from the engine (“remote station”) or a “different remote server.” In my opinion, a POSITA would have had the skill and a reasonable expectation of success in implementing the above-described remote update feature as it would have would have been a routine and conventional implementation of known methods using known hardware components performing their known functions, well within a POSITA’s skills and ability to accomplish. Likewise, a POSITA would have had the skill and a reasonable expectation of success in updating the software of devices from an engine or a different server given that Toge itself at least suggests software may be updated remotely. Accordingly, the Toge-Kumar combination discloses this limitation.

**xi. CLAIM 29. THE METHOD OF CLAIM 15, FURTHER
COMPRISING THE STEP OF ALERTING THE SUBJECT’S**

**TECHNICIAN, CLINICIAN OR PHYSICIAN OF ISSUES RELATED TO
THE THERAPY EFFICACY.**

221. In my opinion, Toge discloses this limitation. For example, Toge discloses “send[ing] an alert to both or either of the physician-side computer 4 and the mobile terminal 5, marking the situation as an emergency where the patient's breathing has drastically weakened,” when the tidal volume falls below certain threshold value(s). Ex. 1044, [0055]. In my opinion, a POSITA would have understood that patient's weakened breathing indicates issues relating to the efficacy of the PAP treatment. Accordingly, Toge discloses this limitation.

**XII. OPINIONS ON GROUND 2: TOGE IN VIEW OF KUMAR AND
NORMAN RENDERS OBVIOUS CLAIMS 15-18, 20-24, AND 25-29**

**A. A POSITA WOULD HAVE BEEN MOTIVATED TO
COMBINE**

222. In my opinion, a POSITA would have been motivated to modify the Toge-Kumar combination in view of Norman's teaching. While Toge discloses a CPAP device, where the provided pressure may be adjusted, Norman teaches an improved CPAP device that allows “automated titration.” Ex. 1059, Abstract, [0007]. Such an automated titration process allows the system to “evaluate the efficacy of the adjusted pressure” and also “enhance[s] the accuracy with which the appropriate pressure is determined.” *Id.*, [0031]. Thus, a POSITA would have found it beneficial to implement an automated titration process similar to as disclosed in Norman in order to improve the accuracy and efficacy of the CPAP treatment

process similar to as disclosed by the Toge-Kumar combination. Moreover, consistent with a POSITA's understanding and as expressly disclosed by Norman, improved accuracy and efficacy of the treatment would have improved the patient's compliance and satisfaction. Ex. 1059, [0033] (“the more accurate the pressure supplied to a particular patient, the more likely the patient will regularly make use of this PAP therapy.”).

223. In my opinion a POSITA would have also been motivated to implement Norman's teaching of collecting patient's data “over a several time periods” to “evaluate the efficacy of the adjusted pressure” in the Toge-Kumar combination because Norman expressly discloses that using multiple types of data collected from multiple nights of treatment would have enhanced the accuracy of the treatment.

A. A POSITA WOULD HAVE HAD A REASONABLE EXPECTATION OF SUCCESS

224. In my opinion, a POSITA would have had a reasonable expectation of success in implementing Norman's teaching associated with automated titration in the Toge-Kumar combination. Indeed, Norman discloses that its disclosed features may be implemented in “*any variety of PAP systems* supplying constant or varying pressure to patients.” Ex. 1059, [0017]. Additionally, 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) combined with

remote engine that stores patient's data, for example (Kumar)) according to known methods (e.g., known methods implemented on a processor to analyze sensor data to determine counts/index associated with respiratory events (Norman)) to yield the predictable result of a PAP device having automated titration capability to improve accuracy and treatment efficacy.

225. In my opinion, a POSITA would have also had a reasonable expectation of success in implementing the Norman's features in the Toge-Kumar combination because it would have involved a combination of known technologies (e.g., known PAP device that collects both air flow and pressure sensor data (Toge)) according to known methods (e.g., known methods of collecting multiple types of data from multiple nights of sleep apnea treatments (Norman)) to yield the predictable result of a method using a rich data set based on data collected from multiple nights of treatment to improve the accuracy of the treatment.

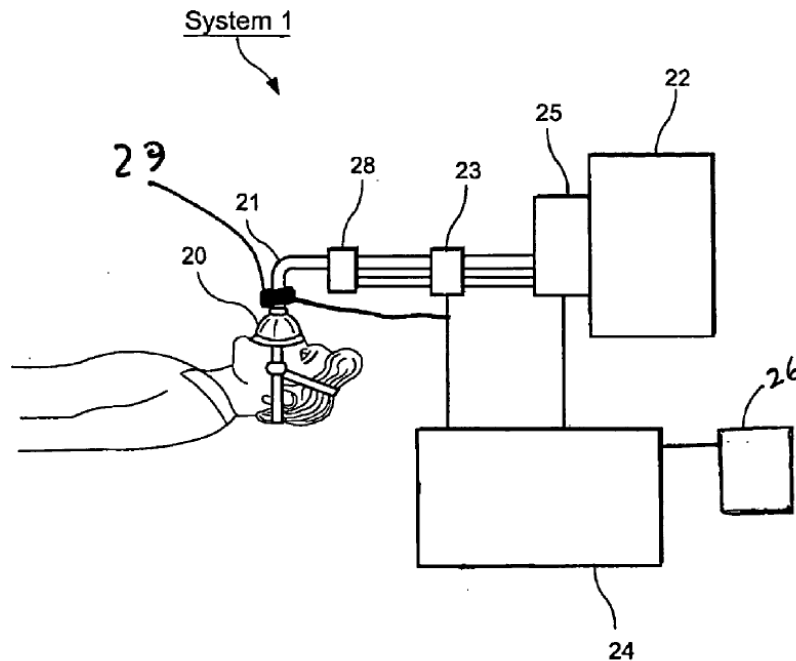
B. CLAIMS 15-17, 20-24, AND 26-29

226. Ground 1 establishes that the Toge-Kumar combination discloses claims 15-17, 20-24, and 26-29. Section VI (Ground 1). To the extent that Toge does not disclose limitation [15.c] ("analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy") and limitation [15.e.1] ("further determining the therapy efficacy data with either the processor of the PAP or CPAP device, the

second processor or server configured with a second software at the remote station, or the cellular phone using the first software”), it would have been obvious to implement these features in the Toge-Kumar combination in light of Norman.

227. Like Toge, Norman discloses a CPAP system including “an air pressure supply providing air pressure to a patient’s airways and a sensor detecting input data corresponding to a patient’s breathing patterns of a plurality of breaths.” Ex. 1059, Abstract.

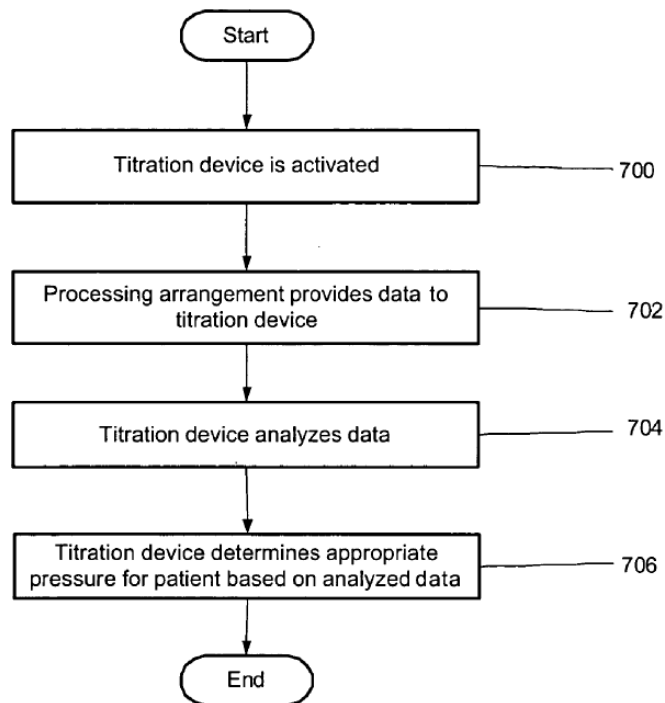
228. Specifically, Norman discloses a CPAP system 1 that includes a mask 20 that is connected via a tube 21 to receive airflow at a particular pressure from a flow generator 22, where “[t]he amount of pressure provided to a particular patient varies depending on that patient’s particular condition.” Ex. 1059, [0019]. “Flow and/or pressure sensors 23” are coupled to the tube 21 to “detect the volume of the airflow to and from the patient and the pressure supplied to the patient” by the generator 22, where “sensors 23 may be internal...to the generator 22.” *Id.*, [0020]. “Signals corresponding to the airflow and the pressure from the sensors 23 are provided to a processing arrangement 24,” which then “generates pressure control outputs signals to a flow control device 25 that “controls the pressure applied to the flow tube 21 by the flow generator 22.” *Id.*



Ex. 1059, FIG. 6

229. Norman explains that system may “detect[] abnormal respirations and flow limitations in the patient’s airway” and/or detect “sleeping disorders (e.g., flow limitations), and may be used for “autotitration and treatment of such sleeping disorders.” Ex. 1059, [0022]. “[S]ystem 1 also includes an **automatic titration device 26** which provides an initial titration (i.e., determination of an appropriate pressure or an appropriate varying pressure function for a particular patient) as well as subsequent retitrations.” *Id.*, [0023]. Titration device 26 may be “built into the system 1 (e.g., the titration device 26 may be combined with the processing arrangement 24).” *Id.*

230. As shown in Figure 7, Norman discloses “an exemplary method...for automatic titration to determine an appropriate pressure or varying pressure function for the PAP therapy.” Ex. 1059, [0024].



Ex. 1059, FIG. 7

231. **In step 700**, the titration device 26 is activated, e.g., “by the patient or medical personnel initially to obtain appropriate data for calculation of the pressure or pressure function for the PAP therapy” or “at such times as may be determined are desired to retitrate to ensure the PAP therapy is properly tailored to the patient's current condition.” Ex. 1059, [0024]. “Once activated, the titration device 26 may remain active for a predetermined period of time,” e.g., “for a specific period of time (e.g., a single sleeping cycle of 6-8 hours)....” *Id.*, [0025]. **In step 702**, “[w]hile

active, the titration device 26...process[es] and analyz[es] data collected by the processing arrangement 24 (step 702).” *Id.* “[P]rocessing arrangement 24 transmits data to the titration device 26,” where the data “includes...the patient’s airflow and the pressure applied to the airways of the patient” and “[s]uch data may be provided continuously or periodically.” *Id.* The data collected by the titration device 26 may be stored in a database with, e.g., data related to each particular patient collected during various titration procedures, where the stored data may be accessed and analyzed by the titration device 26 to determine appropriate pressure controls for that patient. *Id.*, [0026]. Data for multiple patients may be stored in a single memory arrangement that may be a part of system 1 or “situated at a remote location that can be accessed via a communications network. (e.g., the Internet, VPN, etc.).” *Id.*

232. In **step 704**, the titration device 26 analyzes the collected data. Ex. 1059, [0027]. Norman explains that titration device 26 analyzes patient airflow data to “accurately map patient’s breathing patterns.” *Id.* The titration device 26 analyzes breathing patterns to “detect abnormal respiratory events and to identify the conditions under which they arise”, where “[a]bnormal respiratory events...identified include apnea, hypopnea and events of elevated upper airway resistance.” *Id.* Specifically, “[a]pnea is identified by a cessation of respiratory airflow in the patient, where the cessation can last, for example, approximately ten seconds” and “[h]ypopnea is identified by a decrease in amplitude of the airflow

signal relative to a baseline value, where the decrease can last, for example, approximately ten seconds.” *Id.* “Elevations in the resistance of the upper airway may be identified by changes in the shape of the inspiratory airflow contour.” *Id.* Norman explains that the “airflow signal from the entire collection period may be analyzed for the presence of sleep disordered breathing events.” *Id.*

233. Lastly, in **step 706**, “based on the analysis of respiratory events, the titration device 26 determines, using a predefined algorithm, an appropriate pressure or a varying pressure function to be supplied to the patient.” Ex. 1059, [0028]. “The counts [or] other indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) that occurred during the previous collection period indicate the efficacy of the pressure administered.” *Id.* The pressure provided by the CPAP may be adjusted based on whether “the count or index increases to beyond a preset absolute value or relative value (compared to previous values for that patient)” or “[i]f the number of events is below a preset value.” *Id.*; *see also id.*, [0028]-[0029]. “If the titration device 26 is used to adjust a variable pressure supplied to a patient, those skilled in the art will understand that, based on the number of abnormal events identified and the circumstances under which they occurred, any number of modifications of the pressure supply function may be initiated.” *Id.*, [0029]; *see also id.*, [0030] (“The pressure may be adjusted for the subsequent time period. For

example, the pressure may be adjusted once per hour in response to events occurring during the previous hour.”). The titration process may be “repeated during the subsequent time period using the adjusted pressure to evaluate the efficacy of the adjusted pressure.” *Id.*, [0031]. Norman explains that such a process “enhance[s] the accuracy with which the appropriate pressure is determined.” *Id.* Alternatively, “the titration device 26 may be adapted to continually collect data for the entire duration of the treatment so that the titration process is continuously updated.” *Id.*, [0031]; *see also id.*, [0033].

i. NORMAN DISCLOSES LIMITATION [15.C]: “ANALYZING WITH THE PROCESSOR THE COLLECTED DATA TO DETERMINE A QUANTIFIED LEVEL OF SEVERITY DATA BASED ON THE SUBJECT’S SLEEP APNEA SYMPTOMS DURING THE THERAPY”

234. In my opinion, Norman discloses this limitation. As discussed above, Norman discloses that titration device 26 may be combined with processing arrangement 24 (collectively the claimed “processor”). Ex. 1059, [0023]. Norman explains that the volume of the airflow and the pressure supplied to the patient (where the airflow volume and/or the pressure correspond to the claimed “collected data”) are detected by flow and/or pressure sensors 23, provided to processing arrangement 24 (*id.*, [0020]), and processed/analyzed by titration device 26, e.g., in step 702 (*id.*, [0025]). Norman further explains that titration device 26 analyzes the collected data by analyzing breathing patterns to “detect abnormal respiratory events

and to identify the conditions under which they arise”, where “[a]bnormal respiratory events...identified include apnea, hypopnea and events of elevated upper airway resistance.” *Id.*, [0027].

235. Norman explains that “based on the analysis of respiratory events, the titration device 26 determines, using a predefined algorithm, an appropriate pressure or a varying pressure function to be supplied to the patient.” Ex. 1059, [0028]. **“The counts [or] other indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) that occurred during the previous collection period indicate the efficacy of the pressure administered.”** *Id.* Because processing arrangement 24 and titration device 26 (collectively the claimed “processor”) receive and analyze the collected sensor data (“collected data”) to determine the counts or indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) (“a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy”), Norman discloses limitation [15.c]. Additionally, for reasons discussed above, counts or indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) disclosed in Norman are consistent with PO expert’s interpretation of the claimed “level of severity” as discussed in Section X (Claim Construction). *See*

Section X (Claim Construction); Ex. 1058, ¶ 32 (“a commonly used term within the clinical sleep setting has been ‘level of severity’ which clinicians understand to represent the how dire a patient’s calculated symptom data may be”); *see also* Ex. 1054, 23 (citing to Ex. 1058, ¶ 32).

ii. NORMAN DISCLOSES LIMITATION [15.E.1] “FURTHER DETERMINING THE THERAPY EFFICACY DATA WITH EITHER THE PROCESSOR OF THE PAP OR CPAP DEVICE, THE SECOND PROCESSOR OR SERVER CONFIGURED WITH A SECOND SOFTWARE AT THE REMOTE STATION, OR THE CELLULAR PHONE USING THE FIRST SOFTWARE”

236. In my opinion, Norman discloses this limitation. For example, Norman discloses that “[t]he counts [or] other indexes of respiratory events (e.g., a total time of abnormal respiration, a percentage of abnormal breath, total number of events in general and by type, etc.) that occurred during the previous collection period **indicate the efficacy of the pressure administered.**” Ex. 1059, [0028]. For instance, Norman explains that “[w]hen the count or index increases to beyond a preset absolute value or relative value (compared to previous values for that patient) the pressure may be increased for the next CPAP period.” *Id.* Additionally, Norman discloses that the titration process may be “repeated during the subsequent time period using the adjusted pressure to **evaluate the efficacy of the adjusted pressure.**” *Id.*, [0031]. A POSITA would have understood that these data for adjusting the provided pressure correspond to the claimed “therapy efficacy data”

because these are data for adjusting the settings/parameters of the PAP device when treating the patient based on monitoring and analysis of the sensor data, representing the patient's condition and efficacy of the treatment. Accordingly, Norman discloses "further determining the therapy efficacy data with either the processor of the PAP or CPAP device...." Additionally, for reasons discussed above, Norman's data for adjusting the PAP's pressure is consistent with PO's interpretation in the district court for the claimed "therapy efficacy data" as discussed in Section X (Claim Construction). *See* Section X (Claim Construction); Ex. 1054, 23-24 ("[a] POSITA would understand the term 'therapy efficacy data' to mean data calculated based on data collected while a subject is undergoing treatment to determine the severity of a subject's sleep disorder symptoms and whether the PAP device that is part of the method needs to be adjusted.").

iii. A POSITA WOULD HAVE BEEN MOTIVATED TO MODIFY THE TOGE-KUMAR COMBINATION IN VIEW OF NORMAN

237. A POSITA would have been motivated to modify the Toge-Kumar combination in view of Norman's teaching discussed above. While Toge discloses a CPAP device where the provided pressure may be adjusted, Norman teaches an improved CPAP device that allows "automated titration." Ex. 1059, Abstract, [0007]. As discussed above, such an automated titration process allows the system to "evaluate the efficacy of the adjusted pressure" and also "enhance[s] the accuracy

with which the appropriate pressure is determined.” *Id.*, [0031]. Accordingly, a POSITA would have found it beneficial to implement an automated titration process similar to as disclosed in Norman in order to improve the accuracy and efficacy of the CPAP treatment process similar to as disclosed by the Toge-Kumar combination. Moreover, consistent with a POSITA’s understanding and as expressly disclosed by Norman, improved accuracy and efficacy of the treatment would have improved the patient’s compliance and satisfaction. Ex. 1059, [0033] (“the more accurate the pressure supplied to a particular patient, the more likely the patient will regularly make use of this PAP therapy.”).

238. Moreover, similar to reasons discussed for limitation [15.d)-(c) in Ground 1, a POSITA would have been motivated and have had reasonable expectation of success to enable the PAP device (as modified in view of Norman) to wirelessly transmit to the browser-based engine data associated the patient’s treatment, including “the collected data”, “the quantified level of severity data,” and “therapy efficacy data” as discussed above and disclosed in Norman for, e.g., secured storage, data backup, later analysis by the physicians, creation of a database, and sharing of data. Additionally, as discussed for limitations [15.d)-(c) and [15.e.2] in Ground 1, Kumar explains that the remote engine provides a secured storage and access of the stored data to the patient or care provider through web pages which serve as a graphical user interface. Ex. 1008, [0092], Figs. 6-8; *see also id.*, [0010],

[0015]. Accordingly, the Toge-Kumar-Norman combination also discloses limitation [15.e.2] (“further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider”).

239. A POSITA would have had a reasonable expectation of success in implementing the above-discussed features in the Toge-Kumar combination in view of Norman’s teaching and a POSITA’s knowledge. As discussed above for limitations [15.a]-[15.c] in Ground 1, Toge already discloses a CPAP device that collects sensor data and analyzes the sensor data using a processor. Moreover, Norman discloses that its disclosed features may be implemented in “any variety of PAP systems supplying constant or varying pressure to patients.” Ex. 1059, [0017] (“Although this description uses a CPAP system to illustrate the system and method according to the present invention, those skilled in the art will understand that this invention is equally useful in conjunction with any variety of PAP systems supplying constant or varying pressure to patients.”). Additionally, 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) combined with remote engine that stores patient’s data, for example (Kumar)) according to known methods (e.g., known methods implemented on a processor to analyze sensor data to determine counts/index associated with respiratory events (Norman)) to yield the predictable result of a PAP device having automated titration capability to improve

accuracy and treatment efficacy, as discussed above. Accordingly, the Toge-Kumar-Kumar combination discloses these limitations and therefor claim 15.

240. The Toge-Kumar-Norman combination also discloses dependent claims 16-17, 20-24, and 26-29 for reasons similar to those discussed for the same claims in Ground 1. To be sure, the Toge-Kumar-Norman combination discloses claims 16, 20, 22-24, and 26-28 for the same reasons discussed for the same claims in Ground 1 given that the modification of the Toge-Kumar combination in view of Norman (discussed above) does not substantively impact the disclosed features corresponding to claims 16, 20, 22-24, and 26-28.

241. With respect to dependent claims 17, 21, and 29, the Toge-Kumar-Norman combination also discloses these claims. For example, Toge discloses alerts may be sent to the physician based on the patient's condition wirelessly and the PAP device may be remotely controlled/adjusted in real-time. Ex. 1044, [0019], [0039], [0046], [0055]. Kumar likewise discloses that the care provider "may remotely control the client-side device" (e.g., the PAP device). Ex. 1008, [0015]. Thus, a POSITA would have been motivated to enable the PAP device (modified in view of Norman) such that the PAP device (provided treatment) may be adjusted in real-time by a physician remotely based on the wirelessly transmitted data/information, and also that the PAP device may alert the physician issues relating to the therapy efficacy.

242. For example, a POSITA would have found it obvious to adjust, for example, the frequency of the titration process based on the patient's condition and data/alert provided to the physician. Indeed, Norman discloses that "the titration device 26 may be activated by...medical personnel initially to obtain appropriate data for calculation of the pressure or pressure function for the PAP therapy" and **"can be again activated at such times as may be determined are desired to retitrate to ensure the PAP therapy is properly tailored to the patient's current condition."** Ex. 1059, [0024]. Accordingly, the Toge-Kumar-Norman combination discloses dependent claims 17 ("the therapy can be modified based in part on the wirelessly transmitted data or information"), 21 ("the PAP or CPAP is adjusted or titrated in real-time by the...physician from a remote location"), and 29 ("further comprising the step of alerting the subject's...physician of issues related to the therapy efficacy").

C. DEPENDENT CLAIMS 18 AND 25

i. CLAIM 18. THE METHOD OF CLAIM 17, WHERE A RICH DATA SET IS USED TO DETERMINE TREATMENT FROM THE COLLECTED DATA FROM MULTIPLE NIGHTS OF TREATMENT.

243. In my opinion, Toge in view of Kumar and Norman discloses this limitation. As discussed for claim 22 in Ground 1, based on Kumar's teaching and because Toge explains that the PAP treatment may be provided to several patients,

a POSITA would have found it obvious to store each patient's data on the same database of the browser-based engine for the creation of a statistical database.

244. To the extent that the Toge-Kumar combination does not disclose claim 18, in my opinion, a POSITA would have found it obvious to implement those features in the Toge-Kumar combination in view of Norman.

245. Like Toge, Norman discloses “a method and system for automated titration of CPAP,” where the system includes “an air pressure supply providing air pressure to a patient's airways and a sensor detecting input data corresponding to a patient's breathing patterns of a plurality of breaths” and “a titration device which receives and analyzes the input data to determine existence of breathing disorder and corresponding characteristics.” Ex. 1059, Abstract. “The titration device generating output data for adjusting the air pressure supplied to the patient as a function of the characteristics of the breathing disorder.” *Id.*

246. Norman additionally discloses that the titration device “analyze[s] [airflow and pressure sensor] data collected during...a predetermined time period” and repeats the titration process “over a several time periods” to “evaluate the efficacy of the adjusted pressure.” Ex. 1059, [0023], [0030]-[0031]. Thus, the PAP therapy “operat[es] over the course of **several sleeping cycles** to arrive at a more accurate image of the patient's breathing patterns” and “enhance the accuracy with which the appropriate pressure is determined.” *Id.*, [0031], [0033]. Norman explains

that “**the predetermined time period may be a single sleeping cycle such as one night of observation.**” *Id.*, [0030].

247. Norman reflects the general knowledge of a POSITA at the time that more data is better. A patient’s breathing can be impacted by different factors. For example, alcohol consumption, allergy, or indigestion could change a patient’s breathing dramatically for a single observed sleep cycle, and may not reflect a patient’s breathing during a routine sleep cycle. If a therapeutic pressure is prescribed based on that single sleep cycle, that pressure is unlikely to be appropriate. Given that Norman discloses collecting more than one type of data from multiple time periods or cycles to determine/enhance the accuracy of the air pressure provided for the sleep apnea treatment, Norman discloses “a rich data set is used to determine treatment from the collected data from multiple nights of treatment.” Ex. 1059, [0023], [0031], [0033].

248. In my opinion, a POSITA would have been motivated to implement the above-described features from Norman given that Norman expressly discloses that using multiple types of data collected from multiple nights of treatment would have enhanced the accuracy of the treatment.

249. In my opinion, a POSITA would have also had a reasonable expectation of success in implementing the above-discussed features in the Toge-Kumar combination because it would have involved a combination of known technologies

(e.g., known PAP device that collects both air flow and pressure sensor data (Toge)) according to known methods (e.g., known methods of collecting multiple types of data from multiple nights of sleep apnea treatments (Norman)) to yield the predictable result of a method using a rich data set based on data collected from multiple nights of treatment to improve the accuracy of the treatment, as discussed above. Accordingly, the Toge-Kumar-Norman combination discloses claim 18.

ii. CLAIM 25. THE METHOD OF CLAIM 23, WHEREIN THE PAP OR CPAP DEVICE, THE SOFTWARE ON THE CELLULAR PHONE OR THE REMOTE STATION DETERMINE A TOTAL SLEEP TIME.

250. The Toge-Kumar-Norman combination discloses this limitation. Norman discloses the PAP device analyzes data collected over a “predetermined time period,” including a time period encompassing “a single sleeping cycle such as one night of observation.” Ex. 1059, [0030]. In my opinion, a POSITA would have understood analyzing data over a “single sleeping cycle” encompasses one night of observation that involves a determination of “total sleep time.”

XIII. OPINIONS ON GROUND 3: TOGE IN VIEW OF KUMAR AND BURTON RENDERS OBVIOUS CLAIM 19

A. A POSITA WOULD HAVE BEEN MOTIVATED TO COMBINE

251. In my opinion, a POSITA would have been motivated to implement Burton’s features in Toge’s PAP device.

252. First, Burton's features, including an adaptive algorithm to modify a patient's therapeutic treatment and "automatically adjust[ing] the therapeutic treatment based on at least one index or derived data set," including, e.g., "Mixed Sleep Apnea events," "Central Sleep Apnea events," and "Obstructive sleep apnea and hypopnea syndrome," 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.

253. Second, 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 "to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of UARS [i.e., upper airway resistance], OSAHS [i.e., Obstructive sleep apnea and hypopnea syndrome], RERAs [i.e., Respiratory Effort-Related Arousals] and TERAs [i.e., Therapeutic control Related Arousals], while still minimizing sleep fragmentation and optimizing sleep quality." Ex. 1050, 20:14-23; *see also id.*, 26:9-15.

254. Kumar does not teach away from the combination, stating that "virtually any device may be easily incorporated into the system." Ex. 1008, [0074]. Kumar in general encourages the incorporation of existing devices. *Id.*

A. A POSITA WOULD HAVE HAD A REASONABLE EXPECTATION OF SUCCESS

255. In my opinion, a POSITA would have had a reasonable expectation of success in implementing Burton's features in the Toge-Kumar combination.

256. First, 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.

257. Second, 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, such as Toge) according to known methods (e.g., known methods/algorithm implemented on a controller/processor to generate/output data relating to patient's treatment and the treatment's efficacy based on sensor data and calculations of associated information, such as Burton) to yield the predictable result of a PAP device that is capable of self-learning/self-training, based on data from a prior time period, in order to adjust for better identifying and distinguishing between obstructive, central and complex sleep apneas during a subsequent period of time.

258. Kumar states that "virtually any device may be easily incorporated into the system." Ex. 1008, [0074]. Thus, no implementation details of Kumar would

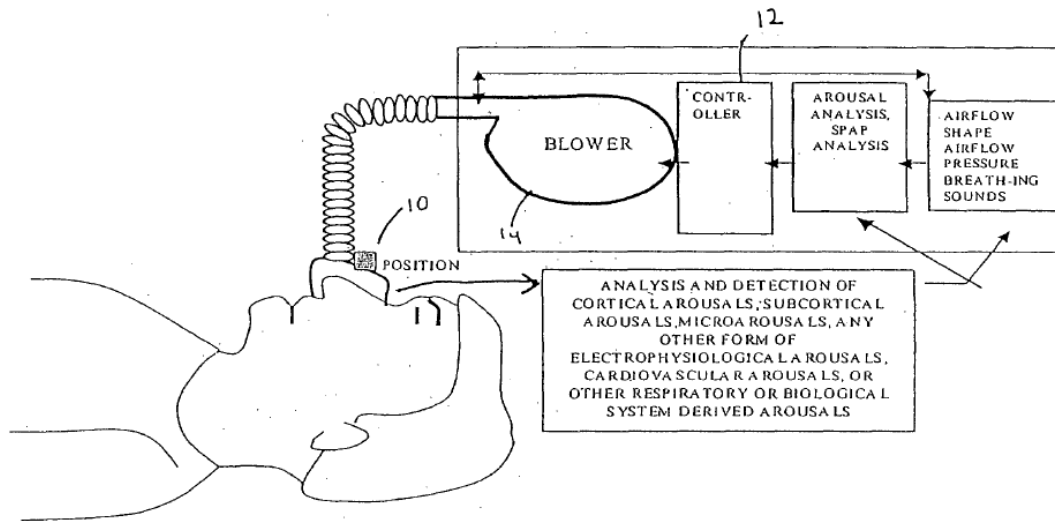
prevent incorporating Toge's PAP device as modified by Burton into its networked system.

B. DEPENDENT CLAIM 19

i. CLAIM 19. THE METHOD OF CLAIM 15, WHEREIN THE STEPS OF THE METHOD CAN BE USED TO TRAIN THE PAP OR CPAP TO ADJUST OR TITRATE ITSELF TO BETTER IDENTIFY AND DISTINGUISH BETWEEN OBSTRUCTIVE, CENTRAL AND COMPLEX SLEEP APNEAS DURING A SECOND TIME PERIOD WITH DATA FROM THE FIRST SENSOR.

259. In my opinion, Toge in view of Kumar and Burton discloses this limitation. To the extent that the Toge-Kumar combination does not disclose the additional features recited in claim 19, in my opinion, a POSITA would have found it obvious to implement those features in the Toge-Kumar combination in view of Burton.

260. Like Toge, Burton teaches providing PAP therapy to patients to treat sleep disordered breathing. Ex. 1050, 1:20-27. Burton discloses an embodiment of its sleep disorder treatment device as shown in Figure 1 below.



Ex. 1050, FIG. 1

261. Burton explains that, while PAP treatments may achieve intended results, the application of inaccurate pressure “often severely affect the quality of sleep” of the patient undergoing these treatments, “causing transient arousals.” Ex. 1050, 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.

262. 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.

263. Burton recognizes that a patient’s breathing, and thus the prescribed pressure, may vary depending on different factors. For example, a patient that may have consumed alcohol immediately prior to sleep may experience more loss of muscle tone in the upper airway, and therefore more respiratory events. Similarly, a cold might be impacting a patient’s breathing, or even different environmental factors.

264. Burton discloses “automatically adjust[ing] the therapeutic treatment based on at least one index or derived data set,” including, e.g., “Mixed Sleep Apnea events,” “Central Sleep Apnea events,” and “Obstructive sleep apnea and hypopnea syndrome.” Ex. 1050, 21:4-22:21. In my opinion, a POSITA would have understood that the afore-mentioned mixed sleep apnea events correspond to the claimed “complex sleep apneas,” which are terms that are often used interchangeably. Mixed apneas are sleep disordered breathing events that are characterized by both reduced

breathing effort (central) and airway obstruction (obstructive). Treating mixed apnea events with CPAP may reduce airway obstruction, although the reductions in breathing effort may still be present. Complex sleep apnea is a condition that refers to change in the proportion of obstructive and central sleep disordered breathing events in the presence of PAP. The most common expression of complex sleep apnea is that when obstructive apneas are treated with PAP that central apneas emerge. Thus, Burton discloses automatically adjusting the PAP operation based on various analysis/data, including the above-mentioned indices which involve “identify[ing] and distinguish[ing] between obstructive, central and complex sleep apneas,” as claimed.

265. Moreover, Burton discloses that “[t]he detection capability...enable the present invention to adopt analysis techniques such as neural networks or other methods that are capable of **adopting self-learning** and algorithm adaptation techniques.” Ex. 1050, 4:29-32. Patients entering different stages of sleep exhibit different sleep patterns. For example, a patient entering REM sleep will often experience more erratic breathing. That said, the breathing pattern of one patient entering REM sleep may be different from another patient. Self-learning and adaptation techniques like that taught by Burton were known to adjust and deliver more individualized pressure for the patient.

266. Additionally, Burton discloses “down-load[ing] from sleep laboratory studies or other types of **previous sleep...investigations**” and associating those data with the patient’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 [unwanted arousal events], while still minimizing sleep fragmentation and optimizing sleep quality.” *Id.*, 20:14-23. Thus, Burton discloses enabling the PAP device to self-learn/self-train using the collected sensor data (“data from the first sensor”) from a prior period in order to improve treatment in a subsequent period (“second time period”). Accordingly, Burton discloses and/or suggests “train[ing] the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during a second time period with data from the first sensor.”

267. 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 (e.g., Toge’s PAP device) 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 “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.

268. 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)) according to known methods (e.g., known methods/algorithm implemented on a controller/processor to generate/output data relating to patient’s treatment and the treatment’s efficacy based on sensor data and calculations of associated information (Burton)) to yield the predictable result of a PAP device that is capable of self-learning/self-training, based on data from a prior time period, in order to adjust for better identifying and distinguishing between obstructive, central and complex sleep apneas during a subsequent period of time,

as discussed above. Accordingly, in my opinion, the Toge-Kumar-Burton combination discloses this limitation.

XIV. OPINIONS ON GROUND 4: TOGE IN VIEW OF KUMAR, BURTON AND NORMAN RENDERS OBVIOUS CLAIM 19

269. In my opinion, the Toge-Kumar-Norman combination in view of Burton discloses claim 19. To start, as I discussed in Ground 2, to the extent that Toge does not disclose limitation [15.c] and limitation [15.e.1], in my opinion, it would have been obvious to implement these features in the Toge-Kumar combination in light of Norman, and that the Toge-Kumar-Norman combination discloses claim 15, from which claim 19 depends.

270. As I discussed in Ground 3, a POSITA would have been motivated to implement Burton's teaching in the Toge-Kumar combination and that the Toge-Kumar-Burton combination discloses claim 19. For the same reasons discussed in Ground 3, a POSITA would have been motivated to implement Burton's teaching in the Toge-Kumar-Norman combination (as discussed in Ground 2). That is, a POSITA would have had the same motivations, capabilities, and reasonable expectation of success discussed above in Ground 3 and knowledge of those discussed above regarding Burton to modify the Toge-Kumar-Norman combination to train the PAP/CPAP device to adjust/titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during a second time period

with data from the first sensor. Further, there is nothing in Norman or Burton that would have prevented the combination. Rather, Norman and Burton disclose similar use of data and analysis. Therefore, for the same reasons that I discussed above and in Ground 3, the Toge-Kumar-Norman-Burton combination discloses claim 19.

XV. CONCLUSION

271. For all the reasons stated above, it is my opinion that the challenged claims of the '333 patent are unpatentable.

272. 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 January 10, 2025.

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,857,333

A handwritten signature in cursive script that reads "Jason Kirkness". The signature is written in dark ink and is positioned above a solid horizontal line.

Jason Kirkness, Ph.D