

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

U.S. Patent No. 11,857,333

**DECLARATION OF DR. SANDEEP CHATTERJEE IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,857,333**

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I, Sandeep Chatterjee, Ph.D., declare as follows:

I. INTRODUCTION

1. I have been retained as an independent expert consultant in this proceeding regarding U.S. Patent No. 11,857,333 (“the ’333 patent”) (Ex. 1001). I have been asked to consider whether certain prior art references disclose or suggest the features recited in claims 15-29 (“the challenged claims”) of the ’333 patent. My opinions are set forth below.

II. BACKGROUND AND QUALIFICATIONS

2. My qualifications are stated more fully in my curriculum vitae, which is attached as Ex. 1006. Below is a summary of my education, work experience, and other qualifications.

3. I am the Chief Executive Officer of Experantis LLC (“Experantis”), a technology consulting company. Previously, I was the Co-founder, Executive Vice President and Chief Technology Officer of SourceTrace Systems, Inc., a technology and services company enabling the delivery of secure remote electronic services over landline and wireless telecommunications networks.

4. I received my Bachelor’s degree in Electrical Engineering and Computer Science from the University of California, Berkeley in 1995. I received my Master’s degree in Computer Science from the Massachusetts Institute of Technology (MIT) in 1997, and my Doctorate in Computer Science from MIT in

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2001. I received a certificate of completion for an executive education program on global leadership from Harvard University in 2011.

5. My doctoral dissertation at MIT, entitled “Composable System Resources for Networked Systems,” involving networked and distributed computer systems and architectures, was selected as one of the top inventions in the history of MIT’s Laboratory for Computer Science. This invention is showcased in a time capsule at the Museum of Science in Boston, Massachusetts. Other recipients of this honor include Bill Gates, the founder of Microsoft, and Tim Berners-Lee, the inventor of the World Wide Web.

6. As part of applications of my doctoral research, I developed hardware and software systems for intelligent environments within homes and offices. Some of these devices included televisions, digital picture frames, refrigerators, and children’s toys. The distributed computing system of these intelligent environments included distributed data storage and retrieval. Many of these devices and applications included various sensors that provided information about one or more users and/or the environment. For example, sensors, such as microphones, were used to identify different users, recognize different types of events or sounds, and accept voice commands. Similarly, infrared sensors were used to detect movement of users and/or objects, while pressure sensors were used to detect pressure, including collisions with objects.

7. In 2011, I was named a Young Global Leader. This honor, bestowed each year by the World Economic Forum, recognizes and acknowledges the top leaders—all below the age of 40—from around the world for their professional accomplishments, commitment to society, and potential to contribute to shaping the future of the world. In 2016, I was appointed to the World Economic Forum’s expert network as an expert in technology and innovation.

8. From 1997, I was the Entrepreneur-in-Residence at FidelityCAPITAL, the venture capital arm of Fidelity Investments. In 1999, I founded and served as President and Chief Technology Officer (CTO) of Satora Networks, which developed tools and technologies for building appliances and services for the Internet using wireless and other technologies to extend it beyond the desktop.

9. In 2001, I joined Bluestone Software’s Mobile Middleware Labs as a Senior Engineer developing applications and systems infrastructure for enterprise Java/J2EE, Web services, and enterprise mobile solutions. After the completion of Hewlett-Packard’s (HP) acquisition of Bluestone, I became a Senior Member of the Technical Staff at HP’s Middleware Division. I was responsible for architecting and developing the company’s next-generation Web services platform for enterprise as well as mobile environments, known as the Web Services Mediator.

10. I was part of the Expert Group that developed the JSR-00172 J2ME (Java 2 Platform, Micro Edition) Web Services Specification, the worldwide

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industry standard for mobile Web services. I am the co-author, with James Webber, of the book “Developing Enterprise Web Services: An Architect’s Guide” (published by Prentice-Hall in 2004). This book has been adopted by over 100 universities and colleges around the world and has been translated or reprinted in several countries around the world.

11. I have significant experience in developing complex computing systems. For example, through a contract between HP and the United States Agency for International Development (USAID), I architected and led the development of one of the first mobile banking solutions. This system enabled customers to use their mobile phones and other wireless handsets to connect with the core banking systems of banks and other financial institutions and perform transactions without having to travel to bank branches. This system supported many banking transactions, including deposits, withdrawals, loan applications, loan disbursements and loan repayments.

12. Later, after SourceTrace Systems’ acquisition of this technology, I led the expansion of this solution into multiple countries and into multiple industries. Banks and other financial services companies utilized this technology to make their tellers more efficient, to provide self-service ATMs within branches, and to provide remote access to banking services. Additionally, through our licensing agreement with Telefonica, one of the largest cellular and telecommunications companies in the world, this solution was deployed in various other industries, including logistics

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and asset management and customer relationship management. Bloomberg Television selected and featured this technology and the company I cofounded to commercialize this technology on Bloomberg TV's "Bloomberg Innovators" program.

13. I have been a retained expert witness for various disputes that involved significant technology issues, and I have been qualified as a technology expert by U.S. District and State Courts, including in California, Delaware, Florida, and Texas in technology areas that are relevant to this case, including but not limited to: computer software systems, distributed computing systems, networked data systems, and mobile and wireless systems. I have previously testified through declaration or expert report, at deposition, and at trial in numerous intellectual property and commercial litigation matters, including for patent litigation, copyright and trade secret misappropriation litigation, and contract dispute cases. I have submitted more than one hundred and fifty expert declarations and expert reports, testified at deposition more than eighty times, and testified at trial or at hearings at least twelve times.

14. Experantis is being compensated for my time on this matter at my standard hourly rate and reimbursed for any expenses that I incur related to my work in this matter. Neither Experantis nor I have any financial interest in the outcome of

this matter, and Experantis will be paid for my time regardless of the outcome of this matter.

III. MATERIALS REVIEWED

15. The opinions contained in this Declaration are based on the documents I reviewed, my professional judgment, as well as my education, experience, and knowledge regarding systems and processes in the field of graphics interface technology.

16. In forming my opinions expressed in this Declaration, I reviewed the following materials:

Exhibit No.	Description
1001	U.S. Patent No. 11,857,333 to Kayyali (“the ’333 patent”)
1002	File History of U.S. Patent No. 11,857,333
1006	Curriculum Vitae of Sandeep Chatterjee, Ph.D.
1008	U.S. Patent Pub. No. 2002/0198473 to Kumar et al. (“Kumar”)
1009	U.S. Patent No. 7,575,005 to Mumford et al. (“Mumford”)
1011	“ <i>T-Mobile USA and HP Launch the First Truly Integrated Wireless iPAQ Handheld - T-Mobile Newsroom</i> ” (July 2004) available at https://www.t-mobile.com/news/press/t-mobile-usa-and-hp-launch-the-first-truly-integrated-wireless
1013	U.S. Patent Pub. No. 2002/0185130 to Wright et al. (“Wright”)
1044	Japan Patent Office Patent Application Pub. No. P2002-291889A to Toge (“Toge”)

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1045	U.S. Pat. Pub. No. 2008/0214903 to Orbach (“Orbach”)
1046	D. Gourley, et. al., HTTP The Definitive Guide (2002)
1047	D. Mauro, et. al., Essential SNMP (2001)
1048	F. Adelstein, et. al., Fundamentals of Mobile and Pervasive Computing (2005)
1049	WIPO Publication No. WO0145014A1 to Quay (“Quay”)
1050	WIPO Publication No. WO2004032719A2 to Burton et al. (“Burton”)
1054	CleveMed Opening Claim Construction Brief
1058	Declaration of Dr. Carolyn D’Ambrosio, submitted by Patent Owner in the District Court litigation
1059	U.S. Patent Pub. No. 2005/0268912 to Norman et al. (“Norman”)

I also considered any other documents and materials I refer to in this Declaration.

17. My opinions contained in this Declaration are based on the documents I reviewed and my knowledge and professional judgment. My opinions have also been guided by my appreciation of how a person of ordinary skill in the art would have understood the state of the art, the prior art, and the claims and the specification of the ’333 patent at the time of the alleged invention, which I discuss below.

18. I have been asked to consider that the time of the alleged invention of the ’333 patent was around November 2005, which corresponds to the filing date of the earliest application associated with the ’333 patent.

19. Based on my experience and expertise, it is my opinion that certain prior art references disclose and/or suggest the features recited in the challenged claims of the '333 patent, as I discuss in detail below.

IV. PERSON OF ORDINARY SKILL IN THE ART AT THE TIME OF ALLEGED INVENTION

20. I understand that the '333 patent was allowed from U.S. Patent Application 15/641,715 filed on July 5, 2017, which claims priority to U.S. 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 person of ordinary skill in the art as of November 4, 2005.

21. I understand that Dr. Jason Kirkness¹ has opined that a person of ordinary skill in the art 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

¹ I understand that Dr. Kirkness is a Professor in Pulmonary, Critical Care and Sleep Medicine, specializing in CPAP and other sleep disorder treatment systems, and is submitting a declaration in this IPR.

systems. Additional experience could substitute for less education, and additional education could likewise substitute for less experience.

22. By 2005, I met or exceeded the level of a person of ordinary skill in the art. Regardless, my opinions do not turn on this precise definition, and the relevant features discussed were taught or obvious from the perspective of any reasonable person of ordinary skill in the art.

23. My opinions in this Declaration regarding the '333 patent and the prior art (including the state of the art) are from the perspective of one of ordinary skill in the art during the relevant timeframe (e.g., the time of the alleged invention), around November 2005. This is true even if stated in the present tense.

V. TECHNICAL BACKGROUND AND STATE OF THE ART

24. Below, I present a brief overview of systems and technology concepts that were well known to those of ordinary skill prior to the time of the alleged invention of the '333 patent. The functionalities and concepts I describe below in this technical background section reflect the state of the art that a person of ordinary skill in the art would have had knowledge of and understood prior to and at the time of the alleged invention of the '333 patent.

A. Mobile Computing

25. Well before 2005, a person of ordinary skill in the art was aware of the trend towards mobile computing. For example, launched in 1996², the Nokia 9000 Communicator rolled all of the features of a computer into a phone, putting email, web browsing, fax, word processing and spreadsheets into a single pocketable device. (<https://medium.com/people-gadgets/the-gadget-we-miss-thenokia-9000-communicator-ef8e8c7047ae>; *see also* <https://www.mobilephonemuseum.com/phone-detail/nokia-9000-communicator>.) The Communicator was a mobile powerhouse, with 8MB of memory and a 33MHz processor. This combination ran Nokia's own GEOS operating system (a predecessor to the Symbian OS used on later models), combined with a suite of business programs that could read and edit Microsoft Office files from a desktop PC. Inside the clamshell style case was a chiclet QWERTY keyboard, complete with function keys for the major features and a series of programmable buttons by the screen. This screen was a black and white

² The US model was launched in 1997 (the Nokia 9000i Communicator), running on the GSM 1900 frequency offered by carriers like Microcell in Canada.

(<https://medium.com/people-gadgets/the-gadget-we-miss-the-nokia-9000-communicator-ef8e8c7047ae>.)

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LCD, with a then-high resolution of 640 x 200 pixels. This long, thin screen meant that it could offer a first: a graphical web browser on a mobile device. *Id.*

26. As shown in the photos below, the Communicator had two screens. One on the outside and a larger screen on the inside of the clamshell. The inside also included a full QWERTY keyboard. *Id.*





27. Previous phones had offered only text web browsing, but the 9000 Communicator could render graphics and connect to the Internet over the built-in 9600 bits per second GSM modem, which worked with the digital GSM phone networks that were being rolled out across the world. *Id.*

28. The device could also be connected to a Windows PC (running Windows 95 or Windows NT 4.0) via the “PC Suite for Nokia 9110 Communicator” software. This allowed users to “transfer information and software between the communicator and a computer”. *Id.*

29. Nokia explained the value of data connectivity on the move describing how wireless services had “evolved beyond voice” and was playing an increasingly important role “not only in business use but also personal lifestyle uses with the

emergence of electronic banking and commerce, electronic postcards and infotainment.” *Id.*

30. In the late 1990s, PDAs became pervasive with Palm jumping to the forefront. In 2000, the first Blackberry smartphone was released with the ability to connect to the internet.

31. As the trend towards mobile computing was happening, a person of ordinary skill in the art would have recognized the importance of mobile and wireless computing, including wireless sensors.

1. Web Clients and Servers

32. Web content lives on web servers. Web servers use HTTP, which stands for Hypertext Transfer Protocol. These HTTP servers store the Internet’s data and provide the data when it is requested by HTTP clients. The clients send HTTP requests to servers, and servers return the requested data in HTTP responses, as sketched in Figure 1-1. Together, HTTP clients and HTTP servers make up the basic components of the World Wide Web. Ex. 1046 at p. 4.

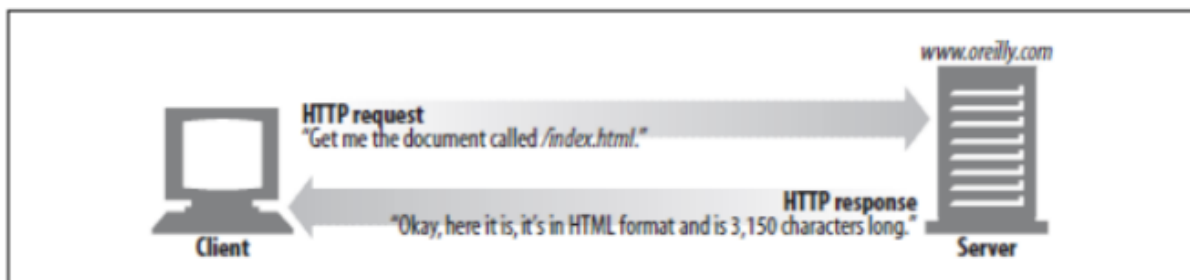


Figure 1-1. Web clients and servers

33. Users use HTTP clients every day. The most common client is a web browser, such as Microsoft Internet Explorer or Netscape Navigator. Web browsers request HTTP objects from servers and display the objects on your screen. *Id.*

34. When a user browses to a page, such as “http://www.oreilly.com/index.html,” your browser sends an HTTP request to the server www.oreilly.com (see Figure 1-1). The server tries to find the desired object (in this case, “/index.html”) and, if successful, sends the object to the client in an HTTP response, along with the type of the object, the length of the object, and other information. *Id.*

2. Resources

35. Web servers host web resources. A web resource is the source of web content. The simplest kind of web resource is a static file on the web server’s filesystem. These files can contain anything: they might be text files, HTML files, Microsoft Word files, Adobe Acrobat files, JPEG image files, AVI movie files, or any other format you can think of. *Id.*

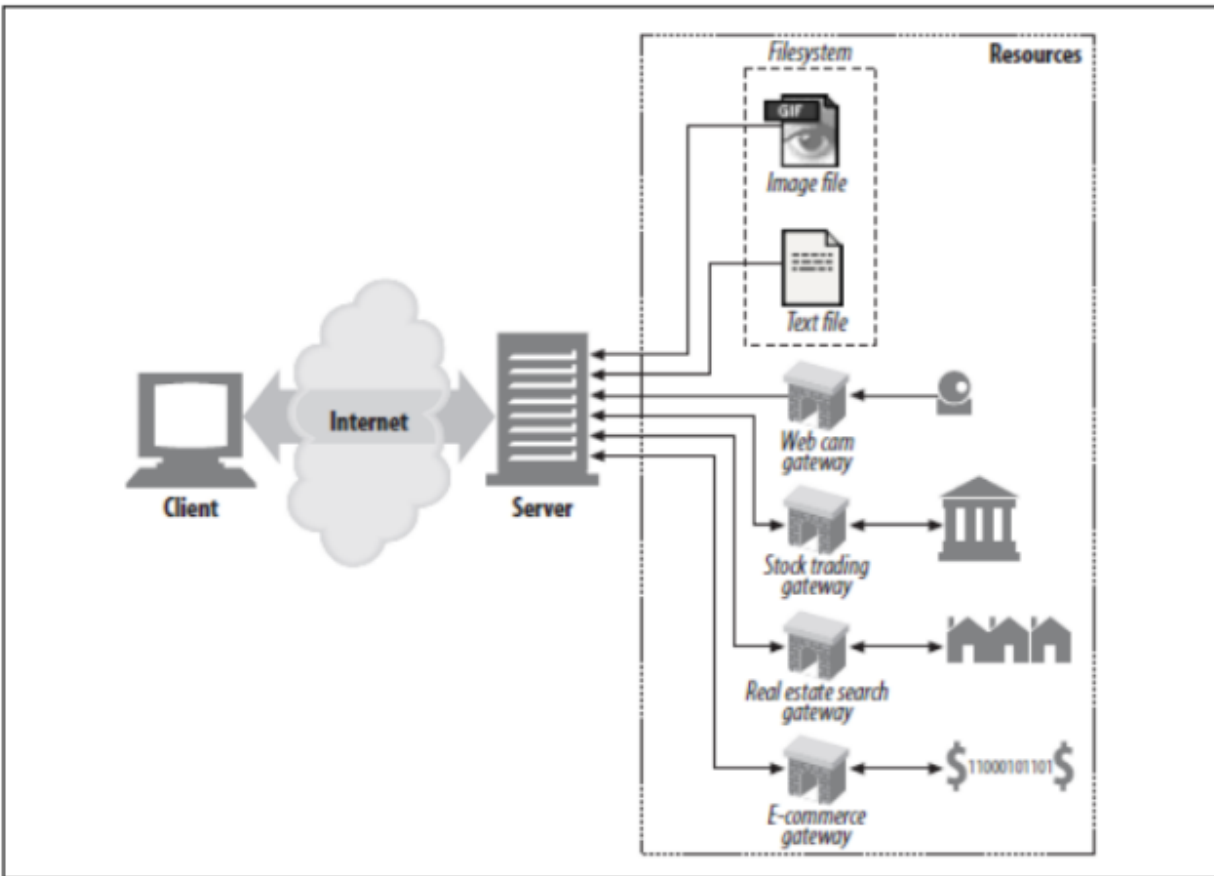


Figure 1-2. A web resource is anything that provides web content

36. As shown in Figure 1-2 above, it was well known to make available data from a web camera (and from other systems) using, for example, a gateway.

3. Resource Gateways

37. An application server is the most common form of gateway and combines the destination server and gateway into a single server. Application servers are server-side gateways that speak HTTP with the client and connect to an application program on the server side (see Figure 8-8). *Id.* at p. 203.

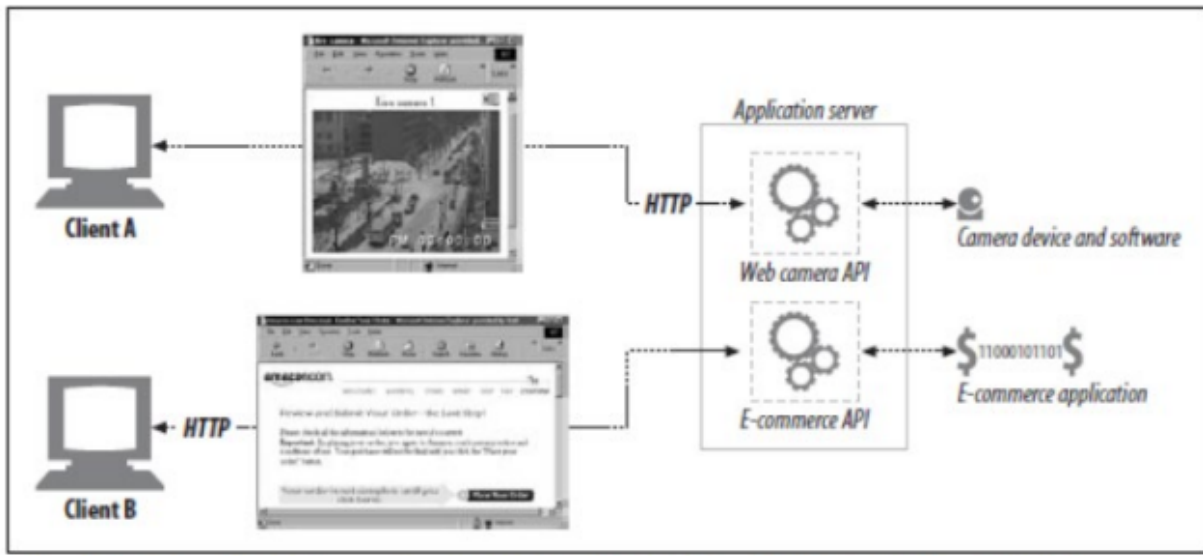


Figure 8-8. An application server connects HTTP clients to arbitrary backend applications

38. In Figure 8-8, two clients are connecting to an application server using HTTP. But, instead of sending back files from the server, the application server passes the requests through a gateway application programming interface (API) to applications running on the server:

- Client A's request is received and based on the URI, is sent through an API to a digital camera application. The resulting camera image is bundled up into an HTTP response message and sent back to the client, for display in the client's browser.
- Client B's URI is for an e-commerce application. Client B's requests are sent through the server gateway API to the e-commerce software, and the results are sent back to the browser. The e-commerce software interacts with the

client, walking the user through a sequence of HTML pages to complete a purchase. *Id.*

39. The first popular API for application gateways was the Common Gateway Interface (CGI). CGI is a standardized set of interfaces that web servers use to launch programs in response to HTTP requests for special URLs, collect the program output, and send it back in HTTP responses. *Id.*

40. Accordingly, it was well known to those of ordinary skill to access and display data from a remote server that had been provided from a physical device, such as a camera, using industry-standard technologies and protocols.

B. Simple Network Management Protocol (SNMP)

41. By 1990s and early 2000s, there was a lot of activity around controlling, retrieving information from, and otherwise communicating with different types of devices. Another well-known industry-standard protocol was Simple Network Management Protocol (SNMP). SNMP was introduced in 1988 to meet the growing need for a standard for managing Internet Protocol (IP) devices. SNMP provides its users with a “simple” set of operations that allows these devices to be managed remotely. Ex. 1047 at p. 7.

42. The core of SNMP is a simple set of operations (and the information these operations gather) that gives administrators the ability to change the state of some SNMP-based device. For example, an administrator can use SNMP to shut

down an interface on a router or check the speed at which an Ethernet interface is operating. SNMP can even monitor the temperature on a switch and warn the administrator when the temperature is too high. *Id.*

43. SNMP is usually associated with managing routers, but it can be used to manage many types of devices. Any device running software that allows the retrieval of SNMP information can be managed. This includes not only physical devices but also software, such as web servers and databases. *Id.*

44. Consider the situation if a file server crashes. If it happens in the middle of the workweek, it is likely that the people using it will notice and the appropriate administrator will be called to fix it. But administrators might be unavailable if it happens after everyone has gone home, including the administrators, or over the weekend. *Id.* at p. 8.

45. This is where SNMP comes in. Instead of waiting for someone to notice that something is wrong and locate the person responsible for fixing the problem, SNMP allows a user or administrator to monitor the network constantly, even when no one is there. For example, it will notice if the number of bad packets coming through a router's interface is gradually increasing, suggesting that the router is about to fail. The administrator can arrange to be notified automatically when failure seems imminent so that the router can be fixed before it breaks. *Id.*

46. In the world of SNMP there are two kinds of entities: managers and agents. A manager is a server running some kind of software system that can handle management tasks for a network. Managers are often referred to as Network Management Stations (NMSs). An NMS is responsible for polling and receiving traps from agents in the network. A poll, in the context of network management, is the act of querying an agent (router, switch, Unix server, etc.) for some piece of information. This information can later be used to determine if some sort of catastrophic event has occurred. A trap is a way for the agent to tell the NMS that something has happened. Traps are sent asynchronously, not in response to queries from the NMS. The NMS is further responsible for performing an action based upon information it receives from the agent. *Id.* at pp. 10-11.

47. The second entity, the agent, is a piece of software that runs on the network devices that are being managed. It can be a separate program, or it can be incorporated into the operating system. By the time of the publication of this book, most IP devices come with some kind of SNMP agent built in. The agent provides management information to the NMS by keeping track of various operational aspects of the device. For example, the agent on a router can keep track of the state of each of its interfaces: which ones are up, which ones are down, etc. The NMS can query the status of each interface on a router and take appropriate action if any of them are down. When the agent notices that something bad has happened, it can send a trap

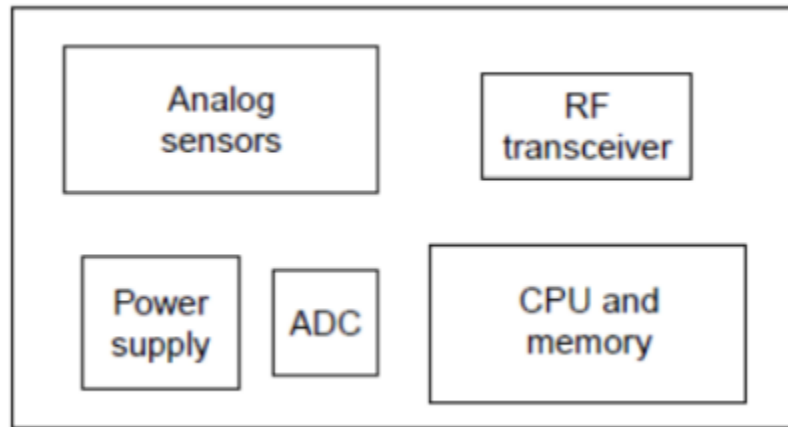
to the NMS. This trap originates from the agent and is sent to the NMS, where it is handled appropriate. *Id.* at 11.

C. Pervasive Computing

1. Smart Sensors

48. Pervasive computing (also referred to as ubiquitous computing) was started in the early 1990s and envisioned that future computing environments would consist of interconnected specialized computers all around us, some embedded in our surroundings and others worn by us. The aim of pervasive or ubiquitous computing is to design computing infrastructures in such a manner that they integrate seamlessly with the environment and become almost invisible. Ex. 1048 at 112. At least as of 2002, wireless networks of smart sensors had become feasible for many applications because of technological advances in semiconductors, energy-efficient wireless communications, and reduced power budgets for computational devices, as well as the development of novel sensing materials. The figure below shows a generic wireless sensor node partitioned into some basic components. Besides the CPU and memory, the sensor node has, of course, several analog sensors. These sensor outputs must be converted to digital data that can be processed by the CPU. This transformation is performed by the analog-to-digital converter (ADC). Batteries or passive power sources could provide the wireless sensor node with power as indicated by the power supply component. Although other wireless communication

mechanisms are possible, most wireless sensor nodes use radio frequency (RF) transmissions, so the final component shown in the sensor node is the RF transceiver. The entire sensor node is encapsulated in the appropriate packaging for the environment in which the sensor node will operate. Ex. 1048 at pp. 191-92.



49. These sensor nodes enabled various types of applications. For example, a sperm whale could carry a small, low-power radio transmitter that has been recording its vital signs for the last 2 months. When above the water, the transmitter establishes contact with a low-earth-orbit satellite and uploads its data. It also uploads vital signs for other similarly equipped whales it passed since the radio last contacted the satellite. *Id.* at p. 16.

2. Medical Applications

50. At least as early as 2003, sensor nodes were being envisioned as medical devices that could be implanted within or reside on the body and perform tasks currently done with additional cost or inconvenience. A few examples include

glucose monitors for diabetic patients (DirecNet, 2003), artificial retinal and cortical implants for the visually impaired (Schwiebert et al., 2001), heart monitors (Conway et al., 2000), and a vital statistics repository (Arnon et al., 2003). *Id.* at p. 205.

51. For example, a glucose monitor could provide continual readings of insulin levels, reporting problems to the patient or giving readings at regularly scheduled times. A log could be kept that would report these fluctuations in readings at subsequent doctor's office visits. In cases of extreme readings of glucose levels, emergency personnel could be notified directly. *Id.*

52. Like a glucose monitor, a heart monitor could be used to keep track of the functioning of the heart. This could replace the need for hospital stays to determine the causes of irregular heartbeats and provide chronic heart monitoring for persons with coronary diseases or other heart-related problems. The vital statistics repository could take the form of a medical smart card that holds medical information on the user, like the tags that some people wear in case of medical emergencies but with the added advantages of having sensors that provide up-to-date medical information. *Id.* at pp. 205-206.

53. It was also known that sensors used for medical applications also have unique requirements. First, these sensors must be safe and biocompatible so that they continue to function inside the body and do not cause damage to the surrounding tissues. Owing to the risks of surgery, power must be provided to these sensors so

that surgical replacement of sensors is not required on a regular basis simply because the node runs out of power. For similar reasons, the sensor node should be designed for long-term operation, which implies that a high level of fault tolerance and redundancy, along with graceful failure modes, must be incorporated into the design. The sensors also need to function correctly even in the presence of RF noise and interference from other wireless devices. Finally, patient confidentiality must be maintained so that unauthorized personnel cannot extract sensor readings from the sensors. *Id.* at p. 206.

D. Wired and Wireless Sensors

54. Sensors can be wired or wireless. Wired sensors communicate their data using a wired connection, while wireless sensors communicate their data using a wireless connection. This wireless connection can be through the use of any available protocol, such as Wi-Fi (802.11), Bluetooth, or a cellular protocol like GSM or GPRS. Additionally, it was well known to transmit data using wireless protocol(s) to a remote Internet site, e.g., for later access of the data. For example, Quy discloses “[T]he patient connects to a specific Internet site and a software program, resident on a remote server located on the Internet, downloads an interactive user interface for that patient and an application for the measurement of the physiological data.” Ex. 1049, 8:8-13. “The software may also be downloaded to the [wireless web device] WWD from a personal computer 15 via a

synchronization operation in known fashion.” *Id.*, 8:13-15; *see also id.*, Abstract, 1:24-31 (“measured or input health data is communicated by a wireless device to and from a software application running on an internet-connected server”), 8:15- 31.

56. As explained *supra* in Section V.C, a person of ordinary skill in the art would have understood that the use of wired sensors would adversely impact the mobility of mobile computing devices. In fact, as also explained *supra*, most wireless sensor nodes included a radio frequency (RF) transceiver to support wireless transmissions to other devices, such as mobile computers.

VI. THE '333 PATENT

55. The '333 patent discloses a networked PAP device. “The sleep disorder treatment system of the present invention can use a diagnosis device to perform various forms of analysis to determine or diagnose a subject's sleeping disorder or symptoms of a subject's sleep disorder.” Ex. 1001, Abstract.

56. 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.

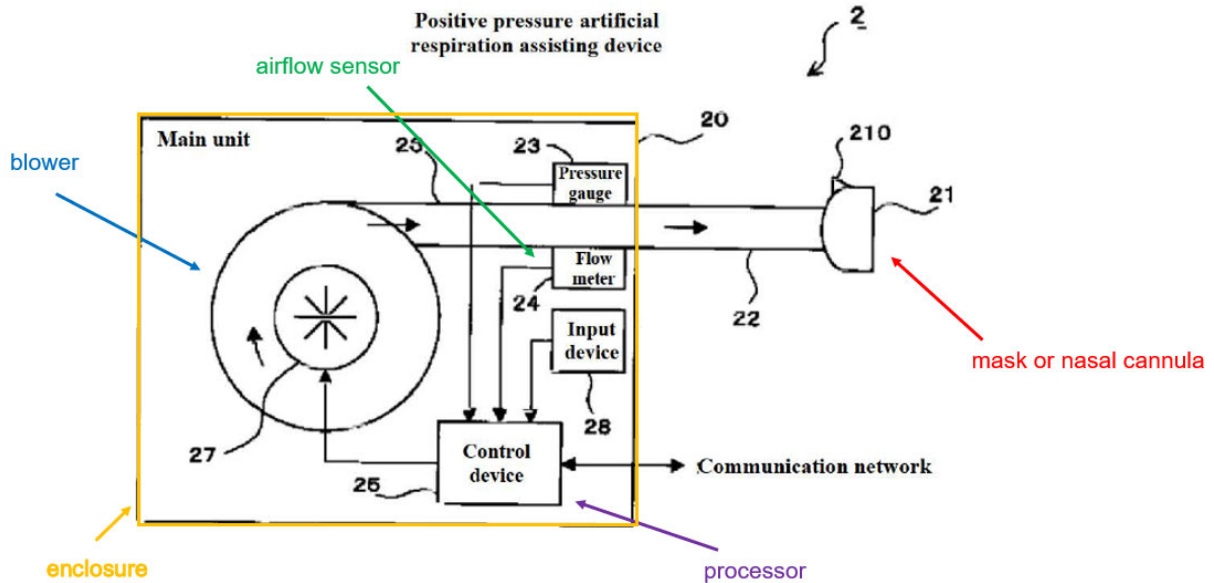
57. The '333 patent acknowledges that various claimed features were known in the art. For example, the '333 patent acknowledges that “collecting data with the PAP or CPAP device from the flow or pressure sensor,” “radio frequency wireless link,” determination of “a quantified level of severity data,” and “Wavelet signal analysis,” as recited in the '333 patent claims were known. *Id.*, 17:7-10, 24:61-65, 26:42-45, 26:67-27:5.

VII. OVERVIEW OF THE PRIOR ART

A. Japan Patent Office Patent Application Pub. No. P2002-291889A to Toge (Ex. 1044)

58. Toge discloses a networked PAP device. The PAP device includes a blower 27, a pressure gauge 23, a flow meter 24, a control unit 250 in a control device 25, and a nasal mask 21. “[T]he present invention is as such wherein a positive artificial respiration assisting device, which delivers positive pressure air containing atmospheric air or air containing more oxygen than atmospheric air mix with atmospheric air to assist the patient’s breathing.” Ex. 1044, [0006].

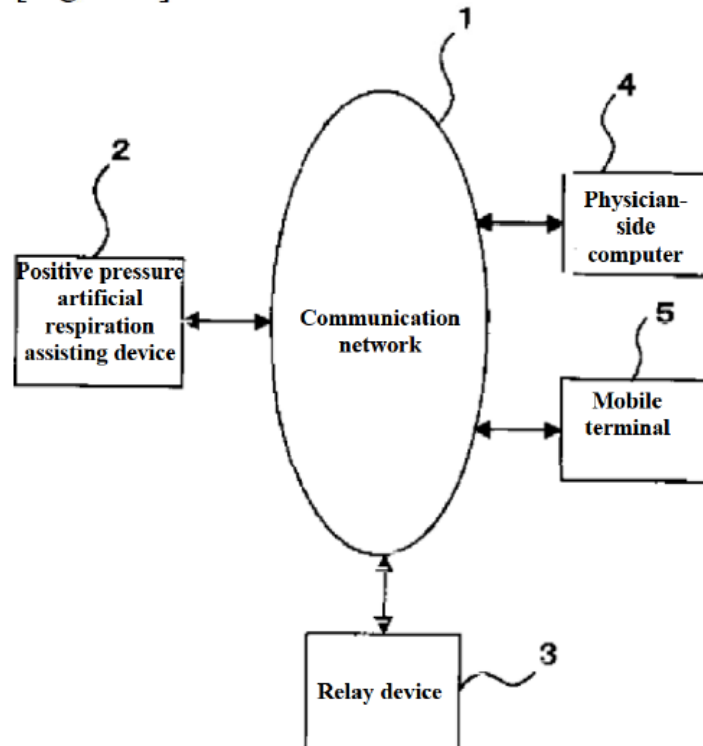
[Figure 2]



59. Toge discloses that the “measured air pressure is provided to the control unit 250 of the control device 25” and the “measured flow rate is [] provided to the control unit 250 of the control device 25.” Ex. 1044, [0028]. Toge further discloses “transmitting data (transmission data) provided from control unit 250.” *Id.*, [0030]. Toge explains that the “transmitted data includes the patient’s treatment data such as the tidal volume F_p , the operational time T of this positive pressure artificial respiration assisting device 2, the air leakage volume F_b (leaking from parts other than the exhalation vent 210) from the nasal mask 21, the internal pressure P of the nasal mask 21, the minute breathing rate N , the inspired oxygen concentration FiO_2 ,

and the operating status of this positive pressure artificial respiration assisting device 2 (such as alarms if the nasal mask is detached).” *Id.*, [0031].

[Figure 1]



60. Toge discloses that the positive pressure device 2 is connected to a communications network by a relay device 3. Ex. 1044, [0008]. The relay device 3 receives data from the positive pressure device 2 and then transmits all or part of the data to the physician side terminal device 4 or mobile terminal 5, which can be a mobile phone or PDA. *Id.*, [0016].

B. WO 2004/032719 to Burton (Ex. 1050)

61. Burton discloses a system that “deliver[es] therapeutic treatments to patients without adversely affecting their sleep.” Ex. 1050, 1:4-6, 3:15-16. The system “maintain[s] the sleep quality of a patient undergoing a therapeutic treatment” by “predict[ing] the onset of arousal and using an adaptive algorithm to modify a patient’s therapeutic treatment.” *Id.*, 3:21-24.

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

C. U.S. Patent Pub. No. 2002/0198473 to Kumar (Ex. 1008)

63. Kumar discloses a telemedicine system “for network-based monitoring of physiological data.” Ex. 1008, Abstract. As shown in Figure 1A, the system includes a patient-side device 102, a computing device 110, such as a wireless phone or pocket PC like iPAQ, and a central server 106 that hosts a browser-based engine

that can be accessed through web pages. To communicate with the patient-side device and the central server, the computing device can download a plug-in that it can request from the central server. *Id.*, [0018] (“[T]he present invention is built on a modular architecture in which the patient-side device and/or the computing device coupled to the patient-side device can send a request to the engine with an identifier of the patient-side device, and the engine will send the appropriate plug-in which allows the computing device to communicate with the patient-side device.”).

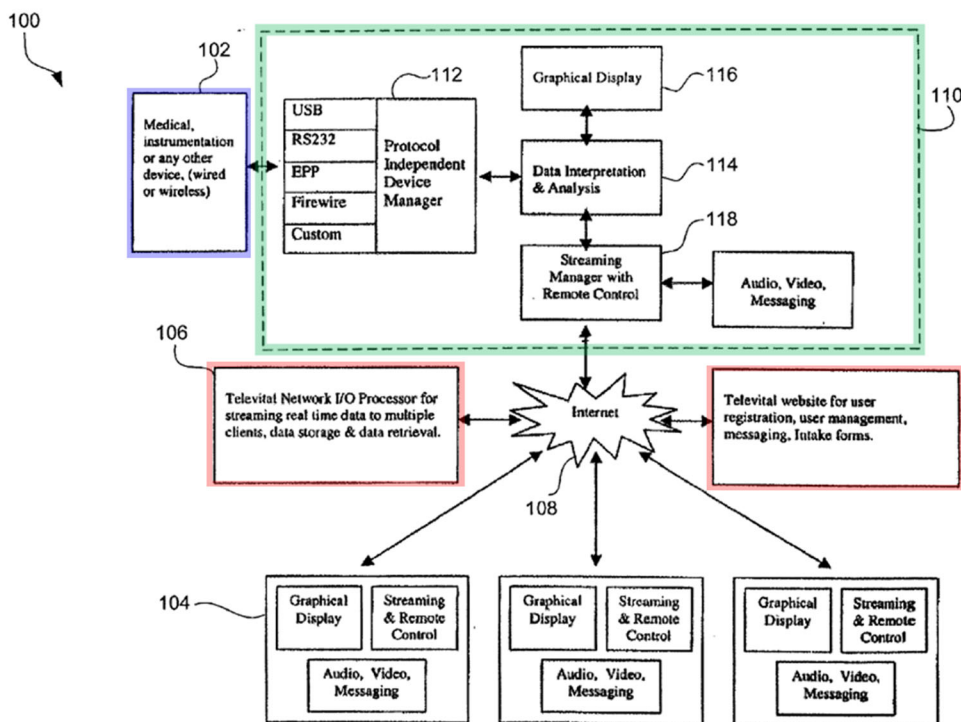


Fig. 1A

64. Kumar teaches that “[e]xisting devices (which are not web-enabled) can be easily web-enabled by installation of the appropriate plug-and-play driver and GUI. Thus, virtually any device can be easily incorporated into the system.” Ex.

1008, [0018]. One of the devices that Kumar teaches can be incorporated into the system is a device for 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.” Ex. 1008, [0240]. Kumar teaches that incorporating devices for sleep apnea-hypopnea “allows remote monitoring of such devices by providing in-home monitoring using polysomnogr[a]phy and oximetry with newer portable and/or disposable devices with on line live monitoring.” *Id.*, [0241].

D. U.S. Patent Pub. No. 2005/0268912 to Norman (Ex. 1059)

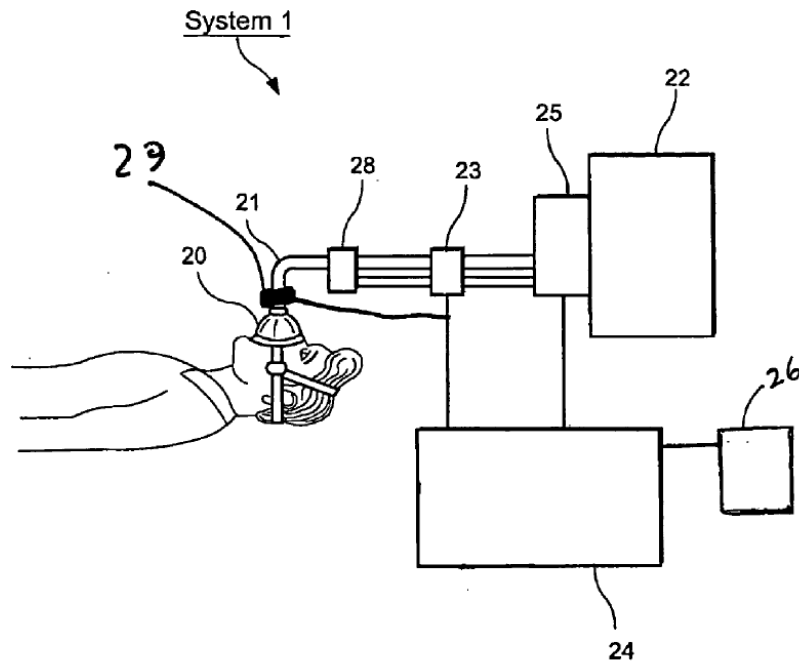
65. Norman discloses a system/method for automated titration of CPAP (Ex. 1059, Abstract), including “generating output data for adjusting the air pressure supplied to the patient as a function of the characteristics of the breathing disorder” (*id.*).

66. Norman additionally discloses a “titration device which receives and analyzes the input data to determine existence of breathing disorder” and “generating output data for adjusting the air pressure supplied to the patient as a function of the characteristics of the breathing disorder.” *Id.*, [0007]. Norman discloses supplying air pressure to a patient and detecting the patient’s breathing patterns: “[t]he present invention relates to a method and system for automated titration of CPAP. The system may include 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. The system also includes a titration device which receives and analyzes the input data to determine existence of breathing disorder and corresponding characteristics. 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.*, Abstract, [0007].

67. The system can be utilized for “detecting abnormal respirations and flow limitations in the patient’s airway” or the “detection of sleeping disorders (e.g., flow limitations), autotitration and treatment of such sleeping disorders.” *Id.*, [0022]. The system “may also be used in ongoing treatment of OSDB patients with varying pressure needs. In these cases, the titration device 26 is connected to the PAP therapy system continually so that the pressure supplied may be constantly adjusted by retitration.” *Id.*, [0034].

68. Norman discloses that “FIG. 6 shows an exemplary embodiment of a system 1 according to the present invention.” Ex. 1059, [0019].



Ex. 1059, FIG. 6

69. The “system 1 may include a mask 20 that is connected via a tube 21 to receive airflow at a particular pressure from a flow generator 22 or any other suitable airway pressure supply system. The amount of pressure provided to a particular patient varies depending on that patient's particular condition.” Ex. 1059, [0019].

70. Norman discloses that the “mask 20 covers the patient's nose and/or mouth and conventional 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. The sensors 23 may be internal or external to the generator 22. Signals corresponding to the airflow and the pressure from the sensors 23 are provided to a processing arrangement 24. The processing arrangement 24

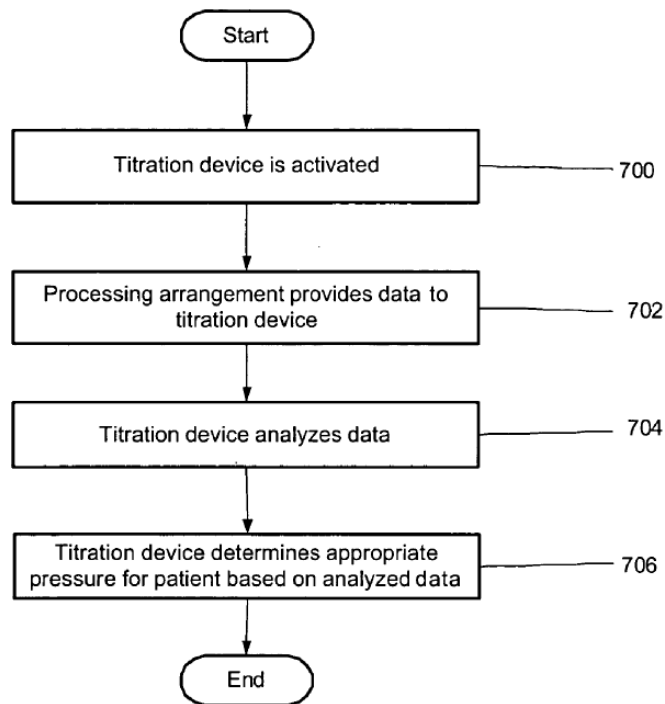
generates pressure control outputs signals to a conventional flow control device 25 that controls the pressure applied to the flow tube 21 by the flow generator 22. Those skilled in the art will understand that, for certain types of flow generators which may be employed as the flow generator 22, the processing arrangement 24 may directly control the flow generator 22, instead of controlling airflow therefrom by manipulating a separate flow control device 25.” *Id.*

71. Norman discloses “that the system 1 may be utilized for the purpose of detecting abnormal respirations and flow limitations in the patient's airway. Alternatively, the system 1 may be utilized for detection of sleeping disorders (e.g., flow limitations), autotitration and treatment of such sleeping disorders.” Ex. 1059, [0022]. Norman discloses that the “system 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. The titration device 26 may be a portable device which is attachable (e.g., using convention wired or wireless techniques) to the processing arrangement 24 when it is necessary to obtain appropriate pressure for the PAP therapy or to update previously calculated pressures. Those skilled in the art will understand that the titration device 26 may be attached to any conventional PAP therapy system. Alternatively, the 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., [0023].

72. Norman discloses that “FIG. 7 shows an exemplary method according to the invention for automatic titration to determine an appropriate pressure or varying pressure function for the PAP therapy.” Ex. 1059, [0024].



Ex. 1059, FIG. 7

73. Norman discloses that “[i]n step 700, the titration device 26 is activated, e.g., (a) by powering the titration device 26 if it is a part of the processing arrangement 24 or (b) by connecting the titration device 26, if it is a stand-alone unit, to the processing arrangement 24. Since it may not be necessary to perform titration on a daily basis, the titration device 26 may be activated by the patient or medical

personnel initially to obtain appropriate data for calculation of the pressure or pressure function for the PAP therapy. The titration device 26 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. The activation process may be performed immediately prior to initiation of the PAP therapy or may be preset to automatically activate at predetermined points, such as days and/or times. Ex. 1059, [0024]. Norman discloses that “[o]nce activated, the titration device 26 may remain active for a predetermined period of time. For example, the titration device 26 may remain active for a specific period of time (e.g., a single sleeping cycle of 6-8 hours) or until it is manually deactivated.” *Id.*, [0025].

74. Norman discloses that in step 702, “[w]hile active, the titration device 26 may work in the background processing and analyzing data collected by the processing arrangement 24 (step 702) without interfering with the PAP therapy. In particular, the processing arrangement 24 transmits data to the titration device 26 data which includes, among other information, the patient's airflow and the pressure applied to the airways of the patient. Such data may be provided continuously or periodically (e.g., every hour). Alternatively, the titration device 26 may be programmed to update immediately the PAP treatment under predetermined conditions.” *Id.*

75. Norman discloses that data collected by the titration device 26 during titration may be stored in a database for analysis to determine appropriate pressure controls for that patient: “The data collected by the titration device 26 may be stored in a database with, for example, data related to each particular patient collected during various titration procedures. Or, collected data may be stored together so that the data from several titration procedures may be accessed and analyzed by the titration device 26 to determine appropriate pressure controls for that patient. For example, the data may be stored on a removable memory arrangement which may be kept by the patient and provided to the titration device 26 each time the titration procedure for this patient is initiated. Alternatively, data for multiple patients may be stored in corresponding files of a single memory arrangement. Those skilled in the art would understand that the single memory arrangement may be a part of the system 1; alternatively, the single memory arrangement may be situated at a remote location that can be accessed via a communications network. (e.g., the Internet, VPN, etc.)” *Id.*, [0026].

76. Norman discloses that “[i]n step 704, the titration device 26 analyzes the collected data. In particular, data relating to patient airflow is utilized to accurately map patient's breathing patterns. The titration device 26 analyzes these breathing patterns to detect abnormal respiratory events and to identify the conditions under which they arise. Abnormal respiratory events that may be

identified include apnea, hypopnea and events of elevated upper airway resistance. Apnea is identified by a cessation of respiratory airflow in the patient, where the cessation can last, for example, approximately ten seconds. Hypopnea 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. Elevations in the resistance of the upper airway may be identified by changes in the shape of the inspiratory airflow contour. The airflow signal from the entire collection period may be analyzed for the presence of sleep disordered breathing events.” *Id.*, [0027].

77. Norman discloses that “[i]n 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. The counts 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. When 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. If the number of events is below a preset value then the pressure may be decreased for the next predefined time period. In addition, the response to previous pressure decreases may also be incorporated into the pressure determination algorithm. For example, the titration

device 26 may determine that a constant pressure supplied to the patient needs to be increased if a number of abnormal events identified reaches a threshold within a specified time period (e.g., when number of apneas, hypopneas or elevated resistance events exceeds the preset limit or increases by a specified amount above the previous values for the patient).” *Id.*, [0028].

78. Norman discloses that “the supplied pressure may need to be decreased or remain unchanged if no abnormal respiratory events are detected or if the number detected is less than the threshold level. 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. For example, if a pressure supplied to the patient varies substantially sinusoidally, an average value or an amplitude of the pressure may be adjusted.” *Id.*, [0029].

79. Norman discloses that “the titration device 26 may analyze data collected during, e.g., a predetermined time period. For example, the predetermined time period may be a single sleeping cycle such as one night of observation. Alternatively, or in addition, the predetermined time period may be a portion of the single sleeping cycle such as one or two hours of observation. 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.” *Id.*, [0030].

80. Norman discloses that the “titration process may then be repeated during the subsequent time period using the adjusted pressure to evaluate the efficacy of the adjusted pressure. Thus, over a several time periods, the titration process may be repeated to enhance the accuracy with which the appropriate pressure is determined. In an alternative embodiment, 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]

VIII. CLAIM CONSTRUCTION

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

82. However, I understand that Patent Owner submitted an opening claim construction brief in a parallel court action. For the purpose of forming my opinions, I have been asked to adopt Patent Owner’s interpretation of the following two terms:

- “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])

83. In reviewing Patent Owner’s Opening Claim Construction brief, 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 identifies examples from the ’333 patent specification 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). I further note that 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 how dire a patient’s calculated symptom data may be.” Ex. 1058, ¶32; *see also* Ex. 1054, 23 (citing to Ex. 1058, ¶32).

84. Patent Owner’s briefing further interprets “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.

IX. ANALYSIS

A. Ground 1: Toge in View of Kumar Renders Obvious the Challenged Claims

1. Motivation to Combine

85. In my opinion, a person of ordinary skill in the art would have been motivated to improve the physician-side computer taught by Toge by implementing it as the central server with browser-based engine as taught by Kumar. Specifically, a person of ordinary skill in the art looking to improve the PAP system of Toge would have looked at known ways to improve a telemedicine system as taught by Toge for at least the following reasons.

86. First, as I discussed above in Section V.C, technological advances in semiconductors, energy-efficient wireless communications, and reduced power budgets for computational devices made wireless networks of sensors more available. For those developing sensor diagnostic systems, the ability to use the data from these sensors wireless was top of mind. This was especially so given the trend

towards mobile computing, pervasive computing, and Web-enabling sensors, as described above in Section V.A., V.B, and V.D.

87. A person of ordinary skill in the art would have looked for ways to make this data more accessible. Kumar provided a way for patients, physicians, and providers to access this data anywhere by providing a browser-based engine that allowed access to this data through webpages.

88. Second, in the early 2000s, there was a general market trend to implement consumer devices into intelligent systems, like the telemedicine system of Toge and Kumar. An intelligent system describes a system of devices with sensors, processing ability, and software that collect and share data with other devices and systems over the Internet and other communication networks. The devices within such system are often referred to as smart or IoT devices. The Internet of Things (also known as IoT) was first coined by Kevin Ashton of Procter & Gamble in 1999. Generally, IoT encompasses the concept of embedding wireless transceivers into daily “things” that enable communications between people and things and between things themselves. The market was looking for any consumer device to connect to the internet. For example, LG introduced the first smart refrigerator in early 2000.

89. A person of ordinary skill in the art improving a networked PAP system, like that described in Toge, Ex. 1044, [0028], would have looked at other

ways such networked PAP systems had been implemented, like that in Kumar. A person of ordinary skill in the art trying to improve Toge would have naturally looked at design options that would provide implementation details that allowed users to better utilize such data, such as the “plug-and-play” telehealth system of Kumar that provided user interfaces to access the data. Ex. 1008, [0010] (“The present invention provides a system and method of remote monitoring of medical and/or biofeedback devices over a wide area network (WAN) such as the Internet”), [0018] (“[T]he present invention may support both plug-and-play web device drivers and customized graphical user interfaces (GUIs) for the various devices.”).

90. The industry recognized that such IoT systems provided core benefits, such as automation, real-time access to information, data collection, improved efficiency, and cost reduction. A person of ordinary skill in the art would have recognized that implementing the PAP system of Toge with the browser-based engine accessible through web pages, like that of Kumar, would result in at least the same benefits.

91. With respect to automation, patients could receive instant software updates if new algorithms are developed to better identify and treat sleep disorders. Such updates are typically difficult to provide to stand-alone patient devices, where the patient can need to go to a facility to update or purchase a new device.

92. With respect to real-time access to information, Kumar expressly noted that it is “desirable to provide an internet-based software system capable of streaming in real-time” health-related data including “respiration.” Ex. 1008, [0007]. Such internet-based, real-time access could provide physicians with more data for diagnoses. It can also help identify medical emergencies, for example, if the patient stopped breathing altogether.

93. With respect to data collection, the ability to build large data sets of patient data allowed physicians to analyze the data to identify patterns and trends in a way that the analysis of individual patient data cannot.

94. With respect to efficiency and cost reduction, the ability to analyze data remotely with an easy-to-use browser-based interface allowed physicians to evaluate the data at their own convenience without expending the cost and resources of meeting with the patient in person.

95. Third, a person of ordinary skill in the art would have been motivated to provide health access. Many advances in telemedicine came from the need to provide access to medicine remotely. For example, in the 1960s, many telemetry systems developed to enable NASA to monitor the health of its astronauts and potentially administer treatment remotely. In the 1970s, Indian Health Services partnered with NASA and Lockheed Martin to provide telemedicine to remote Indian populations in Arizona.

96. Kumar recognized that telemedicine has provided “access to health assessments, diagnoses, interventions, supervision, consultations, education, and information across a distance.” Ex. 1008, [0003]. Implementing the web pages of Kumar allowed anyone with an Internet-browser to access the data without downloading additional software.

2. Reasonable Expectation of Success

97. In my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success modifying the physician-side computer taught by Toge by to implement it as the central server with browser-based engine accessible through web pages as taught by Kumar.

98. A person of ordinary skill in the art would have understood that Toge and Kumar are structurally and functionally similar. The physician-side computer of Toge provides data access to physicians and providers, just as the central server of Kumar. Modifying the physician-side computer to be a web server to allow others to access the data transmitted would just been a matter of providing a web interface for the data. Kumar expressly teaches that “[e]xisting devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI.” Ex. 1008, [0018].

3. Independent Claim 15

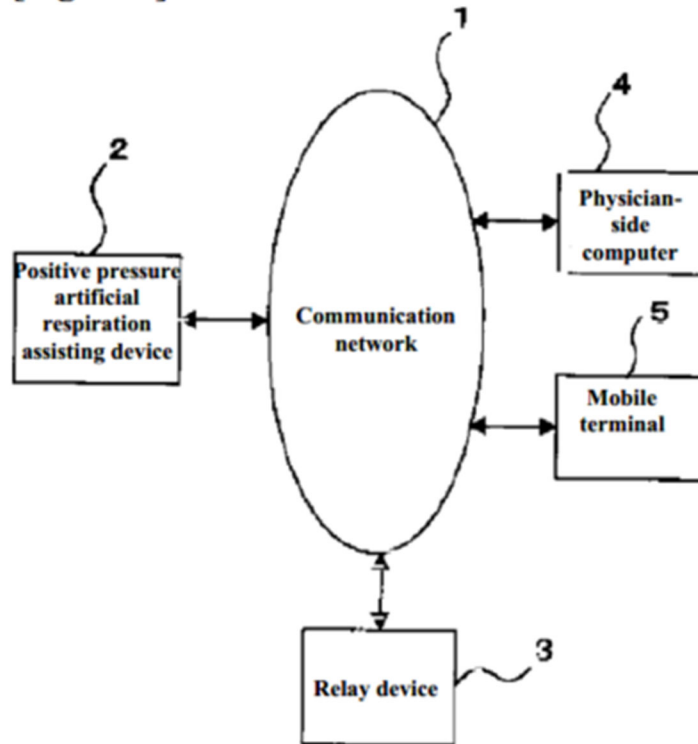
a. Preamble

[Preamble] “*A method of treating a subject’s sleep apnea comprising steps of:*”

99. In my opinion, Toge discloses the preamble to the extent it is limiting.

100. Toge discloses a system for treating patients having sleep apnea (*method of treating a subject’s sleep apnea*). Toge discloses a networked positive pressure artificial respiration assisting device that includes “positive airway pressure devices [that] are primarily provided to patients with conditions such as sleep apnea” as shown in Figure 1. Ex. 1044, [0015]; *see also* [0015] (“The positive pressure artificial respiration assisting device 2 includes . . . continuous positive airway pressure devices.”), [0015] (“The present invention is applicable to . . . continuous positive airway pressure (CPAP) devices.”):

[Figure 1]



Ex. 1044, Fig. 1

101. Toge discloses that “Figure 1 is a block diagram illustrating the overall configuration of a remote medical (telemedicine) system according to the present invention. This telemedicine system comprises a positive pressure artificial respiration assisting device 2, a relay device 3, and physician-side terminal devices, namely a physician-side computer 4 and a mobile terminal 5, all connected to communication network 1.” *Id.*, [0008].

102. Toge discloses that “bilevel positive airway pressure devices are primarily provided to patients with weakened spontaneous breathing ability, 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. The present invention is applicable to both bilevel positive airway pressure (BiPAP) and continuous positive airway pressure (CPAP) devices, and the positive pressure artificial respiration assisting device 2 shown in Figure 1 is equipped with both BiPAP and CPAP functionalities.” Ex. 1044, [0015].

103. Toge explains that the positive pressure artificial respiration assisting device uses positive airway pressure to treat the patient. In particular, the positive pressure artificial respiration assisting device “delivers positive pressure air containing atmospheric air to assist the patient’s breathing.” *See* Ex. 1044, [0078].

104. Toge also refers to the information about the positive airway pressure delivered to be “treatment data.” *See, e.g.*, Ex. 1044, [0070] (“the method comprises the positive pressure artificial respiration assisting device requesting treatment data from a patient using the same device, transmitting all or part of the requested treatment data to the physician-side terminal device via the communication network”).

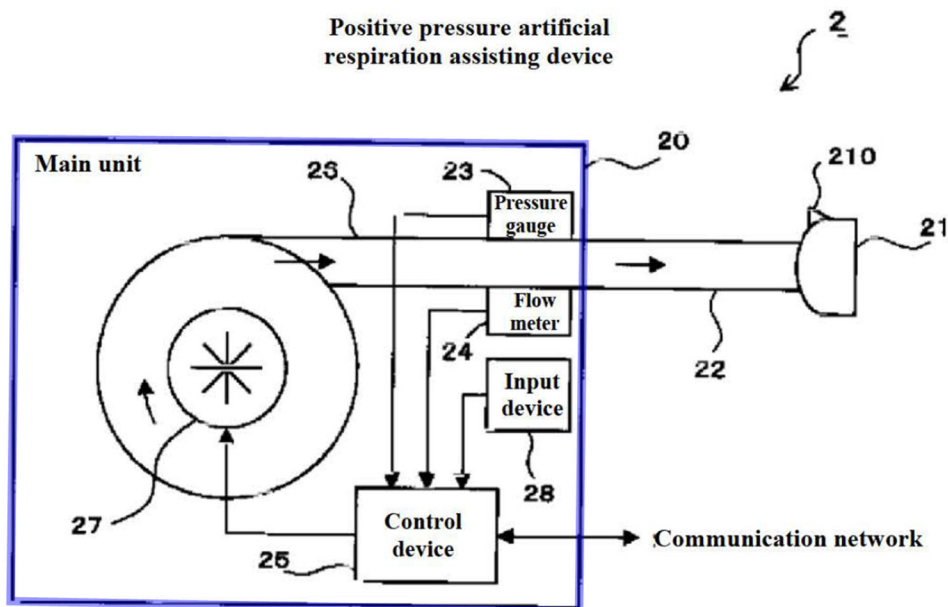
105. Because Toge discloses treating a patient’s sleep apnea using the positive airway pressure device, Toge discloses a *method of treating a subject’s sleep apnea*.

b. Limitation [15.a]

[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;”

106. In my opinion, Toge discloses this limitation.

107. Toge discloses *providing a therapy to a subject using a PAP or CPAP device while sleeping*. Toge discloses a positive pressure artificial respiration assisting device 2:



Ex. 1044, FIG. 2 (annotated)

108. Toge discloses that 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 (hereinafter referred to simply as ‘the patient’) to assist the patient's breathing. Therefore, the

positive pressure artificial respiration assisting device 2 is installed near the patient receiving home medical care (e.g., at the patient's residence).” *Id.*, [0010]; *see also id.*, [0011]-[0015]. As I discussed for the preamble, Toge explains that the positive pressure artificial respiration assisting device includes “continuous positive airway pressure devices [that] are primarily provided to patients with conditions such as sleep apnea.” Ex. 1044, [0015]. Apnea occurs while the patient is asleep, and therefore, the therapy is provided when the patient is sleeping to treat the apnea.

109. In my opinion, Toge discloses *providing a therapy to a subject using a PAP or CPAP device while sleeping* because Toge discloses providing a positive airway pressure therapy to a patient using the positive pressure artificial respiration assisting device 2 (“device 2”) “during sleep.” *Id.*, [0015]; *see also id.*, [0040]

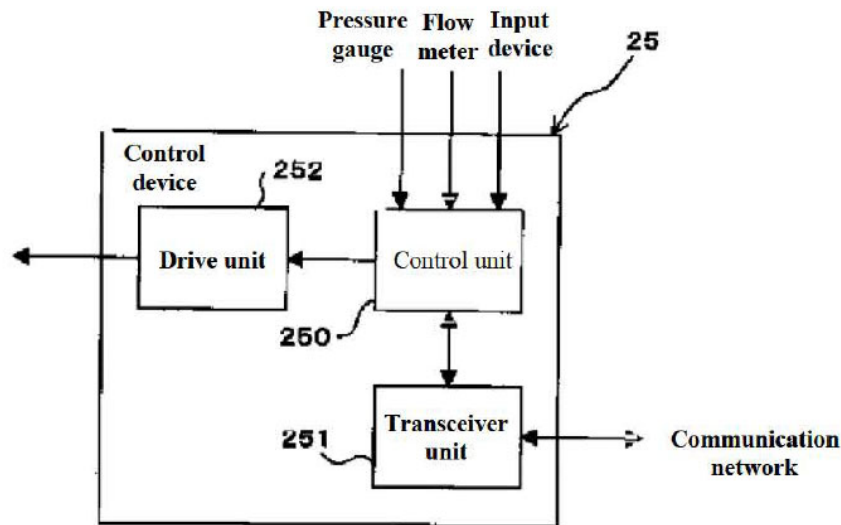
110. Toge discloses *the PAP or CPAP comprising a flow or pressure sensor...integrated into the PAP or CPAP device*. As I discussed for the preamble, Toge discloses that the device 2 includes “continuous positive airway pressure devices.” Ex. 1044, [0015]; *see also* [0015] (“The positive pressure artificial respiration assisting device 2 includes. . . continuous positive airway pressure devices.”), [0015] (“The present invention is applicable to . . . continuous positive airway pressure (CPAP) devices.”).

111. Toge discloses that device 2 has an enclosure (highlighted in blue in Figure 2), 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] (“The positive pressure artificial respiration assisting device 2 comprises a main unit 20”), [0023] (“The main unit 20 is equipped with a pressure gauge 23, a flow meter 24, a control device 25”); *see also* [0022], [0024].

112. Toge discloses that “pressure gauge 23 detects and measures the air pressure inside the flow path 26.” Ex. 1044, [0028]. Toge discloses that flow meter 24 “detects and measures the airflow” within the flow path 26. *Id.* In my opinion, the flow meter 24 and pressure gauge 23 disclose a *flow or pressure sensor*. Figure 2 shows that both pressure gauge 23 and flow meter 24 are enclosed by the main unit 20 and/or the enclosure of the device 2, so the pressure gauge 23 and flow meter 24 are *integrated into the PAP or CPAP device*.

113. Toge discloses *the PAP or CPAP comprising . . . a processor . . . integrated into the PAP or CPAP device*. Toge discloses that device 2 includes a control device 25 (Figure 2), which includes a control unit 250:



Ex. 1044, Figure 3

114. Toge discloses that “control unit 250 can be constructed using a program describing the processing of the control unit 250...along with a CPU.” *Id.*, [0048]. Additionally, 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.” *Id.*, [0060]. Further, relay device 3 (incorporated into control unit 250) data transmits from PAP device 2 “all or part” of the data to physician-side computer 4. *Id.*, [0016], [0061]. In my opinion, Toge discloses that control unit 250 is a *processor* and the control unit 250 is *integrated into* device 2.

115. In my opinion, Toge discloses that the flow meter 24 or pressure gauge 23 (*a flow or pressure sensor*), and control unit 250 (*processor*) or relay device 3 includes a *processor* and both are *integrated into the device 2*.

c. Limitation [15.b]

[1.b] “*collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy;*”

116. In my opinion, Toge discloses this limitation.

117. Toge discloses that measured data (such as flow rate and air pressure) is collected with the control unit 250 of the device 2 (*collecting data with the PAP*) from flow meter 24 (*from the flow sensor*) and pressure gauge 23 (*or pressure sensor*). Ex. 1044, [0028] (“The flow meter 24 consists of, for example, a differential pressure flow meter, and it detects and measures the airflow within the flow path 20, specifically the airflow supplied from the main unit 20 to the mask 21. The measured flow rate is then provided to the control unit 250 of the control device 25”), [0028] (“The pressure gauge 23 detects and measures the air pressure inside the flow path 26. The measured air pressure is provided to the control unit 250 of the control device 25.”). Toge discloses that the device 2 collects this data while device 2 delivers the positive air pressure the patient during the therapy (*id.*, [0022]) according to the prescribed air pressure (*id.*, [0027]) so that the air pressure and/or

flow rate provided to control unit 250 can be used to control the device 2 (*id.*, [0032]-[0038], [0046]).

118. In my opinion, a person of ordinary skill in the art would have understood that because Toge discloses that the device 2 transmits data “at regular intervals” (*id.*, [0030], [0039], [0041], [0044], [0047]), the device 2 is *collecting data* between transmissions. *See also id.*, [0030] (“Under the control of the control unit 250, the transceiver unit 251 of the control device 25 communicates with the communication network 1, transmitting data (transmission data provided from the control unit 250 to the relay device 3, and receiving data (reception data) from the physician-side computer 4 or mobile terminal 5.”). In my opinion, a person of ordinary skill in the art would have understood that the time between the transmissions is a time period, so Toge discloses collecting data *during a time period of the therapy*.

119. Toge discloses that 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]. Toge discloses that “by analyzing this operational time, physicians can determine whether the patient is using the [PAP] device 2 and assess the treatment (patient) compliance.” *Id.*; *see also id.*, [0031] (“The transmitted data includes . . . the operational time T of this positive pressure artificial respiration assisting device 2 . . . and the operating status of this positive pressure artificial

respiration assisting device 2 (such as alarms if the nasal mask is detached).”). In my opinion, a person of ordinary skill in the art would have understood that 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 the operational time (during a time period of the therapy).*

d. Limitation [15.c]

[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;*”

120. In my opinion, Toge discloses this limitation.

121. In my opinion, Toge discloses analyzing with the control unit 250 (*analyzing with the processor*) the air pressure measured by pressure gauge 23 and/or flow rate measured by flow meter 24 (*the collected data*) to determine parameters such as the tidal volume (*determine a quantified level of severity data*) that is based on the subject’s condition while using the device (*based on the subject’s sleep apnea symptoms during the therapy*).

122. Toge discloses that control unit 250 analyzes (*analyzing with the processor*) the air pressure and/or flow rate (*id.*, [0033]-[0037]) (*the collected data*) to determine the tidal volume (*id.*, [0038]) (*determine a quantified level of severity data*). Toge discloses that tidal volume Fp is a *quantified level* of data because Toge discloses that Fp is monitored with respect to threshold values (*id.*, [0051]) and

because F_p is a function of F_t , F_a , and F_b , which are quantitative values. Toge discloses that tidal volume F_p is *severity data* because Toge discloses that tidal volume is indicative of whether the patient's breathing warrants "emergency measures" (*id.*, [0039]) and whether to "send an alert" in "an emergency where the patient's breathing has drastically weakened" (*id.*, [0055]).

123. With respect to *symptoms*, the '333 patent explains: "[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." Ex. 1001, 22:25-28; *see also* 21:39-43 ("The signals from the one or more sensors used in various embodiments of the present invention are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject's sleeping disorder or symptoms."). The '333 patent further explains that the system can predict or identify when "the subject's physiological conditions move toward various critical conditions or symptoms." *Id.*, 23:42-44.

124. Toge discloses determining tidal volume *based on the subject's sleep apnea symptoms during the therapy* because Toge discloses determining tidal volume F_p based on F_t , F_a , and F_b , which include signals or data from the sensors as disclosed in the '333 patent. *Id.*, [0035]. Toge discloses that " F_t is the flow rate measured by the flow meter 24." *Id.* Toge discloses that F_a is calculated from "the

internal pressure P,” which is determined from “the pressure value measured by the pressure gauge 23.” *Id.*, [0036]. Toge discloses that “air leakage volume Fb from the nasal mask 21 is determined by subtracting the exhalation vent flow rate Fa from the flow rate value Ft of the flow meter 24.” *Id.*, [0037]. Toge discloses that this “difference is then integrated over a single breath as well as over multiple breaths to obtain the air leakage volume Fb.” *Id.* Toge explains the tidal volume is based on the patient’s condition, and that “[b]y transmitting the tidal volume Fp almost in real-time or at regular intervals (such as every hour) physicians can remotely monitor the patient’s condition during the use of the positive pressure artificial respiration assisting device 2 remotely from hospitals or other locations.” *Id.*, [0039]

125. Because Toge discloses determining tidal volume (*determine a quantified level of severity data*) based on Ft, Fa, and Fb (*id.*, [0035]), which corresponds to the subject’s condition (*subject’s sleep apnea symptoms*) while using the device (*during the therapy*) (*id.*, [0036], [0037]), Toge discloses *determin[ing] a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy.*

e. Limitation [15.d]

[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”

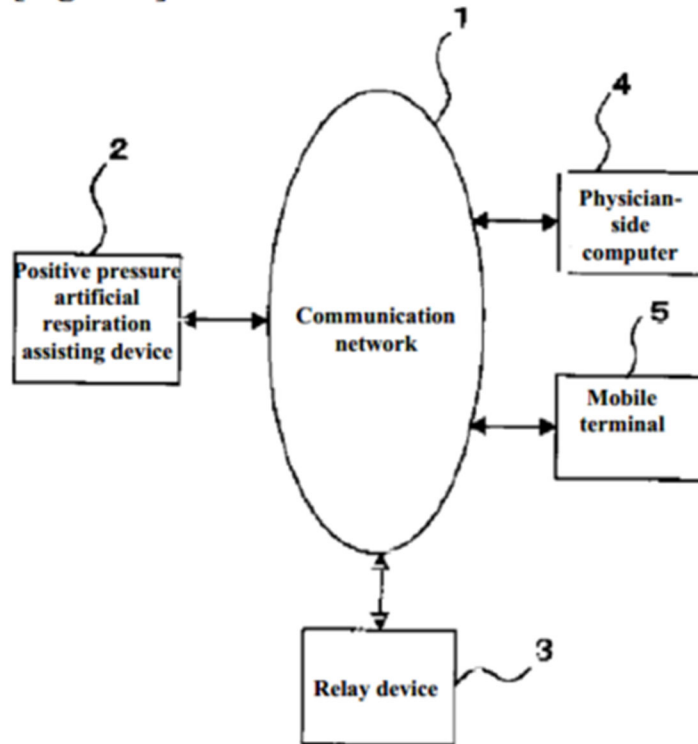
126. In my opinion, Toge alone or in combination with Kumar discloses this limitation.

(i) Toge discloses “transmitting...1)...the quantified level of severity data to a cellular phone via a radio frequency wireless link.”

127. In my opinion, Toge discloses *transmitting . . . 1) . . . the quantified level of severity data to a cellular phone via a radio frequency wireless link* because Toge discloses that the device 2 and relay device 3 transmit the tidal volume (*quantified level of severity data*) to the mobile terminal 5 (*cellular phone*) via a cellular network (*radio frequency wireless link*).

128. Toge discloses that the 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 the devices. *Id.*, [0008]; *see also infra* [15.e] (Sections IX.A.3.f, g).

[Figure 1]



Ex. 1044, Fig. 1

Toge discloses that relay device 3 can be “incorporated into [the control unit 250 of the control device 25 of the device 2], allowing it to be configured as an integrated unit with the device 2.” *Id.*, [0060]. Toge also discloses that the “relay device 3 [incorporated into control unit 250 of the control device 25 of the device 2] is installed within the company providing the positive pressure artificial respiration assisting device or in a visiting nursing station; it receives data (described later) transmitted from the positive pressure artificial respiration assisting device 2, transmitting all or part of said data to the physician-side computer 4.” *Id.*, [0016].

129. Toge discloses that the relay device 3 incorporated in the device 2 can transmit the tidal volume (*transmitting...1*)...*the quantified level of severity data*) to the mobile terminal 5 (*to a cellular phone*) because Toge discloses that “relay device 3...transmits...treatment data to...mobile terminal 5 via the communication network 1. Ex. 1044, Abstract. Toge discloses that the transmission can occur over the network 1 because the mobile terminal 5 is connected to network 1, which can be a mobile network. *Id.*, [0008], [0009].

130. Toge discloses that the “transmitted data includes the patient’s treatment data such as the tidal volume F_p , the operational time T of this positive pressure artificial respiration assisting device 2, the air leakage volume F_b (leaking from parts other than the exhalation vent 210) from the nasal mask 21, the internal pressure P of the nasal mask 21, the minute breathing rate N , the inspired oxygen concentration F_iO_2 , and the operating status of this positive pressure artificial respiration assisting device 2 (such as alarms if the nasal mask is detached).” *Id.*, [0031]. Toge discloses that the tidal volume is “ $F_p = F_t - F_a - F_b$ ” where “ F_t is the flow rate measured by the flow meter” (*id.*, [0035]) and that because “the internal pressure P is nearly the same as the pressure value measured by the pressure gauge 23, this pressure value is used” (*id.*, [0036]). In my opinion, a person of ordinary skill in the art would have understood that Toge discloses transmitting the *quantified level of*

severity data because the transmission data includes tidal volume as I explained for limitation [15.c] (Section IX.A.3.d).

131. Toge discloses that the mobile terminal 5 can be “mobile phones” or “PDAs” (*cellular phone*). Ex. 1044, [0019] (“The mobile terminal 5 includes mobile phones, PHS, PDAs, and PocketBell (registered trademark), etc.”). Toge discloses that the mobile terminal 5 can be mobilized “in emergencies by the physician-side computer 4, relay device 3, or other mobile terminals possessed” by the care provider. *Id.* Toge discloses that the care provider can operate the mobile terminal 5 to “set the necessary data...for device 2.” *Id.* In my opinion, a person of ordinary skill in the art would have understood that the transmissions (e.g., of tidal volume, in emergencies, to set data, etc.) to the mobile terminal 5 would occur via mobile protocol such as GSM or GPRS (the prevalent cellular protocol at the time) transmitted using RF wireless communication (*via a radio frequency wireless link*). Ex. 1011, 2 (known PDA/cell phone in 2004 used GSM and GPRS protocols for wireless/mobile communications).

132. Because Toge discloses the transmission from the relay device 3 incorporated in the device 2, Toge discloses limitation [15.d] if it is read 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 discloses that the treatment data, including tidal volume (*the quantified level*

of severity data), can be transmitted to the mobile terminal 5 (*cellular phone via a radio frequency wireless link*) from the device 2 (*the PAP or CPAP device via a cellular system*). Toge discloses that the transmission can occur over the network 1 because the relay device 3 incorporated in the device 2 is connected to network 1. Ex. 1044, [0008], [0009], [0060]. Toge discloses that the “communication network 1 may be any of a public telephone network, the Internet, a mobile communication network, or a dedicated line network; alternatively, it may also be a combination of these networks.” *Id.*, [0009].

133. In my opinion, a person of ordinary skill in the art would have understood that transmitting to the mobile terminal 5 via the mobile communication network 1 would be via *a radio frequency wireless link* and transmitting from the relay device 3 incorporated in the device 2 via the mobile communication network 1 would be via *a cellular system*. As discussed in Section V.A and V.D, a person of ordinary skill in the art would understand a mobile communication network to be a wireless network that allows the devices to be “mobile.” In particular, “mobile network” is often used interchangeably with “cellular network.” Wireless transceivers use radio waves, also referred to as radio frequency signals, to carry data from one transceiver to another. A cellular network uses radio frequency.

134. To the extent that Toge does not disclose that its telemedicine system includes *a radio frequency wireless link*, such a feature would have been obvious to

a person of ordinary skill in the art. There were a limited number of known techniques for transmitting data wirelessly, including radio frequency communication infrared and optical wireless communications. Thus, a person of ordinary skill in the art would have been motivated to use a radio frequency wireless transceiver to implement communications via radio frequency because it would have been one of a finite number of predictable and known options, and was the most common.

135. A person of ordinary skill in the art would have had the skill and a reasonable expectation of success in implementing a radio frequency wireless transceiver in the PAP device. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers. *See, e.g.* Ex. 1044, Abstract (“Enabling remote monitoring of the patient’s conditions during the use of a positive pressure artificial respiration assisting device”), Fig. 3 (transceiver unit 251); Ex. 1045, ¶ [0155] (“communication module 350 supports ‘blue-tooth’ RF bidirectional wireless communication”), Fig. 3 (communication module 350); Ex. 1013, [0029] (a CPAP device including “a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12.”). Moreover, it would have involved a combination of known technologies (known PAP device that monitors the usage and calculates data

associated with sleep disorder treatment) according to known methods (known methods of transmitting data from patient-side device to computing device, such as a cell phone or PDA, by using a radio frequency wireless transceiver) to yield the predictable result of a PAP device including a radio frequency wireless transceiver to facilitate wireless communication with the cell phone.

(ii) 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.”

136. 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 transmitting treatment data, including the tidal volume, (*transmitting . . . 2) . . . the quantified level of severity data*) to the physician-side computer 4 (*to the remote station*) from the relay device 3 incorporated into the device 2 (*from...a) the PAP or CPAP device*) via the network 1 (*via a cellular system*).

137. Toge discloses that the device 2 has “the functionality of...relay device 3...incorporated into” the control unit 250 of the control device 25 of the device 2 and can transmit “all or part” of the data (*transmitting...2)...the quantified level of severity data*) to physician-side computer 4 (*to the remote station*). Ex. 1044, [0039]; *see also id.*, [0016], [0060]. Toge discloses that the physician-side computer 4 (*remote station*) receives data from device 2 and allows care providers (e.g.,

physicians) to access the transmitted data using the computer 4. *Id.*, [0017], [0018]. Toge discloses that by receiving the tidal volume on the computer 4 from the device 2, “physicians can remotely monitor the patient’s condition during the use of the...device 2.” *Id.*, [0039]; *see also id.*, [0051], [0061], [0063]-[0076] (examples of remote monitoring), [0085].

138. I noticed that the term “remote station” is not recited in the ’333 patent specification. *See generally* Ex. 1001. Only a “remote communication station” is described in the specification: “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.” Ex. 1001, 22:20-24; *see also id.*, 21:54-22:20 (describing various non-limiting examples of a “remote communication station”). If the “remote communication station” discussed in the specification corresponds to the claimed “remote station,” then physician-side computer 4 discloses the *remote station*. In my opinion, a person of ordinary skill in the art would have understood that physician-side computer 4 is a *remote station* because it receives treatment data from the device 2 and/or provides physicians remote access to monitor the patient’s condition. Ex. 1044, [0006], [0017], [0018], [0039].

139. Toge discloses that data (*the quantified level of severity data*) can be transmitted to the physician-side computer 4 (*remote station*) from the relay device

3 incorporated into the device 2 (*from...a) the PAP or CPAP device*) via the network 1 (*via a cellular system*). *Id.*, [0008], [0009], [0016]-[0018], [0031]; *see also id.*, [0063], [0070], [0078], [0080], [0081], claim 1. Toge discloses that the “physician-side computer 4 or mobile terminal 5 receives all or part of the treatment data transmitted from the relay device 3.” *Id.*, Abstract.

140. Toge discloses transmitting from the device 2 via network 1 (*a cellular system*). Toge discloses that device 2 “transmits all or part of the treatment data to the physician-side computer 4...via...network 1.” *Id.*, [0061]. Toge discloses that device 2 (*the PAP or CPAP device*), relay device 3, physician-side computer 4 (*remote station*) are wirelessly connected to network 1 for transmitting data such as the tidal volume (*the quantified level of severity data*) (*id.*, [0006], [0007]; *see also id.*, [0016], [0060], [0063], [0070], [0078], [0080], [0081], claim 1). Toge discloses that network 1 can be “a mobile communication network” (*id.*, [0009]). In my opinion, a person of ordinary skill in the art would have understood that Toge discloses that mobile communication network 1 can be *a cellular system*.

141. Because Toge discloses transmitting the tidal volume (*quantified level of severity data*) to physician-side computer 4 (*remote station*) from device 2 (*from...a) the PAP or CPAP device*) via mobile communication network 1 (*via 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*.

- (iii) **Toge and Kumar combination discloses “transmitting...2)...the quantified level of severity data to the remote station from...a) the PAP or CPAP device via a cellular system.”**

142. In my opinion, Toge in view of Kumar also disclose *transmitting...2)...the quantified level of severity data to the remote station from...a) the PAP or CPAP device via a cellular system*. The Toge-Kumar combination discloses transmitting treatment data (*transmitting...2)...the quantified level of severity data*) to Toge’s physician-side computer 4 and Kumar’s engine (*to the remote station*) from Toge’s relay device 3 incorporated into the device 2 and Kumar’s the patient-side device (*from...a) the PAP or CPAP device*) via Toge’s network 1 and Kumar’s internet 108 (*via a cellular system*).

143. Kumar discloses transmitting data (*transmitting...2)...the quantified level of severity data*) to the engine (*to the remote station*). 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].

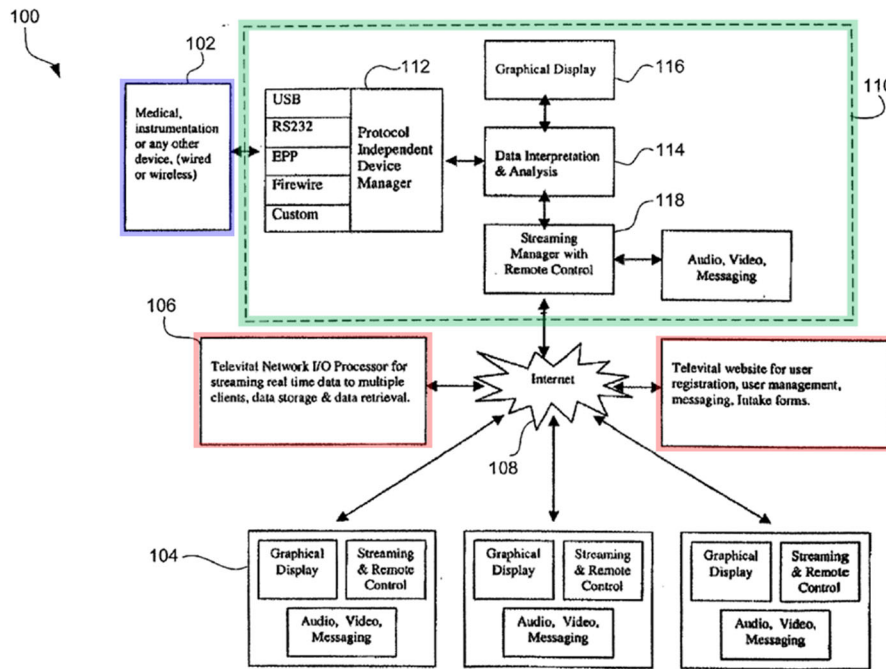


Fig. 1A

Ex. 1008, FIG. 1A

144. The system illustrated in Kumar's Figure 1A includes a patient-side device 102 (in blue, like the device 2) (*PAP or CPAP device*) for collecting data from a patient/client, computing device 110 (in green), provider-side device(s) 104, internet 108, and central server 106 (in red) (*the remote station*) that hosts a browser-based engine accessible through web pages. Ex. 1008, [0018], [0067], [0068], [0072], [0089]. The devices and engine are connected to a wide area network (WAN) 108 such as the Internet. *Id.*, [0067], [0068]. The patient-side device 102 can communicate through a wireless interface (*a cellular system*) and communicate over the Internet. *Id.*, [0013].

145. Kumar discloses *transmitting...2)...the quantified level of severity data* because Kumar discloses that the engine “may receive the data from the patient-side device.” *Id.*, [0081], [0082]. Kumar discloses *transmitting...2)...the quantified level of severity data to the remote station* because Kumar discloses that the engine is the *remote station*. Kumar discloses 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 (*remote station*) 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 person of ordinary skill in the art 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” and other figures below. Ex. 1008, [0092]; *see also id.*, [0010], [0015].

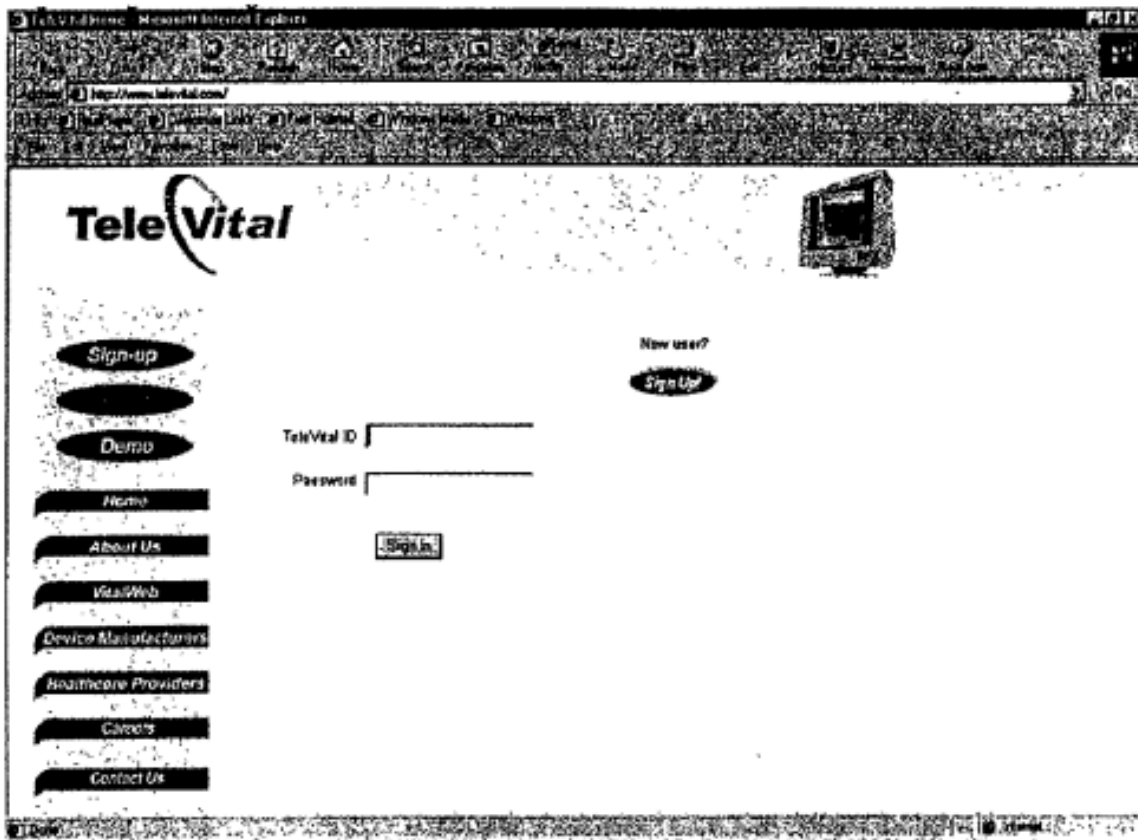


Fig. 2

Ex. 1008, FIG. 2

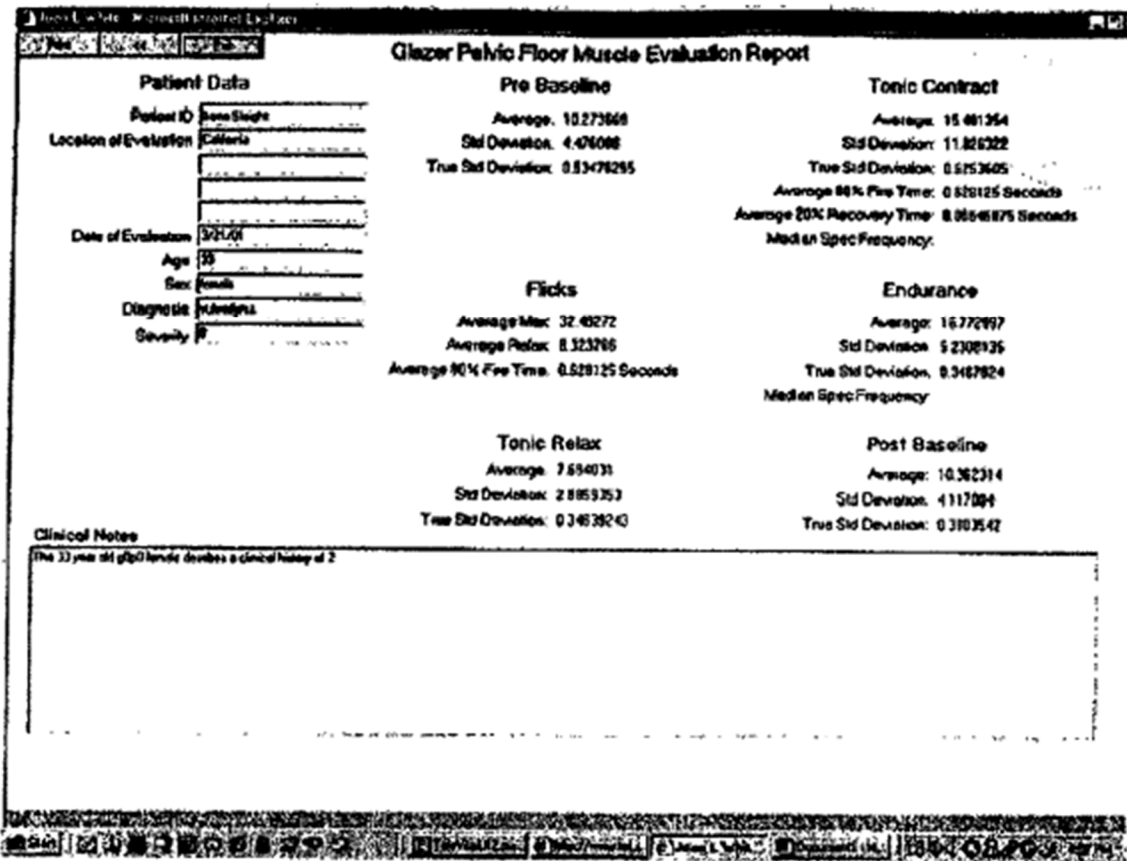


Fig. 6

Ex. 1008, FIG. 6

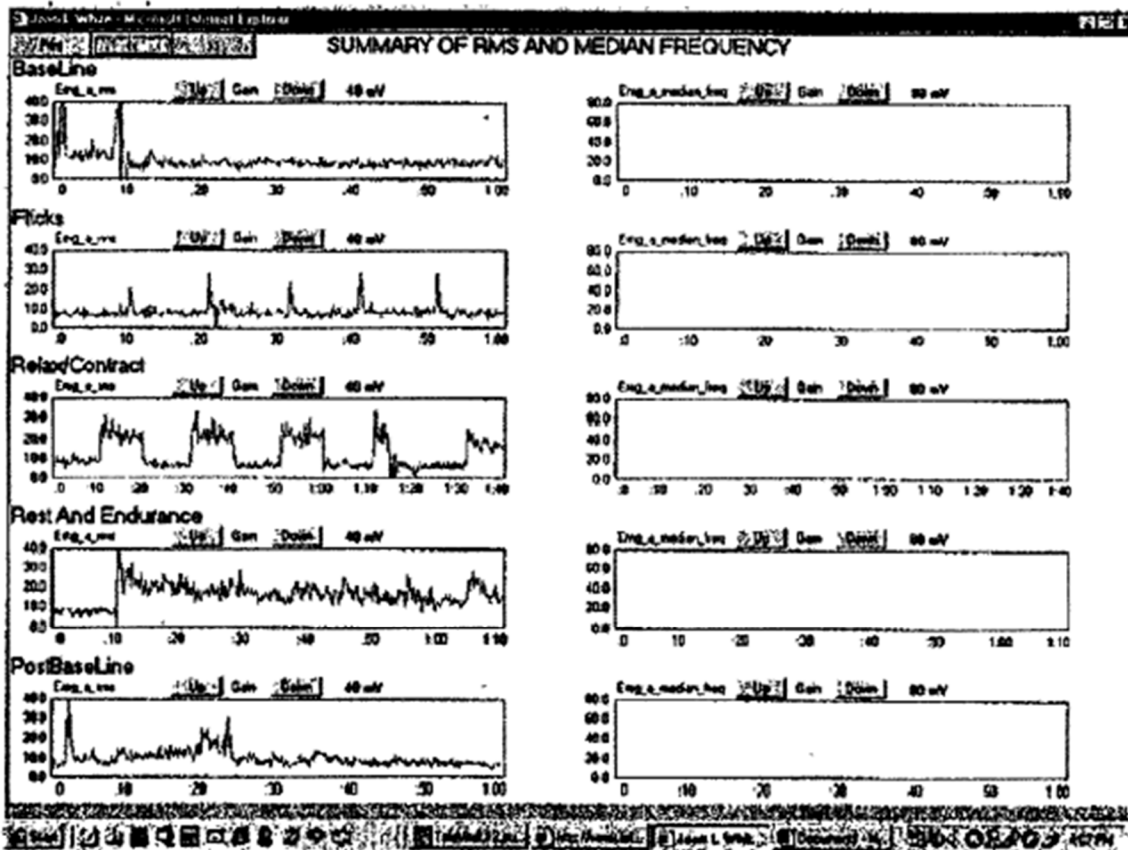


Fig. 7

Ex. 1008, FIG. 7

Session	Date	Subject	ViewView
1	2001-01-29 12:41:08	None	ViewView
2	2001-01-31 16:55:50	None	ViewView
3	2001-01-31 17:17:17	None	ViewView
4	2001-02-04 14:39:07	None	ViewView
5	2001-02-02 10:05:59	None	ViewView
6	2001-02-02 10:17:14	None	ViewView
7	2001-02-05 13:41:31	None	ViewView
8	2001-02-06 13:57:09	None	ViewView
9	2001-02-06 14:06:51	None	ViewView
10	2001-02-06 14:29:50	None	ViewView
11	2001-02-06 15:37:15	None	ViewView
12	2001-02-06 18:38:50	None	ViewView
13	2001-02-06 18:40:29	None	ViewView
14	2001-02-06 17:06:54	None	ViewView
15	2001-02-06 17:06:50	None	ViewView
16	2001-02-06 17:34:06	None	ViewView
17	2001-02-06 17:37:13	None	ViewView
18	2001-02-06 19:15:45	None	ViewView
19	2001-02-06 19:31:34	None	ViewView
20	2001-02-06 19:58:15	None	ViewView
21	2001-02-06 11:07:07	None	ViewView
22	2001-02-06 11:38:10	None	ViewView
23	2001-02-06 11:52:22	None	ViewView
24	2001-02-06 12:02:02	None	ViewView

Fig. 8

Ex. 1008, FIG. 8.

146. In my opinion, a person of ordinary skill in the art would have understood that a browser-based engine hosted on a central server is a *remote station* to which *the quantified level of severity data* is transmitted because the engine provides remote monitoring and, for example, relaying, storing, and processing patient's data as well as providing access to the data. Kumar 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]-[0083], [0087].

147. I noted that the term "remote station" is not recited in the '333 patent specification. The specification does disclose that 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" and examples of a "remote communication station." Ex. 1001, 21:54-22:20. If the "remote communication station" discussed in the specification corresponds to the *remote station*, then Kumar's browser-based engine discloses the *remote station*.

148. Kumar discloses *transmitting...2) ...the quantified level of severity data to the remote station from...a) the PAP or CPAP device* because Kumar discloses transmitting data, such as raw, interpreted, and processed physiological/patient data, to the engine (*remote station*) and that the engine "may receive the data from the patient-side device." *Id.*, [0081], [0082]. In my opinion, Kumar discloses *transmitting...via a cellular system* because Kumar discloses that the "the patient-side device may have a built-in computing device for communication over the WAN" and that the engine "may receive the data from the patient-side device 102" via the internet 108. *Id.*, [0072], [0081].

149. In my opinion, a person of ordinary skill in the art would have understood that Toge and Kumar disclose similar goals of providing access to data collected and/or analyzed by a treatment device. For example, Toge discloses “download all or specified data received from the positive pressure artificial respiration assisting 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” (*id.*, [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]). In my opinion, a person of ordinary skill in the art would have been motivated to implement a remote-monitoring feature such as a browser-based engine into Toge to wirelessly transmit to data associated the patient’s treatment, including *the quantified level of severity data*, such as the tidal volume. For example, a person of ordinary skill in the art would have been motivated to transmit the data for secured storage, data backup, later analysis, creation of a database, and sharing of data.

150. In my opinion, because Toge discloses downloading data, Kumar’s remote-monitoring feature would have been beneficial to Toge because Kumar discloses 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]. Kumar discloses that 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 my opinion, Kumar discloses that the remote-monitoring feature is beneficial by allowing a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. *Id.* Kumar discloses that “[t]he system may also track trends during the recording, and using artificial intelligence, predict future behaviors and physiological responses based on the habits of the particular client hooked up.” *Id.*, [0084].

151. In my opinion, because Toge discloses that the transmitted data can be transmitted from the device 2 to physician-side computer 4, in my opinion, a person of ordinary skill in the art would have understood that storing data at the secured storage of the engine would have provided a backup of the data and a person of ordinary skill in the art 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.

152. In my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success in combining the remote-monitoring feature of Kumar with the system of Toge. Kumar discloses that “virtually any device may be easily incorporated into the system.” Ex. 1008, [0074]. In my opinion, it was well

known to transmit data using wireless protocol(s) to a remote engine for later access of the data. In my opinion, it would have involved a combination of Toge's disclosure of the device 2 incorporated with the relay device 3 that is wirelessly connected to a mobile communication network and transmits sensor data and/or the quantified level of severity data with the Kumar's disclosure of transmitting of data wirelessly from patient-side device 102 to a browser-based engine (*remote station*) to create a system that securely stores data received from the device 2 for simultaneous storage, retrieval, analysis, and play back from anywhere in the world. Because Toge discloses transmissions of tidal volume (*the quantified level of severity data*) via the network 1 and Kumar discloses transmissions via the internet 108, the Kumar-Toge combination discloses transmissions via a mobile network, e.g., mobile network 1 of Toge (*via a cellular system*). In my opinion, the Toge-Kumar combination discloses transmitting *the quantified level of severity data to a remote station from...a) the PAP or CPAP device via a cellular system.*

(iv) Transmitting “in either order” both...

153. In my opinion, Toge discloses transmitting “both” (1) and (2) “*in either order.*” Toge discloses that the 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]. Toge discloses that each of physician-side computer 4 and mobile terminal 5 can request all data from the device 2, and the data is sent

to the requested computer or terminal. *Id.*, [0059]. In my opinion, Toge discloses that the treatment data can be transmitted to both the computer 4 and the terminal 5. Toge 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. In my opinion, the data can be transmitted to computer 4 (*remote station*) that requested the data, and then transmitted to terminal 5 (*cellular phone*) that subsequently requested the data. Conversely, the data can be transmitted to mobile terminal 5 (*cellular phone*) that requested the data, and then transmitted to computer 4 (*remote station*) that subsequently requested the data. I also note that Toge does not require simultaneous transmissions. *See generally* Ex. 1044.

154. In my opinion, the Toge-Kumar combination discloses transmitting “both” (1) and (2) “*in either order.*” Kumar discloses that its system includes patient-side device 102 (which corresponds to the device 2), computing device 110 (which can correspond to the mobile terminal 5 of Toge), provider-side device(s) 104, and central server 106 hosting an engine (which corresponds to the computer 4 of Toge). Ex. 1008, [0018], [0067], [0068], [0072], [0089]. Kumar’s devices and engine are connected to a wide area network (WAN) 108 (which corresponds to the network 1 of Toge). Ex. 1008, [0067], [0068]. Kumar 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]. In my opinion, the data can be transmitted to central server 106 (*remote station*), and then transmitted to computing device 110 (*cellular phone*). Conversely, the data can be transmitted to computing device 110 (*cellular phone*), and then transmitted to central server 106 (*remote station*). I also note that Kumar does not require simultaneous transmissions. *See generally* Ex. 1008.

155. In my opinion, the “order[ed]” data transmission feature recited in claim 15 would have been obvious to a person of ordinary skill in the art. In my opinion, 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.” In my opinion, the “order[ed]” data transmission feature recited in claim 15 would have been obvious because neither Toge nor Kumar require simultaneous transmissions and there would be no order if the transmission were simultaneous, which leaves the second and third options as obvious variants.

156. Kumar 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]. In my opinion, Kumar discloses that the provider-side device (*cellular phone*) can directly receive data from a patient-side device. In my opinion, a person of ordinary skill in the art 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. In my opinion, a person of ordinary skill in the art 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., the device 2 of Toge)), to the engine (*remote station*) from the provider-side device 102. In my opinion, transmitting the data would have allowed simultaneous storage of the physician’s analysis/diagnosis/notes along with the patient’s data in the secured storage of the engine, as discussed above.

157. In my opinion, a person of ordinary skill in the art 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.

- (v) **“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”**

158. Toge alone or in combination with Kumar discloses *for further analysis with a second processor or a server at the remote station and review of...the quantified level of severity data...by a clinician, technician or physician.*

159. Toge discloses *analysis with a second processor at the remote station* because Toge discloses that “physician-side computer 4 is a computer.” *Id.*, [0017]. In my opinion, a person of ordinary skill in the art would have understood that the “computer 4” (*remote station*) includes a processor (*a second processor...at the remote station*). *Id.*

160. Toge discloses *review of...the quantified level of severity data...by a clinician, technician or physician* because Toge discloses that physicians can “access the transmitted data [including tidal volume (*the quantified level of severity*

data)] 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]. Toge discloses that “medical institution personnel can operate the physician-side computer 4 to set the necessary data...for 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]. Toge discloses that the device, e.g., the prescribed air pressure, can be configured or adjusted via network 1 through physician-side computer 4 or mobile terminal 5. *Id.*, [0039].

161. In my opinion, a person of ordinary skill in the art would have understood that there would be analysis with the physician-side computer 4 (*analysis with a second processor...at the remote station*) and review of the received tidal volume data before/while adjusting the pressure of the device 2 by the physician (*review of...the quantified level of severity...by a...physician*). Further, a person of ordinary skill would have understood that physician-side computer 4 includes a processor (second processor). Ex. 1044, [0016], [0018].

162. The Toge-Kumar combination discloses *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*. In my opinion, a person of ordinary skill in the art 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]. In my opinion, a person of ordinary skill in the art would have understood that Kumar’s “engine” (*remote station*) includes a processor or (*a second processor...at the remote station*) or the server 106 (*a server at the remote station*). Kumar discloses that “[t]he system may also track trends during the recording, and using artificial intelligence, predict future behaviors and physiological responses based on the habits of the particular client hooked up.” *Id.*, [0084].

f. Limitation [15.e.1]

[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*”

163. In my opinion, Toge in view of Kumar renders obvious this limitation.

164. Toge discloses *determining the therapy efficacy data with...the second processor or server configured with a second software at the remote station* because the computer 4 would have a processor with software. Toge discloses that “physician-side computer 4 is a computer installed at a medical institution.” Ex. 1044, [0017]. In my opinion, a person of ordinary skill in the art would have understood that computer 4 (*remote station*) includes a processor (*second processor*)

that executes code (*second software*) in order to receive the treatment data (which can 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 device 2. *See, e.g.*, Ex. 1044, [0018], [0047], [0050].

165. Toge discloses *determining the therapy efficacy data with...the remote station* because Toge discloses determining settings (*therapy efficacy data*) with the computer 4 (*remote station*). Toge discloses that device 2 receives mode settings, parameters, or thresholds for adjusting the device 2 from physician-side computer 4. Ex. 1044, [0030], [0031], [0050]. Toge discloses that “the control unit 250 [of the 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]. Toge discloses that “the relay device 3 has predefined thresholds for all or part of the received transmitted data, which are set in advance by a physician, nurse, or other personnel following the physician's instructions. These settings can be performed using the physician-side computer 4 or mobile terminal 5, or directly using the input devices (keyboard, mouse, etc.) of the relay device 3.” *Id.*, [0050].

166. In my opinion, a person of ordinary skill in the art would have understood that the data for adjusting mode settings or parameters are the *therapy efficacy data* because these are data that physician provides to the device 2 in order to adjust the mode settings or parameters of the PAP device when treating the patient

based on monitoring and analysis of the treatment data and tidal volume that represent the patient's condition and efficacy of the treatment.

167. Toge discloses that “[b]y transmitting the tidal volume F_p almost in real-time or at regular intervals (such as every hour), physicians can remotely monitor the patient's condition during the use of the positive pressure artificial respiration assisting device 2 remotely from hospitals or other locations. Furthermore, if there is a decreasing trend in the tidal volume F_a , emergency measures, such as adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4 or mobile terminal 5.” Ex. 1044, [0039].

168. Toge discloses that “by transmitting the air leakage volume F_b from the nasal mask 21 almost in real-time or at regular intervals, physicians can know the actual amount of air leakage when the positive pressure artificial respiration assisting device 2 is being used.” *Id.*, [0040]. Toge discloses that “[b]y transmitting the internal pressure P of the nasal mask 21 almost in real-time or at regular intervals, physicians can determine whether the prescribed pressure air is being delivered to the patient.” *Id.*, [0041]. Toge discloses that “[b]y transmitting the minute breathing rate N almost in real-time or at regular intervals, physicians can also know the real-time or periodic condition of the patient.” *Id.*, [0044]. Toge discloses that “[b]y

transmitting the operating status in real-time, physicians can address emergencies involving the patient.” *Id.*, [0046].

169. Toge discloses that “[b]y transmitting the oxygen saturation measured by the oxygen saturation monitor almost in real-time or at regular intervals, physicians can almost instantly or periodically know the patient's oxygen saturation level. Then, if the oxygen saturation, for example, falls below 90%, physicians can take emergency measures such as adjusting the prescription pressure to a higher level remotely from the physician-side computer 4 or mobile terminal 5, operating the positive pressure artificial respiration assisting device 2 in conjunction with an oxygen concentrator, or adjusting the flow rate from the oxygen concentrator if one is being used in conjunction.” *Id.*, [0047].

170. The Toge-Kumar combination also discloses *determining the therapy efficacy data with...the second processor or server configured with a second software at the remote station.*

171. In my opinion, a person of ordinary skill in the art would have been motivated to determine controls (*therapy efficacy data*) with Kumar’s engine (*remote station*). In my opinion, a person of ordinary skill in the art would have been motivated determine data with the remote engine hosted on central server 106 (*server configured with a second software at the remote station*) because the engine is for “secured storage device at the central server for later access, replay, and/or

analysis.” The transmission would allow a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. Ex. 1008, [0083]. Kumar discloses 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]. Kumar discloses that “based on real-time streaming of vital patient information,” Kumar’s system “may be tailored to forward proper responses to the patient.” *Id.*, [0088].

172. In my opinion, a physician would 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”).

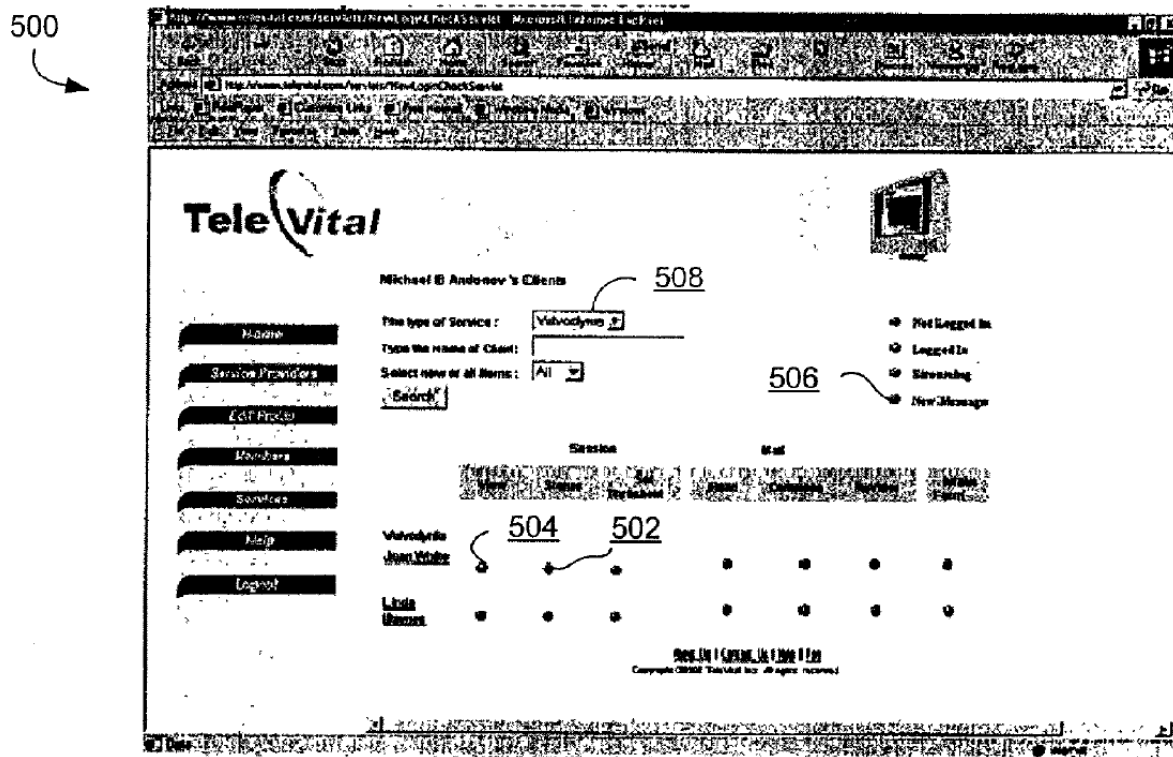


Fig. 5

Ex. 1008, FIG. 5

173. Because 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.*

g. Limitation [15.e.2]

[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*”

174. In my opinion, Toge in view of Kumar renders obvious this limitation.

175. Toge discloses that the computer 4 (*remote station*) can *receive and display the quantified level of severity data...to the subject or a care provider*. As I explained for limitation [15.d] (Section IX.A.3.e), tidal volume (*quantified level of severity data*) is provided to and received by physician-side computer 4 for analysis (*to the subject or a care provider*). Ex. 1044, [0030], [0031], [0039]-[0042].

176. Toge discloses that “by transmitting the air leakage volume Fb from the nasal mask 21 almost in real-time or at regular intervals, physicians can know the actual amount of air leakage when the positive pressure artificial respiration assisting device 2 is being used.” *Id.*, [0040]. In my opinion, a person of ordinary skill in the art would have understood that, for the physicians to monitor and review the tidal volume (*quantified level of severity data*), such information is displayed to the physicians or nurses (*a care provider*) on the physician-side computer 4. In my opinion, it would also have been obvious for the data on the computer 4 to be displayed to *the subject* to manage the therapy provided by the device 2.

177. Toge discloses that “[m]edical institution personnel such as physicians and nurses can access the transmitted data using the physician-side computer 4.

Furthermore, medical institution personnel can operate the physician-side computer 4 to send a data download request to the relay device 3 and download the necessary data onto the physician-side computer 4. Moreover, medical institution personnel can operate the physician-side computer 4 to set the necessary data (as described later) for the positive pressure artificial respiration assisting device 2.” *Id.*, [0018]. Toge disclose 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]. In my opinion, the settings of the PAP device, such as the prescribed pressure, can be configured or adjusted using physician-side computer 4 or mobile terminal 5. *Id.*, [0027], [0039].

178. Toge also discloses *receive and display...therapy efficacy data to...a care provider*. In my opinion, a person of ordinary skill in the art would have understood that 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.

179. In my opinion, a person of ordinary skill in the art would have understood that Toge discloses that the computer 4 (*remote station*) receives and displays *therapy efficacy data* such as the data for adjusting settings and modes (*id.*, [0027], [0039])). In my opinion, the computer 4 displays data to a physician (*care provider*) and the data is the *therapy efficacy data* because it is data that is indicative

of the patient's therapy and represents the patient's condition and efficacy of the treatment.

180. The Toge-Kumar combination also discloses that the *remote station* can *receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider*. For example, as I explained for limitation [15.e.1] (Section IX.A.3.f), Kumar discloses that a physician can use a browser-based engine to receive and review patient data (*quantified level of severity data and/or therapy efficacy data*). In my opinion, a person of ordinary skill in the art 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, adjust, and provide associated settings. In my opinion, a person of ordinary skill in the art would have understood that, for the physicians to monitor and analyze the patient data (*quantified level of severity data and/or therapy efficacy data*), such information is displayed to the physicians (*a care provider*) via the web-browser user interface.

4. Dependent Claims 16, 17, 20-24, and 26-29

a. Dependent Claim 16

"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.”

181. In my opinion, Toge in view of Kumar renders obvious this claim.

182. Kumar discloses the computing device 110 (*cellular phone*) and medical devices (*PAP or CPAP device*). Ex. 1008, [0072]. Kumar discloses that the computing device 110 can be “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.” *Id.* In my opinion, a person of ordinary skill in the art would have understood the examples of the computing device 110 to disclose that the computing device 110 (*cellular phone*) could communicate via Bluetooth (*Bluetooth standard wireless RF connection*). In my opinion, a person of ordinary skill in the art would have understood that devices such as a “wireless phone” or an “IPAQ” can establish wireless communications using the Bluetooth protocol. Ex. 1011, 2 (disclosing that an iPAQ cell phone can communicate using Bluetooth protocol).

183. Kumar discloses that the a “patient-side device can be wired or wireless, and communicates through a serial (RS232, USB, IEEE 1394, etc.), parallel, fire-wire, wireless, or customized interface/protocol.” Ex. 1008, [0072]. In my opinion, a person of ordinary skill in the art would have understood the examples of the connections of the patient-side device to disclose that the patient-side device

such as Toge's device 2 (*PAP or CPAP device*) could communicate with a mobile phone via Bluetooth (*Bluetooth standard wireless RF connection*).

184. In my opinion, because a person of ordinary skill in the art would have understood that the computing device 110 and the patient-side device each communicate via Bluetooth, a person of ordinary skill in the art would have understood that the computing device 110 (*PAP or CPAP device*) and the patient-side device (*PAP or CPAP device*) *each have a Bluetooth standard wireless RF connection*.

185. Kumar discloses that "the computing device establishes a two-way communication with a vast array of client-side devices, including but not limited to medical and/or biofeedback devices, holter monitors, telemetry units, data acquisition units." *Id.*, [0072]. In my opinion, because the '333 patent does not otherwise define or mention the "client-side device" (*see generally* Ex. 1001), a person of ordinary skill in the art would have understood that the client-side device is the same as the patient-side device.

186. Because Kumar discloses that the computing device 110 and the patient-side device establish "two-way communication," a person of ordinary skill in the art would have understood that the computing device 110 (*PAP or CPAP device*) and the patient-side device (*PAP or CPAP device*) *can communicate directly with each other through the wireless connection in real time*. In my opinion, a person

of ordinary skill in the art would have understood that *the wireless connection in real time* corresponds to the *Bluetooth standard wireless RF connection* because the computing device 110 (*PAP or CPAP device*) and the patient-side device (*PAP or CPAP device*) *each have a Bluetooth standard wireless RF connection* and Bluetooth connections are real-time connections. In my opinion, a person of ordinary skill in the art would have understood that a Bluetooth connection is real time connection because Bluetooth is a short-range communication protocol. For example, Bluetooth “is suitable for short-range communication.” Ex. 1009, 14:35-37.

187. Kumar discloses that that the system allows for “remote monitoring” associated with “[s]leep apnea-hypopnea syndrome.” *Id.*, [0239]-[0241]. Kumar discloses that the “patient-side device is located with a patient and can be any device that gathers physiological data from the patient. Illustrative patient-side devices include, but are not limited to, telemetry EKG, EMG and EEG monitors; continuous blood pressure and blood glucose watches; cellular transmission holter monitors.” *Id.*, [0071]. In my opinion, a person of ordinary skill in the art would have been motivated to use Bluetooth to remotely monitor the patient-side device from the computing device 110.

188. In my opinion, Toge discloses that “*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.”

Toge discloses that the device 2 has an input device 28 that allows a physician to adjust or control operations such as power on and off, mode selection, prescription pressure settings. Ex. 1044, [0026]. Toge discloses that “settings can be adjusted by the physician using a separate input terminal that can be detached from the main unit 20 [of the device 2].” *Id.*, [0027]. In my opinion, a person of ordinary skill in the art would have been motivated to configure the mobile terminal 5 (*cell phone*) and device 2 (*PAP or CPAP device*) to each have a Bluetooth connection through which the devices communicate directly with each other for the physician to adjust the device 2 settings from the mobile terminal 5. Providing Bluetooth capability would have allowed the physician to conveniently control or adjust the device 2 as well as to download or review data via Bluetooth directly from the device 2 to the mobile terminal 5. For example, the physician could control or adjust the device 2 during the patient’s initial/follow-up appointment(s) with the physician.

189. In my opinion, a person of ordinary skill in the art would have also had the skill and reasonable expectation of success in implementing Bluetooth. It was known to use the Bluetooth protocol to transmit and/or view data associated with a PAP device. For example, the use of wireless/Bluetooth protocol to transmit data associated with a PAP device. Ex. 1009, 14:54-15:12. In another example, “user data viewing and reports” can be interfaced using “W-LAN and even Bluetooth™

wireless devices.” Ex. 1050, 8:28-9:2. It would have been obvious to use known technologies with known approaches to derive the predictable result of a PAP device to establish a wireless communication with a mobile terminal through the Bluetooth protocol for improved convenience. There were only a handful of other protocols for transmitting data wirelessly, including Wi-Fi, mobile network protocol, optical connection. Using the Bluetooth protocol for wireless transmission would have been obvious because it would have been one of a finite number of predictable, known, and common options for wireless transmissions in real time and over a short range between devices.

b. Dependent Claim 17

“17. The method of claim 15, wherein the therapy can be modified based in part on the wirelessly transmitted data or information.”

190. In my opinion, Toge in view of Kumar renders obvious this claim.

191. Toge discloses that “[b]y transmitting the tidal volume F_p almost in real-time or at regular intervals (such as every hour), physicians can remotely monitor the patient's condition during the use of the positive pressure artificial respiration assisting device 2 remotely from hospitals or other locations. Furthermore, if there is a decreasing trend in the tidal volume F_a , emergency measures, such as adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4 or mobile terminal 5.” Ex. 1044,

[0039]. Toge discloses that “by transmitting the air leakage volume F_b from the nasal mask 21 almost in real-time or at regular intervals, physicians can know the actual amount of air leakage when the positive pressure artificial respiration assisting device 2 is being used.” *Id.*, [0040]. Toge discloses that “[b]y transmitting the internal pressure P of the nasal mask 21 almost in real-time or at regular intervals, physicians can determine whether the prescribed pressure air is being delivered to the patient.” *Id.*, [0041]. Toge discloses that “[b]y transmitting the minute breathing rate N almost in real-time or at regular intervals, physicians can also know the real-time or periodic condition of the patient.” *Id.*, [0044]. Toge discloses that “[b]y transmitting the operating status in real-time, physicians can address emergencies involving the patient.” *Id.*, [0046]. Toge discloses that “[b]y transmitting the oxygen saturation measured by the oxygen saturation monitor almost in real-time or at regular intervals, physicians can almost instantly or periodically know the patient's oxygen saturation level. Then, if the oxygen saturation, for example, falls below 90%, physicians can take emergency measures such as adjusting the prescription pressure to a higher level remotely from the physician-side computer 4 or mobile terminal 5, operating the positive pressure artificial respiration assisting device 2 in conjunction with an oxygen concentrator, or adjusting the flow rate from the oxygen concentrator if one is being used in conjunction.” *Id.*, [0047].

192. As I explained for limitations [15.d]-[15.e] (Section IX.A.3.e-f), the settings such as pressure (*therapy*) of the device 2 can be modified on the physician-side computer 4 based on the data or tidal volume (*quantified level of severity data*) transmitted wirelessly from the device 2 to the computer 4. Ex. 1044, [0006], [0007]; *see also id.*, [0016], [0060], [0063], [0070], [0078], [0080], [0081], claim 1.

c. Dependent Claim 20

“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.”

193. In my opinion, Toge in view of Kumar renders obvious this claim for the same reasons I discussed for claim 17 (Section IX.A.4.b).

d. Dependent Claim 21

“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.”

194. In my opinion, Toge in view of Kumar renders obvious this claim.

195. 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. In my opinion, based on the ’333 patent’s disclosure, a person of ordinary skill in the art would have understood real-time to disclose 24 hours or less to make an adjustment.

196. As I discussed for claim 17 (Section IX.A.4.b), Toge discloses that the device 2 (*the PAP or CPAP*) can be adjusted (*adjusted or titrated in real-time*) by a physician (*technician, clinician or physician*) from the computer 4 (*from a remote location*). Toge discloses that “[b]y transmitting the tidal volume F_p almost in real-time or at regular intervals (such as every hour), physicians can remotely monitor the patient's condition during the use of the positive pressure artificial respiration assisting device 2 remotely from hospitals or other locations. Furthermore, if there is a decreasing trend in the tidal volume F_a , emergency measures, such as adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4 or mobile terminal 5.” Ex. 1044, [0039]. Toge discloses that “by transmitting the air leakage volume F_b from the nasal mask 21 almost in real-time or at regular intervals, physicians can know the actual amount of air leakage when the positive pressure artificial respiration assisting device 2 is being used.” *Id.*, [0040]. Toge discloses that “[b]y transmitting the internal pressure P of the nasal mask 21 almost in real-time or at regular intervals, physicians can determine whether the prescribed pressure air is being delivered to the patient.” *Id.*, [0041]. Toge

discloses that “[b]y transmitting the minute breathing rate N almost in real-time or at regular intervals, physicians can also know the real-time or periodic condition of the patient.” *Id.*, [0044]. Toge discloses that “[b]y transmitting the operating status in real-time, physicians can address emergencies involving the patient.” *Id.*, [0046]. Toge discloses that “[b]y transmitting the oxygen saturation measured by the oxygen saturation monitor almost in real-time or at regular intervals, physicians can almost instantly or periodically know the patient's oxygen saturation level. Then, if the oxygen saturation, for example, falls below 90%, physicians can take emergency measures such as adjusting the prescription pressure to a higher level remotely from the physician-side computer 4 or mobile terminal 5, operating the positive pressure artificial respiration assisting device 2 in conjunction with an oxygen concentrator, or adjusting the flow rate from the oxygen concentrator if one is being used in conjunction.” *Id.*, [0047].

e. Dependent Claim 22

“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.”

197. In my opinion, Toge in view of Kumar renders obvious this claim.

198. Kumar discloses *storing...the quantified level of severity data from either the PAP or CPAP device transmitted to the remote station* because Kumar discloses that “data may be stored in a secured storage device at the central server for later access, replay, and/or analysis. 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, for example. Thus, the exemplary embodiment may allow for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device. This beneficially allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online.” Ex. 1008, [0083].

199. Kumar discloses *storing...on a database with similar data from treatments of many other subjects* because Kumar discloses that “storage of the data allows for the creation of statistical databases, including development of a database of biomedical test results.” *Id.*, [0083]. As I discussed for limitation [15.d] (Section IX.A.3.e), a person of ordinary skill in the art would have been motivated to implement Kumar’s engine and database in the Toge-Kumar combination and would also have a reasonable expectation of success in doing so. Because Toge discloses that the tidal volume (*quantified level of severity data*) can be transmitted to the computer 4 (*remote station*) for monitoring and that the PAP treatment can be

provided to “several patients” (*see, e.g.*, Ex. 1044, [0015], [0058]), a person of ordinary skill in the art 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.

f. Dependent Claim 23

“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.*”

200. In my opinion, Toge in view of Kumar renders obvious this claim.

201. As I discussed for claim 22 (Section IX.A.4.e), a person of ordinary skill in the art would have understood Kumar’s database to be on a *central server remote to the test location* because Kumar discloses that “data may be stored in a secured storage device at the central server for later access, replay, and/or analysis” (Ex. 1008, [0083]) and because “the server may be implemented on the Internet” (*id.*, [0087]). In my opinion, a person of ordinary skill in the art would have understood 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) to disclose that the central server (on which the browser-

based engine is implemented) is remote to the patient-side device (e.g., the device 2 of Toge).

202. Kumar discloses code/program (*second software*) is stored on a *computer readable medium* because Kumar discloses that a “[t]he present invention may be implemented on a program or code that can be stored in a computer-readable...medium.” Ex. 1008, [0020], [0087]. In my opinion, a person of ordinary skill in the art would have understood that because the engine is part of Kumar’s invention, the program or code is *executed by the central server*.

g. Dependent Claim 24

“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.*”

203. In my opinion, Toge in view of Kumar renders obvious this claim.

204. As I discussed for claim 23 (Section IX.A.4.f), Kumar discloses *data on the database* because Kumar discloses storing data “in a secured storage device at the central server for later access, replay, and/or analysis.” Ex. 1008, [0083]. In my opinion, a person of ordinary skill in the art would have understood that Kumar discloses *analyzing the data on the database with a relationship algorithm or a neural network* because Kumar discloses “the creation of statistical databases, including development of a database of biomedical test results.” Ex. 1008, [0083].

Kumar discloses “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 person of ordinary skill in the art would have understood that “artificial intelligence” discloses *a relationship algorithm or a neural network*. In my opinion, a person of ordinary skill in the art would have been motivated to “track trends” and use “artificial intelligence” on the *central server* because Kumar discloses “the creation of statistical databases, including development of a database of biomedical test results.” *Id.*, [0083]. In my opinion, a person of ordinary skill in the art would have understood that “predict future behaviors and physiological responses” discloses *determine an optimal treatment for the subject*.

h. Dependent Claim 26

“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.*”

205. In my opinion, Toge in view of Kumar renders obvious this claim.

206. Toge discloses that *the processor of the PAP or CPAP device analyzes the collected data* because Toge discloses that the control unit 250 of the device 2 analyzes the Ft, Fa, and Fb (*analyzes the collected data*) to determine the tidal volume Fp (*determine the quantified level of severity data*). Ex. 1044, [0038]. Kumar discloses a *Discrete Fourier Transform* or a *Fast Fourier Transform* because Kumar discloses that data can be analyzed “using FFT, DFT.” Ex. 1044, [0075]. The ’333 patent discloses a “Discrete Fourier transform (DFT), and its numerically efficient complement the Fast Fourier Transform (FFT).” Ex. 1001, 23:63-65. In my opinion, a person of ordinary skill in the art would have understood FFT and DFT to be a *Discrete Fourier Transform* or a *Fast Fourier Transform*.

207. In my opinion, a person of ordinary skill in the art would have been motivated to modify Toge’s device 2 to use Kumar’s FFT or DFT techniques to analyze the collected data to determine the tidal volume. In my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success in implementing this feature in the Toge-Kumar combination. The combination would have involved combining Toge’s known device 2 that analyzes collected data with Kumar’s known FFT or DFT techniques for analyzing data to create a device with a processor that analyzes the collected data by using FFT or DFT.

i. Dependent Claim 27

“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.”

208. In my opinion, Toge in view of Kumar renders obvious this claim.

209. As I discussed for claim 26 (Section IX.A.4.h), the Toge-Kumar combination discloses analyzing the collected data with Discrete Fourier Transform (DFT) and Fast Fourier Transform (FFT) to determine tidal volume. In my opinion, a person of ordinary skill in the art would have understood that because DFT and FFT includes Fourier Transform and Fourier Transform techniques transform *time-domain* signals into *frequency-domain* signals, using Fourier Transform discloses using a *time-frequency signal analysis*.

210. In my opinion, a person of ordinary skill in the art would have been motivated to modify Toge’s device 2 to use Fourier Transform techniques to analyze the collected data to determine the tidal volume. In my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success in implementing a Fourier Transform in the Toge-Kumar combination. The combination would have involved combining Toge’s known device 2 that analyzes collected data with known Fourier Transform techniques for analyzing data to create a device with a processor that analyzes the collected data by using *time-frequency signal analysis*.

j. Dependent Claim 28

“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.*”

211. In my opinion, Toge in view of Kumar renders obvious this claim.

212. Toge discloses that the device 2 includes *a third software*. Toge discloses that controlling the device 2 based on “configured mode and prescription pressure.” Ex. 1044, [0032]. Toge discloses that 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]). In my opinion, a person of ordinary skill in the art would have understood that the program on the control unit 250 of the device 2 discloses *a third software*.

213. Toge discloses that the mobile terminal 5 includes *the first software*. Toge discloses that “medical institution personnel can operate the mobile terminal 5 to set the necessary data...for the [PAP] device 2.” Ex. 1044, [0019]. Toge discloses that the “mobile terminal 5 includes mobile phones...PDAs.” *Id.* In my opinion, a person of ordinary skill in the art would have understood that mobile terminal 5 such as a mobile phone or PDA executes software (*first software*) to be operated to set the data.

214. Toge in view of Kumar discloses that *a third software...along with the first software can be updated from the remote station or a different remote server.*

Kumar discloses that “updates to the software are done by simply running the latest software from a website.” Ex. 1008, [0086]. In my opinion, a person of ordinary skill in the art would have understood that because Kumar discloses updates and Toge discloses that the device 2 and the mobile terminal 5 are connected to communication network 1 (*id.*, [0008], [0061]), a person of ordinary skill in the art would have found it obvious to have the software of those devices updated from a *remote server*.

215. In my opinion, a person of ordinary skill in the art 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. In my opinion, a person of ordinary skill in the art 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 updated from the engine (*remote station*) or a *different remote server*. In my opinion, a person of ordinary skill in the art would have had the skill and a reasonable expectation of success in updating the software of network connected devices from a remote station or a different remote server.

k. Dependent Claim 29

“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.*”

216. In my opinion, Toge in view of Kumar renders obvious this claim.

217. Toge discloses *alerting the subject's technician, clinician or physician of issues related to the therapy efficacy*. Toge discloses that “it is possible to set multiple lower or upper threshold values. For example, two lower threshold values can be set for the tidal volume F_p , and if the tidal volume F_p falls below the smaller of the two lower threshold values, the relay device 3 may be configured to send 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.” Ex. 1044, [0055]. As I discussed for claim [15.e.1] (Section IX.A.3.f), Toge discloses setting thresholds (*therapy efficacy data*) for tidal volume of the device 2. *Id.*, [0030], [0031], [0050]. In my opinion, a person of ordinary skill in the art would have understood that an alert about tidal volume thresholds discloses *issues related to the therapy efficacy*. Toge discloses that a physician uses the computer 4 or the mobile terminal 5. *Id.*, [0018], [0019]. In my opinion, a person of ordinary skill in the art would have understood that a physician would be alerted from alerts on the computer 4 or the mobile terminal 5. In my opinion, a person of ordinary skill in the art would have understood that sending an alert to the computer 4 or the mobile terminal 5 of the physician about the patient’s breathing discloses *alerting the subject's technician, clinician or physician of issues related to the therapy efficacy*.

B. Ground 2: Toge in View of Kumar and Norman Renders Obvious the Challenged Claims

1. Motivation to Combine

218. In my opinion, a person of ordinary skill in the art would have been motivated to modify the Toge-Kumar combination in view of Norman's teaching. Toge discloses a CPAP device that adjusts pressure supplied to a patient. *See e.g.*, Ex. 1044, [0039]. Norman discloses an improved CPAP device that allows automated titration: "[t]he present invention relates to a method and system for automated titration of CPAP. The system may include 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. The system also includes a titration device which receives and analyzes the input data to determine existence of breathing disorder and corresponding characteristics. 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." Ex. 1059, Abstract, [0007].

219. Norman discloses automatically updating and refining the titration: "[t]he titration process may then be repeated during the subsequent time period using the adjusted pressure to evaluate the efficacy of the adjusted pressure. Thus, over a several time periods, the titration process may be repeated to enhance the accuracy

with which the appropriate pressure is determined. In an alternative embodiment, 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]. In my opinion, a person of ordinary skill in the art would have found it beneficial to apply Norman's automated titration process to improve the accuracy and efficacy of the CPAP treatment process of the Toge-Kumar combination.

220. Norman discloses that more accuracy leads to more use of the PAP therapy: "The system 1 may determine appropriate pressures by adjusting pressure only at the beginning of a sleeping cycle and by operating over the course of several sleeping cycles to arrive at a more accurate image of the patient's breathing patterns. For example, some patients may have "good" or "bad" nights which may not be representative of an "average" night for the patient. In contrast, conventional automatic titrating systems may generate immediate feedback responses to the abnormal respiratory events from which they attempt to determine a single therapeutic pressure. Conventional titration systems generally obtain data only during a single sleeping cycle, since multiple visits to sleep clinics, where these systems are located, are unlikely. Furthermore, the more accurate the pressure supplied to a particular patient, the more likely the patient will regularly make use of this PAP therapy." *Id.*, [0033].

221. In my opinion, a person of ordinary skill in the art motivated to improve the Toge-Kumar combination would have looked at Norman's known ways to collect and analyze data as taught by Norman. In my opinion, a person of ordinary skill in the art would have been motivated to apply Norman's teaching of collecting patient's data over "several time periods" to "evaluate the efficacy of the adjusted pressure" (Ex. 1059, [0031]) in the Toge-Kumar combination because using data collected from multiple nights of treatment would have enhanced the accuracy of the treatment. In my opinion, a person of ordinary skill in the art would have been motivated to apply Norman's teachings because improved accuracy and efficacy of the treatment would have improved the patient's compliance and satisfaction.

2. Reasonable Expectation of Success

222. In my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success in applying Norman's automated titration teaching to the Toge-Kumar combination. Norman discloses that its system can be applied to any PAP systems: "[a]lthough 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." Ex. 1059, [0017]. In my opinion, a person of ordinary skill in the art would have been able to combine (1) Toge's known device 2 that uses a processor based on received sensor data with

(2) Kumar's engine that stores patient data with (3) Norman's techniques for analyzing sensor data to determine "indexes of respiratory events (e.g., a total time of abnormal respiration." Ex. 1059, [0028]. In my opinion, a person of ordinary skill in the art would have understood that the Toge-Kumar-Noman combination would predictably disclose a PAP device with automated titration capabilities that improve the pressure accuracy and the treatment efficacy.

223. In my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success in applying Norman's features to 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.

3. Claims 15-17, 20-24, and 26-29

224. As I discussed in Ground 1 (Section IX.A) and specifically limitations [15.c] (Section IX.A.3.d) and [15.e.1] (Section IX.A.3.f), the Toge-Kumar combination discloses claims 15-17, 20-24, and 26-29. In my opinion, it would have been obvious to apply Norman to the Toge-Kumar combination to implement those claims.

a. 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”

225. Norman discloses this claim limitation.

226. In my opinion, a person of ordinary skill in the art would have understood that Norman discloses *analyzing with the processor the collected data*. As I discussed above (Section VII.D), in my opinion, a person of ordinary skill in the art would have understood that the combined titration device 26 and processing arrangement 24 (Ex. 1059, [0023]) discloses *processor*. Norman discloses that the flow and/or pressure sensors 23 detect the volume of the airflow and the pressure supplied to the patient (*collected data*) and provided to the processing arrangement 24 (*id.*, [0020]) for analysis by the titration device 26 (*id.*, [0025]). Norman discloses that titration device 26 analyzes the collected data (*analyzing with the processor 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].

227. In my opinion, a person of ordinary skill in the art would have understood that Norman 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 I discussed above (Section VII.D), Norman discloses *a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy* because Norman discloses 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. The counts 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.*, [0028]. In my opinion, a person of ordinary skill in the art would have understood that the processing arrangement 24 and titration device 26 analyze (*analyzing with the processor*) 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*).

b. A POSITA Would Have Been Motivated to Modify the Toge-Kumar Combination in view of Norman

228. In my opinion, a person of ordinary skill in the art would have been motivated to apply Norman's analysis of data to determine appropriate pressure to the Toge-Kumar because Toge discloses a CPAP device that adjusts pressure

supplied to a patient (Ex. 1044, [0039]) and Norman teaches an improved CPAP device that allows “automated titration” (Ex. 1059, Abstract, [0007]). As discussed in Section IX.A, Norman’s automated titration “may then be repeated during the subsequent time period using the adjusted pressure to evaluate the efficacy of the adjusted pressure. Thus, over a several time periods, the titration process may be repeated to enhance the accuracy with which the appropriate pressure is determined.” *Id.*, [0031]. In my opinion, a person of ordinary skill in the art would have been motivated to apply Norman’s data analysis and pressure determination to improve the accuracy and efficacy of the CPAP treatment process of the Toge-Kumar combination. Norman discloses that “the more accurate the pressure supplied to a particular patient, the more likely the patient will regularly make use of this PAP therapy.” *Id.*, [0033]. In my opinion, a person of ordinary skill in the art would have understood that applying Norman’s data analysis and pressure determination for improved accuracy and efficacy of the treatment would have improved the patient’s compliance and satisfaction.

229. As I discussed for limitation [15.d]-(iii) in Ground 1 (Section IX.A.3.e), a person of ordinary skill in the art 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 (*the collected data, the quantified level of severity data, and therapy efficacy data*) associated the

patient's treatment for purposes such as secured storage, data backup, later analysis or access by the physicians or patients, creation of a database, and sharing of data.

230. In my opinion, a person of ordinary skill in the art would have understood that the Toge-Kumar-Norman combination discloses limitation [15.e.2] because as I discussed for limitations [15.d]-(iii) and [15.e.2] in Ground 1 (Sections IX.A.3.e, g), Kumar discloses 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].

231. In my opinion, a person of ordinary skill in the art would have had sufficient knowledge to have a reasonable expectation of success in applying Norman's data analysis and pressure determination to the Toge-Kumar combination. As I explained for limitations [15.a]-[15.c] in Ground 1 (Sections IX.A.3.b-d), Toge discloses a CPAP device that collects sensor data and analyzes the sensor data using a processor. In my opinion, a person of ordinary skill in the art would have understood that Norman could be applied to the Toge-Kumar combination because Norman discloses that "[a]lthough 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." Ex. 1059,

[0017]. In my opinion, a person of ordinary skill in the art would have been able to combine Toge's known PAP device with Kumar's known remote engine and with Norman's data analysis to create the Toge-Kumar-Norman PAP device that *analyzes with a processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy* to improve and enhance the treatment accuracy and efficacy.

232. In my opinion, the Toge-Kumar-Norman combination discloses dependent claims 16-17, 20-24, and 26-29 as I discussed in Ground 1 (Sections IX.A.4). In my opinion, a person of ordinary skill in the art would have understood that because the modification of the Toge-Kumar combination in view of Norman does not substantively impact the disclosed features corresponding to claims 16, 20, 22-24, and 26-28, 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.

233. With respect to dependent claims 17, 21, and 29, the Toge-Kumar-Norman combination also discloses these claims for additional reasons. 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. EX1044, [0019], [0039], [0046], [0055]. Kumar discloses that the care provider "may remotely control the client-side device" (e.g., the PAP device). Ex. 1008, [0015]. In my opinion, a person of ordinary skill in the art would have been

motivated to enable the PAP device (modified in view of Norman) to be adjusted in real-time by a physician remotely based on the wirelessly transmitted data/information. In my opinion, a person of ordinary skill in the art would have been motivated to make this modification so that the PAP device providing treatment may alert the physician issues relating to the therapy efficacy.

234. In my opinion, the Toge-Kumar-Norman combination discloses claims 17, 21, and 29 because a person of ordinary skill in the art would have found it obvious to adjust or modify the titration process. For example, a person of ordinary skill in the art would have adjusted the frequency of the titration process based on the patient's condition and data or alerts provided to the physician. 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].

C. Ground 3: Toge in View of Kumar and Burton Renders Obvious the Challenged Claim

1. Motivation to Combine

235. Burton discloses customizing 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. In my opinion, a person of ordinary skill in the art would have understood that Burton’s algorithm would have improved the accuracy of detecting arousals and treating patient’s sleep disorders by using individual patient’s collected data. Burton discloses improving the treatment with 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” *Id.*, 21:4-22:21. In my opinion, a person of ordinary skill in the art would have understood that Burton’s algorithm would be beneficial to minimize or avoid transient arousals when the patient is undergoing PAP treatments and would have improved the patient’s sleep quality.

236. In my opinion, a person of ordinary skill in the art would have been motivated to improve the control unit 250 of Toge by modifying it to train on data to improve the efficacy of treatment as taught by Burton. In my opinion, a person of ordinary skill in the art would have been motivated to make the modification because additional data would further the objective of Toge to “enable remote monitoring of the patient’s condition during the used of the positive pressure artificial respiration assisting device and the condition of the positive pressure artificial respiration assisting device itself.” Ex. 1044, [0005]. In my opinion, because Toge discloses

“adjusting the prescription pressure” (*id.*, [0039], [0047]), the efficacy data would allow the system to adjust pressure as necessary. In my opinion, a person of ordinary skill in the art would have understood that the modification would further Kumar’s objection to of “providing access to health assessments, diagnoses, [and] interventions.” Ex. 1008, [0003].

2. Reasonable Expectation of Success

237. Burton discloses “use with a CPAP machine” (Ex. 1050, 19:25-26) and that 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). In my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success modify the control unit 250 of Toge by modifying it to generate the efficacy data taught by Burton.

238. In my opinion, a person of ordinary skill in the art would have understood that Toge and Burton are structurally and functionally similar. Both references describe PAP systems that include sensors and processors. Ex. 1044, [0023] (“control unit 250”); Ex. 1050, 10:10-12 (“controller...includes a processor”). Both further discloses that the processor analyzes the signals from the flow sensors. Ex. 1044, [0028]; Ex. 1050, FIG. 1, 6:12-15, 10:3-5, claim 43. Both have the objective of treating sleep disordered breathing using CPAP. Ex. 1044, [0008]; Ex. 1050, 1:20-27.

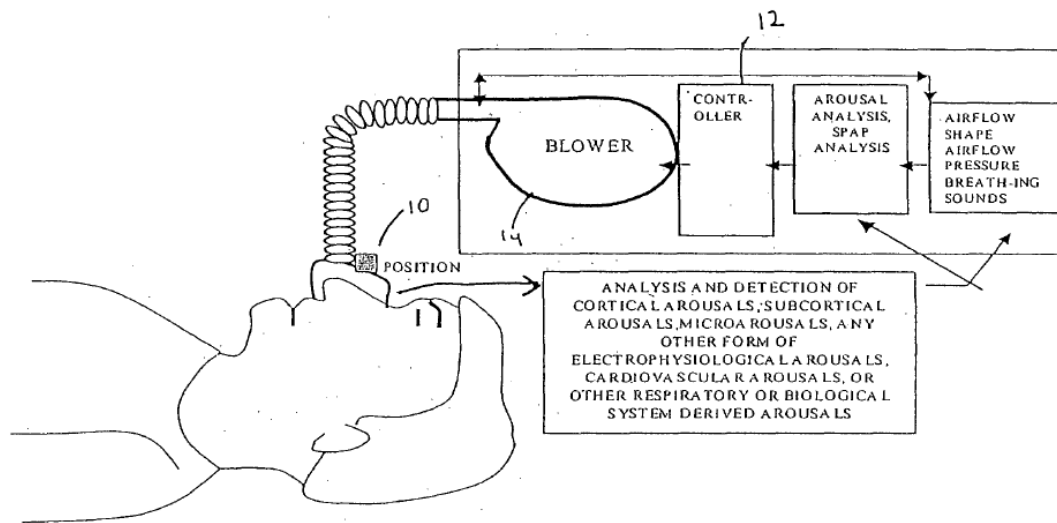
239. In my opinion, a person of ordinary skill in the art would have understood that applying Burton's teachings to the functionality of Toge's control unit 250 and Kumar's central server 106 including the browser-based engine would simply be a programming application or modification. my opinion, a person of ordinary skill in the art would have understood how to program an algorithm that trains on sensor data for adjusting or titrating the PAP to distinguish among apneas.

3. Dependent Claim 19

"19. The method of claim 17, 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."

240. In my opinion, Toge in view of Kumar and Burton renders obvious this claim.

241. Burton discloses using a sleep disorder treatment device to provide PAP treatments to patients. Ex. 1050, 1:20-27.



Ex. 1050, FIG. 1

242. Burton discloses that PAP treatments “often severely affect the quality of sleep” of the patient undergoing these treatments and “caus[e] transient arousals.” Ex. 1050, 1:9-12. Burton discloses that although “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. Burton discloses that the inaccuracy of the PAP device in detecting the upper airway resistance (UAR) events can 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.

243. Burton discloses *train the PAP or CPAP to adjust or titrate itself*. Burton discloses a system that “deliver[s] therapeutic treatments to patients without

adversely affecting their sleep.” Ex. 1050, 1:4-6, 3:15-16. Burton discloses that 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. Burton discloses a therapeutic control algorithm that 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. 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. In my opinion, a person of ordinary skill in the art would have understood that “using an adaptive algorithm” and “analysis techniques such as neural networks” discloses *train the PAP or CPAP to adjust or titrate itself*.

244. Burton discloses train the PAP or CPAP to adjust or titrate itself *to better identify and distinguish between obstructive, central and complex sleep apneas*. 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.” *Id.*, 21:4-22:21. In my opinion, a person of ordinary skill in the art would

have understood that training the algorithm to adjust the treatment based on “Mixed Sleep Apnea events,” (*id.*) “Central Sleep Apnea events” (*id.*), and “Obstructive sleep apnea and hypopnea syndrome” (*id.*) discloses *train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas.*

245. Burton discloses train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between apneas *during a second time period with data from the first sensor.* Burton discloses “down-load[ing] from sleep laboratory studies or other types of previous sleep...investigations” and associating that data (*data from the first sensor*) 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. This is consistent with my discussion of pervasive computing. *See* Section V.A. The trend towards pervasive computing was in part driven by the benefits of larger data sets that would allow clinicians to better identify patterns and develop better training models. In my opinion, a person of ordinary skill in the art would have understood that Burton discloses training the treatment device with the collected sensor data (*data from the first sensor*) from a first period to better identify and distinguish among apneas

during a second time period, such as in the past to better understand the patient's history or to improve future treatment.

246. In my opinion, a person of ordinary skill in the art would have been motivated to apply Burton's algorithm features to Toge-Kumar combination such as the device 2. In my opinion, 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. In my opinion, a person of ordinary skill in the art would have been motivated to train the PAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas. In my opinion, a person of ordinary skill in the art would have been motivated to do so because doing so would have allowed the treatment device to minimize or avoid transient arousals when the patient is undergoing PAP treatments and would have improved the patient's sleep quality.

247. In my opinion, a person of ordinary skill in the art would have had a reasonable expectation of success in implementing Burton's algorithm features in the Toge-Kumar combination. Burton's disclosed features are "adapted for use with a CPAP machine." Ex. 1050, 19:25-26. In my opinion, 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. In my opinion, a person of ordinary skill in the art would have been able to apply Burton’s known algorithms to Toge’s known device 2 that is controlled and adjusted based on received sensor data (e.g., from the pressure and flow sensors). In my opinion, a person of ordinary skill in the art would have been able to do so to have a PAP device that is capable of being trained on data from previous treatments to adjust to better identify and distinguish among apneas during past treatments (e.g., to better understand the patient’s history) or in future treatments (e.g., to improve future treatments).

D. Ground 4: Toge in View of Kumar and Norman Renders Obvious the Challenged Claims

1. Claim 19

248. The Toge-Kumar-Norman combination in view of Burton renders obvious claim 19. As I discussed in Ground 2 (Section IX.B), the Toge-Kumar-Norman combination discloses claim 15 and claim 19 because it would have been obvious to apply Norman’s features to the Toge-Kumar combination. As I discussed in Ground 3 (Section IX.C), a person of ordinary skill in the art would have been motivated to implement Burton’s teaching in the Toge-Kumar combination and that the Toge-Kumar-Burton combination discloses claim 19.

249. In my opinion, a person of ordinary skill in the art would have been motivated to apply Burton's teaching to the Toge-Kumar-Norman combination. In my opinion, a person of ordinary skill in the art would have had the same motivations, capabilities, reasonable expectation of success, and knowledge of those as I discussed in Ground 3 (Section IX.C) to modify the Toge-Kumar-Norman combination to train the PAP/CPAP device to adjust or titrate itself to better identify and distinguish among apneas during a second time period with data from the first sensor. In my opinion, for the same reasons discussed above and in Ground 3 (Section IX.C), the Toge-Kumar-Norman-Burton combination renders obvious claim 19.

X. SECONDARY CONSIDERATIONS

250. I have seen no evidence of, and I am unaware of, any secondary indicia or considerations that would support non-obviousness of the features of the '333 patent, including commercial success, long-felt need, failure of others, skepticism, praise, teaching away, recognition of a problem, or copying competitors. However, to the extent Patent Owner subsequently present such evidence, I respectfully reserve the right to respond at the time.

XI. CONCLUSION

251. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that

Declaration of Dr. Sandeep Chatterjee
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these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: January 10, 2025

By:



Sandeep Chatterjee