

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. 11,786,680

**DECLARATION OF DR. SANDEEP CHATTERJEE IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,786,680**

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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. 11,786,680 (“the ’680 patent”) (Ex. 1001). I have been asked to consider whether certain prior art references disclose or suggest the features recited in claims 1-5, 7, 8, 10-13, 15-18, and 20-31 (“the challenged claims”) of the ’680 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

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

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 a number of 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

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. Experantix 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 Experantix 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:

Ex. 1001	U.S. Patent No. 11,786,680 (“the ’680 patent”)
Ex. 1002	File History of U.S. Patent No. 11,786,680
Ex. 1006	Curriculum Vitae of Sandeep Chatterjee, Ph.D.
Ex. 1008	U.S. Patent Pub. No. 2002/0198473 to Kumar et al. (“Kumar”)
Ex. 1009	U.S. Patent No. 7,575,005 to Mumford et al. (“Mumford”)
Ex. 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
Ex. 1022	U.S. Patent No. 6,342,039 to Lynn et al. (“Lynn”)
Ex. 1044	Japan Patent Office Patent Application Pub. No. P2002-291889A to Toge (“Toge”)
Ex. 1045	U.S. Pat. Pub. No. 2008/0214903 to Orbach (“Orbach”)

Ex. 1046	D. Gourley, et. al., HTTP The Definitive Guide (2002)
Ex. 1047	D. Mauro, et. al., Essential SNMP (2001)
Ex. 1048	F. Adelstein, et. al., Fundamentals of Mobile and Pervasive Computing (2005)
Ex. 1049	WIPO Publication No. WO0145014A1 to Quay (“Quay”)
Ex. 1050	WIPO Publication No. WO2004032719A2 to Burton et al. (“Burton”)
Ex. 1051	U.S. Patent No. 5,309,921 to Kisner et al. (“Kisner”)
Ex. 1053	’680 Patent Ex Parte Re Examination Order
Ex. 1055	WIPO Publication No. WO2006090371A2 to Orbach (“Orbach 2006”)

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 ’680 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 ’680 patent was around November 2005, which corresponds to the filing date of the earliest application associated with the ’680 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 '680 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 '680 patent was allowed from U.S. Patent Application 16/057,963 filed on August 8, 2018, 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 POSITA 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 '680 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 '680 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 '680 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

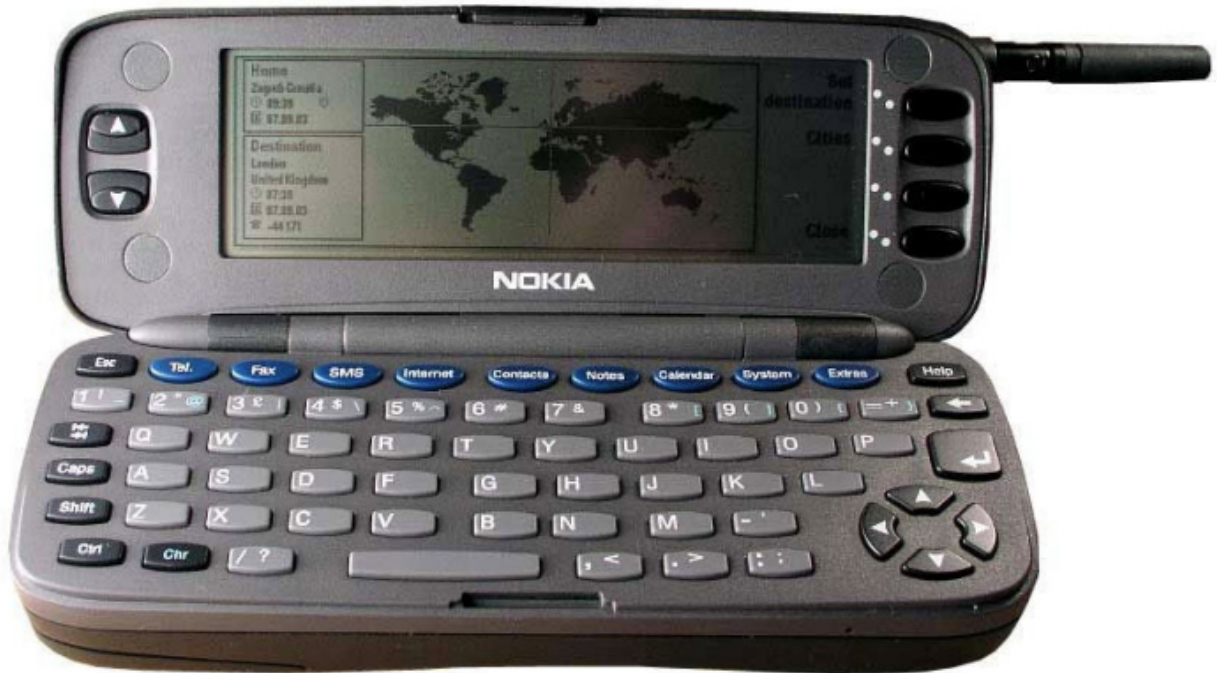
² The US model was launched in 1997 (the Nokia 9000i Communicator), running on the GSM 1900 frequency offered by carriers like Microcell in Canada.

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

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.

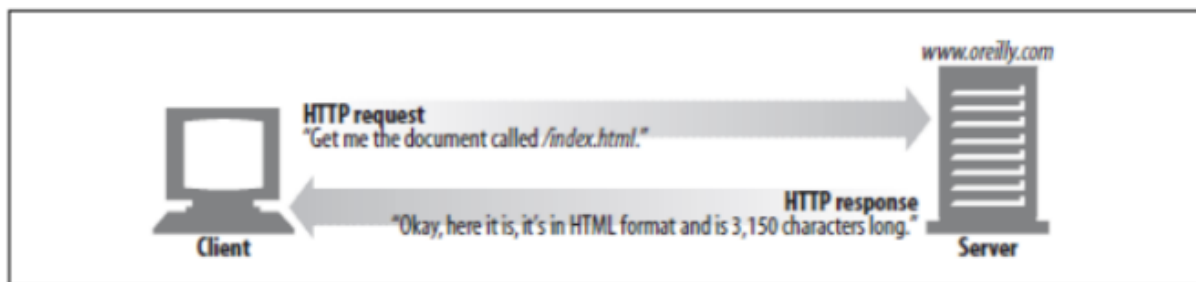


Figure 1-1. Web clients and servers

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.*

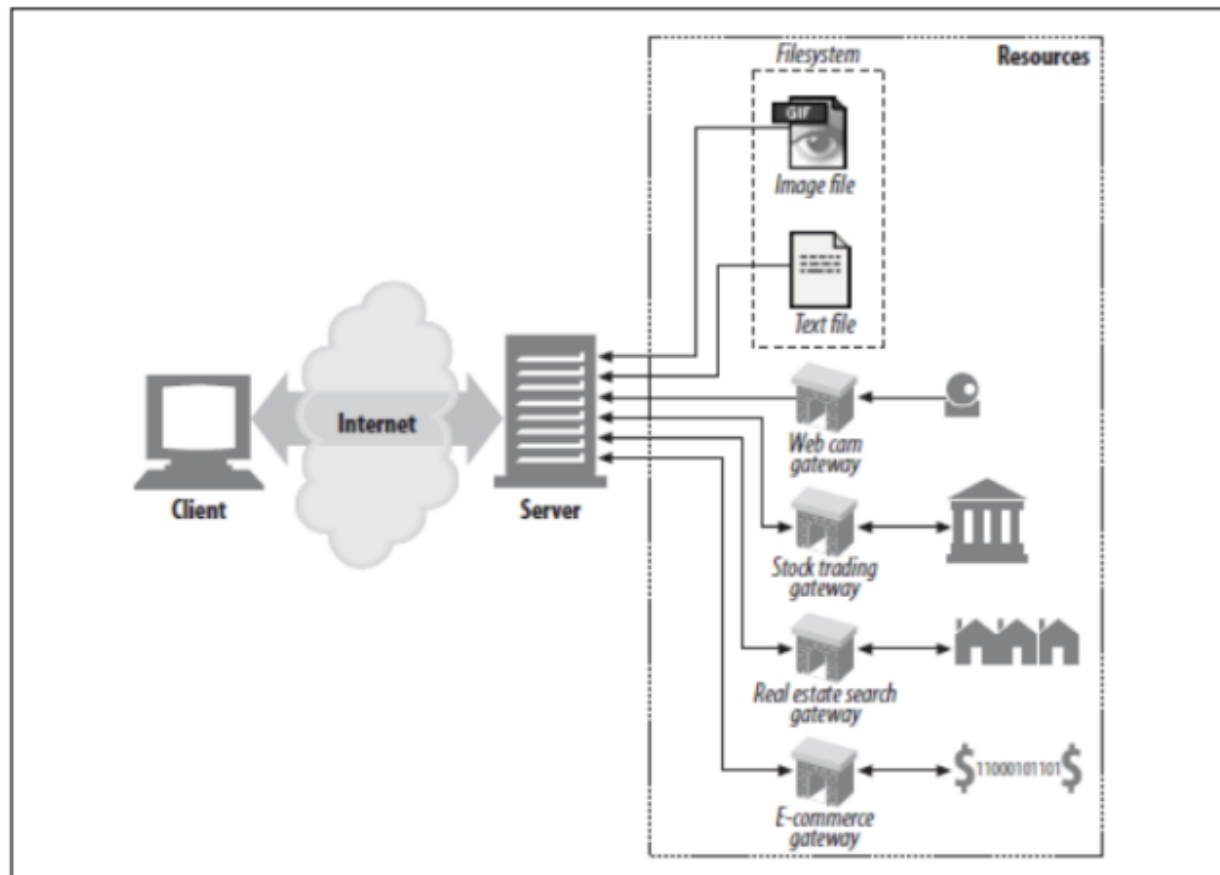


Figure 1-2. A web resource is anything that provides web content

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.

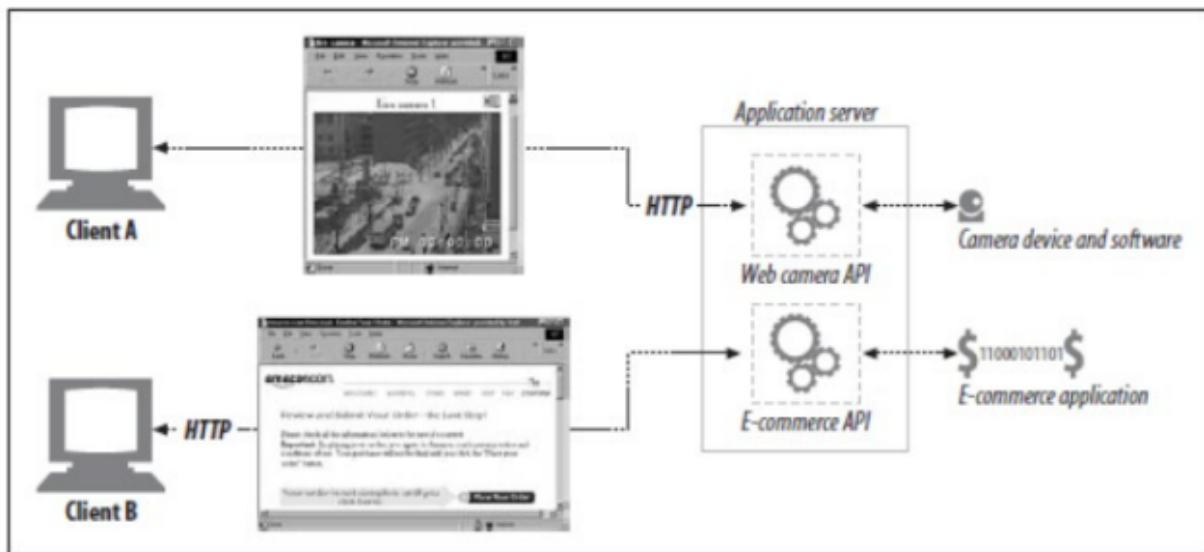


Figure 8-8. An application server connects HTTP clients to arbitrary backend applications

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 what 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 actually 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.

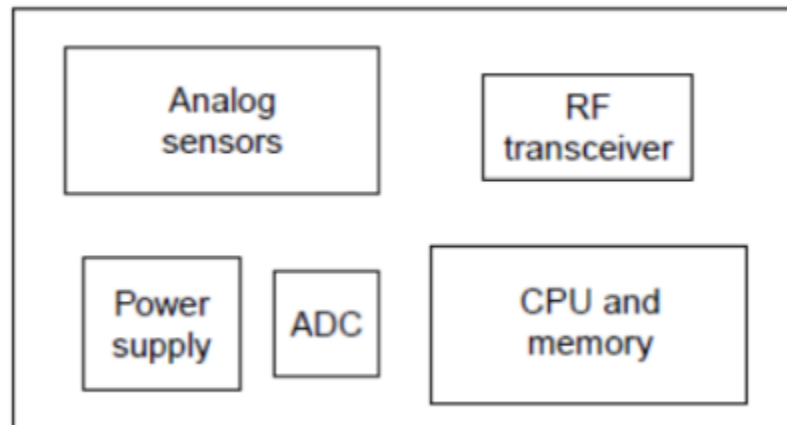
47. The second entity, the agent, is a piece of software that runs on the network devices that are being managed. It can be a separate program, or it can be incorporated into the operating system. By the time of the publication of this book, most IP devices come with some kind of SNMP agent built in. 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 is able to 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 appropriately. *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, a number of 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. Similar to 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 also 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, similar to 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 '680 PATENT

55. The '680 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 diagnostic device 441, which comprises a radio 436; an antenna 434; and a microprocessor 438 for processing the data or signals to determine a level of severity of the subject’s sleeping disorder or symptoms.” *Id.*, 54:3-10. “The diagnostic device 441 then transmits a signal based on this level of severity by either a tether 444 or radio signal...to an actuator...in the CPAP device 428, which controls the flow of air or gas provided to the subject by the air hose or subject circuit 416.” *Id.*, 54:10-16.

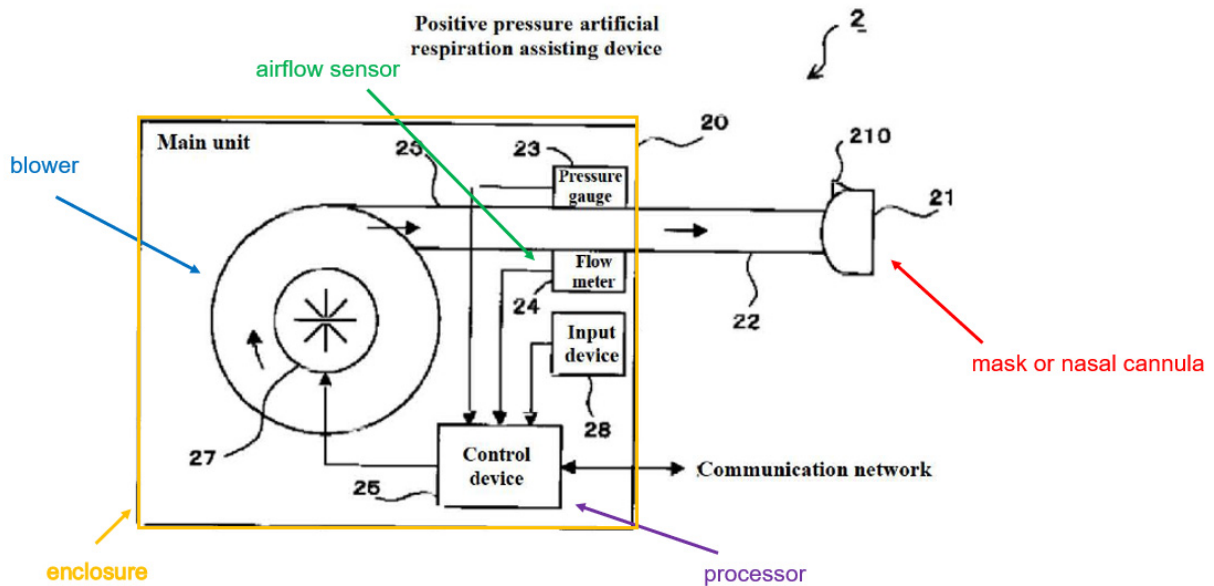
57. The '680 patent acknowledges that various claimed features were known in the art. For example, the '680 patent acknowledges that “a sensor for providing a sensor data to determine airflow,” “radio frequency wireless transceiver,” calculation of “data related to a quantitative measure of symptom severity,” and “signal processing techniques [such as] wavelet analysis,” as recited in the '680 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].

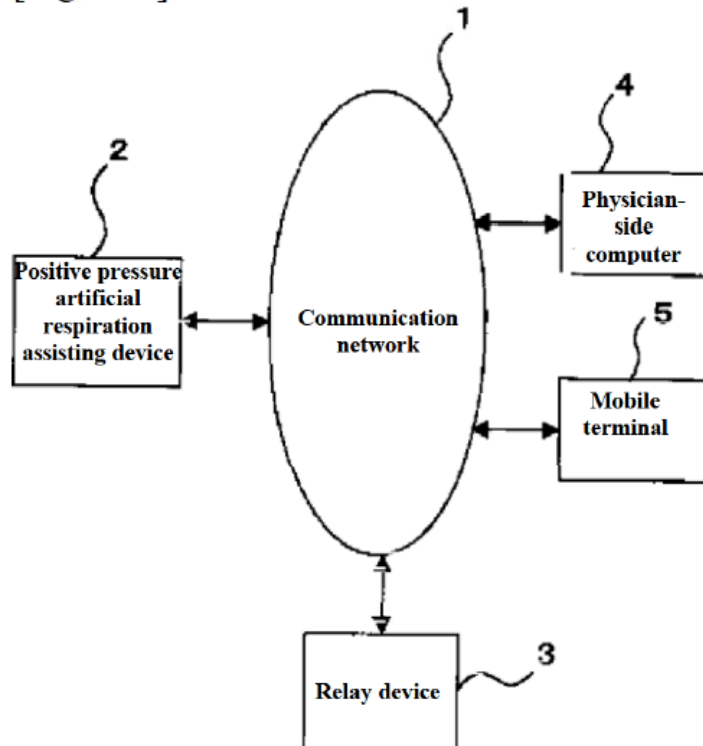
[Figure 2]



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).

[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. To the extent that Toge does not disclose the “generating and outputting” and “measuring and calculating” limitations of claim 1, Burton discloses these limitations.

62. 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.

63. 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)

64. Kumar discloses a central server 106 that hosts a browser-based engine that can be accessed through web pages (*remote Internet site* recited in the independent claims).

65. 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.”).

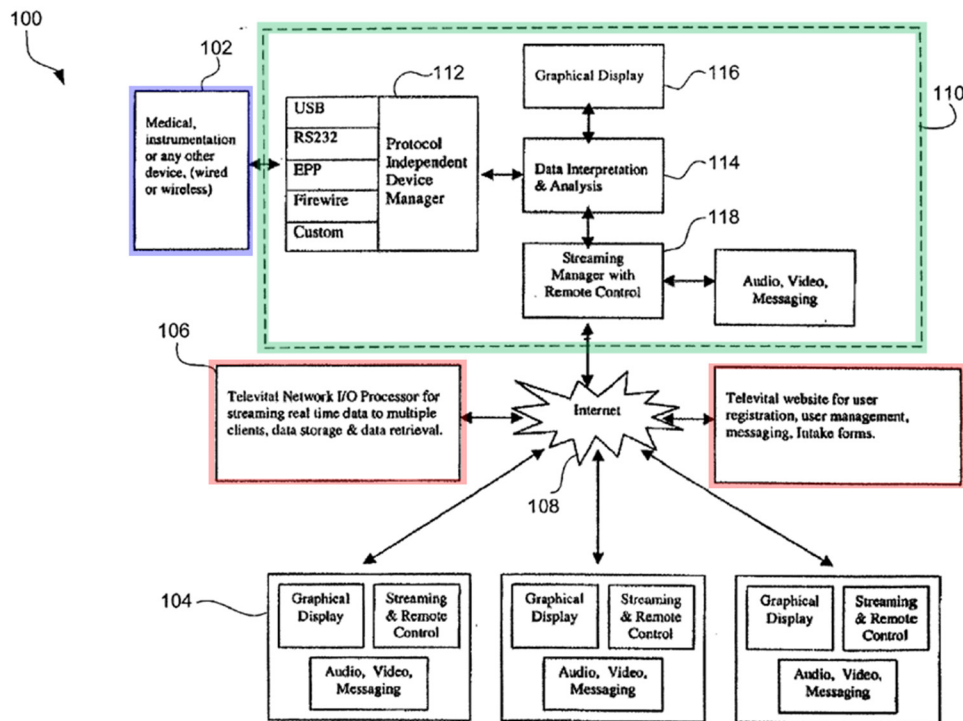


Fig. 1A

66. Kumar 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. Thus, virtually any device may 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 No. 5,309,921 to Kisner (Ex. 1051)

67. To the extent that the combination of the teachings of Toge, Burton, and Kumar do not disclose one of the *signal processing techniques* recited in limitation 1[c.ii]/7[c.ii]/12[c.ii], Kisner discloses applying *wavelet analysis*.

68. Kisner discloses a system “for monitoring the respiration of a subject.” Ex. 1051, Abstract. Like the ’680 patent, Toge, Burton, and Kumar, the system includes a processor that “receives and processes the signals from the reference and component sensors to produce a signal which corresponds to the desired information.” *Id.*, 12:59-63. “Sensor signals 104 are reconstructed using neural networks or other processing algorithms to form true component signals 108.” *Id.*, 13:42-44. “Breathing parameters are extracted from true component signals 108sing wavelet analysis or similar means.” *Id.*, 13:45-47.

VIII. CLAIM CONSTRUCTION

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

IX. ANALYSIS

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

1. Motivation to Combine

a. Combination of Toge and Kumar

70. 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 POSITA looking to improve the PAP system of Toge would have looked at known ways to improve a telemedicine system as taught by Kumar for at least the following reasons.

71. 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.

72. 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.

73. 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.

74. A person of ordinary skill in the art improving a networked PAP system, like that described in Toge, would have looked at other ways such networked PAP systems had been implemented, like that in Kumar. Ex. 1044 [0028]. 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.”).

75. 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.

76. 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 may need to go to a facility to update or purchase a new device.

77. 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.

78. 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.

79. 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.

80. 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.

81. 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.

b. Combination in further view of Burton

82. 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 generate the efficacy data taught by Burton.

83. 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 particular, Toge discusses “adjusting prescription pressure.” Ex. 1044, [0039], [0047]. The efficacy data would allow the system to adjust pressure as necessary.

84. Nothing in Kumar would teach away from the combination. Rather, the modification would also further Kumar’s objection to of “providing access to health assessments, diagnoses, [and] interventions.” Ex. 1008, [0003].

2. Reasonable Expectation of Success

a. Combination of Toge and Kumar

85. 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.

86. 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 “Existing devices (which are not web-enabled) *may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI.*” Ex. 1008, [0018].

b. Combination in further view of Burton

87. 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.

88. 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.

89. The modification would simply be a change of programming to the control unit 250 of Toge to output the efficacy data of Burton. Implementing the details of the central server 106 including browser-based engine of Kumar would not have prevented the programming change of Burton since the Burton modification would be made to control unit 250 whereas the Kumar modification would be on the physician-side computer.

3. Independent Claim 1

a. Preamble

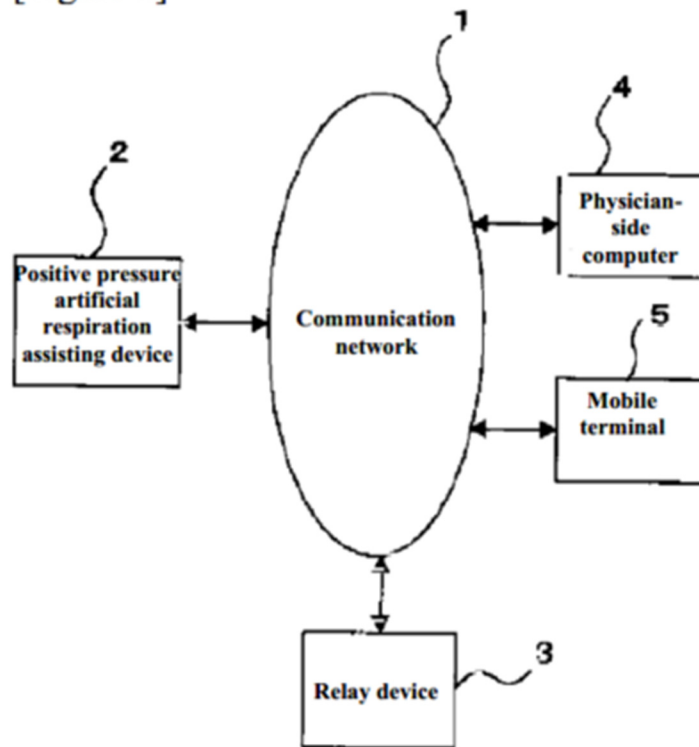
[Preamble] “*A system for remote internet server-based diagnostic monitoring with one or more positive airway pressure (PAP) device(s) for sleep disorder treatment comprising*”

90. In my opinion, Toge in view of Kumar renders obvious the preamble to the extent it is limiting. In particular, the system resulting from the combination of the teachings of Toge and Kumar would modify the physician-side computer of Toge to include the browse-based engine accessible through web pages (*remote internet server-based diagnostic monitoring*).

91. Toge discloses a networked system including a positive pressure artificial respiration assisting device 2 (*one or more positive airway pressure (PAP) device(s)*) for treating patients experiencing apnea (*sleep disorder treatment*). As

shown in Figure 1, the Toge system is shown in Figure 1. In addition to the positive pressure artificial respiration assisting device 2, the system includes physician-side computer and mobile terminal 5, each connected to communication network 1. *Id.*, [0008]. Toge further discloses that network 1 may be the “Internet” or “a mobile communication network.” *Id.*, [0009].

[Figure 1]



92. Positive pressure device 2 provides treatments to patients having “weakened spontaneous breathing ability” or “conditions such as sleep apnea” at the patient’s home. *Id.*, [0010], [0015]; *see also id.*, [0011]-[0014] (describing features associated with PAP device 2). Physician-side computer 4 may be installed at a

hospital or clinic allowing care providers to access the transmitted data using the computer. *Id.*, [0017]-[0018].

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

94. Like Toge, Kumar discloses a 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].

95. Figure 1A of Kumar shows the system includes a patient-side device 102 (like the positive pressure device 2 of Toge), computing device 110 (like the mobile terminal 5 of Toge), and central server 106 (like the physician-side terminal of Toge) that hosts a browser-based engine that can be accessed through web pages. Ex. 1008, [0067], [0072]; *see also id.*, [0018].

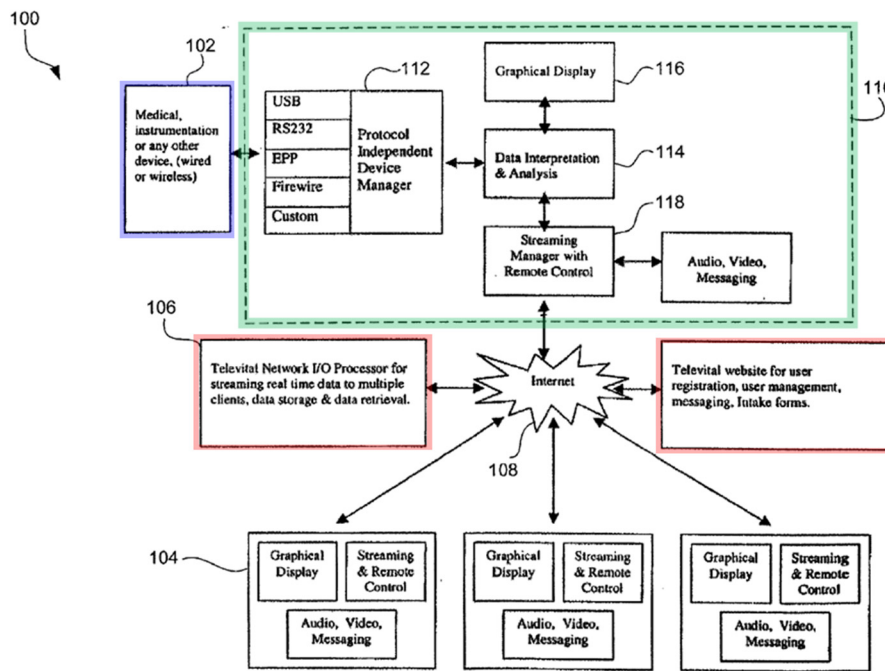


Fig. 1A

96. Kumar discloses that the engine receives the data from the patient-side device—“the engine may configure the devices to transfer the data directly from one device to the other, may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device, may store the data for later transmission to the provider-side device, etc.” Ex. 1008, [0081]. Kumar further discloses that “[b]y receiving data from the patient-side device, a provider is able to monitor the patient’s physiology for research, keeping track of documentation, performing analysis, managing and maintain records, diagnosing the patient, providing treatment in real-time to the patient, etc.” *Id.*, [0078].

97. Kumar explains that “the entire system runs in the context of an Internet browser.” Ex. 1008, [0086]; *see also* [0087] (“The system may be implemented using Apache web server, MySql on Linux, Oracle on Linux, Java servlets, Applets, HTML, JavaScript, Java, C#, Microsoft's .NET etc. Note also that the server may be implemented on the Internet, intranet, or an extranet.”). A patient can access the browser-based engine by going to the login screen, such as that in Figure 2, and logging in “with a secure logon ID and password.” *Id.*, [0089], *see also* [0182] (“The client logs on to the main system website with a secure ID and password.”).

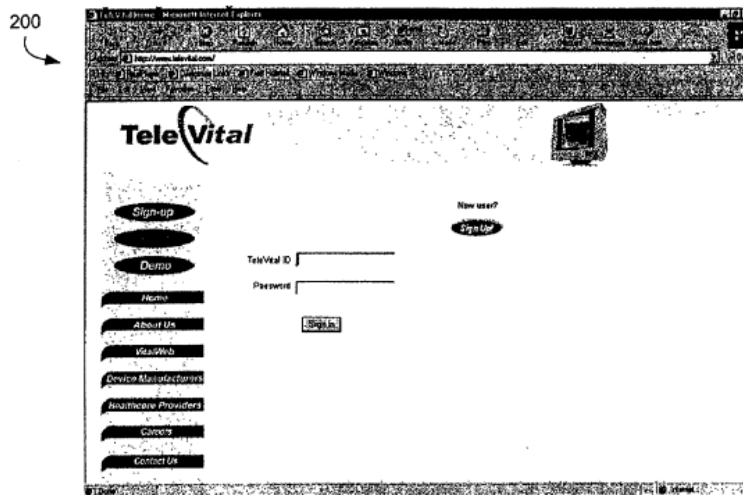


Fig. 2

98. Kumar further discloses that the “patient’s real-physiological data” can be viewed through web pages, like those depicted in Figures 7 and 8. Ex. 1008, [0092]; *see also* Fig. 6. A person of ordinary skill in the art would have understood that web pages serve as a graphical user interface to access the data sent to the browser-based engine. *See also* Ex. 1049 8:8-13 (“[T]he patient connects a specific

Internet site and a software program, resident on a remote server location on the Internet, downloads an interactive user interface for the patient and an application for the measurement of the physiological data.”).

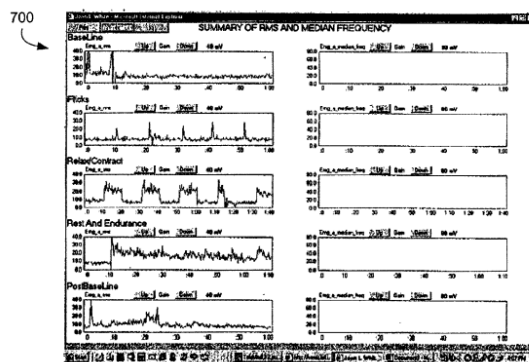


Fig. 7

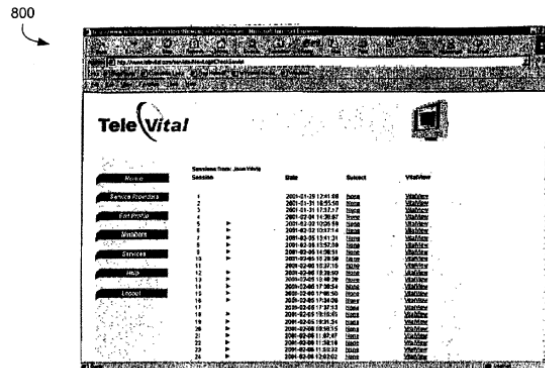


Fig. 8

99. Kumar discloses that: “The engine manages transmission of the data from the patient-side device to the provider-side device” and “may configure the devices to transfer the data directly from one device to the other; may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device; may store the data for later transmission to the provider-side device, etc.” Ex. 1008, [0011].

100. For example, the system includes patient-side device(s) 102 for collecting data from a patient/client, provider-side device(s) 104, and an engine implemented on a central server 106, where the devices and engine are connected to a wide area network (WAN) 108 such as the Internet. Ex. 1008, [0067]. “The system allows for the real-time streaming of raw, interpreted, and/or processed

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

b. Limitation [1.a]

[1a] “A. one or more PAP device(s);”

101. In my opinion, Toge discloses this limitation.

102. Toge discloses a positive pressure artificial respiration assisting device 2 (a PAP device) configured to be in a single disclosure. The positive pressure device 2 is shown in Figure 2. Ex. 1044, Abstract, Fig. 2.

c. Limitation [1.b]-[1.b.iv]

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

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

[1.b.i] “2) the first processor,”

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

[1.b.iv] “4) *a display,*”

103. In my opinion, Toge in view of Kumar renders obvious these limitations.

104. As discussed in the preamble, Toge discloses a mobile terminal 5 that can be a cell phone. *See* Section IX.A.3.1. To the extent that Toge does not expressly disclose that mobile terminal 5 can be the cell phone of the patient (*a cell phone of a subject(s) receiving treatment*), this feature would have been obvious in view of the teachings of Kumar related to the computing device 110.

105. With respect to *a non-transitory computer readable medium*, Kumar recognizes: “The present invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium.” Ex. 1008, [0020]. To store a program or code, the computer readable medium must be non-transitory, such as EEPROM memory. For the methods to be performed, the code necessary to perform those methods must be stored in non-transitory memory which allows a processor to execute the code for those methods.

106. With respect to *the cell phone*, Kumar discloses that computing device 110 may be a wireless phone or pocket PCs, e.g., an iPAQ device (either of which is a “cell phone”). Ex. 1008, [0072]. A wireless phone is a phone that can connect to a wireless network, such as a local area network, wide area network, and/or cellular network. An iPAQ device was considered both a personal digital assistant

(PDA) and pocket PC which was introduced by HP in 2000. The iPAQ device could connect to a number of different wireless networks including cellular (GPRS), Wi-Fi, and Bluetooth. Ex. 1011, 2 (“[T]he HP iPAQ h6315 is a voice calling, Wi-Fi hotspot finding, wireless emailing, Internet connecting, instant message chatting, MP3 playing, picture taking, keypad typing, 64MB data storing powerhouse. The iPAQ h6315 is the first all-in-one wireless device to include built-in GSM global phone capabilities with integrated GPRS wireless data, Wi-Fi (802.11b) wireless broadband, and Bluetooth™ functionality to allow customers to easily navigate and wirelessly communicate through e-mail, text messaging, Internet and phone calls.”).

107. With respect to *the first software is downloaded to a cell phone of a subject(s) receiving treatment*, Kumar discloses a plug-in (*first software*) downloaded by the computing devices, including a cellular device such as an iPAQ (*cell phone*) that allows communications with the patient-side devices (such as PAP device) through a wireless protocol. Ex. 1008, [0074] (“the computing device...can send a request to the engine..., and the engine will send the appropriate plug-in which allows the computing device to communicate with the patient-side device. Thus, the present invention may support both plug-and-play web device drivers and customized graphical user interfaces (GUIs) for the various devices. Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI”), [0073] (“The connection to the

WAN (such as the Internet) can include dialup (56K), satellite phones, Iridium phones, ISDN, Ti, DSL, cable modem, wireless connection, etc.”).

108. A plug-in is a software module that allows for the customization of computer programs. *See also id.*, claim 5 (“the computing device receiving a software module for managing communication with the at least one patient-side device from the engine”). A person of ordinary skill in the art would have understood that the plug-in (*first software*) is *executable by the* processor of the computing device (*a first processor*) in order to allow the computing device (*configured to be used by a cell phone*) to communication with the patient-side device, such as PAP device. The processor executes the code from the plug-in which allows the communication and display. Further, the code must be configured to use on the operating system of the phone to display data. This can be done through plug-in code that talks directly to the operating system, or through code that talks to a program already installed on the phone, such as a web browser.

109. Kumar discloses that “the engine will send the appropriate plug-in which allows the computer device to communicate with the patient-side device.” Ex. 1008, [0018]. A person of ordinary skill in the art would have understood that the plug-in (*first software*) would have been *downloaded* on to the computing device (*cell phone*) in order to communicate with the PAP device and display the data from the PAP device. For example, WO 01/45014 to Quy describes similar software that

allows a patient to view physiological data from a patient-side device. Ex. 1049, 8:8-31. “[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.” *Id.*, 8:8-13. “The software, as well as inputs from the patient or other inputs, can control the manner, content, and display of information presented to the patient.” *Id.*, 8:20-23.

110. With respect to a *first radio frequency wireless transceiver*, Kumar discloses that computing device 110 includes a transceiver that transmits data through the cellular network. To connect to wireless network such as cellular, Wi-Fi, or Bluetooth, the computing device necessarily included a wireless transceiver (*a first radio frequency wireless transceiver*). Wireless transceivers use radio waves, also referred to as radio frequency signals, to carry data from one transceiver to another. For example, Kumar teaches using the iPAQ device which included a radio frequency wireless transceiver (*a first radio frequency wireless transceiver*) to enable GPRS, Wi-Fi, and Bluetooth.

111. With respect to a *first processor*, a person of ordinary skill in the art would have understood that the plug-in (*first software*) is *executable by the* processor of the computing device (*a first processor*) in order to allow the computing device to communicate with the patient-side device, such as PAP device. The processor

executes the code from the plug-in which allows the communication and display. Further, the code must be configured to use on the operating system of the phone to display data. This can be done through plug-in code that talks directly to the operating system, or through code that talks to a program already installed on the phone, such as a web browser.

112. With respect to *a display*, Kumar discloses the data from the patient-side device on the display module of the computing device (*cell phone*). Ex. 1008, [0075] (“The data interpretation and analysis module 114 is used to interpret the data stream from the client-side device, perform mathematical analysis on the data using FFT, DFT, etc., and generate statistics. The data may be displayed graphically on the display module 116.”), Fig. 1. A person of ordinary skill in the art would understand that display module 116 could be the display on a cell phone.

d. Limitation [1.b.v]-[1b.v.A]

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

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

113. In my opinion, Toge alone or in view of Burton renders obvious this limitation.

114. As discussed for limitations [1.b]-[1.b.iv], the downloaded plug-in (*first software*) allows computing device 110 (*cell phone*) to receive data from the patient-side devices (like the positive pressure device 2 of Toge).

115. Toge discloses that control unit 250 receives the measured data from pressure gauge 23 and flow meter 24. In particular, 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].

116. Toge discloses calculating the tidal volume F_p (*a PAP therapy efficacy data . . . based in part on the PAP therapy efficacy data both based on treatment of the subject and its efficacy in whole or in part*). A person of ordinary skill in the art would understand that that the tidal volume F_p provides information which can be used to determine whether the patient is experiencing sleep disorder symptom such as an apnea or hypopnea. If the patient is still experiencing apneas and hypopneas, that symptom indicates whether the therapy is effective.

117. As Toge explains “[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 user of the positive pressure artificial respiration assisting device 2 remotely.” Ex. 1044, [0039]. Toge further explains “if there is a decreasing trend in the tidal volume,” this indicates that the symptoms are severe,

and “emergency measures, such as adjusting the prescription pressure to a high level” can be taken. *Id.*; *see also* [0051], [0055].

118. Toge further discloses calculating the operating status of the positive pressure device 2. Toge expressly describes the usage of the positive pressure device 2 as treatment data, stating “[t]he transmitted data includes the patient’s treatment data such as . . . the operational time T of this positive pressure artificial respiration assisting device 2, the air leakage volume Fb (leaking from parts other than the exhalation vent 210) from the nasal mask 21, . . . and the operating status of this positive pressure artificial respiration assisting device 2 (such as alarms if the nasal mask is detached).” A person of ordinary skill in the art would understand that the operational status of the device is needed to determine if the patient is still experiencing symptoms because of user error. If the patient is still experiencing symptoms even when the device is in proper use, the treatment may need to be adjusted. If the patient is not properly using the device, other measures may be taken. For example, the patient may need a better fitting mask. Ex. 1044, [0040] (“This enables physicians to assess the fit of the nasal mask 21 and the level of discomfort (excessive leakage causing discomfort and potentially affecting the patient’s ability to sleep, for example)”).

119. To the extent that Toge does not expressly disclose this limitation, a person of ordinary skill in the art would have been motivated to implement these features in view of Burton.

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

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

data (from diagnostic study within sleep laboratory or other alternative site) or c) real-time monitored and analyzed data.” *Id.*, 3:24-28.

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

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

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

124. Burton discloses a processor that can calculate when a subject has an apnea or hypopnea event using sensor data from the subject and the average number of such events over the total period of time spent sleeping, and determine a subject’s Apnea Hypopnea Index severity level (*generating and outputting the data related to the subject’s treatment and the treatment’s efficacy*). Burton discloses that “[s]tatistics and indexes such as RAJ, AHI, RERA, RDI, arousals, sleep fragmentation, or sleep architecture index are derived from the monitored parameters and this information is stored for analysis.” Ex. 1050, 28:15-18; *see also* 21:4-22:21. Given that the AHI is a number representing the number apnea or hypopnea events over a period of time, a person of ordinary skill in the art would understand that the Burton processor derives these values from the sensor data in order to derive the AHI.

e. Limitation [1.b.v.B]

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

125. In my opinion, Toge in view of Burton renders obvious this limitation.

126. As discussed for limitation [1.b.v.A], the system resulting from the combination of the teachings of Toge, Kumar, and Burton discloses computing device 110 (*cell phone*) receiving *PAP therapy efficacy data*.

127. Kumar discloses *outputting* the received data (*one or more PAP therapy efficacy measures(s)*) on the display module 116 of the computing device 110 (*on the display of the cell phone*) for the patient to view the data received by the plug-in (*for viewing by the subject based in whole or in part on the data received by the first software*). Kumar discloses “[t]he data interpretation and analysis module 114 is used to interpret the data stream from the client-side device, perform mathematical analysis on the data using FFT, DFT, etc., and generate statistics. The data may be displayed graphically on the display module 116.” Ex. 1008, [0075].

128. A person of ordinary skill in the art would have understood that Kumar teaches outputting the processed data to be “displayed graphically on the display module 116.

f. Limitation [1.c]

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

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

130. As discussed for the preamble, Kumar discloses a browser-based engine (*remote internet site*), which can be accessed through web pages and is implemented on an Internet web server. *See, e.g.*, Ex. 1008, [0010], [0018], [0067], [0072], [0087].

131. Kumar discloses that the central server includes memory (*a second non-transitory computer readable medium*) storing code for the engine (*comprising at least at least one second software for a remote internet site*) and a statistical database (*database*). Kumar discloses that “[t]he present invention may be implemented on a program or code that can be stored in a computer-readable (or electronically-readable) medium.” Ex. 1008, [0020]. Kumar discloses that “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis” and “storage of the data allows for the creation of statistical databases.” *Id.*, [0083].

g. Limitation [1.c.1]

[1.c.1] “*1) be hosted on at least one server, and*”

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

133. Kumar discloses that that the browser-based engine is hosted on a central server 106 (*be hosted on at least one server*). Kumar discloses that the engine is “implemented on a central server 106.” Ex. 1008, [0067]. Kumar further explains that the “secured storage device [is] at the central server.” *Id.*, [0083].

h. Limitation [1.c.2]

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

134. In my opinion, Toge alone or in view of Kumar renders obvious this limitation.

135. Toge discloses that “multiple positive pressure [] devices 2 are provided for each of several patients.” Ex. 1044, [0058]. Similarly, Kumar discloses “[t]he embodiments presented herein contemplate connection of multiple patient-side devices, provider-side devices, and engines.” Ex. 1008, [0012]. A person of ordinary skill in the art would have understood that the multiple devices for multiple patients allowed for remote monitoring of multiple patients.

i. Limitation [1.d]-[1.d.ii]

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

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

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

136. In my opinion, Toge discloses this limitation.

137. As discussed in the preamble, Toge discloses a networked system that includes positive pressure device 2 for treating patients having sleep apnea (“treating

the sleeping disorder of the subject(s) or their symptoms”). Ex. 1044, [0008], [0015].

138. Toge discloses blower 27 which supplies air (*a blower having an air output*). Specifically, Toge discloses “blower 27 functions by rotating to supply air into the flow path 26.” Ex. 1044, [0025]; *see also* [0024] (“The flow path 26 is a guide airway that directs the air supplied from the blower 27 to the air tube 22 for delivery to the nasal mask 21.”), [0025] (“The air pressure supplied is adjusted based on the rotational speed of the blower 27. The blower 27 is driven by the drive unit 252 of the control device 28. The drive of the drive unit 252 is controlled by the control unit 250 of the control device 25, thereby controlling the rotation of the blower 27.”). As shown in Figure 2, blower 27 (identified in blue) is within the enclosure of the positive pressure device 2.

139. Toge discloses pressure gauge 23 and flow meter 24 (together, *sensor for providing a sensor data to determine airflow*) inside the enclosure of positive pressure device 2 (*internal to the PAP device*). Specifically, Toge discloses that “pressure gauge 23 detects and measures the air pressure inside the flow path 26” and “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 nasal mask 21.” *Id.*, [0028]. Toge further

explains that the “measured air pressure is provided to the control unit 250 of the control device 25.” *Id.*

140. Toge discloses that the pressure gauge 23 and flow meter 24 measure data that provide the minute breathing rate N and the operating status of the positive pressure device (*adapted for measuring or deriving the respiratory airflow of the subject while using the PAP*). Specifically, Toge discloses “[t]he transmitted data includes . . . the minute breathing rate N and the operating status of this positive pressure artificial respiration assisting device 2.” Ex. 1044, [0032]..

j. Limitation [1.d.iii]:

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

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

k. Limitation [1.d.iv]

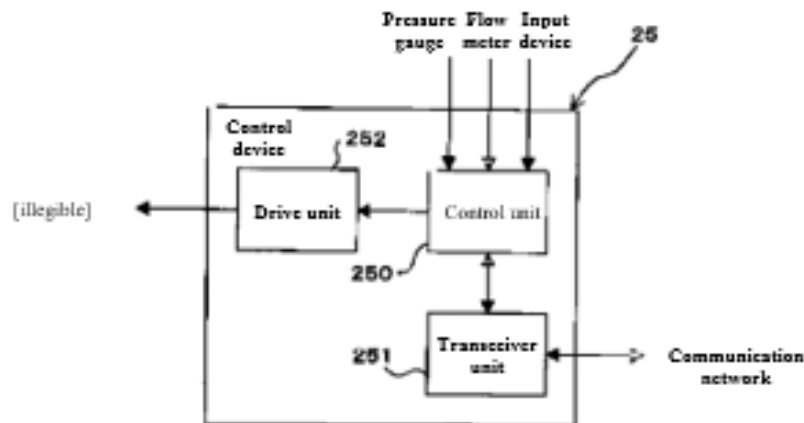
[1.d.iv] “*at least one second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data, and*”

142. In my opinion, Toge in view of Burton renders obvious this limitation.

143. As discussed for limitations [1.b.v.A] and [1.b.v.B], a person of ordinary skill in the art would have been motivated to transmit the efficacy data taught by Burton from the positive pressure device 2 to the computing device (*cell phone*).

144. Toge discloses that the positive pressure device 2 includes a transceiver unit 251 (*at least one second radio frequency wireless transceiver*) for transmitting that data (*for transmitting the PAP therapy efficacy data*). As show in Figure 3, control device 25 includes a transceiver unit 251. Ex. 1044, [0023].

[Figure 3]



145. Toge discloses that transceiver unit 251 uses a mobile network (*radio frequency and wireless*). Toge explains that the “device 2 . . . directly transmits all or part of the treatment data to the physician-side computer 4 or mobile terminal 5 via the communication network 1. *Id.*, [0061]. Toge further explains that the

“transmitting means connected to a wireless . . . communication network [is] for transmitting treatment data stored in the memory means via the communication network.” *Id.*, claim 2; *see also id.*, [0063], [0070], [0078], [0080]-[0081], claim 1.

146. Toge discloses that network 1 may be “a mobile communication network.” *Id.*, [0009]. 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.

147. To the extent that Toge does not disclose that positive pressure device 2 includes *at least one second radio frequency wireless transceiver*, 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.

148. 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.

l. Limitation [1.d.v]

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

149. In my opinion, Toge discloses this limitation.

150. Toge discloses positive pressure device 2 includes nasal mask 21 (*a mask or a nasal cannula*). As shown in Figure 2, Toge discloses a nasal mask 21 (identified in red). Ex. 1044, [0021].

m. Limitation [1.e]

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

151. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

152. As discussed in the preamble and limitation [1.c], Kumar discloses a browser-based engine (*remote internet site*). Kumar further discloses that “the data may be stored in a secured storage device...for later access, replay, and/or analysis” and “storage of the data allows for the creation of statistical databases.” Ex. 1008, [0010], [0018], [0067], [0072], [0083], [0087]. As discussed in limitation [1.c], a person of ordinary skill in the art would have understood that the browser-based engine (*remote internet site*) and secured storage device (*database*) are implemented in code (*second software*).

153. As discussed in limitation [1.d.iv], the system resulting from the combination of the teachings of Toge, Burton, and Kumar includes transceiver unit 251 (*second radio frequency wireless transceiver for transmitting the PAP therapy efficacy data*).

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

a. Dependent Claim 2

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

154. In my opinion, Toge in view of Burton renders obvious this limitation.

155. Burton discloses to “automatically adjust the therapeutic treatment based on at least one index or derived data set,” which includes, e.g., Respiratory Disturbance Index (RDI) and Apnea-hypopnea index (AHI). Ex. 1050, 21:4-22:21.

b. Dependent Claims 3 and 21

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

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

156. In my opinion, Toge in view of Kumar or Burton renders obvious this limitation.

157. As discussed in limitation [1.b]-[1.b.iv], Toge discloses communication network 1 may be “a mobile communication network” (*id.*, [0009]) which is commonly understood to mean a cellular network.

158. Kumar discloses that the provider may “remotely control the client-side device[s].” Ex. 1008, [0015]. For example, “when the patient is sleeping in his/her home..., the provider can start these devices remotely to read the data periodically or whenever needed.” *Id.* As Kumar explains, the provider is able to remotely control and adjust the device by with the patient-side software—“[u]sing optional remote control features built in to the system, remote providers can control the software on the patient’s end.” *Id.*, [0080], [0085], Fig. 1A.

c. Dependent Claim 4

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

159. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

160. As discussed in claim 2, the system resulting from the combination of Toge, Kumar, and Burton determines an index, for example, the Respiratory Disturbance Index (RDI) and Apnea-hypopnea index (AHI).

161. A person of ordinary skill in the art would have understood that AHI is a measured number of apnea and hypopnea events per unit time determined during

the patient's usage of positive pressure device 2 and that RDI is a measured number of respiratory disturbance events per unit time determined during the patient's usage of positive pressure device 2. Therefore, the index would be based on both the data related to a quantitative measure of symptom severity during use of the PAP device (*first data*) and data related to a usage of the PAP device by the subject (*second data*).

d. Dependent Claim 5

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

162. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

163. As discussed in limitation [1.b.v.A], a person of ordinary skill in the art would have implemented generating efficacy data as taught by Burton in control unit 250 for controlling the positive pressure device 2 of Toge.

164. Burton further discloses adjusting the pressure of the positive pressure device 2 based on the efficacy data (*the PAP device for treating the sleeping disorder of the subject is adjusted based in whole or part on the PAP therapy efficacy data generated by the one or more PAP device(s)*). In particular, Burton discloses that "[t]he therapeutic control algorithm . . . has the capability to be adapted during real-

time operation based on” various real-time and analyzed data. Ex. 1050, 3:21-28. Further, Burton discloses that “the process of detecting and monitoring for arousals could occur simultaneously or in virtual real-time with automated gas delivery treatment algorithms which are able to adapt to reduce or eliminate both sleep breathing disorders and sleep fragmentation.” *Id.*, 5:13-20; *see also id.*, 26:9-11.

165. Moreover, as discussed for limitation [1.e], a person of ordinary skill in the art would have been motivated and found it obvious to transmit this efficacy data taught by Burton to the modified physician-side computer with browser-based engine (*remote internet site*) because “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis.” Ex. 1008, [0083].

e. Dependent Claim 7

“7. The system in claim 4, wherein the first software adapted to be executed by the cell phone receives, in whole or part, the PAP therapy efficacy data related to treatment of the subject generated by the one or more PAP device(s) and is then used to retransmit, in whole or part the PAP therapy efficacy data and/or a reprocessed data based in part on the PAP therapy efficacy data related to treatment of the subject to the remote internet site with the at least one first radio frequency wireless transceiver.”

166. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

167. As discussed in limitations [1.b.v] and [1.b.v.A], the plug-in downloaded on the computing device 110 (*cell phone*) receives the efficacy data as taught by Burton.

168. As discussed in limitation [1.b.v.B], Kumar discloses that computing device 110 (*cell phone*) may process the received data by “perform[ing] mathematical analysis” and/or “generat[ing] statistics.” Ex. 1008, [0075].

169. A person of ordinary skill in the art would have found it obvious to retransmit the data to the modified physician-side computer with browser-based engine through the transceiver of the computing device 110 (*at least one first radio frequency wireless transceiver*). The purpose of the statistical database is to store similar processed information to provide access to that data.

f. Dependent Claim 8

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

170. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

171. As I discussed in Section V.A and V.E, Bluetooth wireless protocol is one of the well-known wireless protocols for data transmission in 2005. Ex. 1009,

14:54-15:12 (use of Bluetooth protocol to transmit data associated with a CPAP device); Ex. 1011, 2 (an iPAQ cell phone capable of communicating using Bluetooth protocol).

172. Consistent with the state of the art, Burton explains that the Bluetooth protocol may be used for “user data viewing and reports.” Ex. 1050, 8:28-9:2. Similarly, Kumar explains that “[b]y receiving data from the patient-side device, a provider is able to...keeping track of documentation, performing analysis, managing and maintaining record.” Ex. 1008, [0014]. Thus, a person of ordinary skill in the art would have understood that the care provider would have been interested in downloading and viewing the data related to the treatment on the provider’s device. Ex. 1008, [0081] (disclosing a directly data transfer from a patient-side device to the provider-side device).

g. Dependent Claims 10, 15, and 20

“10. The system in claim 7, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.”

“15. The system in claim 12, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.”

“20. The system in claim 17, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.”

173. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

174. Around 2005, a person of ordinary skill in the art would have been very familiar with these techniques to identify shifts and patterns in signals. In particular, discrete Fourier transform techniques and fast Fourier transform techniques were commonly used in signal processing. In general, a Fourier transform is a mathematical tool that allows signals to be viewed in a different domain, which can simplify analysis. By simplifying the analysis, less memory is used and calculations can be made more quickly.

175. Burton discloses processing flow sensor data by calculating deviations in the data (*the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique*). Specifically, Burton discloses a method for breath detection by using a “similarity” test to determine the “change in respiration pattern.” Ex. 1050, 16:4-17:33. As part of that process, Burton explains that the system

“calculate[s] some statistical measurements for this group of [breaths] such as mean, *deviation*, average and maximum error for all the elements to check with the similarity among [breath].” Ex. 1050, 17:22-25. A person of ordinary skill in the art would have understood that calculating deviation encompasses applying one of the known types of deviation, for example, mean deviation, standard deviation, and quartile deviation. *See, e.g.*, Ex. 1055, 29:1-2 (“Other methods are calculation of the standard deviation or variance of the [heart rate] in a specific interval.”).

176. Kumar also teaches that it is desirable to stream, in real-time, “FFT, and DFT.” Ex. 1008, [0007]. A person of ordinary skill in the art would have understood that FFT and DFT each refers to the claimed “fast Fourier transform technique” and “discrete Fourier transform technique,” which is consistent with the ’680 patent.

177. A person of ordinary skill in the art would have been motivated to apply the discrete Fourier transform or fast Fourier transform taught by Kumar on the data signals from the sensors taught by Toge. Those developing diagnostic and treatment systems recognized that Fourier transform techniques, like FFT, were “a well-understood and well-utilized analysis tool” and provided a “common visualization” tool. Ex. 1022, 19:47-48, 10:9:65-22.

h. Dependent Claims 11, 16, and 22

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

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

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

178. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

179. As discussed in limitation [1.b.v.A], Burton discloses that the *first data* includes *at least one index or derived data set*. Burton further discloses that this data may include “Mixed Sleep Apnea events, Central Sleep Apnea events, Upper Airway Resistance Syndrome (UARS) events, Obstructive sleep apnea and hypopnea syndrome (OSAHS) events.” Ex. 1050, 21:4-22:21.

i. Dependent Claim 12

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

180. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

181. Toge discloses that the patient treatment data (or efficacy data taught by Burton) is “transmitted . . . to the physician-side computer 4.” Ex. 1044, [0053]. “Medical institution personnel such as physicians and nurses can access the

transmitted data using the physician-side computer 4.” *Id.*, [0018]. When “emergency measures” must be taken, for example, by adjusting the prescription pressure to a high level” this can be done by the physician-side computer 4. Because the data is also sent to mobile terminal 5, a person of ordinary skill of in the art would have understood that the tidal volume data (or efficacy data of Burton) would have been sent to mobile terminal 5 along with an indication that the physician-aide computer 4 had adjusted the pressure, so that the a physician at mobile terminal 5 would not also adjust the pressure.

182. Similarly, a person of ordinary skill in the art would have found this feature obvious in view of Kumar. Kumar explains that “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis.” Ex. 1008, [0083]. The stored data includes “all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system.” *Id.*

183. By saving the patient’s data, Kumar teaches that the data can be retransmitted because the system “allow[s] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device.” *Id.*

j. Dependent Claim 13

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

184. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

185. As discussed for limitation [1.b.iv], Toge discloses that communication network 1 may be “a mobile communication network” which is commonly understood to be a cellular network. Ex. 1044, [0009]. Toge also discloses that communication network 1 can be the Internet. *Id.*

k. Dependent Claim 17

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

186. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

187. As discussed for limitation [1.e], the system resulting from the combination of Toge, Kumar, and Burton discloses the physician-side computer with a browser-based engine (*remote internet site*) that receives efficacy data. Kumar additionally discloses that data may be transferred “directly from one device to the other.” Ex. 1008, [0081].

l. Dependent Claim 18

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

188. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

189. As discussed for limitation [1.e], the Toge-Burton-Kumar combination discloses that the positive pressure device 2 transmits the efficacy data (*the PAP therapy efficacy data*) to the physician-side computer with browser-based engine (*remote internet site*). As discussed for the preamble, Toge discloses the positive pressure device 2 is connected to a mobile network (*cellular network*).

190. As discussed for claim 8, the system resulting from the combination of the teachings of Toge, Kumar, and Burton discloses using the Bluetooth protocol to transmit the efficacy data (*the PAP therapy efficacy data*).

m. Dependent Claims 23 and 25

“23. The system of claim 4, wherein the at least one second software with the remote internet site and the database are adapted to be accessible to a clinician or doctor of the subject for a remote monitoring of the patient and/or their PAP therapy when hosted on the at least one server.”

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

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

191. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

192. As discussed for limitations [1.c] and [1.c.1], the system resulting from the combination of the teachings of Toge, Kumar, and Burton discloses that the physician-based computer with a browser-based engine (*remote internet site*) and database are hosted on a central server. *See, e.g., Ex. 1008, [0010], [0018], [0067], [0072], [0083], [0087].* Kumar explains that “the system’s Internet browser-based software that allows the remote provider, and other healthcare providers, to remotely view their patient’s real-time physiology.” *Id.*, [0192]; *see also id.* [0067] (“The system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider”).

n. Dependent Claims 24 and 26

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

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

193. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

194. Kumar discloses that storing data at the browser-based engine allows “the creation of statistical databases.” Ex. 1008, [0083]. Moreover, Kumar explains that “the healthcare provider can view a statistical summary report” and “a graphical report that can also be displayed” for use with remote monitoring. *Id.*, [0092]. A person of ordinary skill in the art would have understood that the statistical summary report or the graphical report (*data analysis*) are automatically generated by the central server.

o. Dependent Claim 27

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

195. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

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

p. Dependent Claim 28

“28. The system in claim 1, wherein the database with the PAP therapy efficacy data is adapted to be analyzed to recognize patterns of sleep disorders or therapy for sleep disorders.”

197. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

198. Burton discloses that its algorithm “detect[s] a number of *patterns* which are indicative of sleep apnea symptoms” to prevent respiratory event related arousals (RERA). *Id.*, 14:1-7.

q. Dependent Claim 29

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

199. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

200. Burton discloses that its “algorithm for detecting variation in airflow shape that could be indicative of the incidence or probable onset of upper airway resistance (UAR) or variations of UAR, respiratory event related arousals (RERA) or treatment event related arousals (TERA).” Ex. 1050, 4:24-27. Burton further discloses that variations of the airflow shape can be used to train analysis techniques including “*neural networks* or other methods that are capable of adopting self-learning and algorithm adaptation techniques.” *Id.*, 4:29-32.

r. Dependent Claim 30

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

201. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

202. As discussed in claim 29, Burton discloses that the algorithm detects variation in airflow shape. Ex. 1050, 4:24-27. Burton further discloses the airflow shape analysis techniques may be improved based on “variations of the airflow shape” by using “neural networks or other methods that are capable of *adopting self-learning* and algorithm adaptation techniques.” *Id.*, 4:29-32. Burton explains that the algorithm may be adapted by using “individual patient collected or *collected data (from diagnostic study within sleep laboratory or other alternative site.*” *Id.*, 26:12-15.

203. As discussed in limitation [1.c.2], the data from multiple subjects is collected.

s. Dependent Claim 31

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

204. In my opinion, Toge in view of Kumar and Burton renders obvious this limitation.

205. Burton discloses that the database storing the efficacy data is analyzed with *a relationship algorithm*. Burton discloses “down-load[ing] [data] from sleep laboratory studies or other types of *previous sleep, respiratory and/or cardiac related investigations*.” Ex. 1050, 20:14-15. Burton further explains that data are “associated with a subject’s breathing and sleep arousal parameters,” are “used to customize a gas delivery device to be more sensitive and accurate for both minimizing incidence of [different types of arousal events], while still minimizing sleep fragmentation and optimizing sleep quality.” *Id.*, 20:15-19. A person of ordinary skill in the art would have understood that the data is aggregated in order to determine relationships within the data.

B. Ground 1: Toge in View of Burton, Kumar, and Kisner Renders Obvious Dependent Claims 10, 15, and 20

1. Dependent Claims 10, 15, and 20

“10. The system in claim 7, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device(s) is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.”

“15. The system in claim 12, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.”

“20. The system in claim 17, wherein the signal from the sensor for providing the sensor data to determine airflow on the one or more PAP device is processed, in whole or part, using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.”

206. In my opinion, Toge in view of Kisner discloses this limitation.

207. Kisner discloses a system “for monitoring the respiration of a subject.”

Ex. 1051, Abstract. Like the '680 patent, Toge, Burton, and Kumar, the system includes a processor that “receives and processes the signals from the reference and component sensors to produce a signal which corresponds to the desired information.” *Id.*, 12:59-63.

208. Kisner explains that “[s]ensor signals 104 are reconstructed using neural networks or other processing algorithms to form true component signals 108.” *Id.*, 13:42-44. Kisner further explains that “[b]reathing parameters are extracted from true component signals 108 using wavelet analysis or similar means.” *Id.*, 13:45-47. As Kisner demonstrates, wavelet analysis is a mathematical technique that breaks down signals into components to identify their characteristics and patterns.

209. Wavelet analysis was a known approach to determine breathing information from sensors. *See, e.g.*, Ex. 1055, 29:28-30:2 (determining breathing cycles “by identifying the peaks, the valleys or zero crossing in the [heart rate]

sequence, by performing auto correlation or using FFT analysis or wavelet analysis”).

2. Motivation to Combine

210. In my opinion, a person of ordinary skill in the art would have been motivated to improve the control unit 250 taught by Toge by programming it to perform wavelet analysis on the sensor data as taught by Kisner.

211. First, an objective of both Toge and Kisner is to treat a patient’s breathing using positive airway pressure. Ex. 1044, [0006]; Ex. 1051, 1:4-6. A person of ordinary skill in the art would understand that to treat sleep disordered breathing, the sensor data would need to be analyzed to identify breathing patterns. Wavelet analysis was a known way to determine such breathing patterns. *See, e.g.*, Ex. 1055, 29:28-30:2 (determining breathing cycles “by identifying the peaks, the valleys or zero crossing in the [heart rate] sequence, by performing auto correlation or using FFT analysis or wavelet analysis”).

212. Second, wavelet analysis as taught by Kisner, was one of many known signal processing techniques. Wavelet analysis allows for signal decomposition into various parts, components, and properties. Such decomposition would have allowed for more complex analysis of the breathing data.

213. Burton and Kumar would have provided further motivation to implement the wavelet analysis taught by Kisner. Burton and Kumar both taught

that signal processing techniques, such as the standard deviation technique of Burton and the Fourier transform techniques of Kumar, could be applied to the sensor data to extract more information. A person of ordinary skill in the art would have understood that applying a different technique, such as wavelet analysis, could provide additional information.

3. Reasonable Expectation of Success

214. A person of ordinary skill in the art would have had a reasonable expectation of success in programming the control unit 250 taught by Toge to perform wavelet analysis on the sensor data as taught by Kisner.

215. First, Toge and Kisner are functionally and structurally similar. Both discloses sensors measuring sleep data. Ex. 1044, [0028]; Ex. 1051, Abstract. Both further discloses a processor to process that sensor data. Ex. 1044, Fig. 3 (control unit 250); Ex. 1051, Fig. 10B (microcontroller 78).

216. Second, the modification would have involved a simple programming change. This was a combination of known prior art elements (sensor data) according to known methods and techniques (wavelet analysis) to yield predictable results (identify breathing information).

217. Implementing the processing of Burton would not have prevented the programming change of Kisner. Instead, by implementing the wavelet analysis of

Kisner on the data first, the analysis of Burton would have been simplified as breathing patterns would have already been identified.

218. Implementing the details of the central server 106 including browser-based engine of Kumar would not have prevented the programming change of Kisner since the Kisner modification would be made to control unit 250 whereas the Kumar modification would be on the physician-side computer.

X. SECONDARY CONSIDERATIONS

219. 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 '680 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

220. 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 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.

Declaration of Dr. Sandeep Chatterjee
U.S. Patent No. 11,786,680

Dated: December 6, 2024

By: _____

Sandeep Chatterjee