

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.
Patent Owner

Case IPR2025-00247

**DECLARATION OF DR. SANDEEP CHATTERJEE
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,872,029**

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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. 11,872,029 (“the ’029 patent”) (Ex. 1001)¹. I have been asked to consider whether certain prior art references disclose or suggest the features recited in claims 1-19 (“the challenged claims”) of the ’029 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.

^{1 1} In this Declaration, I refer to exhibits that I understand are to be attached to the petition for *Inter Partes* Review of the ’029 patent.

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 co-founded to commercialize this technology on Bloomberg TV's "Bloomberg Innovators" program.

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

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

III. MATERIALS REVIEWED

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

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

Ex. 1001	U.S. Patent No. 11,872,029 (“the ’029 patent”)
Ex. 1002	File History of U.S. Patent No. 11,872,029
Ex. 1006	Curriculum Vitae of Sandeep Chatterjee, Ph.D. (“Chatterjee”)
Ex. 1007	U.S. Patent No. 6,644,311 to Truitt et al. (“Truitt”)
Ex. 1008	U.S. Patent App. Pub. 2002/0198473 to Kumar et al. (“Kumar”)

Ex. 1011	T Mobile USA and HP Launch the First Truly Integrated Wireless iPAQ Handheld, T Mobile Newsroom, https://www.t-mobile.com/news/press/t-mobile-usa-and-hp-launch-the-first-truly-integrated-wireless (July 26, 2004)
Ex. 1013	U.S. Pat. Pub. No. 2002/0185130 to Wright et al. (“Wright”)
Ex. 1014	U.S. Patent No. 5,424,942 to Dong et al. (“Dong”)
Ex. 1018	U.S. Patent No. 7,591,265 to Lee et al. (“Lee”)
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., <u>HTTP The Definitive Guide</u> (2002)
Ex. 1047	D. Mauro, et. al., <u>Essential SNMP</u> (2001)
Ex. 1048	F. Adelstein, et. al., <u>Fundamentals of Mobile and Pervasive Computing</u> (2005)

Ex. 1049	WIPO Publication No. WO0145014A1 to Quy (“Quy”)
Ex. 1054	CleveMed Opening Claim Construction Brief

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 '029 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 '029 patent was around November 2005, which corresponds to the filing date of the earliest application associated with the '029 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 '029 patent, as I discuss in detail below.

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

20. I understand that the '029 patent originates from U.S. Patent Application No. 11/266,899 filed on November 4, 2005, and ultimately issued on January 16, 2024 through a series of continuations.

21. I understand that Dr. Jason Kirkness² 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 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 '029 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.

² 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.

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 '029 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 '029 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 1996,³ 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-the-nokia-9000-communicator-ef8e8c7047ae>; *see also* <https://www.mobilephonemuseum.com/phone-detail/nokia-9000-communicator>.) The Communicator was a mobile

³ 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>.)

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 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.

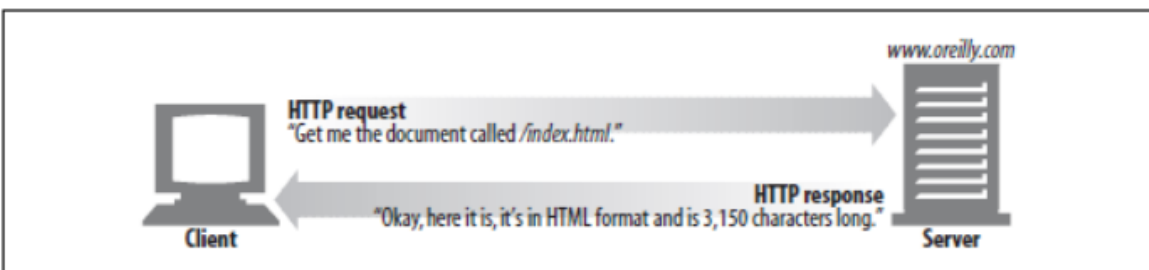


Figure 1-1. Web clients and servers

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.*

36. However, resources don’t have to be static files. Resources can also be software programs that generate content on demand. These dynamic content resources can generate content based on your identity, on what information you’ve requested, or on the time of day. They can show you a live image from a camera, or let you trade stocks, search real estate databases, or buy gifts from online stores (see Figure 1-2). In summary, a resource is any kind of content source. A file containing

your company's sales forecast spreadsheet is a resource. A web gateway to scan your local public library's shelves is a resource. An Internet search engine is a resource.

Id. at pp. 4-5.

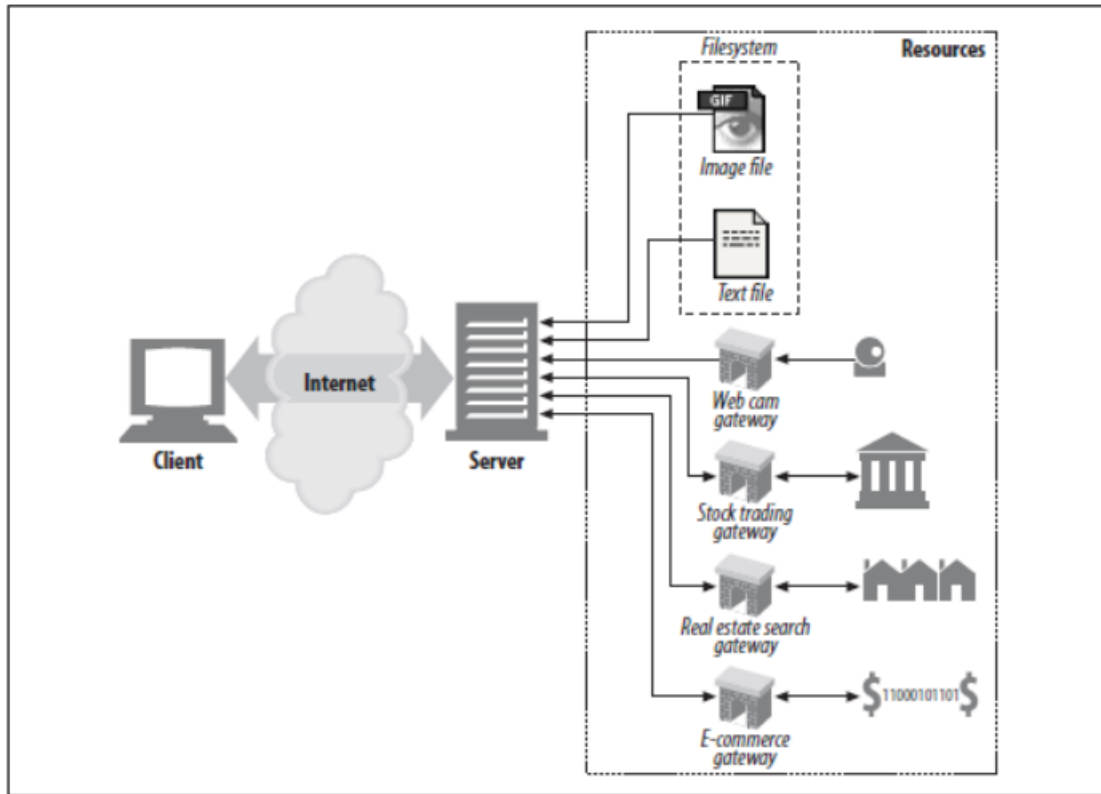


Figure 1-2. A web resource is anything that provides web content

37. 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

38. 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.

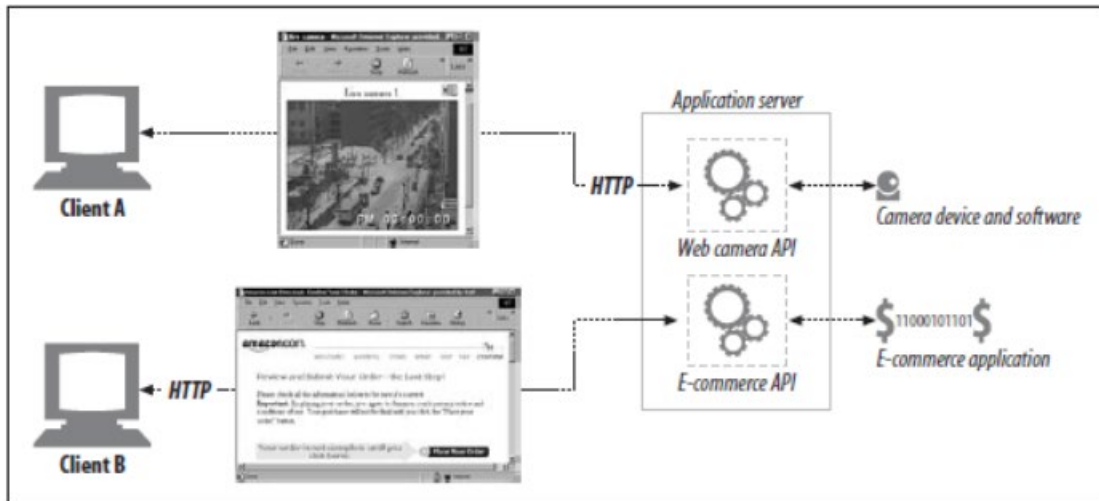


Figure 8-8. An application server connects HTTP clients to arbitrary backend applications

39. 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.*

40. 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.*

41. 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)

42. 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.

43. 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.*

44. 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.*

45. 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.

46. 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.*

47. 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.

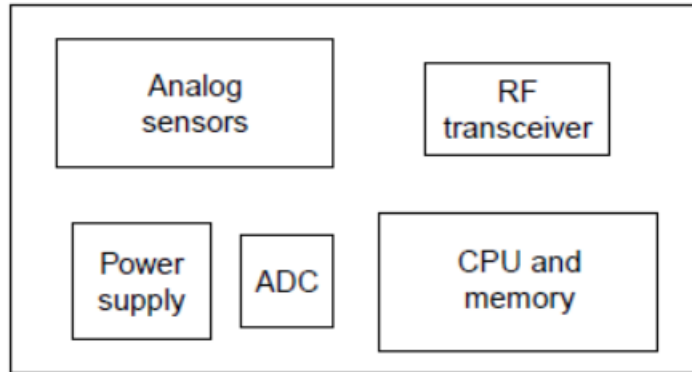
48. The second entity, the agent, is a piece of software that runs on the network devices that are being managed. It can be a separate program, or it can be incorporated into the operating system. By the time of the publication of this book, most IP devices come with some kind of SNMP agent built in. 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

49. 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.



50. 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. Web Clients and Servers

51. 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.

52. 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.*

53. 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.

54. 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

55. 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.A, 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. OVERVIEW OF THE '029 PATENT

57. The '029 patent discloses a networked PAP device. The PAP device a blower 312, an airflow sensor 320, and a processor 324 within enclosure 310, as well as a mask or nasal cannula 316. “The present invention is envisioned to be particularly valuable in the treatment of sleep apnea.” Ex. 1001, 22:42-43. “[W]ith a subject who has sleep apnea, delivery of a physical treatment such as CPAP can be adjusted during the treatment based on the sleep diagnosis results.” Ex. 1001, 22:48-50.

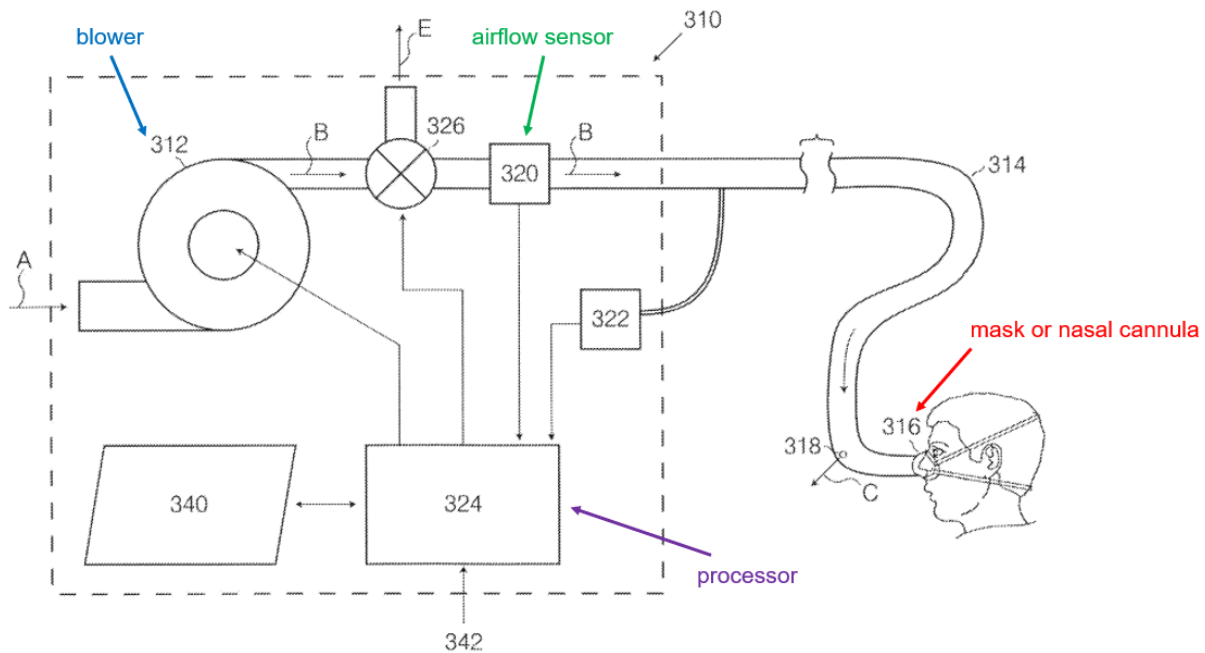


Fig. 7

Ex. 1001, Figure 7 (annotated)

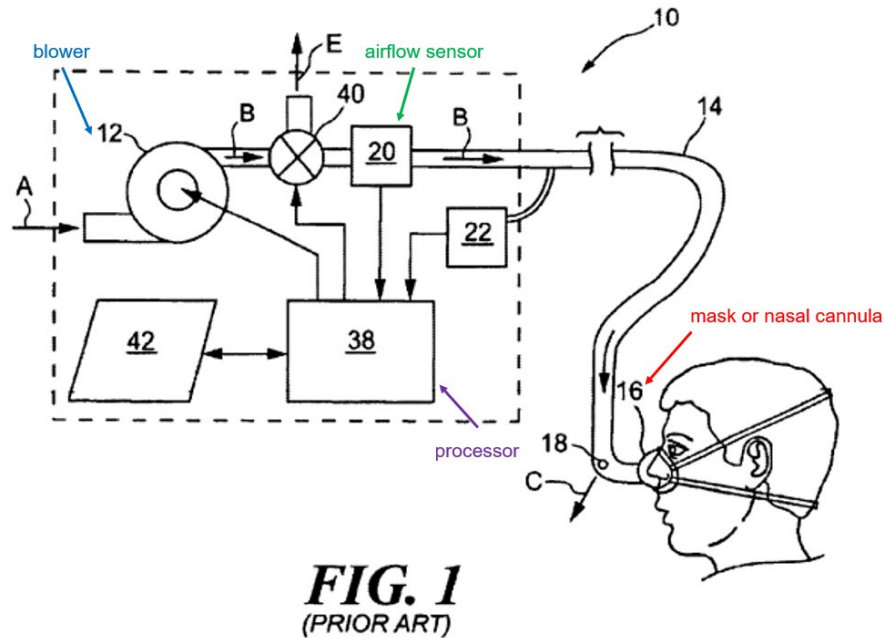
58. “The signals from the one or more sensors used in various embodiments of the present inventions are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject’s sleeping disorder symptoms.” *Id.* 19:8-12.

VII. OVERVIEW OF THE PRIOR ART

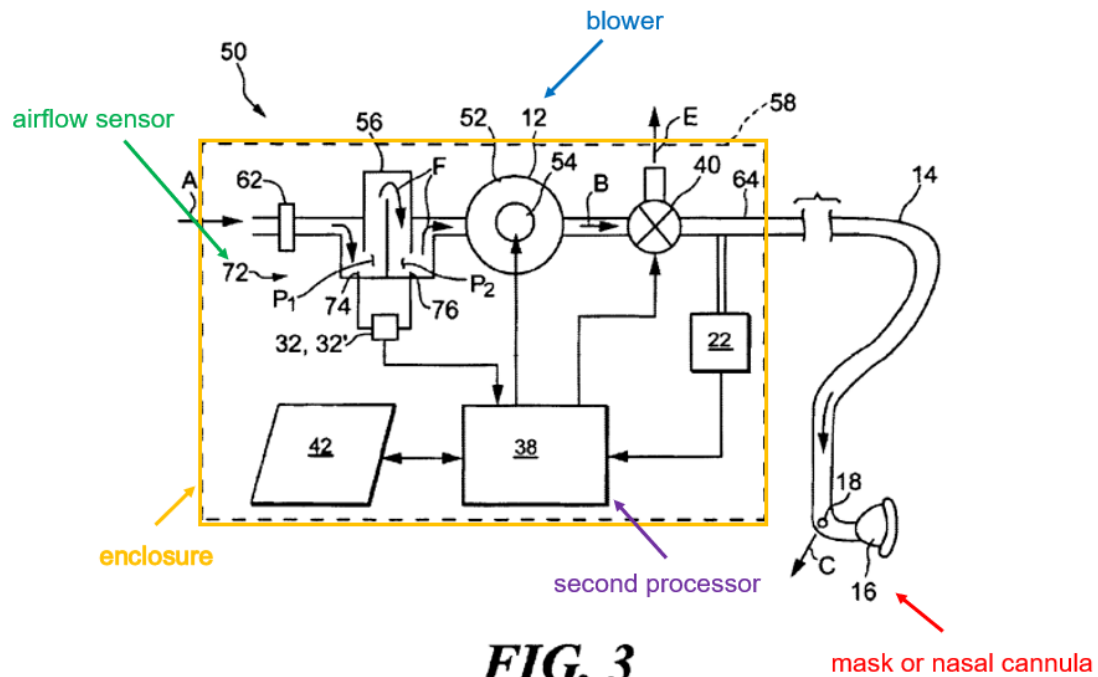
A. U.S. Patent No. 6,644,311 to Truitt et al. (Ex. 1007)

59. Truitt improves upon a conventional “continuous positive airway pressure (CPAP) device to supply a constant positive pressure to the airway of a patient to treat obstructive sleep apnea (OSA) as well as other disorders” like the

prior art system shown below in Figure 1 (which is virtually identical to Figure 7 of the '029 patent). Ex. 1007, 1:24-30.



60. Like the prior art and '029 patent, the improved pressure support system 50 of Truitt includes a blower 12, a patient interface device 16 (which can be a mask or nasal cannula), and a processor 38 as shown below in Figure 3. System 50 also includes an improved flow sensing assembly 72.



61. Also like the '029 patent, Truitt also discloses analyzing the patient's condition and adjusting treatment based on that analysis. Ex. 1007, 3:4-11 (“[i]n the auto-titration mode of pressure support, where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient.”); *see also* 3:60-64 (“in a simple CPAP device, controller 38 monitors the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.”). Specifically, system 50 can “detect snoring, apnea, hypopneas” and “flow and/or volume of gas passing through conduit 56” for the flow sensing assembly. *Id.*, 3:8-9, 6:46-48. System 50

will then control the pressure and/or flow “to counteract or prevent these conditions” if they still exist to make the treatment more effective. *Id.*, 3:9-11

B. U.S. Patent Pub. No. 2002/0198473 to Kumar et al. (Ex. 1008)

62. 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.”).

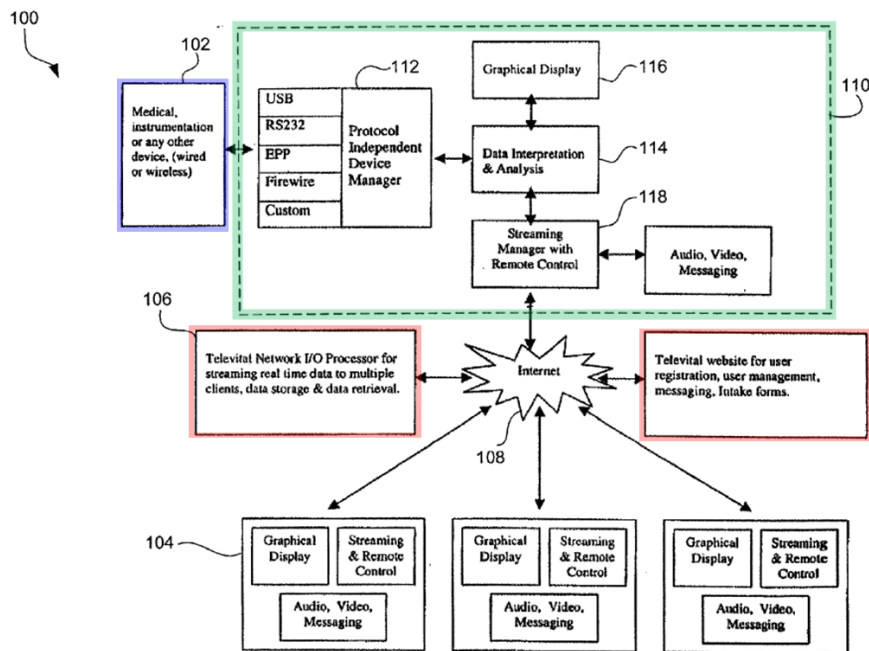


Fig. 1A

Ex. 1008, FIG. 1A

63. 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].

C. U.S. Patent No. 5,424,942 to Dong et al. (Ex. 1014)

64. Dong discloses an extended horizon, adaptive predictive controller. Ex. 1014, Abstract. Dong teaches that current adaptive controllers have two potential limitations: “(1) computational complexity, which limits their feasibility in multivariable applications; and (2) sensitivity to the choice of the input-output delays and model order selection.” Ex. 1014, 1:39-42. Dong discloses improved extended horizon predictive control methods to address these limitations.

65. I note that Dong is incorporated by reference in the ’029 patent. *See* Ex. 1001, 20:60-64 (“[T]he controller is the ORICATM controller, an extended horizon, adaptive, predictive controller, produced by Orbital Research, Inc. and patented under U.S. Pat. No. 5,424,942, which is incorporated herein by reference.”).

VIII. CLAIM CONSTRUCTION AND ANALYSIS

66. Generally, 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).

67. However, I have been asked to adopt Patent Owner’s interpretation of certain terms, as set forth in Patent Owner’s opening claim construction brief in the

parallel district court action for the purposes of this IPR. Ex. 1054. Specifically I've been asked to adopt Patent Owner's interpretation of two phrases:

- “calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i) and ii)”
- “related to the subject's treatment and the treatment's efficacy.”

68. With respect to the first phrase, Patent Owner's opening claim construction brief states that a POSITA would readily understand this phrase, arguing that “[f]or this calculation the system uses data regarding the severity of symptoms, data reflecting the subject's usage of the PAP device, and/or an index that is based on either or both of these categories of data. *See, e.g.*, '029 patent at 19:61-20:5 (collection of sensor data), 20:16-23 (preparation of data for analysis), 20:24-46 (identifying exemplary “sleeping disorder data or signal analysis techniques”), 22:14-21 (describing output).” Ex. 1054 at 16-17. Patent Owner asserts that a “POSITA would be able to use the severity and usage data to determine an index of the patient's sleep disorder symptoms and treatment efficacy.” *Id.* at 17. Patent Owner states that “because the '029 Patent is a continuation of the '284 Patent, the Delaware Court's claim construction order in regards to the '269 calculating terms are again instructive” and goes on to state that “the Delaware Court acknowledged that a POSITA would recognize that each value calculated for a

specific type of symptom data is representative of the level of severity of a subject's sleeping disorder." *Id.* at 19; *see also id.* at 12,13 (stating that the "generating and outputting" and "measuring and outputting" limitations are met when "[t]he claimed system 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 ("AHI") severity level, which is an example of a medical measurement of the severity of a subject's sleep disorder and is used to diagnose the severity of sleep apnea.").

69. With respect to the "related to the subject's treatment and the treatment's efficacy" term, Patent Owner states that "the '029 Patent specification amply describes collecting data related to, analyzing, and quantifying the severity of a subject's sleep disorder symptoms in order to diagnose sleeping disorders. *See, e.g.,* '029 patent at 18:66-19:22 (describing sensors used to determine a quantitative level of severity of a subject's sleeping disorder and/or symptoms), 20:16-23:30 (quantifying the level of severity of a subject's sleeping disorder or symptoms). Patent Owner also states that "[t]wo terms at issue in the '284 PGR involved data related to a subject's treatment and its efficacy: 'an index of treatment efficacy' and a claim term covering retransmission of, inter alia, 'the data of usage related to the subject's treatment and the treatment efficacy, in whole or part, calculated by the PAP device'" and relies on the Patent Office's determination that the '284

specification disclosed that ‘the system uses data collected from the sensors to evaluate the severity of the subject’s sleeping disorder and efficacy of the current treatment, and can adjust the treatment without human intervention as needed,’ such as by ‘regulat[ing] the physical or chemical treatment.’” Ex. 1054 at 21. Based on this, Patent Owner states that a POSITA would “understand with reasonable certainty that the shared specification of the ’029 Patent and ’284 Patent discloses what types of data may be related to a subject’s treatment and how a system collects, analyzes, and uses such information.” *Id.*

A. Ground 1: Truitt in View of Kumar Renders Obvious Claims 1-11, 13-16, and 18-19

1. Motivation to Combine

70. In my opinion, a person of ordinary skill in the art would have been motivated to improve the PAP device taught by Truitt by implementing it into a networked telemedicine system as taught by Kumar.

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 make 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. Wireless sensors had many advantages over wired sensors. They were more convenient to use and made the data from those sensors more widely and easily accessible. *See also* Section V.D.

73. Second, in the early 2000s, there was a general market trend to implement consumer devices, like the PAP device of Truitt, into intelligent systems, like the telemedicine system of 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 PAP system, like that described in Truitt, would have been prime to implement into an intelligent system given that Truitt already discloses sensors that collect data. Ex. 1007, 2:3-5 (“The information from flow sensor 20 and/or pressure sensor 22 is used, for example, to control the pressure or flow of gas provided to the patient, monitor the condition of the patient, monitor the usage of the pressure

support device (patient compliance), or any combination thereof.”). A person of ordinary skill in the art trying to improve Truitt would have naturally looked at design options that would have allowed users to better utilize such data, such as the “plug-and-play” telehealth system of Kumar. 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 Truitt in an intelligent environment, 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 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 allowed physicians to evaluate the data at their own convenience without expending the cost and resources of meeting with the patient in person. Similarly having the patient data online would “allow physicians to more easily seek expert consultations for clinically difficult cases” as Kumar discloses. Ex. 1008, ¶ [0083].

80. Third, a person of ordinary skill in the art would have been motivated to provide health access to more people. 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].

2. Reasonable Expectation of Success

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

83. First, a person of ordinary skill in the art would have understood that combining the teachings of Truitt and Kumar to implement an intelligent PAP treatment system would have been a simple matter of embedding wireless transceivers into the PAP machine of Truitt, and installing the appropriate software into the PAP machine’s processor. This is expressly what Kumar teaches: “Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI. Thus, virtually any device may be easily incorporated into the system.” Ex. 1008, ¶ [0018].

84. Second, the components in the flow sensing assembly in Truitt were known hardware and implementing them wirelessly was well within the skill set of a person of ordinary skill in the art. At the time, many PAP devices and other sensor diagnostic systems already included wireless transceivers to communicate signals from the sensors. *See, e.g.,* Ex. 1013, ¶ [0029] (“a wireless communication

transceiver and/or a network card, for communication with other devices or computers such as hand-held display or control devices.”). Further, as Truitt teaches, microphones are often used for flow sensors in PAP machines. Ex. 1007, 3:4-9. Wireless microphones have been around since the 1950s. For example, McClelland Sound, Shure Brothers, and Sennheiser all marketed wireless microphones.

85. Third, the proposed modification would have involved a simple programming change and the installation of wireless transceivers. This was a combination of known prior art elements (sensors and wireless transceivers) according to known methods and techniques (to collect and transmit data) to yield predictable results (networked data system).

3. Independent Claim 1

a. Preamble

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

86. In my opinion, Truitt discloses the preamble to the extent that it is limiting.

87. Truitt discloses an improved “continuous positive airway pressure (CPAP) device to supply a constant positive pressure to the airway of a patient to treat obstructive sleep apnea (OSA) as well as other disorders.” Ex. 1007, 1:27-30.

b. Limitation [1.a]

[1a] “*a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone an index of treatment efficacy of the subject using a PAP device, the index based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject, the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, and a display;*”

88. In my opinion, Truitt in view of Kumar renders obvious this limitation.

This limitation generally recites features of a networked cell phone that can receive and display data from a PAP device.

89. Kumar discloses the networked cell phone features of this limitation. Specifically, Kumar teaches *a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone and the cell phone comprising at least one first radio frequency wireless transceiver, the first processor, the first software when downloaded, and a display.*

90. 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 Kumar’s 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.

91. With respect to *a non-transitory computer readable medium comprising a first software, the first software adapted to be downloaded to a cell phone and executable by a first processor on the cell phone to display to a subject for viewing on the cell phone*, 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.”).

92. 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.

93. 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.

94. Kumar also discloses that the plug-in (*first software*) is *to display to a subject for viewing* 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 for displaying/viewing information on a cell phone.

95. 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.”).

96. To connect to wireless network such as cellular, Wi-Fi, or Bluetooth, the computing device necessarily included a wireless transceiver (*at least one 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 (*at least one first radio frequency wireless transceiver*) to enable GPRS, Wi-Fi, and Bluetooth.

97. Truitt discloses the PAP device data aspects of this limitation, and specifically *index of treatment efficacy of the subject using a PAP device, the index based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject*. I note that the specification of the '029 patent does not discuss an “index of treatment efficacy.” Instead, the '029 patent explains that “signals from these sensors are ... analyzed to determine the level of severity of the symptoms of the subject’s sleep disorder and in some cases to diagnose the sleep disorder itself.” Ex. 1001, 3:41-44. The '029 patent does not provide any further details on how to determine the level of severity.

Further, the '029 patent only states that “[t]he information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to . . . monitor the usage of the pressure support device.” *Id.*, 23:25-30.

98. Truitt discloses *data of severity of sleep disorder symptoms of the subject*, and specifically, data on the patient’s condition. Ex. 1007, 3:4-11 (“[i]n the auto-titration mode of pressure support, where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient.”); *see also* 3:60-64 (“in a simple CPAP device, controller 38 monitors the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.”).

99. Truitt further discloses *data of usage of the PAP device by the subject*, and specifically, Truitt discloses “flow and/or volume of gas passing through conduit 56.” Ex. 1007, 6:46-48.

100. Truitt discloses that an “*index [of treatment efficacy of the subject using a PAP device is] based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.*” As discussed above, Truitt discloses adjusting/controlling the PAP system’s gas pressure/flow based on received sensor signals in “feedback fashion to meet the desired prescription pressure level” (Ex. 1007, 2:57-3:4) and/or based on the patient’s conditions to “counteract or prevent these conditions” (*id.*, 3:4-11). In other words, Truitt uses

the data/signal(s) from the sensor(s) to adjust the operations of the PAP system in order to treat or prevent the sleep disorder symptoms. A person of ordinary skill in the art would have understood that this involves determining/calculating the effectiveness of the PAP system's operation with respect to treating the patient (*the index [of treatment efficacy of the subject using a PAP device]*) based on the data of level of severity of the patient's conditions/symptoms and the data of the patient's usage of the PAP system (including those calculated based on the information from the sensors) to "counteract or prevent these conditions."

101. As I discussed above, a person of ordinary skill in the art would have been motivated to combine the teachings of Truitt and Kumar with a reasonable expectation of success, and specifically, to modify the PAP device of Truitt to transmit data to computing devices as taught by Kumar. *See* Section VIII.A.1-2 (motivation to combine and reasonable expectation of success).

102. In particular, the market trend towards implementing consumer devices in intelligent systems was partly driven by the rise of mobile computing. *Id.* The introduction of PDAs, pocket PCs, and cell phones, starting in the mid-1990s provided users with instant access to data. A person of ordinary skill in the art looking to improve the PAP device of Truitt would have been motivated to share the data provided by the PAP device with personal mobile devices as taught by Kumar to advance data access and convenience.

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

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

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

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

[1.b.iii] *“a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating:”*

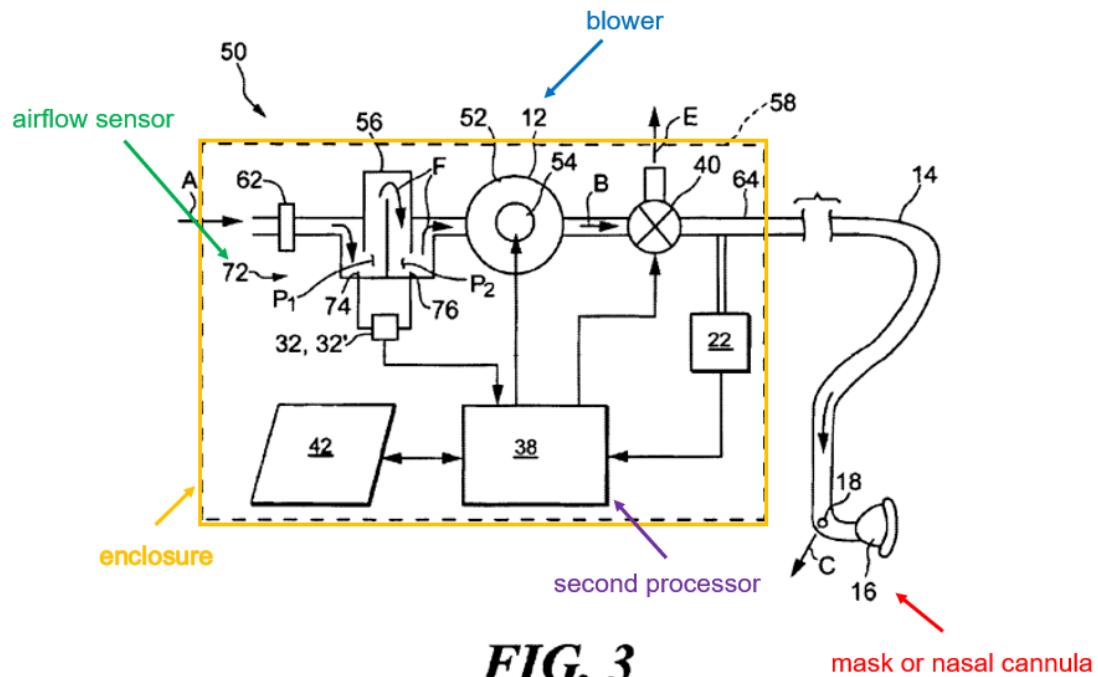
[1.b.iii.1] *“i) the data of a severity of the sleep disorder symptoms of the subject”*

[1.b.iii.2] *“ii) the data of usage of the PAP device by the subject, and/or”*

[1.b.iii.3] *“iii) the index based in whole or in part on either i) or ii) or both i) and ii),”*

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

103. In my opinion, Truitt discloses limitation [1.b] – [1.b.iv]. See Ex. 1007, Fig. 3.



Ex. 1007, FIG. 3 (annotated)

104. Truitt discloses a pressure support system (*PAP device*) with housing 58 (*an enclosure*) identified in orange in Figure 3 above. *See also* Ex. 1007, 5:12-13 (“A housing 58 identified by the dashed line in FIG. 3 contains these elements of the pressure support system.:”).

105. Truitt discloses a pressured generator 12 in the form of a blower assembly 42 within housing 58 (*a blower having an air output within the enclosure*) identified in blue in Figure 3 above. *See also* Ex. 1007, 5:1-3 (“Pressure support system 50 includes a pressure generator 12 in the form of a blower assembly 52 driven by a motor 54.”); 5:52-55 (“The present invention also contemplates changing

the speed of motor 54 to control the pressure or rate of flow of gas generated by the blower assembly, either alone or in combination with pressure control via valve 40.”).

106. Truitt discloses flow sensing assembly 72 within housing 58 (*an airflow sensor being any type of sensor internal to the enclosure of the PAP device*) identified in green in Figure 3 above. *See also* Ex. 1007, 6:14-17 (“[T]he flow signal output of flow sensing system 72 can be used to control the operation of the pressure support system, monitor the operation of the system, or monitor the patient.”). The flow sensing assembly 72 resides within housing 58 of the pressure support system (*internal to the PAP device*) that measures the pressure differential that can be used be used for calculating the flow of gas (*adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data*). *See id.*, 6:39-43 (“A conventional pressure sensor 32 measures the pressure differential ΔP ($P_2 - P_1$) via ports 74 and 76, and provides a signal indicative of this pressure differential to controller 38 for calculating the flow and/or volume of gas passing through conduit 56.”), 6:46-48 (“The output of flow sensor 32’ is provided to controller 38 for calculating the flow and/or volume of gas passing through conduit 56.”).

107. Truitt discloses controller 38 within housing 58 (*a second processor within the enclosure*) identified in purple in Figure 3 above. *See also* Ex. 1007, 6:8-

10 (“[C]ontroller 38 for controlling the operation of the pressure support system, monitoring the operation of the system, or monitoring the patient, for example.”). Controller 38 receives the signals from the components within flow sensing assembly 72, including conventional pressure sensor 32 and flow sensor 32' (*adapted for receiving the airflow sensor data and for calculating*). See *id.*, 6:39-43 (“A conventional pressure sensor 32 measures the pressure differential ΔP ($P_2 - P_1$) via ports 74 and 76, and provides a signal indicative of this pressure differential to controller 38 for calculating the flow and/or volume of gas passing through conduit 56.”); 6:46-48 (“The output of flow sensor 32' is provided to controller 38 for calculating the flow and/or volume of gas passing through conduit 56.”).

108. As I discussed above for limitation [1.a], controller 38 also receives the data on the patient's conditions, adjustment and control data, and usage data (*i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i) and ii)*). See Section VIII.A.3.b (Limitation [1.a]).

109. As discussed above for limitation [1.a] Truitt discloses i), ii), and iii). See Section VIII.A.3.b (Limitation [1.a]).

110. As I discussed above for limitation [1.a], Truitt discloses calculating “i) the data of a severity of the sleep disorder symptoms of the subject” because it discloses monitoring the patient's condition, and specifically detecting snoring,

apneas, and hypopneas. Ex. 1007, 3:4-11 (“[i]n the auto-titration mode of pressure support, where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient.”)

111. Also as I discussed for limitation [1.a], Truitt discloses calculating “ii) the data of usage of the PAP device by the subject” because the controller of the Truitt PAP device calculates the flow and volume of gas from the PAP device and uses that information to, among others “monitor the usage of the pressure support device (patient compliance).” Ex. 1007, 2:1-11.

112. Additionally as I discussed in limitation [1.a], Truitt discloses that “iii) the index [of treatment efficacy of the subject using a PAP device is] based in whole or in part on either i) or ii) or both i) and ii).”

113. Truitt discloses patient interface device 16 (*a mask or cannula connected to the enclosure*) identified in red in Figure 3 above. *See also* Ex. 1007, 6:1-2 (“This pressure can be used to estimate the pressure at the patient, i.e., within patient interface device 16.”), 1:58-61 (“Examples of patient interface devices include a nasal mask, nasal and oral mask, full face mask, nasal cannula, oral mouthpiece, tracheal tube, endotracheal tube, or hood.”).

d. Limitation [1.b.v]

[1.b.iv] “*at least one second radio frequency wireless transceiver within the enclosure, the at least one second radio frequency wireless transceiver adapted for transmitting i) and ii), and/or iii); and*”

114. In my opinion, Truitt in view of Kumar renders obvious this limitation.

115. A person of ordinary skill in the art would have been motivated to implement a radio frequency wireless transceiver within housing 58 of the PAP device to facilitate wireless communication with the cell phone to transmit the claimed “i) the data of a severity of the sleep disorder symptoms of the subject,” “ii) the data of usage of the PAP device by the subject” and/or the “iii) the index based in whole or in part on either i) or ii) or both i) and ii).”

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

117. As discussed for limitation [1.a], a person of ordinary skill in the art would have understood that computing device 110, such as a wireless phone or an iPAQ device (*cell phone*) includes a radio frequency wireless transceiver to facilitate wireless communications using wireless protocols including, e.g., GSM, GPRS, Wi-

Fi, and Bluetooth. Such a person would have been motivated to implement a radio frequency wireless transceiver in the PAP device for using protocols similar to those used by computing device 110, like the GSM, GPRS, Wi-Fi, and Bluetooth functionality on the iPAQ, to enable the PAP device to wirelessly communicate with the computing device, including to transmit the “data” and/or “index,” as discussed above.

118. As I discussed above, during the relevant time, the rise in mobile computing as well as the advances in technology to make it smaller and more affordable, was driving the embedding of wireless transceivers into consumer devices. *See* Section V.A and V.E. Wireless transceivers were becoming pervasive to allow more convenient and access to data. *See* Section V.D. A person of ordinary skill in the art would have also understood that a wireless transceiver could be implemented to communicate using a number of different protocols, balancing range and power consumption. For instance, a person of ordinary skill in the art would have understood that a Bluetooth-enabled radio frequency wireless transceiver would have allowed a short-range radio link between the PAP device and computing device 110 for data communication. A Wi-Fi-enabled radio frequency wireless transceiver would have allowed the PAP device to connect to both the cell phone and the remote engine for uploading data. A GSM- or GPRS-enabled radio

frequency wireless transceiver would have allowed the PAP device to communicate with the remote engine if a Wi-Fi network is not available.

119. Additionally, 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.

120. A POSITA would have also understood that it would have been advantageous place the to implement the radio frequency wireless transceiver within housing 58 of the PAP device. A POSITA would have been motivated to do this to better protect the transceiver from damage and thereby increasing the PAP device's lifespan.

121. 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 within housing 58 of 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.”).

122. Prior to November 2005, it was known that wireless communication transceivers and/or network cards could be implemented within the housing of PAP devices. For example, Wright discloses a communication port or module 10, which may be a wireless communication transceiver and/or a network card is implemented within a PAP device. Ex. 1013, [0029], FIG. 1.

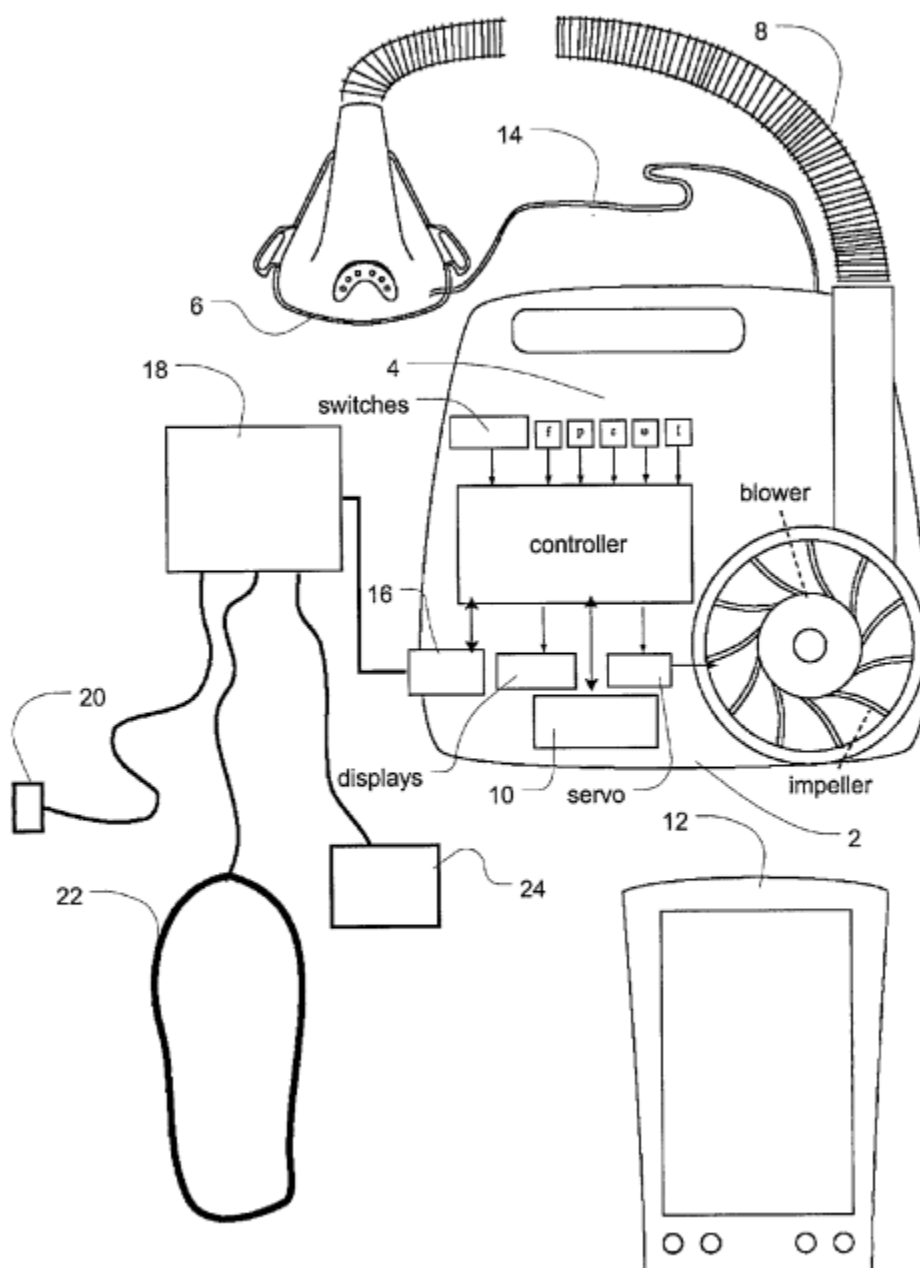


Fig. 1

Ex. 1013, FIG. 1

123. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that monitors the usage and calculates data associated with sleep disorder treatment, as taught in Truitt) according to known methods (e.g., known methods of transmitting data from patient-side device to computing device, e.g., cell phone, by using a radio frequency wireless transceiver, as taught in Kumar) to yield the predictable result of a PAP device including a radio frequency wireless transceiver within the PAP device's housing to facilitate wireless communication with the cell phone.

e. Limitation [1.c]

[1.c] *“a remote internet site, the remote internet site adapted for receiving i) and ii), or i), ii), and iii), related to the subject's treatment and the treatment's efficacy in whole or part, generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.”*

124. In my opinion, Truitt in view of Kumar renders obvious this limitation. This limitation generally recites a remote internet site that receives data from the PAP device.

125. As discussed in limitations [1.a] and [1.b.4], Truitt teaches providing and “index of treatment efficacy” as well as severity and usage data from the PAP device.

126. Kumar teaches *a remote internet site*, and specifically, a browser-based engine for receiving data from the patient-side device. As discussed for limitation [1.a], Kumar discloses “at least one patient-side device for collecting data from a

patient/client, a provider-side device, and an engine, each coupled to the WAN,” such as the Internet. Ex. 1008, ¶ [0011]; Section VIII.A.3.b (Ground 1, Claim 1, Limitation [1.a]). Also as discussed above in limitation [1.b.v], the combination of Truitt and Kumar teaches that the patient-side device is the PAP device of Truitt that includes a wireless transceiver to transmit data from the PAP device (*second radio frequency wireless transceiver*). See Section VIII.A.3.d (Ground 1, Claim 1, Limitation [1.b.v]).

127. 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].

128. 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.”).

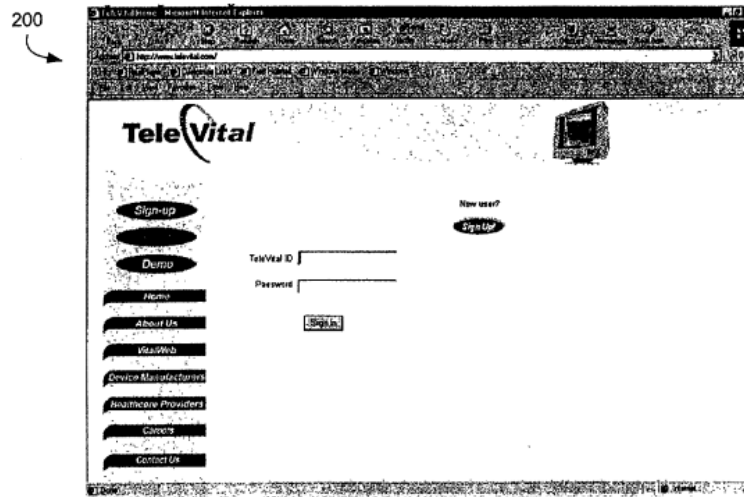


Fig. 2

129. 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.”).

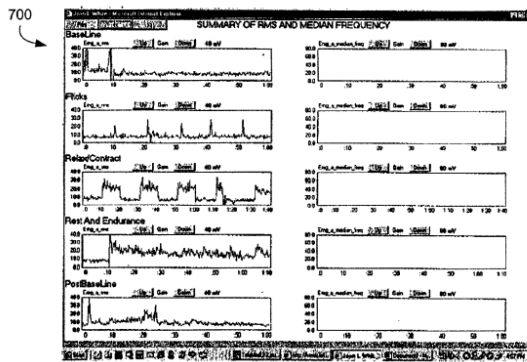


Fig. 7

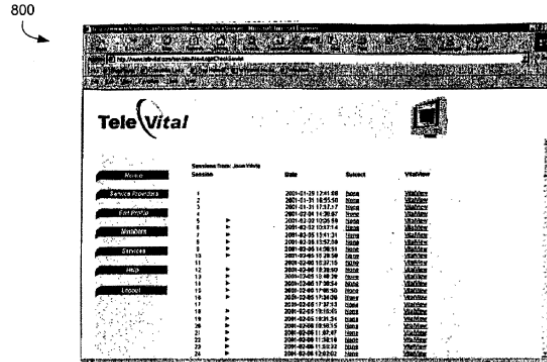


Fig. 8

130. 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].

131. 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].

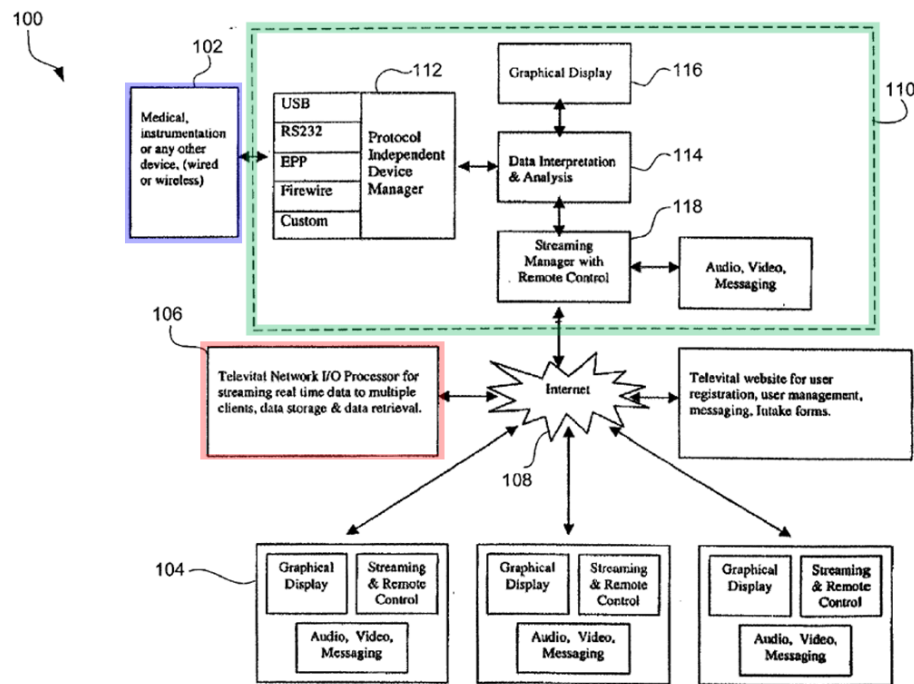


Fig. 1A

Ex. 1008, FIG. 1A (annotated)

132. At this time, remote-monitoring was widely known, as I discussed in above in the background section. *See* Section V.C (Pervasive Computing). A person of ordinary skill in the art would have been motivated to implement a remote-monitoring feature, including a browser-based engine (*a remote internet site* as described in Kumar to enable the PAP device to wirelessly transmit data associated the patient’s treatment, including *i) the data of a severity of the sleep disorder*

symptoms of the subject, ii) the data of usage of the PAP device by the subject and iii) the index based in whole or in part on either i) or ii) or both i) and ii) to the engine to provide data access to patients, physicians, and providers.

133. 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]. Kumar further explains that this feature beneficially allows access anywhere around the world: “The storage device may also be used to store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system,” “allow[ing] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device.” *Id.* Kumar further explains that such a feature is beneficial since it allows a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. *Id.*

134. Another benefit of the remote monitoring system is data collection and analysis. Kumar also teaches “[t]he system may also track trends during the recording, and using artificial intelligence, predict future behaviors and physiological responses based on the habits of the particular client hooked up.” *Id.*, ¶ [0084]. This would allow physicians and providers to better leverage data and to perform analyses to find patterns that they may not be able to identify without a large set of data.

135. Still another benefit of the remote monitoring system is data backup. A POSITA would have understood that storing data at the secured storage of the engine would have provided a backup of the data from the PAP device which would be beneficial in the event that the PAP device and/or the patient's cell phone were damaged, misplaced, or malfunction. Having a copy of the data stored at the engine would ensure that the physician and/or the patient would be able to continue to access the data in such a situation.

136. A person of ordinary skill in the art would have also had a reasonable expectation of success in implementing the networked PAP device of Truitt and Kumar to remote-monitoring feature. Kumar states that "virtually any device may be easily incorporated into the system." Ex. 1008, ¶ [0074]. Additionally, it was well known to transmit data using wireless protocol to a remote internet site, e.g., for later access of the data. *See* Section V.A-B. Moreover, it would have involved a combination of known technologies (PAP device that monitors the usage and calculates data associated with sleep disorder treatment, like taught by Truitt) according to known methods (transmitting data wirelessly from patient-side device to a remote engine on the internet, like taught by Kumar) to yield the predictable result of a system including a remote engine that receives and stores data received from a patient-side device (the PAP device, for simultaneous storage, retrieval, analysis, and play back from anywhere in the world, as discussed above).

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

4. Dependent Claim 2

“2. The system of claim 1, wherein the remote internet site is adapted to be hosted on a remote communication system with a third processor and a recording medium for reprocessing, storing and/or outputting data received from the first and/or second radio frequency wireless transceiver in whole or part, and to further output the reprocessed and/or the outputted data.”

138. In my opinion, Truitt in view of Kumar renders obvious this limitation.

139. Kumar discloses that the engine (*remote internet site*) is adapted to be hosted on central server 106 (*a remote communication system*). Specifically, Kumar explains that the “engine [is] implemented on a central server 106.” Ex. 1008, ¶ [0067]; *see also* ¶ [0069] (“For simplicity, the discussion will proceed with description of a system having a single patient-side device, provider-side device, and engine/central server; it being understood that one skilled in the art would be able to use the system with multiple devices connected without undue experimentation.”), Fig. 1A.

140. The central server 106 (*remote internet site*) includes a network I/O processor (*a third processor*), as shown below in pink. *Id.*, Fig. 1A.

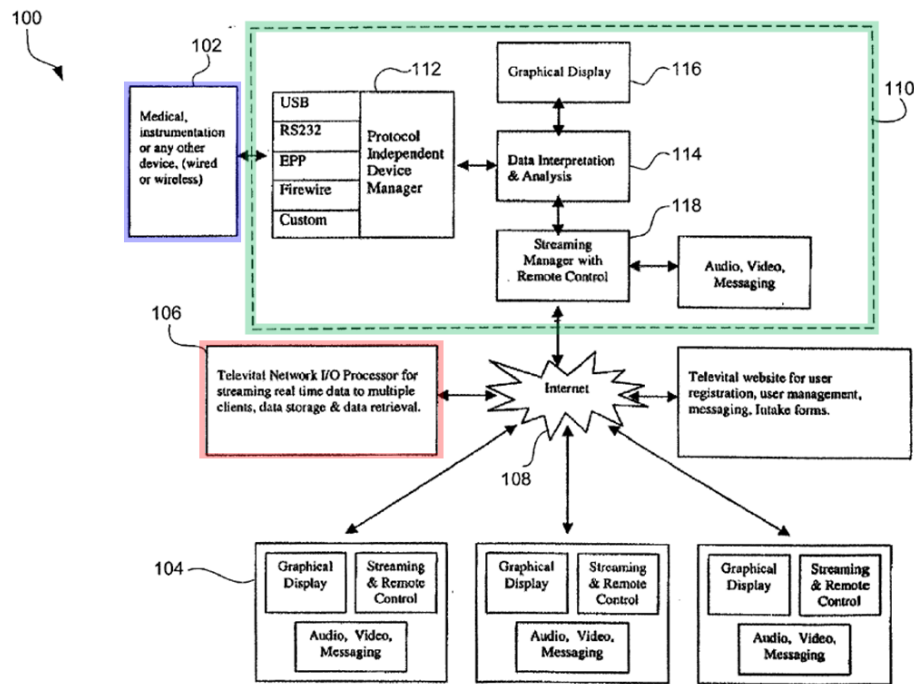


Fig. 1A

141. The network I/O processor (*third processor*) is responsible for *reprocessing and/or outputting data received from the patient-side device through the wireless transceiver of computing device 110 (first or second radio frequency wireless transceiver) in whole or part*, and “forms the core of the real time data streaming portion of the engine.” Ex. 1008, ¶ [0082]. As Kumar explains, “The I/O processor is responsible for streaming device data, audio, video, messages, and remote control information between multiple clients and hosts” and “may also handle data storage and retrieval of the streamed data.” *Id.* Kumar includes a secured storage device (*a recording medium*). *Id.* [0083].

142. The engine (*remote internet site*) adapted to output as a statistical summary report (*data received from the first and/or second radio frequency wireless transceivers*). Kumar explains that “the exemplary embodiment may allow for ... print ... from anywhere in the world with access to the storage device” of the central server, where “a statistical summary report” may be provided. Ex. 1008, ¶ [0083]. A person of ordinary skill in the art would have understood that the engine allows this remote accessibility so that “the healthcare provider can view a statistical summary report” that “includes a field for adding clinical notes” at any location. *Id.*, ¶ [0092]. “This beneficially allows a provide to seek expert consultation for clinically difficult cases,” whether or not the expert is located locally or not. *Id.*, ¶ [0083].

143. Alternatively, the engine (*remote internet site*) is also adapted to *output* to a graphical display (*a second display*). Kumar discloses that “[b]y receiving data from the patient-side device, a provider is able to monitor the patient/client’s physiology for research, keeping track of documentation, performing analysis, managing and maintaining records, diagnosing the patient/client, providing treatment in real-time to the patient/client, etc.” Ex. 1008, ¶ [0014]. Kumar further discloses that its system supports “customized graphical user interfaces (GUIs) for the various devices” and “as well as textual/audio/video data from a patient to a health care provider.” *Id.*, ¶¶ [0074], [0067].

144. A person of ordinary skill in the art would understand that the GUIs and data would be formatted in a way to be displayed on the graphical display of provider-side devices Kumar teaches in Figure 1A highlighted in yellow below.

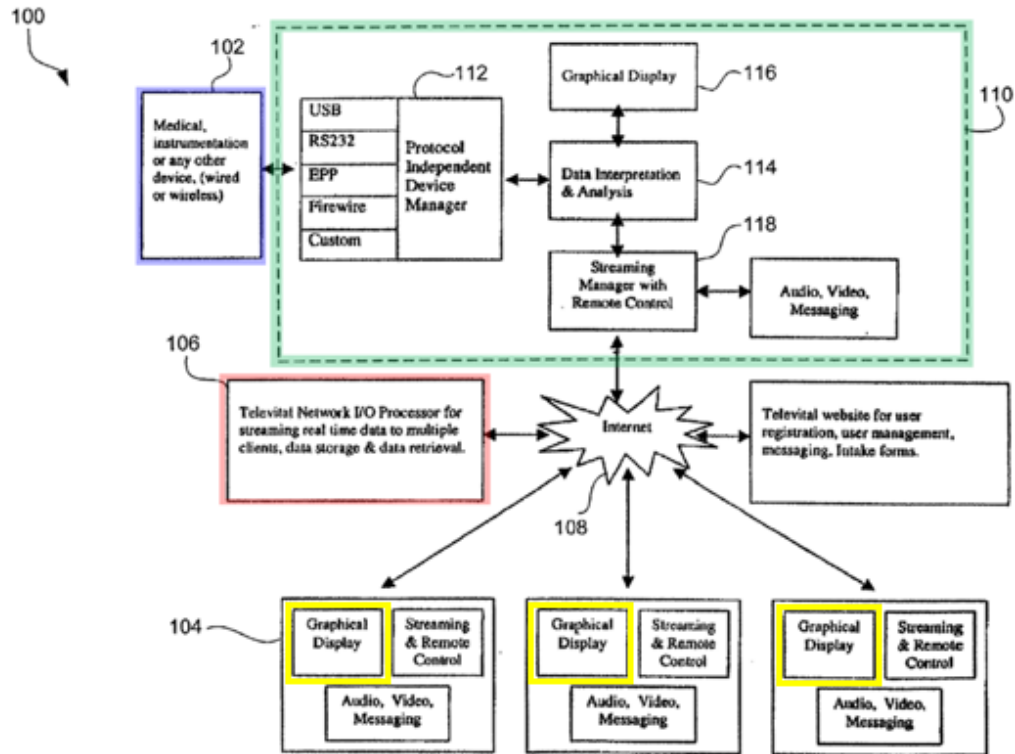


Fig. 1A

5. Dependent Claims 3 and 5

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

"5. The system of claim 4, wherein the at least one second radio frequency wireless transceiver of the PAP device and the first radio frequency wireless transceiver of the cell phone are adapted to communicate using Bluetooth wireless protocol."

145. In my opinion, Truitt in view of Kumar renders obvious these limitations.

146. As I discussed above for limitation [1.a], Kumar discloses that the computer device (*cell phone*) may be “personal digital assistants (PDAs) and pocket PCs such as iPAQ with Windows CE operating system and Palm devices based on Palm OS.” Section VIII.A.3.b (Ground 1, Claim 1, Limitation [1.a]). By 2005, the iPAQ had Bluetooth functionality. Ex. 1011, 2 (“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.”).

147. A person of ordinary skill in the art would have understood that the wireless transceiver of the iPAQ (*first radio frequency wireless transceiver of the cell phone*) was adapted to communicate using Bluetooth wireless protocol since it included Bluetooth functionality. The Bluetooth protocol was first introduced in May 1998. A manufacturer was required to meet Bluetooth standards in order to market it as a Bluetooth device.

148. In the combination resulting from the teachings of Truitt and Kumar, it would have been obvious to implement the wireless transceiver in the PAP device (*the at least one second radio frequency wireless transceiver of the PAP device*) to

include Bluetooth functionality (*adapted to communicate using Bluetooth wireless protocol*). As discussed in above, a person of ordinary skill in the art would have been motivated to improve the PAP device taught by Truitt by implementing it into a networked telemedicine system as taught by Kumar with a reasonable expectation of success. *See* Section VIII.A.1-2 (motivation to combine and reasonable expectation of success). A person of ordinary skill in the art would have been specifically motivated to implement Bluetooth functionality in the PAP device of Truitt to provide an additional or alternative data communication channel between the PAP device the iPAQ. The Bluetooth protocol quickly became popular because of its simple setup process for connecting two devices for data transmission, and relatively low power consumption. As a result, consumer electronic products began incorporate Bluetooth very early, including phones, printers, headsets, and even vehicles.

149. By 2003, the first Bluetooth-enabled medical device was cleared by the U.S. Food and Drug Administration (FDA) for sale by Striker Endoscopy. This system incorporated Bluetooth Seri Port adapter modules from connectBlue AB (now u-blox) to replace RS-232 cabling between devices in hospital operating rooms.

6. Dependent Claim 4

“4. The system of claim 2, wherein the at least one second radio frequency wireless transceiver is adapted to transmit the data to the remote internet site in whole or in part via cell towers.”

150. In my opinion, Truitt in view of Kumar renders obvious this limitation. As I discussed above for limitation [1.a], Kumar discloses that the computer device (*cell phone*) may be “personal digital assistants (PDAs) and pocket PCs such as iPAQ with Windows CE operating system and Palm devices based on Palm OS).” See Section VIII.A.3.b (Ground 1, Claim 1, Limitation [1.a]). By 2005, the exemplary computing device, such as the iPAQ device would have transmitted and received data using the GSM/GPRS wireless protocol when using the cellular network. Ex. 1011, 2 (“The lightweight HP iPAQ h6315 coupled with the muscle of T-Mobile's national GSM/GPRS wireless voice and high-speed data network”).

151. A person of ordinary skill in the art would have understood that the data transmitted and received using the GSM/GPRS wireless protocol would have been transmitted in part by cell towers (*adapted to transmit the data . . . via in part by cell towers*). A cell tower, sometimes called a base station, is a structure that produces a cellular signal in a cellular network. When a cell phone is used, it will emit a radio frequency signal that is received by the nearest cell tower. Once the cell tower receives this signal, the cell tower will then transmit the signal to a switching tower

where the cell phone will be connected to another cellular device or to a telephone network. GSM and GPRS were the predominant cellular protocols at the time.

152. As I discussed for limitation [1.a], a person of ordinary skill in the art would have been motivated to configure a PAP device, as taught in Truitt, to wirelessly transmit to a patient's cell phone data associated the patient's treatment, including adjustment and control data. Section VIII.A.3.b. Further a POSITA would have been motivated to place the wireless transceiver inside housing 58 of the PAP as discussed above. Kumar also discloses that the patient-side device may be connected via a computing device to the Internet, with which the engine implemented in the central server 106 is connected. Ex. 1008, [0013], [0067], [0073], FIG. 1.

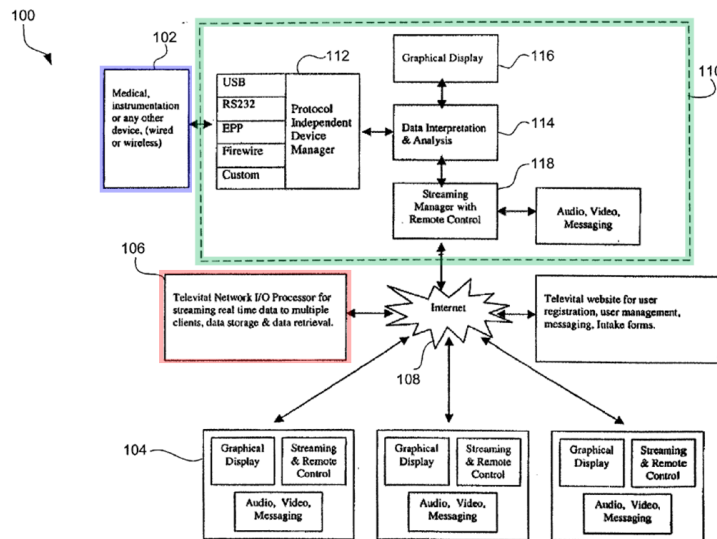


Fig. 1A

Ex. 1008, FIG. 1A

153. The modification would have resulted in the wireless transceiver in the PAP device (*at least one second radio frequency wireless transceiver*) transmitting to the computing device, such as the iPAQ, (*is configured to transmit the data to the remote internet site and/or the cell phone*) the patient's data on adjusting or controlling the pressure, patient's condition, and patient's usage data (*data of the severity of the symptoms of the subject and/or the index, and the data of usage*) through the GSM/GPRS cellular network, including the cell towers (*via in part by cell towers*). See also Ex. 1008, ¶ [0081] ("receive the data from the patient-side device and transmit the raw or processed data to the provider-side device.").

7. Dependent Claims 6 and 7

"6. The system of claim 5, the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is adapted for calculating the data in whole or in part, wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site."

"7. The system of claim 4, the PAP device further comprising at least one second software stored on a memory and executed by the second processor, the at least one second software which is adapted for calculating the data in whole or in part, wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site."

154. In my opinion, Truitt in view of Kumar renders obvious these limitations.

155. As discussed for the [1.b.iii], Truitt discloses a second processor adapted for calculating the data. *See* Section VIII.A.3.c (Ground 1, Claim 1, Limitation [1.b.iii]; *see also* Ex. 1007, 6:1-10 (“[C]ontroller 38 for controlling the operation of the pressure support system, monitoring the operation of the system, or monitoring the patient, for example.”). Controller 38 receives the signals from the components within flow sensing assembly 72, including conventional pressure sensor 32 and flow sensor 32' (*adapted for receiving the airflow sensor data and for calculating*). *See id.*, 6:39-43 (“A conventional pressure sensor 32 measures the pressure differential ΔP ($P_2 - P_1$) via ports 74 and 76, and provides a signal indicative of this pressure differential to controller 38 for calculating the flow and/or volume of gas passing through conduit 56.”); 6:46-48 (“The output of flow sensor 32' is provided to controller 38 for calculating the flow and/or volume of gas passing through conduit 56.”).

156. Truitt further discloses that “[c]ontroller 38 receives the signals output from sensors 20 and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof in a feedback fashion based on these received signals.” *Id.*, 2:57-60. A POSITA would have understood that Truitt’s PAP device includes a certain program/code (*at least one second software*) that is executed by controller 38 to perform the disclosed processes, including calculating “data of usage of the PAP device by the subject,” “data of severity of sleep disorder symptoms of the

subject,” and “index [of treatment efficacy of the subject using a PAP device],” as discussed for limitations [1.a] and [1.b.iii]-[1.b.iii.3]. In addition, a POSITA would have understood that such a program/code is stored on a certain storage medium (“memory”) to allow the PAP device to repeatedly perform the disclosed processes after power cycles.

157. With respect to the *adapted to be reprogrammed or to modify the at least one second software from the remote internet site* limitation, Kumar discloses “remote control features built in to the system,” where “remote providers can control the software on the patient’s end.” Ex. 1008, [0080]. Additionally, a “remote client module...allows remote hosts to view the data being streamed in real time” and “can also control the software being run on the patient’s and/or provider’s end.” *Id.*, [0085]. Moreover, Kumar explains that “[i]ntegration of the **client-side device driver** is performed in two steps”: “[f]irst, the appropriate device driver is incorporated into the system, preferably via a web page,” and “[a] customized or standard GUI is incorporated or developed based on user and/or device manager specifications.” *Id.*, [0086]. “Thus, a user does not have to install any software, and **updates to the software are done by simply running the latest software from a website.**” *Id.* Kumar discloses “remote control features built in to the system,” where “remote providers can control the software on the patient’s end.” Ex. 1008, [0080]. Additionally, a “remote client module...allows remote hosts to view the data

being streamed in real time” and “can also control the software being run on the patient’s and/or provider’s end.” *Id.*, [0085]. Moreover, Kumar explains that “[i]ntegration of the **client-side device driver** is performed in two steps”: “[f]irst, the appropriate device driver is incorporated into the system, preferably via a web page,” and “[a] customized or standard GUI is incorporated or developed based on user and/or device manager specifications.” *Id.*, [0086]. “Thus, a user does not have to install any software, and **updates to the software are done by simply running the latest software from a website.**” *Id.*

158. It is my opinion that a POSITA would have been motivated to implement these features as they would allow the PAP device to be reprogrammed or its software modified remotely from the browser-based engine (“wherein the PAP device is further adapted to be reprogrammed or to modify the at least one second software from the remote internet site or a second remote internet site”). For example, the provider may monitor the received data and adjust the PAP device to operate in different modes, e.g., operating as “bi-level pressure support” or as “an auto-titration mode of pressure support,” as discussed in Truitt. Ex. 1007, 1:30-43, 8:13-24. Moreover, as explained in Kumar itself, the remote control features (e.g., those discussed above) would have been beneficial as the “patients do not need to know how to operate the software” (Ex. 1008, [0080]) and “a user does not have to install any software, and updates to the software are done by simply running the

latest software from a website” (*id.*, [0086]). Additionally or alternatively, for similar reasons as discussed above, a POSITA would have likewise been motivated to modify the processor of the PAP device, e.g., controller 38 disclosed in Truitt, such that it may be adjusted remotely given that such a processor/controller controls operations of the PAP device, and thus adjustments to the PAP device operations may be readily executed by the processor and run by the software. Ex. 1007, 2:38-42, 2:57-64, 6:6-10.

159. A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described reprogramming/modifying features as it would have would have been a routine and conventional implementation of known methods using known hardware components performing their known functions, well within a POSITA’s skills and ability to accomplish.

8. Dependent Claims 8 and 11

“8. The system of claim 4, wherein the airflow sensor data is processed by the second processor, at least in part using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.”

“11. The system of claim 2, wherein the airflow sensor data is processed by the second processor, at least in part using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernals, and a wavelet analysis.”

160. In my opinion, Truitt in view of Kumar renders obvious these limitations.

161. As a preliminary matter, I note that the '029 patent explains that well-known signal processing techniques are used to identify various characteristic shifts in the power spectrum of the sensors. In particular, the '029 patent explains that “[v]arious sleeping disorders have symptoms that can be predicted based on various combinations of physiological signals or data.” Ex. 1001, 20:24-26. “Various embodiments of the present invention include the approach to identifying these symptoms prior to onset by identifying various characteristic shifts in the power spectrum of the sensors being used to monitor these physiological conditions.” *Id.*, 20:26-30. These approaches include “(i) the standard deviation technique, (ii) a recursively fit ARMAX system identification model, (iii) the Short-Time Fourier Transform (SFFT) technique, and (iv) time-frequency signal analysis with a variety of different kernels.” *Id.*, 20:37-41.

162. 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. As the '029 patent explains, “[a] Discrete Fourier transform (DFT), and its numerically efficient complement the Fast Fourier Transform (FFT), both provide frequency information of a digitized signal or data

from the sensors.” Ex. 1001, 21:32-36. 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.

163. As discussed in Ground 1 above for limitation [1.b.iii]-[1.b.iii.3], Truitt discloses “a second processor within the enclosure adapted for receiving the airflow sensor data and for calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i).” Thus, Truitt discloses that “the airflow sensor data is processed by the second processor.”

164. Truitt does not expressly disclose processing and calculating the data using *a discrete Fourier transform technique* or *fast Fourier transform technique*, but it would have been obvious to a person of ordinary skill in the art to do so in view of Kumar. Kumar teaches that is desirable to stream, in real-time, “FFT, and DFT.” Ex. 1008, ¶ [0007]. A POSITA would have understood that FFT and DFT each refers to the claimed “fast Fourier transform technique” and “discrete Fourier transform technique,” which is consistent with the ’029 patent. In fact, the ’029 patent states that “[a] Discrete Fourier transform (DFT), and its numerically efficient complement the Fast Fourier Transform (FFT), both provide frequency information of a digitized signal or data from the sensors.” Ex. 1001, 21:32-34.

165. 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 airflow sensors taught by Truitt. Those developing diagnostic 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.

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

9. Dependent Claims 9 and 13

“9. The system of claim 4, wherein the remote internet site is adapted to retransmit to the first radio frequency wireless transceiver on the cell phone the data, in whole or in part, the data of i) and ii), or i), ii), and iii) or a second index related to the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device.”

“13. The system of claim 2, wherein the remote internet site is adapted to retransmit the data to the first radio frequency wireless transceiver on the cell phone, in whole or in part, of i) and ii), or i), ii), and iii) related to the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device”

167. In my opinion, Truitt in view of Kumar and the knowledge of a person of ordinary skill in the art renders obvious these limitations.

168. As I discussed for limitation [1.c], a person of ordinary skill in the art would have been motivated to configure a PAP device, as taught in Truitt, to wirelessly transmit data associated the patient's treatment including, data on the patient's condition (*data of severity of sleep disorder symptoms of the subject*), patient's usage data (*data of usage of the PAP device by the subject*), or adjustment and control data (*a second index related to the data*), to the engine (*remote internet site*). See Section VIII.A.3.e (Ground 1, Claim 1, Limitation [1.c]).

169. As I discussed for limitation [1.c], a POSITA would have been motivated to combine Truitt and Kumar's teachings such that the remote engine ("the remote internet site") is adapted to receive and store the various data/index generated/calculated by the PAP device. See Section VIII.A.3.e (Ground 1, Claim 1, Limitation [1.c]). 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.*

170. 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.* A person of ordinary skill in the art would have understood that the computing device, in particular, the iPAQ could access the engine (remote internet site) through a browser-based interface, such as a web page, and request the patient’s data. The engine would then retransmit the data to the computing device through its wireless transceiver.

171. Moreover, “[t]he storage device may also be used to store all patient data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system,” “allow[ing] for simultaneous storage, **retrieval**, print, analysis, and play back from anywhere in the world with access to the storage device.” *Id.*; Section VIII.A.3.e (Ground 1, Claim 1, Limitation [1.c]).

172. As I discussed for limitation [1.c], a person of ordinary skill in the art would have been motivated to configure a PAP device, as taught in Truitt, to wirelessly transmit data associated the patient’s treatment, including adjustment and control data (*an index*), data on the patient’s condition (*data of severity of sleep disorder symptoms of the subject*), and patient’s usage data (*data of usage of the PAP device by the subject*) to the engine (*remote internet site*). See Section VIII.A.3.e (Ground 1, Claim 1, Limitation [1.c]).

173. Kumar further discloses that the engine (*remote internet site*) is *configured* to receive, store, and transmit (*to retransmit*) the patient's data to the wireless transceiver of the computing device (*first radio frequency wireless transceiver on the cell phone*). 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.*

174. 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.* A person of ordinary skill in the art would have understood that the computing device, in particular, the iPAQ could access the engine (*remote internet site*) through a browser-based interface, such as a web page, and request the patient's data. The engine would then retransmit the data to the computing device through its wireless transceiver.

175. For instance, as a POSITA would have understood, the patient would be interested in reviewing data/index associated with prior use of the PAP device and/or a set of data/index integrated/summarized by the remote engine (including those provided by a physician, for example). Moreover, given that the remote engine

may store the analysis of the data/index (e.g., those analyzed by the doctor) and “for later access” and “retrieval” (Ex. 1008, [0083]), a POSITA would have found it beneficial to configure the remote engine to transmit those data/index, in whole (e.g., data/index stored from prior treatment(s)) or in part (e.g., analysis of the data/index provided by the doctor), to the first radio frequency wireless transceiver on the cell phone to allow the patient to review those information, which would have improved user experience, communication between the patient and the medical care provider, and patient compliance. *Id.*

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

177. It was well within the skill of a POSITA to implement the features discussed in claim 1 to transmit a “second” index, e.g., an index associated with the treatment efficacy of another sleep disorder such as central apnea. To the extent that “retransmit” means sending the same data to the first radio frequency wireless transceiver of the cell phone at least twice, this would have been obvious.

10. Dependent Claims 10 and 16

“10. The system of claim 9, wherein the remote communication system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer

and/or a second display for review by a clinician to determine the treatment efficacy.”

“16. The system of claim 2, wherein the remote communication system is further adapted to output a report and/or the reprocessed and/or outputted data to a printer and/or a second display for review by a clinician to determine the treatment efficacy.”

178. In my opinion, Truitt in view of Kumar renders obvious these limitations.

179. Kumar discloses the central server 106 (*remote communication system*) includes a network I/O processor, as shown below in pink. *Id.*, Fig. 1A.

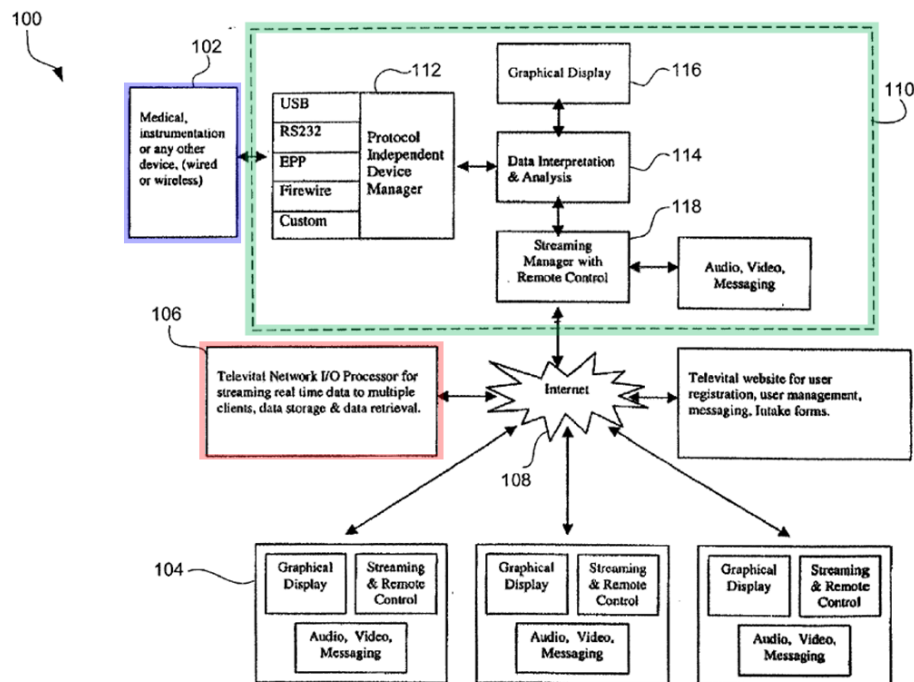


Fig. 1A

Ex. 1008, Fig. 1A

180. The network I/O processor is responsible for outputting data (*is further adapted to output*) to the patient-side device through the wireless transceiver of

computing device 110 and “forms the core of the real time data streaming portion of the engine.” Ex. 1008, ¶ [0082]. As Kumar explains, “The I/O processor is responsible for streaming device data, audio, video, messages, and remote control information between multiple clients and hosts” and “may also handle data storage and retrieval of the streamed data.” *Id.*

181. The engine hosted on central server 106 (*remote communication system*) is further adapted to output a statistical summary report (*a report*). A person of ordinary skill in the art would have understood that the engine allows remote accessibility so that “the healthcare provider can view a statistical summary report” that “includes a field for adding clinical notes” at any location. *Id.*, ¶ [0092]. “This beneficially allows a provide to seek expert consultation for clinically difficult cases,” whether or not the expert is located locally or not. *Id.*, ¶ [0083].

182. The engine hosted on central server 106 (*remote communication system*) is further adapted to output the reprocessed and outputted data to output devices including a printer (*the reprocessed and/or outputted data to a printer*). Kumar explains that “the exemplary embodiment may allow for ... print ... from anywhere in the world with access to the storage device.” Ex. 1008, ¶ [0083].

183. The engine on the central server 106 (*remote communication system*) is also configured to output to the reprocessed and outputted data (*the reprocessed and/or outputted data*) to a graphical display (*a second display for review by a*

clinician to determine the treatment efficacy). Kumar discloses that “[b]y receiving data from the patient-side device, a provider is able to monitor the patient/client’s physiology for research, keeping track of documentation, performing analysis, managing and maintaining records, diagnosing the patient/client, providing treatment in real-time to the patient/client, etc.” Ex. 1008, ¶ [0014]. Kumar further discloses that its system supports “customized graphical user interfaces (GUIs) for the various devices” and “as well as textual/audio/video data from a patient to a health care provider.” *Id.*, ¶¶ [0074], [0067].

184. A person of ordinary skill in the art would understand that the GUIs and data would be formatted in a way to be displayed on the graphical display of provider-side devices Kumar teaches in Figure 1A highlighted in yellow below.

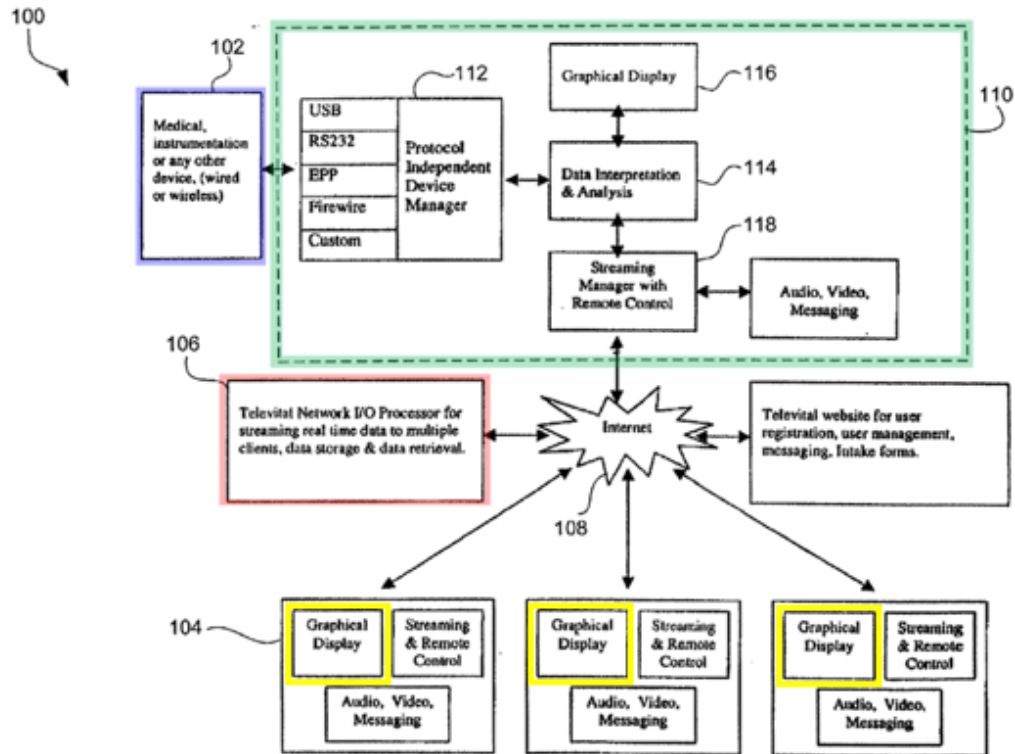


Fig. 1A

Ex. 1008, Fig.1A

11. Dependent Claims 14 and 15

“14. The system of claim 2, wherein the PAP device further comprises an adaptive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.”

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

185. In my opinion, Truitt alone or in view of the knowledge of a POSITA renders obvious these limitations.

186. Truitt discloses a controller that can adapt to and/or predict the patient's condition (*an adaptive controller* recited in claim 14 and *an adaptive predictive controller* recited in claim 15) to adjust pressure provided by the blower (*to adjust the flow of the blower*) to counteract or prevent the patient's snoring, apnea, or hypopnea as processed by the controller (*based in part on the data of the severity of the symptoms of the subject calculated by the second processor*). Truitt explains that “in a simple CPAP device, controller 38 monitors the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.” Ex. 1007, 2:60-64. Truitt also explains “[i]n the auto-titration mode of pressure support, where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient, ... [t]he pressure and/or flow is then controlled to counteract or prevent these conditions.” Ex. 1007, 3:4-10.

187. An adaptive and adaptive predictive controller is a controller that takes into account a longer sequence of predicted states when making control decisions. A person of ordinary skill in the art would understand that to “adjust pressure on a feedback fashion” or to predict “pressure and/or flow ... to counteract or prevent [certain] conditions,” the controller must take into account a longer sequence of predicted states when making control decisions.

188. To the extent that Truitt does not disclose *an adaptive controller* or *an adaptive predictive controller*, it would have been obvious to modify Truitt to include one to adjust pressure in a feedback fashion or counteract or prevent certain conditions. Such controllers were known and available on the market. *See* Ex. 1014. I note that the '284 patent recognizes that this limitation was known. The '284 patent states that an “embodiment of a method to identify the shift in measured power spectrum of the signal from the pressure transducer to identify stall utilizes a recursively identified system model, particularly an Auto-Regressive Moving Average (ARMA) model.” Ex. 1001, 20:51-55. The '284 patent notes that the controller running the model is “the ORICATM controller, an extended horizon, adaptive, predictive controller, produced by Orbital Research, Inc. and patented under U.S. Pat. No. 5,424,942.” *Id.*, 20:55-59.

12. Dependent Claim 18

“18. The system of claim 1, wherein the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely based on the data received by the remote internet site.”

189. In my opinion, Truitt in view of Kumar renders obvious this limitation.

190. As I discussed for limitation [1.c], a person of ordinary skill in the art would have been motivated to configure a PAP device, as taught in Truitt, to wirelessly transmit data associated the patient's treatment, including adjustment and control data, data on the patient's condition, and patient's usage data and display this

data to the patient. Section VIII.A.3.e. In this combination, this data would be measured by the airflow sensors and calculated by the processor of the PAP device and then transmitted to the browser-based engine (*remote internet site*) by the wireless transceiver in the PAP device. Section VIII.A.3.e.

191. Kumar further discloses that *the PAP device further comprises at least one electronic component adapted to allow the PAP device to be adjusted remotely*, and specifically, discloses that the processor of the PAP device includes code that allows the PAP device to be adjusted remotely. 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 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.

192. A person of ordinary skill in the art would understand that the *electronic component* executing that software is the processor. For a device to perform certain methods, the code associated with those methods must be loaded and executed by the processor.

193. Kumar also discloses that discloses that the remote adjustment is *based on the data received by the remote internet site* because the remote adjustment is based on the transmitted patient data received by the browser-based engine. Kumar explains that “[a] remote client module (not shown) allows remote hosts to view the data being streamed in real time” and that “[t]he remote client module can also control the software the software being run on the patient’s . . . end.” *Id.*, [0085]. The remote providers can control the software on the patient’s end using “optional remote control features built in to the system.” *Id.*, [0080]. This feature allows remote providers to adjust the PAP device remotely based on the provider’s review of the patient’s data received by the browser-based engine.

194. A person of ordinary skill in the art would have been motivated to implement a remote control feature to adjust and control the PAP device taught by Kumar based on the data transmitted to the remote browser-based engine because it would have allowed the patient, physician, and provider to leverage the multiple benefits of an intelligent system. For example, as I discussed above in Section VIII.A.1 (Motivation To Combine), one of the benefits is providing instant updates that would allow physicians to provide the most up-to-date care. If a new treatment is available for a patient’s condition, that treatment could be applied instantaneously based on the data received. Without this remote control feature, the software on the PAP device would have to be updated first to reflect the new treatment.

195. Further, as Kumar itself recognized, the remote control feature would have been beneficial as the “patients do not need to know how to operate the software.” Ex. 1008, ¶ [0080]. A remote control feature improves the patient experience by simplifying the actions that patient must take. A person of ordinary skill in the art would have been looking for ways to provide less friction for the patient, and providing a remote control feature would have been a known way to do that as it was a known benefit of intelligent systems.

196. This modification would have had a reasonable expectation of success as it would have been well within the skill set of a person of ordinary skill in the art to program remote control software (code that allows the device to accept commands remotely) that could be executed by the processor of the PAP device. It would have been a routine and conventional implementation of known methods (remote control software) using known hardware components (network equipment and processor) performing their known functions (execute software that would allow the processor to take commands that were sent over the network). *See also* Section VIII.A.2 (Reasonable Expectation of Success).

13. Dependent Claim 19

“19. The system of claim 1, wherein the first software is adapted to be reprogrammed or modified remotely.”

197. In my opinion, Truitt in view of Kumar renders obvious this limitation.

198. 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.”)

199. 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 is executable by the processor of the computing device 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 the display of data. Further, the code must be configured to communicate with 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.

200. 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], [0074]. Moreover, Kumar explains that “the entire system runs

in the context of an Internet browser” and that “a user does not have to install any software, and updates to the software are done by simply running the latest software from a website.” *Id.*, [0086].

201. Further, Kumar discloses that its system “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.” Ex. 1006, [0074]. The system “may support both plug-and-play web *device drivers* and customized graphical user interfaces (GUIs) for the *various devices*.” *Id.* “Existing devices (which are not web-enabled) may be easily web-enabled by installation of the appropriate plug-and-play driver and GUI.” *Id.* In other words, Kumar discloses that the *first software* executed and stored on the cell phone may be modified remotely by the central server to accommodate multiple devices. Thus, Kumar discloses the software on the cell phone *first software* may be *reprogrammed or modified remotely*.

202. A person of ordinary skill in the art would have been motivated to implement these features as it would allow the software running on the patient’s cell phone to be reprogrammed or modified without minimal effort from the user. Moreover, the remote reprogram/update features may reflect any updates made to

the software running on the PAP device. For example, if there was a new feature implemented in an update to the software on the PAP device, a person of ordinary skill in the art would have been motivated to also update the software on the patient's cell phone to reflect the availability of this new feature.

203. A POSITA would have had the skill and a reasonable expectation of success in implementing the above-described reprogramming features as it would have would have been a routine and conventional implementation of known methods using known hardware and software components performing their known functions, well within a POSITA's skills and ability to accomplish. In particular, it known at the relevant time to modify or reprogram code using software updates or plug-ins. Accordingly, Truitt in view of Kumar discloses this limitation.

B. Ground 2: Truitt in View of Kumar and Dong Renders Obvious Claims 14 and 15

1. Motivation to Combine

204. In my opinion, a person of ordinary skill in the art would have been motivated to improve the Truitt-Kumar combination by incorporating the controller as taught by Dong. For example, such a person would have incorporated the teachings of Dong to improve the performance of the Truitt-Kumar PAP controller. Additionally, a person of ordinary skill in the art would have naturally looked to Dong because – like Kumar – it is expressly directed to “real time” systems. *See, e.g.,* Dong at 1:8-10 (“The present invention is particularly applicable to real time

automatic control systems and apparatus.”); see also Kumar at Title (“System and Method for Real-time Monitoring, Assessment, Analysis, Retrieval, and Storage of Physiological Data Over a Wide Area Network.”); *see also* [0004].) Specifically, a person of ordinary skill in the art would have recognized that Dong’s teaching of an “adaptive block predictive controller” would improve the “biofeedback” of Kumar. As discussed below, the Dong controller addresses two potential limitations with existing adaptive controllers relating to computational complexity and sensitivity to the choice of input-output delays and model order prediction. Ex. 1014, 1:38-42.

2. Reasonable Expectation of Success

205. A person of ordinary skill in the art would have had a reasonable expectation of success in modifying the Truitt-Kumar to incorporate the teachings of the Dong controller.

206. Such a skilled person would have modified the Truitt-Kumar system to incorporate the Dong controller. Neither Truitt nor Kumar specifies the use of any particular type of controller, and the Dong controller would have just been one of a limited number of design choices that a person of ordinary skill in the art would have needed to select to implement the system.

3. Dependent Claims 14 and 15

“14. The system of claim 2, wherein the PAP device further comprises an adaptive controller to adjust the flow of the blower based in part on the data of the severity of the symptoms of the subject calculated by the second processor.”

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

207. In my opinion, Truitt in view of Kumar and Dong renders obvious these limitations. As I discussed for claim 14 and 15 in Ground 1, the combination of Truitt and Kumar discloses the additional limitations of these claims. Section VIII.A.11 (dependent claim 14). To the extent that the Truitt-Kumar combination does not disclose that the controller is *an adaptive controller* (as recited in claim 14) or *adaptive predictive controller* (as recited in claim 15), a person of ordinary skill in the art would have found it obvious to implement the features recited therein in view of Dong.

208. Similar to Truitt, which discloses a controller determining a PAP device's operation based on input from sensors (*see* Section VIII.A.3.c), Dong discloses a controller determining a system's operation (e.g., operations of actuators) based on multiple inputs (e.g., input from sensors). Ex. 1014, Abstract (“A hardware implementation of the subject extended horizon predictive control system includes a computing means, memory means, and dynamic system input and output signal processing means.”), FIG. 15 (disclosing an exemplary embodiment including sensors providing input signals and actuators receiving output signals), 19:5-20:56 (discussions associated with the exemplary embodiment relating to Figure 15).

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

210. Figure 1 of Dong discloses an “overall structure of extended horizon adaptive block predictive controller with an efficient prediction system.” Ex. 1014, 7:60-8:53. Dong explains that “[a] block of potential system inputs (block controls)...is determined by Block Control System 1, based upon a block of the desired output trajectory...a block of predicted outputs...when no filtering of the system outputs is used, or a block of predicted filtered outputs...when filtering of the system outputs is used, both being generated by Block Predictor System 2.” *Id.*, 7:62-8:2.

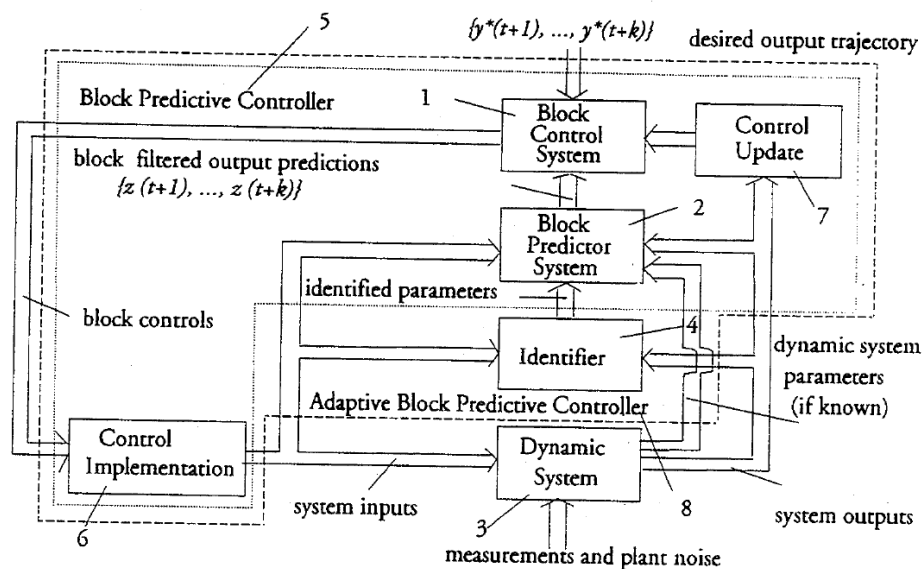


FIG. 1

Ex. 1014, FIG. 1

211. “The block of predicted outputs are based upon measurements of the system outputs of the Dynamic System 3, and either dynamic system parameters from 3, if known or identified parameters from the Identifier 4....” Ex. 1014, 8:3-9. “The Block Predictive Controller 5 consists of the Block Control System 1, the Block Predictor System 2, the Control Implementation 6 and the Control Update 7. The Block Predictive Controller 5 together with Identifier 4, comprises the Adaptive Block Predictive Controller 8.” *Id.*, 8:9-14. “This Adaptive Block Predictive Controller 8 resides within a computational engine....” *Id.*, 8:14-16; *see also id.*, 8:17-53.

212. In my opinion, a person of ordinary skill in the art would have been motivated and found it obvious to include in the Truitt-Kumar combination an extended horizon adaptive block predictive controller, similar to as taught in Dong. As Dong explained and consistent with the knowledge of a person of ordinary skill in the art, because a “dynamic system has an input-output delay, predictive controllers are used to account for such a delay. Ex. 1014, 1:49-54. “[P]redictive controllers that consider time horizons beyond the system input-output delay (extended horizon predictive controllers) have been used in engineering applications,” for example, to maintain “the system input-output stability.” *Id.*, 1:54-68. A person of ordinary skill in the art would have understood that Dong’s controller/system is beneficial because it “avoids computation of a large number of the predictor parameters associated with the prior art...method, so that memory requirements and computational complexity are significantly reduced.” *Id.*, Abstract; *see also id.*, 6:42-46 (“The subject invention contemplates a new and improved prediction system for multivariable dynamic system output prediction. The subject invention reduces run time and memory requirements.”) Thus, in my opinion, a person of ordinary skill in the art would have been motivated to implement such a controller in the Truitt-Kumar combination to control the PAP device without requiring significant memory resource or computational complexity while achieving system stability. This is particularly true because Truitt or Kumar does not expressly

disclose in detail its control system and thus a person of ordinary skill in the art implementing the Truitt-Kumar combination would have been motivated to implement an efficient controller, similar to that of Dong.

213. A person of ordinary skill in the art would have had the skill and a reasonable expectation of success in implementing features similar to those disclosed in Dong in the Truitt-Kumar combination. For example, Dong specifically discloses that “[t]here are many computational engines which can work in conjunction with the extended horizon adaptive block predictive controller with efficient prediction system,” such as microcontrollers/microprocessors, which the Truitt-Kumar combination already uses to control the PAP device. Ex. 1014, 19:5-9; Section VIII.A.3.c (discussions relating to controller 38 of a PAP device). Additionally, as a person of ordinary skill in the art would have recognized, the modification would have involved a combination of known technologies (e.g., known PAP device that includes sensors to monitor physiological information of a patient and a controller/processor to control the PAP operation based on the physiological information (Truitt-Kumar combination)) according to known methods (using an extended horizon adaptive block predictive controller capable of controlling a dynamic system associated with multiple input and output, like taught by Dong) to yield the predictable result of a system including a PAP device with an improved control without requiring significant memory resource or computational

complexity while achieving system stability, as discussed above. Accordingly, in my opinion, Truitt in view of Kumar and Dong discloses these limitations.

IX. SECONDARY CONSIDERATIONS

214. 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 '029 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.

X. CONCLUSION

215. 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.

Dated: January 10, 2025

By: 
Sandeep Chatterjee