

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

U.S. Patent No. 11,690,512

**DECLARATION OF DR. SANDEEP CHATTERJEE
IN SUPPORT OF PETITION FOR INTER PARTES REVIEW
OF U.S. PATENT NO. 11,690,512**

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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. 11,690,512 (“the ’512 patent”) (Ex. 1001).¹ I have been asked to consider whether certain prior art references disclose or suggest the features recited in claims 1-20 (“the challenged claims”) of the ’512 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 In this Declaration, I refer to exhibits that I understand are to be attached to the petition for *Inter Partes* Review of the ’284 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. 11,690,512 to Kayyali (“the ’512 Patent”)
Ex. 1002	File History of U.S. Patent No. 11,690,512
Ex. 1004	Curriculum Vitae of Jason Kirkness, Ph.D.
Ex. 1006	Curriculum Vitae of Sandeep Chatterjee, Ph.D.
Ex. 1007	U.S. Patent Application Publication No. 2003/0199945 to Ciulla (“Ciulla”)
Ex. 1008	World Intellectual Property Organization International Publication No. WO 2006/090371 to Orbach (“Orbach”)
Ex. 1009	U.S. Patent Application Publication No. 2002/0198473 to Kumar (“Kumar”)
Ex. 1010	U.S. Patent Application Publication No. 2006/0173257 to Nagai (“Nagai”)
Ex. 1011	U.S. Patent Application Publication No. 2003/0066529 to Truschel (“Truschel”)

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Ex. 1014	U.S. Patent Application Publication No. 2004/0016433 to Estes (“Estes”)
Ex. 1015	U.S. Patent No. 5,947,115 to Lordo (“Lordo”)
Ex. 1016	U.S. Patent No. 5,746,699 to Fredberg (“Fredberg”)
Ex. 1017	Specification of the Bluetooth System, Bluetooth, v1.0 B (Dec. 1, 1999)
Ex. 1018	U.S. Patent No. 5,684,460 to Scanlon (“Scanlon”)
Ex. 1019	U.S. Patent Application Publication No. 2004/0034293 to Kimball (“Kimball”)
Ex. 1020	U.S. Patent Application Publication No. 2008/0319277 to Bradley (“Bradely”)
Ex. 1021	U.S. Patent No. 6,712,762 to Lichter (“Lichter”)
Ex. 1022	U.S. Patent Application Publication No. 2002/0032386 to Sackner (“Sackner”)
Ex. 1023	U.S. Patent No. 6,083,156 to Lisiecki (“Lisiecki”)
Ex. 1024	U.S. Patent No. 4,825,872 to Tan (“Tan”)
Ex. 1025	U.S. Patent Application Publication No. 2006/0174871 to Jagger (“Jagger”)
Ex. 1030	U.S. Patent No. 6,236,906 to Müller (“Müller”)
Ex. 1031	U.S. Patent No. 5,774,113 to Barnes (“Barnes”)
Ex. 1032	U.S. Patent No. 5,002,170 to Parsons (“Parsons”)
Ex. 1033	U.S. Patent Application Publication No. 2003/0163054 to Dekker (“Dekker”)

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Ex. 1034	U.S. Patent No. 5,437,275 to Amundsen (“Amundsen”)
Ex. 1035	U.S. Patent No. 7,575,005 to Mumford (“Mumford”)
Ex. 1036	U.S. Patent Application Publication No. 2007/0208262 to Kovacs (“Kovacs”)
Ex. 1037	U.S. Patent Application Publication No. 2004/0133079 to Mazar (“Mazar”)
Ex. 1038	U.S. Patent No. 6,658,292 to Kroll (“Kroll”)
Ex. 1039	U.S. Patent No. 7,130,689 to Turcott (“Turcott”)
Ex. 1041	U.S. Patent Application Publication No. 2007/0002837 to Tan (“Tan”)
Ex. 1042	U.S. Patent Application Publication No. 2006/0283446 to Chua (“Chua”)
Ex. 1043	U.S. Patent Application Publication No. 2006/0224074 to Ouchi (“Ouchi”)
Ex. 1044	U.S. Patent Application Publication No. 2002/0029004 to Starr (“Starr”)
Ex. 1045	U.S. Patent Application Publication No. 2007/0273504 to Tran (“Tran”)
Ex. 1064	H. Colten, “Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem”, https://docs.wind-watch.org/Sleep-Disorders-Sleep-Deprivation.pdf (2006) (“Colten 2006”)
Ex. 1065	W. Flemons, “Home Diagnosis of Sleep Apnea: A Systematic Review of the Literature” CHEST, 124:1543-1579 (2003), (“Flemons 2003”)

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Ex. 1070	ResMed Corp.’s Opening Claim Construction Brief, <i>ResMed Corp., v. Cleveland Medical Devices</i> , Case No. 1:23-cv-02221-BMB (N.D. Ohio Nov. 25, 2024)
Ex. 1071	U.S. Patent Application Publication No. 2002/0185130 to Wright (“Wright”)
Ex. 1072	Japan Patent Office Patent Application Pub. No. P2002-291889A to Toge (“Toge”)
Ex. 1073	D. Gourley, et. al., HTTP The Definitive Guide (2002)
Ex. 1074	D. Mauro, et. al., Essential SNMP (2001)
Ex. 1075	F. Adelstein, et. al., Fundamentals of Mobile and Pervasive Computing (2005)
Ex. 1076	World Intellectual Property Organization International Publication No. WO0145014A1 to Quay (“Quay”)

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 ’512 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 ’512 patent was around June 2006, which corresponds to the filing date of the earliest application associated with the ’512 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 '512 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 '512 patent originates from U.S. Patent Application No. 11/454,482 filed on June 16, 2006.

21. I understand that Dr. Jason Kirkness² has opined that a person of ordinary skill in the art in 2006 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.

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. *See* Ex. 1004.

22. By 2006, 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 '512 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 June 2006. This is true even if stated in the present tense.

V. TECHNICAL BACKGROUND AND STATE OF THE ART

24. Below, I present a brief overview of systems and technology concepts that were well known to those of ordinary skill prior to the time of the alleged invention of the '512 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 '512 patent.

A. Mobile Computing

25. Well before 2006, 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 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

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>.)

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.

B. Web-based Resources

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. 1073 at p. 4.

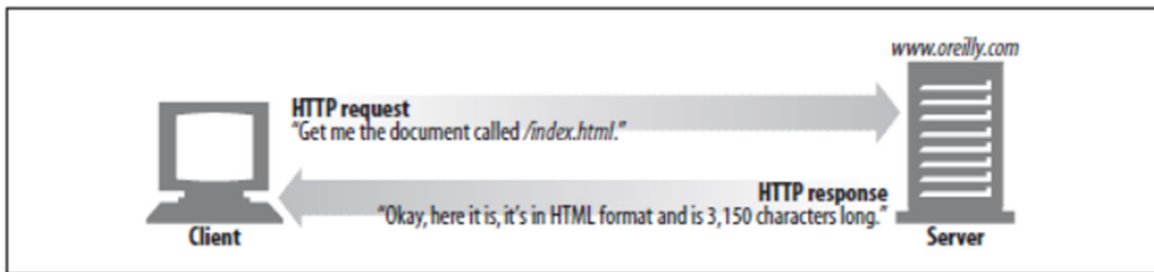


Figure 1-1. Web clients and servers

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.

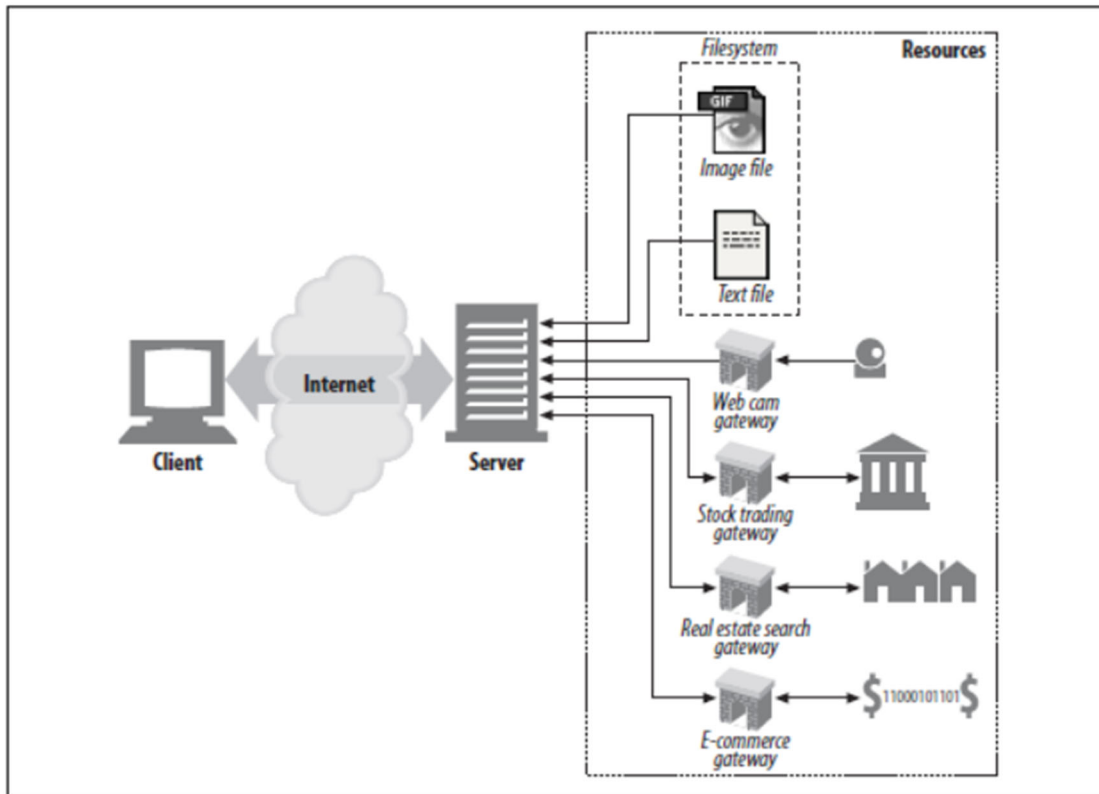


Figure 1-2. A web resource is anything that provides web content

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.

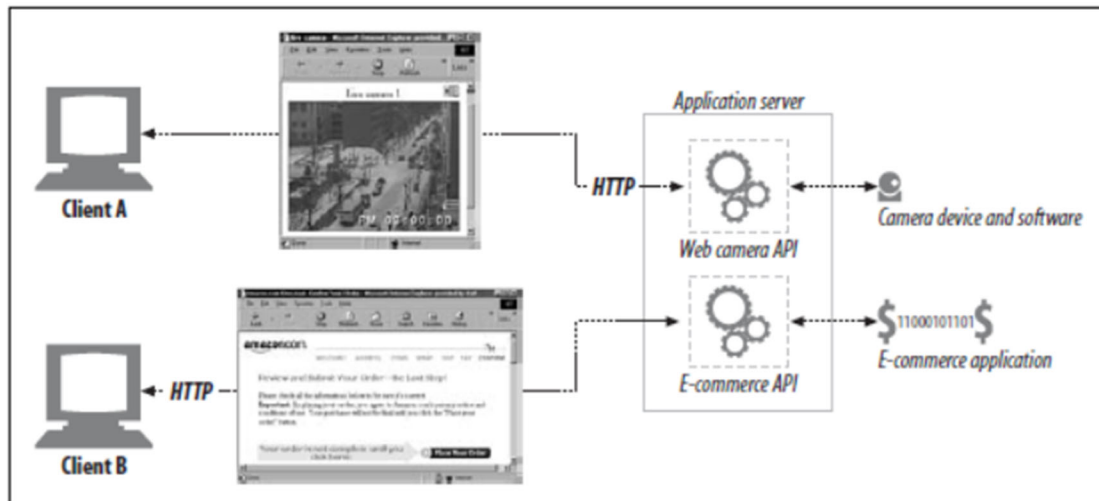


Figure 8-8. An application server connects HTTP clients to arbitrary backend applications

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.

C. 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. 1074 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

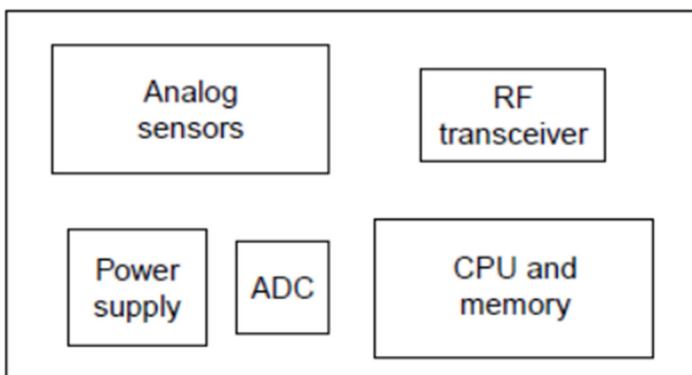
incorporated into the operating system. By the time of the publication of this book, most IP devices come with some kind of SNMP agent built in. The agent provides management information to the NMS by keeping track of various operational aspects of the device. For example, the agent on a router is able 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.

D. 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. 1075 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. 1075 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. Medical Applications

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. *See generally* Ex. 1064, Ch. 6; Ex. 1065. 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).

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.

E. Wired and Wireless Sensors

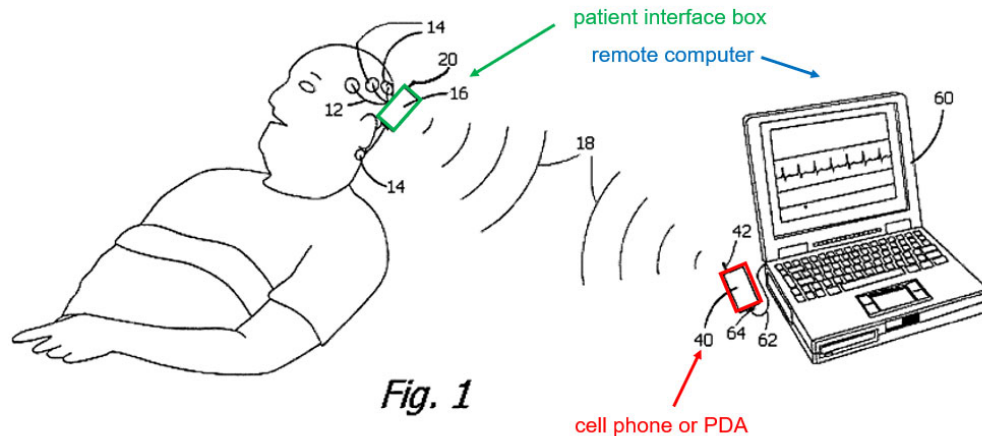
55. Sensors can be wired or wireless. Wired sensors communicate their data using a wired connection, while wireless sensors communicate their data using a wireless connection. This wireless connection can be through the use of any available protocol, such as Wi-Fi (802.11), Bluetooth, or a cellular protocol 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. 1076, 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. Wired connections may have advantages depending on the application. For example, if power is limited, a wired connection may be more power efficient.

VI. OVERVIEW OF THE '512 PATENT

57. The '512 patent a networked sleep diagnostic data acquisition system. The system includes a wearable patient interface box that acquires sleep data, a cell phone or PDA with software to receive the sleep data, and a remote computer to analyze the sleep data allow for diagnosis. Ex. 1001, Abstract, Fig. 1.

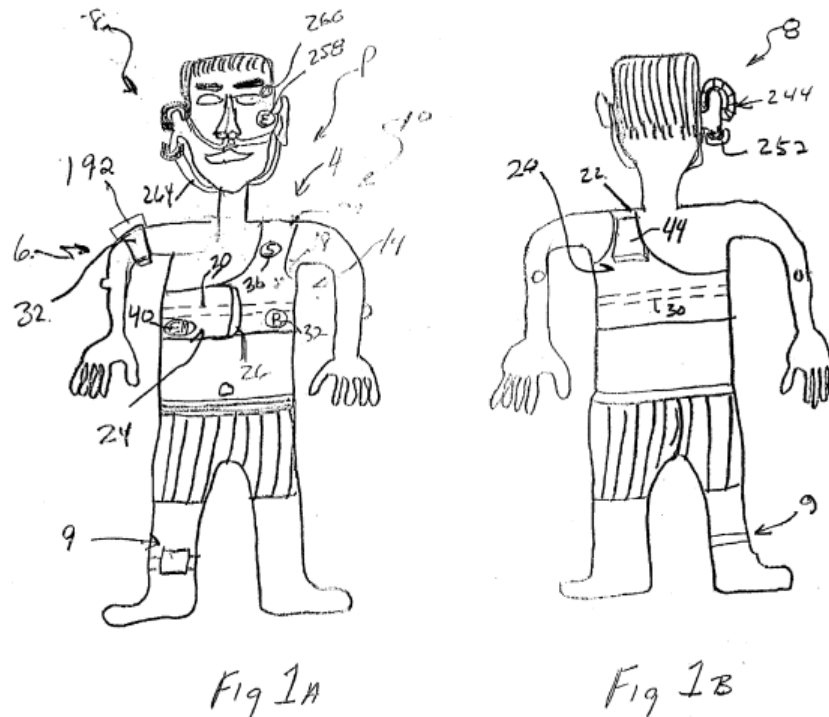


58. The patient interface box includes electrical components for receiving the electrical signals from sensors 14. *Id.*, 16:8-61. The patient interface box also includes a module that generates a signal 18 encoded with data to transmit to base station 40, which can be a cell phone or PDA. *Id.*, 16:16-21. The cell phone or PDA can then transmit the data to external programming means 60, which can be a remote computer. *Id.*, 16:45-54.

VII. OVERVIEW OF THE PRIOR ART

A. U.S. Patent App. Pub. No. 2003/0199945 to Ciulla (Ex. 1007)

59. Ciulla discloses all the limitations of independent claim 1 except transmitting its sensor data to a remote computer via a cell phone or PDA.



60. Ciulla discloses a wearable sleep disordered (SDB) treatment device. The SDB device includes a “main module 44 [] disposed on the back of the patient” that receives signals from sensors. *Id.*, [0100], [0117]-[0122], FIG. 8. These sensors can be hard-wired to the main module 44 or communicate wirelessly with main module 44. *Id.*, [0100], [0106], [0124], [0145].

61. The device also has “[a] clinical trial version [] designed to transmit the multiple sensors’ outputs wirelessly (RF, BlueTooth, WAN, LAN, IT Ethernet Modem or other)” and “incorporate[s] a wireless receiver allowing the researcher

to... observ[e] the patient's responses in a montage display format on the receiving computer's screen." *Id.*, [0213].

B. WO 2006/090371 to Orbach (Ex. 1008)

62. Orbach discloses transmitting sensor to a remote computer via a cell phone or PDA.

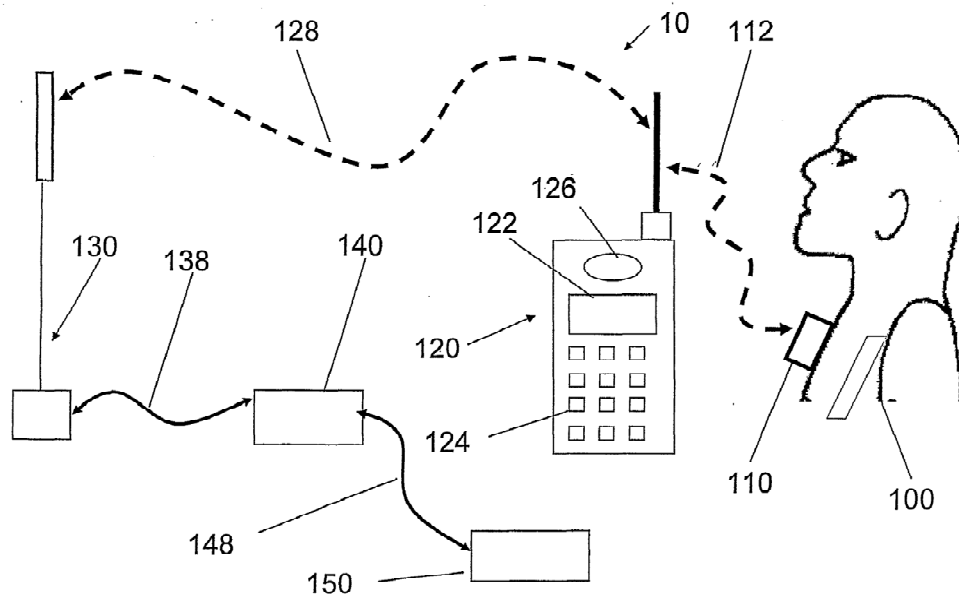


Fig. 1

63. Orbach discloses wearable sensor modules that measure physiological parameter data of a user. Ex. 1008, Abstract, FIG. 1, 13:21-14:2. The sensor modules can transmit the physiological data wirelessly to a mobile monitor, such as a cellular phone or PDA, for subsequent transmission to a remote server. *Id.*, 13:14-27, 16:13-20, 22:4-27. Analyzing the data at the remote server, an expert can

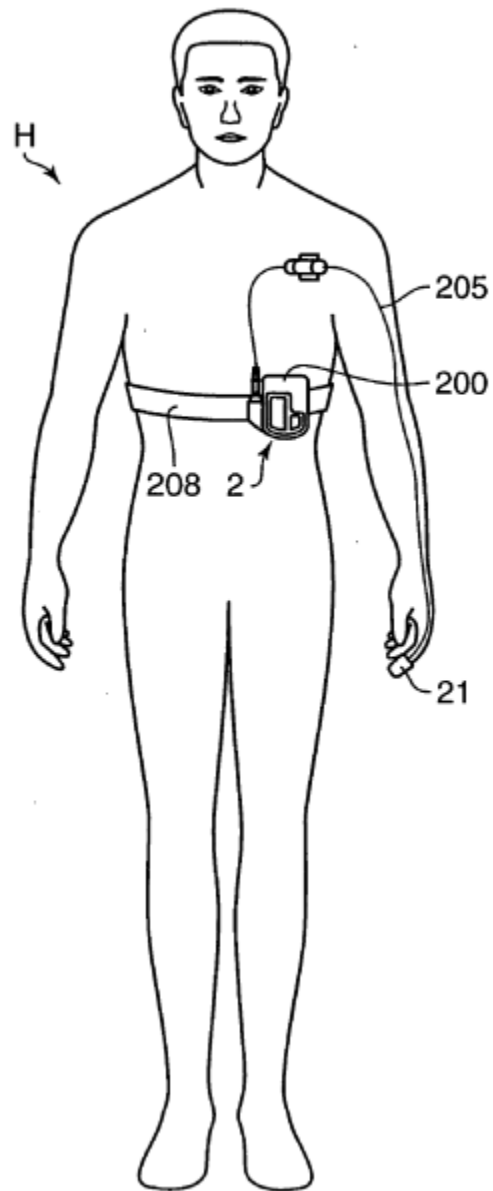
“help identify and possibly correct sleep disorders.” Ex. 1008, 13:14-14:2, 22:20-23:4, 41:25-27, 44:1-11.

C. U.S. Patent App. Pub. No. 2006/0173257 to Nagai (“Nagai”) (Ex. 1010)

64. To the extent not disclosed in Ciulla or Orbach, Nagai discloses a pulse oximeter that is *hardwired* as recited for limitation [1.b.iii.C] and [1.c.iii] and *releasably connected* as required for limitation [1.b.iii.C] and limitation [1.c.iii]. To the extent that claim 10 is interpreted to only require that the pulse oximeter and accelerometer is used, Nagai teaches such a system.

65. Nagai discloses a “sleep evaluation system” using two sensors—specifically, “a pulse oximeter 2 for concurrently or simultaneously measuring a blood oxygen saturation and a body angle of a subject for storing the measurement data” and “a three-axis acceleration sensor 22 serving as the body position detector 12.” Ex. 1010, [0057]-[0058]. The sensors are “detachably attached to the subject” through a probe cable 205. Ex. 1010, [0054], [0058]-[0060], Fig. 3.

FIG.3



D. U.S. Patent App. Pub. No. 2003/0066529 to Truschel (“Truschel”) (Ex. 1011)

66. Truschel discloses software to dynamically extract a snore signal using a filtering process as recited in claims 7 and 18. Truschel discloses a “snore analysis device 64” and “digital band pass filter 58.” Ex. 1011, [0043], [0046]. The system of Truschel modifies the “digital band pass filter 58 to further limit the qualifying range to a specific frequency range tailored for a particular patient.” *Id.*, [0051]. “For example, it has been found that snoring males tend to produce lower audible frequencies and snoring females tend to snore at higher audible frequencies.” *Id.* The system uses “archive sample snores for a given patient” to individualize the identification of the snore signal. *Id.*

E. U.S. Patent Pub. No. 2002/0198473 to Kumar et al. (Ex. 1009)

67. Kumar discloses a telemedicine system “for network-based monitoring of physiological data.” Ex. 1009, 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.”).

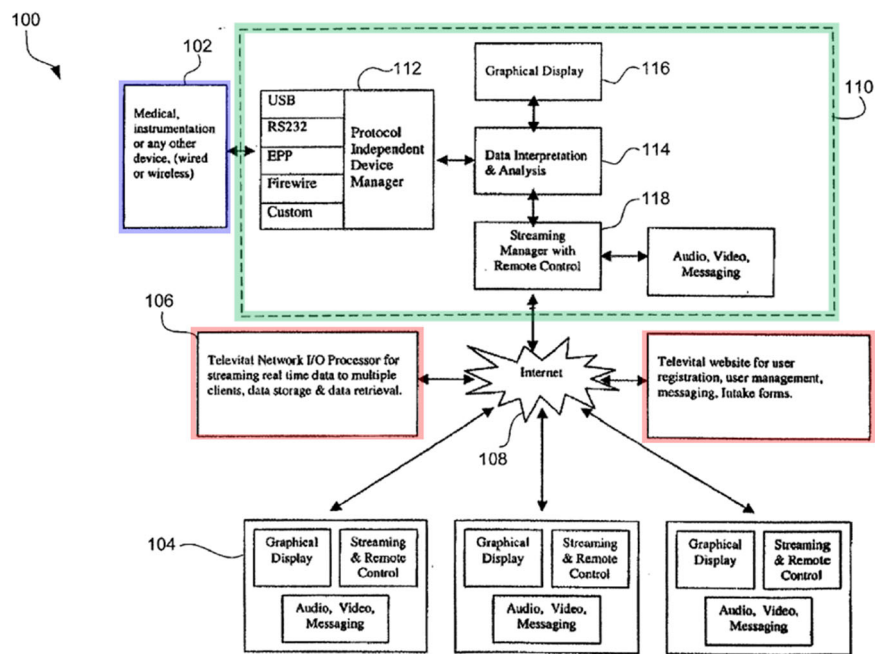


Fig. 1A

Ex. 1008, FIG. 1A

68. Kumar teaches that incorporating data acquisition devices “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]

VIII. CLAIM CONSTRUCTION

69. I understand that words are generally given their “ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of invention, i.e., as of the effective filing date of the patent application.” In my analysis, I have applied the ordinary and customary meaning of the terms and phrases to a person of ordinary skill in the art in question around 2006.

IX. ANALYSIS

A. Ground 1: Ciulla in view of Orbach Renders Obvious Claims 1-6, 8-17, and 19-20

1. Motivation To Combine

70. In my opinion, a person of ordinary skill in the art would have been motivated to improve the wearable sleep data acquisition system taught by Ciulla to transmit its sensor data to a remote computer for diagnosis as taught by Orbach.

71. In my opinion, a person of ordinary skill in the art would have been motivated to improve the wearable sleep data acquisition system taught by Ciulla by implementing it into a wider networked system as taught by Orbach.

72. In the early 2000s, there was a general market trend to implement consumer devices, like the sleep data acquisition system of Ciulla, into intelligent systems, like the networked system of Orbach. 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.

73. A system, like that described in Ciulla, would have been ready to implement into an intelligent system given that this was an option that Ciulla suggested. In particular, Ciulla taught that its data acquisition device has “[a] clinical trial version [] designed to transmit the multiple sensors’ outputs wirelessly (RF, BlueTooth, WAN, LAN, IT Ethernet Modem or other)” and “incorporate[s] a wireless receiver allowing the researcher to... observ[e] the patient’s responses in a

montage display format on the receiving computer's screen." Ex. 1007, [0213]. Specifically, Ciulla taught that that it would have been beneficial to transmit the sleep data to a remote computer, disclose that the device's microprocessor can "directly transmit [analysis] reports by IT to the therapist's computer and/or the company's main frame system for further analysis, research or documentation." *Id.*, [0214].

74. A person of ordinary skill in the art trying to improve Ciulla would have naturally looked at design options that would have taught how to implement a data acquisition device into a networked data system like Orbach. In particular, Orbach provides a number of applications, uses, and benefits to transmitting sensor data to a mobile monitor like a cell phone or PDA. For example, Orbach teaches that the system can be "programmed to alert the user or someone else when certain conditions occur." Ex. 1008, 38:24-25. By way of another example, "the system may be used to record physiological reading while the user is sleeping in order to help identify and possibly correct sleep disorders." *Id.*, 41:25-27.

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 data acquisition system of Ciulla in an intelligent environment, like that of Orbach, 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, Orbach expressly teaches that “[t]he mobile monitor includes a processor processing the signals received from the transmitter in real time using expert knowledge.” Ex. 1008, Abstract; *see also* 25:27-29 (“The users can receive feedback in real time directly from the system by audio-visual feedback in real time, and at the same time the system can transmit the information to an expert or coach who can help them improve their reactions.”). 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.

80. 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. Orbach teaches that providing real-time access to data “can be relevant for health issues -e.g. a child with asthma who can get feedback in time from the system and/or physician.” Ex. 1008, 25:29-26:2.

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 Ciulla wearable data acquisition device in a networked system as taught by Orbach.

83. First, a person of ordinary skill in the art would have understood that combining the teachings of Ciulla and Orbach to implement an intelligent sleep diagnostic data acquisition system would have been a simple matter of embedding appropriate wireless transceivers into the wearable data acquisition device of Ciulla, which is already suggested by Ciulla itself. Ciulla discloses that “wireless transmitter/receiver within the main back module could be used to transfer data to (or from) the data recorder. . . . so that the data[a] could be reported in real time and displayed in real time at a location spatially removed from the main back module, such as a room next door from the room in which the patient is sleeping.” Ex. 1007, [0125]; *see also* [0230] (“The system is also designed to permit total monitoring, control and analyses to be performed in a different location from where the patient is sleeping by being capable of transmitting data it obtains at any distance, either wirelessly or by a modem.”). A person of ordinary skill in the art would have understood that a short-range connection to a cell phone or PDA would have been ideal for sending data “a room next door.”

84. Orbach similarly teaches that a number of different protocols can be used to wirelessly transmit the data from a sensor module to a cellular phone or PDA, include Bluetooth, WiFi, or Wireless LAN. Ex. 1008, 5:22-27. This is

consistent with my discussion in Section V.E (Wired and Wireless Sensors) of the known design options at the time.

85. Second, the sensors of Ciulla 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, Orbach and other sensor diagnostic systems already included wireless transceivers to communicate signals from the sensors:

This invention utilizes portable,, cordless wearable sensors, which enable users to monitor their emotional and physiological responses to events as they occur. These results, gathered in real time, may be more effective and relevant to the user than those recreated days later under completely different conditions. The sensors of the invention utilize mobile phones to display the user's physiology and emotional state.

Ex. 1008, 42:13-17; *see also* Ex. 1071, [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.”); Ex. 1072, 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).

86. Third, the modification would have involved a simple installation of wireless transceivers and software. 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

“1. A sleep diagnostic data acquisition system comprising”

87. In my opinion, Ciulla in view of Orbach discloses the preamble to the extent that it is limiting.

88. In particular, a person of ordinary skill in the art would have found it obvious to modify the sleep diagnostic data acquisition system of Ciulla to transmit its sensor data to a cellular phone or PDA to relay that data to a remote computer to analyze the data and diagnose sleep disorders as taught by Orbach. This combinations would have resulted in the *sleep diagnostic data acquisition system* of claim 1.

89. Ciulla discloses a wearable sleep disordered breathing (SDB) treatment device. Ex. 1007, Figs. 1B, 8. In particular, Ciulla discloses that the sensor data can be used for “the detection of a sleep breathing disorder event.” Ex. 1007, [0123]; *see also* [0128] (“The output data can be time correlated with the input data to give the researcher or medical practitioner a chronologically-based

report that reflects the user's sleep pattern, including the user's quiescent sleep episodes, and the user's sleep disordered breathing event episodes.”). Ciulla further explains that the sleep data can be used for diagnosis by adjusting the device “to serve as a diagnostic or screening device for SDB [sleep disordered breathing].” *Id.*, [0219].

90. Similarly, Orbach discloses “wearable sensor modules sensing . . . physiological parameters.” Ex. 1008, Abstract. Orbach further discloses that “transmitters wirelessly transmit signals indicative of values of the one or more physiological parameters to a mobile monitor.” *Id.* “[A] communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.” *Id.*, 13:21-23.

91. Incorporating the Ciulla wearable device into a networked system as taught in Orbach would have been driven by the mobile computing and pervasive computing trends at the time. *See* Sections V.A (Mobile Computing) and V.D (Pervasive Computing).

b. Limitation [1.a]

[1.a] “*a) a first software stored on a non-transitory computer readable medium and executable by a first processor, the software configured to be loaded on a cell*

phone or Personal Digital Assistant (“PDA”) comprising at least one first wireless transceiver and the first processor;”

92. In my opinion, Ciulla in view of Orbach discloses this limitation.

93. As discussed in the preamble, Ciulla discloses a wearable sleep disordered breathing (SDB) treatment device. Although Ciulla does not expressly disclose that its SDB treatment device transmits sensor data to a cell phone or PDA, this feature would have been obvious in view of the teachings of Orbach.

94. Orbach discloses a mobile monitor (*cell phone or Personal Digital Assistant (“PDA”)*). In particular, Orbach discloses a sensor module that transfers sensor data to the mobile monitor. “[A] communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.” Ex. 1008, 13:21-23. Orbach specifically discloses that “[i]n one preferred embodiment, the mobile monitor 120 is ***a cellular phone or a Personal Digital Assistant (PDA)***.” *Id.*, 22:5-6; *see also* 4:21-24 (“The mobile monitor may be selected, for example, from the group comprising: (a) a cellular phone; (b) a personal digital assistant (PDA)”). Orbach also discloses that in Figure 1, “the mobile monitor is ***a cellular phone***” and “communication link

128 is cellular RF link to a cellular base station 130 which is linked to a remote server 140 by a data link 138.” *Id.*, 13:24-27.

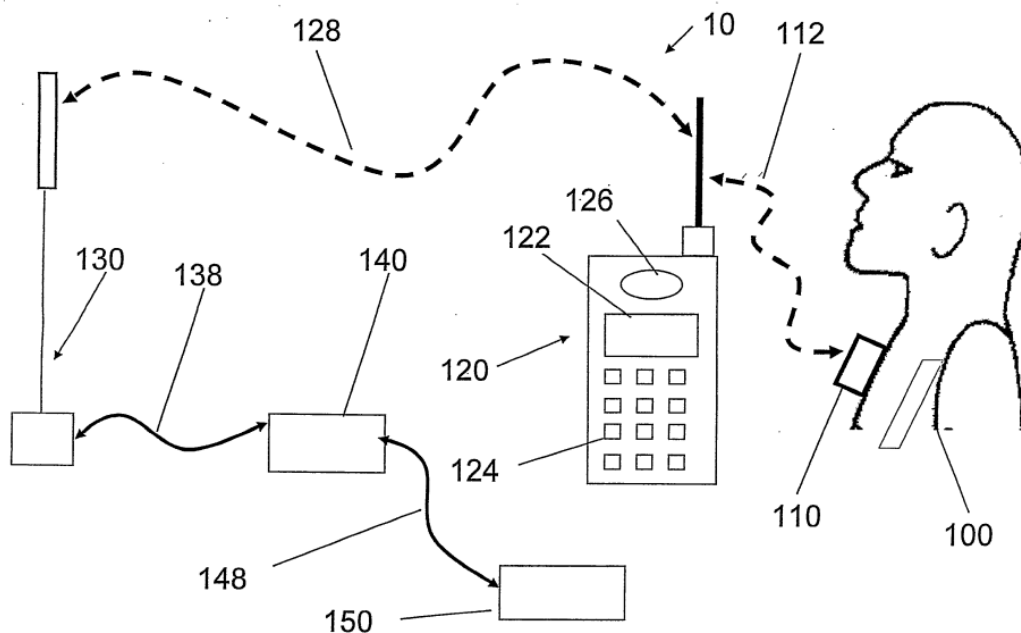


Fig. 1

Ex. 1008, Fig. 1

95. Orbach discloses that the mobile monitor (*cell phone or Personal Digital Assistant (“PDA”)*) includes a communication means (*comprising at least one first wireless transceiver*). Orbach discloses that “the mobile monitor 120 is a cellular phone or a Personal Digital Assistant (PDA) equipped with . . . means to communicate with both sensor module and remote server.” Ex. 1008, 22:5-9; *see*

also 22:22-23 (“the [m]obile monitor is equipped with means to connect to a remote server wirelessly over the cell network preferably using the Internet.”).

96. A person of ordinary skill in the art would have understood that wireless transceiver was necessary to connect over the cell network. A wireless transceiver is an electronic device that both receives and transmits radio frequency signals. When a cell phone is used, it will emit a radio frequency signal through a wireless transceiver to a 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. *See* Ex. 1041, [0007]; Ex. 1012, [0004] (“Cellular telephone systems...minimally include...cell towers.”); Ex. 1013, [0011] (similar).

97. 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 (Mobile Computing) and V.E (Wired and Wireless Sensors). Wireless transceivers were becoming pervasive to allow more convenient and access to data. *See* Section V.D (Pervasive Computing).

98. 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 device and for data communication. A Wi-Fi-enabled radio frequency wireless transceiver would have allowed a sensor device to connect to the cell phone for uploading data. A GSM- or GPRS-enabled, or other cellular network-enabled, radio frequency wireless transceiver would have allowed the device to communicate with a remote server if a Wi-Fi network is not available.

99. Orbach discloses that the mobile monitor (*cell phone or Personal Digital Assistant ("PDA")*) includes a processor (*comprising . . . the first processor*). Orbach discloses that “[t]he mobile monitor includes a processor processing the signals received from the transmitter [of the sensor module].” Ex. 1008, Abstract; 3:14-16 (“the mobile monitor, wherein the mobile monitor comprises: a first processor processing the first signals received from the transmitter”).

100. Orbach discloses that a program loaded on the mobile monitor to interface with the sensor module (*a first software . . . software configured to be loaded on a cell phone or Personal Digital Assistant (“PDA”)*). Orbach discloses that “[s]pecific programs necessary for interfacing with the sensor module and for providing feedback to the user may be uploaded by the user.” Ex. 1008, 22:10-11. Orbach explains that the program is *configured to be loaded on a cell phone or Personal Digital Assistant (“PDA”)* because “the program may be loaded into a cellular phone wirelessly in the same way a new game or ring tone is loaded.” *Id.*, 22:11-13.

101. Orbach discloses that the program is stored in the memory of the mobile monitor (*first software stored on a non-transitory computer readable medium*). Orbach discloses that “[i]n the case where the mobile unit 120 is a cellular phone, the data analysis and screen display may be created by an application ***loaded into the cellular phone memory***.” Ex. 1008, 33:24-26.

102. A person of ordinary skill in the art would have understood that the application referenced by Orbach is part of the program. Orbach explained that “[s]pecific programs necessary . . . for providing feedback to the user may be uploaded by the user.” Orbach similarly discloses that the application to display

information to the user can be loaded on the cellular phone. At the relevant time, software, program, and application were often used interchangeably to refer to the entire software or parts of the software.

103. A person of ordinary skill in the art would have understood that the cellular phone memory is *a non-transitory computer readable medium*, such as a ROM, EEPROM, flash memory or other non-volatile memory. At the relevant time, to store code (instructions to execute software) and later execute that code, an electronic device would have needed a non-transitory computer readable medium (such as a ROM, EEPROM, flash memory or other non-volatile memory).

104. Orbach discloses that the program is executed by the processor in the mobile monitor (*first software . . . executable by a first processor*). Orbach discloses that “[i]n the case where the mobile unit 120 is a cellular phone, the data analysis and screen display may be created by an application loaded into the cellular phone memory and *executed by the processor within the cellular phone*.”

Ex. 1008, 33:24-26.

c. Limitations [1.b]

[1.b] *“b) a portable, wearable patient interface box adapted to be secured to a subject at a first location and providing a single device for measuring and then wirelessly transferring sleep data from at least two sensors used for diagnosing sleep disorders, the portable, wearable patient interface box comprising:”*

105. In my opinion, Ciulla in view of Orbach discloses this limitation.

106. Ciulla discloses sleep device 10, which includes a main module 44 (*patient interface box*). I note that the '512 patent explains that “an interface box . . . is preferably used to protect one or more electrical components and allow for the connection of various sensors to the electrical components inside the box.” Ex. 1001, 7:15-19.

107. Like the '512 patent, Ciulla explains that the main module 44 is used to protect electrical components and allows for the connection of various sensors to the electrical components inside the main module 44. In particular, Ciulla explains that “[t]he main module 44 includes a case 50 . . . [that] houses the electronic circuitry that comprises the “brains” of the device 10, the most component [sic] of which is the processor.” Ex. 1007, [0101]. A person of ordinary skill in the art would have understood that housing is used to protect the components inside the housing, especially given the description of housing the “brains” of the device. Ciulla further explains that “various sensor inputs are received by the

microprocessor from the various sensors, and various output commands are delivered to the various output devices.” *Id.*, [0126].

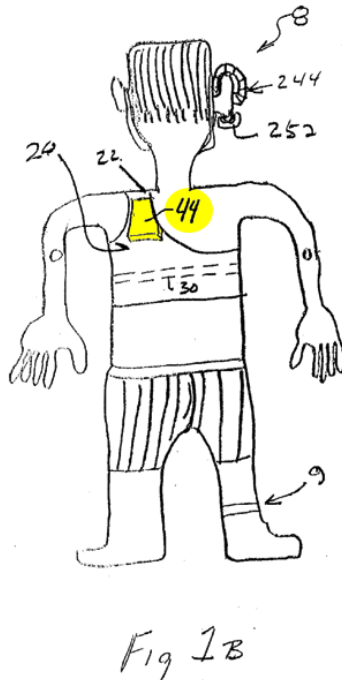
108. The main module 44 further interfaces with the patient. In particular, Ciulla discloses that main module 44 includes input and output devices to interface with the patient. For example, Ciulla explains that main module 44 “contains a LCD display screen 62” that “may be a touch screen so that the screen 62 also serves as an input device.” Ex. 1007, [0103]. “Alternatively, an input device 66 can also be placed on the base of the main module.” *Id.* The input device 66 can be a “12-button touch pad 68 . . . that permits the user to input information into the main module.” *Id.*, [0104].

109. Ciulla discloses that the main module 44 (*patient interface box*) is *portable, wearable* and *adapted to be secured to a subject at a first location*. As I discussed above in Section V.A (Mobile Computing) and Section V.D (Pervasive Computing), advances in semiconductors, form factors, and power sources like batteries enabled electronic devices to be more mobile, and thus more portable and wearable. Ciulla picks up on this trend, explaining that “[a] power source, such as a plurality of batteries provide the power for the main module 44 to operate.” Ex. 1007, [0102]. With batteries, instead of a wired power source, “[t]he device [] does

not need to be removed if the patient gets up, walks around or changes the place they are sleeping in.” *Id.*, [0185]. Ciulla further explains that the batteries allows the device to be portable, so that “[p]atients can site in their living room and watch television or read, etc. and not worry about falling asleep without having their SDB treatment device on and activated.” *Id.*

110. The advancements in form factors also allowed wearable electronic devices to be more practical. Electronic devices could be smaller and lighter. *See, e.g.*, [0072] (“[I]t is likely that the use of a smaller, less intrusive and obstructive device is that it is likely to result in greater patient compliance, when compared to a larger, bulkier, more uncomfortable device, especially if that device is to hooked up, connected to, or worn by the user during the user's sleep.”). Again, Ciulla picks up on this trend, disclosing that the main module 44 (*patient interface box*) is worn (*wearable*) by securing the device “on the back of the patient” (*adapted to be secured to a subject at a first location*). Ex. 1007, [0100]; *see also* [0078] (“showing a patient **wearing** the sleep disordered breathing treatment device of the present invention”), [0078] (“a rear-view of a patient wearing the sleeping device”), [00183] (“The preferred embodiment can be designed to be wearable during the day or kept in a manner that is basically invisible to other people when

worn under a shirt or pajama, unless an embodiment utilizing a small oral-nasal canula is employed.”), Fig. 1B.



Ex. 1007, Fig. 1B (annotated)

111. Ciulla discloses the main module 44 *providing a single device for measuring and then wirelessly transferring sleep data from at least two sensors.* Ciulla discloses that the main module 44 measures sleep data from at least two sensors (*measuring . . . from at least two sensors*). Ex. 1007, Abstract (“The device includes a processor for receiving sensor inputs, [and] processing the received sensor inputs”), [0098] (“A plurality of sensors are fixedly coupled to the chest engaging shoulder wrap 14.”), [0100] (“Each of the sensors described above,

Declaration of Dr. Sandeep Chatterjee
U.S. Patent No. 11,690,512

including chest sensor 30, snoring sensor 36, breathing sensor 32 and EMG sensor 40 are provided with either a hard wire or wireless communication, to provide input to the main module 44 of the device 10.”); *see also* Fig. 3.

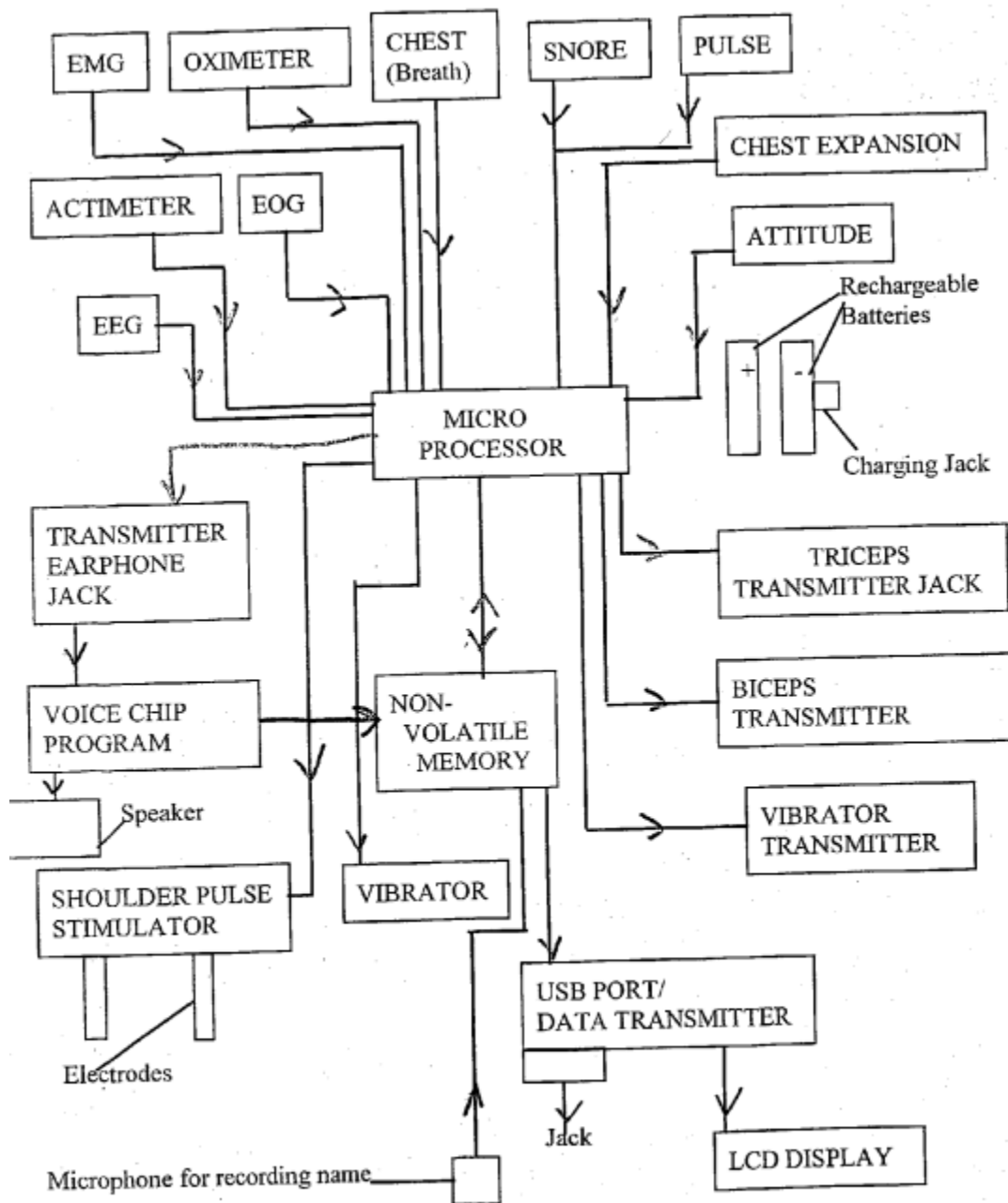


Fig. 3

112. The data from the sensors relates to the user's sleep. *See, e.g., id.*, [0060] ("The first, second and third sensors, and the first and second output devices are operatively coupled to the processor to permit the processor to receive information input from the sensors, process the input information to detect the existence of a sleep-breathing disorder event, and to generate command to at least one of the first and second output devices."), [0123] ("Upon the detection of a sleep breathing disorder event, outputs are transmitted to one or more of the various output devices that are coupled to the unit."), [0128] ("downloading data . . . about the condition of a patient during a sleeping episode. This information can include . . . the information sensed from the patient"), [0230] ("total monitoring, control and analyses to be performed in a different location from where the patient is sleeping").

113. Ciulla discloses that the main module includes a transmitter/receiver/antenna 92 for wireless transferring sleep data from at least two sensors (*wirelessly transferring sleep data from at least two sensors*). In particular, Ciulla discloses "[a]n internal, transmitter/receiver/antenna 92 [that] is provided for enabling the main module 44 to communicate wirelessly with the various sensors and output devices of the present invention." Ex. 1007, [0106].

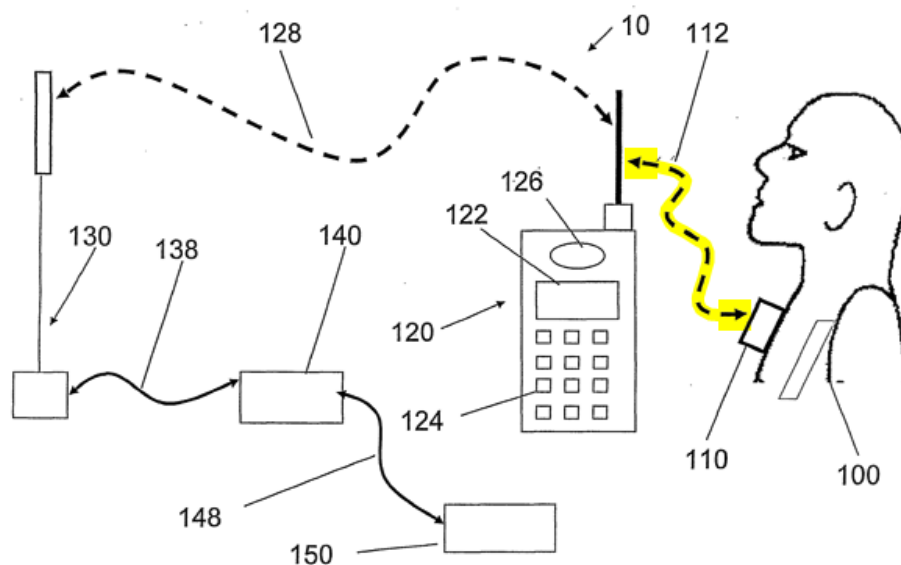
114. Ciulla discloses that the sensor data (*sleep data*) is used for *diagnosing sleep disorders*. In particular, Ciulla discloses that the sensor data can be used for “the detection of a sleep breathing disorder event.” Ex. 1007, [0123]; *see also* [0128] (“The output data can be time correlated with the input data to give the researcher or medical practitioner a chronologically-based report that reflects the user's sleep pattern, including the user's quiescent sleep episodes, and the user's sleep disordered breathing event episodes.”). Ciulla further explains that the sleep data can be used for diagnosis by adjusting the device “to serve as a diagnostic or screening device for SDB [sleep disordered breathing].” *Id.*, [0219].

115. Ciulla discloses that the main module 44 is a single device that measures and wirelessly transmits the sensor data (*providing a single device for measuring and then wirelessly transferring sleep data*). Like the '512 patent which “allow for the connection of various sensors to the electrical components inside the box” (Ex. 1001, 7:15-19), Ciulla explains that the main module 44 connects to sensors to measure sleep data and includes “a radio frequency transmitter and receiver for wireless communication.” Ex. 1007, [0102].

116. To the extent Ciulla does not explicitly disclose wirelessly transferring sleep data or a portable, wearable patient interface box, Ciulla in view of Orbach discloses this limitation.

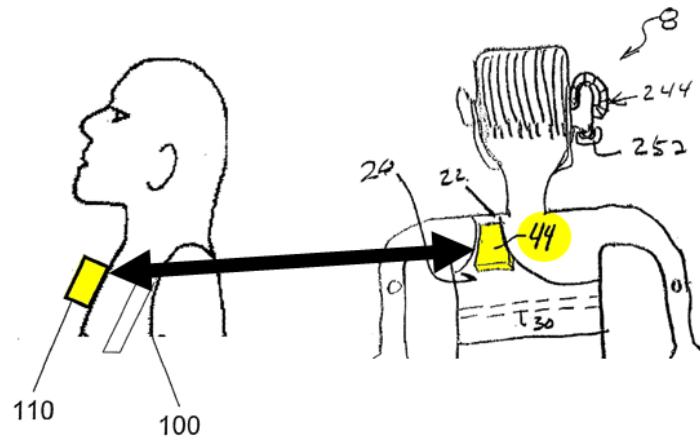
117. The sensor module 110 of Orbach and the Ciulla's main module 44 are similar. Orbach discloses that the sensor module 110 transmits sensor data wirelessly over a "Bluetooth" communication link 112 to a cell phone (*wirelessly transferring*). Ex. 1008, 13:14-27 (link 112 is "Bluetooth"), 15:9-15 (link is for "blue-tooth" bidirectional wireless communication), 16:9-20 (transmitted data is "information indicative of the user's physiological state"), 22:20-27, 41:13-15,

FIG. 1.



Ex. 1008, FIG. 1 (wireless communication between cell phone 120 and sensor module 110). The data is sleep data because it is used to “help identify and possibly correct sleep disorders.” Ex. 1008, 41:25-27, FIG. 1.

118. Orbach discloses that the sensor module 110 is a *portable, wearable patient interface box*. Figures 1 and 2 of Orbach illustrate that the user wears the sensor module 110 as a single device on the user’s chest. The sensor module 110 can be attached to another part of the body (*wearable*) and includes a battery 360 such that measurements can be taken at various locations (*portable*). Ex. 1008, FIGs. 1-3, 13:14-16:20. The sensor module 110 couples to various sensors, including a Plethysmograph Electronics 320 and “additional sensors 372,” “to monitor” and “measur[e]” physiological signals as a patient interface that are wirelessly transmitted (*measuring and then wirelessly transferring*). Ex. 1008, FIGs. 1-3, 13:14-16:20, 13:14-27, 15:9-15, 16:9-20, 22:20-27, 41:13-15. The sensor module 110 box includes indicator 380 that “provid[ing]es visual or audio indication as to the [module] status” to the monitored patient (*patient interface*). Ex. 1008, 15:4-8.



Ex. 1008, FIG. 1 (annotated and excerpted) (left); Ex. 1007, FIG. 1B (annotated and excerpted) (right).

d. Limitation [1.b.i]

[1.b.i] “*i) an enclosure of a rigid material;*”

119. In my opinion, Ciulla discloses this limitation. In particular, Ciulla discloses that case 50 that houses the electronic circuitry of main module 44 (*an enclosure of a rigid material*). Ex. 1007, [0101], [0103]-[0104], FIG. 8.

120. A person of ordinary skill in the art would understand that a case that is housing electronic components must be made of rigid material. Cases, such as a computer case or the casing of a cellular phone, are used to protect the electronic components inside from damage, especially connections between different circuits. It is especially important for case 50 to be made of rigid material since “the main module [is] over the scapular area” where the user

e. Limitation [1.b.ii]

[1.b.ii] “*ii) a battery;*”

121. In my opinion, Ciulla discloses this limitation. In particular, Ciulla discloses that the main module 44 (*patient interface box*) includes a power source, such as a plurality of batteries (*a battery*)

122. As discussed in limitation [1.b], Ciulla discloses “[a] power source, such as a plurality of batteries provide the power for the main module 44 to operate.” Ex. 1007, [0102]. Ciulla explains that the power source is one of the “[a]dditional componentry” that is housed within case 50 of main module 44. *Id.*

f. Limitation [1.b.iii]

“*iii) [1.b.iii.A] one or more electrical components within the portable, wearable patient interface box for receiving electrical signals from the at least two sensors, the one or more electrical components include a signal processing unit for receiving the electrical signals from the sensors, [1.b.iii.B] the at least two sensors which are attached to the subject and/or within the portable, wearable patient interface box that is secured to the subject, [1.b.iii.C] the at least two sensors further which are hardwired to connect through at least one connector of the portable, wearable patient interface box and/or are built within the portable, wearable patient interface box, the signal processing unit configured for receiving and processing the sleep data from one or more input channels; and*”

123. In my opinion, Ciulla alone or in combination with the knowledge of a person of ordinary skill in the art discloses this limitation.

124. Ciulla discloses electronic circuitry to receive the signals from the at least two sensors I identified in limitation [1.b] (*one or more electrical components . . . for receiving electrical signals from the at least two sensors*). “Each of the sensors . . . are provided with either a hard wire or wireless communication, to provide input to the main module 44 of the device 10.” Ex. 1007, [0100]. And as discussed, Ciulla discloses the “main module 44 includes a case 50 . . . [which] houses the electronic circuitry.” *Id.*, [0101]. A person of ordinary skill in the art would have understood that the sensors would have communicated signals to the electronic circuitry of the main module.

125. Ciulla discloses that electronic circuitry is housed within main module 44 (*one or more electrical components within the portable, wearable patient interface box*). Specifically, as discussed, Ciulla discloses the “main module 44 includes a case 50 . . . [which] houses the electronic circuitry.” Ex. 1007, [0101].

126. Ciulla discloses that the electronic circuitry includes a processor for receiving signals from the sensors (*one or more electrical components include a signal processing unit for receiving the electrical signals from the sensors*). Ciulla discloses that “the electronic circuitry [] comprises the ‘brains’ of the device 10, the most component [sic] of which is the processor.” Ex. 1007, [0101]. Ciulla

reiterates that the processor “is the ‘heart and brains’ of the device, that is provided for receiving a wide variety of inputs from various sensors, [and] processing the input so received.” *Id.*, [0126]; *see also* Fig. 3.

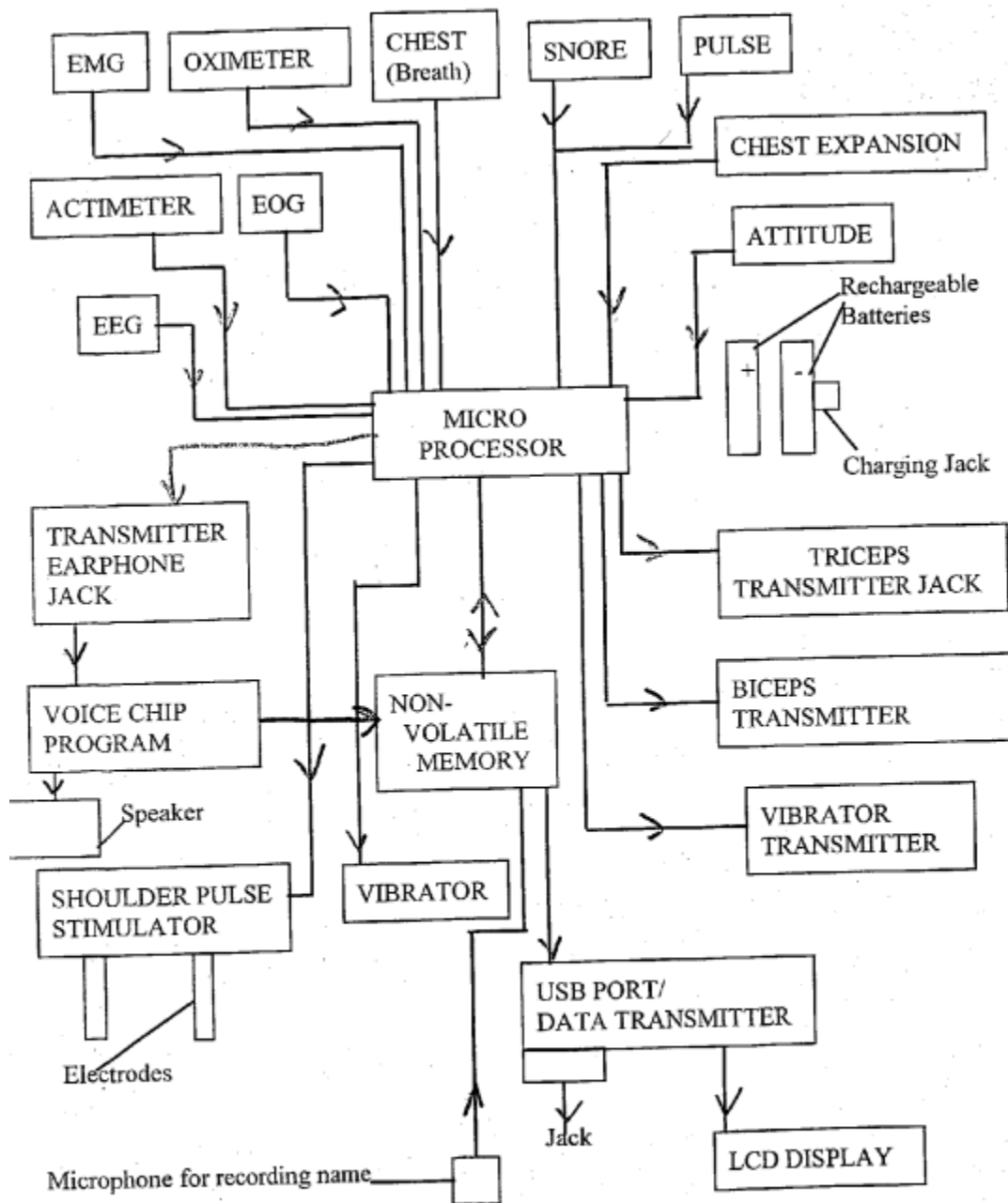


Fig. 3

127. Ciulla discloses that *the at least two sensors which are attached to the subject* and that *the at least two sensors which are within the portable, wearable patient interface box that is secured to the subject*. First, a snore sensor is also secured on the chest. For example, a chest expansion sensor 30 that attaches around the patient's chest. Ciulla explains "[t]he sensors include a chest expansion sensor 30, that essentially comprises a tubular member that extends around the chest, and is utilized to measure the expansion of the chest, which provides an indication of the breathing, (or lack thereof) being performed by the patient." Ex. 1007, [0098], Fig. 1B.

128. Ciulla also discloses that the oximeter can attach to the ear, finger, or toe of the patient. Ex. 1007, [0118] ("sensors that can be coupled to the ear-engaging processing unit 238 include an earlobe oximeter 252, that is provided for sensing the oxygen saturation of the user's blood"), [0202] ("an oximeter (with probe on finger, earlobe, or toe)").

129. Ciulla further discloses numerous other sensors attached to the patient:

A breathing sensor 32 is positioned adjacent to the chest cavity of the patient, and functions similarly to a stethoscope, insofar as it senses breathing sounds. A snoring sensor 36 is positioned on the shoulder portion

22, to detect snoring sounds and breathing sounds emitted from the mouth and nose of the patient. Snoring sensor 36 essentially comprises a microphone. An EMG sensor 40 may be placed upon the chest or strap portion.

Ex. 1007, [0099]; *see also* [0143] (“snore sensor is also secured on the chest”).

130. Second, Ciulla discloses that the sensors are *within the portable, wearable patient interface box that is secured to the subject*. Ciulla discloses that “breath sounds monitor, snore monitor, heart rate monitor an attitude indicator, and/or chest expansion module, may be designed to be incorporated ***within the main back module*** as a part thereof.” Ex. 1007, [0124]; *see also* [0143] (“the attitude sensor is made a part of the CPU containing main module”). As discussed in limitation [1.b], the main module is attached to the patient’s scapular area.

131. Ciulla discloses that the sensors are hardwired connected through ports 96 of the main module (*the at least two sensors further which are hardwired to connect through at least one connector*). Ciulla discloses that “breath sounds monitor, snore monitor, heart rate monitor, an attitude indicator, and/or chest expansion module, may be designed to be incorporated within the main back module as a part thereof, and as such, would be connected to the main back module for a ***hard-wired connection***.” Ex. 1007, [0124]. Ciulla further explains “[a] plurality of jacks and/or plug receivers and/or ports (collectively referred to herein

as “ports”) 96 are provided on the main module 94 for enabling the main module 44 to be hard-wired to various sensor-type input device.” *Id.*, [0106]; *see, e.g.*, Ex. 1019, FIG. 1, [0035] (interconnect coupling a sensor to a signal processing unit); Ex. 1020, [0024] (connecting a processor/recorder to a nasal cannula or a SpO₂/pulse finger sensor), [0040], FIG. 1; Ex. 1021, 11:16-38 (pulse oximeter cable connected to a pulse oximeter finger clip), 12:53-56 (nasal cannula or thermistor provides input to a pressure sensor), FIGs. 7, 10; Ex. 1022, [0086] (a signal cable connected to a pulse oximeter); Ex. 1023, 7:5-9 (describing a finger pulse oximeter as a standard oximeter), FIG. 2); Ex. 1024, 1:9-19, FIG. 1, 2:65-3:3 (multiwire cable attached to a finger sensor); Ex. 1025, [0092], [0106] (wire connected to a nasal pressure sensor).

132. Ciulla discloses that the processor is configured to receive sleep data from the various communication channels with the sensors (*the signal processing unit configured for receiving and processing the sleep data from one or more input channels*). Again, Ciulla discloses that the processor “is the ‘heart and brains’ of the device, that is provided for receiving a wide variety of inputs from various sensors, [and] processing the input so received.” *Id.*, [0126]; *see also* Fig. 3. As

discussed on limitation [1.b], the data received from the sensors relate to sleep. *See* Section IX.A.3.c.

133. The data is sent through various connections, which a person of ordinary skill in the art would have understood to be input channels. *Id.*, [0202] (“one or two channel EEG leads”). A channel is a connection that transmits or receives data. A channel that transmits data is an output channel. A channel that receives data is an input channel. Given the hardwired connections that allow the main module 44 to receive data, these hardwired connections necessarily include an input channel.

g. Limitation [1.b.iv]

[1.b.iv] “*iv) a second wireless transceiver or transmitter is adapted for operating at frequencies above 2 GHz and transmitting the sleep data collected with the portable, wearable patient interface box wirelessly to the at least one first wireless transceiver of the cell phone or PDA with the first software loaded;*”

134. In my opinion, Ciulla in view of Orbach discloses this limitation.

135. As discussed in limitation [1.b], Ciulla discloses an internal transmitter/receiver/antenna 92 (*a second wireless transceiver or transmitter*). *See* Section IX.A.3.b. In particular, Ciulla discloses “[a]n internal, transmitter/receiver/antenna 92 [that] is provided for enabling the main module 44

to communicate wirelessly with the various sensors and output devices of the present invention.” Ex. 1007, [0106].

136. Ciulla discloses that the transmitter/receiver/antenna 92 is *adapted for operating* wirelessly through “RF, BlueTooth, WAN, LAN, IT Ethernet modem or other” (*at frequencies above 2 GHz*). Ex. 1007, [0213]. A person of ordinary skill in the art would have understood that “Bluetooth networks transmit on the 2.4-GHz band.” Ex. 1075, 338; *see also generally* Ex. 1017, 18 (Bluetooth “operat[es] in the 2.4 GHz ISM band.”). As I discussed above in Section V.E (Wired and Wireless Sensors), 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 device and for data communication. “Bluetooth was designed to be a sort of ‘wireless cable’ that connects devices, such as a computer and a printer or a CD player and headphones, it has a small coverage area, typically targeted at approximately 10 m.” *Id.*, 337-38.

137. Although Ciulla does not disclose that the main module 44 transmits the sensor data wirelessly to a cell phone or PDA, this would have been obvious in view of the teachings of Orbach. Orbach discloses transmitting the data collected by the sensor modules to the communication means of the mobile monitor

(transmitting . . . data collected with the portable, wearable patient interface box wirelessly to the at least one first wireless transceiver of the cell phone or PDA with the first software loaded). As discussed in limitation [1.a], Orbach discloses that “the mobile monitor 120 is a cellular phone or a Personal Digital Assistant (PDA) equipped with . . . means to communicate with both sensor module and remote server.” Ex. 1008, 22:5-9; *see also* Section IX.A.3.b.

138. A person of ordinary skill in the art would have been motivated to wirelessly transfer to the data from the main module 44 as taught by Ciulla to a mobile monitor, such as a cell phone or PDA, as taught by Orbach and as discussed in Section IX.A (Motivation to Combine).

h. Limitation [1.c]

[1.c] *“c) the at least two sensors are selected from a group consisting of: accelerometer(s), pulse oximeter(s) including fingertip pulse oximeter(s) and those built into the portable, wearable patient interface box, RIP belt(s), respiratory effort belt(s), pressure sensor(s), microphone(s), strain gauge(s), pressure transducer(s), and transducer(s), the at least two sensors adapted:”*

139. In my opinion, Ciulla discloses this limitation.

140. Ciulla discloses the at least two sensors can be at least an accelerometer, pulse oximeter, microphones, and transducers. Ex. 1007, [0202] (“The main sensor inputs analyzed by the microprocessor to accomplish the

device's purposes include, preferably, a piezo-electric snore monitor, a small breath sounds *microphone*, a heart rate sensor, *an attitude monitor*, and an upper chest expansion sensor (either strain gauge, piezo, pneumatic tubing or other), all of which are well known in the art and commercially available. *See also* Ex. 1014, [0034]; Ex. 1015, 7:66-67; Ex. 1016, Abstract; Ex. 1018, 4:12-13 (all describing microphones as pressure transducers or pressure sensors). Additional options that can be included in various embodiments of the design can include an EMG muscle tension probe (either on the inferior portion of the sternocleidomastoid or the lateral intercostal area above the diaphragm), a thin non-obtrusive oral nasal airflow canula (such as the canula sold by ProTech) with the *transducer* in the shoulder module, an *oximeter* (with probe on finger, earlobe, or toe), *accelerometer* wirelessly transmitting from the lower leg, blood pressure monitor, one or two channel EEG leads, and including one EOG lead that simultaneously serves as one EEG lead, and can even include a LED for photic stimulation if desired (as a cue in a special CAST).”). *See also* Ex. 1033, [0006] (pulse oximeters “typically” measure blood oxygen saturation and sometimes heart rate); Ex. 1034, 1:11-21 as support for a POSITA’s understanding of pulse oximeters).

141. I note that the disclosure of an attitude sensor also discloses an accelerometer. An attitude sensor measures the motion of an objection, such as an angular velocity and acceleration. Generally, an attitude sensor includes a gyroscope and an accelerometer. *See also* Ex. 1030, 5:46-49; Ex. 1031, 11:20-22; Ex. 1032, 11:56-57 (all describing attitude sensors as transducers). A POSITA would have also understood to implement Ciulla's attitude sensor as an accelerometer, especially when considering how well-understood accelerometer-based position sensors were for patient monitoring by 2006. *See* Ex. 1039, 15:63-16:4; Ex. 1035, 2:18-21; Ex. 1045, [0248]; Ex. 1036, [0035]; Ex. 1037, [0005]; Ex. 1038, Title (all describing accelerometers for sensing body position).

142. Ciulla also discloses a pressure sensor to the extent that a microphone is a type of pressure sensor. Microphones measure variations of pressure around the atmospheric pressure. In other words, microphones capture changes in sound pressure.

i. Limitation [1.c.i]

[1.c.i] *"i) to be applied to the subject, a first and a second of the at least two sensors of the portable, wearable patient interface box when the one or more of the sensors are built into the portable, wearable patient interface box are adapted to be applied to a finger, arm and/or torso of the subject;"*

143. In my opinion, Ciulla discloses this limitation.

144. As discussed in limitation [1.b.iii], Ciulla discloses the sensors are attached to the subject to measure data from the patient (*applied to the subject*). See Section IX.A.3.f.

145. As discussed in limitation [1.b.iii], Ciulla discloses the oximeter is attached to the finger (*adapted to be applied to a finger, arm and/or torso of the subject*). See Section IX.A.3.f.

146. As discussed in limitation [1.b.iii], Ciulla further discloses numerous other sensors attached to the torso of the patient, such as at the scapular or chest (*adapted to be applied to a finger, arm and/or torso of the subject*). For example, Ciulla discloses:

A breathing sensor 32 is positioned adjacent to the chest cavity of the patient, and functions similarly to a stethoscope, insofar as it senses breathing sounds. A snoring sensor 36 is positioned on the shoulder portion 22, to detect snoring sounds and breathing sounds emitted from the mouth and nose of the patient. Snoring sensor 36 essentially comprises a microphone. An EMG sensor 40 may be placed upon the chest or strap portion.

Ex. 1007, [0099]; *see also* [0143] (“snore sensor is also secured on the chest”).

147. Further, Ciulla discloses that other sensors are within the main back module, which is attached to the patient’s back (*when the one or more of the*

sensors are built into the portable, wearable patient interface box are adapted to be applied to a finger, arm and/or torso of the subject). Ex. 1007, [0124]

(“Additionally, breath sounds monitor, snore monitor, heart rate monitor an attitude indicator, and/or chest expansion module, may be designed to be incorporated within the main back module as a part thereof”), Fig. 8.

j. Limitation [1.c.ii]

[1.c.ii] *“ii) to measure or derive respiratory ventilation directly or indirectly, blood oxygenation and body position of the subject during testing; and”*

148. In my opinion, Ciulla in view of Orbach discloses this limitation. I understand that the Petitioner and Patent Owner have provided different constructions for the term “respiratory ventilation.” Ex. 1070. This limitation is disclosed under either construction.

149. Ciulla discloses snore sensor 36, breathing sensor 32, nasal cannula-type sensor 264 which measure different aspects of breathing (*to measure or derive respiratory ventilation directly or indirectly*). Ciulla explains that “a nasal cannula- type sensor 264 can be provided for sensing nasal and mouth emitted breath sounds and/or pressure, or for inducing a flow of air into the patient's nostrils and/or mouth.” Ex. 1007, [0119]. Ciulla discloses “breathing sensor 32 . . . senses breathing [s]ounds.” Ex. 1007, [0099]. Ciulla further discloses that “[a]

snoring sensor 36 is positioned on the shoulder portion 22, to detect snoring sounds and breathing sounds emitted from the mouth and nose of the patient.” Ex. 1007, [0099].

150. Similarly, Orbach discloses a system *to measure or derive respiratory ventilation directly or indirectly*. Specifically, Orbach discloses “an image indicative of breathing activity includes a bar having a length indicative of the breathing activity” and displays that “may vary in accordance with the lung volume of the user.” Ex. 1008, 32:8-30 (“Alternatively, another type of display....represents the volume of the lungs.”), 56 (Claim 21).

151. Because the sensors of Ciulla and Orbach can determine airflow and the breathing sounds, the amount of air during inspiration and expiration can be determined and also whether the patient is in the process of inspiration or expiration.

152. Ciulla discloses an oximeter *to measure or derive . . . blood oxygenation*. Specifically, Ciulla discloses that the pulse oximeter “sens[es] the oxygen saturation of the user’s blood.” Ex. 1007, [0118], [0202], FIG. 1B.

153. Ciulla also discloses an attitude sensor *to measure or derive . . . body position of the subject*. Specifically, Ciulla discloses that the attitude sensor

“determin[es] the patient’s sleeping position (*e.g.* on back, on side, etc.).” Ex. 1007, [0143].

154. Ciulla further discloses that the sensors measure and derive the information during use (*during testing*). Specifically, are used as a part of sleep monitoring or analysis system, and during “tests conducted.” Ex. 1007, [0150], [0128], [0143], [0230].

155. Similarly, Orbach discloses that the sensor modules may be “used in the practice or testing of the present invention” (*during testing*). Ex. 1008, 11:8-10, 41:25-27, FIG. 1.

k. Limitation [1.c.iii]

[1.c.iii] “*iii) to be releasably connected and/or electrically hardwired to or within the portable, wearable patient interface box adapted to be worn by the subject;*”

156. In my opinion, Ciulla discloses this limitation.

157. As discussed in limitation [1.b.iii], the sensors are *hardwired* and *within the portable, wearable patient interface box adapted to be worn by the subject*. See Section IX.A.3.f; *see also* Ex. 1007, [0124] (“breath sounds monitor, snore monitor, heart rate monitor an attitude indicator, and/or chest expansion module, may be designed to be incorporated ***within the main back module*** as a part thereof, and as such, would be connected to the main back module for a ***hard-***

wired connection.”). A person of ordinary skill in the art would understand that the sensors would be *electrically* hardwired given that the signals are transmitted to electronic circuitry of the main module 44 as discussed in limitation [1.b]. *See* Section IX.A.3.c. Also, as discussed in limitation [1.b], the main module is worn on the user’s back in the shoulder area (*adapted to be worn by the subject*). *See id.*

I. Limitation [1.d]

[1.d] “*d) an at least second software stored on a non-transitory computer readable medium and executable by a computer or a second processor at one or more sites remote to the first location;*”

158. In my opinion, Ciulla in view of Orbach discloses this limitation.

159. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. *See* Section IX.A.3.a.

160. Orbach discloses the remote server (*a computer or a second processor at one or more sites remote to the first location*) receives sensor data from the mobile monitor. Ex. 1008, 3:19-23, 5:3-5, 8:11-15, 13:21-14:2, 22:20-27, 33:27-34:2. The remote server has a processor (*second processor*) that “provide[s] additional processing” of the sensor data. *Id.*, 3:19-23, 22:28-23:4. A person of

ordinary skill in the art would have understood that because the server is “remote,” the server resides at a site that is remote from the location of the patient (*the first location*).

161. To process the sensor data, a person of ordinary skill in the art would have understood that the remote serve must include instructions or code stored in memory (*second software stored on a non-transitory computer readable medium*) so that the processor can execute to process the data (*executable by*). In general, Orbach recognizes that “[p]rograms executed by [a] processor . . . [are] stored in the memory.” Ex. 1008, 16:20.

m. Limitation [1.e]

[1.e] “*e) the first software, when executed by the first processor of the cell phone or PDA, configured to wirelessly receive and re-transmit the sleep data, or optionally send the sleep data further processed with the first processor of the cell phone or the PDA, with the at least one first wireless transceiver over cell towers to the computer or the second processor for analysis;*”

162. In my opinion, Ciulla in view of Orbach discloses this limitation.

163. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. *See* Section IX.A.3.a. As discussed in

limitation [1.a], Orbach discloses a program configured to be loaded on the mobile monitor. *See* Section IX.A.3.b.

164. Orbach discloses that the program on the mobile monitor can receive and transmit wirelessly the sensor data (*configured to wirelessly receive . . . the sleep data*). Orbach discloses that “the mobile monitor 120 is a cellular phone or a Personal Digital Assistant (PDA) equipped with . . . means to communicate with both sensor module and remote server.” Ex. 1008, 22:5-9. Orbach explains that “transmitters wirelessly transmit signals indicative of values of the one or more physiological parameters to a mobile monitor” and the “mobile monitor includes a processor processing the signals received from the transmitter.” *Id.*, Abstract. In the combination, the data that would be received and transmitted would be the sleep data from the main module 44.

165. Orbach discloses that the program on the mobile monitor relay the sensor data to the remote server (*configured to wirelessly . . . re-transmit the sleep data*). Specifically, Orbach discloses that “communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.” Ex. 1008, 13:21-27; *see also* 22:22-23

(“the [m]obile monitor is equipped with means to connect to a remote server wirelessly over the cell network preferably using the Internet.”).

166. Orbach discloses that the mobile monitor may re-transmit the sleep data after further processing (*optionally send the sleep data further processed with the first processor of the cell phone or the PDA*). Specifically, Orbach discloses that “[t]he mobile monitor includes a processor processing the signals received from the transmitter.” Ex. 1008, Abstract. Orbach further explains “transmitting second signals from the mobile monitor to a remote server.” *Id.*, 8:11-12.

167. Orbach discloses sending the data further processed by the processor of the mobile monitor using its communication means (*with the at least one first wireless transceiver*) as discussed in limitation [1.a]. *See* Section IX.A.3.b. Ex. 1008, 22:5-9 (“the mobile monitor 120 is a cellular phone or a Personal Digital Assistant (PDA) equipped with . . . means to communicate with both sensor module and remote server.”).

168. Orbach further discloses using a cellular protocol to send the data to the remote server (*over cell towers to the computer or the second processor*). In particular, Orbach discloses “the [m]obile monitor is equipped with means to connect to a remote server wirelessly over the cell network preferably using the

Internet.” Ex. 1008, 22:22-23. A person of ordinary skill in the art would have understood that the data transmitted and received using a cell network would have been transmitted in part by cell towers (*configured 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. *See* Ex. 1041, [0007]; Ex. 1012, [0004]; Ex. 1013, [0011] (all describing cellular phones as using cellular towers). Such communications over cell towers would have been obvious to operate in accordance with standard cellular networks to increase usability and reach, and to obtain the benefit of sending data to the remote server from multiple locations over an existing network of cell towers. *See* Ex. 1041, [0007]; Ex. 1012, [0004]; Ex. 1013, [0011].

169. Orbach discloses that the remote server will analyze the data received from the mobile monitor (*the computer or the second processor for analysis*). In particular, Orbach discloses “a communication link 128 is used to connect the

mobile monitor 120 to a remote server 140 where *in-depth analysis* of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.” *Id.*, 13:21-23; *see also* 22:20-23:4 (“Remote servers may provide additional processing of the sensor’s data.”).

n. Limitation [1.f]

[1.f] “*f) the second software when executed by the computer or the second processor configured to analyze, output and/or format the sleep data at the one or more sites remote from the first location where the sleep data was collected; and*”

170. In my opinion, Ciulla in view of Orbach discloses this limitation.

171. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. *See* Section IX.A.3.a. As discussed in limitation [1.d], the remote server includes code to process the received data (*second software*).

172. Orbach discloses that the code on the remote server can analyze, output, and display the sensor data at the location of the remote server (*the second software when executed by the computer or the second processor configured to analyze . . . format the sleep data at the one or more sites remote from the first*

location where the sleep data was collected). Orbach discloses “a communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where ***in-depth analysis*** of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.” *Id.*, 13:21-23; *see also* 22:20-23:4 (“Remote servers may provide additional processing of the sensor’s data.”).

173. Orbach discloses that the is transmitted for display to the the viewing station associated at the remote server (*output and/or format the sleep data at the one or more sites remote from the first location where the sleep data was collected*). Orbach discloses that “the remote server associated with a viewing station having a second processor, the remote server being configured to perform at least one of the following: (a) transmitting the second signals to a viewing station for analysis, the analysis; (b) accessing historical data relating to the subject; (c) transmitting the historical data to the viewing station; (d) ***receiving from the viewing station results of the analysis***; (e) transmitting the results of the analysis to the mobile unit.” Ex. 1008, 3:19-4:4; *see also* 13:29-14:2 (“an additional data link 148 such as Local Area Network (LAN) or Internet networking or RF cellular link connects the remote server 140 to a viewing station 150 where a human expert

may provide interpretation of the data”), claim 40 (“displaying on a display associated with the mobile monitor an image indicative of bio-feedback information”).

174. A person of ordinary skill in the art would understand that to display the information on the view station associated with the mobile monitor, the data would have needed to be formatted. In particular, for “a human expert” to interpret the data, the data would have needed to be organized (i.e., formatted) in human-readable form.

o. Limitation [1.g]

[1.g] “g) *the at least second software, when executed by the second processor or the computer, configured to display both, in part, the sleep data and/or analyzed sleep data to allow for diagnosis of a sleep disorder and, if necessary, provide a basis to modify a sleep treatment of the subject.*”

175. In my opinion, Ciulla in view of Orbach discloses this limitation.

176. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. See Section IX.A.3.a. As discussed in limitation [1.d], the remote server includes code to process the received data (*second software*).

177. As discussed in limitation [1.f], Orbach discloses that the program when executed by the processor on the remote server is configured to transmit the data for display on the viewing station (*the at least second software, when executed by the second processor or the computer, configured to display . . . the sleep data*). Ex. 1008, 3:19-4:4; *see also* 13:29-14:2 (“an additional data link 148 such as Local Area Network (LAN) or Internet networking or RF cellular link connects the remote server 140 to a viewing station 150 where a human expert may provide interpretation of the data”), claim 40 (“displaying on a display associated with the mobile monitor an image indicative of bio-feedback information”).

178. Orbach also discloses that the program is configured to display the analyzed data to diagnose sleep disorders and modify treatment as needed (*configured to display . . . analyzed sleep data to allow for diagnosis of a sleep disorder and, if necessary, provide a basis to modify a sleep treatment of the subject*). Orbach explains that both historical data and analyzed data can be displayed on the viewing station. Ex. 1008, 3:28-4:3 (“(d) receiving from the viewing station **results of the analysis**; (e) transmitting the results of the analysis to the mobile unit; the analysis being based upon the second signals, and one or more of the **historical data**, expert knowledge and computerised protocols.”). Further,

Orbach discloses based on the data, a “human expert may provide interpretation of the data and transmit recommendations to the user.” *Id.*, 13:21-14:2.

179. Similarly, Ciulla discloses “[a] clinical trial version [] designed to transmit the multiple sensors’ outputs wirelessly (RF, BlueTooth, WAN, LAN, IT Ethernet Modem or other)” and “incorporate[s] a wireless receiver allowing the researcher to... observ[e] the patient’s responses in a montage display format on the receiving computer’s screen.” Ex. 1007, [0213]. Moreover, the processor of the main module can “directly transmit [analysis] reports by IT to the therapist’s computer and/or the company’s main frame system for further analysis, research or documentation.” *Id.*, [0214].

4. Dependent Claim 2

“2. The sleep diagnostic data acquisition system of claim 1, further comprising an at least third sensor wherein the at least third sensor is adapted for measuring respiratory ventilation such as respiratory effort and/or snore.”

180. In my opinion, Ciulla discloses the additional limitation of claim 2.

181. Ciulla discloses a nasal cannula-type sensor 264 (*third sensor*). Ciulla explains that the nasal-cannula-type sensor 264 is used to measure the patient’s breath sounds (*adapted for measuring respiratory ventilation such as respiratory effort and/or snore*). Ciulla explains that “a nasal cannula- type sensor 264 can be

provided for sensing nasal and mouth emitted breath sounds and/or pressure, or for inducing a flow of air into the patient's nostrils and/or mouth.” Ex. 1007, [0119].

182. Ciulla also discloses a breathing sensor 32 (*third sensor*). Ciulla explains that the breathing sensor 32 detects breathing sounds (*adapted for measuring respiratory ventilation such as respiratory effort and/or snore*). Specifically, Ciulla discloses “breathing sensor 32 . . . senses breathing [s]ounds.” Ex. 1007, [0099]; *see also* Ex. 1014, [0034], Ex. 1015, 7:66-67, Ex. 1016, Abstract, Ex. 1018, 4:12-13 (all describing pressure transducers as including microphones).

5. Dependent Claim 3

“3. The sleep diagnostic data acquisition system of claim 2, further comprising an at least fourth sensor wherein the third sensor is adapted for measuring respiratory effort and the fourth sensor is adapted for measuring snore.”

183. In my opinion, Ciulla discloses the additional limitation of claim 3.

184. As I discussed in dependent claim 2, Ciulla discloses either a nasal cannula-type sensor 264 or breathing sensor 32 as a *third sensor*. *See* Section IX.A.4.

185. Ciulla further discloses a snoring sensor 36 (*fourth sensor*). Ciulla explains that snoring sensor 36 detects snoring sounds and breathing sounds

(*adapted for measuring snore*). In particular, Ciulla discloses that “[a] snoring sensor 36 is positioned on the shoulder portion 22, to detect snoring sounds and breathing sounds emitted from the mouth and nose of the patient.” Ex. 1007, [0099].

6. Dependent Claims 4, 11, and 15

“4. The sleep data acquisition system in claim 2, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis.”

“11. The sleep data acquisition system in claim 10, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis.”

“15. The sleep data acquisition system in claim 1, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis.”

186. In my opinion, Ciulla in view of Orbach discloses the additional limitations of claims 4 and 15. I note that the ’512 patent explains that a communication station “can be any device known to receive RF transmissions used by those skilled in the art to receive transmissions of data,” including “***a computer with wireless capabilities***, a PDA with wireless capabilities, a processor, a

processor with display capabilities, and combinations of these devices.” Ex. 1001, 15:16-28.

187. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. *See* Section IX.A.3.a. As discussed in limitation [1.a], Orbach further discloses a communication means in the mobile monitor (*the at least one first wireless transceiver*). *See* Section IX.A.3.b.

188. Orbach discloses that the remote server is a computer with wireless capabilities (*communication station*). Orbach discloses that “the mobile monitor 120 is a cellular phone or a Personal Digital Assistant (PDA) equipped with . . . means to communicate with both sensor module and remote server.” Ex. 1008, 22:5-9; *see also* 22:22-23 (“the [m]obile monitor is equipped with means to connect to a remote server wirelessly over the cell network preferably using the Internet.”).

189. A person of ordinary skill in the art would have understood that wireless transceiver was necessary to connect over the cell network. A wireless transceiver is an electronic device that both receives and transmits radio frequency

signals. When a cell phone is used, it will emit a radio frequency signal through a wireless transceiver to a 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.

190. 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 (Mobile Computing) and V.E (Wired and Wireless Sensors). Wireless transceivers were becoming pervasive to allow more convenient and access to data. *See* Section V.D (Pervasive Computing).

191. 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 device and for data communication. A Wi-Fi-enabled radio frequency wireless transceiver would have allowed a sensor device to connect to the cell

phone for uploading data. A GSM- or GPRS-enabled, or other cellular network-enabled, radio frequency wireless transceiver would have allowed the device to communicate with a remote server if a Wi-Fi network is not available.

192. Orbach discloses that the sensor data is transmitted to the remote server for analysis (*to transmit the sleep data over cell towers and/or the Internet for analysis*). Specifically, Orbach discloses that “communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.” Ex. 1008, 13:21-27.

7. Dependent Claims 5, 12, and 16

“5. The sleep data acquisition system in claim 4, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver.”

“12. The sleep data acquisition system in claim 11, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver.”

“16. The sleep data acquisition system in claim 15, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver.”

193. In my opinion, Ciulla and Orbach discloses the additional limitations of claims 5 and 16.

194. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. *See* Section IX.A.3.a. As discussed in limitation [1.a], Orbach further discloses a communication means in the mobile monitor (*the at least one first wireless transceiver*). *See* Section IX.A.3.b. As discussed in limitation [1.b.iv], Ciulla discloses a transmitter/receiver/antenna 92 (*second transceiver*) in the main module 44 to wireless transmit data. *See* Section IX.A.3.g.

195. As discussed in limitation [1.b.iv], the system resulting from the combination of Ciulla and Orbach would have resulted in a Bluetooth communication link between the transmitter/receiver/antenna 92 and communication means of the mobile monitor (*two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver*). Bluetooth is a communication protocol that would have allowed both the transmitter/receiver/antenna 92 and communication means of the mobile monitor to transmit and receive data. *See also* Ex. 1007, [0213]; Ex. 1008, 15:12 (“supports ‘blue-tooth’ RF bidirectional wireless communication”). A person of

ordinary skill in the art would have understood that because data could both be transmitted and received, the transmission would be *bi-directional*. See Ex. 1008, 16:13-14 (“The communication link 112 is preferably bidirectional”); Fig. 1 (showing bidirectional communication between the sensor module and the mobile monitor); *see also* Ex. 1075, 389 (“bidirectional communication requires a pair of transceivers—each transceiver consists of a transmitter and a receiver”). A person of ordinary skill in the art would have also understood that because both the transmitter/receiver/antenna 92 and communication means of the mobile monitor would have been able to send bi-directional data transmission, that this transmission would be *two-way*.

8. Dependent Claims 6, 13, and 17

“6. The sleep data acquisition system in claim 5, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.”

“13. The sleep data acquisition system in claim 12, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.”

“17. The sleep data acquisition system in claim 16, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.”

196. In my opinion, Ciulla and Orbach discloses the additional limitations of claims 6 and 17.

197. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. *See* Section IX.A.3.a.

198. Orbach discloses that the remote server can send instructions and commands to the sensor module through the communication means of the mobile monitor (*communication station can control the sleep data transmission from the at least first transceiver*). Specifically, Orbach discloses “[i]nstructions and commands may be initiated by the remote server 140 or expert station 150 and relayed to sensor module 110 through mobile monitor 120.” Ex. 1008, 17:19-20. A person of ordinary skill in the art would have understood that these instructions and commands would have been relayed through the communication means of the mobile monitor. Orbach further explains that “[s]uch commands and instruction may control the operation mode of the sensor module.” Ex. 1008, 16:16-17. Accordingly, the commands and instructions allow the remote server to control the sensor module.

199. Orbach states that one of the aspects of the sensor module that the remote server can control is the data transmission. In particular, Orbach identifies as an example, “the data sampling rate may be changed by such a command” including “accuracy or range.” This will allow the amount of data that is sampled and therefore transmitted.

9. Dependent Claims 8, 14, and 19

“8. The sleep data acquisition system in claim 6, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.”

“14. The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.”

“19. The sleep data acquisition system in claim 17, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.”

200. In my opinion, Ciulla in view of Orbach discloses the additional limitations of claims 8 and 19. I note that in the '512 patent, “[s]oftware is used to synchronize video with physiological signals for display,” for example, to remove signal “artifacts” or isolate certain signals such as a “snore signal.” Ex. 1001, 2:31-42; 9:44-51.

201. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. *See* Section IX.A.3.a.

202. Orbach discloses that the analysis code on the remote computer can extract from the sensor data (*software filter is adapted to determine . . . from the sleep data*) breathing depth (*tidal volume*) and breathing rate (*airflow or ventilation rate*). In particular, Ciulla discloses a number of sensors, such as a pulse oximeter and heart rate monitor, that provide signals related to heart activity. Ex. 1007, [0121], [0202]. As Orbach explains that these types of sensors are “adapted to detecting light reflected from the skin surface.” Ex. 1008, 6:6-8. “The intensity of scattered light 326 reflected from the skin and received by the light detector 328 depends on the blood flow in the skin” and “may be used to monitor heart activity.” *Id.*, 14:17-23.

203. Orbach discloses using these heart activity signals to breathing depth (BD) and breathing rate (BR). Ex. 1008, 29:25-26 (“an embodiment of the current invention infers the breathing from HR [heart rate] information”); 30:23-24 (“An additional method to analyze the data and extract breathing patter is to perform

autocorrelation on the $HR(t)$.”). For example, Orbach discloses that “BD is defed as the Minimum HR subtracted from the maximum HR during the breathing cycle normalized by the AHR.” *Id.*, 30:7-8. Orbach further discloses that “BR per minute is defined as 60 over the duration of the breathing cycle in seconds.” *Id.*, 30:5-6.

10. Dependent Claims 9 and 20

“9. The sleep data acquisition system in claim 5, wherein the portable, wearable patient interface box further comprises an A/D converter and a digital memory for receiving the sleep data.”

“20. The sleep data acquisition system in claim 16, wherein the portable, wearable patient interface box further comprises an A/D converter and a digital memory for receiving the sleep data.”

204. In my opinion, Ciulla discloses the additional limitations of claims 9 and 20.

205. Ciulla discloses that the main module 44 (*patient interface box*) includes an analog to digital converter (*A/D converter*) and digital storage (*digital memory*). In particular, Ciulla discloses that “[t]he device can be constructed using off-the-shelf sensor inputs with the main module containing . . . an analog to digital converter.” Ex. 1007, [0204]. Ciulla further discloses that after the signal is converted into digital, the signal can be filtered and stored in “digital storage (DDD technology) for greater accuracy.” *Id.*

206. A person of ordinary skill in the art would have understood that the main module (*patient interface box*) include the digital memory to store the sensor data (*digital memory for receiving the sleep data*). Ciulla discloses that the microprocessor in the main module 44 “performs a variety of functions for the device and process, including digitally analyzing and storing data.” Ex. 1007, [0073]. The main module 44 includes electronic circuitry including “a non-volatile memory, such as a smart card.” *Id.*, [0102]; *see also* [0230] (“The system is designed to have its digital storage on a SMART card”). Ciulla explains that “the non-volatile memory servers as a repository of data collected by the sensor during the operation of the device.” *Id.*, [0128].

11. Dependent Claim 10

“10. The sleep data acquisition system in claim 1, wherein the at least two sensors consist of a pulse oximeter and an accelerometer.”

207. In my opinion, Ciulla alone or in view of the knowledge of a person of ordinary skill in the art discloses the additional limitation of claim 10.

208. As discussed in limitation [1.c], Ciulla discloses an oximeter (*pulse oximeter*) and an attitude sensor (*accelerometer*). *See* Section IX.A.3.h.

B. Ground 2: Ciulla in view of Orbach and Nagai Renders Obvious Claims 1-6, 8-17, and 19-20

1. Disclosures of Nagai

209. As discussed in limitation [1.b.iii] and [1.c.iii], Ciulla teaches that the pulse oximeter and attitude sensor are hardwired because “[e]ach of the sensors . . . are provided with either a hard wire or wireless communication, to provide input to the main module 44 of the device 10.” Ex. 1007, [0100]; *see also* Sections IX.A.3.f and IX.A.3.k.

210. To the extent that the system resulting from the combination of the teachings of Ciulla and Orbach does not teach that the pulse oximeter and accelerometer are *hardwired* as recited for limitation [1.b.iii.C] and [1.c.iii] or *releasably connected* recited for limitation [1.b.iii.C] and limitation [1.c.iii], the Ciulla and Orbach combination in further view of Nagai renders these limitations obvious.

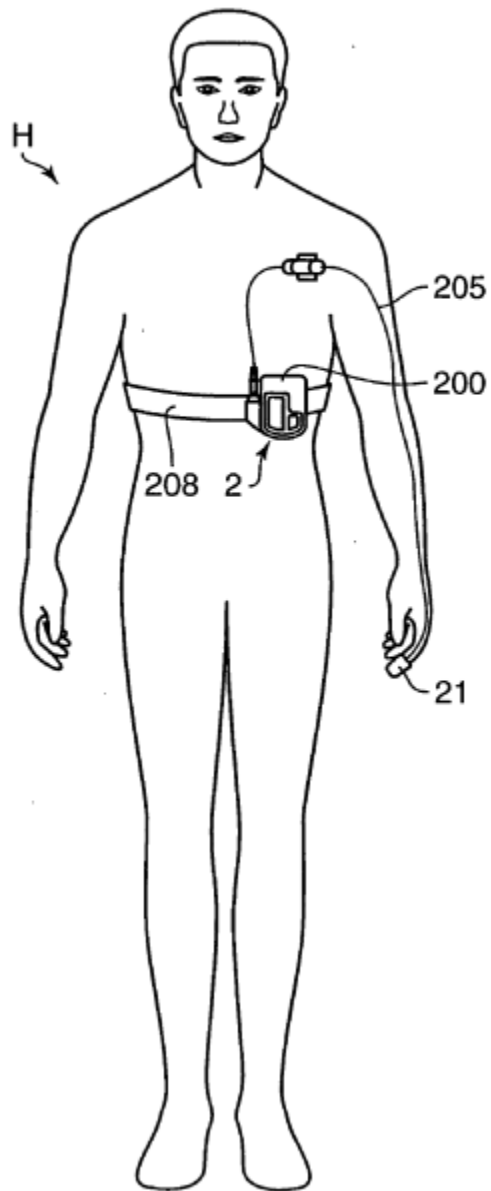
211. Further, to the extent that claim 10 is interpreted to require that the pulse oximeter and accelerometer are the only sensors used, the Ciulla and Orbach combination in further view of Nagai also renders this limitation obvious.

212. With respect to limitations [1.b.ii.C] and [1.c.iii], it would have been obvious to modify Ciulla to hardwire or releasably connect a standard pulse

oximeter to the main module through the ports as taught by Nagai. Nagai discloses a pulse oximeter 2 (*pulse oximeter*) that electrically connects the probe 21 to the main body 200 with a probe cable 205 (*hardwired*) that is detachably attached to the subject (*releasably connected*).

213. In particular, Nagai discloses a “evaluating sleep of subject in diagnosing sleep apnea syndrome” using sensors including “a pulse oximeter 2 for concurrently or simultaneously measuring a blood oxygen saturation and a body angle of a subject for storing the measurement data” and “a three-axis acceleration sensor 22 serving as the body position detector 12.” Ex. 1010, [0057]. The sensors are “detachably attached to the subject” through a probe cable 205. Ex. 1010, [0054], [0058]-[0060] (“The oximeter main body 200 and the probe 21 are detachably attached to a subject H in the manner as shown in FIG. 3”), Fig. 3.

FIG.3



214. With respect to claim 10, Nagai teaches using just the pulse oximeter and acceleration sensor “for evaluating sleep of subjects in diagnosing sleep apnea syndrome.” Ex. 1010, Abstract.

215. Nagai discloses that “body position detector 12” “detects a body position of the subject in terms of angle information.” Ex. 1010, [0047], [0049], [0070]-[0071], FIG. 1. The body position detector uses “a three-axis acceleration sensor” comprising a sensor body 220 comprising piezoresistive devices 224. *Id.*, [0049], [0070], [0071].

216. Nagai further discloses “a pulse oximeter 2 for concurrently or simultaneously measuring a blood oxygen saturation and a body angle of a subject for storing the measurement data.” Ex. 1010, [0057]. Nagai discloses that pulse oximeter information can also be considered with body position information to determine a “correlation between apnea and body position of the subject in sleep.” *Id.*, [0172], [0142]-[0145].

217. Nagai discloses evaluating the pulse oximeter information with body position information to determine a “correlation between apnea and body position of the subject in sleep” for sleep disorder diagnosis. *Id.*, [0172], [0142]-[0145].

2. Motivation To Combine

218. To the extent that the sensors of the system resulting from the combination of the teachings of Ciulla and Orbach are not *hardwired* or *releasably connected*, a person of ordinary skill in the art would have been motivated to include such a feature in further view of Nagai.

219. First, it was a known design option. As discussed in Section V.E, wired and wireless connections were known at the time. A person of ordinary skill in the art would have known that each option had their advantages and disadvantages in a wearable application. Although a wireless connection would have provided more mobility, a wired connection would have been more power efficient. Further, the limitations on mobility could be offset in part by making the sensor *releasably connected* as taught by Nagai. Thus, a *hardwired* but *releasably connected* option would have been obvious.

220. Second, Ciulla teaches “using off-the-shelf sensor inputs,” which would have included “standard” sensors such as disclosed in Nagai. Ex. 1007, [0204]. Using standard sensors, would “help reduce production costs.” *Id.*, [0072].

221. Third, a person of ordinary skill in the art would have been motivated to implement the Ciulla and Orbach combination as a two-sensor system as taught

by Nagai because it would reduce cost and hardware and software complexity, and improve the user experience. Limiting the sensors to two would mean less components to purchase and simplify the physical design by lowering power consumption and decreasing the number of necessary connections. With less data, the algorithms necessary to process the data would also be simplified. Less sensors would also make the wearable lighter and more comfortable.

3. Reasonable Expectation of Success

222. A person of ordinary skill in the art would have had a reasonable expectation of success in modifying the system resulting from the teachings of Ciulla and Orbach with the *hardwired* or *releasably connected* two sensor system teachings of Nagai.

223. First, Ciulla, Orbach, and Nagai each disclose functionality and structurally similar sleep monitoring systems. Each disclose the use of sensors, and specifically, sensors to derive oxygen saturation. Ex. 1007, [0118], [0202]; Ex. 1008, 14:17-23; Ex. 1010, [0057]. Orbach and Nagai both further disclose additional information that can be derived from data from a pulse oximeter. Ex. 1008, 29:27-30:22; Ex. 1010, [0172], [0142]-[0145].

224. Second, the modification would have involved the implementation of the system of Ciulla using the sensors taught by Nagai. This was an implementation already taught by Ciulla, which stated that “[t]he device can be constructed using off-the-shelf sensor inputs.” Ex. 1007, [0204]. This was a combination of known prior art elements (sensors working with wearable devices) according to known methods and techniques (to collect and transmit data) to yield predictable results (sensor diagnostic system).

C. Ground 3: Ciulla in view of Orbach and Truschel Renders Obvious Claims 7 and 18

1. Disclosures of Truschel

“7. The sleep data acquisition system in claim 6, further comprising a software filter configured to extract a high frequency portion of a signal from one of the three sensors to obtain a snore signal.”

“18. The sleep data acquisition system in claim 17, further comprising a software filter configured to extract a high frequency portion of a signal from one of the at least two sensors to obtain a snore signal.”

225. In my opinion, Ciulla in view of Orbach and Truschel discloses the additional limitations of claims 7 and 18.

226. As discussed in the preamble, a person of ordinary skill art would have modified Ciulla to incorporate its wearable data acquisition device into the

networked system of Orbach to transmit data to a remote computer through mobile monitor, such as a cell phone or PDA. *See* Section IX.A.3.a.

227. Although the system resulting from the combination of the teachings of Ciulla and Orbach does not disclose *a software filter configured to extract a high frequency portion of a signal from one of the three sensors to obtain a snore signal*, this would have been obvious in further view of Truschel.

228. Truschel discloses a “snore analysis device 64” and “digital band pass filter 58” are implemented within a controller 50 using “suitable programming” (*software filter*). Ex. 1011, [0043]; *see also* [0046] (“[c]ontroller 50 is programmed to function as a snore detection device”). The band pass filter 58 “check[s] for vibrations in pressure signal 72 within a broad range of 40 to 160 Hz” (*extract a high frequency portion of a signal . . . to obtain a snore signal*). *See, e.g.*, Ex. 1042, [0058], Ex. 1043, [0044], [0045], Ex. 1044, [0091] (all describing snoring as having high frequency).

229. The signal would be extracted from the data provided by the pressure sensor disclosed in Ciulla (*extract a high frequency portion of a signal from one of the three sensors*). Like Ciulla, Truschel uses a “pressure sensor 48 as a microphone” that “convert[s] a snore pressure wave into a proportional analog

signal.” Ex. 1011, [0045]. Thus, in the modified system the snore signal would be extracted from the signal from Ciulla’s pressure sensor.

2. Motivation To Combine

230. A person of ordinary skill in the art would have been motivated to modify the system resulting from the combination of the teachings of Ciulla and Orbach to incorporate the snore detection software filter as taught by Truschel.

231. First, an objective of Ciulla, Orbach, and Truschel is to obtain data on sleep disordered breathing to diagnose or treat. *See, e.g.*, Ex. 1007, [0062] (“During sleep, the device has the potential to stop or at least reduce sleep disordered breathing events”); Ex. 1008, 41:25-27 (“the system may be used to record physiological reading while the user is sleeping in order to help identify and possibly correct sleep disorders”); Ex. 1011, [0003] (“a method and apparatus for detecting disordered breathing in a patient”). A person of ordinary skill in the art improving the system of Ciulla and Orbach would have naturally looked at other known techniques, such as Truschel, to detect sleep disordered breathing events.

232. Second, implementing the snore detection software filter of Ciulla would have improved the ability of the system to detect sleep disordered breathing events. For example, Truschel explains that its software filter provides

individualized health care by accounting for “age, gender, or health of a patient.” Ex. 1011, [0050]. The Truschel software filter also would have improved the snore detection of Ciulla by avoiding “false snore indications” which fail to “take into account dynamic background noise” and “other noise.” Ex. 1011, [0040], [0051]. Adding dynamic adjustments to snore calculations would have enhanced Ciulla’s handling of changes in “background noise and patient noises.” Ex. 1011, [0052]-[0054], [0068], FIG. 3.

3. Reasonable Expectation of Success

233. A person of ordinary skill in the art would have had a reasonable expectation of success modifying the system resulting from the combination of Ciulla and Orbach with the snore detection software filter of Truschel.

234. First, Ciulla, Orbach, and Truschel are functionally and structurally similar. Each uses sensors and processors to process the sensor data. *See* Section IX.A.3; Ex. 1010, Abstract, [0005]-[0007], [0041]. Importantly, like Ciulla, Truschel uses a “pressure sensor 48 as a microphone” that “convert[s] a snore pressure wave into a proportional analog signal.” Ex. 1011, [0045].

235. Second, the modification would have involved a simple change in a programming algorithm that was well within the skill of a person of ordinary skill

in the art. Modifying software to implement a dynamic baseband filter was well-known. Thus, the modification was nothing more than a combination of known prior art elements according to known methods and known techniques (programming a processor to extract high frequency signal using a baseband filter) to yield predictable results (dynamically filtering snore data).

D. Ground 4: Ciulla in view of Orbach and Kumar Renders Obvious Claims 6, 8, 13-14, 17, and 19

1. Disclosures of Kumar

236. To the extent that the system resulting from the combination of the teachings of Ciulla and Orbach does not teach that the remote server *can control the sleep data transmission* recited by claims 6, 13 and 17, the Ciulla and Orbach combination in further view of Kumar renders this limitation obvious.

237. Kumar discloses that the provider may “remotely control the client-side device[s].” Ex. 1009, [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. Specifically, Kumar discloses “[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.

238. A person of ordinary skill in the art would have understood that the remote control disclosed by Kumar controls the sleep data transmission because it allows the provider (such as a provider at the remote server of Orbach) to start the sensors remotely, thereby starting a data transmission.

2. Motivation To Combine

239. A person of ordinary skill in the art would have had a reasonable expectation of success modifying the system resulting from the combination of Ciulla and Orbach with the remote control feature of Kumar.

240. First, Ciulla, Orbach, and Kumar are functionally and structurally similar. Each uses sensors and processors to process the sensor data. *See* Section IX.A.3; Ex. 1009, [0015], [0068], [0239]-[0241], Abstract. Importantly, like Orbach, Kumar discloses using a patient-side device 102 (like Orbach's sensor module), a computing device 110 (like Orbach's mobile monitor), and a central server 106 (like Orbach's remote server). Ex. 1011, [0045].

241. Second, the modification would have involved a simple change in a programming algorithm that was well within the skill of a person of ordinary skill

in the art. Modifying software to implement a dynamic baseband filter was well-known. Thus, the modification was nothing more than a combination of known prior art elements according to known methods and known techniques (programming a processor to extract high frequency signal using a baseband filter) to yield predictable results (dynamically filtering snore data).

3. Reasonable Expectation of Success

242. A person of ordinary skill in the art would have had a reasonable expectation of success modifying the system resulting from the combination of Ciulla and Orbach with the remote control feature of Kumar.

243. First, Ciulla, Orbach, and Kumar are functionally and structurally similar. Each uses sensors and processors to process the sensor data. *See* Section IX.A.3; Ex. 1009, [0015], [0068], [0239]-[0241], Abstract. Importantly, like Orbach, Kumar discloses using a patient-side device 102 (like Orbach's sensor module), a computing device 110 (like Orbach's mobile monitor), and a central server 106 (like Orbach's remote server). Ex. 1009, [0018], Fig. 1A.

244. Second, the modification would have involved a simple change in programming at the remote server and in the main module that was well within the skill of a person of ordinary skill in the art. Modifying software to implement a

remote control was well-known. Specifically, it would have been a matter of programming the remote server to be able to send commands and instructions to the processor of the main module to control the sensors. Thus, the modification was nothing more than a combination of known prior art elements according to known methods and known techniques (remote control) to yield predictable results (remote control sensors and data transmissions). As I discussed in Section V.A (Mobile Computing) and V.D (Pervasive Computing), remote control was part of the benefits of the mobile computing and pervasive computing trends.

E. Grounds 5: Ciulla in View of Orbach, Truschel, and Kumar Renders Obvious Claims 7 and 18

245. As discussed in Ground 3, the combination of the teachings of Ciulla, Orbach, and Truschel renders obvious each of the limitations of claims 6 and 17. *See* Section IX.C. As further discussed in Ground 4, Kumar discloses a remote control feature (*can control the sleep data transmission*) of claims 6 and 17. *See* Section IX.D.

246. Accordingly, to the extent that the combination of the teachings of Ciulla, Orbach, and Truschel does not disclose the additional limitations of claims 6 and 17, these limitations would have been rendered obvious by Kumar.

247. A person of ordinary skill in the art would have been motivated to implement the system of Ciulla, Orbach, and Truschel to include the remote control feature taught by Kumar with a reasonable expectation of success. *See* Section IX.D.2 (Motivation to Combine) and Section IX.D.3 (Reasonable Expectation of Success).

248. There is nothing in Truschel that would have prevented this combination. Instead, like Kumar, Truschel is also directed to a system that collects and monitors sleep data. Ex. 1009, [0015], [0068], [0239]-[0241], Abstract; Ex. 1011, [0003] (“a method and apparatus for detecting disordered breathing in a patient”).

F. Grounds 6: Ciulla in View of Orbach, Nagai, and Kumar Renders Obvious 6, 8, 13-14, 17, and 19

249. As discussed in Ground 2, the combination of the teachings of Ciulla, Orbach, and Nagai renders obvious each of the limitations of claims 6, 8, 13-14, 17, and 19. *See* Section IX.B. As further discussed in Ground 4, Kumar discloses a remote control feature (*can control the sleep data transmission*) of claims 6, 13, and 17. *See* Section IX.D. As also discussed in Ground

250. To the extent that the combination of the teachings of Ciulla, Orbach, and Nagai does not disclose the additional limitations of claims 6, 13, and 17

(which are also required by their dependent claims 8, 14, and 19), these limitations would have been rendered obvious by Kumar.

251. A person of ordinary skill in the art would have been motivated to implement the system of Ciulla, Orbach, and Nagai to include the remote control feature taught by Kumar with a reasonable expectation of success. *See* Section IX.D.2 (Motivation to Combine) and Section IX.D.3 (Reasonable Expectation of Success).

252. There is nothing in Nagai that would have prevented this combination. Instead, like Kumar, Nagai is also directed to a system that collects and monitors sleep data. Ex. 1009, [0015], [0068], [0239]-[0241], Abstract; Ex. 1010, [0057].

G. Grounds 7: Ciulla in View of Orbach, Nagai, and Truschel Renders Obvious Claims 7 and 18

253. As discussed in Ground 2, the combination of the teachings of Ciulla, Orbach, and Nagai renders obvious each of the limitations of claims 6 and 17. *See* Section IX.B. As further discussed in Ground 3, Truschel discloses a remote control feature (*can control the sleep data transmission*) of claims 7 and 18. *See* Section IX.C.

254. A person of ordinary skill in the art would have been motivated to implement the system of Ciulla, Orbach, and Nagai to include the snore detection

software filter taught by Truschel with a reasonable expectation of success. *See* Section IX.C.2 (Motivation to Combine) and Section IX.C.3 (Reasonable Expectation of Success).

255. There is nothing in Nagai that would have prevented this combination. Instead, like Truschel, Nagai is also directed to a system that collects and monitors sleep data. Ex. 1011, [0003] (“a method and apparatus for detecting disordered breathing in a patient”); Ex. 1010, [0057].

H. Grounds 8: Ciulla in View of Orbach, Nagai, Kumar, and Truschel Renders Obvious Claims 7 and 18

256. As discussed in Ground 6, the combination of the teachings of Ciulla, Orbach, Nagai, and Kumar renders obvious each of the limitations of claims 6 and 17. *See* Section IX.F. As further discussed in Ground 3, Truschel discloses a remote control feature (*can control the sleep data transmission*) of claims 7 and 18. *See* Section IX.C.

257. A person of ordinary skill in the art would have been motivated to implement the system of Ciulla, Orbach, Nagai, and Kumar to include the snore detection software filter taught by Truschel with a reasonable expectation of success. *See* Section IX.C.2 (Motivation to Combine) and Section IX.C.3 (Reasonable Expectation of Success).

258. There is nothing in Kumar that would have prevented this combination. Instead, like Truschel, Kumar is also directed to a system that collects and monitors sleep data. Ex. 1011, [0003] (“a method and apparatus for detecting disordered breathing in a patient”); Ex. 1009, [0015], [0068], [0239]-[0241], Abstract.

X. SECONDARY CONSIDERATIONS

259. 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 ’284 patent, including commercial success, long-felt need, failure of others, skepticism, praise, teaching away, recognition of a problem or copying competitors. However, to the extent Patent Owner subsequently present such evidence, I respectfully reserve the right to respond at the time.

XI. CONCLUSION

260. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Declaration of Dr. Sandeep Chatterjee
U.S. Patent No. 11,690,512

Dated: December 6, 2024

By: _____

Sandeep Chatterjee