

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Case IPR2023-00565

U.S. Patent No. 10,076,269

Issue Date: September 18, 2018

Title: Devices and Methods for Sleep Disorder Diagnosis and Treatment

DECLARATION OF JACOB SHARONY, Ph.D.

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I. INTRODUCTION

I, Jacob Sharony, declare as follows:

1. I have been retained as a technical expert for ResMed Corp. to provide technical assistance in analyzing U.S. Patent No. 10,076,269. I may refer to this patent as the '269 Patent or as the "Challenged Patent" in this Declaration.

2. I am familiar with the technology at issue in the period prior to the earliest priority date that is claimed by the '269 Patent. In formulating my opinions, I have relied upon my knowledge, education, training, skill, and experience in the relevant art, as well as on the documents and information described below. I have also considered the viewpoint of a person of ordinary skill in the art ("POSITA") as of the time of the invention, i.e., as of the date of the earliest priority filing date. I may review other materials throughout this proceeding, including any other documents or testimony that may emerge. Those materials may affect my opinions in this matter.

3. I have reviewed the '269 Patent, its prosecution history (application 13/440,116), and the prosecution of its parent application (11/266,899). I have also reviewed the Exhibits cited in this Declaration. A full list of the documents that I have considered in forming these opinions appears in a subsequent section of this Declaration.

4. I have been asked to consider certain prior art and to provide in this Declaration my opinions related to the patentability of the claims recited in the Challenged Patent.

5. I am being compensated at my standard hourly rate of \$550 per hour. My compensation is not dependent on the outcome of the IPR and in no way affects the substance of my statements in this Declaration. I have no financial interest in or against ResMed, the Challenged Patent, or who I understand to be the Patent Owner, **Cleveland Medical Devices, Inc.**

6. I make this Declaration based on my own personal knowledge and, if called upon to testify, would testify competently to the matters contained herein.

7. This Declaration is a statement of my opinion on issues related to the patentability of claims 1-20 of the '269 Patent (the "Challenged Claims"). I reserve the right to supplement my opinions expressed in this Declaration to address any new information obtained in the course of this proceeding.

II. BACKGROUND AND QUALIFICATIONS

8. Included as an **Appendix** to this Declaration is a copy of my *curriculum vitae*, which includes a detailed record of my professional qualifications, including a list of publications, awards and honors, and professional activities. Relevant highlights are summarized below.

9. I have over 35 years of experience working in data networks and mobile and wireless technologies, which has resulted in over 50 issued patents and numerous publications in scientific journals and conferences. I have also served on various government expert panels, including for the National Science Foundation and National Institutes of Health.

10. Since 2010, I have been an Adjunct Professor in Electrical Engineering at Columbia University, teaching graduate level courses on advanced wireless technologies including in the areas of wireless sensing and Auto ID technologies, mmWave communications, and applications for 5G wireless networks and systems. I have experience working with and analyzing physiological sensors, including but not limited to human activity sensors, heart rate and pulse sensors, and environmental sensors (e.g., proximity, temperature).

11. I received a Bachelor's Degree (1979) and Master's Degree (1984) in Electrical Engineering from Tel Aviv University. I have M.Phil. (1991) and Ph.D. (1993) Degrees in Electrical Engineering from Columbia University. I also have an MBA Degree (1989) from Tel Aviv University.

12. I have been involved with mobile and wireless networking technologies since the mid-1990s working as a researcher, developer and educator on wireless wide, local and personal area networks (WWAN, WLAN and WPAN), infrastructure and mobile devices. Over these two and a half decades I have

witnessed the change from voice-centric to data-centric networks, and have worked on enterprise mobility products and solutions as early as the late 1990s.

13. After obtaining my Ph.D., I led the advanced mobile networking group at BAE Systems, developing tactical mesh-based wireless network systems for the U.S. Department of Defense. I also conducted research and development in advanced mobile and wireless networks. My work resulted in several issued patents such as U.S. Patent No. 5,652,751 titled “Architecture for mobile radio networks with dynamically changing topology using virtual subnets,” and U.S. Patent No. 5,742,593 titled “On-line distributed TDMA/FDMA/CDMA link assignment in mobile radio networks with flexible directivity.”

14. From 1997 to 2005, I held various positions at Symbol Technologies (acquired by Motorola Solutions). While working at Motorola/Symbol I gained substantial experience in application-specific and data-capture mobile devices, and wireless networking and architecture solutions in several vertical applications, e.g., transportation and logistics, healthcare, warehousing, retail, and education, among others. As Senior Director, Research and Development, I initiated and led several research and development programs in wireless LAN technologies including mobile device management and security. As Senior Director, Technology Strategy and Development, I was responsible for the research and development of new mobile applications for delivering multimedia-rich content to mobile devices

connected over heterogeneous networks. That work resulted in several U.S. patents, including U.S. Patent Nos. 7,019,663 and 7,706,809 titled “RF tracking system and method,” U.S. Patent No. 7,778,649 titled “System and method for asset location in wireless networks,” and U.S. Patent No. 6,925,094 titled “System and method for wireless network channel management.”

15. In 2004, I founded Mobius Consulting, a consulting firm providing professional services in mobile wireless strategy, technologies, systems, and applications, including enterprise mobility, wireless communication networks, mobile embedded devices, device management, and mobile applications and services. In this capacity, I have worked with many companies in the mobile and wireless ecosystem including service providers and operators, equipment vendors, and semiconductor companies. Since founding Mobius Consulting, I have worked with many enterprises interested in deploying mobile and wireless solutions in order to become more productive, efficient, and cost effective. These solutions spanned numerous industry sectors and involved various mobile and wireless technologies including 3G/4G/5G Cellular, Wi-Fi, Bluetooth, ZigBee, and RFID. That work resulted in several U.S. patents, including U.S. Patent No. 9,014,702 titled “Location processing in small cells implementing multiple air interfaces,” U.S. Patent No. 9,088,923 titled “Small cells implementing multiple air

interfaces,” and U.S. Patent No. 10,080,177 titled “Unlicensed spectrum offload architecture for small-cell base stations.”

16. I worked for several years in the field of data capture devices, including digital images, and wireless communications. For example, I worked at Symbol Technologies, conducting research and development in data capture devices such as bar code imagers. Many of those devices used solid state image sensors, such as CMOS or CCD, which are particularly useful in capturing two-dimensional images in which machine readable code might be found. Such image sensors could be used as physiological sensors to sense changes in blood oxygen saturation or blood vessels volume and detect various vital signs. My involvement included reviewing illumination devices that project optical energy toward a surface, image capture devices such as those mentioned earlier in this paragraph, and communications systems like Bluetooth® and Wi-Fi which transmitted data from these data capture devices to physically separate devices such as mobile and wrist computers. For example, in logistics and warehousing applications we used a ring barcode scanner connected to a wrist computer via Bluetooth. The wrist computer was connected via Wi-Fi to the enterprise computing network.

III. LEGAL PRINCIPLES

17. My opinions are informed by my understanding of the relevant law, which I have been provided by counsel.

18. I understand that prior art to the Challenged Patent includes patents and printed publications in the pertinent art that predate the earliest priority date of the inventions recited in the patent's claims. I understand that the Challenge Patent claims priority to application 11/266,899 filed on November 4, 2005, as indicated on the Challenged Patent's front page.

19. I understand that the words of a patent claim are generally given their ordinary and customary meaning, which is the meaning that the term would have to POSITA at the time of the invention, *i.e.*, as of the effective filing date of the patent application (November 4, 2005). I understand that patent claims are interpreted in view of their specification and prosecution history.

20. I understand that a patent claim is invalid as anticipated under 35 U.S.C. § 102 where a single prior art reference discloses each and every limitation of the claimed invention.

21. I understand that under the doctrine of inherency, a prior art reference may anticipate the claimed invention even without explicitly disclosing each of the claim limitations, if the missing limitation(s) are necessarily present, or inherent, in the prior art reference.

22. I understand that a patent claim is invalid under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to POSITA. A claim may be found obvious in view of a single prior art reference or from a combination of two or more prior art references.

23. I understand that when relying on a combination of prior art references to establish obviousness under 35 U.S.C. § 103, it is necessary to show: (1) that the claim elements were known in the prior art; (2) that a person of ordinary skill in the art would have been motivated to combine these known elements; and (3) that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving the claimed invention by combining the cited references.

24. In determining whether a prior art reference would have been combined with other prior art or other information known to POSITA, I understand that the following principles may be considered:

- whether the references to be combined involve non-analogous art;
- whether the references to be combined are in different fields of endeavor than the alleged invention in the Patent;
- whether the references to be combined are reasonably pertinent to

the problems to which the inventions of the Patent are directed;

- whether the combination is of familiar elements according to known methods that yields predictable results;
- whether a combination involves the substitution of one known element for another that yields predictable results;
- whether the combination involves the use of a known technique to improve similar items or methods in the same way that yields predictable results;
- whether the combination involves the application of a known technique to a prior art reference that is ready for improvement, to yield predictable results;
- whether the combination is “obvious to try”;
- whether the combination involves the known work in one field of endeavor prompting variations of it for use in either the same field or a different one based on design incentives or other market forces, where the variations are predictable to a person of ordinary skill in the art;
- whether there is some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill in the art to modify the prior art reference or to combine prior art reference teachings to

arrive at the claimed invention;

- whether the combination requires modifications that render the prior art unsatisfactory for its intended use;
- whether the combination requires modifications that change the principle of operation of the reference;
- whether the combination is reasonably expected to be a success; and
- whether the combination possesses the requisite degree of predictability at the time the invention was made.

25. I understand that, to qualify as prior art for an obviousness analysis, a reference must qualify as “analogous art.” I further understand that a reference is considered analogous if it is from the same field of endeavor or is reasonably pertinent to the particular problem with which the inventor is involved. I further understand that a reference is reasonably pertinent if, as a result of its subject matter, it logically would have commended itself to an inventor’s attention in considering his/her problem.

26. I understand the motivation to combine analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, but instead can take account of the inferences and creative steps that POSITA would employ. I understand that the combination of familiar elements in the art

according to known methods in the field is likely to be obvious when it does no more than yield predictable results.

27. I understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

28. I understand that in addition to showing a motivation to combine, there is a separate requirement to show that a person of ordinary skill in the art would have a reasonable expectation of success in combining prior art references to meet the limitations of the claimed invention.

29. I understand that secondary considerations may support or rebut the obviousness of a claim. I understand that such secondary considerations that tend to rebut an obviousness argument include, among other things: (i) commercial success of the claimed invention, (ii) skepticism of those having ordinary skill in the art at the time of invention, (iii) unexpected results of the claimed invention, (iv) any long-felt but unsolved need in the art that was satisfied by the claimed invention, (v) the failure of others to make the claimed invention, (vi) praise of the claimed invention by those having ordinary skill in the art, and (vii) copying of the claimed invention by others in the field. I understand that contemporaneous and independent invention by others may be a secondary consideration tending to show

obviousness. I understand that there must be a nexus between any such secondary consideration and the claimed invention.

30. I understand that a patent claim is invalid for indefiniteness if, when read in light of the specification delineating the patent, and the prosecution history, it fails to inform, with reasonable certainty, a POSITA about the scope of the invention. Counsel informs me that indefiniteness is not an issue that can be addressed in an IPR proceeding so I have not endeavored to reach any opinion regarding the indefiniteness of any claim in the Challenged Patent.

31. I understand that a patent claim is invalid if the specification does not convey to a POSITA that the named inventor(s) had possession of the claimed invention. Counsel informs me that this so-called “written description” issue cannot be addressed in an IPR proceeding so I have not endeavored to reach any such opinion for any claim in the Challenged Patent.

32. I understand that a patent claim is invalid if the specification fails to teach a POSITA how to make and use the full scope of the claimed invention without undue experimentation. Counsel informs me that this so-called “enablement” issue cannot be addressed in an IPR proceeding so I have not endeavored to reach any such opinion for any claim in the Challenged Patent.

IV. INFORMATION CONSIDERED

33. In forming my opinions, I have considered, in addition to my knowledge and experience, the documents and materials listed below. Additional documents might be referenced in the body of this Declaration.

Exhibit	Description
EX1001	U.S. Patent No. 10,076,269 (Kayyali et al.)
EX1002	U.S. Patent No. 10,076,269 Prosecution History
EX1003	U.S. SN 11/266,899 ('269 parent) Prosecution History
EX1004	RESERVED for this Expert Declaration
EX1005	WO 02/078775A2 (Genger et al.)
EX1006	U.S. Patent No. 6,167,258 (Schmidt et al.)
EX1007	U.S. Patent Application Publication 2002/0165462A1 (Westbrook et al.)
EX1008	WO 2005/096737A2 (Farrell et al.)
EX1009	Paradiso, et al., <i>Wearable Health Care System for Vital Signs Monitoring</i> , 4 th Annual IEEE Conf. on Information Technology Applications in Biomedicine, 2003, at 283 ("Paradiso")
EX1010	WO 2005/028029A2 (Stahmann et al.)
EX1011	U.S. Patent Application Publication 2005/0171160A1 (Edgar et al.)
EX1012	U.S. Patent Application Publication 2003/0236450A1 (Kocinski)
EX1013	Guilleminault, et al., <i>Obstructive sleep apnea syndromes</i> , Med. Clin. N.Am. Vol. 88, No. 3 (May 1, 2004), pp.611-630.

	("Guilleminault-2004").
EX1014	Guilleminault, et al., <i>Clinical Overview of the Sleep Apnea Syndromes</i> , Sleep Apnea Syndromes (1978), pp.1-12. ("Guilleminault-1978).
EX1015	"Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research: The Report of an American Academy of Sleep Medicine Task Force," SLEEP Vol. 22, No. 5 (1999), pp.667-689 ("Chicago Criteria")
EX1016	Morón, et al., <i>A wireless monitoring system for pulse-oximetry sensors</i> , 2005 Systems Communications (ICW'05, ICHSN'05, ICMCS'05, SENET'05), Montreal, Quebec, August 14-17, 2005, pp.79-84.
EX1017	Bluetooth Ver.1.0B (Parts A and B) (November 1999)
EX1018	Roux et al., <i>Continuous positive airway pressure: new generations</i> , Clinics in Chest Medicine, Vol. 24 (2003), pp.315-342.
EX1019	U.S. Patent Application Publication 2005/0115561A1 (Stahmann et al.) ("Stahmann-EX1019")
EX1020	U.S. Patent No. 7,757,690 (Stahmann et al.) ("Stahmann-EX1020")
EX1022	Nieto et al., <i>Association of Sleep-Disordered Breathing, Sleep Apnea, and Hypertension in a Large Community-Based Study</i> , JAMA Vol. 284, No. 14 (April 12, 2000), pp.1829-1985.

V. OVERVIEW OF PRIOR ART AND THE CHALLENGED PATENT

Sleep Disorders such as Apnea and Hypopnea.

34. “During an apnea or hypopnea ... oxygen levels in the brain decrease, while the carbon dioxide (CO₂) levels rise, causing the sleeper to awaken.”

EX1007 (Westbrook), [0005].

35. “Apnea” is the cessation of airflow at the nostrils and mouth lasting a predetermined time. *See* EX1014 (Guilleminault-1978), 2. Among other types of data that quantify the level of severity of sleep disorders, an apnea “index,” such as “the number of apneas per sleep-hour, frequently gives a better indication of the seriousness of the disorder.” *Id.*

36. “Hypopnea” is a related condition tied to shallow breathing. In 1999, the American Academy of Sleep Medicine convened a Sleep Apnea Definitions Task Force whose report, often called the Chicago Criteria (EX1015), set forth definitional criteria for, *inter alia*, hypopnea as a relative reduction by more than 50% (from baseline) in breathing airflow amplitude (p.676, Sec. 5.1.2.2) **or** a less-than-50% decrease in airflow amplitude “associated with oxygen desaturation of $\geq$ 3% or an arousal.” *Id.*, 675-676 (Sec. 5.1.2.4) (emphasis added). Accordingly, POSITA have long known that hypopnea events can be detected by measuring **both** breathing volume **and** blood oxygen saturation. Choosing whether to detect

hypopnea events from the finite number of identified, predictable methods that were known at the time of the Challenged Patent's purported invention – such as by using airflow amplitude alone or airflow amplitude in combination with oxygen desaturation – and knowing there would be reasonable expectations of success, demonstrates that it would have been at least obvious to try either method in a given system. Considering oxygen desaturation together with airflow amplitude would also have helped POSITA to confirm whether a particular shallow-breathing event should indeed be classified as a hypopnea event.

37. The association between hypopnea and a decrease in blood oxygen saturation level has been known for many years (much before 2005), and various definitions of hypopnea were used, where the threshold for oxygen desaturation varied (2-4%). For example, *Association of Sleep-Disordered Breathing, Sleep Apnea, and Hypertension in a Large Community-Based Study*, JAMA Vol. 284, No. 14 (April 12, 2000), pp.1829-1985 (EX1021), called for at least 4% drop in oxyhemoglobin saturation. The American Academy of Sleep Medicine (AASM) defined hypopnea in relation to a decreased level of blood oxygen saturation of at least 3% in 2007. Nevertheless, no matter what threshold is used, there is a need to measure the blood oxygen level to count hypopnea events.

AHI (Apnea Hypopnea Index) and RDI (Respiratory Disorder Index).

38. A prior art “apnea hypopnea index” or “AHI” is a measured number of apnea and hypopnea events per unit time. EX1008 (Farrell), 8:8-17; EX1015 (Chicago Criteria), Sec.4.1.2.1, 4.1.2.3. Because AHI includes the detection of hypopnea events (in addition to apnea events), POSITA would have known that AHI, like hypopnea, can be determined by measuring **both** breathing volume **and** blood oxygen saturation. AHI was admitted by Patent Owner during prosecution to be “an indicator of the level of severity of a patient’s sleep disordered breathing...,” which resembles language in the Challenged Claims. EX1003, pp.35-36; p.39 (same).

39. Indeed, “OSA [Obstructive Sleep Apnea] can be classified based on the apneas plus hypopneas per hour of sleep index (AHI) or respiratory disturbance index ([RDI] apneas plus hypopneas plus respiratory event-related arousals per hour of sleep) into mild ($5 < \text{AHI or RDI} < 15$); moderate ($15 < \text{AHI or RDI} < 30$); or severe ($\text{AHI or RDI} > 30$). UARS [Upper Airway Resistance Syndrome] has been defined as having a RDI less than 4 and arterial oxygen saturation (SaO_2) greater than 93%.” EX1013 (Guilleminault-2004), 615-616. Others have used different thresholds: “Patients with an RDI of 10 or less were classified as low risk ... between 11 and 40 were grouped as moderate risk [and] RDI greater than 40 were classified as high risk.” EX1007 (Westbrook), [0152].

CPAP Treatment Devices.

40. Sleep disorder treatment devices that use positive air pressure, often called “continuous positive airway pressure” or “CPAP” devices, were developed in the early 1980s (EX1013 (Guilleminault-2004), 2) and remain common today. A subset of such devices that “respond[ed] to changes in upper airway resistance by variably increasing or decreasing the [air] pressure generated” were sometimes referred to as “APAP” or “automated positive airway pressure devices.” EX1018 (Roux), p.315.

Prior Art Systems Described in the Challenged Patent Used Sensor Feedback to Adjust a Sleep Disorder Treatment Device.

41. The Challenged Patent acknowledges that “the most common method of treating the sleeping disorder of sleep apnea is by apply[ing] a continuous positive gas pressure to the patient’s airway, which has the effect of forcing the patient to breath[e] through application of the pressure. More advanced, but still very basic *devices have been developed that adjust this continuous positive gas pressure through sensors built into the device* for creating the positive gas pressure, *which measure gas flow through the device.*” EX1001, 2:17-25 (emphasis added).

42. The Challenged Patent also concedes that sleep disorders had been diagnosed using objective physiological evaluations such as “polysomnography to

evaluate the patient[']s sleep architecture (e.g., obtaining respiratory disturbance index to diagnose sleep apnea) followed by an all day test such as the Multiple Sleep Latency Test (MSLT) or its modified version, Maintenance of Wakefulness Test (MWT).” *Id.*, 1:40-56.

43. Despite PO’s acknowledgement that prior art CPAP devices already used feedback sensors to adjust their operation, and that objective “indices” of a patient’s respiratory disturbance had already been used to evaluate the severity of their disorder, the Challenged Patent purports to disclose an inventive “integrated apnea diagnosis and treatment device” and a “method of sleep diagnosis and treatment” (1:21-23) where “an object of the present invention [is] to provide a system and method of treatment, which analyzes a subject’s sleeping disorder or symptoms and adjusts a treatment device based, in part, on this analysis.” *Id.*, 2:38-41. Among the calculations the Challenged Patent uses are an *unspecified* “index” or “level of severity” of the patient’s sleep disorder. *See* Challenged Claims.

The Challenged Patent Likewise Uses Sensor Feedback to Adjust a Sleep Disorder Treatment Device.

44. Ten columns of the Challenged Patent’s specification – from 8:57 to 18:50 – copy the entire Detailed Description of U.S. 6,167,258 (Schmidt) (EX1006). The Challenged Patent also copies all of Schmidt’s Figures 1-6. Schmidt is not identified on the front two pages of the Challenged ’269 Patent.

45. The Challenged Patent's Figures 1-6 come from Schmidt, and Figure 7 (below) illustrates a "conventional pressure support system 310" (EX1001, 22:47-48) which leaves only Figure 8 in the Challenged Patent as illustrating allegedly inventive material.

46. Schmidt disclosed a wireless physiological data acquisition system that gathers patient data, including an "SpO₂" signal (*id.*, 4:7-22) which reflects blood oxygen saturation and can be obtained from a pulse oximeter sensor. *See* EX1007 (Westbrook), [0065]. As in the Challenged Patent, Schmidt's SpO₂ sensor, PO₂ sensor (partial pressure of oxygen dissolved in blood), PCO₂ sensor (partial pressure of CO₂ in blood), "air flow" sensor, respiration sensor, and others supply data to signal processing module 16 for conditioning and processing by its "module microcontroller [which dynamically] adapts the signal processing module in response to variation in the range, character and type of the physiological signal such that the adaptation occurs during signal processing module operation." *See* EX1006 (Schmidt), 4:7-22; 14:40-54; EX1001, 18:36-50. The processing module 16 wirelessly transmits data to base station 40 via bidirectional transceivers (*id.*, 5:32-38; Fig. 1), as in the Challenged Patent (9:26-32).

47. Schmidt's invention was designed to "be adapted for different applications by software programming" (*id.*, 1:15-20) including a "biomedical

environment” (*id.*, 8:32-33; 6:28-35) and, in fact, as a “universal platform design [that] can be utilized for all applications.” *Id.*, 6:40-41; 7:16-20.

The Challenged Patent Uses Known Treatment Devices

48. The Challenged Patent does not disclose a new sleep disorder treatment device. Instead, “[t]he treatment device can be any device known to those skilled in the art. The treatment device can either physically or chemically treat the subject’s sleeping disorder. An example of physically treating the subject’s sleeping disorder would be a device to provide positive airway pressure to a subject.” EX1001, 3:48-53; *see also* 4:1-3 (“a continuous positive airway pressure (CPAP) device [is] for treating the subject’s sleep apnea”); 2:18-19 (aka “continuous positive gas pressure” devices). A “conventional” CPAP device 310 (Figure 7) is acknowledged as including “a pressure generator 312, a blower, a piston or bellows, that receives a supply of gas from a gas source, such as ambient atmosphere ... or pressurized gas tanks ... [and] a flexible conduit [that] delivers the elevated pressure breathing gas to the airway of the subject.” *Id.*, 22:47-56.

49. The Challenged Patent further acknowledges that “[p]hysical and chemical methods to treat sleeping disorders ***are known to those skilled in the art.*** ... Physical methods to therapeutically treat sleeping disorders and symptoms of these disorders include [CPAP], electrical stimulation of the muscles and nerves,

and the like. Chemical methods to therapeutically treat sleeping disorders and symptoms while less common include various pharmaceutical agents with various delivery techniques including oral delivery, injection, transdermal delivery, injection with a controlled pump, inhalation therapy and the like.” *Id.*, 22:13-28 (emphasis added).

The Challenged Patent Uses Known Sensor(s)

50. The Challenged Patent also did not invent a new type of sensor. “Sensors which can be used are known to those skilled in the art.” EX1001, 4:10-11. “The diagnostic part of the system of device can use various sensors for measuring the subject’s brain wave signals, respirations and the like. ... Sensors for measuring the subject’s respirations or oxygen levels include sensors to measure airflow, respiratory effort, oxygenation and ventilation, and the like.” *Id.*, 3:9-15. “Measurement of oxygenation and ventilation is preferably measured by pulse oximetry, transcutaneous oxygen monitoring, transcutaneous carbon dioxide monitoring, expired end carbon dioxide monitoring, and the like.” *Id.*, 3:25-28; *see* 7:40-43.

The Challenged Patent Uses Known Data Analysis Algorithms

51. The Challenged Patent relies on data analysis algorithms that were known in the art. “Various algorithms known to those skilled in the art are used to

filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms." EX1001, 20:1-4. "Various sleeping disorders have symptoms that can be predicted based on various combinations of physiological signals or data. Various embodiments of the present invention include the approach to identifying these symptoms prior to onset by identifying various characteristic shifts in the power spectrum of the sensors being used to monitor these physiological conditions." *Id.*, 20:9-15. The purported invention "would also include other on-line signal processing algorithms known to those skill in the art, such as wavelet analysis...." *Id.*, 20:26-31.

VI. ADDITIONAL BACKGROUND KNOWN BY POSITA

52. I explained above that the specification of the Challenged Patent relies on *known* CPAP devices, *known* patient sensors (including Schmidt's), and *known* algorithms (including Schmidt's signal processing).

Pulse Oximeters Sense Blood Oxygen Level.

53. POSITA knew, before the purported invention, that pulse oximeters existed, and transmitted their signals by wired or wireless (e.g., Bluetooth®) methods. "A pulse oximeter is a noninvasive sensor which provides a continuous estimation of arterial hemoglobin oxygen saturation as well as the pulse rate. These important measurements inform about the blood oxygenation and can be updated

with each heartbeat.” Morón, 81 (EX1016, p.14). “The pulse oximeter consists of a transducer which employs two Light Emitting Diodes (LEDs) and a photodetector diode. One of the LEDs emits red light (with a wavelength of $\lambda = 660$ nm) while the other generates infrared light ($\lambda = 940$ nm). The sensor is based on the fact that the colour of blood varies depending on the oxygen it contains. In particular the hemoglobin molecules reflect more red light when they are oxygenated than when reduced while its behaviour is the opposite when the light is infra-red. The oximeter shines two beams of light through a finger (or earlobe etc.) which are finally received in the photodetector. By comparing the light intensity that is received (not reflected by the finger) for each wavelength, the oximeter is able to derive the light that is being absorbed by the blood and, consequently, the oxygen saturation. Moreover, the heart rate can be estimated from the slight change in the colour provoked by a beat of the heart pushing arterial blood into the finger. Conventional pulse-oximetry probes (as other traditional medical sensors) are attached to the medical monitors by wires. This technology limits the movements of the patient who is normally obliged to stay in bed. Recently, different vendors such as Nonin, Numed or Cardguard have developed [B]luetooth pulse-oximeters. This type of sensors results in greater flexibility and freedom of movement for both the patient and the healthcare provider.” Morón, 81-82 (EX1016, 14-15) (brackets omitted).

54. Accordingly, when the prior art discusses blood oxygen sensors, POSITA would have understood that a pulse oximeter was a known and obvious choice, and would have expected success because pulse oximeters were known to supply reliable blood oxygen measurements.

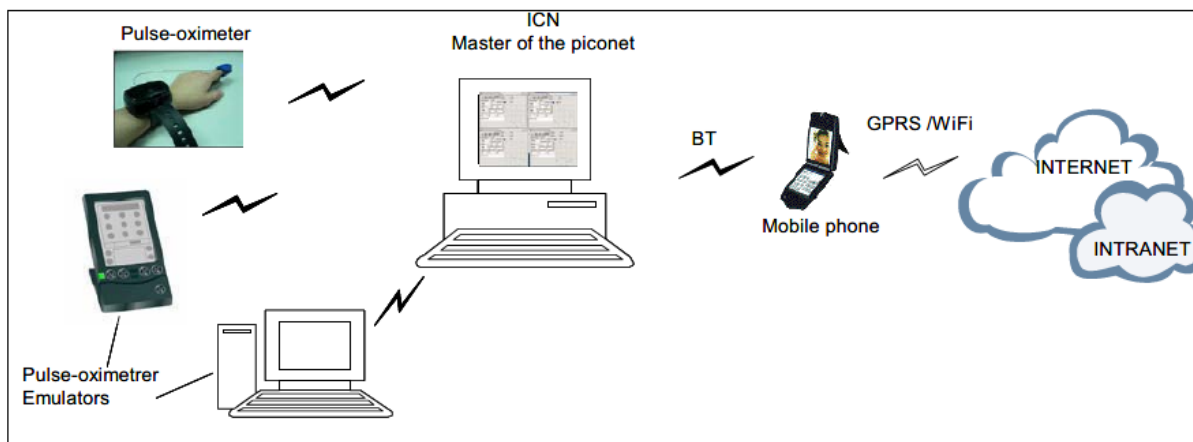


Figure 1. Prototype of the *piconet*

Morón, Figure 1.

A Pulse Oximeter's Signal was Best Filtered and Processed.

55. The prior art Schmidt patent supplied its external sensor's signal, such as the SpO₂ signal, to an analog-to-digital converter 24 which "conditions it" (EX1006 (Schmidt), 6:47-49) and provides "inherent" filtering such as antialiasing filtering (*id.*, 11:1-5). Schmidt prefers a controllable A/D converter in order to provide a specific "sampling rate, filtering and gain." *Id.*, 6:56-59. Schmidt suggests use of a filter to "reject offset voltages in an AC-coupled application, or to reject extremely high frequencies which fall well beyond the frequency band of

interest, or a combination of the two.” *Id.*, 9:67-10:4. An AC coupling filter 225 is also suggested (*id.*, 10:32-52), as is an antialias filter for lowpass filtering “to guard against false signals caused by aliasing between external input 12 content and sampling rate of downstream sampling functions such as multiplexing and analog-to-digital conversion.” *Id.*, 10:53-57. A programmable gain amplifier 241 is also suggested to adjust amplitude “to match the amplitude accepted by the A/D converter”. *Id.*, 11:11-13. In short, “utilization of programmable firmware allows [for] inexpensive and flexible operation for the inputting, conditioning and processing of any type, character and range of the external inputs. This also allows the module microcontroller, in response to the variation of the extern inputs 12, or in response to instructions received by RF signal through the module receiver 29, to adapt the signal processing module 16 based upon the variations allowing the signal processing means 16 to input, condition, process and transmit said external input notwithstanding said variation.” *Id.*, 14:40-50.

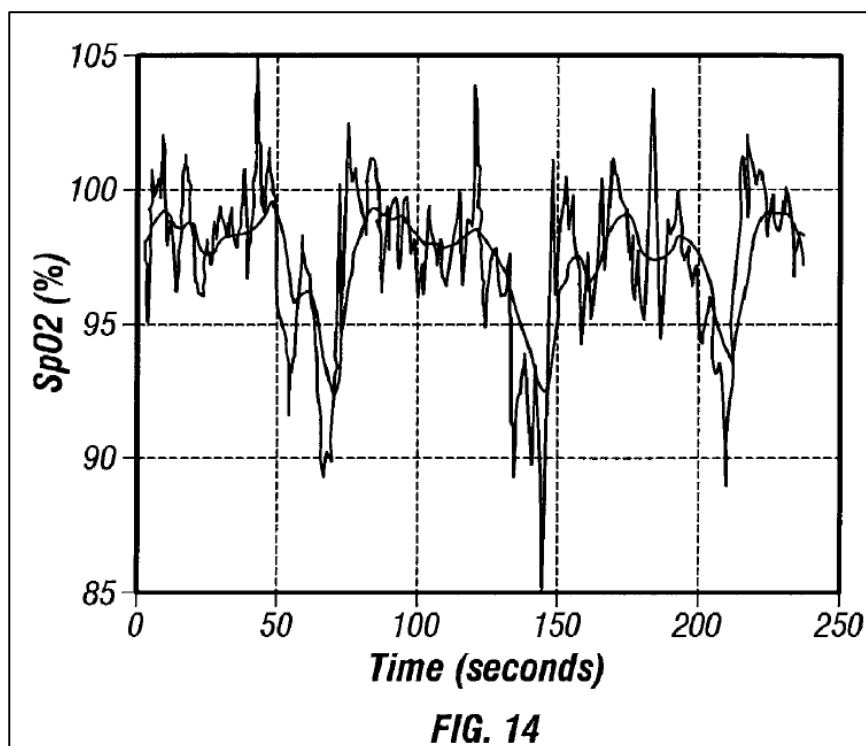
56. Separately, POSITA knew that “[t]he measurement of oxyhemoglobin saturation using pulse oximetry was developed in the 1940s, but became practical and universally available with the availability of microprocessors. A pulse oximeter typically utilizes two different light sources (e.g., red and infrared), which measure different absorption or reflection characteristics for oxyhemoglobin (i.e., the red, saturated blood) and deoxyhemoglobin (the blue, unsaturated blood). The

oximeter then measures the ratio (percent) of saturated to unsaturated hemoglobin. One method to determine blood oxygen saturation is by transmission oximetry [which] operate by transmitting light through an appendage, such as a finger or an earlobe, and comparing the characteristics of the light transmitted into one side of the appendage with that detected on the opposite side. Another method ... is by reflectance oximetry, which uses reflected light to measure blood oxygen saturation.” EX1007 (Westbrook), [0021]; *see* [0022] (“Pulse-oximeter devices commonly used for the diagnosis of sleep apnea....”); [0023] (“Most commercial pulse-oximetry sensors in use today are designed to be taped or affixed to the body with a wire lead that is inserted into the pulse-oximeter monitoring equipment. This wire lead, however, is one of the main sources of measurement artifacts.”).

57. POSITA also knew, well before the purported invention, that a pulse oximeter’s signal was best filtered and processed (e.g., by slew limitation and/or averaging by IIR filtering) to reduce the effects of noise and to increase the detection of desaturation events. *First*, the Challenged Patent acknowledges that “algorithms known to those skilled in the art are used to filter out noise from the signal or data, and then to quantify the level of severity of the subject’s sleeping disorder or symptoms.” EX1001, 20:1-4. *Second*, POSITA also knew that such filtering and processing were used in CPAP environments. For example, Westbrook disclosed in Figure 10 “a block diagram representation of the

physiological monitor of the present invention integrated with a CPAP device. The integrated device 910 contains both a CPAP with the ‘smart system’ (hereinafter referred to as ‘smart CPAP’) (that monitors compliance by recording and storing the time the CPAP device is on at the prescribed pressure) and the physiological monitor 12 of the present invention. By incorporating the physiological monitor, the integrated device 910 not only monitors compliance, but also provides data on the efficacy and the time of use of the CPAP. When used routinely as part of the smart CPAP headgear (integrated device 910), the data analysis procedures of the current invention may be implemented in real-time so that only summary data (i.e., the occurrence and duration of respiratory events) would be stored for periodic review to assess the fit of the mask and adjustment of the pressure, rather than storing a full-disclosure recording. In the preferred embodiment, respiratory events would be monitored in real-time using a digital signal processing chip or micro-controller capable of processing the data (or signals).” EX1007 (Westbrook), [0166]; *see* [0167]. “The SpO2 [‘pulse oximeter sensor’; *see* [0065]] values calculated from red and infrared signals should be smoothed in order to reduce the effects of noise and increase the detection of desaturation events. In the preferred embodiment, this smoothing is done in three successive steps ***using median filtering, slew limitation, and averaging by IIR filtering***. FIG. 14 displays a raw SpO2 signal and the SpO2 signal after application of the three step smoothing. It

should be understood that fewer than all three smoothing operations may be performed, and smoothed data produced from one smoothing operation may be used as data input for a next smoothing operation, in any sequence.” *Id.* (Westbrook), [0108] (emphasis added).



EX1007 (Westbrook), Figure 14.

58. Accordingly, when the prior art used a pulse oximeter, POSITA would have understood that its signal was best filtered and processed to create a more useful signal, and thus would have found it obvious, and expected success, to filter and process it.

Bluetooth Ver.1.0B (1999).

59. POSITA knew that, since its inception and certainly before the purported invention, Bluetooth® devices exchanged information using bidirectional radio transceivers. “The Bluetooth transceiver is operating in the 2.4 GHz ISM band. This specification defines the requirements for a Bluetooth transceiver operating in this unlicensed band.” EX1017, p.18; *see* p.41 (“Bluetooth is a short-range radio link intended to replace the cable(s) connecting portable and/or fixed electronic devices. Key features are robustness, low complexity, low power, and low cost. Bluetooth operates in the unlicensed ISM band at 2.4 GHz. ...The Bluetooth system consists of a radio unit (see Radio Specification), a link control unit, and a support unit for link management and host terminal interface functions.... The Bluetooth system provides a point-to-point connection (only two Bluetooth units involved), or a point-to-multipoint connection, see Figure 1.2 on page 42. In the point-to-multipoint connection, the channel is shared among several Bluetooth units. Two or more units sharing the same channel form a *piconet*.”). “The Bluetooth system is operating in the 2.4 GHz ISM (Industrial Scientific Medicine) band. In a vast majority of countries around the world [including the U.S.A.] the range of this frequency band is 2400 - 2483.5 MHz. Some countries have however national limitations in the frequency range. In order to comply with these national limitations, special frequency hopping algorithms have been

specified for these countries.” *Id.*, p.19 (Sec. 2 – Frequency Bands and Channel Arrangement). “The Bluetooth transceiver applies a time-division duplex (TDD) scheme.” *Id.*, p.87.

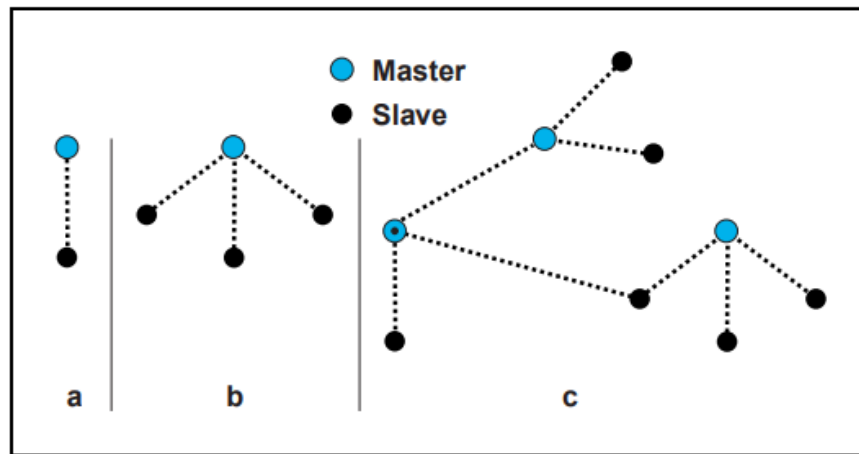


Figure 1.2: Piconets with a single slave operation (a), a multi-slave operation (b) and a scatternet operation (c).

Bluetooth 1.0B, Figure 1.2.

VII. PROSECUTION HISTORY

60. The Challenged Patent was filed as application SN 13/440,116 (EX1002) on April 5, 2012, as a continuation of SN 11/266,899 (EX1003) filed November 4, 2005, now U.S. Patent No. 8,172,766.

Parent Application 11/266,899.

61. During prosecution of the parent '899 application, PO made notable concessions to the Examiner. In a September 2010 response, PO's representative acknowledged that Stahmann (EX1019 – U.S. Publication 2005/0115561A1) disclosed CPAP devices with closed-loop control by physiological sensors.

EX1003, p.155 (“Stahmann teaches that the respiratory therapy device 200 (i.e., the CPAP of Stahmann) ‘may be coupled to an array of data acquisition devices 222’ ([0190]).”); p.137 (same); p.158 (Stahmann “teach[es] a CPAP controlled by an implantable cardiac therapy device (i.e., a pacemaker) or vice versa.”).

62. For pulse oximetry, PO’s representative agreed “a ‘pulse oximeter’ as understood in the art is an externally-worn device and the Applicants’ specification indicates no differently. (‘Preferably, pulse oximeters are placed on a subject’s earlob[e] or fingertip. More preferably, the pulse oximeter is placed on the subject’s index finger.’” EX1003, p.156 (quoting specification p.14:13-15 (Challenged Patent, 8:23-25)); *see* p.138 (same, Appeal Brief, p.9/16). PO noted that “Stahmann[’s] paragraphs [1383]-[1384] disclose the two ways contemplated by Stahmann for delivery of pulse oximeter signals – either from the sensor, *wirelessly*, to an implanted device [like a pacemaker], or *from the sensor to the therapy device (CPAP)*.” *Id.*, p.138 (Appeal Brief, p.9/16) (emphasis added).

63. Also, as previously explained herein (see Par. 38, *supra*), then-applicant admitted that AHI was “an indicator of the level of severity of a patient’s sleep disordered breathing...,” which resembles language in the Challenged Claims. EX1003, pp.35-36; p.39 (“AHI is indeed an indicator of the level of severity of a patient’s sleep disordered breathing”).

64. During prosecution of the parent '899 application, the Examiner's first office action dated November 9, 2009, rejected certain claims as anticipated by Chervin (U.S. Patent 7,190,995). EX1003, p.213. After claim amendments (EX1003, pp.198-201), the Examiner's final office action on May 25, 2010, rejected certain claims as anticipated by Stahmann (U.S. Publication 2005/0115561A1). EX1003, pp.169-179.

65. The applicant filed a Brief on Appeal (EX1003, pp.130-145), and the Examiner subsequently rejected certain claims over Wright (U.S. Publication 2002/0185130A1) (EX1003, pp.114-123) which the then-applicant conceded discloses an apparatus having "a computer-controlled blower 2, flow and pressure sensors 4, a mask 6, an air delivery conduit 8, a communication port or module 10, an oximeter, and a sense tube 14." EX1003, p.96 (response p.7/21). Furthermore, it conceded that Wright's breathing apparatus has "an interface for connection to a diagnosis unit ... [that] 'includes a pulse oximeter 20, respiratory movement sensors 22, EEG & ECG 24.'" *Id.* (quoting Wright, par.29). As for Wright's pulse oximeter output signal, then-applicant stressed that this output signal is **not**, by itself, "an output of the level of severity of a subject's sleeping disorder or symptoms." EX1003, p.97 ("While paragraph 29 [of Wright] does indicate that the diagnosis unit of Wright includes a pulse oximeter 20 and respiratory movement sensors 22, it is silent regarding the use of signals from these sensors to create an

output of the level of severity of a subject's sleeping disorder or symptoms.”). The applicant also noted in the same response that Wright referred to an existing product that “can automatically increase the CPAP pressure during an obstructive apnea to stabilize the airway.” EX1003, p.99.

66. In a subsequent August 9, 2011, office action (EX1003, pp.57-87), the Examiner relied on Wright in combination with secondary references like Farrell (U.S. Patent 7,878,198). The focus of the claims and the prosecution arguments centered around the claimed requirement for “diagnosing” a level of severity of a subject's apneas (which is not recited in the Challenged Claims addressed in this Declaration) but then-applicant's response on October 28, 2011, conceded (when discussing Wright's disclosure) that “While paragraph [0045] of Wright states that the apparatus disclosed therein can generate an apnea hypopnea index, or AHI, and while AHI is an indicator of the level of severity of a patient's sleep disordered breathing, one of ordinary skill in the art would recognize that the method of obtaining AHI described in paragraph [0045] does not even require the use of a respiration belt sensor and pulse oximeter sensor as does claim 1.” EX1003, pp.35-36; *see* p.39 (“while AHI is indeed an indicator of the level of severity of a patient's sleep disordered breathing, one of ordinary skill in the art would recognize that AHI alone is not sufficient to diagnose the type of sleep disordered

breathing that patient has, because AHI alone as described in paragraph [0045] [of Wright] does not distinguish between central apneas and obstructive apneas.”).

67. The claim amendments that accompanied the applicant’s October 28, 2011, response (EX1003, pp.31-34) led the Office to allow the ‘899 application. EX1003, pp.21-26.

Challenged Patent’s Application 13/440,116.

68. A preliminary amendment on or about April 5, 2012, added new claims 21-40. EX1002, pp.472-478. The Examiner issued a Restriction Requirement but withdrew it (EX1002, p.388) after the applicant’s traversal. The Examiner rejected most claims as being anticipated by Farrell (U.S. Patent 7,878,198) or as obvious in combination with Tsukashima (U.S. Patent 47,1091,341) or Burton (U.S. Patent Application Publication 2005/0217674A1). EX1002, pp.386-406. The applicant amended the claims on May 26, 2016, and conceded that “Farrell makes clear that flow and pressure measurements of the delivered air [in a PAP device] are used to adjust the PAP device....” EX1002, p.372. In the same sentence, applicant conceded that “respiratory effort ... is commonly used to look for central sleep apneas” and that “pulse oximetry ... shows the prolonged effects of multiple apnea events.” *Id.* Applicant also “point[ed] out that the air flow and air pressure signals of the PAP device in Farrell are used to determine the output level of the PAP device – not the respiratory effort

or pulse oximeter – these are merely used in Farrell to provide the physician with more information about the subject’s physiological characteristics during apnea incidents – not for adjusting the output through the processor of the PAP device as claimed.” EX1002, p.373.

69. Thereafter on September 6, 2016, the Examiner allowed certain dependent claims and rejected most amended claims as anticipated by Miles (U.S. Patent 5,353,788) or, for three claims, obvious over Miles and Stahmann (U.S. Patent 7,757,690). EX1002, 335-350. In response (EX1002, pp.319-333), the applicant amended all independent claims. Thereafter, the Examiner combined Miles with either Hedner (U.S. Patent Application Publication 2008/0257349A1) or Wright (U.S. Patent 6,832,609) and/or Stahmman (U.S. Patent 7,757,690). EX1002, pp.262-284. In a response dated April 3, 2017 (EX1002, pp.244-260), applicant again amended each independent claim. In the next office action on July 12, 2017 (EX1002, pp.202-239) the Examiner indicated that applicant’s amendments and arguments were not persuasive, so the same prior art was applied. On October, 12, 2017, the applicant’s next response (EX1002, pp.179-195) amended two of the three independent claims and added a fourth (claim 41). The examiner’s next office action on November 27, 2017 (EX1002, pp.132-166) rejected most claims as anticipated by Wright (U.S. Patent Application Publication 2002/0185130A1) or obvious when combined with Khair (U.S. Patent 6,533,729)

or Mumford (U.S. Patent 7,575,005) and/or Bowen (U.S. Patent 7,225,809). Thereafter the applicant amended a handful of claims and argued primarily that Wright's system treated stroke patients rather than sleep disorders. EX1002, pp.107-110. The Examiner and applicant had an interview in April 2018 (EX1002, pp.101-102) and thereafter an Examiner's Amendment placed the claims into allowable form. EX1002, pp.22-38. The Examiner's Amendment added limitations to several claims including each independent claim, e.g., claim 21 (now patent claim 1), claim 28 (now patent claim 5), claim 34 (now patent claim 8) and claim 41 (now patent claim 15).

VIII. LEVEL OF ORDINARY SKILL IN THE ART

70. A POSITA as of the priority date of the Challenged Patent (November 4, 2005) would have had a bachelor's degree in mechanical engineering, electrical engineering, computer science or an equivalent field and two years of industry experience working with diagnostic sensor systems and networked data systems. An increase in experience could compensate for less education, and vice-versa.

IX. CLAIM CONSTRUCTION

71. I do not believe any claim term needs formal construction for purposes of evaluating the Challenged Claims' patentability in view of the prior art

cited herein. I reserve the right to propose constructions in response to Patent Owner's arguments in this proceeding.

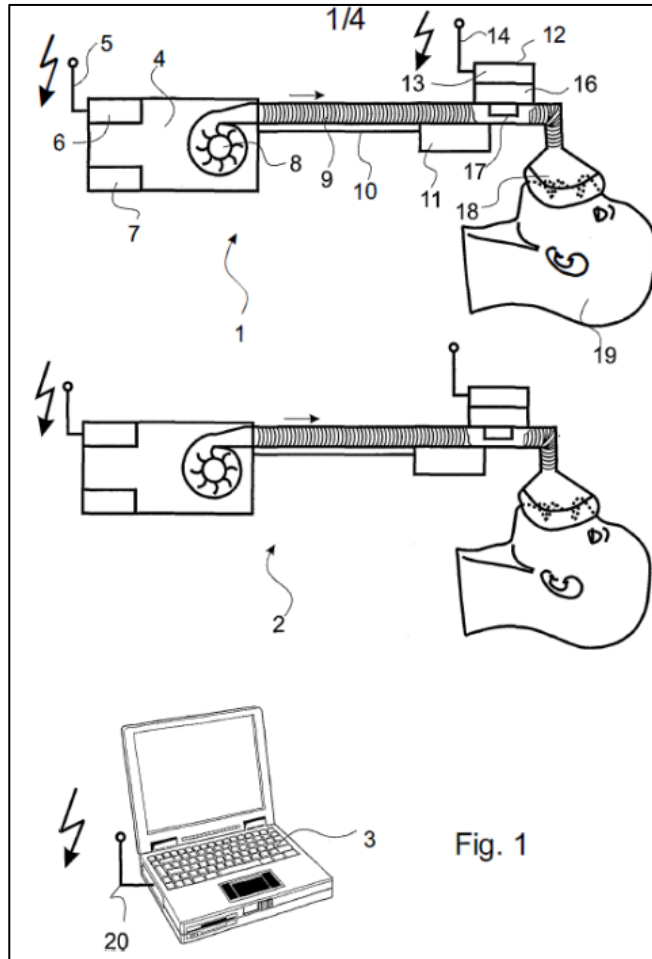
X. GROUND 1: CLAIMS 1-3, 5, 7 ARE OBVIOUS OVER GENDER IN VIEW OF SCHMIDT, WESTBROOK AND FARRELL.

72. Each prior art reference cited in this Ground 1 and subsequent Grounds identified in this Declaration is “analogous art” as explained to me (see the Legal Principles, *supra*). They are analogous art to each other and to the Challenged Patent because they are in the same field of endeavor – they describe the collection and communication of data among components of sleep disorder diagnosis and treatment systems (and the Bluetooth 1.0B specification explains the meaning of the term “Bluetooth” when used in the cited references). They are also reasonably pertinent to the problem alleged in the Challenged Patent, such as “adjust[ing] a patient’s treatment, whether physical or chemical, based on the patient’s current physiological state” or “adjust[ing] a patient’s treatment, based on the patient’s current symptoms.” ’269 Patent, 2:27-31. The references are thus from the same field of endeavor and/or faced the same problems as the Challenged Patent.

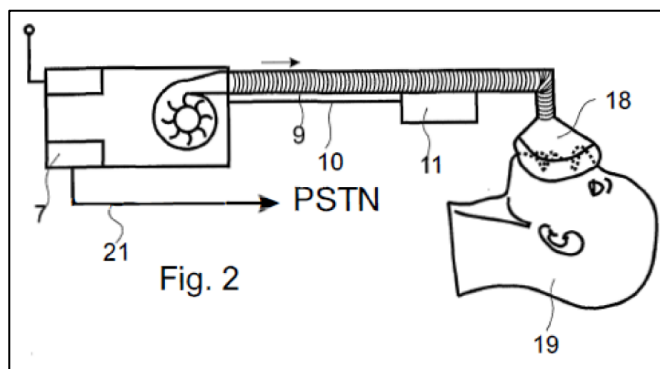
[Claim 1.pre] A positive airway pressure (PAP) sleep disorder treatment system comprising:

73. Genger discloses a PAP sleep disorder treatment system. Genger’s “invention relates in particular to CPAP (continuous positive airway pressure; *see*

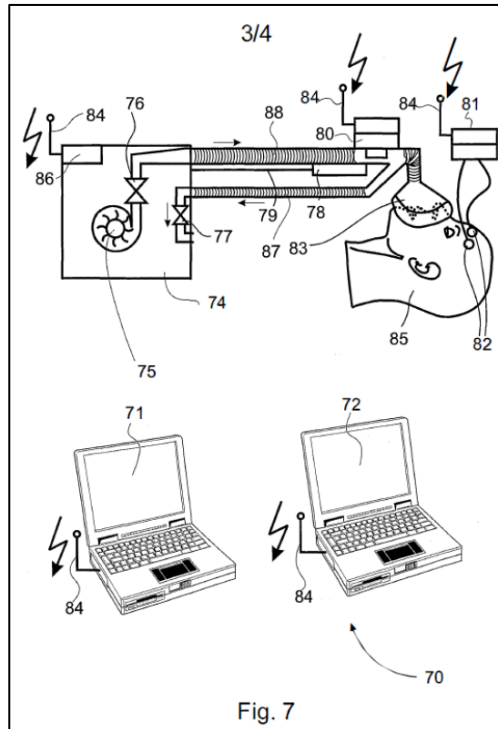
1:27) treatment devices, which communicate, in a wireless manner, with sensor units and monitoring devices, to radio modules that are suitable for use in the medical field, to respiratory devices, which likewise communicate, in a wireless manner, with sensor units and monitoring devices and to an intelligent networking of treatment rooms in a hospital, of a hospital network, of national organizations, of medical establishments and also of domestic environments.” EX1005, Abstract. “It is the purpose of the present invention to provide a radio module, a respirator, a therapeutic device for carrying out CPAP treatment and monitoring devices therefor, systems and methods for making medical devices more user-friendly.” *Id.*, 4:19-21. *See* Figures 1-8. In Figure 1, “[e]ach CPAP set-up station [1, 2] comprises a CPAP treatment device and a patient 19.” *Id.*, 10:15-16.



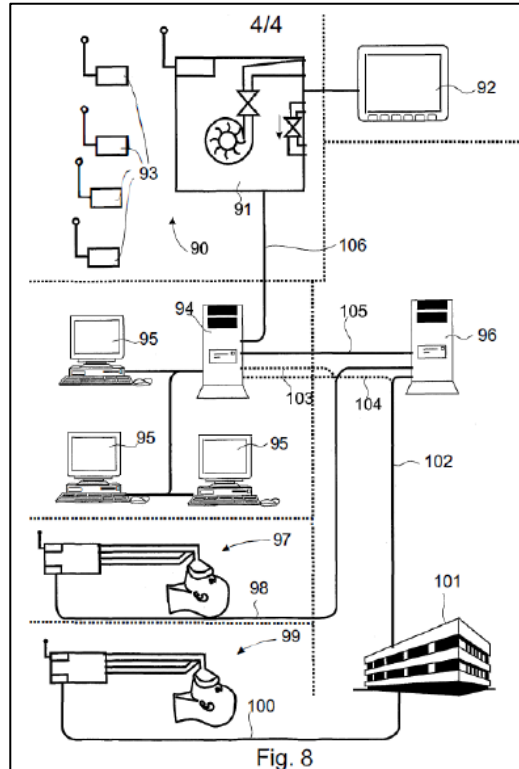
Genger, Figure 1 (sleep laboratory environment; *see* 11:21).



Genger, Figure 2 (domestic environment, *see* 12:19).



Genger, Figure 7 (intensive care environment, *see* 14:30).



Genger, Figure 8 (combined hospital and private home network, *see* 10:11-12).

[1.a] a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data;

74. Genger discloses this limitation or renders it obvious in combination with Schmidt and Westbrook.

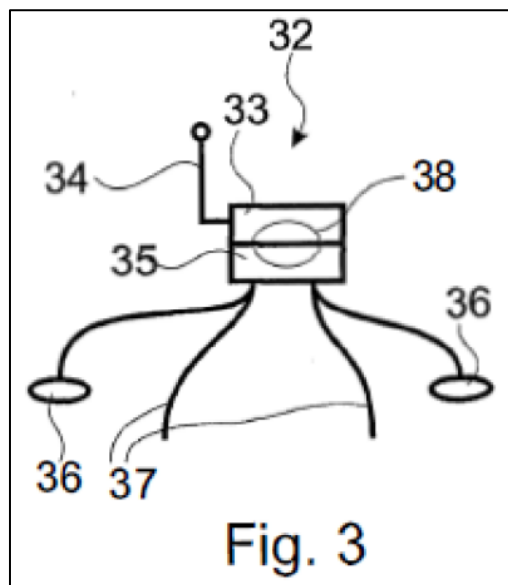
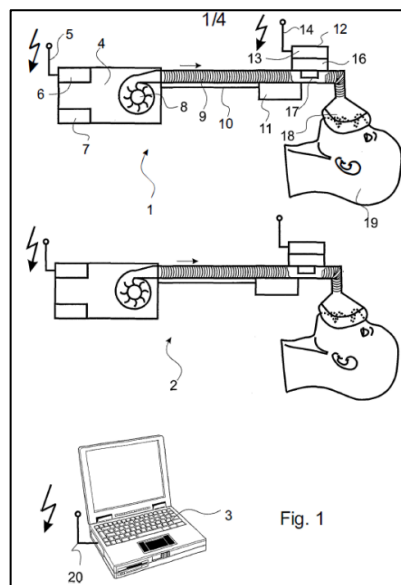
75. **Signal Processing Module**: The claimed signal processing module is met by Genger's sensor unit which includes (a) radio module 13 (Fig. 1) or 33 (Fig. 3) or the comparable component shown in Figures 7 (e.g., at sensor unit 80 (p.15:1, 20:57)) and 8, and (b) sensor module 16/35. Note, for example, that Genger's claim 1 mentions that "wherein the radio module (13; 33) digitizes the output signal of the sensor, and the radio module transmits the digitized data," so it seems that the radio module (not the sensor module) performs the signal processing. The sensor module seems to include only resistors and capacitors, see 13:31-33. In any event, the sensor unit has an input (not shown) for connecting to a sensor. *Id.*, 11:2 ("the sensor module [16] includes the actual sensor, which is shown in Fig. 1 as heating wire 17, as an example."). The sensor unit can sense blood oxygen content. *See* 10:28-30 ("wireless sensor units may be provided for recording the respiration volume, the air pressure with which the patient is ventilated, ***or the patient's blood oxygen content.***") (emphasis added); *see* Genger claims 4, 6.

76. Genger's sensor module 16/35 contains only resistors and amplifiers (14:4-5) so Genger's radio module 13/33 (rather than the entire sensor unit) can alternatively be interpreted to meet the claimed module because it includes electronics for filtering and processing the signal, e.g., it "digitizes" (processes) the sensor signal for radio transmission. Genger, claim 1. To the extent electronics for filtering and processing of the sensor signal (addressed further below) are deemed not to be in Genger's sensor unit or its radio module, POSITA would have found it obvious, with reasonable expectations of success, to implement Genger's radio module using Schmidt's signal processing module 16, which has the same electronics disclosed in the Challenged Patent's module 16 and was designed to process the same blood oxygen signal (SpO₂, 4:17) as Genger, in biomedical environments (EX1006 (Schmidt), 8:32-33).

77. **Pulse Oximeter**: POSITA would have understood Genger as using a pulse oximeter to sense blood oxygen level because of the prevalence and reliability of pulse oximeters. To the extent deemed otherwise, POSITA would have found it obvious to use a pulse oximeter like Westbrook's as Genger's blood oxygen level sensor. POSITA would have had expectations of success for this modification because pulse oximeters were known, reliable sensor for measuring blood oxygen. Motivation would have come from the known prevalence of pulse oximeters in sleep apnea systems, evidenced by Westbrook who details how

common such sensors have been in sleep apnea systems. EX1007, [0021]-[0022], [0064]-[0067]; *see* [0137]-[0139] (explaining that oxygen desaturation **and** airflow help evaluate sleep events like apneas and hypopneas).

78. **Filtering and Processing:** Genger processes the sensor signal by, for example, filtering (e.g., averaging; 12:27-30) and by processing (e.g., digitizing). Digitization is described at 4:6, 12:27-30 and claim 1 (“A radio module (13; 33) for a sensor (17; 36, 37), ... wherein the sensor (17; 36, 37) measures parameters on the body of a patient (19; 85), *wherein the radio module (13; 33) digitizes the output signal of the sensor*, and ... transmits the digitized data.”)(emphasis added); *see* claim 4 (digitized signal of claim 1 is “patient’s respiration volume, the air pressure with which the patient is ventilated, or *the blood oxygen content*.”)(emphasis added).



Genger, Figures 1, 3.

79. Alternatively, POSITA's motivation and expectations of success to filter and process Genger's oxygen signal would have come from Schmidt who puts an SpO2 signal 12 through the same signal processing module 16 as the Challenged Patent. EX1006 (Schmidt), 6:56-59 (filter and gain); Fig. 4 (filters 223, 225, 226; amplifiers 224, 241; A/D 242). Schmidt's module 16 and the Challenged Patent's module 16 (which are identical) are similar to the radio module 13 in Genger. Additional motivation and expectations of success would have come from Westbrook to filter and process Genger's blood oxygen sensor signal obtained from a pulse oximeter. "The SpO2 ['pulse oximeter sensor'; [0065]] values calculated from red and infrared signals *should be smoothed [i.e., filtered and processed]* in order to reduce the effects of noise and increase the detection of desaturation events. In the preferred embodiment, this smoothing is done in three successive steps using *median filtering, slew limitation, and averaging by IIR filtering [i.e., processing]*." EX1007, [0108]. Smoothing a signal's rate of change (slew rate) can be regarded as signal processing, while a slew limiter can use filtering to limit the signal's rate of change (with audio/music signals, for example, a slew limiter is sometimes called a "lag processor"). Because Westbrook's smoothing (step 3) is done on digital samples (*after* A/D), POSITA would regard it as digital signal processing. See Westbrook [114-115] that detail how the digital samples are processed using equation $SpO2_{avg}[n] = kxSpO2[n] + (1 -$

$k) \times \text{SpO}_2 \text{avg}[n-1]$ and then through another level of processing in paragraphs [0116]-[0117] to identify significant desaturations.

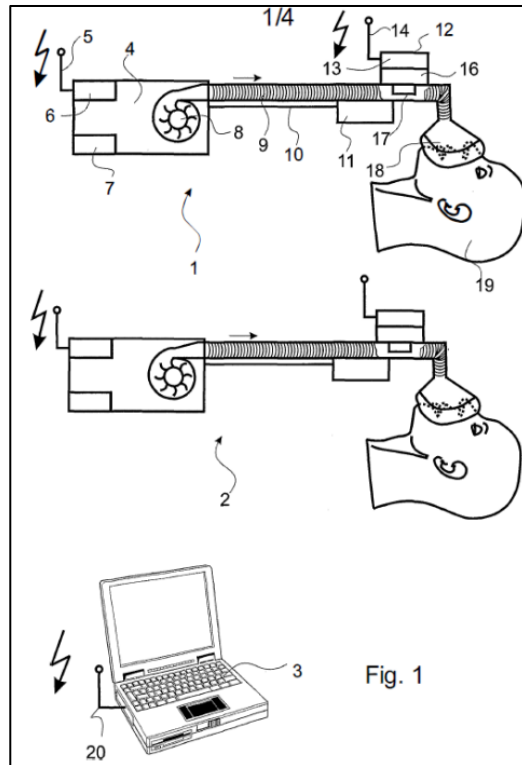
80. **Outputting Sensor Data**: Genger's radio module includes antenna 14 (Fig. 1) which "send[s] their data both to the radio modules 6 in the compressors, and to the radio module in the monitoring device." EX1005, 11:7-9. With the aforementioned obvious use of pulse oximetry, Genger's sent data meets the claimed "outputting pulse oximetry sensor data."

[1.b] a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module further comprising:

81. The claimed PAP device is met by Genger's CPAP device for treating the subject's 19 sleep disorder. It includes compressor 4, antenna 5 (12:13-16), the compressor's (Bluetooth®) radio module 6 (10:23-25; 11:12-14), optional modem 7 (10:23-25) and turbine 8 which produces positive air pressure (11:17-19; 10:14-19) shown in Figure 1. Analogous CPAP devices are shown in Figures 2, 7 and 8.

82. Genger's CPAP has a separate enclosure (shown left in Figures 1, 2, 7, 8) from the processing module (shown right). POSITA would understand that the specific location of Genger's processing module would depend on what it senses, and that it need not be joined to Genger's tube 9 as illustrated in Figure 1. Only the air flow sensor needs to be joined to Genger's tube, but a pulse oximeter

could be separate, e.g., worn on the finger and transmitting via Bluetooth® its sensor data. *See* examples 32 (Fig. 2), 81 (Fig. 7), 93 (Fig. 8).



Genger, Figure 1.

[1.b.1] a blower having an air output,

83. Turbine 8 would be understood by POSITA to be Genger's blower having an air output. EX1005, 10:18-19 ("To generate a positive pressure, the compressor contains a turbine 8.").

[1.b.2] a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,

84. The claimed second input is found at Genger's radio module 6 (using antenna 5) in the CPAP which receives sensor data from antenna 14 of the sensor

unit's radio module. Genger's "sensor units send their data both to the radio modules 6 in the compressors, and to the radio module in the monitoring device." EX1005, 11:7-9.

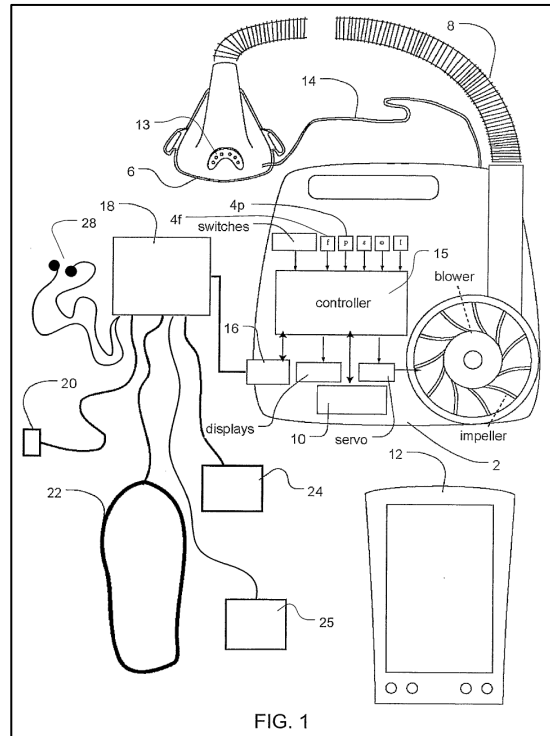
[1.b.3] an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device, and

85. Genger's "treatment devices are supplemented by a wireless flow sensor unit as an example" of its sensor. *See id.*, 10:26-27. Genger suggests that, "in addition to the flow sensor unit 12," the system may have the previously addressed sensor for "the patient's blood oxygen content." *Id.*, 10:27-30. POSITA would understand Genger's flow sensor as measuring respiratory airflow of the subject 19.

86. Although Genger shows the airflow sensor outside the CPAP device, POSITA would have found it obvious to locate the airflow sensor *internally* because that location was common. As support for this being known and common to POSITA, note for example that Farrell references an older publication (U.S. Patent 5,704,345 (Berthon-Jones)) at p.7:17-24, which described the knowledge of POSITA as of its 1993 filing date – twelve years before the Challenged Patent's 2005 priority date. At 8:31-36, Berthon-Jones explained that: "Further, it may not be convenient to mount the [air] flow transducer 44 at or near the mask 30, nor to measure the mask pressure at or near the mask. An alternative arrangement, where

the flow and pressure transducers are mounted at or near the air pressure generator (in the embodiment being the turbine 34) is shown in FIG. 3.” POSITA would have had expectations of success because the location of the sensor is immaterial as long as its measurements are accurate.

87. Motivation would have come from, for example, Farrell (EX1008) whose CPAP main unit 2 (comparable to Genger’s CPAP 4/5/6/7/8) includes “a flow sensor 4f [so] mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal $F(t)$” EX1008, 5:5-7. Sensors 4f and 4p “have only been shown symbolically in FIG. 1 since it is understood that those skilled in the art would understand how to measure flow and pressure.” *Id.*, 5:9-11.



Farrell, Figure 1.

88. Motivation for modifying Genger's CPAP would also have come from the fact that Genger wants the CPAP device 4/5/6/7/8 to have the airflow data. That is, Genger's external flow sensor sends its data to radio module 6 of the CPAP device. *Id.*, 11:7-9. Providing the airflow sensor *within* Genger's CPAP device puts the airflow data where Genger wants it, and avoids the need to transmit airflow data from an external sensor or change external sensor batteries.

- [1.b.4] a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device;

89. The claimed processor is met by Genger's "controller in the compressor [the CPAP treatment device] [that] controls the operation of the CPAP treatment device; in particular, the speed of the turbine, and optionally, the temperature of an air humidifier. Optionally, *the controller determines trend data from the sensor signals*" (e.g., pulse oximeter signals received from antenna (at the second input) 5 and airflow sensor signals). *Id.*, 12:18-25 (emphasis added). "Trend data refer to data obtained from the measurement data by the sensors, but the amount of data is significantly reduced, for example, by averaging. For example, the sensor signal is digitized at a sampling rate of 1 KHz. One cycle of respiration lasts approx. 4 seconds and thus comprises 4000 measured values. For example, the average respiratory rate from 100 to 1000 respiratory cycles is calculated as trend data. Alternatively, the oxygen saturation may be averaged over a certain time or the number of apneas in a predetermined period may be determined as trend data. Furthermore, the controller in the compressor is able to determine alarms if, for example, the number of apneas increases sharply. The alarms can also be forwarded via the modem 7 and the public switched telephone network (PSTN), to a relevant unit." *Id.*, 12:27-13:10.

90. POSITA would have understood Genger's controller in the CPAP compressor device 4 to be implemented by a processor, and the "trend data," such as "the number of apneas in a predetermined period" (13:3-6) to constitute the

claimed “sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject’s sleep disorder symptoms measured during use of the PAP device” based at least in part on the respiratory airflow and pulse oximetry data.

91. Motivation to use Genger’s airflow data and pulse oximetry data together to calculate the claimed “sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject’s sleep disorder symptoms” would have come from Westbrook, whose methods “improve the accuracy and resolution of the detection of oxyhemoglobin desaturation events caused by sleep apnea or hypopneas” ([0032]). Those methods do so, in some embodiments, by integrating a CPAP with a physiological monitor ([0166]). The monitor “detects and records ... oximetry” and Westbrook says an “airflow signal could be added to the physiological monitor with minimal intrusiveness.” EX1007, [0161]; [0064]-[0065] (“system 10 utilizes a physiological monitor 12 having a pulse oximeter (SpO₂) sensor affixed to the patient’s forehead to acquire pulse and oximetry readings.”). “Results from the algorithms described previously that quantify the type of the desaturation and detect arousals can be combined to classify the type of respiratory event. The example provided in Table 1 demonstrates these results can be combined to more accurately identify significant obstructive respiratory events, as well as recognize other respiratory events that

may have clinical implications.” *Id.*, [0147]. In other words, POSITA would have been motivated to make this modified calculation of the claimed “sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject’s sleep disorder symptoms measured during use of the PAP device” because Westbrook advises using both oxygen levels and airflow in order to “classify the type of respiratory event” ([0147]) or to “confirm that the [oxygen] desaturation is due to inspiratory flow limitation or a decrease in airflow” ([0139]). For similar reasons, POSITA would have recognized that monitoring blood oxygen saturation helps to determine whether the sleep treatment (*e.g.*, CPAP) is indeed helping the patient.

92. Separate from the above analysis, POSITA also knew it was well known for a CPAP device’s processor to use respiratory airflow and blood oxygen saturation to calculate AHI, which meets the claimed “sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject’s sleep disorder symptoms.” See my Paragraphs 36-38, *supra*. POSITA therefore would have been motivated, with reasonable expectations of success, to modify Genger to use its airflow and oximetry data to “calculat[e], based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device,” as

claimed. At the very least, POSITA would have found it obvious to try such a modification because of the potential link in a given patient between his/her shallow breathing and low blood oxygen level. As Patent Owner conceded during prosecution of the Challenged Patent's parent application, "AHI is indeed an indicator of the level of severity of a patient's sleep disordered breathing." EX1003, p.39; *see* pp.35-36. Farrell would have motivated POSITA because indices such as AHI were useful to evaluate the patient's disorder. Farrell's "controller 15 or processor ... may include chips, a memory and/or other instruction or data storage medium." EX1008, 5:20-22. The controller helps provide "efficacy tracking by detecting and recording or scoring SDB [sleep disordered breathing] events or related information or *indices* over time, for example, by tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring. This is illustrated in step 44 of FIG. 2. Similarly, pressure and/or flow versus time data may also be recorded for analysis. In so doing, the device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting. Methods for detecting and recording such information are known in the art [and] may record *AHI (apnea hypopnea index)* over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. ... Similarly, *the device may determine an*

index comparing central apneas versus obstructive apneas as disclosed in U.S. Patent 6,832,609, the entire disclosure of which is incorporated by reference herein. These events may be recorded with the time they occur or added to a total for a particular time period. Those skilled in the art will recognize other methods or modifications for detecting sleep disordered breathing information such as hypopneas or apneas and determining an AHI over time or within time periods.” Farrell, 7:35-8:24.

93. Genger’s processor also determines “alarms” (EX1005, 13:13-14) based on the information it calculates, which POSITA would have considered to be the claimed “level of severity” data of the subject’s sleep disorder symptoms.

[1.c] a mask or a nasal cannula; and

94. Genger uses mask 18/83.

[1.d] a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject’s sleep disorder symptoms to a remote location.

95. Genger’s modem 7 meets the claimed module transceiver. *See* Figs. 1, 2. It receives from Genger’s processor the calculated “sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject’s sleep disorder,” as explained for claim element 1.b.4, and transmits that information to a remote server (remote location) 94/96 using PSTN/ISDN/DSL or

a cellphone connection. *Id.*, p.12:22-25; 13:8-14; 17:19-26; Fig. 8. Genger explains that data received and transmitted by modem 7 can include trend data “and/or alarms” (*id.*, 13:13-14), so POSITA would have found it obvious to transmit all data, alarms, AHI and other ‘index’ or level of severity data to the remote server 94/96 so the recipient receives full information about the patient’s status. Genger’s remote location includes a server 94 in a hospital, server 96 of a national insurance company and/or of a medical and health care supplier 101 (Fig. 8) and/or alarm unit. *Id.*, 12:18-25; 13:10; Genger’s claim 25.

96. Modem 7 is a transceiver because POSITA would understand PSTN, ISDN, DSL and/or cellphone communications to be bidirectional, thereby requiring Genger’s modem 7 to both receive and transmit data over the communication line (in addition to receiving data from the CPAP controller and transmitting that data to the remote location).

[Claim 2] The system of claim 1 wherein the second input in the PAP device and the output in the signal processing module are in wireless radio frequency bidirectional communication.

97. In Genger, “[a]ll radio modules operate to the same standard, preferably the Bluetooth standard.” Genger, 11:5-6. These include radio module 13 whose antenna 14 outputs the pulse oximeter data as well as CPAP device 4/5/6/7/8 whose antenna (at the “second input”) receives over-the-air data from

antenna 14. *See* Figure 1. POSITA knew Bluetooth® was a bidirectional, wireless radio frequency communication architecture. *See* Paragraph 59, *supra*.

[Claim 3] The system of claim 2 wherein the PAP device is adapted to command the signal processing module to reconfigure the output in the signal processing module by improving the gain for the signal or the A/D conversion of the signal.

98. Genger's "[t]rend data refer to data obtained from the measurement data by the sensors, but the amount of data is significantly reduced, for example, by averaging. For example, the sensor signal is digitized at a sampling rate of 1 KHz." Genger, 12:27-29. POSITA would have found it obvious for Genger's CPAP device to "reconfigure the output of the signal processing module by improving A/D conversion of the signal," as claimed. POSITA would have been motivated by the need to obtain more data points during high volatility periods, and fewer data points when data has less fluctuation, and would have had expectations of success because A/D adjustments were known. For example, Schmidt (whose specification is copied in the Challenged Patent) discloses: "Referring now to FIG. 4, there is shown a block diagram of the input means 22 and A/D means 24 of the signal processing module 16, which provides for the data acquisition function of the present invention. The signal processing module 16 is variably configurable through software programming initiated by the external programming means 60 to the EEPROM 261 of the microcontroller 26. The variable configurability enables the signal processing module 16 to receive

external inputs 12 having different characteristics and ranges and to provide variable sampling rate, filtering and gain of the external inputs 12 based upon such characteristics and range and/or the specific application. For example, if the present invention is utilized in a biomedical environment, EEG diagnosis and monitoring for instance, the sampling rate will need to be much higher than it would be for an industrial setting measuring thermocouple readings. The ability to reconfigure the system for varying signal characteristics arises at three separate levels in the present invention. For maximum flexibility, such reconfiguration can be carried out during a series of measurements by means of the wireless link, which is understood in this context to be bidirectional. Depending on the characteristics of the received signal 18, the base station 40 can command the signal processing module 16 to reconfigure the input means 22 and/or A/D means 24 to accept an external input 12 of larger amplitude, or a different frequency range, where signal characteristics change significantly during the course of a series of measurements. Alternatively, for cost, size, and power advantages, this adjustment could be carried out prior to a series of measurements, with the configuration information stored in memory in the signal processing module 16, where this memory is advantageously implemented in a nonvolatile form such as EEPROM 261, allowing the configuration information to be retained, for instance, across power outages and obviating the need for module receiver 29 and base

transmitter 84, saving cost. A third alternative, which provides advantages in certain technical parameters, is to arrange the implementation of the signal processing module 16 such that minor changes in component values or parameters can reconfigure the same basic hardware to accept widely divergent external input 12 types. This reconfiguration could take place at the factory, providing cost and inventory advantages to the manufacturer, or it could be performed by the end user, providing similar cost advantages to the user in allowing one piece of equipment to perform multiple tasks.” EX1006 (Schmidt), 8:20-65; *see* 6:63-7:3.

[5pre] A sleep disorder treatment system comprising:

99. See analysis for claim 1pre.

[5.a] a data acquisition system;

100. See analysis for claim 1.a. POSITA would have understood this “data acquisition system” to be analogous to the “signal processing system” recited in claim 1.a, and to be disclosed in the prior art for the same reasons I provided in my analysis of claim 1.a.

[5.b] a positive airway pressure (PAP) device; and

101. See analysis for claim 1.b.

[5.c] a processor;

102. See claim 1.b.4, including Genger’s CPAP controller/processor.

[5.d] the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device;

103. See analysis for claim 1.a, including Schmidt's signal processing module (the claimed data acquisition device) which receives SpO2 signals at a first input (12), puts them through an electronic component (Figure 2) for filtering (e.g., RC filter 223, antialiasing filter 226, switched capacitor filter (11:6-7), digital filter 243, etc., in 22 and 24) and processing (e.g., by converter 222, amplifiers 224, 241, A/D converter 242) to remove artifacts from the pulse oximeter signal. EX1006, 11:1-10. Schmidt's output at antenna 20 transmits the resulting SpO2 data, which is based on the SpO2 signal, to base station 40. POSITA would understand that, when combining Schmidt's module 16 in an obvious fashion with Genger's system, Schmidt's SpO2 data is sent by Genger's sensor unit to the CPAP device 4/5/6/7/8. EX1006(Schmidt), 7:49-60 (frequencies including Bluetooth's 2.4GHz).

**[5.e.1] the PAP device comprising:
a hose,**

104. See claim 1.c., including Genger's tube 9.

[5.e.2] a blower,

105. See claim 1.d., including Genger's turbine 8.

[5.e.3] an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject,

106. See analysis for claim 1.b.3.

[5.e.4] a second input for receiving pulse oximeter sensor data from the data acquisition device; and

107. See analysis for claim 1.b.2.

[5.e.5] a mask or nasal cannula for treating a subject's sleep disorder symptoms; and

108. See analysis for claim 1.c.

[5.f.1] the processor adapted for receiving pulse oximetry [sic] sensor data from the second input and the respiratory airflow data from the airflow sensor, the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device,

109. See claim 1.b.4, including calculating AHI and alarm(s).

[5.f.2] the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the

index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.

110. See claim 1.d. Genger's controller/processor is part of the CPAP and the "second output" goes to modem 7 for the claimed "later transmission" to a remote location of Genger's data, AHI and alarm(s) which meet the claimed "data and/or [] index".

111. The claimed nonvolatile memory is not disclosed in the Challenged Patent but POSITA would have found it obvious for Genger's CPAP to put data/AHI/alarm(s) into nonvolatile memory prior to transmission by modem 7. Motivation, and reasonable expectations for success, would have come from the desire to permit retransmission in the event of communication errors with the remote location and from Genger's own desire to make sure remote parties such as insurance, etc., are informed about a patient's situation. Motivation and expectations of success would have come from Westbrook's use of flash memory 44 to assist transmitting "forty hours of sleep data" from the physiological monitoring system 12 to a remote host computer system 20 . EX1007 (Westbrook), [0058], [0078], Figure 2.

[Claim 7] The sleep disorder treatment system of claim 5 wherein the first output in the data acquisition system and the second

input in the PAP device are in wireless bidirectional radio frequency communication.

112. See analysis for claim 2.

XI. GROUND 2: CLAIMS 4 AND 6 ARE OBVIOUS OVER GENDER, SCHMIDT, WESTBROOK, FARRELL AND PARADISO.

[Claim 4] The system of claim 1 wherein the signal is processed by the signal processing module using one or more of the signal processing techniques from the group consisting of[:]

a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

[Claim 6] The sleep disorder treatment system of claim 5 wherein the first signal is processed by the signal processing module using one or more of the signal processing techniques from the group consisting of[:]

a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

113. I note that, for claim 6, there is no previous recitation of a “signal processing module” so it is not clear what “*the* signal processing module” refers to. I have tried to analyze the claim despite this error.

114. POSITA would have found it obvious, and had reasonable expectations of success, to incorporate one or more of the claimed signal processing techniques, all of which were well-known to POSITA, into Genger’s

CPAP system. For example, Paradiso discloses a patient's "breathing pattern" sensor (EX1009, 283) that uses "wavelet analysis" in a biomedical monitoring and communication system wherein: "One of the main goals of the digital processing stage is to compress or even directly extract the most appropriate features to reduce communication data rates and expenses for the selected physiological parameters. This processing may typically make use of neuro-fuzzy or *other advanced processing techniques like wavelet processing*, particularly suited to extract weak biomedical signals from a noisy environment (due to the user movements and activities) and to dramatically reduce the data volume." Paradiso, 283 (emphasis added).

An overview of the technology in WEALTHY is shown below in Fig. 1, where the main phases of the process are shown, namely: sensing, pre-processing, transmission, processing and data management.

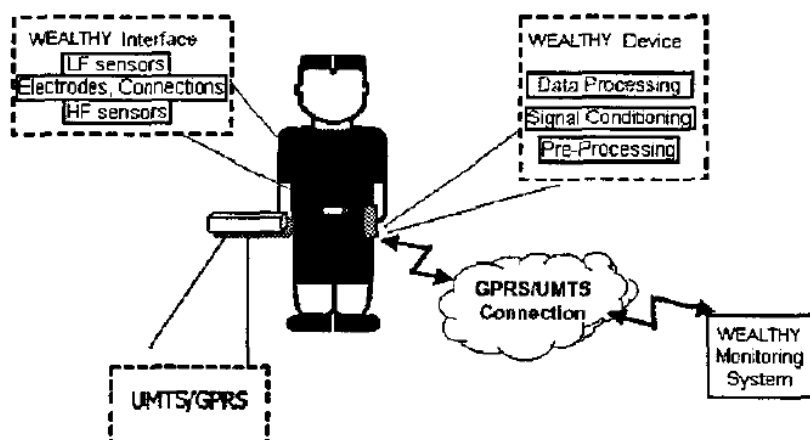


Fig. 1: The processing and communication mechanism

Paradiso, Figure 1.

115. Paradiso's reasoning would have motivated POSITA to make obvious use of known signal processing techniques, and expected success, for the blood oxygen sensor signals at Genger's CPAP device, including a pulse oximeter's signal.

116. Notably, the '269 patent relies on the knowledge of a POSITA to implement this well-known feature: "*The present invention would also include other on-line signal processing algorithms known to those skilled in the art, such as wavelet analysis*, which is similar to time-frequency analysis with a particular kernel function, to identify the shift in power spectrum associated with imminent flow separation that is discussed herein." EX1001, 20:9-31. For at least the same reasons, a POSITA would have found it obvious, and known how, to successfully implement these techniques in Genger to arrive at the claimed system.

XII. GROUND 3: CLAIMS 8-11, 13 ARE OBVIOUS OVER STAHMANN IN VIEW OF EDGAR.

[8.pre] A sleep disorder treatment system comprising:

117. Stahmann teaches a sleep disorder treatment system including a CPAP device. "All types of respiratory therapy devices are referred to generically herein as xPAP devices. The respiratory therapy device 300 [Figure 3] may include, for example, any of the positive airway pressure devices, including CPAP...."

EX1010, 48:15-18. In Figure 53, described below, device 5340 is generically

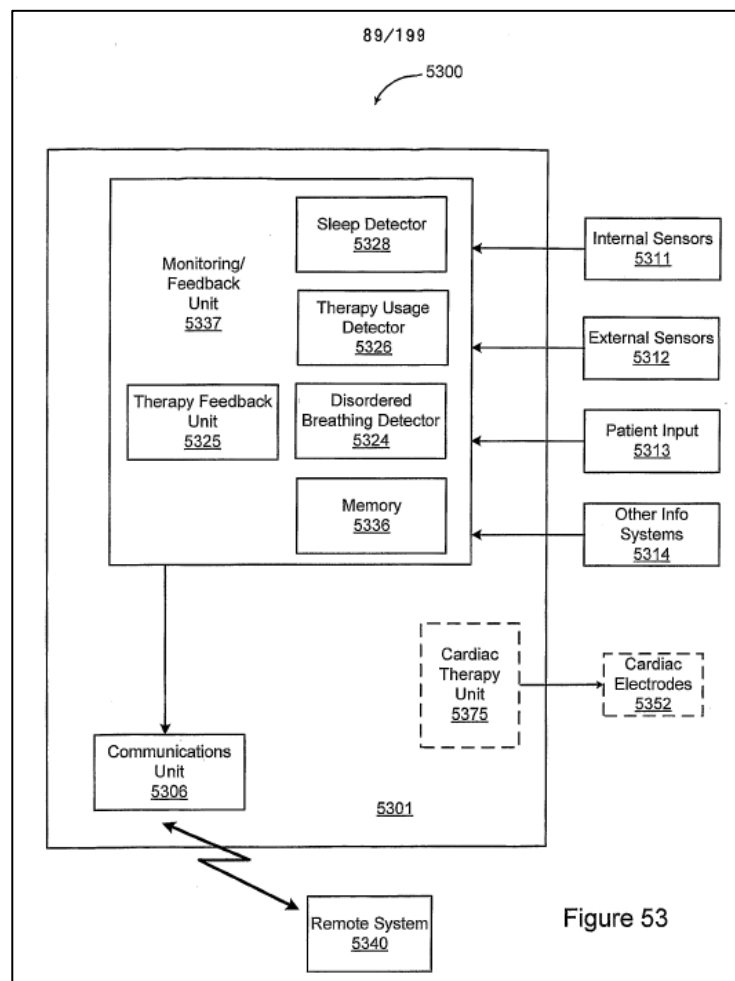
described as a “sleep disordered breathing therapy device” (*id.*, 238:8-9) which POSITA would have interpreted as including, or found it obvious to implement a CPAP in light of Stahmann’s own use of CPAPs throughout its various embodiments.

[8.a] a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject’s sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and

118. Stahmann’s Figure 53 shows a data acquisition system whose “circuitry 5327 [*sic*:5337, the claimed data acquisition device] may include one or more of a disordered breathing detector 5324, a sleep detector 5328, and/or a therapy usage detector 5326 [receiving input signals from physiological sensors 5311-5314; *see* Table 1 list of sensed conditions (below)]. ... The monitoring circuitry 5327 [*sic*:5337] may be used to calculate various indices, e.g., AHI, %PB, and/or arousals per unit time, used for evaluating therapy efficacy, and/or therapy impact. ... [C]ircuitry 5327 [*sic*:5337] communicates with a therapy feedback unit 5325 that develops feedback information based on the monitored conditions, the detected events, and/or the calculated indices.” *Id.*, 236:32-237:8. POSITA would understand at least AHI to be the claimed “output of the level of severity of a

subject's sleep disorder or symptoms" based on PO's admission during prosecution of the patent application (see Par. 38, *supra*).

119. Circuitry 5337 also "detect[s] sleep-related events" like onset, offset, stages and arousals using patient-external sensors 5312 (EX1010, p.237:15), and stores "sleep and disordered breathing events, and/or information related to calculated indices" into memory 5336. EX1010, 237:17-22. POSITA would understand these events and indices to include the claimed "output of the level of severity of a subject's sleep disorder or symptoms."



Stahmann, Figure 53.

Table 1

Condition Type		Condition	Sensor type or Detection method
Physiological	Cardiovascular System	Heart rate	EGM, ECG
		Heart rate variability	
		QT interval	
	Respiratory System	Ventricular filling pressure	Intracardiac pressure sensor
		Blood pressure	Blood pressure sensor
		Snoring	Accelerometer Microphone
		Respiration pattern (Tidal volume Minute ventilation Respiratory rate)	Transthoracic impedance sensor (AC)
		Patency of upper airway	Intrathoracic impedance sensor
		Pulmonary congestion	Transthoracic impedance sensor (DC)
	Nervous System	Sympathetic nerve activity	Muscle sympathetic nerve Activity sensor
		Brain activity	EEG

	Blood Chemistry	CO2 saturation	Blood analysis
		O2 saturation	
		Blood alcohol content	
		Adrenalin	
		Brain Natriuretic Peptide (BNP)	
		C-Reactive Protein	
	Muscle System	Drug/Medication/Tobacco use	
		Muscle atonia	EMG
		Eye movement	EOG
		Patient activity	Accelerometer, MV, etc.
		Limb movements	Accelerometer, EMG
		Jaw movements	Accelerometer, EMG
Contextual/ Non-Physiological	Environmental	Posture	Multi-axis accelerometer
		Ambient temperature	Thermometer
		Humidity	Hygrometer
		Pollution	Air quality website
		Time	Clock
		Barometric pressure	Barometer
		Ambient noise	Microphone
		Ambient light	Photodetector
		Altitude	Altimeter
		Location	GPS, proximity sensor
	Historical/Background	Proximity to bed	Proximity to bed sensor
		Historical sleep time	Patient input, previously detected sleep onset times
		Medical history	Patient input
		Age	
		Recent exercise	
		Weight	
		Gender	
		Body mass index	
		Neck size	
		Emotional state	
		Psychological history	
		Daytime sleepiness	
		Patient perception of sleep quality	
		Drug, alcohol, nicotine use	

Stahmann, Table 1 (pp.44-45).

- [8.b] a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system.**

120. Stahmann's Figure 53 shows "memory 5336 for storing information derived from signals produced by the ... patient-external sensors 5312, [etc.]. The memory 5336 may also store information about detected events, e.g., sleep and disordered breathing events, and/or information related to calculated indices characterizing various events such as sleep and/or disordered breathing events. The stored data may be transferred to the feedback unit 5325 and used to develop feedback information to control disordered breathing therapy." EX1010, 237:17-24. A "medical device 5301 may optionally include a therapy unit" (237:30) and "may further include a communications unit 5306" (238:1) to "facilitate communications between medical device 5301 and a remote device 5340 such as the sleep disordered breathing therapy device" (238:7-9). POSITA would understand the breathing therapy device to include a CPAP device. *Id.*, 255:3-5 ("respiratory therapy device may comprise ... positive airway pressure device").

121. Therapy feedback unit 5325 (237:5-8) or a "separate medical device may develop the feedback information. ... The feedback information may be used to ... automatically adjust the sleep disordered breathing therapy. The feedback

information may be used by the therapy device to automatically adjust the sleep disordered breathing therapy.” *Id.*, 241:19-25; 237:24-26. POSITA would understand each of (a) unit 5325 or (b) the “separate medical device” or (c) the CPAP’s internal controller that receives and reacts to the “feedback information,” to be the claimed “controller” for the PAP apparatus.

122. Stahmann summarizes the feedback processes in Figures 54A-54F. In Figure 54C, for example, Stahmann adjusts therapy based on detected sleep disorder events (5436) or characteristics of such events (5438). The detected disorder events or characteristics can include “severity, frequency, and/or duration” of sleep disordered breathing events like “apnea/hypopnea index (AHI) ... among other indices.” *See* 241:31-242:9.

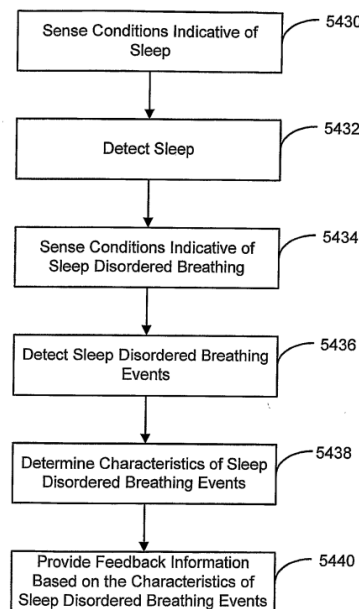


Figure 54C

123. Immediately before introducing the Figure 53 embodiments, Stahmann explains that “[d]rug therapy may also be used to treat disordered breathing. Drugs may be delivered to the patient through one or more automatically controllable drug delivery devices, e.g., ... a controllable nebulizer....” EX1010, 236:12-15; 273:3-6; 302:31-34. This introduction would have motivated POSITA to adjust drug therapy using the embodiments of Figures 53 and 54, e.g., based on the detected sleep events and/or what Stahmann calls “characteristics” of such events like AHI. Stahmann does not detail its drug therapy, but Edgar teaches a system for providing a pharmaceutical compound, e.g., “doxepin analog compounds ... or a pharmaceutically effective salt thereof” (Abstract), to a patient via their CPAP device. “In one aspect, the compound of the invention is administered in conjunction with a CPAP device to promote sleep. In another aspect, the compound of the invention is administered in conjunction with a CPAP device to improve sleep. In another aspect, the compound of the invention is administered in conjunction with a CPAP device to improve compliance regarding with CPAP treatment...[I]t is thought that by administering an effective amount of a sleep promoting compound of the invention to a patient in conjunction with CPAP treatment, the patient will sleep better and more soundly and therefore, not be as likely to remove the mask. In one embodiment, the compound of the present invention is administered prior to the CPAP treatment. In another

embodiment, the compound of the present invention is administered at substantially the same time as the CPAP treatment. In one embodiment, parallel administration of an effective amount of the compound is accomplished by adding an additional aerosol channel to the air pressure treatment portion of the CPAP device, thus administering the compound of the present invention in a nebulized form via the nasal or oral mask of the CPAP device. Alternatively, an effective amount of the compound can be added to the water or into the liquid reservoir that is typically part of the CPAP treatment device. Using the CPAP mask treatment, the compound of the invention is administered in a low concentration throughout the night, or at higher concentrations, as a bolus, at different time points in the beginning and during the course of the night.” EX1011, [0407]-[0409]. “[T]he compounds are formulated to deliver the active agent by pulmonary administration, e.g., administration of an aerosol formulation containing the active agent from, for example, a manual pump spray, nebulizer or pressurized metered-dose inhaler. In some embodiments, suitable formulations of this type also include other agents, such as antistatic agents, to maintain the disclosed compounds as effective aerosols. A drug delivery device for delivering aerosols comprises a suitable aerosol canister with a metering valve containing a pharmaceutical aerosol formulation as described and an actuator housing adapted to hold the canister and allow for drug delivery.” *Id.*, [0392]-[0393].

124. POSITA would have found it obvious, and expected success, by using Edgar's pharmaceutical delivery in Stahmann's adjustable-therapy PAP device. The motivation would have been to let patients "sleep better and more soundly" (Edgar, [0407]) to accomplish Stahmann's goal of improving patient's sleep through therapy feedback.

[Claim 9] The sleep disorder treatment system of claim 8 wherein the at least one physiological sensor comprises a pulse oximeter sensor.

125. As explained in my Paragraphs 36-38, POSITA understood that AHI can consider blood oxygen saturation, thereby motivating POSITA, e.g., under at least an "obvious to try" rationale, to use pulse oximetry to help Stahmann calculate AHI in Figures 53-54. Stahmann already uses external pulse oximeters (EX1010, 248:13-15; 311:2; 333:28) so POSITA would have found it obvious to borrow from those embodiments to modify Figures 53-54 to arrive at the limitations of claim 9. Stahmann, in fact, itself suggests using the pulse oximeter embodiments "in combination with one or more processes and systems exemplified by other embodiments described herein" (*see* 248:1-6; 311:20-25; 332:14-18) further motivating POSITA to use a pulse oximeter to sense blood oxygen for Figure 53's AHI calculation. Also note that Stahmann's AHI calculation uses monitoring circuitry 5337 that interfaces with various patient external or internal sensors ("[t]he monitoring circuitry 5327 [*sic*: 5337] may be

used to calculate various indices, e.g., AHI,...”) (237:2-3, Fig. 53). And “[t]he blood gas sensors may be implemented using either a patient-internal sensor or a patient-external sensor.” (247:5-6). This ties the pulse oximeter to the AHI calculation.

[Claim 10] The sleep disorder treatment system of claim 9 wherein the at least one physiological sensor further comprises a respiratory effort sensor.

126. Stahmann suggests using, with the embodiment of Figure 53, a transthoracic impedance sensor (239:1-6) which is a type of respiratory effort sensor. EX1010, 81:26 (“motion associated with respiratory effort may be detected using a transthoracic impedance sensor.”). Such sensors help detect and “classify the disordered breathing event based on the respiratory effort motion.” EX1010, 4:9-10; 67:8-68:2 (“futile inspiratory efforts associated with obstructive sleep apnea may trigger a series of secondary responses...”); 4:5-8 (“Various embodiments may include ... a motion sensor configured to sense motion associated with respiratory effort of a patient during the disordered breathing event.”); 12:12-30; 78:19-79:3; 79:30-8:4 (“Obstructive apnea may be identified by insufficient respiratory inspiration for at least about 10 seconds accompanied by respiratory effort.”); Fig. 16A (1602); Fig. 16B (1661). POSITA understood that such sensors often sense chest wall, abdominal or other movement. *Id.*, 50:15-24; 80:15-19; 81:16-30. Thus, even if not explicitly disclosed for use in the

embodiments relied upon for claim 8, POSITA would have been motivated, with expectations of success, to use a respiratory effort sensor to help identify and classify the patient's disorder.

[Claim 11] The sleep disorder treatment system of claim 8 wherein the output of the level of severity from the data acquisition system is transmitted wirelessly by bidirectional radio frequency between the data acquisition system and a receiver in the positive airway pressure apparatus.

127. Stahmann suggests transmitting outputs (e.g., AHI) from circuitry 5327/5337 to a CPAP 5340 or a “separate medical device” (*see* 241:19-25; 237:24-26) which controls therapy device (CPAP) 5340, and suggests using “wireless protocols, including, for example, Bluetooth, IEEE 802.11, and/or a proprietary wireless protocol. EX1010, 238:7-12. These suggestions would have motivated POSITA, with expectations of success, to incorporate the controller into the CPAP and, thus, to provide the CPAP with a bidirectional RF (e.g., Bluetooth®) receiver.

[Claim 13] The sleep disorder treatment system of claim 8 wherein the positive airway pressure apparatus comprises a nebulizer or a controlled pump to administer the pharmaceutical agent.

128. Stahmann suggests using a nebulizer to deliver drug (pharmaceutical agent) to the patient. EX1010, 236:12-15. POSITA would have found this suggestion to motivate the obvious combination with Edgar (claim 8, *supra*) who uses nebulizers to adjust pharmaceutical administration via CPAP. EX1011, [0407]-[0409], [0358]-[0363].

XIII. GROUND 4: CLAIM 12 IS OBVIOUS OVER STAHMANN, EDGAR AND SCHMIDT.

[Claim 12] The sleep disorder treatment system of claim 11 wherein the controller is adapted to command a signal processing module in the data acquisition system to reconfigure the output of the data acquisition system.

129. Stahmann suggests using feedback “to adjust the sleep threshold” (239:22-23) or “sleep thresholds or indices” (239:29-30) which POSITA would understand as a reconfiguration of the output of the data acquisition system. For example, sleep threshold identifies arousals and waking, so its adjustment reconfigures the conditions under which those events are identified; its adjustment can be based on breathing volume (“tidal volume”; 240:10) or minute ventilation (*id.*) which POSITA understand is a parameter for evaluating hypopnea events.

130. To the extent deemed otherwise, POSITA would have found it obvious, based on Stahmann’s suggestion of using a wide “array of data acquisition devices” including internal and external sensors 5311-5312 and inputs 5313 (236:19-22) to adopt Schmidt’s output reconfiguration of signal processor 16 into Stahmann’s monitoring/feedback unit 5337 (Fig. 53) so it can accommodate different inputs 5311/5312/5313. For example, Schmidt (whose specification is copied in the Challenged Patent) discloses excerpts quoted previously for

challenged claim 3, which provide motivation for modifying Stahmann and why POSITA would expect success.

XIV. GROUND 5: CLAIM 14 IS OBVIOUS OVER STAHMANN, EDGAR AND PARADISO.

[Claim 14] The sleep disorder treatment system of claim 8 wherein the signals from the at least one physiological sensor are processed by a signal processing module in the data acquisition system using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

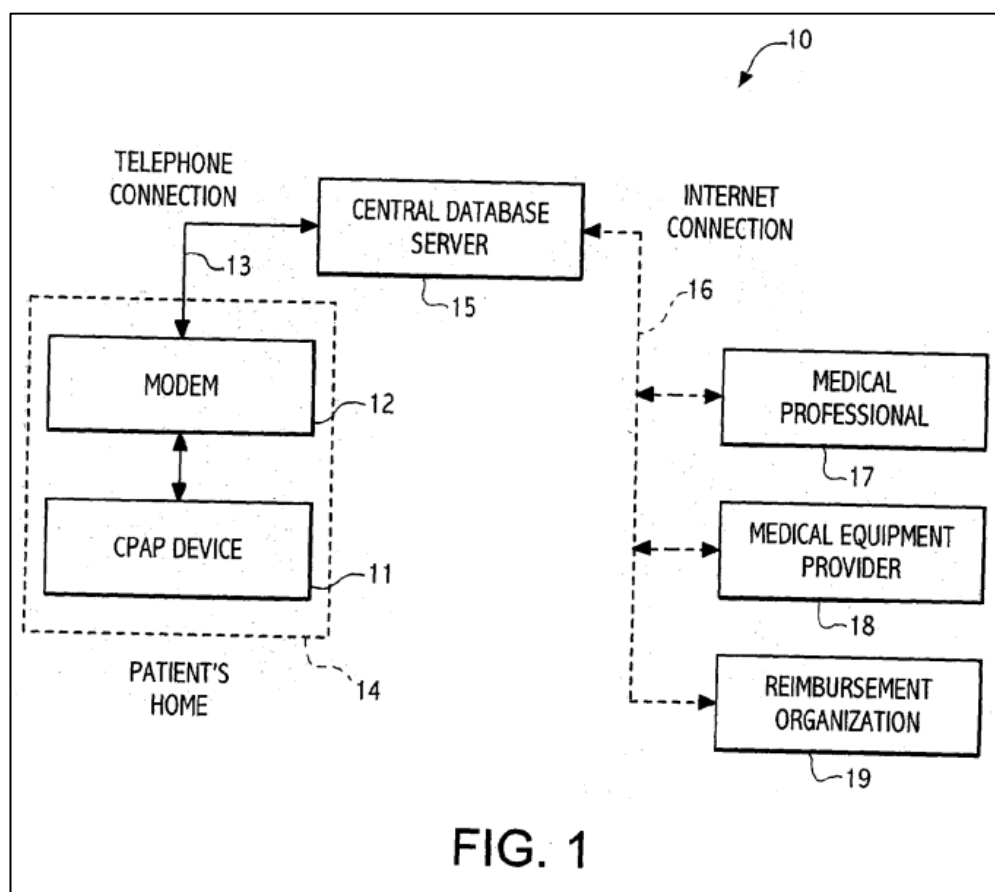
131. For similar reasons expressed for claims 4 and 6, POSITA would have found it obvious, and had reasonable expectations of success, to incorporate Paradiso's wavelet analysis to the processing of cardiac and/or respiratory sensor signals listed in Stahmann's Table 1 (pp.44-45) which are suggested for the Figure 53-54 embodiments. EX1010, 236:23-29.

XV. GROUND 6: CLAIMS 15-16, 18-19 ARE OBVIOUS OVER KOCINSKI IN VIEW OF FARRELL AND BLUETOOTH.

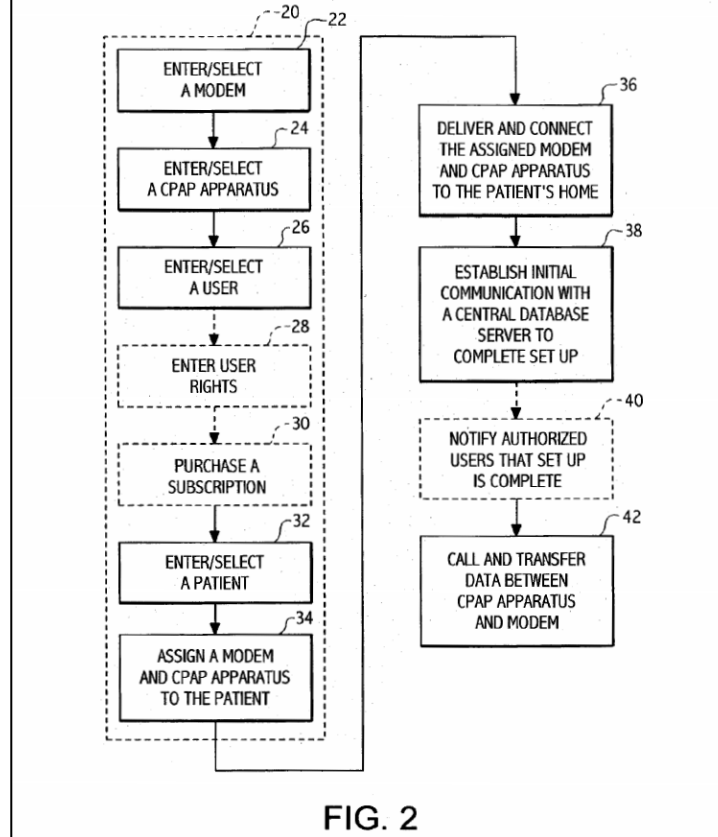
[15pre] A positive airway pressure (PAP) sleep disorder treatment system comprising:

132. Kocinski discloses a PAP sleep disorder treatment system. "A CPAP apparatus is used to apply a continuous positive airway pressure to a person during

sleep to treat sleep-related illnesses, such as sleep apnea.” EX1012, [0002]. “Once the [sleep disorder] problem is diagnosed, the patient may be connected to a CPAP apparatus that is used to deliver an optimum positive pressure setting for preventing apnea events.” *Id.*, [0003].



Kocinski, Figure 1.



Kocinski, Figure 2.

[15.a] a PAP device with an enclosure further comprising:

133. Kocinski's "FIG. 1 [shows] a system for providing communications between a CPAP apparatus located in a patient's home or premises and a medical professional, and/or a medical equipment provider and, optionally, a medical insurance or other reimbursing organization. ...The CPAP apparatus 11 and modem 12 are adapted to be located in a patient's home 14." EX1012, [0024]. The claimed "enclosure" of the CPAP apparatus 11 is illustrated in a front perspective view in Figure 9 (EX1012, [0020], Figure 9) but even without the

benefit of Figure 9, POSITA would understand Kocinski's "CPAP apparatus" to have an enclosure.

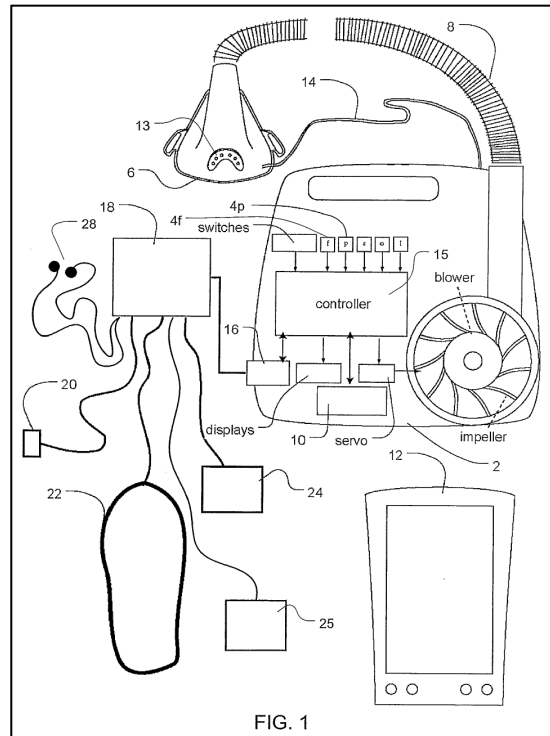
[15.a.1] a blower having an air output,

134. Kocinski explains that a "CPAP apparatus ... includes a turbine connected through a hose to a nasal mask to apply a positive pressure to the patient's airway." EX1012, [0002]. POSITA would understand Kocinski's CPAP enclosure to include the turbine (blower) having an air output.

[15.a.2] an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data;

135. Kocinski's CPAP preferably has "auto-adjust capabilities, which uses an internal pressure transducer ... and will adjust to give the patient more or less pressure...." EX1012, [0046]. To the extent the pressure transducer is deemed not to constitute an airflow sensor, POSITA would have found it obvious to add such a sensor, like Farrell's, to Kocinski's CPAP enclosure to better monitor airflow to the patient. POSITA would have had expectations of success because such sensors are common. Motivation would have come from Farrell (EX1008) whose CPAP 2 includes "a flow sensor 4f [so] mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal $F(t)$" EX1008, 5:5-7. Sensors 4f and 4p "have only been shown

symbolically in FIG. 1 since it is understood that those skilled in the art would understand how to measure flow and pressure.” *Id.*, 5:9-11.



Farrell, Figure 1.

[15.b] a processor adapted for receiving the airflow sensor data, and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device;

136. Kocinski's "CPAP apparatus 11 may be *programmed*, for example, to send a message to the central database server 15 which is relayed to the medical professional 17 *if the number of apnea events per hour exceed a programmed threshold, or if the number of hypoapnea events per hour exceed a programmed threshold, or if the blood desaturation exceeds a programmed threshold.* [It] also

can be *programmed* to send a message to the medical professional 17 via the central database server 15 *if there is no or very little patient usage of the CPAP apparatus 11 over a predetermined period of time*, such as a preset number of days.” EX1012, [0028] (emphasis added). POSITA would understand these passages to mean Kocinski’s CPAP includes a programmable processor that receives airflow sensor data, e.g. Farrell’s, to detect apnea and/or hypopnea events. POSITA would also understand from these passages that Kocinski’s processor calculates Apnea Index (AI) and/or Hypopnea Index (HI), each being an example of the claimed index of a subject’s symptoms measured during use of the CPAP device. Moreover, because Kocinski counts apnea and hypopnea events, POSITA would have found it obvious to calculate AHI and/or RDI because these indices are commonly used to assess the severity of sleep disorders. AHI measures apneas and hypopneas, while RDI also includes the number of respiratory effort–related arousals per hour of sleep (in addition to apnea and hypopnea events).

137. To the extent deemed otherwise, Farrell would have motivated POSITA to make an obvious calculation of the claimed symptom data (apnea/hypopnea events and counts) or index (e.g., AI, HI, AHI, RDI) in Kocinski’s system because symptom data and indices are useful to evaluate the patient’s disorder. Farrell’s “controller 15 or processor ... may include chips, a memory and/or other instruction or data storage medium.” EX1008, 5:20-22. The

controller helps provide “efficacy tracking by detecting and recording or scoring SDB [sleep disordered breathing] events or related information or indices over time, for example, by tracking or detecting central apneas, obstructive apneas, hypopneas, partial obstructions (e.g., flow flattening) or snoring [see Fig. 2]. Similarly, pressure and/or flow versus time data may also be recorded for analysis. In so doing, the device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical summaries and charting. Methods for detecting and recording such information are known in the art [and] may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. ... Those skilled in the art will recognize other methods or modifications for detecting sleep disordered breathing information such as hypopneas or apneas and determining an AHI over time or within time periods.”

EX1008, 7:35-8:24. POSITA would have had expectations of success because AHI was a common way to assess sleep disorders.

138. For the claimed “data of usage,” Kocinski advises “[a]t a minimum, it is preferable that the CPAP apparatus 11 collect and transfer *information on patient usage compliance of the CPAP apparatus 11*. Information may be collected and stored regarding the output pressure, startup delays and pressures in which a lower pressure is initially applied to the patient, [and] if there is no or very

little patient usage of the CPAP apparatus 11 over a predetermined period of time, such as a preset number of days.” EX1012, [0028] (emphasis added). POSITA would understand “information on usage compliance” to meet the claimed “data of usage” by identifying how often and/or how long the CPAP device was used. *See* EX1012, Figure 10 (chart showing “Days Used”). POSITA would also understand the listed pressure data, startup delays, pressures and initial pressures to meet the claimed “data of usage.” POSITA would also understand Kocinski to calculate time-of-use (or nonuse) data, such as elapsed time and start/stop times (since it is already calculating data “per hour” (see above)), which meets the claimed “usage data.”

[15.c] a mask or a nasal cannula;

139. Kocinski explains that a CPAP apparatus “includes ...a *nasal mask*,” ([0002]) and POSITA would understand Kocinski’s system to include a mask.

[15.d] a first radio frequency wireless module transceiver; and

140. Kocinski suggests connecting the CPAP to a local device that he calls a “computer” which, in turn, communicates with the central server. “...CPAP apparatus 11 can optionally be connected directly to a computer (not shown). The computer can communicate with the central database server 15 via the modem 12....” EX1012, [0049]; Kocinski’s claim 16.

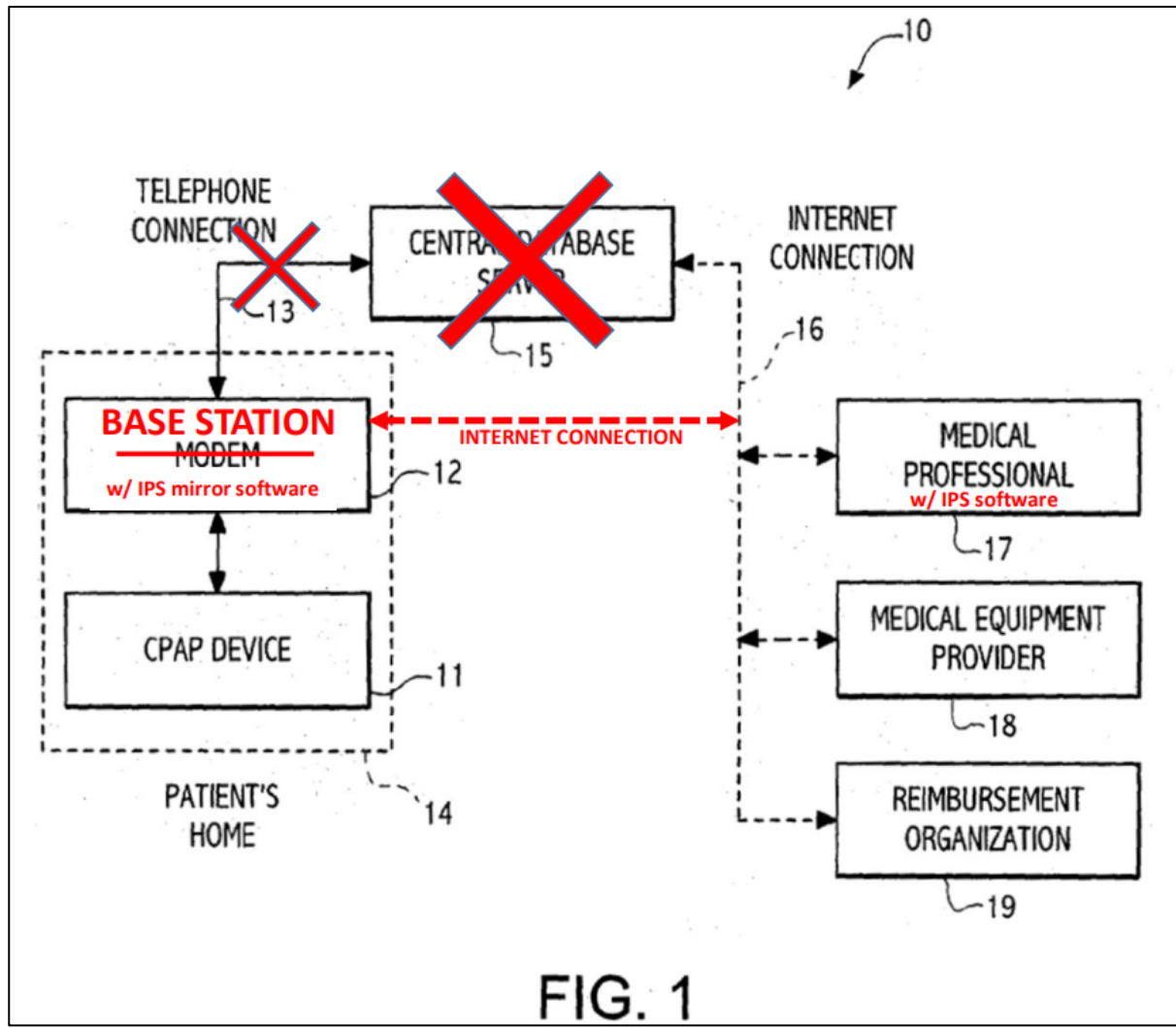
141. Kocinski advocates any method of communication to/from the CPAP 11, including wired or wireless. “Data transfer between the CPAP apparatus 11 in the patient’s home 14 and the central database server 15 ... may be made through other available communications channels, for example, via a cable modem and the internet or via a satellite communications system....” Kocinski, [0026]. POSITA would have found it obvious to use Bluetooth® (EX1017) between Kocinski’s CPAP and local “computer” (*see* limitation 15.e), the motivation being convenience of Bluetooth® pairing and of putting the computer anywhere in the home 14, without being tethered by wires. Expectations of success would have come from the reliability of Bluetooth®.

142. POSITA knew that Bluetooth® was a bidirectional RF architecture and, thus, that Kocinski’s so-modified CPAP and computer would use Bluetooth® transceivers. *See* EX1017, p.18, p.41; *see* Paragraph 59, *supra*. Also, Kocinski wants to “transfer information *to and from* the central database server 15” and CPAP ([0024]) thus motivating use of transceivers between the CPAP and local computer.

[15.e] a base station, cellular phone, or PDA;

143. The Challenged Patent differentiates “a computer” from a “base station, cell phone, [or] a PDA....” EX1001, 19:5-7; *see* 9:12-15; 18:65-66; 19:15-24. Kocinski’s local device is labelled as “a computer” ([0049]) but it uses a

modem 12 that is “assigned to [a] patient[.]” ([0042], [0046], [0019], Fig. 3) and “deliver[ed] and connect[ed]” to the patient’s home by a medical equipment provider ([0036], [0032], [0047], Fig. 2 @36). Kocinski states that “[t]he computer can communicate with the central database server 15 via the modem 12 *or* can have the same software as the central database server 15 *and thus function as the central database server 15* and bypass the modem 12.” Kocinski, [0049] (emphasis added). In other words, Kocinski uses and maintains tight controls over its proprietary equipment including the CPAP, “computer,” and modem – see [0032]-[0035] – which informs POSITA that Kocinski’s “computer” ([0049]) would likewise be dedicated and maintained by the medical equipment provider. In the embodiment where the server 15’s software is integrated into the local device, POSITA would have understood the home-located device to be a dedicated, proprietary base station (rather than a general purpose computer) for transceiving information to/from the third parties shown in Figure 1 such as the medical professional 17, medical equipment provider 18 and reimbursement organization 19. Kocinski thus discloses the claimed base station. Below is an annotated version of Kocinski’s Figure 1 to illustrate the integration of server software (and loss of modem 12) into the device located at the patient’s home.



144. To the extent Kocinski's "computer" is deemed not to be a base station, POSITA would have found it obvious, in light of the above-cited excerpts from Kocinski, to have used a base station rather than a general purpose computer as a transceiving device between the CPAP and the remote server, with expectations of success because base stations were known to be reliable mechanisms to transceive information between destination devices.

145. In addition, POSITA would have found the hand-held display and control device 12 (e.g., PDA) disclosed by Farrell (5:28-31, Fig. 1) to be more convenient for transceiving information to/from Kocinski's server. Being hand-held, it would have given Kocinski's patient the advantage of viewing information without leaving bed, and allowed family and visiting medical professionals to see, more conveniently, the patient's data on-site. See Kocinski, [0039] (describing viewing rights). Accordingly, POSITA would have been motivated, with expectations of success, to use a PDA in place of Kocinski's base station.

[15.f] the first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and the data of usage to the base station, cellular phone or PDA;

146. As explained above, Kocinski's CPAP enclosure's processor calculates the claimed symptom data and index, and data of usage; POSITA would understand the CPAP's Bluetooth® transceiver as receiving these data from the processor and transmitting it to the base station (or PDA) because Kocinski wants the central server to have these data ([0028], [0031], [0045]).

[15.g.1] the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display,

147. The base station (or PDA) would be understood to contain a complementary Bluetooth® transceiver card (the claimed second RF wireless

module transceiver) that communicates with the CPAP. Being a base station (or PDA), POSITA would understand it has a processor that, using software, controls its communications, settings, and a display to assist the user with connecting the base station to CPAP devices and to an external network, and to display information like Kocinski's Figures 10-12.

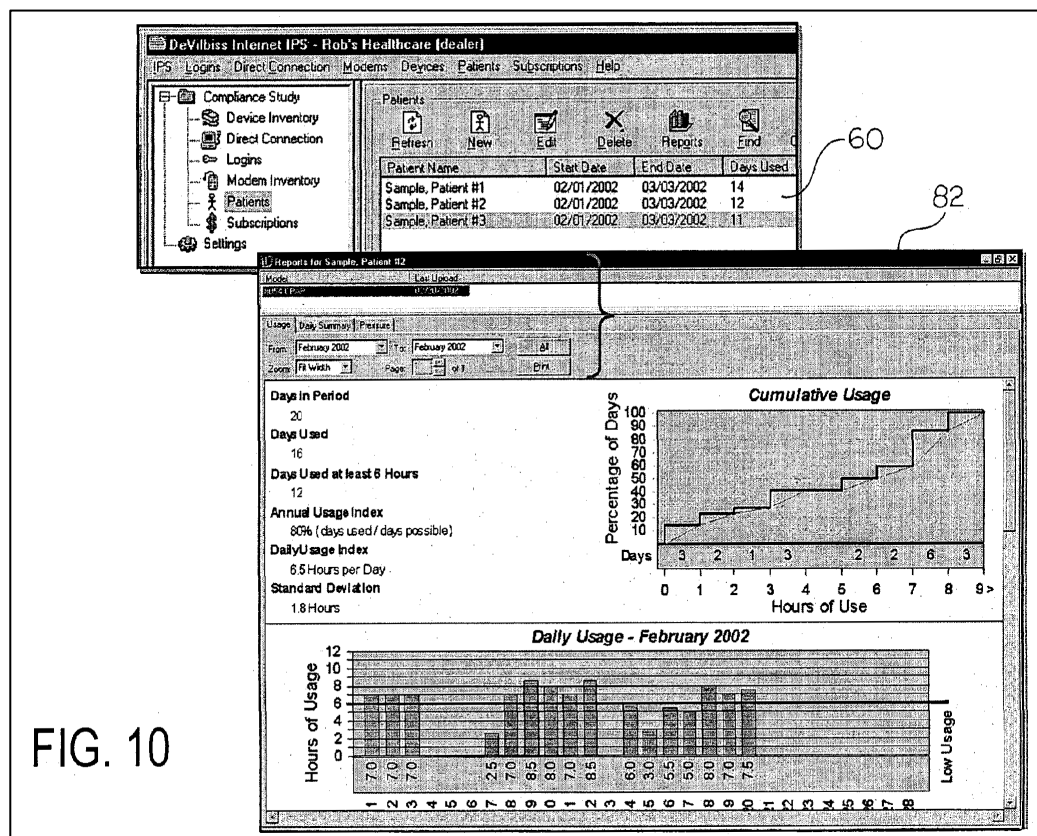


FIG. 10

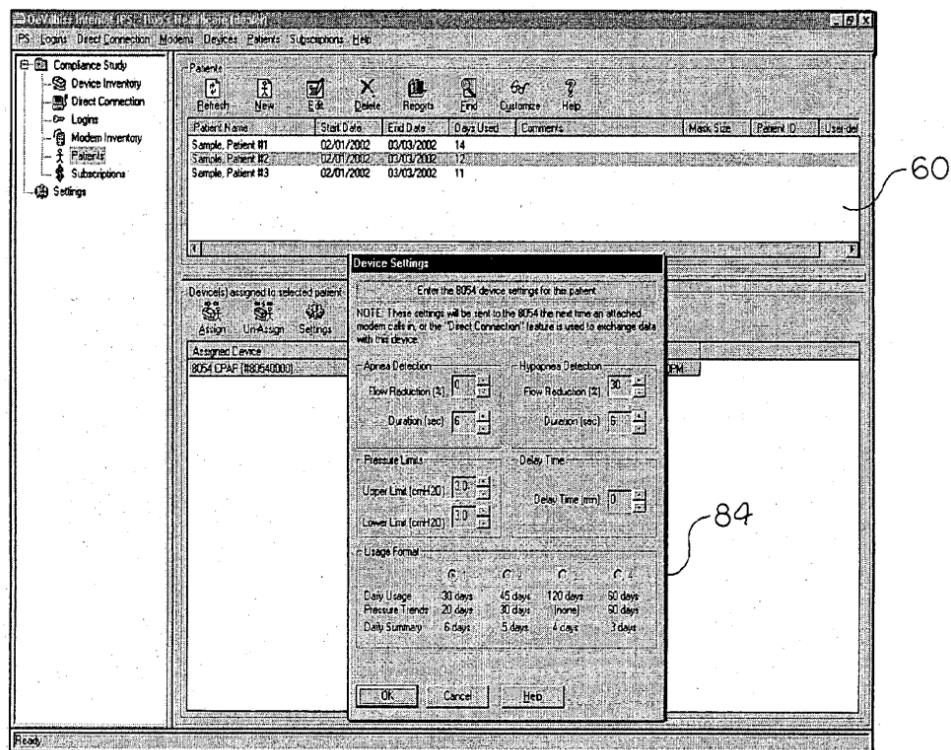


FIG. 11

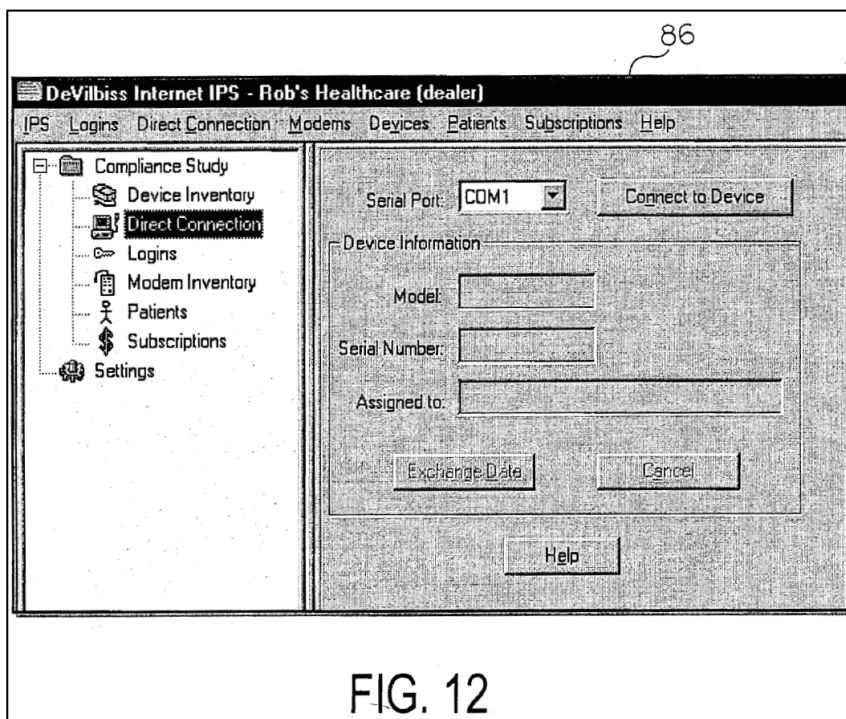
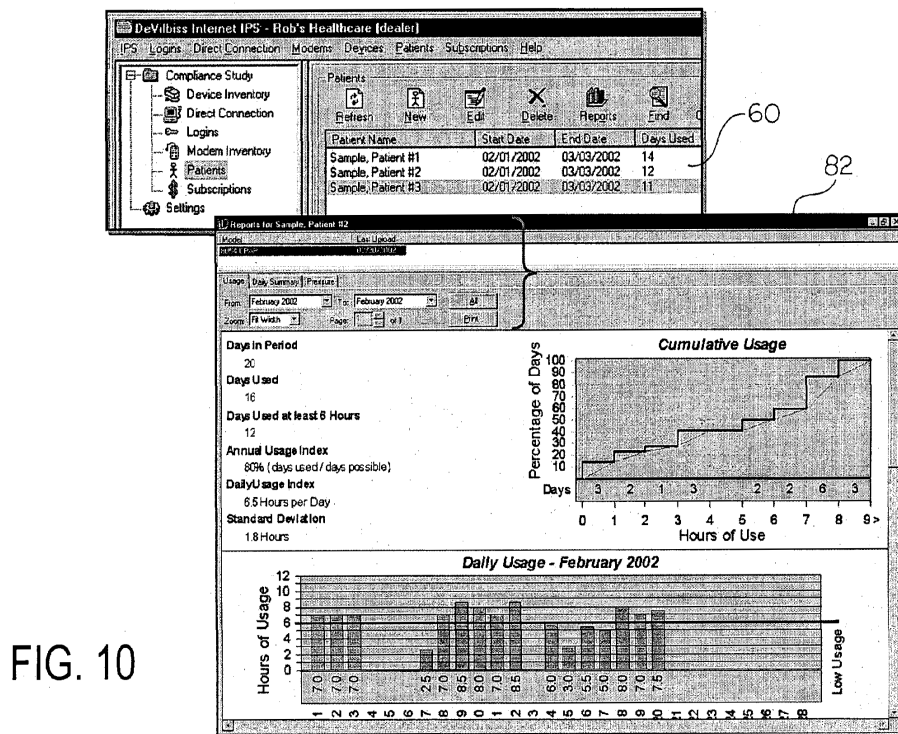


FIG. 12

[15.g.2] the base station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.

148. As explained above, the base station (or PDA's cell connection) retransmits via cellular, etc., the symptom data, index, and usage data to the medical professional 17, medical equipment provider 18 and/or reimbursement organization 19. EX1012, [0049]; [0028], [0031], [0045]. Those entities are connected by an "Internet Connection 16" in Figure 1 and therefore POSITA would understand each to be a remote internet site. *Id.*

149. Kocinski displays patient-specific data as shown in Figure 10, and to the extent Figure 10 does not explicitly display the calculated symptom data and/or index (or usage data), POSITA would have found it obvious to do so, and likewise to display such information on the base station (or PDA). Motivation would have been to allow the patient, patient's family, and visiting medical professionals to see the patient's data on-site. Motivation also comes from the need to incorporate what Kocinski calls "two-way" "IPS" software ("Internet Processing Software," ([0035]) onto the base station located at the patient's home in order to exchange data with the IPS software located at the third parties 17-19. *See* Kocinski, [0035]-[0039], and the "exchange data" button on the IPS interface of Figure 12.



Kocinski, Figure 10.

[Claim 16] The system of claim 15, wherein the first radio frequency wireless module transceiver of the PAP device and the second radio frequency wireless module transceiver of the base station, cellular phone or PDA communicate using Bluetooth wireless protocol.

150. As explained for claim 15, POSITA would have found it obvious for Kocinski's CPAP-to-base station (or PDA) communications to be Bluetooth®.

[Claim 18] The system of claim 15, wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the symptom data of the severity of the subject's sleep disorder and/or the index of the subject's symptoms transmitted to the remote internet site.

151. Kocinski's bidirectional communication system "also allows the operating settings for the CPAP apparatus to be remotely programmed." EX1012, Abstract. "Operating information and programming information may be stored in a memory either in the CPAP apparatus 11 or in the modem 12." *Id.*, [0025]. "[T]he CPAP apparatus 11 can be controlled remotely. This is accomplished by highlighting a patient and then highlighting the assigned devices and then clicking the 'Settings' button. A 'Device Settings' window 84, as indicated in FIG. 11, will open. An authorized user can make changes as desired. The next time the modem 12 calls, the CPAP apparatus 11 will be updated. This feature may be available only on certain model CPAP apparatus 11, such as a CPAP apparatus 11 that has auto-adjust capabilities, which uses an internal pressure transducer and has internal memory that allows a range of pressure to be used and will adjust to give the patient more or less pressure, depending on their needs through the night. Such a CPAP apparatus 11 will react to the patient's sleep and breathing patterns for maximum comfort." *Id.*, [0046].

152. The above passages inform POSITA that Kocinski's CPAP contains an electronic component (e.g., internal memory, pressure range regulator, and airflow rate regulator (based on the obvious use of airflow sensor(s) explained previously) adapted to be adjusted remotely by a medical professional. The passages also inform that these components have "auto-adjust" capability that

“react to the patient’s sleep and breathing patterns,” which POSITA would understand to mean remote adjustment by the home-located base station and/or remote third parties 17-19 (without human intervention) based on the CPAP-calculated symptom data and/or index transmitted to those remote internet sites.

[Claim 19] The system of claim 15, wherein the base station, cellular phone or PDA is adapted to be reprogrammed or modified remotely.

153. Kocinski’s Figure 12 illustrates a “Direct Connection” interface that allows the CPAP to communicate with the third parties 17-19 through the aforementioned base station (or PDA). “Compliance data can be downloaded to the computer [or to the home-located base station that includes the server 15’s software] and settings can be sent to the CPAP apparatus 11 via an internet connection 16 simply by pressing the ‘Exchange Data’ button in the ‘Direct Connection’ window.” Kocinski, [0049]. POSITA would understand this passage to mean that third parties 17-19 can reprogram or modify the base station (or PDA), such as settings that the base station (or PDA) stores for subsequent transmission to the CPAP.

154. In addition, Kocinski’s system is subscription-based ([0036], [0040]), allowing patients to be “Added” or “Removed” ([0041]). POSITA would understand that a new or removed subscription would cause a reprogramming or

modification to the base station (or PDA) being used with the patient's CPAP, such as by enabling or disabling connectivity to the third parties 17-19.

XVI. GROUND 7: CLAIMS 17 IS OBVIOUS OVER KOCINSKI, FARRELL, BLUETOOTH, GUILLEMINAULT-2004 AND WESTBROOK.

[Claim 17] The system of claim 15, wherein the index of the subject's symptoms is a respiratory disturbance index.

155. Because Kocinski counts apneas, hypopneas, etc., per unit time, POSITA would have been motivated to calculate a patient's "RDI" because it has been long recognized that "OSA [Obstructive Sleep Apnea] can be classified based on the apneas plus hypopneas per hour of sleep index (AHI) or respiratory disturbance index ([RDI] apneas plus hypopneas plus respiratory event-related arousals per hour of sleep) into mild ($5 < \text{AHI or RDI} < 15$); moderate ($15 < \text{AHI or RDI} < 30$); or severe ($\text{AHI or RDI} > 30$). UARS [Upper Airway Resistance Syndrome] has been defined as having a RDI less than 4 and arterial oxygen saturation (SaO_2) greater than 93%." EX1013 (Guilleminault-2004), 615-616. Others used different thresholds: "Patients with an RDI of 10 or less were classified as low risk ... between 11 and 40 were grouped as moderate risk [and] RDI greater than 40 were classified as high risk." EX007 (Westbrook), [0152].

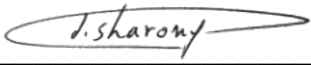
XVII. GROUND 8: CLAIM 20 IS OBVIOUS OVER KOCINSKI, FARRELL, BLUETOOTH AND PARADISO.

[Claim 20] The system of claim 15, wherein the airflow sensor data is processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.

156. For similar reasons expressed for claims 4 and 6, POSITA would have found it obvious, and had reasonable expectations of success, to incorporate Paradiso's wavelet analysis to the processing of potentially noisy and/or weak physiological sensor data that helps Kocinski identify the "frequency and nature of events detected while the patient sleeps, such as apnea events, maintenance warnings," etc. EX1012, [0028].

XVIII. CONCLUSION

157. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true. I further understand that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code. I declare under penalty of perjury that the foregoing is true and correct.

Date: March 21, 2023 Signed: 
Jacob Sharony, Ph.D.

APPENDIX A

(curriculum vitae)

Seasoned professional with over 35 years experience and expertise in information communications technologies (ICT), wireless networks, mobile devices/applications, data capture and sensing; visionary, creative and innovative with strong technology and business skills.

EXPERIENCE

MOBIUS CONSULTING, Huntington Station, NY

2004 –

Founder, Principal Consultant

- Professional consulting services in mobile wireless strategy, technologies, systems and applications.
- “Trusted Advisor” role facing large clients in telecom, vertical enterprises and government, building trust and relationships.
- Expertise includes WiFi, 4G LTE and 5G, WiMAX, picocell/femtocell, DAS, mesh networking, Internet of Things (IoT), M2M, RFID, RTLS, smart antennas, MIMO/beamforming, cloud computing, mobile crowd sourcing/sensing, enterprise mobility, security protocols, mobile embedded devices, device management, mobile applications/services, LBS, VoIP, video streaming, Zigbee, Bluetooth, sensor networks, RTLS, smart grid, m-health, m-learning, smart home networking.
- System and network protocol analysis, modeling and simulations of wireless systems (e.g., WiFi, LTE) for network performance assessment and optimization.
- Participated in a lead role in several medium-large projects in various vertical, enterprise and government/military markets, e.g., smart grid, mobile health, WiFi and 4G deployments.
- Selected consulting engagements are listed below: Lattice Semiconductor, SiBEAM, Powerwave Technologies, Time Warner Cable, and Corning-MobileAccess.

COLUMBIA UNIVERSITY, New York, NY

2010 –

Adjunct Professor

- Professor of Electrical Engineering. Teaching graduate courses on advanced wireless technologies: mmWave Wireless Communications and Applications for 5G, Wireless Sensing (RFID, RTLS, M2M communications, smart grid/energy, smart infrastructure, intelligent transportation, m-health).

LATTICE SEMICONDUCTOR, Sunnyvale, CA

2014 – 2016

CTO Office Senior Advisor

Developing 5G solutions using mmWave and Phased Array Antenna technologies. Applications include ‘wireless fiber’ backhaul/front-haul, connected cars, in-home connectivity.

SIBEAM, Silicon Valley

2014 – 2016

Technology Strategy Senior Consultant

Developing intelligent millimeter wave (60 GHz) technologies for wireless communications (802.11ad) and fixed access solutions for 5G.

POWERWAVE TECHNOLOGIES, Santa Ana, CA

2011 – 2013

CTO Office Senior Principal Consultant / VP Innovation

- Leading innovation, strategy and development of HetNets, DAS and small cells (picocell) solutions using 4G LTE and WiFi technologies to enhance coverage and capacity of wireless network infrastructure.

CENTER OF EXCELLENCE IN WIRELESS & IT, SUNY, Stony Brook, NY

2006 – 2010

Director, Network Technologies Research Division

- Leading network technologies research, development and commercialization efforts
- Industry liaison, working on smart energy, wireless healthcare and intelligent transportation solutions.
- Deployed mobile WiMAX pico/femto solution as part of the 4G-campus initiative.
- Key contributor to the Long Island Broadband Wireless Access Initiative using WiFi and 4G.

TIME WARNER CABLE, Stamford, CT

2007 –2008

Wireless Strategy & Development Senior Consultant

- Worked on a large wireless project involving WiFi, WiMAX and 3G with advanced mobile devices.
- Developed concept and product requirements documents, architecture and RF design, and test plans.
- Supported the business development group on femtocells models, MVNO's models and services, etc.

MOBILE-ACCESS (Acquired by Corning), Vienna, VA

2006 –2008

CTO Office DAS Strategy & Development Senior Consultant

- Worked with the CTO and senior engineers to develop WiFi DAS systems.
- Developed detailed analysis and novel method to support MIMO (802.11n) in DAS systems.

MOTOROLA (formerly Symbol Technologies), Holtsville, NY

1997 – 2005

Senior Director, Technology Strategy and Development

2003 – 2005

- Served as “the eyes of the company” – Charter was to identify and evaluate emerging/disruptive technologies, and conduct technology/business due diligence of possible partners/acquisitions. Team leader.
- Guided the company technology roadmap by generating Technology Position Statements (TPS). Selected topics include: 802.11a/b/g migration strategy, 802.11e (QoS), Broadband Wireless Access - 802.16d/e fixed and mobile WiMAX, mesh networks, RFID, RTLS, and MIMO. These TPS were fact based and relied on results obtained through modeling, analysis and simulations.
- Explored a new family of products based on multi-point MIMO architecture in mesh wireless networks.
- Investigated VoIP capacity in 802.11a/b/g networks and initiated work on admission control algorithms/policies.
- Researched and developed new mobile applications delivering multimedia-rich content to heterogeneous networked mobile devices.
- Developed strategic alliances and led technology initiatives with technology/business partners.
- Participated actively in IEEE 802.11, 802.15 and 802.16 standards meetings.
- Awarded several patents.

Senior Director, Research and Development

1997 – 2003

- Initiated and led several R&D programs in wireless LAN technologies: intelligent access point, reliable multicast video streaming, mobile device management/security and spatial wireless switching.
- Conceived, investigated and developed a novel wireless switching architecture based on MIMO technology.
- Conducted innovative research in WLAN QoS, Bluetooth interference mitigation, multicast video streaming, mobile security, RFID, RTLS - location tracking (RSSI/TDOA), VoIP and smart antennas.
- Participated in strategic planning and impacted the technology/business direction of the company.
- Awarded several patents.

BAE SYSTEMS, Greenlawn, NY

1994 – 1997

Research Scientist

- Led the advanced mobile networking group.
- Developed tactical mesh-based wireless network systems for DoD.
- Worked on advanced antenna techniques including beam steering/switching.
- Awarded several patents.

NEC RESEARCH INSTITUTE, Princeton, NJ

1992 – 1994

Research Fellow

- Worked on optical interconnects for parallel processing.
- Investigated multi-dimensional switches using wavelength, space and time.
- Designed a wavelength router/switch using free-space optics.

IBM RESEARCH CENTER, Hawthorne, NY

1990 – 1992

Research Associate

- Developed and prototyped a gigabit switch.
- Built a testbed of multi-wavelength optical network.
- Developed algorithms for WDMA using AO tunable filters.

Head of Fiber-optics Systems Engineering

- Pioneered security products using fiber optic sensors.
- Conducted research & development in fiber optic sensors.
- Co-developed and deployed a large fiber optic data communications network.

EDUCATION

COLUMBIA UNIVERSITY, New York, NY

- Ph.D., Electrical Engineering, 1993.
- M.Phil, Electrical Engineering, 1991.

TEL AVIV UNIVERSITY, Tel Aviv, Israel

- MBA, Recanati Business School, 1989.
- MSc., Electrical Engineering, 1984.
- BSc., magna cum laude, Electrical Engineering, 1979.

PUBLICATIONS / PATENTS / OTHER

- Numerous publications in proceedings and conference papers.
- Numerous US and international patents issued.
- Served on several government agencies expert panels (NSF, NIH).
- IEEE Senior Member.
- Featured speaker on several industry sponsored webinars.
- Served as an expert witness/consultant in District Court, IPR, ITC, FRAND, PCA, AAA cases.

COURSES TAUGHT

- Introduction to Auto ID and Data Capture (AIDC) Technologies (State University NY, Stony Brook)
- Wireless Sensing Networks (Columbia University)
- mmWave Communications and Applications for 5G (Columbia University)

RECENT EXPERT WITNESS CONSULTING¹

- 2023: Ericsson Inc. and Oracle Corporation v. Telecom Network Solutions (IPR)
- 2022: Cleveland Medical Devices v. ResMed Corp (Litigation/IPR)
- 2022: Lone Star Systems v. Zebra Technologies (Litigation/IPR)
- 2022: Telecom Network Solutions v. AT&T, Verizon, and T-Mobile (Litigation/IPR)
- 2021: BillJCo v. Apple (Litigation/IPR)
- 2021: BillJCo v. Cisco Systems et al. (Litigation)
- 2021: Zebra Technologies v. OnAsset Intelligence (ITC)
- 2021: CellSpin Soft v. Under Armour (Litigation)
- 2021: CellSpin Soft v. Nike (Litigation)
- 2021: Intellectual Ventures v. Hewlett Packard Enterprise (Litigation)
- 2021: AEGIS v. Hisense (Litigation)
- 2020: Soter Technologies v. IP Video Corp. et al (Litigation)
- 2020: Intellectual Tech v. Zebra Technologies (Litigation)
- 2020: Uniloc v. Apple (Litigation)
- 2020: American Patents v. Juniper Networks (Litigation)
- 2020: Proxicom Wireless v. Target Corporation (Litigation)
- 2020: Sol IP v. AT&T et al. (Litigation)
- 2019: Cellular Evolution v. AT&T et al. (Litigation)
- 2019: Philips v. HTC (Litigation, UK)

¹ Represented parties are underlined.

- 2019: Ericsson v. Tishman Interiors (AAA Arbitration)
- 2019: Uniloc v. Samsung, Huawei (Litigation)
- 2018: Intel et al. v. Hera Wireless (IPR)
- 2018: Deutsche Telecom v. The Republic of India (UNCITRAL Arbitration, Paris Tribunal)
- 2017: Devas v. The Republic of India (UNCITRAL Arbitration, The Hague Tribunal)
- 2017: RPX Corp. et al. v. Iridescent Networks (IPR)
- 2017: Intellectual Ventures v. FedEx (Litigation)
- 2017: FedEx v. Intellectual Ventures (IPR)

PREVIOUS TESTIMONY

- *Deutsche Telekom AG v. The Republic of India*, PCA Case No. 2014-10 (UNCITRAL) Expert Reports + Arbitration Hearing.
- *Devas (Mauritius) Ltd. et al v. The Republic of India*, PCA Case No. 2013-09 (UNCITRAL) Expert Reports + Arbitration Hearing.
- *Philips v. HTC*, Claim HP-2015-000063 (UK) Expert Report.
- *Ruckus Wireless, Inc. et al v. Hera Wireless S.A.*, Case IPR2018-01419 (PTAB) Expert Declaration.
- *Ruckus Wireless, Inc. et al v. Hera Wireless S.A.*, Case IPR2018-01736 (PTAB) Expert Declaration.
- *Intel Corporation v. Hera Wireless S.A.*, Case IPR2018-01702 (PTAB) Expert Declaration.
- *Ruckus Wireless, Inc. et al v. Hera Wireless S.A.*, Case IPR2018-01418 (PTAB) Expert Declaration.
- *Ruckus Wireless, Inc. et al v. Hera Wireless S.A.*, Case IPR2018-01739 (PTAB) Expert Declaration.
- *Intel Corporation et al v. Hera Wireless S.A.*, Case IPR2018-01700 (PTAB) Expert Declaration.
- *Intel Corporation et al v. Hera Wireless S.A.*, Case IPR2018-01701 (PTAB) Expert Declaration.
- *Ruckus Wireless, Inc. et al v. Hera Wireless S.A.*, Case IPR2018-01732 (PTAB) Expert Declaration.
- *Ruckus Wireless, Inc. et al v. Hera Wireless S.A.*, Case IPR2018-01737 (PTAB) Expert Declaration.
- *Intel Corporation et al v. Hera Wireless S.A.*, Case IPR2018-01686 (PTAB) Expert Declaration.
- *Ruckus Wireless, Inc. et al v. Hera Wireless S.A.*, Case IPR2018-01420 (PTAB) Expert Declaration.
- *Intel Corporation et al v. Hera Wireless S.A.*, Case IPR2018-01687 (PTAB) Expert Declaration.
- *Ruckus Wireless, Inc. et al v. Hera Wireless S.A.*, Case IPR2018-01738 (PTAB) Expert Declaration.
- *RPX Corporation et al v. Iridescent Networks, Inc. (McEwen, Kathy, inventor)*, Case IPR2018-00254 (PTAB) Expert Declaration.
- *RPX Corporation et al v. Iridescent Networks, Inc. (McEwen, Kathy, inventor)*, Case IPR2017-01661 (PTAB) Expert Declaration.
- *RPX Corporation et al v. Iridescent Networks, Inc.*, Case IPR2017-01662 (PTAB) Expert Declaration.
- *Intellectual Ventures II LLC v. FedEx Corp.*, (2:16-cv-00980), Expert Report + Deposition + Trial (Texas Eastern District Court).
- *FedEx Corp. v. Intellectual Ventures II LLC*, Case IPR2017-00729 (PTAB) Expert Declaration.
- *FedEx Corp. v. Intellectual Ventures II LLC*, Case IPR2017-02030 (PTAB) Expert Declaration.
- *FedEx Corp. v. Intellectual Ventures II LLC*, Case IPR2017-00741 (PTAB) Expert Declaration.
- *Uniloc USA, Inc., Uniloc Luxembourg, S.A., and Uniloc 2017 LLC (Uniloc) v. Samsung*, (2:18-cv-00042) Expert Report + Deposition.
- *Uniloc USA, Inc., Uniloc Luxembourg, S.A., and Uniloc 2017 LLC (Uniloc) v. Samsung*, (2:18-cv-00044) Expert Report + Deposition.
- *SoL IP v. AT&T et al.*, (2:18-cv-00526), Expert Report + Deposition.
- *Juniper Networks v. American Patents*, Case IPR2020-01114 (PTAB) Expert Declaration.
- *Juniper Networks v. American Patents*, Case IPR2020-01115 (PTAB) Expert Declaration.
- *Intellectual Tech v. Zebra Technologies*, (6:19-cv-00628) Expert Declaration.
- *Aegis 11 S.A. v. Belkin Int'l, Inc.*, Civ. Nos. 19-1161-RGA, -1162-RGA, and 1163-RGA Expert Declaration.
- *Aegis 11 S.A. v. TTE Tech., Inc.*, Civ. No. 19-1165-RGA Expert Declaration
- *Aegis 11 S.A. v. Funai Electric Co.*, Civ. No. 20-03890
- *AEgis v. Hisense*, (1:20-cv-03891) Expert Declaration.
- *Soter Technologies, LLC v. IP Video Corp. et al*, SDNY 20-cv-05007(LJL) Expert Declaration.
- *Soter Technologies, LLC v. IP Video Corp. et al*, EDNY 2:20-cv-02989(GRB)(AKT) Expert Declaration + Deposition.

- *Cellspin Soft, Inc. v. Nike, Inc.*, NDCA 4:17-cv-05931YGR Expert Report.
- *Cellspin Soft, Inc. v. Under Armour, Inc.*, NDCA 4:17-cv-05932YGR Expert Report.
- *BillJCo, LLC v. Cisco Systems, Inc. et al.*, EDTX 2:21-cv-181, 183-JRG Expert Reports + Deposition.
- *BillJCo, LLC v. Apple, Inc.*, WDTX 6:21-cv-528-ADA Expert Declaration.
- *Zebra Technologies v. OnAsset Intelligence, Inc.*, ITC Washington DC, Investigation No. 337-TA-1278 Expert Reports on Infringement & Validity + Deposition + Trial/Hearing.
- *Intellectual Tech LLC v. Zebra Technologies*, WDTX 6:19-cv-00628-ADA Expert Report.
- *Hewlett Packard Enterprise v. Intellectual Ventures II LLC*, Case IPR2021-01377 (PTAB) Expert Declaration + Deposition.
- *Hewlett Packard Enterprise v. Intellectual Ventures II LLC*, Case IPR2022-00096 (PTAB) Expert Declaration + Deposition.
- *Ericsson Inc. and Oracle Corporation v. Telecom Network Solutions LLC*, Case IPR2022-1572 (PTAB) Expert Declaration.
- *Ericsson Inc. and Oracle Corporation v. Telecom Network Solutions LLC*, Case IPR2022-1573 (PTAB) Expert Declaration.

ADDENDUM

Publications

- J. Sharony, "Understanding Het-Nets, Antennas and other Advanced Techniques in LTE-Advanced; Advanced Systems and Techniques," LTE-Advanced: Understanding 3GPP Release 10 and Beyond – Workshop presented by 4G Americas, Marina del Rey, CA, October 2012.
- J. Sharony, V. Ramanna, "Self Learning Real Time Location Tracking in Wireless Sensor Networks," Accepted to WiCOM, The 5th International Conference on Wireless Communications, Networking and Mobile Computing, China, 2009.
- J. Sharony, "Introduction to Wireless MIMO – Theory and Applications", IEEE LI, November 2006.
- J. Sharony, M. Sen, "Bandwidth management in 802.11 wireless LANs," ICC 2004 - IEEE International Conference on Communications, vol. 27, no. 1, Paris, France, June 2004 pp. 3837-3843.
- L-T.Cheok, J.Sharony and A.Eleftheriadis, "A SMIL-enabled Mobile Shopping Mall Application," SMILEurope Conference, Paris, France, February 2003.
- L-T.Cheok, J.Sharony and A.Eleftheriadis, "Symshop: A Mobile Shopping Mall Application," International Conference on Mobile and Ubiquitous Multimedia (MUM), Oulu, Finland, December 2002.
- J. Sharony, "Effective Throughput of 802.11 Wireless LAN with Interference from Nearby Cells," Proc. of Mobile Multimedia Communications (MoMuC), 7th International Workshop, Tokyo, Japan, 2000.
- J. Sharony, "An Architecture for Mobile Radio Networks With Dynamically Changing Topology Using Virtual Subnets," Mobile Networks & Applications, vol. 1, no. 1, 1996 pp. 75-86.
- J. Sharony, "A Multi-Star Optical Backbone Network Suitable for Distributed Microcellular Wireless Systems," Proc. of IEEE GLOBECOM'96, London, UK, November, 1996.
- J. Sharony, A. C. Sevdinoglou, "On-line distributed TDMA/FDMA/CDMA Link Assignment in Mobile Radio Networks with Flexible Directivity," Hazeltine Technical Bulletin, 1996.
- Y. Li, T. Wang, Z. G. Pan, J. Sharony, "Minimum-Complexity Free-Space Optical Nonblocking Networks for Multicast Interconnect Applications," Optical Letters, vol. 19, no. 8, April 1994 pp. 515-517.
- Y. Li, T. Wang, Z. G. Pan, J. Sharony, "Complexity-Minimized Optical Non-Blocking Interconnects for Multicast Computer Communications," Proceedings of the SPIE - Advances in Optical Information Processing VI 2240:192-204, 1994.
- Y. Li, T. Wang, J. Sharony, "Free-Space Optical Interconnects Using Connectivity-Enhanced Mesh-Based Networks," Optical Engineering, vol. 33, no. 5, 1994 pp. 1532-1542.
- Y. Li, T. Wang, Z. G. Pan, J. Sharony, "Free-Space Optical Implementations of Connectivity-Enhanced Mesh-Based Networks," Proceedings of the SPIE - International Society for Optical Engineering Optoelectronic Interconnects II, vol. 2153 pp. 57-68, 1994.
- J. Sharony, T. Stern, Y. Li, "The universality of multidimensional switching networks," IEEE/ACM Transactions on Networking, vol. 2, no. 6, December 1994 pp. 602-612.
- J. Sharony, "Broadcast and switch – A new class of WDM networks for high switching-speed, high connectivity applications," in Photonics in Switching Topical Meeting'93 Digest, Palm Springs, CA, Mar. 1993.
- J. Sharony, K. W. Cheung, T. E. Stern, "The Wavelength Dilation Concept in Lightwave Networks – Implementation and System Considerations," Journal of Lightwave Technology, vol. 11, no. 5/6, May/June 1993 pp. 900-907.
- J. Sharony, "Architectures of Dynamically Reconfigurable Wavelength Routing/Switching Networks," Ph.D. Thesis, Columbia University, May 1993.
- J. Sharony, K. W. Cheung, T. E. Stern, "Wavelength Dilated Switches (WDS) – A New Class of Suppressed Crosstalk, Dynamic Wavelength-Routing Crossconnects," OFC'92, paper TuO3, San Jose, CA, Feb 1992.
- J. Sharony, C. Georgiou, "Wavelength Selective Optical Crossconnect," IBM Technical Disclosure Bulletin, vol. 34, no. 10A, March 1992.
- J. Sharony, S. Jiang, T. Stern, K. Cheung, "Wavelength Rearrangeable and Strictly Non-Blocking Networks," Electronics Letters, vol. 28, no. 2, March 1992 pp. 536-537.
- J. Sharony, K. W. Cheung, T. E. Stern, "The Wavelength Dilation Concept – Implementation and System Considerations," Proc. ICC'92, paper 330.3, Chicago, IL, June 1992.
- J. Sharony, K. W. Cheung, T. E. Stern, "Wavelength Dilated Switches (WDS) – A New Class of High Density, Suppressed Crosstalk, Dynamic Wavelength-Routing Crossconnects," IEEE Photonics Technology Letters, vol. 4, no. 8, August 1992 pp. 933-935.

- Y. Li, T. Jiang, J. Sharony, "Massively Parallel Free-Space Optical Clos Network Using Wavelength-Division Multiple Access," Electronics Letters, vol. 28, no.21, October 1992 pp. 2001-2002.
- J. Sharony, T. E. Stern, K. W. Cheung, "Extension of Classical Rearrangeable and Non-Blocking Networks to the Wavelength Dimension," Proc. of IEEE GLOBECOM'92, December, 1992.
- J. Sharony, "Bounds on Threshold Effects in Frequency Estimation," Master Thesis, Tel Aviv University, April 1984.

Issued U.S. Patents

- 10,200,924 - Small-cell gateway configured for multiple air interfaces
- 10,080,177 - Unlicensed spectrum offload architecture for small-cell base stations
- 10,028,188 - Location processing in small cells implementing multiple air interfaces
- 9,854,489 - Location processing in small cells implementing multiple air interfaces
- 9,807,657 - Small-cell gateway configured for multiple air interfaces
- 9,474,500 - Method and system for transfer of cardiac medical image data files
- 9,161,273 - Small cells implementing multiple air interfaces
- 9,148,835 - Small cells implementing multiple air interfaces
- 9,143,996 - Small cells implementing multiple air interfaces
- 9,125,121 - Small cells implementing multiple air interfaces
- 9,088,923 - Small cells implementing multiple air interfaces
- 9,014,702 - Wireless location processing in small cells implementing multiple air interfaces
- 7,827,610 - Wireless LAN intrusion detection based on location
- 7,778,649 - System and method for asset location in wireless networks
- 7,706,809 - RF tracking system and method
- 7,668,201 - Bandwidth management in wireless networks
- 7,596,388 - Sectorized wireless communication network operating under 802.11 specifications
- 7,426,383 - Wireless LAN intrusion detection based on location
- 7,373,154 - System and method for asset location in wireless networks
- 7,174,172 - System and method for asset location in wireless networks
- 7,164,929 - Method and apparatus for location tracking in a multi-path environment
- 7,069,024 - System and method for determining location of rogue wireless access point
- 7,039,358 - Coexistence techniques in wireless networks
- 7,019,663 - RF tracking system and method
- 6,990,587 - Cryptographic architecture for secure, private biometric identification
- 6,925,094 - System and method for wireless network channel management
- 6,853,293 - Wearable communication system
- 6,735,445 - System and method for medium access control in a wireless network
- 6,577,609 - Local addressing of mobile units in a WLAN with multicast packet addressing
- 6,411,608 - Method and apparatus for variable power control in wireless communications systems
- 5,953,143 - Multidimensional switching networks
- 5,742,593 - On-line distributed TDMA/FDMA/CDMA link assignment in mobile radio networks with flexible directivity
- 5,652,751 - Architecture for mobile radio networks with dynamically changing topology using virtual subnets
- 5,495,356 - Multidimensional switching networks
- 4,867,820 - Preparation of laminated structure containing an optical fiber
- 4,847,596 - Wallpaper comprising an optical fibre

Issued International Patents

- EP2974520 - Unlicensed spectrum offload architecture for small-cell base stations
- EP1906294 - Wearable communication system
- EP1851978 - System and method for asset location in wireless networks
- EP1678960 - System and method for determining location of rogue wireless access point
- EP0886981 - An architecture for mobile radio networks with dynamically changing topology using virtual subnets
- EP1552632 - Apparatus and method for wireless network channel management

- EP1207654 - Coexistence techniques in a gateway between Bluetooth and WLAN wireless networks
- CA2599012 - Sectorized wireless communication network operating under 802.11 specifications
- AU2011202551 - Sectorized wireless communication network operating under 802.11 specifications
- CA2599406 - System and method for asset location in wireless networks
- AU783921 - Coexistence techniques in wireless networks

Published U.S. Patent Applications

- 20180220347 - SMALL-CELL GATEWAY CONFIGURED FOR MULTIPLE AIR INTERFACES
- 20170150412 - LOCATION PROCESSING IN SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20150382272 - UNLICENSED SPECTRUM OFFLOAD ARCHITECTURE FOR SMALL-CELL BASE STATIONS
- 20150365861 - SMALL-CELLS GATEWAY CONFIGURED FOR MULTIPLE AIR INTERFACES
- 20150257077 - LOCATION PROCESSING IN SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20130090119 - LOCATION PROCESSING IN SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20130089077 - SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20130089072 - SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20130089071 - SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20130089070 - SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20130089069 - SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20130084873 - SMALL CELLS IMPLEMENTING MULTIPLE AIR INTERFACES
- 20080201377 - Wireless LAN Intrusion Detection Based on Location
- 20080182593 - System and Method for Asset Location in Wireless Networks
- 20070105566 - System and method for asset location in wireless networks
- 20060221928 - Wireless device and method for wireless multiple access
- 20060221904 - Access point and method for wireless multiple access
- 20060221873 - System and method for wireless multiple access
- 20060211372 - Coexistence techniques in wireless networks
- 20060194616 - Sectorized wireless communication network operating under 802.11 specifications
- 20060194587 - System and method for asset location in wireless networks
- 20060194568 - System and method for determining location of rogue wireless access point
- 20060172756 - System and method for clustering mobile devices in a wireless network
- 20060125631 - RF tracking system and method
- 20050153713 - Method and apparatus for location tracking in a multi-path environment
- 20050136891 - Wireless lan intrusion detection based on location
- 20050135321 - Spatial wireless local area network
- 20050113090 - System and method for determining location of rogue wireless access point
- 20050096091 - Method and system for wireless communications using multiple frequency band capabilities of wireless devices
- 20050047343 - Bandwidth management in wireless networks
- 20040157604 - System and method for medium access control in a wireless network
- 20040057459 - System and method for wireless network channel management
- 20040038695 - SYSTEM AND METHOD FOR MEDIUM ACCESS CONTROL IN A WIRELESS NETWORK
- 20040027251 - RF tracking system and method
- 20030020629 - Wearable communication system
- 20020152391 - Cryptographic architecture for secure, private biometric identification
- 20020150098 - Local addressing of mobile units in a WLAN with multicast packet addressing
- 20020018451 - Method and apparatus for variable power control in wireless communications systems

Published International Patent Applications

- WO2013036487 - Small cells implementing multiple air interfaces

- WO0227989 - Logical addressing of mobile units in a wlan with multicast packet addressing
- WO2005046256 - Method and system for wireless communication using multiple frequency band capabilities of wireless devices
- WO2009146082 - Rfid monitoring of drug regimen compliance
- WO2004019539 - System and method for medium access control in a wireless network
- WO2005060172 - Wlan with a plurality of antennas in both access point and mobile unit
- WO2006093884 - Sectorized wireless communication network operating under 802.11 specifications
- WO2014140877 - Unlicensed spectrum offload architecture for small-cell base stations
- WO2006107538 - System and method for wireless multiple access
- WO2004028054 - System and method for wireless network channel management
- WO0205578 - Method and apparatus for variable power control in wireless communications systems
- WO2005072000 - Method and apparatus for location tracking in a multi-path environment
- WO2006093710 - System and method for asset location in wireless networks
- WO2005046254 - System and method for determining location of rogue wireless access point
- WO2006083535 - System and method for clustering mobile devices in a wireless network
- WO2006107537 - Wireless device and method for wireless multiple access
- WO2006107535 - Access point and method for wireless multiple access
- WO9736444 - An architecture for mobile radio networks with dynamically changing topology using virtual subnets
- JP2017225127 - Small cells implementing multiple air interfaces
- JP2002185476 - Coexistence technique in wireless network
- CA2495618 - System and method for wireless network channel management
- CA2602569 - System and method for wireless multiple access
- CA2543459 - Method and system for wireless communication using multiple frequency band capabilities of wireless devices
- CA2602399 - Wireless device and method for wireless multiple access
- CA2602572 - Access point and method for wireless multiple access
- EP2752051 - Small cells implementing multiple air interfaces
- EP1232594 - Logical addressing of mobile units in a wlan with multicast packet addressing
- EP1678836 - Method and system for wireless communication using multiple frequency band capabilities of wireless devices
- EP1702491 - Method and apparatus for location tracking in a multi-path environment
- EP1864396 - System and method for wireless multiple access
- EP1733511 - Wlan with a plurality of antennas in both access point and mobile unit
- EP1300029 - Method and apparatus for variable power control in wireless communications systems
- EP1844615 - System and method for clustering mobile devices in a wireless network
- EP1864404 - Wireless device and method for wireless multiple access
- EP1864516 - Access point and method for wireless multiple access
- EP0886981 - An architecture for mobile radio networks with dynamically changing topology using virtual subnets
- EP1906294 - Wearable communication system
- AU9483001 - Logical addressing of mobile units in a wlan with multicast packet addressing
- AU2003272648 - System and method for wireless network channel management
- AU2006218786 - Sectorized wireless communication network operating under 802.11 specifications
- AU2003265675 - System and method for medium access control in a wireless network
- AU2001294830 - Logical addressing of mobile units in a wlan with multicast packet addressing
- GB2319439 - Network Architecture for Linking Base Stations