UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,

Petitioner,

v.

OMNI MEDSCI, INC.,

Patent Owner.

Patent No. 9,861,286

IPR2019-00914

DECLARATION OF BRIAN ANTHONY, PH. D. REGARDING U.S. PATENT NO. 9,861,286

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I. INTRODUCTION

A. Engagement

1. I have been retained by counsel for Apple Inc. as an expert witness in the above-captioned proceeding. I have been asked to provide an opinion regarding the patentability of certain claims in U.S. Patent No. 9,861,286 ("the '286 Patent") (Exhibit 1001). The face of the '286 patent identifies Omni MedSci, Inc. ("Omni") as the assignee. I have been asked to provide a discussion of the meaning of certain words and phrases in the claims of the '286 patent, to provide a description of state of the art of the technology described in the '286 patent, and to analyze various references that I understand are prior art to these patents.

B. Background and Qualifications

2. As indicated in my curriculum vitae ("CV"), Ex.1053, I am currently a Principal Research Scientist at the Massachusetts Institute of Technology ("MIT"). My CV includes additional information about my professional history and contains further details on my experience, publications, patents, and other qualifications to render an expert opinion. Below, I highlight some of my experience that is relevant to the technology of the patent at issue.

3. I earned a Bachelor of Science in Engineering from Carnegie Mellon University in 1994 and a Master's degree in Engineering from MIT in 1998. My thesis topic related to anisotropic wave guides and acoustic non-destructive testing.

In 2006, I earned my Ph.D. in Engineering from MIT. My research focused on high-performance computation, signal processing, and electro-mechanical system design.

4. In 1997, I co-founded Xcitex Inc., a company that specialized in video-acquisition and motion-analysis software. I served as the Chief Technology Officer and directed and managed product development until 2006. Our first demo product was an optical ring for human motion measurement used to capture user hand motion in order to control the user's interaction with a computer. Many of the structural elements of our optical ring addressed the same system issues as those described and claimed in the patent at issue. For example, our optical ring included multiple light emitting diodes, multiple photodetectors, techniques for modulation and synchronization, noise reduction algorithms, and optical components for light blocking, light redirection, and light capture, and structural components for holding and geometrically arranging the various components. We estimated human hand-motion based on how that motion changed the detected light. In our application we did not try to eliminate motion artifact, we tried to measure it. In developing our ring, we considered well-known problems such as ambient light and noise, which are, unsurprisingly, also mentioned in the patent at issue. Motion Integrated Data Acquisition System (MiDAS) was our flagship video and data acquisition product which relied upon precise synchronization of

multiple clocks for optical sensor and video acquisition, data acquisition, and external illumination.

5. I joined MIT in 2006 and was the Director of the Master of Engineering in Advance Manufacturing and Design Program for over ten years. The degree program covers four main components: Manufacturing Physics, Manufacturing Systems, Product Design, and Business Fundamentals. Many of the courses, projects, and papers my students undertake involve technologies relevant to the patent at issue, for example, sensor devices including non-invasive optical biosensors.

6. In 2011, I co-founded MIT's Medical Electronic Device Realization Center ("MEDRC") and currently serve as co-director. The MEDRC aims to create and deploy revolutionary medical technologies by collaborating with clinicians, the microelectronics, and medical devices industries. We combine expertise in computation; communications; optical, electrical, and ultrasound sensing technologies; and consumer electronics. We focus on the usability and productivity of medical devices using, for example, image and signal processing combined with intelligent computer systems to enhance practitioners' diagnostic intuition. Our research portfolio includes low power integrated circuits and systems, big data, micro electro-mechanical systems, bioelectronics, sensors, and microfluidics. Specific areas of innovation include wearable, non-invasive and

minimally invasive optical biosensor devices, medical imaging, laboratory instrumentation, and the data communication from these devices and instruments to healthcare providers and caregivers. My experience with these devices is directly applicable to the technology in the patent at issue. For example, in one current project related to this work, we use a patient-mounted mobile near infrared (NIR) camera to image and characterize the surface and subsurface structures of the skin.

7. I am the Associate Director of MIT.nano, MIT's new 200,000 sq-ft nanofabrication and characterization facility and one of the major research initiatives with MIT.nano is on sensors and sensing systems. Our research in sensing science and sensing engineering is targeting innovations in advanced manufacturing, healthcare, environmental remediation, smart infrastructure, and the creation of advanced machines and materials. I also co-founded the Center for Polymer Micro-fabrication at MIT. The Center’s research focuses on polymer-based manufacturing processes and the large-scale commercialization of micro fluidic devices for chemical, biomedical, and photonic applications. My experience under these initiatives is directly applicable to the technology in the patent at issue. We develop optical sensors to noninvasively monitor soft flexible materials during the manufacturing process.

8. Furthermore, my research focuses on computational instrumentation, including the development of instrumentation and measurement solutions for manufacturing systems and medical devices. Additionally, my teaching interests include the design and modeling of large-scale systems in a wide variety of decision-making domains and developing optimization algorithms and software for analyzing and designing such systems. I teach or have taught courses in Electrical Engineering, Controls, Optics, and Signal Processing, all pertinent subject matter to the patent at issue.

9. I have published approximately 85 papers, and have received a number of best paper and distinguished paper awards. I am a co-author of a number of papers that relate to the technology in the patent at issue.

C. Compensation

10. I am being compensated for my time at the rate of $500 per hour for my work in connection with this matter. I am being reimbursed for reasonable and customary expenses associated with my work in this investigation. This compensation is not dependent in any way on the contents of this Declaration, the substance of any further opinions or testimony that I may provide or the ultimate outcome of this matter.

D. Information Considered

11. My opinions are based on my years of education, research, and experience, as well as my investigation and study of relevant materials. In forming my opinions, I have considered the materials I identify in this report and those listed in the attached Exhibit List.

12. I may rely upon these materials and/or additional materials to respond to arguments raised by Omni. I may also consider additional documents and information in forming any necessary opinions—including documents that I have not yet identified or may not yet have been provided to me.

13. My analysis of the materials produced in this investigation is ongoing, and I will continue to review any new material as it is provided. This report represents only those opinions I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided.

II. LEGAL STANDARDS FOR PATENTABILITY

14. Certain basic legal principles have been explained to me by counsel for Apple. Below, I have recorded these legal standards as they were explained to me.

15. I understand that for an invention claimed in a patent to be found patentable, it must be, among other things, new and not obvious from what was known before the invention was made.

16. I understand that the effective filing date of the claimed invention is the actual filing date of the claims, unless the applicant claims priority to an earlier filed application that supports the claimed subject matter in the manner required by 35 U.S.C. § 112. I understand that this section requires the patent's specification to contain a sufficient written description of the claimed invention to demonstrate that the applicant actually possessed the invention as of the filing date as broadly as it is claimed. In considering whether this written description requirement is met, I understand that I should consider the written description from the viewpoint of a person of ordinary skill in the art. I also understand that I should consider whether this person of ordinary skill would have recognized that the written description describes the full scope of the claimed invention and that the inventor actually possessed that full scope as of the claimed effective filing date.

17. I understand the information that is used to evaluate whether an invention is new and not obvious is generally referred to as "prior art" and can include patents and printed publications. I also understand that a patent will be prior art if it was filed before the earliest effective filing date of the claimed invention, while a printed publication will be prior art if it was publicly available

before that date. I understand that in this proceeding, the information that may be evaluated to show unpatentability is limited to patents and printed publications.

18. I understand that in this proceeding Apple has the burden of proving that the challenged claims are unpatentable over the prior art by a preponderance of the evidence. I understand that "a preponderance of the evidence" is evidence sufficient to show that a fact is more likely true than it is not.

19. I understand that there are two ways in which prior art may render a patent claim unpatentable. First, the prior art can be shown to "anticipate" the claim. Second, the prior art can be shown to have made the claim "obvious" to a person of ordinary skill in the art.

A. Anticipation

20. I understand that, for a patent claim to be "anticipated" by the prior art, each and every requirement of the claim must be found, expressly or inherently, in a single prior art reference as recited in the claim.

21. I understand that claim limitations that are not expressly described in a prior art reference may still be there if they are "inherent" to the thing or process being described in the prior art.

22. I understand that it can be acceptable to consider evidence other than the information in a particular prior art document to determine if a feature is necessarily present in or inherently described by that document.

23. I understand that if a reference incorporates other documents by reference, the incorporating reference and the incorporated reference(s) should be treated as a single prior art reference for purposes of analyzing anticipation.

24. I understand that to be anticipatory, a reference must not only explicitly or inherently disclose every claimed feature, but those features must also be "arranged as in the claim." Differences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation.

B. Obviousness

25. I understand that a claimed invention is not patentable if it would have been obvious to a person of ordinary skill in the field of the invention at the time the invention was made. I understand that in determining whether a patent claim is obvious, one must consider the following four factors: (i) the scope and content of the prior art, (ii) the differences between the prior art and the claims at issue, (iii) the knowledge of a person of ordinary skill in the pertinent art; and (iv) objective factors indicating obviousness or non-obviousness, if present (such as commercial success or industry praise).

26. I understand the objective factors indicating obviousness or non-obviousness may include: commercial success of products covered by the patent claims; a long-felt need for the invention; failed attempts by others to make the

invention; copying of the invention by others in the field; unexpected results achieved by the invention; praise of the invention by those in the field; the taking of licenses under the patent by others; expressions of surprise by experts and those skilled in the art at the making of the invention; and the patentee proceeded contrary to the accepted wisdom of the prior art. I also understand that any of this evidence must be specifically connected to the invention rather than being associated with the prior art or with marketing or other efforts to promote an invention. I am not presently aware of any evidence of "objective factors" suggesting the claimed methods are not obvious, and reserve my right to address any such evidence if it is identified in the future.

27. In addition, I understand that the obviousness inquiry should not be done in hindsight, but must be done using the perspective of a person of ordinary skill in the relevant art as of the effective filing date of the patent claim.

28. I understand that the Supreme Court has rejected a rigid approach to determining the question of obviousness, such as one that requires a challenger to identify a "teaching, suggestion, or motivation to combine" known elements. Instead, a challenger needs to articulate reasoning for combining known elements. Such reasoning can be based on design considerations, market demands, looking to solutions to related problems in related fields, and on the "ordinary innovation" and creativity that would be applied by a person of ordinary skill in the art.

29. I understand that an invention that might be considered an obvious variation or modification of the prior art may be considered non-obvious if one or more prior art references discourages or leads away from the line of inquiry disclosed in the reference(s). A reference does not "teach away" from an invention simply because the reference suggests that another embodiment of the invention is better or preferred. My understanding of the doctrine of teaching away requires a clear indication that the combination should not be attempted (*e.g.*, because it would not work or explicit statements saying the combination should not be made).

III. BACKGROUND INFORMATION ABOUT THE '286 PATENT

A. Effective Filing Date of the '286 Patent

30. The '286 patent issued from U.S. Application No. 15/686,198, which was a continuation of U.S. Patent No. 9,757,040 (filed November 21, 2016), which was a continuation of U.S. Patent No. 9,500,635 (filed December 17, 2013). The '286 patent claims benefit to U.S. Provisional Application No. 61/747,477 (filed December 31, 2012).

31. I have reviewed the '477 and '698 provisional applications and do not believe that they support the claims of the '286 patent in the manner required by 35 U.S.C. § 112. Neither provisional describes a device that measures light when LEDs are both on and off as specified in claim 16 of the '286 patent:

the measurement device further comprising a receiver configured to:

capture light while the LEDs are off and convert the captured light into a first signal and

capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue;

the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal;

The ’286 specification describes these concepts at Ex.1001, 30:3-4, where it states that “the detection system captures the signal with the light source on and with the light source off…. Then, the signal with and without the light source is differenced.” Ex.1001, 24:21-23. This passage does not appear in either provisional application. Nor does any other portion of either provisional application provide support for these limitations. It is therefore my opinion that neither provisional application demonstrates that the inventor was in possession of a device with this element of the claims.

B. The Prosecution History of The ’286 Patent

32. I have reviewed the file history of the ’286 patent (Exhibit 1002) and the ’286 patent was allowed without rejection.

C. Technical Field

33. The ’286 patent generally relates to optical sensors and devices that use optical sensors for measurement of physiological signals or biological parameters.

D. Level of Ordinary Skill in the Art

34. I have been instructed that the claims of a patent are to be reviewed from the point of view of a hypothetical person of ordinary skill in the art at the time of the filing of the patent.

35. Based on my knowledge and experience, it is my opinion a person of ordinary skill in the art at the relevant timeframe would have been a person with a good working knowledge of optical sensing techniques and their applications, and some familiarity with optical system design and signal processing techniques. That knowledge would have been gained via an undergraduate education in engineering (electrical, mechanical, biomedical or optical) or a related field of study, along with relevant experience in studying or developing physiological monitoring devices (e.g., non-invasive optical biosensors) in industry or academia. This description is approximate; varying combinations of education and practical experience also would be sufficient.

36. Well before December 2012, my level of skill in the art was at least that of a person of ordinary skill in the art in the field of the ’286 patent, as

discussed above. I am qualified to provide opinions concerning what a person of ordinary skill in the art would have known and understood at that time. In preparing this declaration, I have considered the issues from the perspective of a hypothetical person of ordinary skill in the art at the relevant timeframe.

IV. TECHNICAL BACKGROUND

A. Photoplethysmography

37. The use of optical sensors to detect physiological parameters, including photoplethysmography (detect blood volume changes), has been known for decades. Optical techniques are commonly used in medical monitoring systems such as pulse oximetry systems that measure a person's pulse rate and blood oxygen saturation. Ex.1019 (Biomedical Engineering Handbook 1995) at 769-76, 1346-55 (discussing oximetry and other applications).

38. Photoplethysmography works by directing light into a person's tissue and measuring the light that is reflected back from or transmitted through the tissue. Ex.1019 (Biomedical Engineering Handbook) at 764. Different components of blood or tissue absorb different wavelengths of light. By measuring how much light is absorbed by the tissue and how the absorption changes over time, a device can calculate parameters that are related to the properties of the tissue.

39. For example, hemoglobin (the protein molecule in blood that carries oxygen to cells) reflects more red light when it is more oxygenated than when it is deoxygenated; it absorbs more red light when it is deoxygenated. Ex.1019 (Biomedical Engineering Handbook) at 769. Hemoglobin reflects the same amount of infrared (IR) light whether oxygenated or deoxygenated. Ex.1019 (Biomedical Engineering Handbook) at 769. If a device measures the absorbed red and IR light multiple times per second, the device can determine several things: (i) the ratio of oxygenated to deoxygenated hemoglobin (oxygen saturation), and (ii) how the volume of blood in the tissue changes, allowing it to detect a person's pulse. Ex.1019 (Biomedical Engineering Handbook) at 769, 771.

40. Photoplethysmography is an optical technique, and it uses basic optical components or building blocks. The "basic building blocks" of optical sensor systems include lenses, mirrors, reflective surfaces, filters, beam splitters, light sources, fiber optics, light detectors, and other passive components and various active components to convert light signals to electrical signals. Ex.1019 (Biomedical Engineering Handbook) at 765.

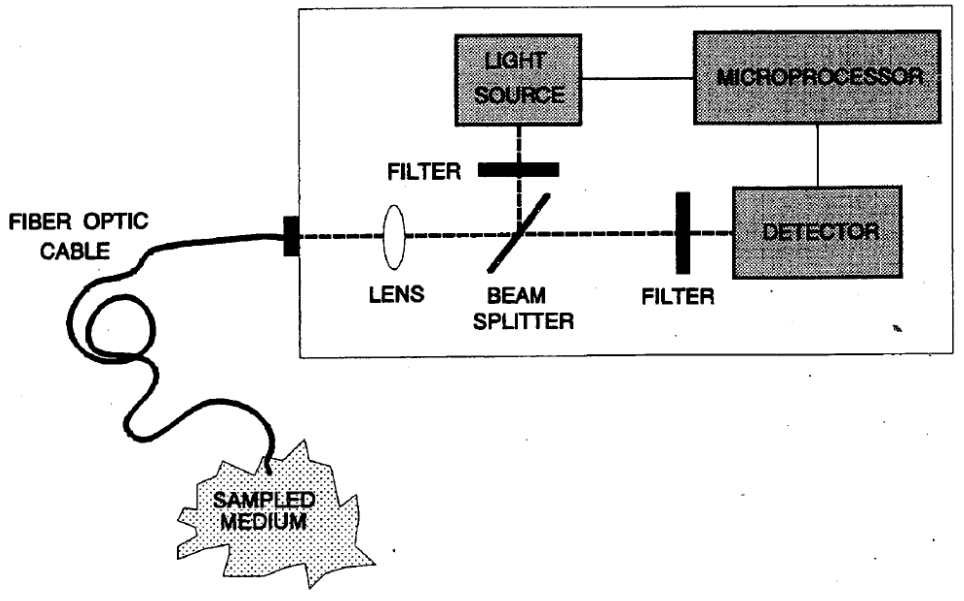


FIGURE 52.1 General diagram representing the basic building blocks of an optical instrument for optical sensor applications.

Ex.1019 (Biomedical Engineering Handbook) at 765. In portable devices, the light sources are typically light emitting diodes (LEDs) because they are small and have low power requirements. Ex.1019 (Biomedical Engineering Handbook) at 765. LEDs are manufactured with a wide range of packaged form factors and are easily assembled into systems with standard circuit board assembly processes; surface mount technology (SMT) is widely used to mount the LED packages for practical application.

41. The light from the light sources is directed through a lens and onto a sample. Ex.1019 (Biomedical Engineering Handbook) at 765. The sample or tissue reflects back the light, which is filtered and sensed by a photodetector. Ex.1019 (Biomedical Engineering Handbook) at 765. The photodetector outputs a

signal proportional to the measured light intensity, which is the measurable amount of light (number of photons), and then analog-to-digital conversion and signal processing are performed to extract data. Ex.1019 (Biomedical Engineering Handbook) at 766.

42. Photodetectors are devices used for the detection of light and conversion into an electrical signal. There are many types of photodetectors which may be appropriate in a particular case, depending on the application, design intent and design constraints, a photodetector and photodetector-based measurement system has to satisfy. For example, it must be sensitive in (be able to detect) some given spectral region (range of optical wavelengths). The detector must be suitable for some range of optical powers. The size of the active area of a detector can be important, *e.g.*, divergent or scattered light require larger active areas. For detecting pulses of light, the timing precision may be of interest so that the photodetector and measurement system can detect when the pulses of light are triggered. After detection of a pulse, some detectors may have a "dead time" during which they are not active. The pulses of light and the detection of pulses of light are synchronized by operating from a common clock, and therefore have a common time base, or may operate from different clocks and are then synchronized based on knowledge of the characteristics or nature of the timing of

transmitted light with various techniques, phase-locked (lock-in) amplifiers being one example.

43. Different types of detectors and applications require different levels of complexity in the system electronics. Trade-offs in terms of size and cost will result. Size, sensitivity, efficiency, speed of response, and cost tradeoffs are made in any applications. Photodiodes are semiconductor devices with a p–n junction or p–i–n structure ("p" (positive) side contains an excess of holes, while the "n" (negative) side contains an excess of electrons "i" is the intrinsic material), where light is absorbed in a depletion region and generates a photocurrent. Such devices can be very compact, fast, highly linear, and possess high quantum efficiency (generate nearly one electron per incident photon) and a high dynamic range, provided that they are operated in combination with suitable electronics. Phototransistors are similar to photodiodes but exploit internal amplification of the photocurrent. Photoresistors are also based on certain semiconductors. They are cheaper than photodiodes, but they are generally slower, not as sensitive, and exhibit a strongly nonlinear response.

44. The detected signal may include signal and noise from, for example, ambient light or motion induced artifacts. There are various well-known techniques used to reduce the amount of noise in the detected signal and improve the signal-to-noise ratio. For example, the light source is often modulated which

improves signal detectability and therefore serves to improve the signal-to-noise ratio. Ex.1019 (Biomedical Engineering Handbook 1995) at 764. The detector uses synchronized lock-in amplifier detection to isolate signals that occur at the modulation frequency to improve signal-to-noise ratio by extracting information encoded at the modulation frequency thereby reducing the impact of noise at other frequencies in the detected signal. Biomedical Engineering Handbook at 766.

45. Modulation is a standard technique to enhance the detectability of signal in noise. Ex.1019 (Biomedical Engineering Handbook) at 764. The goal is to encode and then detect or extract the information in the modulated signal. Modulation can be periodic or aperiodic. A receiver receives the modulated signal, which is composed of carrier and information signals, then detects or extracts the information from the modulated signal. This is called demodulation. How information is detected depends on the modulation techniques used. Examples of analog modulation techniques include amplitude modulation (AM) and frequency modulation (FM). A lock-in amplifier is a type of amplifier that can extract a signal with a known carrier frequency from an extremely noisy environment. Pulsed and digital modulation techniques include amplitude-shift keying (ASK), frequency-shift keying (FSK), and phase-shift keying (PSK). Each modulation technique has its own pros and cons and needs to be considered in context of an entire measurement system. Different modulation schemes can be used to

simultaneously transmit information from multiple transmitters through a single physical medium (e.g. wire, space, water, tissue). Frequency division multiplexing (FDM) is a technique for sending two or more signals over the same telephone line, radio channel, or other medium. The signal associated with separate information channel is transmitted as a unique range of frequencies within the broader frequency bandwidth of the physical channel as a whole, enabling several lines of communication to be transmitted simultaneously. Time-division multiplexing (TDM) is a technique of transmitting and receiving independent signals over a common signal path by means of synchronized switches. Each signal appears on the line only a fraction of time in an alternating pattern. Code division multiplexing (CDM) is a multiplexing technique that uses spread spectrum communication. In spread spectrum communications, a narrowband signal is spread over a larger band of frequency or across multiple channels. In Code Division Multiple Access (CDMA), each transmitter or information channel is given a unique code and individual conversations are encoded in a digital sequence.

46. LED packages are typically molded with polymer plastic materials. *See generally* Ex. 1035 (Light Emitting Diodes), 97-98, 191-99. Encapsulants and lens materials of LEDs are of high transparency, high refractive index, chemical stability, high temperature stability, and hermeticity to enhance the extraction of

light into free space as well as reliability performance. A lens is an optical element (or optical components) that focuses or otherwise modifies the direction of propagation of light. A lens is often a transparent material with curved surfaces for concentrating or dispersing light rays. High power LEDs may use a plastic lens as well as an encapsulant. Silicone retains mechanical softness in its cured state, the silicone encapsulant is enclosed in a plastic cover that serves as a lens to give mechanical protection. The plastic lenses control the angular projection and direction of the light cone from the LEDs into the next optical component of an optics system or into free space.

47. Components such as mirrors, beam splitters, and optical fibers are used to control and change the direction of light paths or to split light sources into multiple paths in order to create references for relative measurements.

B. Industry Trends

48. In the 2000 to 2012 time-frame, several market trends were pushing the medical device and semiconductor industries to develop wearable sensor devices that could communicate data to remote devices. During that time, there was a push to develop remote monitoring technology to allow more cost-effective and widespread medical care to be provided to remote populations or for monitoring in the home environment. Ex.1021 (Patel) at 2; Ex.1024 (BLE), 462; Ex.1027 (EU Report) at 15-31. Along with advances in the miniaturization of

electronics and in communication technology, these trends led to the development of many remote, wearable monitoring systems. Ex.1021 (Patel) at 3.

49. During that time frame, there was also a push to bring heart rate sensing devices to consumers for personal fitness tracking and other wellness related uses. Ex.1009 (Carlson), [0004] ("Pulsoximetry measuring devices are also used in sports for control and survey of athletes."); Ex.1005 (LeBoeuf2012/0197093), [0003] ("There is growing market demand for personal health and environmental monitors, for example, for gauging overall health, fitness, metabolism, and vital status during exercise, athletic training, work, public safety activities, dieting, daily life activities, sickness, and physical therapy."); Ex.1020 (FitnessCoach),at 3 ("A multitude of commercial health devices and sensors, such as oximeters and heart rate monitors, formerly reserved for professional use, are now available and can be connected to smartphones. GPS watches, pedometers and heart rate monitors, allow recording and tracking of physical activity."); Ex.1027 (EU Report) at 33 ("For many sport enthusiasts measuring body functions and storing the results of sports activities has become integrative part of their training. Emerging social computing communities and web 2.0 now enable people engaging in different sports to exchange their experiences, tips and warnings."), 35; Ex.1029 (Sensor Mania), 221 ("Wristband sensors are a predecessor to smartwatches and remain a successful product category on their

own…. Current examples… feature accelerometry and include the Nike Fuelband ($149, monitoring steps taken), the Jawbone UP wristband and iPhone app ($99, tracking steps taken, distance, calories burned, pace, intensity level, active versus inactive time, and GPS), the Adidas MiCoach ($70, providing heart rate monitoring, real time digital coaching, interactive training, and post-workout analysis of pace, distance, and stride rate)… Other sensor platforms also focus on fitness and athletic training…”).

50. This includes systems which monitor heart rate changes resulting from athletic activity and non-athletic activity and provides information based on the monitored activity. Such systems may be used to encourage individuals to participate, for example, in athletic activities to improve their fitness levels. This is accomplished by using activity monitoring techniques that provide incentives and social, or individual goal, oriented motivation for users to engage in athletic activities. Such “activity monitoring environments” may be customized based on factors derived from a user’s behavior, and athletic activity, and are used to improve the user’s performance. Ex.1031 (Hoffman); Ex.1032 (Hjelt). Accordingly, there was a general motivation in the field to integrate medical optical sensing techniques into wearable and mobile consumer devices for fitness, wellness, and heath uses.

51. The above trends and the advances in the miniaturization of electronics and communication technology led to the development of many wearable monitoring systems for mobile and fitness applications. Ex.1021 (Patel), 3; Ex.1020 (FitnessCoach), 2 ("Advances in the miniaturization of (inertial) sensing technology, along with the increasing availability of smartphones as a sensing platform, have given rise to many commercial appliances, apps, and general academic interest into people's physical activity.").

52. The continuous and rapid development of mobile phone and computing technology over this same period allowed mobile wearable device technology to be rapidly developed and deployed. Ex.1021 (Patel) at 4; *see also* Ex.1023 (Adil) at 5 (One of "the biggest usage of tablets stems from… Patient monitoring and data collection…, includ[ing] using the Bluetooth enabled sensor devices and Wi-Fi+ Bluetooth enabled interfaces to patient monitoring devices, to medical instruments that can transmit information to the tablet when in the vicinity."); Ex.1027 (EU Report) at 41. The global market trend in the medical industry was to use apps and smartphones to deliver care. Ex.1027 (EU Report) at 9-10, 40-49; Ex.1023 (Adil) at 1-2 ("Doctors and nurses were the early adopters of tablets"). It also led to the prevalent use of cloud-based data transfer and storage of data. Accordingly, there was a general motivation in the field to design wearable devices that interface with smartphones and tablets.

53. The architecture, and vendor or application specific variations, of these sports and remote/mobile monitoring systems was well-known by 2012. An example of the architecture is depicted below:

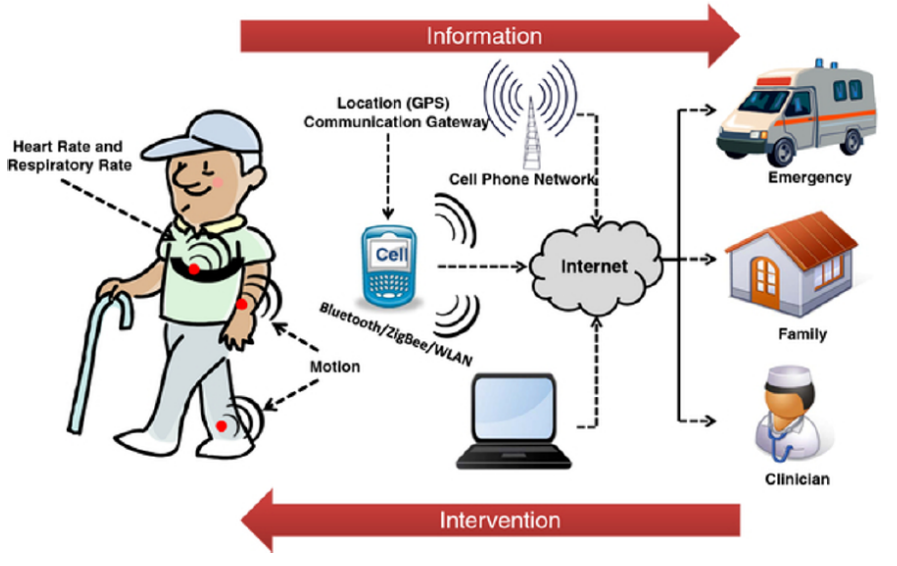


Figure 1 Illustration of a remote health monitoring system based on wearable sensors. Health related information is gathered via body-worn wireless sensors and transmitted to the caregiver via an information gateway such as a mobile phone. Caregivers can use this information to implement interventions as needed.

Ex.1021 (Patel) at 2. Data from wearable sensors is transmitted to a cell phone (or another mobile device worn or kept close to the individual). On the cell phone or mobile device, the data may be processed or preprocessed with the intent of filtering out noise, reducing data size via compression or processed with the intent of feature extraction or identification. The cell phone or mobile device in turn transmits the raw or processed data, along with GPS information over the internet (or other communication medium) to remote devices, such as another computer on the network for further data analysis (*e.g.*, further extraction of features of the data, comparing those features to trends for the individual or comparing features of the

data to norms for a population of similar individuals). Such remote network/internet connected devices are used to review the data by either by a clinician, family member, or emergency care provider. The data can also be transmitted to and stored in the cloud. Ex.1021 (Patel) at 4.

54. Another example of known architecture for sports and remote/mobile monitoring systems is shown below:

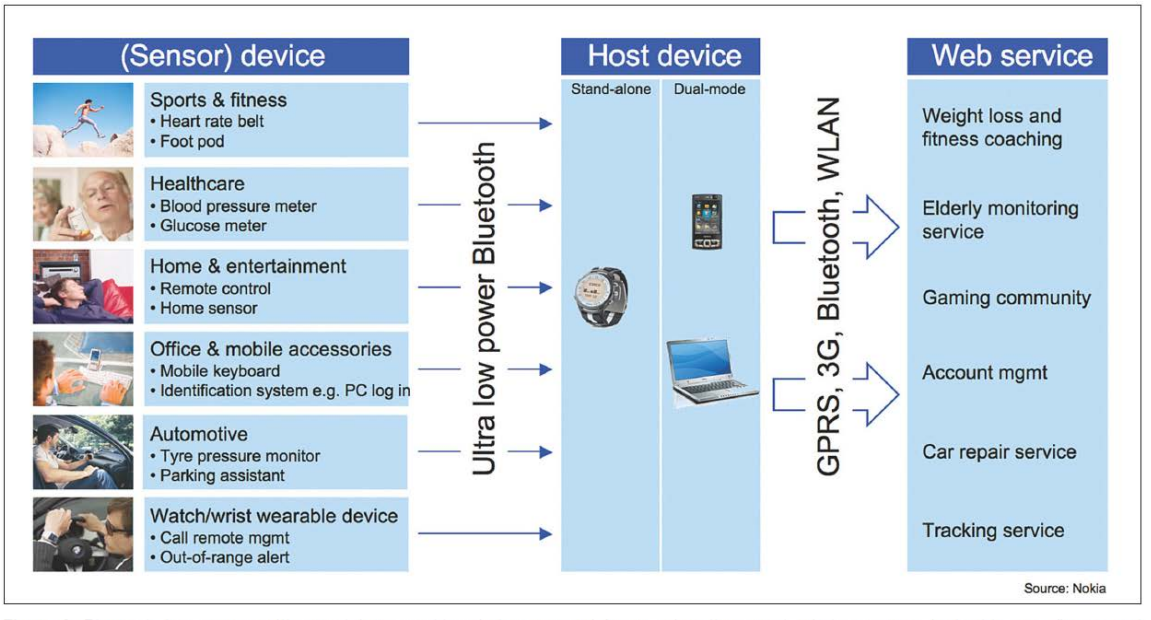
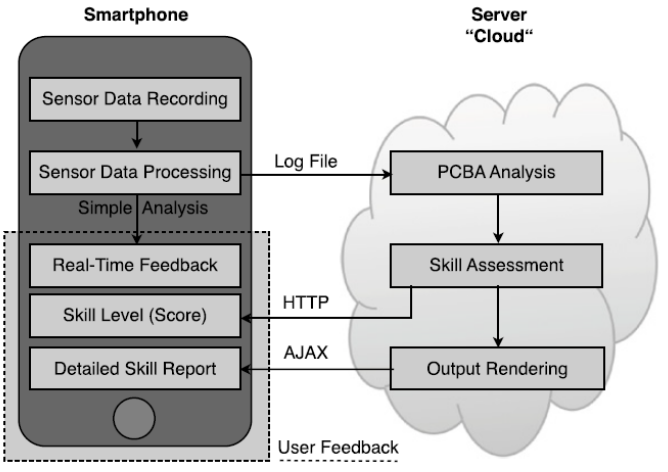


Figure 2. Bluetooth low energy will extend interoperable wireless connectivity to coin-cell-powered wireless sensors in health care, fitness, and related sectors. WLAN, wireless local area network; GPRS, general packet radio service.

Ex.1024 (BLE), 460. In this set up, the medical data can be sent from a wireless sensor device to a host device (*e.g.*, smart phone or computer) and then to a remote service (*e.g.*, physician). Ex.1024 (BLE), 459.

55. Another example of known architecture implemented for a fitness application is shown below:



(a) Iteration 1: the smartphone records sensor data during exercising, which are processed by a server after the training to generate skill assessment.

Ex.1020 (Fitness Coach), 7. A smartphone records and processes sensor data and sends the raw or processed data to a cloud server for further processing. The cloud server then returns the processed data back to the smartphone, which displays the data, and extracted information, to the user. Ex.1020 (Fitness Coach), 7, 6 ("The logged information is sent to a server, where the automatic analysis is performed… [to determine] the user's skill. The calculated skill level sent back to the mobile phone.]"), 12 ("GymSkill is a representative example for future mobile interactive applications that incorporate activity recognition…"). It was known in the art that this type of system could be used with heart rate monitors and optical sensors. Ex.1020 (Fitness Coach), 12 ("Coupling with devices like heart rate monitors using e.g. ANT+ further would increase the sensed database and allow for further, more detailed physical and physiological assessments.").

56. This same basic architecture had been known for decades. For example, a 1995 textbook depicted a similar architecture for a remote monitoring system based on wired technology:

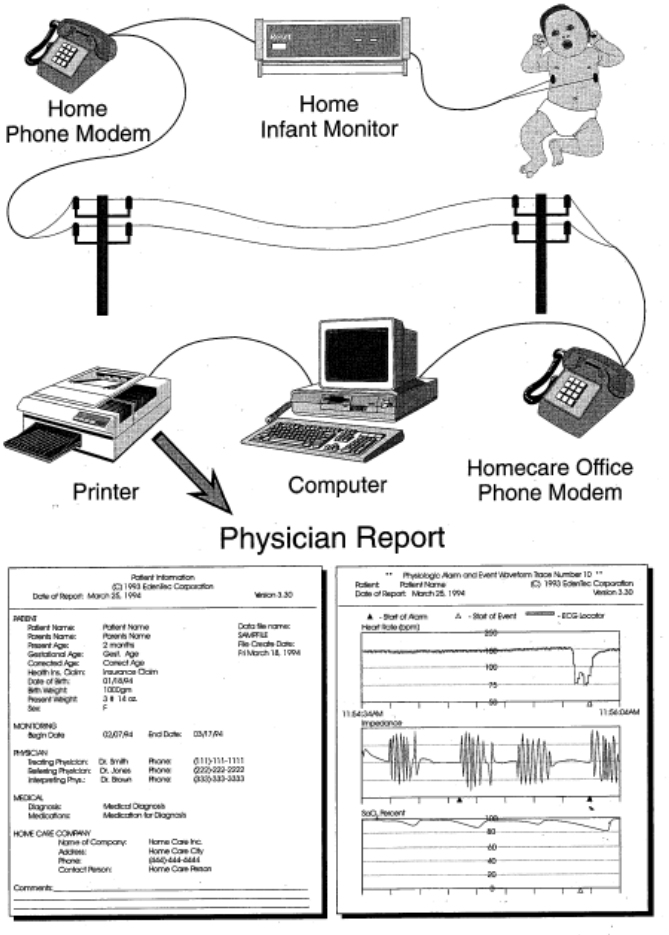


FIGURE 89.3 Infant apnea monitor with memory allows data to be sent by modem to generate physician report (drawing courtesy of EdenTec Corporation).

Ex.1019 (Biomedical Engineering Handbook) at 1363. Similar to the wireless version, in this system, data from a worn sensor is transmitted to a monitoring instrument (*e.g.*, home infant monitor). The monitoring instrument may process or pre-process the received data with the intent of filtering for noise, reducing data size via compression or with the intent of feature extraction or identification. The

monitoring instrument transmits the raw or processed data over the wired network to another computer on the network for further data analysis, for example, further extraction of features of the data, comparing those features to trends for the individual or comparing features of the data to norms for a population of similar individuals. The user interfaces and displays of the remote computer (or a printed report printed from a printer connected to the remote computer) are used to review the received data.

V. ANALYSIS OF THE ’286 PATENT

A. Overview of the ’286 Patent

57. The ’286 patent generally describes optical sensors and systems for using such sensors (for measurement of chemical properties or physiological signals). The challenged ’286 claims recite known features of prior art optical sensor systems, such as photoplethysmography systems and combine those features in known configurations.

58. The ’286 specification provides little description of the claimed elements. For example, the specification uses the terms “modulation,” “lock-in techniques,” and “synchronized” detection, but it does not explain what those terms mean or how to implement such functionality. Ex.1001, 24:12-20. These concepts were well-known to those of skill in the art at the time, and these terms

are not used in a manner inconsistent with the understanding of a person of ordinary skill in the art.

B. Construction of Terms Used in the ’286 Patent Claims

59. I understand that the parties have agreed in a related district court proceeding that all of the terms in the asserted claims, except for three, should be given their plain and ordinary meaning to a person of ordinary skill in the art. I understand that the plain and ordinary meaning should be determined in the context of the intrinsic record of the patent, including the claims, specification and the prosecution history, as well as any relevant extrinsic evidence of record. I also understand that when a patent applicant provides an explicit definition of a claim term in the specification, that definition may control the interpretation of that term in the claim.

60. I have been informed that the parties disagree over the meaning of the following three claim terms, and that the district court has provided preliminary constructions for these terms as follows:

“Beam”	**Apple**: Photons or light transmitted to a particular location in space.
	Omni: Photons or light transmitted to a location in space, which may be modulated or unmodulated, and which may or may not contain information.
	District Court: Photons or light transmitted to a particular location in space. A beam does not include randomly directed light. A beam is not necessarily collimated or focused.

"*One or more lenses*"	**Apple**: One or more transparent surfaces used to collimate (make parallel) or focus rays of light.
	Omni: No construction needed. Plain and ordinary meaning.
	District Court: Plain and ordinary meaning. Reject "used to collimate (make parallel) or focus rays of light." Reject that a lens can be other than transparent.
"*Modulating at least one of the LEDs*"	**Apple**: Varying the frequency of the light produced by at least one of the LEDs.
	Omni: Pulsing the light, or varying the frequency of the light, produced by at least one of the LEDs.
	District Court: Varying of the amplitude, frequency, or phase of the light produced by at least one of the LEDs to include information.

61. It is my opinion that the term "*beam*" as it is used in the asserted claims would be understood by a person of ordinary skill in the art to mean photons or light transmitted to a particular location in space. The claim term "beam" is expressly defined in the specification to "refer to photons or light transmitted to a particular location in space." Ex.1001, 10:14-16. The definition is also consistent with extrinsic evidence defining a "beam" to mean "a collection of nearly parallel rays." Ex.1047 at 106; *see also* Ex.1042 at 1. A beam is not comprised of scattered or randomly directed light. As the '286 patent seems to recognize, a collection of nearly parallel rays would necessarily travel to a particular location in space, as opposed to scattering in different directions. Ex.1001, 8:50-53 (distinguishing a beam from "stray light from a reflection or scattering"), 18:54-57 (directing an array of beams), 5:3-7 (delivering a beam to a

sample), Fig. 12C and 23:47-65(showing a beam directed to sample and scattered light reflected from the sample).

62. Based on this intrinsic and extrinsic evidence, as well as my own knowledge and experience, it is my opinion that a person of ordinary skill in the art would have understood the term "*beam*" as used in the asserted claims to mean photons or light transmitted to a particular location in space. This is the definition I use in this declaration when comparing the prior art to the claims. I have also considered the prior art in light of the definitions offered by Omni and by the district court, and it is my opinion that the prior art discloses a "beam" regardless of which definition is used.

63. It is my opinion that the term "*one or more lenses*" as it is used in the asserted claims would be understood by a person of ordinary skill in the art to mean one or more transparent surfaces used to collimate (make parallel) or focus rays of light. There is only one type of lens described by the '286 patent, and that is one that will "collimate or focus the light." Ex.1001, 13:62-63; 14:26-27, 14:61-63; 18:16-17. Collimate means to make parallel. In addition, the claims require the lenses to be configured to perform certain functions, including receiving and delivering a portion of the input optical beam received from the LEDs to tissue. In order to perform these claimed functions, the lens must be transparent to the received light so that it can pass through the lens and travel to the tissue. And, in

order to deliver a portion of a beam to tissue as required by the claim, the lens must collimate or focus the light, rather than scatter it. These functions of the claimed lens are consistent with the Merriam Webster's Collegiate Dictionary definition of lens:

> a piece of transparent material (as glass) that has two opposite regular surfaces either both curved or one curved and the other plane and that is used either singly or combined in an optical instrument for forming an image by focusing rays of light.

Ex.1046 at 712; Ex.1041 at 481 ("[a] piece of glass or other transparent material").

64. Based on this intrinsic and extrinsic evidence, as well as my own knowledge and experience, it is my opinion that a person of ordinary skill in the art would have understood that "one or more lenses" as used in the asserted claims would be construed to mean one or more transparent surfaces used to collimate (make parallel) or focus rays of light. This is the definition I use in this declaration when comparing the prior art to the claims. I have also considered the prior art in light of definitions offered by Omni and by the district court, and it is my opinion that the prior art discloses "one or more lenses" regardless of which definition is used.

65. I understand that for the purposes of this proceeding, Apple is adopting the district court's preliminary construction of the term "*modulating at least one of the LEDs*" to mean varying the amplitude, frequency, or phase of the light produced by at least one of the LEDs to include information. This

construction follows from the statement from the ’286 patent, that beams “may be modulated or unmodulated, *which also means that they may or may not contain information*.” Ex.1001, 10:17-19 (emphasis added). I understand that Apple has urged the district court to revise its preliminary construction to delete “amplitude” because the specification and claims distinguish modulating from varying the amplitude of the signal. For the purposes of this IPR, whether “amplitude” is included in the construction of modulating is irrelevant to my opinions as the prior art I have analyzed renders the claims unpatentable under both Apple’s and the district court’s preliminary constructions.

66. For the purposes of this IPR, I have assumed that “*modulating at least one of the LEDs*” as used in the asserted claims would mean varying the amplitude, frequency, or phase of the light produced by at least one of the LEDs to include information. This is the definition I use in this declaration when comparing the prior art to the claims. I have also considered the prior art in light of definitions offered by Omni and by Apple, and it is my opinion that the prior art discloses “*modulating of at least one of the LEDs*” regardless of which definition is used.

VI. IDENTIFICATION OF THE PRIOR ART

67. ***Exhibit 1011 (Lisogurski)*** is a copy of U.S. Patent No. 9,241,676, titled “Methods and Systems for Power Optimization in a Medical Device.”

Lisogurski was filed on May 31, 2012 and issued on January 26, 2016. I understand it is prior art to the challenged claims.

68. ***Exhibit 1009 (Carlson)*** is a copy of U.S. Patent Pub. 2005/0049468, titled "Increasing the Performance of an Optical Pulsoximeter." Carlson was published on March 3, 2005. I understand it is prior art to the challenged claims.

69. ***Exhibit 1014 (Rulkov)*** is a copy of U.S. Patent No. 8,172,761, titled "Monitoring Device with an Accelerometer, Method and System." Rulkov was filed on October 4, 2011 and issued on May 8, 2012. I understand it is prior art to the challenged claims.

70. ***Exhibit 1008 (Mannheimer)*** is a copy of U.S. Patent No. 5,746,206, titled "Isolated Layer Pulse Oximetry." Mannheimer was filed on June 10, 1996 and issued on May 5, 1998. I understand it is prior art to the challenged claims.

71. ***Exhibit 1007 (Hanna)*** is a copy of U.S. Patent 6,505,133 titled "Simultaneous Signal Attenuation Measurements Utilizing Code Division Multiplexing." Hanna was filed on November 5, 2000 and issued on January 7, 2003. I understand it is prior art to the challenged claims.

VII. ANALYSIS OF THE PRIOR ART AND '286 CLAIMS

A. Lisogurski Describes the Elements of Claims 16, 17, and 19-20 of

the ’286 Patent

1. Overview of Lisogurski

72. Lisogurski describes a portable physiological monitoring system that uses an optical sensor to measure a person’s pulse rate and oxygen saturation. Ex.1011 (Lisogurski) at 3:66-4:5. The system includes a sensor, a monitor, and remote devices such as a server. Ex.1011 (Lisogurski) at 11:28-32, 15:43-48.

73. Lisogurski explains that the sensor can be worn in various locations, such as on a fingertip, toe, forehead or earlobe, or in the case of a neonate, across a foot, Ex.1011 (Lisogurski) at 4:6-8, or also at the neck, wrist, ankle. Ex.1011 (Lisogurski) at 4:15-20. Lisogurski explains that some locations may be more suitable for pulse pressure measurement and others may be more suitable for oxygen saturation measurement. A person of ordinary skill in the art would understand that different body locations may require different form factors such as modifications to the size, geometrical arrange of components yet the principal of operation would remain the same. Locations that are typically exposed such as the face would require different mounting, structural and aesthetics consideration than a location that is typically covered. Different locations on the body experience different patterns and magnitudes of motion and would also require different amounts of noise rejection or motion rejection yet the principal of operation would remain the same.

74. The sensor can include several light emitting diodes (LEDs) and photodetectors. Ex.1011 (Lisogurski) at 17:37-45, 10:48-63, 11:9-13. A person of ordinary skill in the art would understand the value of include several emitters and detectors for creating redundancy and therefore being more tolerant to faults or unexpected use, improving signal-to-noise ratio (SNR). Making measurement at several wavelengths further enable the ability that can extract properties as a function of wavelength. One of the LEDs uses infrared light with a wavelength between 800 nm and 1000 nm. Ex.1011 (Lisogurski) at 10:52-58.

75. Lisogurski explains that the brightness of the LEDs can be varied. This variation can be achieved by turning the lights on and off, or by making the LEDs brighter and then less bright (e.g., by varying the amplitude of their power source or by varying the duty-cycle of the power source). Ex.1011 (Lisogurski) at 7:38-40, 8:27-45, 12:23-41. Lisogurski describes a light drive signal, which is the electric current provided to the LEDs that turns them on and determines their brightness. Ex.1011 (Lisogurski), 11:38-41, 11:50-54, 25:52-55. For a particular LED, the emitted light intensity increases as a higher current is applied.

76. The light is passed into a person's tissue, reflected by or transmitted through it, and then detected by a detector, which applies signal processing techniques to isolate the signal.

77. Lisogurski explains that the light drive parameters (*e.g.*, brightness, duty cycle, firing rate) can be varied to adapt to changes in the environment, which allows the signal-to-noise ratio of the device to be increased when interference is encountered. Ex.1011 (Lisogurski) at 5:55-61, 9:46-52, 27:44-49. For example, Lisogurski describes several modulation schemes that can be used to vary these parameters. Ex.1011 (Lisogurski) at 5:25-6:9.

78. A control algorithm may adjust drive signal brightness, to compensate for ambient light variation, every several seconds. Ex.1011 (Lisogurski) at 5:55-67. It may be beneficial to acquire more measurements in a period of time in order to implement an averaging scheme and to be less sensitive to high frequency motion artifact or changing ambient light, or to be more responsive if activity levels of the user increased.

79. The modulations of the light drive signal and the detector measurement sampling rate may be synchronized. The system may sample the received signal at a low rate during a period of low light output and at a high rate during a period of high light output or in a subset of this approach, may only sample when the light is high and not at all when low. Ex.1011 (Lisogurski) at 10:33-34.

2. Overview of Carlson

80. Carlson describes a wearable pulse oximeter that can be worn on parts of the human body, such as the ear, finger, or toe. Ex.1009 (Carlson), [0052], [0078]. The device uses a conventional sensor that emits optical wavelengths in the red (*e.g.*, 660 nm) and infrared (*e.g.*, 800 to 1000 nm) ranges and detects light that has been transmitted or reflected. Ex.1009 (Carlson), [0003], [0050], [0052]. The device is mobile and can wirelessly transmit data to a doctor or hospital. Ex.1009 (Carlson), [0072], [0077]-[0078].

81. Carlson notes that while sensors can be used in telemedicine, athletics, and other mobile applications, these standard sensors "suffer from signal instability and insufficient robustness versus environmental disturbances." Ex.1009 (Carlson), [0004]. Carlson states that it describes potential solutions to these issues, explaining various techniques for "increasing the technical performance of pulsoximetry in terms of quality and robustness of the measurement signal versus environmental disturbances and energy consumption." Ex.1009 (Carlson), [0002]. For example, Carlson describes techniques for increasing signal-to-noise ratio to account for environmental conditions, such as sunlight, shadow, artificial light, etc. Ex.1009 (Carlson), [0010].

3. A Person of Ordinary Skill in the Art Would Have Modified

Lisogurski to Incorporate Elements Shown in Carlson

82. A person of ordinary skill in the art would have considered making modifications to the systems described in Lisogurski based on Carlson.

83. Lisogurski describes a PPG system that is designed to optimize power consumption. Ex.1011 (Lisogurski) at 1:4-6, 3:50-53. Lisogurski's system allows "for increased battery life in portable systems or for increased portability." Ex.1011 (Lisogurski) at1:16-18. For example, Lisogurski explains that its techniques could improve oximeter systems by reducing power requirements, which would allow for smaller devices or longer life. Ex.1011 (Lisogurski) at 4:63-67. Lisogurski describes several techniques for increasing the signal-to-noise ratio of the signals measured by its devices while minimizing power consumptions. Ex.1011 (Lisogurski) at 9:46-52, 14:50-55, 37:8-11.

84. Based on my knowledge and experience, a person of ordinary skill in the art reading Lisogurski would have considered other references that explained techniques for improving the operation of portable optical sensing systems, particularly those with wearable sensors. Such a person would recognize that improvements to these systems involve trade-offs, such as adding a sensor component to improve detection could also increase the size of the device. It was part of the ordinary design process to characterize the positive and negative

attributes of the many ways to improve the operation of a device by comparing, and selecting or combining, different designs and techniques.

85. Based on my knowledge and experience, a person of ordinary skill in the art would have looked to Carlson, which is a reference that describes techniques for improving pulse oximetry devices by improving both signal measurement and energy consumption. Ex.1009 (Carlson), [0002]. These techniques include processes and structures for increasing the signal-to-noise ratio, even where optical conditions of the environment are changing. Ex.1009 (Carlson), [0010]. The techniques are energy efficient and can be used in devices that are battery-powered. Ex.1009 (Carlson), [0048]. Carlson explains that its techniques can be used in hospital devices used at and also mobile monitoring devices used in telemedicine. Ex.1009 (Carlson), [0004]. In addition, Carlson explains that the devices can be used to monitor athletes in sports applications. *Id*. Based on my knowledge and experience, it is my opinion that a person of ordinary skill in the art would have recognized the benefits described by Carlson, and would be motivated to include these same benefits in Lisogurski's system. The quality of measuring a physiological parameter derives ultimately from the quality of the signal being analyzed. Consistent with the general knowledge in the field, Carlson explains that noise such as that from ambient light diminishes that signal quality.

86. Lisogurski and Carlson are analogous references, both describing techniques for improving the power consumption of portable and wearable optical sensing devices, such as pulse oximeters. *See* Ex.1011 (Lisogurski) at 4:15-20, 17:51-58 (describing improvements in a system that includes a wearable sensor, *e.g.*, one worn on a wrist); Ex.1009 (Carlson), [0048], [0052] (describing devices that can be worn, for example, on an earlobe or finger). Both references describe techniques for improving the power consumption of portable, wireless, and wearable optical sensing devices, such as pulse oximeters, while improving their performance (e.g., signal-to-noise ratio) and utility. Based on my knowledge and experience, it is my opinion that a person of ordinary skill in the art would have considered the references together when implementing Lisogurski's system.

87. As I explained in § IV.B, above, by 2012, there was a general trend in the industry to create wearable devices, to allow the device to be used in mobile monitoring systems or to allow the device to be used for sports and personal fitness applications. Thus, a person of ordinary skill in the art would have had reason to look to analogous references to create wearable devices that performed better in mobile and consumer applications.

88. Therefore, a person of ordinary skill in the art would have been motivated to consider Lisogurski and Carlson together, and to include features

from Carlson in Lisogurski's system. I describe these features, and more specific reasons for integrating them into Lisogurski, in my analyses below.

4. Lisogurski and Carlson Describe the Elements of Claim 16

89. It is my opinion that Lisogurski in combination with Carlson renders claim 16 obvious. Claim 16 (Ex.1001) is reproduced below.

> 16. A wearable device for use with a smart phone or tablet, the wearable device comprising:
>
> a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters, the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths, wherein at least a portion of the plurality of optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;
>
> the measurement device comprising one or more lenses configured to receive and to deliver a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the optical beam delivered to the tissue, and wherein the measurement device is adapted to be placed on a wrist or an ear of a user;
>
> the measurement device further comprising a receiver configured to:
>
> capture light while the LEDs are off and convert the captured light into a first signal and
>
> capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue;

the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal;

the light source configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs;

the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue; and

wherein the receiver includes a plurality of spatially separated detectors, wherein at least one analog to digital converter is coupled to the spatially separated detectors.

a) Preamble

90. The preamble of claim 1 specifies "*[a] wearable device for use with a smart phone or tablet*." I understand that Apple is asserting that the preamble is not limiting, and that this means the prior art does not need to disclose the elements of the preamble for the claim to be unpatentable. However, if the claim preamble is found to be limiting, Lisogurski discloses or renders it obvious.

91. Lisogurski describes a sensor that may be worn on various portions of a person's body, including "a fingertip, toe, forehead or earlobe… additional suitable sensor locations include, without limitation…, the wrist to monitor radial artery pulsatile flow… and around or in front of the ear." Ex.1011 (Lisogurski), 4:6-20. The sensor is battery-powered and can communicate with the monitor over a wireless connection, which a person of ordinary skill in the art would understand

means that the sensor is wearable and separate from the monitor. Ex.1011 (Lisogurski), 17:55-59 ("Sensor unit 312 may be powered by an internal power source, e.g., a battery… [T]he sensor may be wirelessly connected to monitor 314."). For these reasons, the sensor is a "*wearable device*."

92. Lisogurski's sensor is designed to be used with a monitor 104 that includes back-end processing circuitry that is connected to both a user interface and a communication interface. The user interface may include "any type of user input device such as a keyboard, a mouse, a touch screen, buttons, switches, a microphone, a joy stick, a touch pad, or any other suitable input device." Ex.1011 (Lisogurski), 15:20-23; Fig. 1. The user interface also includes a display and a speaker. Ex.1011 (Lisogurski), 15:19-20, Fig 1. The communication interface that "may include one or more receivers [or] transmitters" each of which "may be configured to allow …wireless communication." Ex.1011 (Lisogurski), 15:49-56.

93. Monitor 104 also includes a display and user interface that allows a user to see the monitored person's physiological parameters and to configure the operation of the system. Ex.1011 (Lisogurski), 15:19-42. The display is a typical feature of such monitoring systems.

94. Lisogurski describes its monitor as a portable, battery powered computing system that includes a touchscreen. Ex.1011 (Lisogurski), 1:16-18 (portable), 15:20-23 (touch screen), 18:65-66 (battery powered). Based on my

knowledge and experience, a person of ordinary skill in the art would have understood that Lisogurski was describing devices such as tablets and smartphones, which as I explained above (§IV.B), were commonly used in monitoring systems at the time. Based on Lisogurski's disclosures, a person of ordinary skill in the art would have recognized that there were a finite number of options for what that monitor could be and would have immediately envisioned that the monitor could be a laptop, tablet computer, a smartphone, or other custom-made device. As I explained above in §IV.B, by 2012, tablets and smartphones were already being used in mobile sensor systems, and there was a general trend in the industry to develop devices that would interface with tablets and smartphones. A person of ordinary skill in the art would have considered Lisogurski to disclose a smartphone or tablet. And at the very least, the person of ordinary skill in the art would have found it obvious to implement Lisogurski's monitor as a tablet or smart phone.

b) "a measurement device…"

(i) "a measurement device…for measuring one or more physiological parameters…"

95. The sensor is part of a system for measuring physiological parameters. Ex.1011 (Lisogurski), 3:61-4:5, 4:22-25, 15:30-35. Lisogurski describes "an optical physiological monitoring system" that "may be used to determined physiological parameters such as blood oxygen saturation, hemoglobin, blood

pressure, pulse rate, other suitable parameters, or any combination thereof." Ex.1011 (Lisogurski), 1:10-25; *id.*, 3:43-46. Lisogurski describes a measurement device, for example, "a pulse oximeter… [that] may non-invasively measure the oxygen saturation of a patient's blood." Ex.1011 (Lisogurski), 3:61-4:3; *see id.*, Abstract, 3:43-46, 4:52-62, Figs. 1 & 3.

96. For the reasons stated above, the sensor is a "*measurement device…for measuring one or more physiological parameters*."

(ii) "a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) … the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths, wherein at least a portion of the plurality of wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers"

97. Lisogurski describes a wearable sensor that can include a light source comprising multiple LEDs. Ex.1011 (Lisogurski), 17:42-45 ("In an embodiment, sensor unit 312 may include multiple light sources and detectors."), 10:48-49, 10:58-64 ("light source 130 may include any number of light sources with any suitable characteristics"); Figs. 1 (130) & Fig. 3 (316).

98. The sensor can include multiple LEDs ("*a plurality of … light emitting diodes*"), each configured to output a different optical wavelength. Ex.1011 (Lisogurski), 7:38-8:3 ("For example, in a system with two light

sources…the first light source may be a high efficiency infrared (IR) LED while the one or more additional light sources may be lower efficiency red LEDs.”).

99. The light drive parameters of each of the LEDs may be varied, such as through periodic or aperiodic modulation. *E.g.*, Ex.1011 (Lisogurski), 7:38-40 (“the system may modulate multiple light sources using a plurality of modulation techniques”), 5:2-7, 5:25-47; 5:48-61, 6:31-38, 8:16-44. Lisogurski explains that the LEDs have an initial brightness level (“*an initial light intensity*”), but the system may adjust that level for various reasons. Ex.1011 (Lisogurski), 5:67-6:6 (“In response to a signal with high amplitudes, ***the system may reduce emitter brightness***. In a further example, the quality of a low amplitude signal may be degraded by quantization noise by an analog to digital converter. In response, ***the system may increase the emitter brightness***.”) (emphases added).

100. The LEDs “emit photonic signals having one or more wavelengths of light (e.g., Red and IR)” (“*an optical beam having one or more wavelengths*”). Ex.1011 (Lisogurski), 10:49-52; *see id.*, 4:42-45. “[T]he IR wavelength may be between about 800 nm and about 1000 nm” (“*at least a portion of the one or more wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers*”). Ex.1011 (Lisogurski), 10:56-58. The light source may include any number of LEDs, such as multiple IR LEDs and multiple red LEDs. Ex.1011, 10:58-63, 17:37-45, 19:25-31 (“In some embodiments, the light source may

include LEDs of multiple wavelengths, for example, a red LED and an IR led. In some embodiments, the light source may include multiple LEDs of the same wavelength, multiple LEDs of different wavelengths, any other suitable arrangement, or any combination thereof.”). The system is designed so that these photonic signals are sent “into a subject’s tissue,” (*id.*, 10:49-52), which means the LEDs emit light “transmitted to a particular location in space” as required by the claimed “*beam.*”

101. Lisogurski explains that light drive circuitry controls the modulation of the LEDs, and can alter light drive parameters, such as “drive current or light brightness, duty cycle, [and] ***firing rate***” amongst others. Ex.1011 (Lisogurski), 27:44-52; *id.*, 2:1-2 (“light source firing rate”), 8:29-35, 25:49-55. Lisogurski explains that the frequency (firing rate) of the LEDs can change over time. The firing rate of an LED can be correlated to the sampling rate of an analog-to-digital converter in the detector. Ex.1011 (Lisogurski), 33:47-49 (“In some embodiments, sampling rate modulation may be correlated with light drive signal modulation.”), *see also id.*, 11:43-46; 11:52-55. Lisogurski explains “[f]or example, the time between ‘on’ periods [for an LED] may be the length of time of ‘off’ period 220 of FIG. 2A… [D]ecreasing the duration of the ‘off’ periods (i.e., ***increasing the emitter firing rate***) relates to an increased sampling rate.” Ex.1011 (Lisogurski), 35:27-31 (emphasis added). Thus, Lisogurski explains that as the sample rate

increases, the firing rate of the LED also increases. Therefore, Lisogurski can change the modulation frequency of the LEDs as specified by Apple's proposed construction of "*modulation*."

102. A skilled artisan also would have read Lisogurski as describing use of a beam that includes information as specified by the district court's preliminary construction. Lisogurski explains that its system can use a variety of modulation schemes, including for example, drive cycle modulation and cardiac cycle modulation. Ex.1011 (Lisogurski), 5:25-6:6.

103. Lisogurski explains that its "system may ***modulate*** multiple light sources using ***a plurality of modulation techniques***," and throughout the patent it identifies examples of several such techniques. Ex.1011, 7:38-40. Lisogurski states these techniques include frequency division multiplexing, time division multiplexing, and code division multiplexing (CDM), amongst others. Ex.1011, 6:19-24. I described these techniques in the background section, above. In CDM, each channel has a unique code and that code is embedded into the signal for that channel. For example, each IR and red LED might be identified using its own code, and this can be used on the receiver side to apportion the signal attributable to each channel. The person of ordinary skill in the art would have understood that use of CDM in Lisogurski would have embedded information in the signal in the

form of a unique code for each LED or channel of light. Therefore, Lisogurski meets the district court's preliminary construction of "*modulation*."

104. A beam can either contain information or not contain information, as the '286 patent recognizes. Ex.1001, 10:17-19 (beams "may be modulated or unmodulated, which also means that they may or may not contain information"). A person of ordinary skill in the art would recognize that Lisogurski's use of the term "modulation" describes that beams of light are altered to include information or not. Ex. 1011 (Lisogurski), Fig. 4 (step 406), 19:65-20:38. The above identified paragraphs also provide support for this limitation based on Omni's proposed definition of modulating, as "pulsing the light, or varying the frequency of the light, produced by at least one of the LEDs," and based on Apple's originally proposed definition of modulating, as "varying the frequency of the light produced by at least one of the LEDs."

105. To the extent that one argues Lisogurski does not teach that its LEDs are modulated to contain information, a person of ordinary skill in the art would have read Lisogurski to teach this limitation. Specifically, and based on my knowledge and experience, a skilled artisan would have read Lisogurski as describing use of a beam that includes information, and would also have considered it obvious to use a beam of light that is modulated to include information. A beam can either contain information or not contain information, as

the ’286 patent recognizes. Ex.1001, 10:17-19 (beams “may be modulated or unmodulated, which also means that they may or may not contain information.”). Based on my knowledge and experience, a person having ordinary skill in the art would recognize that this was a well-understood technical fact. That person of ordinary skill in the art would have understood that a modulated beam as described by Lisogurski would have encompassed beams that are comprised of modulated light to include information and beams that are not.

106. Based on my knowledge and experience, it is my opinion that a person having ordinary skill in the art would have selected between these known options based on the desired application. That person of ordinary skill in the art would recognize that Lisogurski’s use of the term “modulation” describes that beams of light are altered to include information or not. There are many applications for, and many reasons why, a person of ordinary skill in the art would have used a beam that was modulated to include information in the context of the Lisogurski device. The beam of light could be uniquely modulated, containing the information required to make it easily detected via demodulation.

107. Based on my knowledge and experience, a person of ordinary skill in the art would modulate a beam of light to uniquely to embed identification information to enable a detector to identify the number of sources or source identity of received light. Ex. 1048 (Fein), 4:44-55 (encoding LED pulses to

information related to "the brand or type of sensor being used… [or] the wavelength of a second LED."); *id.*, 4:61-64 (encoding LED pulses with a "digital code" to represent the number of LEDs to allow the device to "select an appropriate strategy for operating the LEDs and interpreting the light pulses seen by the detector."). This technique would be particularly useful when used in a device with multiple emitters located at different distances from the detector, such as the devices described in Lisogurski, (Ex. 1011, 17:43-45), or for simultaneous measurements at many wavelengths as achieved by modulating different pairs of sources at different frequencies - frequency division multiplexing (FDM). Ex. 1049 (Trebino), 9:4-8 ("Each pair [of LEDs] is modulated at a respective one of N fundamental frequencies…This is a type of frequency division multiplexing and achieves simultaneous measurement at all wavelengths."). Within a single device, the light could be modulated with identifying information keyed to the measurement of different physiological parameters, such as attenuation properties (e.g., modulated with code division multiplexing (CDM)). Ex. 1007 (Hanna), 2:26-29 ("The invention allows for analysis of a multiplexed signal to distinguish between two or more signal components thereof based on codes modulated into the signal components" sent by LEDs).

108. Similarly, and based on my knowledge and experience, a person of ordinary skill in the art would be motivated to encode a unique identifier in the

modulate light keyed to the person or to the serial number of the device, to enable unique identification by the receiver in order to reduce the risks for device tampering. Also, such a person would be motivated to modulate a signal with encryption information for security purposes.

109. As another reason, a person of ordinary skill in the art would recognize that the signal also could be modulated to contain information about the operational characteristics of the LED, such as a number representing the expected intensity of the LED, which would allow the detector to determine if the LED is operating properly. Ex. 1048 (Fein), 4:52:-55 ("The additional [encoded] information provided…could improve the accuracy of calibration coefficients determined by the oximeter, because more information about the sensor would be known to the oximeter.").

110. Based on my knowledge and experience, a person of ordinary skill in the art would have been motivated to implement any one of these techniques in order to improve the performance of the Lisogurski device. This is consistent with the described goal of Lisogurski to "enable[e] high quality physiological parameters to be determined." Ex. 1011, 3:50-53. Modulating a signal to include information for the reasons described above would have been one way to improve and enhance the performance of the Lisogurski device. It would also have

provided a way to determine if the sensor is operating properly, as one way to ensure that it produces more accurate data.

111. Based on my knowledge and experience, using the modulation techniques described by Lisorgurski (disclosing that modulation may be implemented using "time division multiplexing…, code division multiplexing, carrier frequency division multiplexing, phase division multiplexing…") (Ex. 1011, 6:19-24) to include any of these types of information would have been well within the capabilities of a person of ordinary skill in the art in 2012-2013 time frame. Indeed, modulating a beam to contain information when so desired is a conventional technique that has been used for decades in any number of contexts, such as fiber optic communications to naval vessel communication using signal lamps. A person of ordinary skill in the art would have expected that such an alteration to the Lisogurski device would result in conveying the desired information in the ways described above.

112. Nothing in the prosecution history or '286 Patent explains why modulating a beam to carry information has any significance to patentability of the claimed invention. The Patentee did not argue in any response that modulating a beam was a distinction over the prior art, let alone use it to obtain allowance of the claims. Likewise, a person of ordinary skill in the art would recognize that the '286 Patent does not identify any benefit of using modulated light to convey

information, nor does it describe the nature of information to be conveyed or a reason for doing so.

c) "the measurement device comprising…"

(i) "one or more lenses configured to receive and to deliver a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the optical beam delivered to the tissue"

113. Lisogurski uses red and infrared LEDs to emit an optical beam. Ex.1011 (Lisogurski), 10:53-56, 7:38-8:3. Although Lisogurski does not explicitly describe using a lens, the person of ordinary skill in the art would have understood that Lisogurski likely would use a lens with each LED, or at least it would have been obvious to do so.

114. Based on my knowledge and experience, it was well-known to those in the art that a conventional LED package includes a light emitting semiconductor, such as a semiconducting material doped with impurities to create a p-n junction, that creates the light. That semiconductor typically is encapsulated in glass or another medium which is called an encapsulant. The encapsulant can serve several purposes. One is that it protects the semiconductor from the environment (*e.g.*, moisture, dust). But another common purpose of the encapsulant is to act as a lens. The encapsulant typically is shaped to focus the light emitted by the LED. In the 2012 time frame, the vast majority of commercially available LEDs were designed this way.

115. A person of ordinary skill in the art would have understood that there were three types of LEDs: (i) LEDs with no encapsulant, (ii) LEDs with an optically inert encapsulant, and (iii) LEDs with an encapsulant that acts as a lens. *See generally* Ex. 1035 (Light Emitting Diodes), 97-98, 191-99, 266-67. A lens that is part of the LED package is called a primary optic.

116. A person of ordinary skill in the art designing a system based on Lisogurski would have recognized that Lisogurski was describing a device that would benefit from selecting an LED that uses an encapsulant that functions as a lens, as this was a common configuration at the time. Even if Lisogurski did not explicitly or implicitly describe an LED that included a lens, it would have been obvious to select one. The lens on the LED can be used to direct all of the emitted light at an angle closer to perpendicular to the chip or substrate. For example, instead of emitting light 180°, light might be emitted over a 90° or 120° range. Using a lens would increase the amount of light that is directed toward the sample or person by directing more of the LED's light outward toward the tissue. Using a lens is a standard way to increase the directional intensity of, in a reduced solid angle from, the LED without using more power. Conserving power is particularly important for mobile, battery-powered, wireless devices, which have limited power compared to stationary devices that are powered by, for example, wall outlets.

117. Where Lisogurki is implemented using LEDs with lenses, Lisogurski meets this claim element. Each of Lisogurski's LEDs would emit a portion of an "*optical beam*," which would be captured by the encapsulant lens ("*one or more lenses*") on that LED and focused on the tissue.

118. LEDs also can be used with lens that are separate from the LED packaging. These are called secondary optics. As I explained in the background section above, it was well-known in the art that a lens is a "basic building block" of an optical sensor (Ex.1019 (Biomedical Engineering Handbook), 765) and that lenses commonly were part of optical sensors.

119. To the extent one argues Lisogurski's LEDs do not suggest the use of lenses ("transparent surfaces used to collimate (make parallel) or focus rays of light" per Apple's construction or within that term's ordinary meaning as proposed by Omni), using a lens for each LED would have been obvious based on a the knowledge of a person of ordinary skill in the art. Using a lens to focus light was a well-known technique that has been around for a long time, is a central tool for most optical and optical measurement systems, and is done in most optical and optical measurement systems. Based on my knowledge and experience, a skilled artisan would recognize that a lens would collimate or focus light is the same concept that eye-glasses use to correct a person's vision. That person would recognize that the lens in glasses collimates or focuses light. Accordingly, that

skilled artisan would further understand that it would be obvious to use a lens with an LED to focus the light in a way that improves detection.

120. Even if Lisogurski itself does not render the use of one or more lenses obvious, the combination of Lisogurski and Carlson does.

121. Carlson discloses using "at least one beam shaping optical element to direct the emitted light" towards a sample. Ex.1009 (Carlson) [0013]. The beam shaping element can be "diffractive or refractive lenses, to direct the emitted optical radiation of, e.g., the LED light source into the human or animal tissue …." Ex.1009 (Carlson), [0013], [0014], [0024], [0062]. A "refractive lens" is one that focuses rays of light, and as described in Carlson, this lens would be a transparent surface that focuses or collimates rays of light. Put another way, a refractive lens focuses rays of light thereby meeting Apple's construction of "*lens*." Figure 4 shows two lenses 21 receiving light beams 8 emitted by LEDs 15 ("*a portion of the optical beam*") and delivering light bundles or beams 12 to sample 2 ("*deliver an output beam to tissue*"). Ex.1009 (Carlson), [0054], [0062].

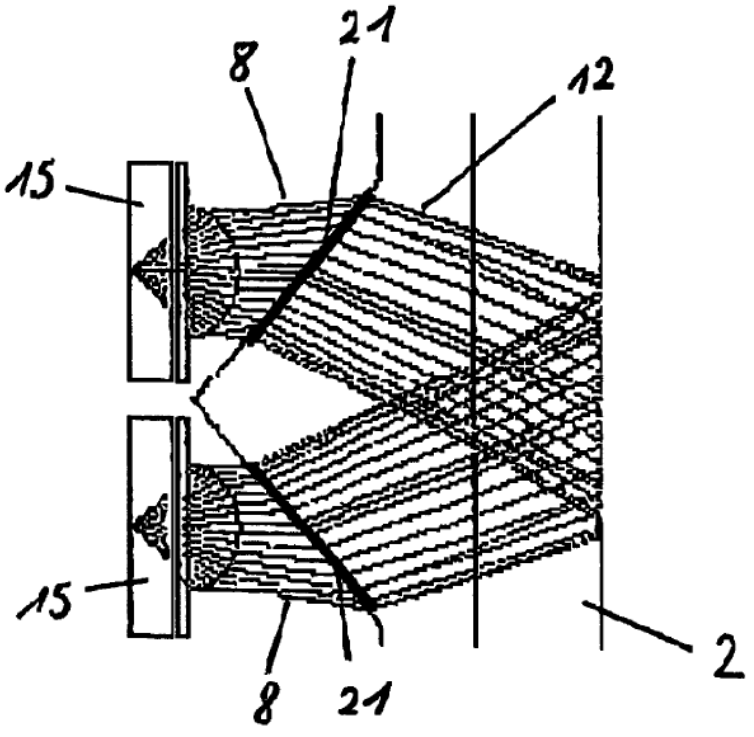


Figure 4

Ex.1009 (Carlson), Fig.4, [0054] ("in Fig. 4, using the beam shaping optics 21, the two initial light beams 8 are guided in the form of bundled beams 12"). As shown in the figure, the rays of light out of each lens are substantially parallel. By doing so, the lens direct the light in way that "collimates (makes parallel) rays of light," which meets Apple's construction of the term "*one or more lenses*." And as shown in the figure, the light within each beam is "transmitted to a particular location in space" (the person's skin and tissue) and meets the construction of "beam."

122. In addition, the LEDs emit light via the lens that is "transmitted to a particular location in space" as required by the claim term "beam." Specifically, the lens help "guide" light to a particular location by making the rays substantially

parallel. *Id.*, [0054]. Accordingly, and based on my knowledge and experience, a skilled artisan would recognize that Carlson's lenses guide the light within each beam is "transmitted to a particular location in space" and meets Apple's construction of the term "*beam*."

123. It would have been obvious to include these lenses in Lisogurski's sensor to focus the light emitted by the LEDs onto a person's skin as described by Carlson. Carlson itself explains that it is beneficial to include lens in optical sensors to increase the optical signal power without increasing the actual power used by the system and that the lens focuses light on (delivers light to) the tissue. Ex.1009 (Carlson), [0014] ("The basic idea… is to use ***a beam-shaping element, such as e.g., … lenses***…, in order to increase the optical signal power…, thus increasing the Signal/Noise … ratio."), [0010] (emphasis added). A person of ordinary skill in the art would have been motivated to include lenses in Lisogurski because Lisogurski is directed to a system for improving the power consumption of optical sensing devices and that includes techniques for improving the signal-to-noise ratio of the measured optical signal. Ex.1011 (Lisogurski), 6:3-6, 9:49-60, 13:60-14:10, 14:40-55, 37:6-20. Adding lenses to Lisogurski would further its own goals and improve its operation.

124. A person of ordinary skill in the art would have recognized that adding lenses to Lisogurski would complement its operation. It was well-known

that lenses are one of the "basic building blocks" of optical sensors, (Ex.1019 (Biomedical Engineering Handbook), 765), and that incorporating lenses into Lisogurski's sensor was a predictable arrangement of known elements, with each performing the same function it was known to perform and yielding what one would expect from the arrangement.

125. For all of these reasons, Lisogurski and Carlson render obvious "*one or more lenses configured to receive and to deliver a portion of the optical beam to tissue*."

126. The tissue reflects at least a portion of the light emitted from the LED back to a photodetector. Lisogurski's detectors receive "the light that is reflected by or has traveled through the subject's tissue." Ex.1011 (Lisogurski), 17:40-42, 11:12-20 ("In operation, ***light may enter detector 140 after passing through the subject's tissue***. Detector 140 may convert the intensity of the received light into an electrical signal. ***The light intensity may be directly related to the*** absorbance and/or ***reflectance of light in the tissue***. That is, when more light at a certain wavelength is absorbed or reflected, less light of that wavelength is received from the tissue by detector 140.") (emphases added). For these reasons, Lisogurski discloses that "*the tissue reflects at least a portion of the optical beam delivered to the tissue*."

(ii) "wherein the measurement device is adapted to be placed on a wrist or an ear of a user"

127. Lisogurski explains that its sensor may be worn on a person's body, including "the wrist to monitor radial artery pulsatile flow . . . and around or in front of the ear." Ex.1011 (Lisogurski), 4:6-20. Accordingly, Lisogurski discloses "*wherein the measurement device is adapted to be placed on a wrist or an ear of a user*."

d) "the measurement device further comprising a receiver configured to:"

128. Lisogurski's sensor includes "[o]ne or more detector 318… for detecting the light that is reflected by or has traveled through the subject's tissue." Ex.1011 (Lisogurski), 17:40-42, *see also id.*, 11:9-10, 17:43-45; Fig. 1; Fig. 3. Each detector "convert[s] the intensity of the received light into an electrical signal." Ex.1011 (Lisogurski), 11:14-16; 11:20-22, Figs. 1, 3.

129. Lisogurski's detectors are connected to front-end processing circuitry (together, "*a receiver*"), which "may receive a detection signal from detector 140 and provide one or more processed signals to back-end processing circuitry 170." Ex.1011 (Lisogurski), 12:42-44, Fig. 1 (150). The detectors generate electrical signals that are received by the front-end processing circuitry, and those signals are passed between the components of the circuitry. Ex.1011 (Lisogurski), 13:6-60.

130. The relevant components are depicted in the below annotated Figure 1 of Lisogurski:

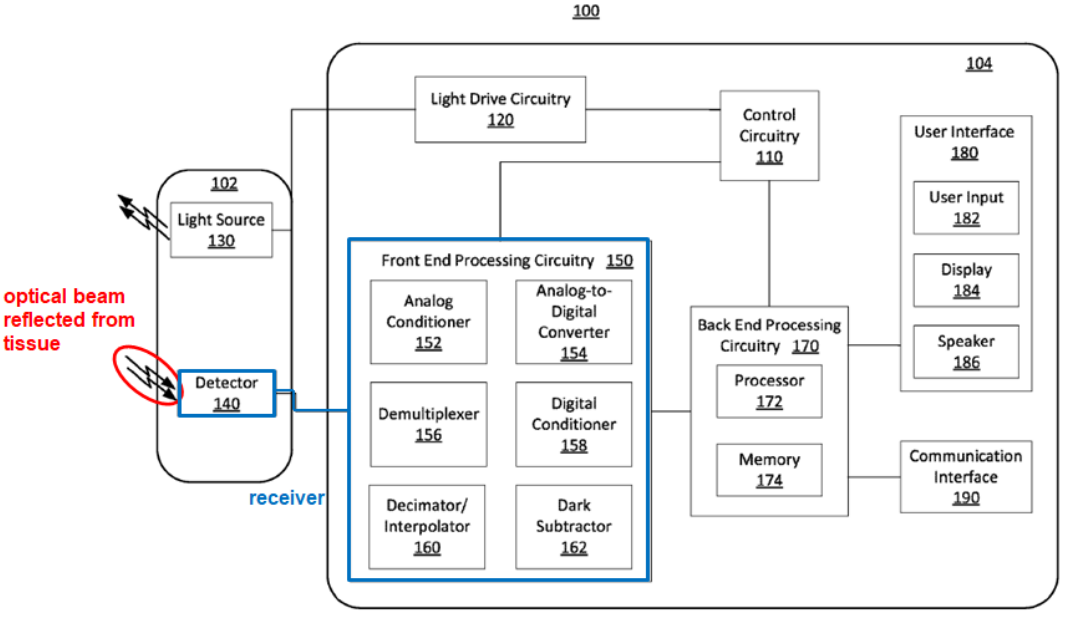


FIG. 1

131. I understand that Patent Owner may argue that Lisogurski does not describe this claim element because the front-end processing circuitry is depicted in monitor 104 which is separate from wearable sensor 102 that contains the detector. Even if that were required, it would have been obvious to include the front-end processing circuitry and detector in Lisogurski's wearable sensor.

132. It would have been obvious to a person of ordinary skill in the art to implement the front-end processing circuitry and detector in the same device. Lisogurski's sensor can "preprocess" the electrical signal before transmitting the signal to the monitor. Ex.1011 (Lisogurski), 11:20-27. The sensor may be a separate device that is wirelessly connected to the monitor. Ex.1011 (Lisogurski), 17:55-59 ("Sensor unit 312 may be powered by an internal power source, e.g., a battery (not shown)…. [T]he sensor may be wirelessly connected to monitor 314

(not shown)."), 18:23-25, *see also id.*, 18:16-31. Based on these disclosures, a person of ordinary skill in the art at the very least would have found it obvious to configure the system this way even though this wireless embodiment is not explicitly depicted in Lisogurski's figures.

133. It would have been obvious to a person of ordinary skill in the art to include the front-end processing circuitry in the sensor so that the sensor could process the detected signal before wirelessly transmitting it to the monitor. A person of ordinary skill in the art would have known that in order for information contained in the analog signal output from the detector to be wirelessly transmitted effectively, it would have to be converted to digital form. The analog-to-digital conversion (and other processing) is performed by the front-end processing circuitry. The person of ordinary skill in the art would have understood that measurement accuracy would be improved by performing the analog-to-digital conversion prior to wireless transmission, and by being able to tune the measurement process by, for example, adjusting any gain values. Accordingly, it would have been obvious to include the front-end processing circuitry in the sensor. Adding the front-end processing circuitry to the sensor would not have affected the operation of the device because the necessary circuitry is small and power efficient, and could easily be integrated into the wearable sensor.

134. Integrating the detector and front-end processing circuitry into the same device is consistent with Lisogurski's explanation that "[i]n some embodiments the functionality of some of the components may be combined in a single component… [or] the functionality of some of the components of monitor 104… may be divided over multiple components." Ex.1011 (Lisogurski), 16:2-9.

135. This also is consistent with general trends in the industry. As I explained in § IV.B, above, by 2012, there was a general trend in the industry to include additional features in wearable devices to improve those device's operation in mobile monitoring systems or for sports and personal fitness applications.

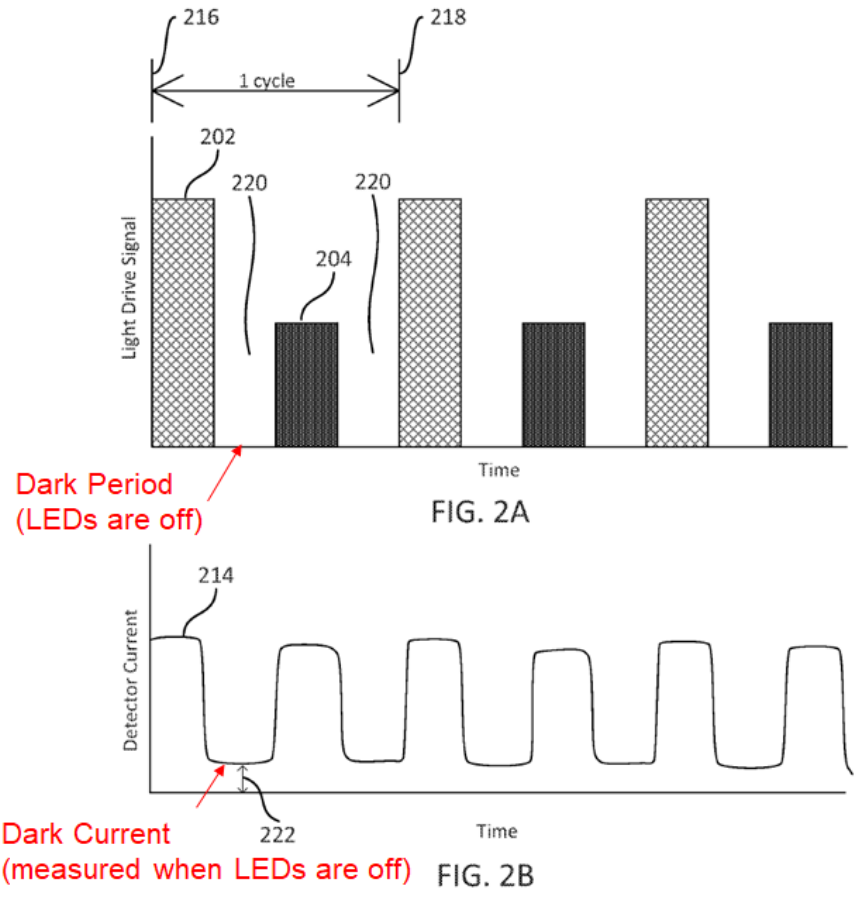
(i) "capture light while the LEDs are off and convert the captured light into a first signal"

136. Lisogurski describes a technique for "remov[ing] ambient and background signals" "in addition to or in place of a power saving light modulation scheme." Ex.1011 (Lisogurski), 6:7-10. This technique is called dark subtraction. Ex.1011 (Lisogurski), 13:60, *see generally*, Ex.1011 (Lisogurski), 6:7-19, 13:60-14:10, 16:33-54 (describing dark signal subtraction process). The detectors are used to measure the light when the LEDs are on and when they are off to remove "dark current" or ambient light from the signal. Ex.1011 (Lisogurski), 12:59-13:6 ("The peaks of detector current waveform 214 may be synchronous with light 'on' periods… The valleys of detector current waveform 214 may be synchronous with periods of time during which no light is being emitted by the light source… Since

dark current 222 may interfere with accurate determinations of physiological characteristics, dark current 222 may be removed as discussed in more detail below.”).

137. When the LEDs are modulated, “the system [may] turn[] on a first light source, followed by a ‘dark’ period, followed by turning on a second light source, followed by a ‘dark’ period.” Ex.1011 (Lisogurski), 6:12-15. “The system may measure the ambient light detected by the detector during the ‘dark’ period and then subtract this ambient contribution from the signals received during the first and second ‘on’ periods.” Ex.1011 (Lisogurski), 6:16-19.

138. The detectors and front-end processing circuitry measure the light received by the detectors while the LEDs are off—“dark signal”—by “determining the amount of dark signal during [each] ‘off’ period 220.” Ex.1011 (Lisogurski), 13:67-14:6. To determine the dark signal, each detector “converts the intensity of the received light into an electrical signal.” Ex.1011 (Lisogurski), 11:14-16;, 13:35-41. Figure 2A of Lisogurski depicts the amount of current used to illuminate the LEDs over time. Figure 2B of Lisogurski depicts the amount of current output by the detector over time. Annotated Figures 2A and 2B below depict that dark signal 222 (also called dark current 222) is measured during dark period 220:



Ex.1011 (Lisogurski), Figs. 2A, 2B, 12:64-13:6; *see id.*, 13:67-14:6 ("in reference to FIG. 2A, a detection signal peak corresponding to red 'on' period 202 may be adjusted by determining the amount of dark signal during the 'off' period 220 preceding red 'on' period 202").

139. The front-end processing circuitry uses the current measured when the LEDs are off to generate a "dark signal." Ex.1011 (Lisogurski), 13:35-41 ("Demultiplexer 156 may operate on detector current waveform 214 of FIG. 2B to generate… a ***first dark signal*** (e.g., corresponding to the dark component that occurs immediately after the Red component), and ***a second dark signal*** (e.g.,

corresponding to the dark component that occurs immediately after the IR component).”).

140. Accordingly, Lisogurski’s detectors capture light during a dark period (“*while the LEDs are off*”) and to convert that to a dark signal (“*first signal*”).

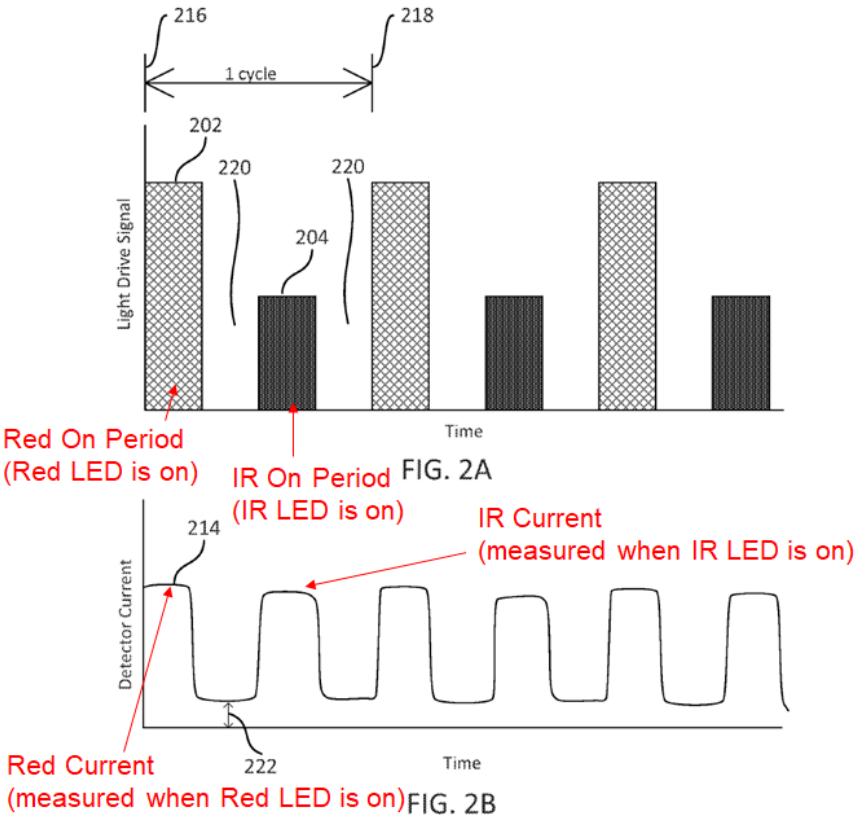
(ii) “capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the input optical beam reflected from the tissue”

141. In Lisogurski’s dark signal subtraction process, the detectors and front-end processing circuitry also measure the detected light while at least one LED is on: “The system [may] turn[] on a first light source, followed by a ‘dark’ period, followed by a second light source, followed by a ‘dark’ period.” Ex.1011 (Lisogurski), 6:12-15. Lisogurski’s system then subtracts the signals received during the dark period from the signals received when the LEDs are on. Ex.1011 (Lisogurski), 6:16-19 (“The system may measure the ambient light detected by the detector during the ‘dark’ period and then subtract this ambient contribution from the signals received during the first and second ‘on’ periods.”).

142. The light received by the detectors includes “the light that is reflected by or has traveled through the subject’s tissue.” Ex.1011 (Lisogurski), 17:40-42; 11:12-20 (“In operation, light may enter detector 140 after passing through the subject's tissue. Detector 140 may convert the intensity of the received light into an electrical signal. ***The light intensity may be directly related to the*** absorbance

and/or ***reflectance of light in the tissue***. That is, when more light at a certain wavelength is absorbed or reflected, less light of that wavelength is received from the tissue by detector 140.") (emphasis added). This includes the IR light ("*optical beam*") emitted by the LEDs. Ex.1011 (Lisogurski), 13:67-14:2 ("a detection signal peak corresponding to red 'on' period 202"), 17:8-10 ("the levels received during… IR 'on' period 278."), 13:35-41.

143. As depicted in annotated Figures 2A and 2B below, Lisogurski's system measures a red signal, Ex.1011 (Lisogurski), 13:67-14:2 ("a detection signal peak corresponding to red 'on' period 202") and an IR signal, Ex.1011 (Lisogurski), 17:8-10 ("the levels received during… IR 'on' period 278."), 11:14-16 (each detector "converts the intensity of the received light into an electrical signal"), 13:35-41 ("Demultiplexer 156 may operate on detector current waveform 214 of FIG. 2B to generate ***a Red signal*** [and] ***an IR signal***…") (emphasis added).



Ex.1011 (Lisogurski), Figs. 2A & 2B, 12:52-13:6. Thus, Lisogurski's detectors capture light when the IR LED(s) is on ("*while at least one of the LEDs is on*") and convert that to an electrical signal ("*second signal*").

e) "the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal"

144. As explained above, Lisogurski's "[d]ark subtractor 162 may operate on the digital signal." Ex.1011 (Lisogurski), 13:60, 11:43-46, 33:65-34:13, *id.*, 13:35-41. Thus, the analog-to-digital converter converts the dark signal and the IR signal into digital form before the dark subtractor operates on the signals.

145. The ambient light in the dark signal is noise. Ex.1011 (Lisogurski), 14:46-55 (discussing "ambient light noise" in the analog signals). Thus, the dark signal subtractor subtracts the digital dark signal from the digital IR signal to generate an "adjusted… IR signal[]" (an "*output signal*"):

> [D]ark subtractor 162 may subtract dark values from the Red and IR components to generate adjusted Red and IR signals. For example, dark subtractor 162 may determine a subtraction amount from the dark signal portion of the detection signal and subtract it from the peak portion of the detection signal in order to reduce the effect of the dark signal on the peak. For example, in reference to FIG. 2A, a detection signal peak corresponding to red "on" period 202 may be adjusted by determining the amount of dark signal during the "off" period 220 preceding red "on" period 202. The dark signal amount determined in this manner may be subtracted from the detector peak corresponding to red "on" period 202.

Ex.1011 (Lisogurski), 13:60-14:10, 16:51-54 ("The system may subtract the background or dark level from the levels received during red 'on' portion 274 and IR 'on' period 278."). Accordingly, Lisogurski discloses subtracting ("*differencing*") the dark signal ("*first signal*") from the IR signal ("*second signal*"). As I explained above in §VII.A.4.d.ii, the IR signal "*includ[es] at least a portion of the optical beam reflected from the tissue*."

146. The signal-to-noise ratio is calculated by dividing the signal power by the noise power: $\frac{S}{N}$. Decreasing the noise necessarily increases the signal-to-noise

ratio. Thus, by removing noise (ambient light) from the light signal, the dark signal subtraction process increases the signal-to-noise ratio.

f) "the light source configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs"

147. Lisogurski explains that the light source is in the wearable sensor 102. Ex.1011 (Lisogurski), 10:48-49. The circuitry may alter the light drive parameters of the LEDs in response to "the level of noise, ambient light, [or] other suitable reasons," and "increas[ing] the brightness of the light sources in response to [increased level of background] noise to improve the signal-to-noise ratio." Ex.1011 (Lisogurski), 9:46-52, *id.*, 5:55-6:6 (discussing modulation techniques and "conventional servo algorithms" for adjusting the signals emitted by the LEDs), 1:67-2:3.

148. The changes in the light drive parameters can be made to mitigate the effects of noise and changes from motion, or ambient light, for example, to thereby increase the signal-to-noise ratio. Conventional feedback control, or servo, algorithms would adjust the light drive signals due to, for example, ambient light changes, sensor positioning, and other sources external to the body variation. Conventional feedback control approaches would vary parameters at a slower rate than cardiac cycle modulation. A conventional feedback control, or servo,

algorithm may adjust drive signal brightness, to compensate for ambient light variation, every several seconds. Cardiac cycle modulation schemes would adjust the brightness of a light in a way that is synchronized to the cardiac cycle and similar to or faster than the cardiac pulse rate. The cardiac cycle modulation techniques may depend on the desired physiological parameter or unique characteristics of the individual's cardiac pulse patterns. Ex.1011 (Lisogurski), 5:59; 9:46-52, 9:57-60, 14:49-55.

149. The signal modulation techniques are controlled by control circuitry and light drive circuitry, which generate a light drive signal for activating and controlling the sensor's light sources. Ex.1011 (Lisogurski), 1:44-46, 11:38-41, 11:50-54. Light drive signal "[p]arameters that may be varied include light intensity, firing rate, duty cycle, other suitable parameters, or any combination thereof." Ex.1011 (Lisogurski), 1:19-21. These parameters correspond to instantaneous brightness (light intensity), frequency (firing rate), and pulse width which is the duration of each pulse of light (duty cycle).

150. Lisogurski explains that the signal-to-noise ratio can be increased by varying the modulation of the light source.

> In some embodiments, ***the system may alter the cardiac cycle modulation technique based on the level of noise, ambient light, other suitable reasons***, or any combination thereof. The system may receive, for example, an increased level of background noise in the

> signal due to patient motion. ***The system may increase the brightness of the light sources in response to the noise to improve the signal-to-noise ratio***. In some embodiments, the system may increase brightness throughout the cardiac cycle because the system may require increased signal amplitudes to differentiate between fiducial and other points of interest related to physiological parameters and those related to noise or motion. In some embodiments, the system may change from a modulated light output to a constant light output in response to noise, patient motion, or ambient light.

Ex.1011 (Lisogurski), 9:46-60. Although Lisogurski describes how varying the light drive parameters increases the signal-to-noise ratio in the context of cardiac cycle modulation, the same principle applies to all the modulation processes, including drive cycle modulation and the servo algorithms. Lisogurski also explains that all three types of modulation may be used. Ex.1011 (Lisogurski), 6:26-31 ("The cardiac cycle modulation may represent a lower frequency envelope function on the higher frequency drive cycle. For example, cardiac cycle modulation may be an envelope on the order of 1 Hz superimposed on a 1 kHz sine wave drive cycle modulation."), 8:22-26 ("cardiac cycle modulation may be implemented in addition to a drive cycle modulation, conventional servo algorithms, or any combination thereof."), 17:21-29. Lisogurski explains that the frequency of the light source can be changed for the same reason. Ex.1011 (Lisogurski), 5:57-61, 9:46-51, 35:5-9 ("It will also be understood that the earlier

described embodiments relating to varying light output may also apply to sampling rate.”). So the person of ordinary skill in the art would understand Lisogurski to disclose varying the frequency (firing rate) of the light source to increase the signal-to-noise ratio, just as Lisogurski discloses increasing the light source amplitude for that same reason.

151. Lisogurski explains that a conventional servo algorithm can vary the modulation parameters of the light source for the same reasons it does with respect to cardiac cycle modulation.

> In some embodiments, conventional servo algorithms may be used in addition to any combination of cardiac cycle modulation and drive cycle modulation. Conventional servo algorithms may adjust the light drive signals due to, for example, ambient light changes, emitter and detector spacing changes, sensor positioning, other suitable parameters, or any combination thereof. Generally, conventional servo algorithms vary parameters at a slower rate than cardiac cycle modulation. For example, a conventional servo algorithm may adjust drive signal brightness due to ambient light every several seconds.

Ex.1011 (Lisogurski), 5:55-64.

152. A conventional servo, or feedback control, algorithm would vary parameters at a slower rate than cardiac cycle modulation. Conventional feedback control algorithms would adjust the light drive signals due to, for example, ambient light changes, sensor positioning, and other sources external to the body variation.

A conventional servo algorithm may adjust drive signal brightness, to compensate for ambient light variation, every several seconds.

153. Lisogurski explains that the signal-to-noise ratio can be increased by increasing the "brightness" of a light source. For example, Lisogurski explains that the sensor may receive "an increased level of background noise in the signal due to patient motion. The system may ***increase the brightness of the light sources*** in response to the noise ***to improve the signal-to-noise ratio***." Ex.1011 (Lisogurski), 9:46-52 (emphases added), *see id.*, 37:6-22. Lisogurski explains that the frequency of the light source can be changed for the same reason. Ex.1011 (Lisogurski), 5:57-61, 9:46-51, 35:5-9 ("It will also be understood that the earlier described embodiments relating to varying light output may also apply to sampling rate.").

154. Lisogurski also explains that a dim light signal can be "degraded by quantization noise" due to the analog-to-digital conversion process and increasing the brightness of the light source can improve the signal-to-noise ratio.

> The system may use conventional servo algorithms in part to keep received signal levels within the range of an analog to digital converter's dynamic range. For example, a signal with amplitudes that are large may saturate an analog to digital convertor. In response to a signal with high amplitudes, the system may reduce emitter brightness. In a further example, the quality of a low amplitude signal

may be degraded by quantization noise by an analog to digital converter. In response, the system may increase the emitter brightness. Ex.1011 (Lisogurski), 5:65-6:6.

155. For a fixed wavelength, the intensity of a light source is its brightness squared, and consequently, increasing the brightness of a light source also increases its intensity. Therefore, Lisogurski describes increasing the light intensity of that light source, and that doing so improves (increases) the signal-to-noise ratio.

156. Annotated Figure 1 below depicts the relevant circuitry in Lisogurski:

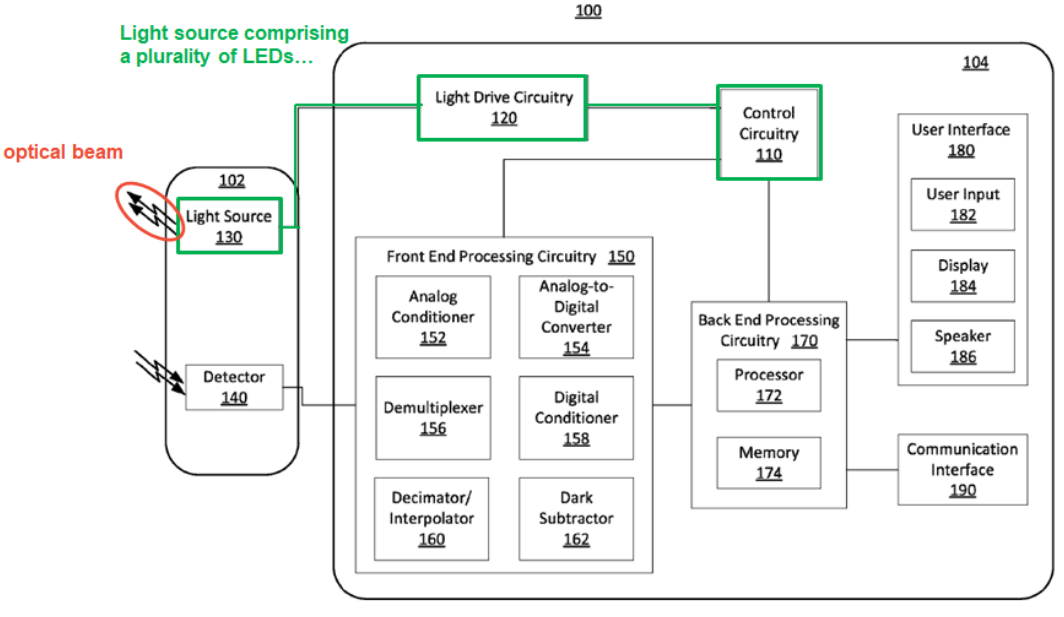


FIG. 1

157. I understand that Patent Owner may argue that Lisogurski does not disclose this element because the control and light drive circuitry that control the LEDs is depicted in monitor 104 which is separate from the wearable sensor 102

that contains the LEDs. Even if that were required, that configuration of Lisogurski would have been obvious.

158. It would have been obvious to integrate the control and light drive circuitry into the sensor. Lisogurski discloses an embodiment where the sensor is a separate device that is wirelessly connected to the monitor. Ex.1011 (Lisogurski), 17:55-59 ("Sensor unit 312 may be powered by an internal power source, e.g., a battery (not shown)…. [T]he sensor may be wirelessly connected to monitor 314 (not shown)."), 18:23-25, *see also id.*, 18:16-31. While this configuration of the sensor is not depicted in Lisogurski's figures, a person of ordinary skill in the art would have found it obvious to configure the sensor and monitor to work in this wireless embodiment based on Lisogurski's own description of these elements.

159. The control circuitry directs the light drive circuitry to generate the light drive signal, which is the electric current provided to the LEDs that turns them on and determines their brightness. Ex.1011 (Lisogurski), 11:38-41, 11:50-54, 25:52-55. It would have been obvious to include the light drive circuitry in the sensor because that is where the LEDs are. The electrical current cannot be transferred wirelessly from the monitor to the sensor. Because these circuits work together to output the electric current that is applied to the LEDs, a person of ordinary skill in the art would have understood that this circuitry would need to be

in the sensor with the LEDs, or at least that it was obvious to include the circuitry there.

160. Adding the light drive and control circuitry to the sensor would not have affected the operation of the device. These circuits would have been small and power efficient, and could easily be integrated into the wearable sensor. Lisogurski itself recognizes its components can be divided in the difference ways, explaining that "[i]n some embodiments the functionality of some of the components may be combined in a single component… [or] the functionality of some of the components of monitor 104… may be divided over multiple components." Ex.1011 (Lisogurski), 16:2-9.

161. This also is consistent with general trends in the industry. As I explained in § IV.B, above, by 2012, there was a general trend in the industry to include additional features in wearable devices to improve those device's operation in mobile monitoring systems or for sports and personal fitness applications.

g) "the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue"

162. Lisogurski's dark subtraction process results in adjusted IR signals to "determine one or more physiological parameters," such as blood oxygen saturation of hemoglobin, heart rate, blood pressure, and others. Ex.1011

(Lisogurski), 14:60-64, *see id.*, 1:22-25, 1:48-52, 4:36-59, 8:4-8, 11:20-25. A determination of "blood constituent concentration" such as the blood oxygen saturation of hemoglobin are a non-invasive measurement on blood contained within the tissue because they use reflected light signals to take various blood measurements. Thus, the adjusted IR signal ("*output signal*") represents "*a non-invasive measurement on blood contained within the tissue*."

h) "wherein the receiver includes a plurality of spatially separated detectors, wherein at least one analog to digital converter is coupled to the spatially separated detectors"

163. As I explained above §VII.A.4.d, the detectors and front-end processing circuitry together are the "*receiver*." Lisogurski's sensor includes "[o]ne or more detector 318… for detecting the light that is reflected by or has traveled through the subject's tissue." Ex.1011 (Lisogurski), 17:40-42, *see also id.*, 11:9-10, Figs. 1 (140), 3 (318). The sensor "may include multiple light sources and detectors, which may be spaced apart." Ex.1011 (Lisogurski), 17:43-45. Accordingly, Lisogurski's sensor includes "*a plurality of spatially separated detectors*."

164. Each of Lisogurski's detectors "converts the intensity of the received light into an electrical signal." Ex.1011 (Lisogurski), 11:14-16, 11:20-22, Figs. 1, 3. These electrical signals are received by the front-end processing circuitry, and

are passed between the components of the circuitry. Ex.1011 (Lisogurski), 13:6-60. The front-end processing circuitry includes an analog-to-digital converter. Ex.1011 (Lisogurski), 13:21-27, 13:27-30 ("Analog-to-signal converter 154 may be any suitable type of analog-to-digital converter of sufficient resolution to enable a physiological monitor to accurately determine physiological parameters.").

165. As shown in annotated Figure 1 below, the detector is coupled to the front-end processing circuitry, which includes an analog-to-digital converter:

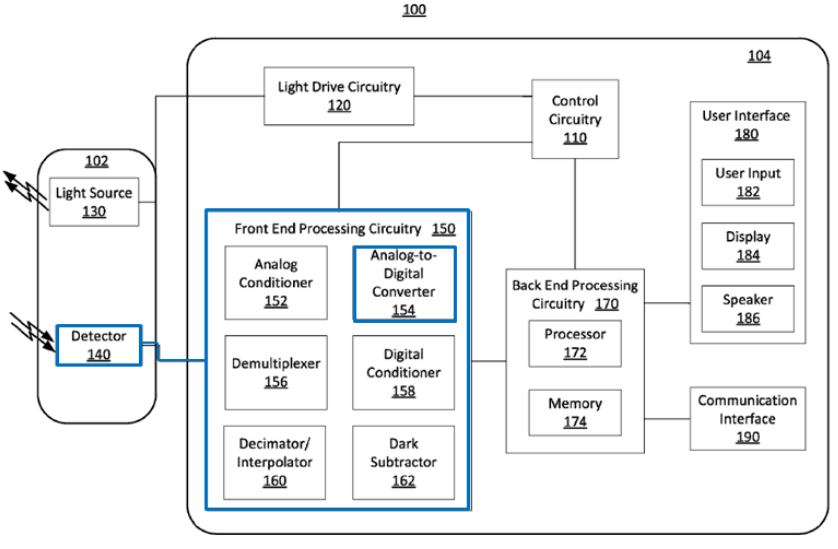


FIG. 1

Ex.1011 (Lisogurski), Fig. 1, 13:7-12.

5. Claim 17

166. Claim 17 depends from claim 16 and further recites "*wherein at least one LED emits at a first wavelength and at least another LED emits at a second wavelength, and wherein the first wavelength has a first penetration depth into the*

tissue and wherein the second wavelength has a second penetration depth into the tissue different from the first penetration depth."

167. Lisogurski's LEDs can "emit photonic signals having one or more wavelengths of light (*e.g.*, Red and IR)." Ex.1011 (Lisogurski), 10:49-52, *see id.*, 4:42-45. For example, Lisogurski provides that "[t]he Red wavelength may be between about 600 nm and about 700 nm, and the IR wavelength may be between about 800 nm and about 1000 nm." Ex.1011 (Lisogurski), 10:56-58.

168. A person of ordinary skill in the art would have understood that Red light and IR light, which have different wavelengths, inherently have different penetration depths into a person's tissue. The IUPAC defines the "depth of penetration of light" as the inverse of the absorption coefficient. Ex.1028 (IUPAC), 394. According to the Beer-Lambert Law, the distance that light will transmit through a medium (such as tissue that includes blood) depends on the light's wavelength because a medium absorbs light of different wavelengths at different rates. Ex.1028 (IUPAC), 153-54. The medium's absorption coefficient—an inherent property of a medium—is the rate at which a medium absorbs a wavelength of light. Because red light and IR light have different absorbance coefficients in blood and tissue, they have different penetration depths. It was well-known that the optical penetration depth into human tissue depends on the wavelength of the light. Ex.1034 (Bashkatov) at 2550, 2552-53.

169. The IUPAC's description of depth penetration of light is consistent with Lisogurski's recognition that red and IR lights are absorbed differently depending on the composition of the blood. Ex.1011 (Lisogurski), 4:45-51, 12:9-11 ("red light may be absorbed and scattered more than IR light when passing through perfused tissue at certain oxygen saturations"). Pulse oximetry itself depends on the fact that blood and tissue absorb different wavelengths at different rates. Ex.1019 (Biomedical Engineering Handbook), 766 ("Quite often two different wavelengths of light are utilized to perform a specific measurement. One wavelength is usually sensitive to changes in the species being measured, and the other wavelength is unaffected by changes in the analyte concentration."), 769 ("The measurement is performed at two specific wavelengths, λ_1, where there is a large difference in absorbances between Hb and HbO_2 (e.g., 660 nm red light), and λ_2, which can be an isobestic wavelength (e.g., 805 nm infrared light), where the absorbance of light is independent of blood oxygenation"), 1347.

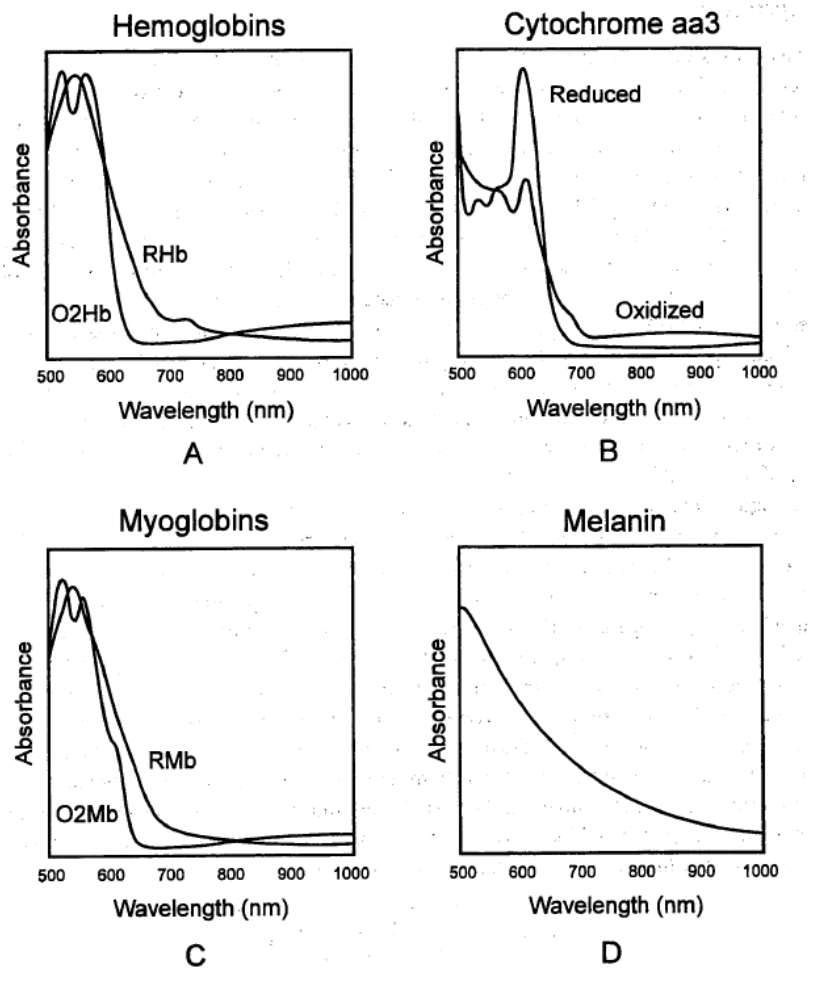


FIGURE 88.1 Absorption spectra of some endogenous biologic materials (*a*) hemoglobins, (*b*) cytochrome *aa3*, (*c*) myoglobins, and (*d*) melanin.

170. It is also consistent with the'286 patent's description of penetration depth "as the inverse of the absorption coefficient, although it may also be necessary to include the scattering in the calculation." Ex.1001, 8:18-20.

171. The figure below illustrates this general principle using human tissue as the medium:

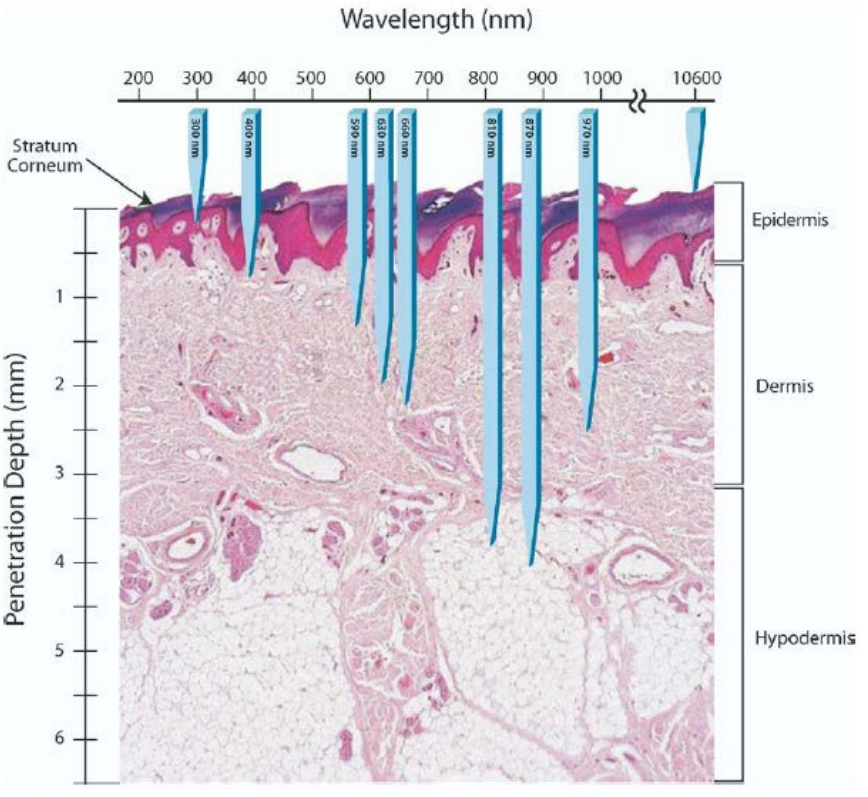


Figure 6 Optical penetration depth.

Ex.1036, 230; *see also* Ex.1025 (showing similar example but with seawater). Tissue inherently absorbs different wavelengths of visible light (*e.g.*, in the 600-700 nm range compared to the 800-1000 nm range) at different rates, and therefore, each wavelength penetrates tissue a different depth.

6. Claim 19

172. Claim 19 depends from claim 16 and further recites "*wherein the receiver is configured to be synchronized to the modulating of at least one of the LEDs*."

173. As I explained above in §VII.A.4.d, Lisogurski's detectors and front-end processing circuitry together are "*a receiver*." Ex.1011 (Lisogurski), 12:42-44, Fig. 1. The front-end processing circuitry is synchronized with the light drive circuitry that controls the modulation or pulses of the LEDs. Ex.1011 (Lisogurski), 11:41-46 ("front end processing circuitry 150 may… operate ***synchronously*** with light drive circuitry 120. For example, front end processing circuitry 150 may ***synchronize*** the operation of an analog-to-digital converter and a demultiplexer with the light drive signal based on the timing control signals.") (emphasis added). Therefore, the front-end processing circuitry and the detector ("*receiver*") are coordinated in time ("*synchronized*") to the light drive signal ("*the modulating of at least one of the LEDs*").

174. Another way that Lisogurski's front-end processing circuitry and the detector are coordinated in time with the light drive signal is by correlating the firing rate of an LED to the sampling rate of an analog-to-digital converter in the detector. Ex.1011 (Lisogurski), 33:47-49 ("In some embodiments, sampling rate modulation may be correlated with light drive signal modulation."), *see also* 2:1-2, 27:44-52 (LED firing rate can be modulated). In those embodiments, the firing rate of the LED and the sampling rate increase or decrease together:

> In some embodiments, the sampling rate may represent the amount of time between "on" periods. For example, the time between "on" periods may be the length of time of "off" period 220 of FIG. 2A.

> Increasing the duration of the "off" periods (i.e., ***decreasing the emitter firing rate***) ***relates to a decreased sampling rate***. Similarly, decreasing the duration of the "off" periods (i.e., ***increasing the emitter firing rate***) ***relates to an increased sampling rate***.

Ex.1011 (Lisogurski), 35:27-31 (emphasis added). Lisogurski describes an embodiment where the measurements taken by the receiver have a one-to-one correlation, with one sample taken per on period. Ex.1011 (Lisogurski), 35:17-19. Because the measurements taken by the receiver in this embodiment are coordinated in time with the pulses emitted by the LEDs, the LEDs and the receiver are synchronized.

175. Lisogurski's use of timing signals to synchronize the operation of the light source and detection circuitry is consistent with the disclosure of the '286 patent: "In one embodiment, the light source may be modulated, and then the detection system would be synchronized with the light source." Exhibit 1001, 24:14-17.

7. Claim 20

176. Claim 20 depends from claim 16 and further recites "*wherein the receiver is located a first distance from one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals*."

177. Lisogurski describes using multiple light sources and multiple detectors "which may be spaced apart." Ex.1011 (Lisogurski), 17:43-45. "Any suitable configuration" of sources and detectors maybe used. Ex.1011 (Lisogurski), 17:39-45. "Sensor unit 312 may include one or more light source 316 for emitting light at one or more wavelengths into a subject's tissue. One or more detector 318 may also be provided in sensor unit 312 for detecting the light that is reflected by or has traveled through the subject's tissue." Ex.1011 (Lisogurski), 17:37-42.

178. There are just two options for how two LEDs can be spaced in relation to a detector: either they are each the same distance from the detector or they are different distances from it. A person of ordinary skill in the art reading Lisogurski's disclosure that the sensors can be spaced apart would have immediately envisioned both options. Therefore, Lisogurski discloses that each LED can be a different distance from the photodetector.

179. Even if Lisogurski does not explicitly disclose spacing two LEDs different distances from the detector, this configuration would have been obvious. There are just two choices for how to space the LEDs from the detector, and the selection of one of those two ways is a system design choice. It was common to space LEDs different distances from a detector to, for example, account for differences in the performance or intensity of each LED. LEDs that are different

distances from the detector would mean that the propagation lengths of the light in the tissue would be different from the source to the two detectors. This configuration would be advantageous for some algorithms that, for example, were operating on differential signals. Such an approach would be appropriate if characterizing the path length dependent absorption properties of tissue. A configuration with different distances would also be helpful for either reducing motion artifacts or instead for characterizing the tissue motion.

180. Lisogurski explains that "in a system with two light sources… the first light source may be a high efficiency infrared (IR) LED while the one or more additional light sources may be lower efficiency red LEDs." Ex.1011 (Lisogurski), 7:38-8:3. Lisogurski separately measures the signal from each LED. Ex.1011 (Lisogurski), 12:29-33 ("The period from time 216 to time 218 may be referred to as a drive cycle, which includes four segments: a Red light 'on' periods 202, followed by an 'off' period 220, followed by an IR light 'on' period 204, and followed by an 'off' period 220."), Figs. 2A & 2B. Lisogurski can separately use each measured signal, for example, to calculate blood oxygen saturation using the ratio-of-ratios calculation, which is the ratio of the measured IR signal to the measured red signal. Ex.1011 (Lisogurski), 4:45-56; Ex.1019 (Biomedical Engineering Handbook), 769-70. A person of ordinary skill in the art would have understood Lisogurski's photodetector detects a red signal ("*a third signal*') from

the red LED ("*from the first light emitting diode*") and an infrared signal ("*a fourth signal*") from the infrared LED ("*from the second light emitting diode*").

181. Two lights sources of the same wavelength may be used to increase signal to noise ratio by acquiring multiple and redundant measurements. Two lights sources of different wavelengths may be used to increase signal to noise ratio by acquiring multiple measurements of light from each light source. They may be more or less sensitive to ambient noise or be more or less sensitive to the physiological parameter of interest. Two lights sources of different wavelengths may be used to estimate a physiological property that is not directly observable by measurement with a single wavelength. System level design considerations and the target physiological parameter may make it advantageous to modulate the light sources synchronously at the same frequency with or without a phase offset, synchronously at different frequencies with or without a phase offset, or asynchronously.

182. Lisogurski describes using red and infrared LEDs "because it has been observed that highly oxygenated blood will absorb relatively less red light and more IR light than blood with a lower oxygen saturation***. By comparing the intensities of two wavelengths*** at different points in the pulse cycle, it is possible to estimate the blood oxygen saturation of hemoglobin in arterial blood." Ex.1011 (Lisogurski), 4:45-51 (emphasis added). This comparison can be done, for

example, by calculating blood oxygen saturation using the ratio-of-ratios calculation, which is the ratio of the measured IR signal to the measured red signal. Ex.1011 (Lisogurski), 4:45-56; Ex.1019 (Biomedical Engineering Handbook), 769-70. Accordingly, Lisogurski generates an output signal by comparing the detected infrared signal ("*third signal*") and the detected red signal ("*fourth signal*").

B. Lisogurski, Carlson, and Hanna Render Obvious Claims 16-17 and 19-20

1. Overview of Hanna

183. Hanna is a patent that issued on January 7, 2003. Hanna describes a pulse oximeter, shown below, that can be worn on a user's ear or finger to measure oxygen saturation or other constituents of the user's blood:

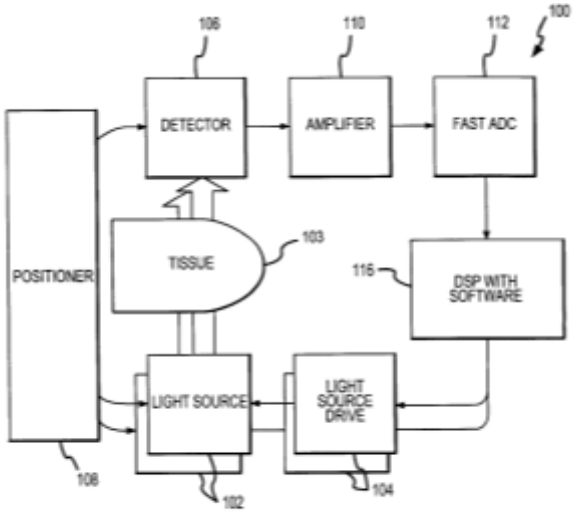


FIG.1

Ex.1007 (Hanna), Fig. 1, 1:25-39. The sensor has multiple emitters 102, which can be a red LED and an infrared LED. *Id.*, 4:34-43. The signals from these light sources "are modulated using different code sequences." *Id.*, 4:43-51, Fig. 2-4, 6:13-8:25 (describing encoded signals). The modulated light is applied to the user's tissue 103, and the transmitted or reflected light is detected by one or more detectors 106. *Id.*, 4:67-5:18, 8:26-33, 1:48-49. The purpose of encoding the light is to "allow the contribution of each source to the detector output to be determined." Ex.1007 (Hanna), 1:49-51, 2:23-29. Based on my knowledge and experience, a person of ordinary skill in the art would recognize that modulating signals using codes create non-periodic signals. This modulation technique allows the detector to discriminate between noise sources that are periodic in nature and the modulated signal because the modulated light generated by each emitter includes a unique code that is not found in noise. Ex.1007 (Hanna), 2:29-31; 2:59-62, 4:51-54.

184. As Hanna describes, each code is identifying information that is included in a modulated emitter signal. Ex.1007 (Hanna), 6:13-8:25. Therefore, Hanna teaches modulating light to include information, as required by the district court's preliminary claim construction.

2. A Person of Ordinary Skill in the Art Would Have Modified Lisogurski and Carlson to Incorporate Elements Shown in

Hanna Rendering Claims 16-17 and 19-20 Obvious

185. To the extent Omni argues that Lisogurski and Carlson does not teach or suggest that its LEDs are modulated to include information, it is my opinion that a person of ordinary skill in the art would have found it obvious to do so based on Hanna. It is therefore my opinion that the combination of Lisogurski and Carlson and Hanna renders claim 16 obvious.

186. Based on my knowledge and experience, a person of ordinary skill in the art would recognize that signals can be modulated using non-periodic codes. As Hanna explains, this modulation technique allows the detector to discriminate between noise sources that are periodic in nature and the modulated signal because the modulated light generated by each emitter includes a unique code that is not found in noise. Ex.1007, 2:29-31, 2:59-62, 4:51-54. As Hanna discloses, each code is identifying information that is included in a modulated emitter signal. Ex.1007, 6:13-8:25. This modulation technique allows the detector to discriminate between noise sources that are periodic in nature and the modulated signal because the modulated light generated by each emitter includes a unique code that is not found in noise. Ex.1007, 2:29-31; 2:59-62, 4:51-54. Thus, Hanna teaches modulating light to include information.

187. Based on my knowledge and experience, a person of ordinary skill in the art would have been well aware in the 2012-2013 time frame of the importance

of building a wearable wireless sensor that can extract a signal of interest in the presence of noise. User movement is a significant source of this noise, particularly in the context of fitness applications. Large body motions can make it difficult to produce accurate tissue property measurements that are correlated and induced by motions from blood flow and pulsation or induced by respiration. Ambient light is also a significant source of noise. This problem is exacerbated in the context of a mobile device, because ambient light conditions can change as the user moves. A typical example would be a user running along a tree-lined path, so that the device is moving quickly between areas of light and shade (while also bouncing and vibrating from the user running).

188. Based on my knowledge and experience, a person of ordinary skill in the art would have been well aware in the 2012-2013 time frame of the many techniques already developed to mitigate the impact of noise in optical sensors. This is demonstrated by the many references cited in this petition, including in the background section. Lisogurski, for example, states that the objective of the invention is to "enable[e] high quality physiological parameters to be determined." Ex. 1011, 3:50-53. Specifically, Lisogurski teaches use of multiple LEDs and corresponding detectors, and adding Hanna's technique would have allowed the detector to efficiently determine the signal contribution from each LED. Ex. 1011 (Lisogurski), 7:38-8:3, 17:40-42; 11:12-20; Ex.1016 (Hanna), 2:3-31. In addition,

a person of ordinary skill in the art in the 2012-2013 time frame who was interested in building a wearable wireless device would have been motivated to read and understand other publications describing how to improve performance of a mobile optical sensor. This would have led the person of ordinary skill in the art to Hanna.

189. A person of ordinary skill in the art following ordinary design processes would consider and evaluate known techniques and structures used in analogous systems such as Hanna that could improve performance. Improving performance by making signals of interest more detectable in noisy environments is a specific objective of Hanna's coding technique. Ex.1007, 2:3-31. Hanna explains that use of its non-periodic codes provides a specific benefit when in the presence of periodic noise sources as compared to time division multiplexed signals (as was typically used Lisogurski). Ex.1007, 4:21-24 ("As will be described below, the invention has particular advantages in the context of pulse oximetry including allowing for improved noise reduction…"); *id.*, 1:49-51 (using modulation mechanisms to "allow the contribution of each source to the detector output to be determined."), *id.*, 2:23-29 ("The invention allows for analysis of a multiplexed signal to distinguish between two or more signal components based on codes modulated into the signal components."). In addition, Hanna explains that modulating technique uses coded signal with "nonperiodic characteristics." *Id.*,

2:59-60. Hanna further explains that "due to the codes, there is at least a component of each source signal that is not described by a regularly repeating temporal pattern," which is a non-periodic component. *Id.*, 2:60-63. Based on my knowledge and experience, a person of ordinary skill in the art would have recognized that these non-periodic characteristics allow a detector to be able to differentiate between the signal of interest and other periodic noise signals.

190. Based on my knowledge and experience, it would have been obvious to use the modulation techniques used by the Lisorgurski (disclosing that modulation may be implemented using "time division multiplexing…, code division multiplexing, carrier frequency division multiplexing, phase division multiplexing…") (Ex. 1011, 6:19-24) to include information as described by Hanna. Hanna teaches using this technique in the same kind of optical sensor described by Lisogurski, and identifies the benefits of doing so, including to better extract discrete optical signals from multiple emitters in the presence of noise. Ex.1007, 2:3-31, 2:59-62, 4:21-54. Hanna also explains that the use of its non-periodic codes provides a specific benefit allowing the mitigation of periodic noise sources. Ex. 1007 (Hanna), 2:59-62, 4:51-54. A person of ordinary skill in the art would have recognized that implementing the Hanna technique in the Lisogurski's sensor would improve its performance in the same way the techniques improved the performance of the Hanna sensor. In addition, and as I explained above, a

person of ordinary skill in the art would be motivated to use Hanna's codes to identify the LED source when there are multiple LEDS. *See* Ex.1007 (Hanna), 2:26-29 ("The invention allows for analysis of a multiplexed signal to distinguish between two or more signal components thereof based on codes modulated into the signal components" sent by LEDs). A person of ordinary skill in the art therefore would have been motivated to incorporate the modulated coding techniques described by Hanna into the sensor described by Lisogurski in order to improve the performance of a wearable, wireless device consistent with prevailing market demands.

191. Based on my knowledge and experience, a person of ordinary skill in the art would also have turned to the coding technique described by Hanna for another reason: as a known way of accomplishing this objective. By using Hanna code division modulation technique, the multiple LEDs of Lisogurski would use different codes as described in Hanna. Based on my knowledge and experience, a person of ordinary skill in the art would recognize that this modulation technique would mitigate interference and improve system detection. Thus, that person of ordinary skill in the art would have been motivated to use Hanna's modulation technique in the Lisogurski device to obtain the performance benefits described by Hanna.

192. Such a person also would have recognized that incorporating Hanna's coding technique into the Lisogurski sensor would involve combining familiar elements according to known methods, yielding predictable results. Both Lisogurski and Hanna describe optical sensors that use multiple emitters, which were common and well-known components of these types of devices. Ex. 1019 at 765. Modulating light to convey information was also a well-known technique, both in the context of optical sensors and in many other contexts. Notably, modulating a beam to contain information when so desired is a conventional technique that has been used for decades in any number of contexts, such as free space optical communication, such as naval vessel communication using signal lamps. Lisogurski teaches using modulation, and a person of ordinary skill in the art would have been able to reasonably predict that incorporating Hanna's known modulating technique into the Lisogurski device would make it easier to distinguish signals of interest from noise and to thereby improve performance.

193. Hanna and Lisogurski also describe analogous optical sensors for measuring physiological characteristics. Both references, directed to the same technology, describe analogous systems with common applications and utility, and they both describe techniques for improving the performance of measurement devices that include an optical sensor by removing noise. Based on my knowledge and experience, a person of ordinary skill in the art would have considered the

references together when implementing a system based on the teachings of Lisogurski, taking into consideration different design trade-offs and system attributes obtained by different design decisions. Such a person would do that as part of the ordinary design process he or she follows to improve the operation of a device, particularly given the emphasis both references place on providing accurate health data.

194. Based on my knowledge and experience, a person of ordinary skill in the art would recognize that modulating light to convey information was also a well-known technique, both in the context of optical sensors and in many other contexts. The ’286 specification provides no explanation of how or why a signal would be modulated to include information (*see* Ex.1001, 10:17-18), presumably because this was well known at the time. Lisogurski teaches using modulation, and a person of ordinary skill in the art would have been able to reasonably predict that incorporating Hanna’s known modulating technique into the Lisogurski device would be to make it easier to differentiate signals of interest from noise and to thereby improve performance.

195. Hanna, Lisogurski, and Carlson also describe analogous optical sensors. As I explained above, Lisogurski and Carlson describe analogous sensors. Like Lisogurski and Carlson, Hanna describes use of its techniques in devices used in the medical or health care fields. Ex.1007, 1:24-26. Lisogurski, Carlson, and

Hanna, all in the field of optical sensing technology for measuring physiological signals or biological signals, thus describe analogous systems with common applications and utility, and all describe techniques for improving the performance of measurement devices that include an optical sensor by removing noise. Ex.1007, 2:3-31. Accordingly, and based on my knowledge and skill, a person of ordinary skill in the art would have considered the references together when implementing a system based on the teachings of Lisogurski, and Carlson.

196. As I explained above, Lisogurski and Carlson render obvious claims 16-17 and 19-20. To the extent Lisogurski and Carlson do not teach modulating an LED to create a beam that contains information, configuring Lisogurski to do so would have been obvious based on Hanna, as I explained above.

C. Lisogurski and Carlson, With or Without Hanna, in Combination with Mannheimer Render Obvious Claim 20

1. Overview of Mannheimer

197. Mannheimer discloses a pulse oximetry monitoring and measurement system. Ex.1008 (Mannheimer), 6:17-36, Figs. 2, 4. The sensor uses one or more LEDs to alternately emit red and infrared light at a desired modulation frequency. Ex.1008 (Mannheimer), 6:20-21, 6:66-7:4. The emitted light is dispersed by the user's tissue, and the reflected light is collected by one or more detectors. Ex.1008 (Mannheimer), 6:22-23.

198. Mannheimer discloses using emitters that are spaced at different distances from a detector in order to obtain deep and shallow tissue measurements. Ex.1008 (Mannheimer), 1:40-54, 2:1-6, 3:25-35, Figs. 1B, 7. For example, Mannheimer includes an embodiment with two LEDs each spaced a different distance from a single detector. Ex.1008 (Mannheimer), Fig. 1B, 3:38-40, 5:58-62. In this way, reflected light from a surface layer of skin, which is non-vascular and susceptible to noise from motion and ambient light, can be removed so that light reflected by deeper, more vascular tissues layers can be used to identify a pulsatile signal of interest. Ex.1008 (Mannheimer), 3:25-35, 5:1-5.

2. A Person of Ordinary Skill in the Art Would Have Modified Lisogurski and Carlson, with or without Hanna, to Incorporate Elements Shown in Mannheimer

199. As described with respect to Lisogurski and Carlson, a person of ordinary skill in the art would have found it obvious to incorporate a plurality of lenses into the measurement system of Lisogurski, as described by Carlson, in order to optimize power consumption and increase the signal-to-noise ratio of measured signals. A person of ordinary skill in the art reading Lisogurski and Carlson would have looked to other references that disclosed additional techniques for improving the operation of an optical sensing systems. It was part of the ordinary design process to characterize the positive and negative attributes of the

many ways to improve the operation of a device by comparing and selecting or combining, different designs and techniques.

200. Lisogurski recognizes that light is attenuated differently depending on the tissue, and that skin pigmentation in particular can have a variable effect on signal quality. Ex.1011 (Lisogurski), 19:42-50 ("The interaction of the emitted light with the subject may cause the light to become attenuated… [T]he attenuation or the light may depend on… the tissue with which the light interacts."), 44:43-48 ("The red waveforms may be 25% of the intensity of the IR waveforms, as may occur in patients with dark skin pigmentation"). Mannheimer describes a solution to this problem, teaching that interference from skin can be removed by using signal detected from LEDs spaced different distances from a detector. Ex.1008 (Mannheimer), 3:25-35, 5:1-5.

201. A person of ordinary skill in the art would have looked to Mannheimer for the additional reason that it describes how to position emitters at different distances relative to a detector. While Lisogurski teaches using multiple light sources and multiple detectors "which may be spaced apart," Ex.1011 (Lisogurski), 17:45, it does not specifically identify the spacing that should be used. A person of ordinary skill in the art would have looked to how others in the art had arranged the LEDs with respect to a sensor, one example of which is described in Mannheimer.

202. Lisogurski, Carlson, and Mannheimer are also analogous references, each describing techniques for improving the measurements taken by optical sensing devices, such as pulse oximeters. Hanna likewise describe techniques for improving the operation of optical sensing devices used in the medical or heath care fields. Ex.1007, 1:24-26, 2:3-31. The person of ordinary skill in the art would have considered the references together when implementing a system based on Lisogurski's teachings.

203. The person of ordinary skill in the art would have been motivated to include features from Carlson, Hanna, and Mannheimer in Lisogurski's system. These features, and more specific reasons for combining them, are described in the analyses below.

3. Claim 20

204. Claim 20 depends from claim 16 and further recites "*wherein the receiver is located a first distance from a first one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals.*"

205. Fig. 1B of Mannheimer shows emitters E_1 and E_2 and detector D. Ex.1008 (Mannheimer), 5:58-62.

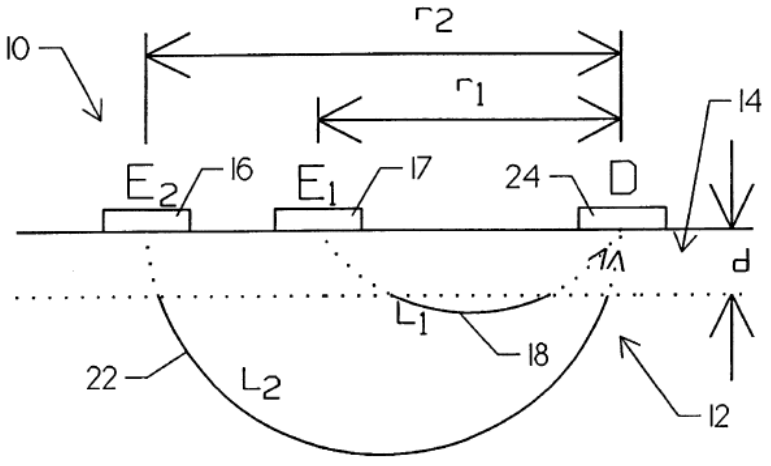


FIG. 1 B

Emitter E_1 is located a first distance r_1 from the detector. Ex.1008 (Mannheimer), 3:23. Emitter E_2 is located a second distance r_2 from the detector, wherein r_2 is greater than r_1. Ex.1008 (Mannheimer), 3:24. The detector receives light signal 18 from emitter E_1 that has a path length L_1. Ex.1008 (Mannheimer), 3:18-21. The detector receives light signal 22 from emitter E_2 that has a path length L_2, wherein L_2 is greater than L_1. Ex.1008 (Mannheimer), 3:19-22.

206. It would have been obvious to spatially arrange the emitters and detector of the Lisogurski sensor in the manner described by Mannheimer. Lisogurski describes using multiple light sources and multiple detectors "which may be spaced apart." Ex.1011 (Lisogurski), 17:45. "Any suitable configuration" of sources and detectors maybe used. Ex.1011 (Lisogurski), 17:39-45. A person of ordinary skill in the art who is interested in identifying such a suitable

configuration would look to Mannheimer, which provides a detailed disclosure of an advantageous configuration.

207. A person of ordinary skill in the art would have included in Lisogurski's sensor two red LEDs spaced different distances from a detector, as described in Mannheimer, and two IR LEDs also spaced different distances from the detector. Configuring the emitters to be different distances from a detector has known advantages, such as by allowing for the removal of the effects of light interaction with a surface layer of skin so that a signal of interest can be extracted from a deeper tissue layer. Ex.1008 (Mannheimer), 3:25-35, 5:1-5. A person of ordinary skill in the art would have been motivated to arrange the Lisogurski emitters relative to the detector as described by Mannheimer in order to remove interference caused by a person's skin, which Lisogurski recognizes can be a problem.

208. Mannheimer describes "calculating an arterial oxygen saturation level of [a] patient" from the intensity of signals 18 and 22. Ex.1008 (Mannheimer), 2:16-18. This calculation includes determining a first intensity I_1 corresponding to the signal 18 detected from light emitted by E_1 and a second intensity I_2 corresponding to the signal 20 detected from light emitted by E_2. Ex.1008 (Mannheimer), 3:35-54, 4:15-20. Mannheimer then describes calculating a ratio R from I_1 and I_2 for purposes of calculating "a result related only to the arterial blood

saturation of…deeper tissue." Ex.1008 (Mannheimer), 3:55-5:9; *see also*, Ex.1008 (Mannheimer), 5:23-57 (providing an alternative calculation for the ratio R based on I_1 and I_2). Therefore, Mannheimer compares signal 18 reflected by surface tissue and signal 22 reflected by deep tissue in order to subtract the effects of light reflected by the surface tissue.

209. It would have been obvious for Lisogurski's sensor to perform the comparison in the manner described by Mannheimer in order to remove the effects of noise at the surface layer of skin. Lisogurski recognizes that light is attenuated differently depending on the tissue, and that skin pigmentation in particular can have a variable effect on signal quality. Ex.1011 (Lisogurski), 19:42-50 44:43-48. By removing light reflected by the surface layer of the skin, as described in Mannheimer, the adverse effect on signal quality, identified by Lisogurski, can be mitigated. A person of ordinary skill in the art would have been motivated use the comparison described in Mannheimer in implementing Lisogurski's system in order to increase the signal-to-noise ratio and provide an improved measurement device.

* * *

I, Brian W. Anthony, do hereby declare and state, that all statements made herein of my own knowledge are true and that all statements made on information

and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, under Section 1001 of Title 18 of the United States Code.

Executed on: April 10, 2019

Exhibit List

The list of exhibits that I relied upon in forming my opinions is below.

Exhibit #	Reference Name
1001	U.S. Patent No. 9,861,286
1002	File History of U.S. Patent No. 9,861,286
1003	Declaration of Brian W. Anthony, PhD
1004	Proof of Service of Summons in Omni MedSci, Inc. v. Apple Inc., No. 2:18-cv-134 (E.D. Tex.)
1005	U.S. Patent Publication No. 2012/0197093 ("Valencell '093")
1006	U.S. Patent Publication No. 2010/0217099 ("Valencell '099")
1007	U.S. Patent No. 6,505,133 ("Hanna")
1008	U.S. Patent No. 5,746,206 ("Mannheimer")
1009	U.S. Patent Publication No. 2005/0049468 ("Carlson")
1010	U.S. Patent No. 9,596,990 ("Park")
1011	U.S. Patent No. 9,241,676 ("Lisogurski")
1012	RESERVED
1013	RESERVED
1014	U.S. Patent No. 8,172,761 ("Rulkov")
1015	U.S. Provisional Application No. 61/747,487
1016	U.S. Provisional Application No. 61/747,472
1017	U.S. Provisional Application No. 61/747,477
1018	U.S. Provisional Application No. 61/754,698
1019	"The Biomedical Engineering Handbook," by Joseph D. Bronzino (1995) ("BE Handbook")
1020	M. Kranz, et al., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, Pervasive and Mobile Computing (June 2012)

Exhibit #	Reference Name
1021	Patel, et al., A review of wearable sensors and systems with application rehabilitation, Journal of Neuroengineering & Rehabilitation (2012)
1022	ScienceDirect Report on M. Kranz, et al., The mobile fitness coach: Towards individualized skill assessment using personalized mobile devices, Pervasive and Mobile Computing (2012), available at https://www.sciencedirect.com/science/article/pii/S1574119212000673?via%3Dihub
1023	"The Usage of Tablets in the HealthCare Industry," by Rauf Adil, available at https://www.healthcareitnews.com/blog/usage-tablets-healthcare-industry (Aug. 2, 2012)
1024	A. More, Bluetooth Low Enegery: Wireless Connectivity for Medical Monitoring, Journal of Diabetes Science & Technology (Mar. 2010)
1025	1. Absorption Coefficient and Penetration Depth, available at https://eng.libretexts.org/Bookshelves/Materials_Science/Supplemental_Modules_(Materials_Science)/The_Science_of_Solar (Accessed October 29, 2018)
1026	Buttussi, Fabio, Chittaro, Luca, MOPET: A context-aware and user-adaptive wearable system for fitness training (2008)
1027	P. Baum, et al., Strategic Intelligence Monitor on Personal Health Systems, Phase 2: Market Developments - Remote Patient Monitoring and Treatment, Telecare, Fitness/Wellnes and mHealth, JRC Scientific and Policy Reports of European Commission (2013)
1028	Compendium of Chemical Terminology Gold Book Version 2.3.3, February 24, 2014
1029	M. Swan, Senior Mania! The Internet of Things, Wearable Computing, Objective Metrics, and the Quantified Self 2.0, Journal of Sensor and Actuator Networks (2012)
1030	Merriam-Webster's Collegiate Dictionary, Eleventh Edition
1031	U.S. Patent Publication No. 2012/0041767 ("Hoffman")
1032	U.S. Patent No. 7,278,966 ("Hjelt")
1033	Lister et al., Optical properties of human skin (Journal of Biomedical Optics 2012)
1034	Bashkatov et al., Optical properties of human skin, subcutaneous and mucous tissues in the wavelength range from 400 to 2000 nm, Journal of Physics D: Applied Physics (2005)

Exhibit #	Reference Name
1035	E.F. Schubert, Light-Emitting Diodes (Cambridge Univ. Press, 2nd ed. reprinted 2014)
1036	Barolet, Daniel, Light-Emitting Diodes (LEDs) in Dermatology (Seminars in Cutaneous Medicine and Surgery 2008)
1037	RESERVED
1038	RESERVED
1039	RESERVED
1040	RESERVED
1041	Exhibit E from , Excerpts from the American Heritage Dictionary, 5th Edition, filed January 14, 2019, No. 2:18-cv-134-RWS
1042	Exhibit O, Excerpts from the American Heritage Dictionary, 5th Edition. Filed January 14, 2019. No. 2:18-cv-134-RWS
1043	RESERVED
1044	RESERVED
1045	RESERVED
1046	Exhibit G, Excerpts from Merriam-Webster's Collegiate Dictionary, Eleventh Edition, No. 2:18-cv-134-RWS
1047	Exhibit N, Excerpts from Merriam-Webster's Collegiate Dictionary, Eleventh Edition, No. 2:18-cv-134-RWS
1048	U.S. Patent No. 6,044,283 ("Fein")
1049	U.S. Patent No. 5,774,213 ("Trebino")
1050	U.S. Patent No. 5,855,550 ("Lai")
1051	U.S. Patent No. 6,898,451 ("Wuori")
1052	U.S. Patent No. 4,972,331 ("Chance")